Providence Health Plan

Providence Health Assurance

Healthcare Services Medical & Pharmacy Policy Alerts

Number 105

April 1, 2025

This is the April 1, 2025 issue of the Providence Health Plans, Providence Health Assurance and Providence Plan Partners, Medical and Pharmacy Policy Alert to our providers. The focus of this update is to communicate to providers' new or revised Medical or Pharmacy policy changes. The Health Plan has a standard process to review all Medical & Pharmacy Policies annually. Policies will be available for review on ProvLink and via the PHP website at: https://healthplans.providence.org/providers/provider-support/medical-policy-pharmacy-policy-and-provider-information/

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

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

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

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

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

MEDICAL POLICY COMMITTEE

MEDICAL

COMPANY POLICIES

Effective 6/1/2025

Ambulance Transport **MP118**	**Annual Review** **Recommendation**: • Significant changes to policy format. • Continue to base criteria primarily on CMS references, but instead of only supplying a link to the CMS manual, criteria will be spelled out. • While historically, the policy *only* indicated CMS guidance was used, this updated version does include situations that are not addressed by CMS. Many of these changes are due to clinical rationale (e.g., transport for urgent transplant situation, neonatal emergencies or high-risk pregnancy situations, none of which are called out by Medicare), while other revisions are due to current practice or scenarios we already approve, such as adding IP rehab facilities (IRF) as a covered origin/destination site, and adding approval for non-emergent air ambulance when the closest facility is OON. **Codes/PA:** Added ambulance-related HCPCS codes to this policy, but no change to current configuration. Effective 6/1/2025, prior authorization will be required for **non-emergent** air ambulance transports. Prior authorization will not be required for urgent or emergent air ambulance transports, but air ambulance transports may continue to be subject to retrospective medical necessity review. **OHP: These changes do not apply to OHP. The Prioritized List and the Oregon Administrative Rules will be followed.**
Benign Skin Lesions **MP422**	**New Policy** **Recommendation:** New policy establishing pair-to-pay configuration for benign skin lesion removal. **Codes/PA:** Added diagnosis code configuration to the relevant CPT codes.

	OHP: These changes do not apply to OHP. The Prioritized List and the Oregon Administrative Rules will be followed.
Total Shoulder Arthroplasty **MP 430**	**New Policy** **Recommendation:** New policy for shoulder arthroplasty (replacement) procedures. Company coverage criteria based on third-party vendor (InterQual®) criteria. **Codes/PA:** • CPT codes 23470 and 23472 currently require review if performed at an inpatient place of service (POS), to review the necessity of the inpatient status. Added PA to these codes to review for medical necessity of the shoulder joint replacement for any setting (patient or outpatient), in addition to the current inpatient POS review. • Added PA to CPT 23473 and 23474 for medical necessity review of the shoulder joint replacement, regardless of setting. **OHP: These changes do not apply to OHP. The Prioritized List and the Oregon Administrative Rules will be followed.**
Advanced Diabetes Management Technology **MP27**	**Annual Update** **Recommendation:** • Added d-Nav Technology as an example of non-covered diabetes management software (Criterion VII.B) **Codes/PA:** Code and configuration changes are as follows: • Added PA to HCPCS A4238 and A4239 (supply codes) to align with Pharmacy PA requirements for same codes. • Added 0740T, 0741T to policy, and add NMN edit. **OHP: These changes do not apply to OHP. The Prioritized List and the Oregon Administrative Rules will be followed.**
Surface Electromyography (sEMG) Testing (Company) **MP136**	**Annual Update** **Recommendation:** No changes. **Codes/PA:** S3900 - NMN denial for was removed in error in 2023, as such the NMN denial will be put back in place. **OHP: These changes do not apply to OHP. The Prioritized List and the Oregon Administrative Rules will be followed.**
Spinal Fusion and Decompression Procedures **MP10**	**Interim Update** **Recommendation:** Deny bone marrow aspiration as adjunct to spinal fusion procedures as “not medically necessary.” (Criterion VI.) **Codes/PA:** Configure CPT 20939 to deny as “not medically necessary” (currently requires PA). **OHP: These changes do not apply to OHP. The Prioritized List and the Oregon Administrative Rules will be followed.**

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MEDICARE POLICIES

Effective 6/1/2025

Ambulance Transport **MP386**	**Annual Review** **Recommendation**: No change to policy criteria, but updates to policy format. Continue to base criteria on CMS references, but added specific CMS manual sections for various clinical situations. **Codes/PA:** Added ambulance-related HCPCS codes to this policy, but no change to current configuration. Effective 6/1/2025, prior authorization will be required for **non-emergent** air ambulance transports. Prior authorization will not be required for urgent or emergent air ambulance transports, but air ambulance transports may continue to be subject to retrospective medical necessity review.
Benign Skin Lesions **MP423**	**New Medicare Advantage medical policy** **Recommendation:** New policy for Medicare Advantage. The Noridian local coverage determination (LCD) was used. **Codes/PA:** Added diagnosis code configuration to the relevant CPT codes, based on Noridian local coverage article (LCA).
Cosmetic and Reconstructive Procedures **MP232**	**Interim Update** **Recommendation:** No change to intent; update is to transfer procedures for benign skin lesion treatments to the new "Benign Skin Lesions" policy. **Codes/PA:** Removed CPT codes from this policy that will now be addressed in the new policy
Total Shoulder Arthroplasty **MP431**	**New Medicare Advantage medical policy** **Recommendation:** New policy for Medicare Advantage for total shoulder arthroplasty. Due to the absence of Medicare coverage policy for our service area (no NCD, no LCD), internal Company coverage criteria will be used, which is based on third-party vendor (InterQual®) criteria. **Codes/PA:** • CPT codes 23470 and 23472 currently require review if performed at an inpatient place of service (POS), to review the necessity of the inpatient status. Added PA to these codes to review for medical necessity of the shoulder joint replacement for any setting (patient or outpatient), in addition to the current inpatient POS review. • Added PA to CPT 23473 and 23474 for medical necessity review of the shoulder joint replacement, regardless of setting. • Added PA to these codes to review for medical necessity of the shoulder joint replacement, regardless of setting (inpatient or outpatient).

Advanced Diabetes Management Technology **MP25**	**Annual Review** **Recommendation:** • No change to criteria for existing services in policy. • Added non-covered devices/systems that are in the Company policy version, but not in the Medicare version. Some of these are reported with HCPCS code A9280, others with A9279. • Also added d-Nav to the policy (0740T, 0741T). No Medicare coverage criteria, so internal Company policy criteria apply. **Codes/PA:** Code and configuration changes are as follows: • Added PA to HCPCS A4238 and A4239 (supply codes) to align with Pharmacy PA requirements for same codes. Remove current frequency limit because it has been overriding the PA. • Added 0740T, 0741T to policy, and added NMN edit. • Added A9280 to policy, no edits as code currently denies not a benefit for all LOBs. • No change to existing codes in the policy or their configuration.
Spinal Fusion and Decompression Procedures **MP358**	**Interim Update** **Recommendation:** Added CPT 20939 for bone marrow aspiration for spinal surgery. No Medicare coverage policy criteria are available for this specific service, so will use Company policy criteria. **Codes/PA:** CPT 20939: Removed PA and adedd NMN edit. No change to other codes in policy already.

VENDOR UPDATES

Carelon Cardiology Utilization Management	**New Policies/Vendor Program** **Background/Recommendation:** • The Carelon Clinical Appropriateness Guidelines for Cardiovascular are developed through a rigorous process integrating evidence-based literature with expert physician review.

	• With Carelon Medical Benefits Management review we can ensure that members are receiving the right care at the right time. • For commercial and Medicare only, it is recommended that as of 5/6/2025, the below outpatient cardiology services require Prior Authorization through Carelon: **Cardiovascular Ultrasound** ▪ Arterial Duplex ▪ Arterial Physiologic Study **Coronary Angiography and Interventions** ▪ Diagnostic Coronary Angiography ▪ Percutaneous Coronary Intervention ▪ Cardiac Ablation ▪ Electrophysiology Study ▪ Septal Defect Closure (PFO) **Cardiac Devices** ▪ Cardioverter Defibrillators o Implantable o Wearable (Commercial only) ▪ Cardiac Resynchronization Therapy ▪ Pacemakers ▪ Cardiac Rhythm Monitors **Vascular Interventions** ▪ Dialysis Circuit Access Intervention ▪ Peripheral Arterial Revascularization ▪ Vascular Embolization or Occlusion • Procedures conducted in an inpatient setting or on an emergent basis, such as those performed during an ER evaluation before patient discharge, are excluded from the program. • Medical Policies pertaining to outpatient cardiac services (e.g., External Ambulatory Electrocardiography) will be archived as of Carelon program effective date 5/6/2025 **Effective Date:** 5/6/2025; initial provider notification was given 60 days prior. **Codes/PA:** • As of Carelon Program effective date 5/6/2025, the Providence Health Plan Prior Authorization List will include all applicable CPT/HCPCS codes for cardiac services requiring PA through Carelon. • Medicaid and ASO groups are excluded from this change.

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

Pharmacy & Therapeutics (P&T) Committee

Oregon Region P&T Committee Meeting February 7, 2025
Go-Live Date: Tuesday, April 01, 2025, unless otherwise noted

Table of Contents:

New Drugs and Combinations:

1. **Marstacimab-hncq (Hympavzi) Pen Injctr**
    a. **Indication**: For routine prophylaxis to prevent or reduce the frequency of bleeding episodes in adults and pediatric patients 12 years of age and older with:
        a. Hemophilia A (congenital factor VIII deficiency) without factor VIII inhibitors, or
        b. Hemophilia B (congenital factor IX deficiency) without factor IX inhibitors
    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	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: Hemophilia A: Advate®, Adynovate®, Afstyla®, Altuviiio®, Eloctate®, Esperoct®, Jivi®, Kogenate® FS, Kovaltry®, NovoEight®, Nuwiq®, Recombinate™, Xyntha®, Hemlibra®, Roctavian®			

Hemophilia B: Alprolix®, BeneFix®, Idelvion®, Ixinity®, Rebinyn®, Rixubis®, Hemgenix®, Beqvez™

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

PA PROGRAM NAME	Hympavzi®
MEDICATION NAME	Marstacimab-hncq (Hympavzi®)
PA INDICATION INDICATOR	1 - All FDA-Approved Indications
OFF-LABEL USES	N/A
EXCLUSION CRITERIA	Use with other prophylactic therapies (such as emicizumab-kxwh)
REQUIRED MEDICAL INFORMATION	For initial authorization: 1. Use is for routine prophylaxis to prevent or reduce the frequency of bleeding episodes 2. Must meet criteria for one of the following (Hemophilia A **OR** Hemophilia B): a. Diagnosis of severe hemophilia A (congenital factor VIII deficiency) defined as pre-treatment factor VIII level less than 1 IU/dL or less than 1% of normal factor levels b. Diagnosis of moderately severe to severe hemophilia B (congenital factor IX deficiency) defined as pre-treatment factor IX level less than 2 IU/dL or less than or equal to 2% of normal factor levels 3. Patient does not have inhibitors defined as one of the following: a. For Hemophilia A: factor VIII inhibitor titer less than 0.6 Bethesda units (BU) per mL b. For Hemophilia B: factor IX inhibitor titer less than 0.6 Bethesda units (BU) per mL 4. Weigh 35 kg or more at treatment initiation 5. Dose and frequency must be in accordance with FDA-approved labeling For reauthorization: 1. Documentation of response to therapy indicating a beneficial response (such as a reduction in bleeding events, in the severity of bleeding episodes, in the number of bleeding events that required treatment, and/or in the number of spontaneous bleeds) 2. Dose and frequency must be in accordance with FDA-approved labeling
AGE RESTRICTIONS	Age must be appropriate based on FDA-approved indication.
PRESCRIBER RESTRICTIONS	Must be prescribed by, or in consultation with, a hematologist
QUANTITY LIMIT	N/A
COVERAGE DURATION	Authorization and reauthorization will be approved for one year.

2. **Foscarbidopa-foslevodopa (Vyalev) Vial**
   a. **Indication**: For the treatment of motor fluctuations in adults with advanced Parkinson's disease (PD).
   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
Specialty Medication	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: carbidopa/levodopa			

3. **Inavolisib (Itovebi) Tablet**
   a. **Indication**: For the treatment of adults with endocrine-resistant, PIK3CA-mutated, hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative, locally advanced or metastatic breast cancer (mBC), as detected by an FDA-approved test, following recurrence on or after completing adjuvant endocrine therapy.
   b. **Decision**:

	Commercial	Medicaid	Medicare
Formulary Status*	Formulary	Formulary	Part D: Formulary Part B: N/A
Tier**	Tier 6 - Non-Preferred Specialty	N/A	Specialty
Affordable Care Act Eligible	No	N/A	N/A
Utilization Management Edits	Prior Authorization	Prior Authorization	Prior Authorization
Quantity Limit	9 mg: one tablet per day 3 mg: two tablets per day	9 mg: one tablet per day 3 mg: two tablets per day	9 mg: one tablet per day 3 mg: two tablets per day
* Recommendations for placement may differ between lines of business due to regulatory requirements. ** Medications will be placed on recommended tier above for the base formulary; tier placement for custom formulary(ies) will be based on designation above. For example, Commercial Tier 6 designation above means that the medication will be placed on the highest cost-sharing tier on the respective formulary(ies).			
Formulary Alternatives: anastrozole, letrozole, exemestane, or fulvestrant along with Kisqali, Verzenio or Ibrance			

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

4. **Levacetylleucine (Aqneursa) Gran Pack**
   a. **Indication**: For the treatment of neurological manifestations of Niemann-Pick disease type C (NPC) in adults and pediatric patients weighing equal to or over 15 kilograms.
   b. **Decision**:

	Commercial	Medicaid	Medicare
Formulary Status*	Non-formulary	Non-formulary	Part D: Non-formulary Part B: N/A
Tier**	N/A	N/A	N/A
Affordable Care Act Eligible	No	N/A	N/A
Utilization Management Edits	Prior Authorization	Prior Authorization	N/A
Quantity Limit	4 packets/day	4 packets/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: N/A			

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

PA PROGRAM NAME	Medications for Rare Indications
MEDICATION NAME	Levacetylleucine (Aqneursa) granule
PA INDICATION INDICATOR	1 - All FDA-Approved Indications
OFF-LABEL USES	N/A
EXCLUSION CRITERIA	For Aqneursa only – concurrent therapy with arimoclomol citrate 4/1/(Miplyffa)
REQUIRED MEDICAL INFORMATION	1. Confirmation of FDA-labeled indication and drug-specific criteria (See Table 1) 2. Dosing is within FDA-labeled guidelines OR documentation has been submitted in support of therapy with a higher dose for the intended diagnosis such as high-quality peer reviewed literature, guidelines, other clinical information Table 1:

	For Aqneursa: Diagnosis of Niemann-Pick disease type C (NPC) confirmed by mutations in both alleles of NPC1 or NPC2, or mutation in only one allele of NPC1 or NPC2 plus either positive filipin staining or elevated cholestane triol/oxysterols (over two times the upper limit of normal) Reauthorization Criteria: For Aqneursa®: Documentation of benefit of therapy as evidence by improvement from baseline in the 5-domain NPC Clinical Severity Scale (NPCCSS) score, SARA score, or mSARA score
AGE RESTRICTIONS	Age must be appropriate based on FDA-approved indication
PRESCRIBER RESTRICTIONS	Must be prescribed by, or in consultation with a specialist in the respective disease state.
COVERAGE DURATION	For Aqneursa: Initial authorization will be approved for 12 months. Reauthorization will be approved for 12 months.

5. **Nemolizumab-ilto (Nemluvio) Pen Injctr**
   a. **Indication**: For the treatment of adults with prurigo nodularis and treatment of moderate to severe atopic dermatitis in adults and pediatric patients at least 12 years of age whose disease is not adequately controlled with topical
   b. **Decision**:

	Commercial	Medicaid	Medicare
Formulary Status*	Non-formulary	Non-formulary	Part D: Non-formulary Part B: N/A
Tier**	N/A	N/A	N/A
Affordable Care Act Eligible	No	N/A	N/A
Utilization Management Edits	Prior Authorization	Prior Authorization	N/A
Quantity Limit	1 mL/56 days	1 mL/56 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: dupilumab (Dupixent®)			

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

PA PROGRAM NAME	Interleukin (IL)-31 Inhibitors
MEDICATION NAME	Nemolizumab-ilto (Nemluvio)
PA INDICATION INDICATOR	1 - All FDA-Approved Indications

EXCLUSION CRITERIA	Combination therapy with another therapeutic immunomodulator (TIM) agent
REQUIRED MEDICAL INFORMATION	**For Commercial:** For initial authorization for Prurigo Nodularis: 1. Diagnosis of prurigo nodularis as defined by the following: a. Presence of firm, nodular lesions b. Itching which has lasted for at least six weeks 2. Patient has had an inadequate response, intolerance, or contraindication to both of the following: a. Two-week trial of a moderate to high potency topical corticosteroid b. Six-month trial of dupilumab For initial authorization for Moderate-Severe Atopic Dermatitis: 1. One of the following must be met: a. Patient has a body surface area (BSA) involvement of at least 40% b. Patient has a BSA involvement of 10-39%, or involvement of the palms of the hands and/or soles of the feet, AND had an inadequate response, intolerance, or contraindication to a four-week trial of both of the following therapies: i. Moderate to high potency topical corticosteroid ii. Topical calcineurin inhibitor (such as tacrolimus ointment). This criterion may be waived with trial of systemic immunosuppressant (such as methotrexate, azathioprine, mycophenolate, cyclosporine) 2. Inadequate response, intolerance, or contraindication to a three-month trial of dupilumab **For Medicaid:** For Atopic Dermatitis, all the following must be met: 1. One of the following: a. Diagnosis of severe atopic dermatitis with functional impairment as indicated by both of the following: i. Dermatology Life Quality Index (DLQI) of at least 11, Children's Dermatology Life Quality Index (CDLQI) of at least 13, or severe score on another validated tool ii. At least 10% of body surface area involved or hand, foot, face, or mucous member involvement b. Patient is less than 21 years of age with documentation that the condition is of sufficient severity that it impacts the patient's health (such as quality of life, function, growth, development, ability to participate in school, or perform activities of daily living) 2. Inadequate efficacy of a four-week trial (unless intolerant or contraindicated) of at least one of the following: a. Combination of moderate to high potency topical corticosteroid and topical calcineurin inhibitor

	b. Oral immunomodulator therapy (e.g., cyclosporine, methotrexate, or oral corticosteroids) **For Prurigo Nodularis (PN), one of the following must be met for initial authorization**: 1. Diagnosis of severe prurigo nodularis with functional impairment as indicated by both of the following: a. Dermatology Life Quality Index (DLQI) of at least 11, Children's Dermatology Life Quality Index (CDLQI) of at least 13, or severe score on another validated tool b. At least 10% of body surface area involved or hand, foot, face, or mucous member involvement 2. Patient is less than 21 years of age with documentation that the condition is of sufficient severity that it impacts the patient's health (such as quality of life, function, growth, development, ability to participate in school, or perform activities of daily living) **For reauthorization:** Response to therapy indicating improvement or stabilization of condition **For quantity limit exceptions**: If the request is for more than 1 mL per 56 days: • For AD: A request for 1 mL per 28 days may be approved if patient has not achieved clear or almost clear skin in the last six months • For PN: A request for 2 mL per 28 days may be approved if patient weighs at least 90 kg
AGE RESTRICTIONS	Age must be appropriate per FDA-label
PRESCRIBER RESTRICTIONS	Must be prescribed by, or in consultation with, a dermatologist, allergist, or immunologist
COVERAGE DURATION	Initial authorization will be approved for six months. Reauthorization will be approved for one year.
QUANTITY LIMITS	1 mL per 56 days

6. **Revumenib citrate (Revuforj) Tablet**
   a. **Indication**: For the treatment of relapsed or refractory (R/R) acute leukemia with a lysine methyltransferase 2A gene (KMT2A) translocation in adult and pediatric patients 1 year and older.
   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	Two tablets per day	Two tablets per day	Two tablets per day
* Recommendations for placement may differ between lines of business due to regulatory requirements. ** Medications will be placed on recommended tier above for the base formulary; tier placement for custom formulary(ies) will be based on designation above. For example, Commercial Tier 6 designation above means that the medication will be placed on the highest cost-sharing tier on the respective formulary(ies).			
Formulary Alternatives: N/A			

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

7. **Zolbetuximab-clzb (Vyloy) Vial**
   a. **Indication**: For the first-line treatment of adults with locally advanced unresectable or metastatic human epidermal growth factor receptor 2 (HER2)-negative gastric or gastroesophageal junction (GEJ) adenocarcinoma whose tumors are claudin (CLDN) 18.2 positive as determined by 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	No	N/A	N/A
Utilization Management Edits	Prior Authorization	Prior Authorization	Prior Authorization
Quantity Limit	N/A	N/A	N/A
* Recommendations for placement may differ between lines of business due to regulatory requirements. ** Medications will be placed on recommended tier above for the base formulary; tier placement for custom formulary(ies) will be based on designation above. For example, Commercial Tier 6 designation above means that the medication will be placed on the highest cost-sharing tier on the respective formulary(ies).			
Formulary Alternatives: nivolumab, pembrolizumab			

New Indications:

The following information is gathered from the United States Food and Drug Administration (FDA) Approved Drug Products database from 10/1/2024 – 11/30/2024

Therapies with Prior Authorization Policies (Non-oncology)

1. **BIMZELX** (BIMEKIZUMAB-BKZX)
    a. Previous Indication(s):
        i. Moderate to severe plaque psoriasis (PSO) in adults who are candidates for systemic therapy or phototherapy
        ii. Adults with active psoriatic arthritis (PsA)
        iii. Adults with active non-radiographic axial spondyloarthritis (nraxSpA) with objective signs of inflammation
        iv. Adults with active ankylosing spondylitis (AS)
    b. New indication approved 11/19/2024:
        i. Adults with moderate to severe hidradenitis suppurativa (HS)
    c. **RECOMMENDATION:** Inform prescribers via Medical Policy Alert. Update policy with new indication. No updates to criteria required.

2. **BOTOX** (**ONABOTULINUMTOXINA**)
    a. Previous Indication(s):
        i. Treatment of overactive bladder with symptoms of urge urinary incontinence, urgency, and frequency, in adults who have an inadequate response to or are intolerant of an anticholinergic medication.
        ii. Treatment of urinary incontinence due to detrusor overactivity associated with a neurologic condition (e.g., SCI, MS) in adults who have an inadequate response to or are intolerant of an anticholinergic medication.
        iii. Treatment of neurogenic detrusor overactivity (NDO) in pediatric patients 5 years of age and older who have an inadequate response to or are intolerant of anticholinergic medication.
        iv. Prophylaxis of headaches in adult patients with chronic migraine (≥15 days per month with headache lasting 4 hours a day or longer). Limitations of Use: Safety and effectiveness have not been established for the prophylaxis of episodic migraine (14 headache days or fewer per month) in seven placebo-controlled studies.
        v. Treatment of spasticity in patients 2 years of age and older. Limitations of Use: BOTOX has not been shown to improve upper extremity functional abilities, or range of motion at a joint affected by a fixed contracture.
        vi. Treatment of adults with cervical dystonia, to reduce the severity of abnormal head position and neck pain associated with cervical dystonia.
        vii. Treatment of severe primary axillary hyperhidrosis that is inadequately managed with topical agents. Limitations of Use: The safety and effectiveness of BOTOX for hyperhidrosis in other body areas have not been established. Weakness of hand muscles and blepharoptosis may occur in patients who receive BOTOX for palmar hyperhidrosis and facial hyperhidrosis, respectively. Patients should be evaluated for potential causes of secondary hyperhidrosis (e.g., hyperthyroidism) to avoid symptomatic treatment of hyperhidrosis without the diagnosis and/or treatment of the underlying disease. Safety and effectiveness of BOTOX have not been established for the treatment of axillary hyperhidrosis in pediatric patients under age 18.
        viii. Treatment of strabismus and blepharospasm associated with dystonia, including benign essential blepharospasm or VII nerve disorders in patients 12 years of age and older.

b. New indication approved 10/18/2024:
    i. Temporary improvement in the appearance of moderate to severe platysma bands associated with platysma muscle activity in adult patients.
c. **RECOMMENDATION:** Update Botulinum Toxin Commercial/Medicaid Prior Authorization Policy with new indication and add as new exclusion criteria as it is cosmetic. Update Botulinum Toxin Medicare Part B Prior Authorization Policy with new indication. Inform prescribers via Medical Policy Alert.

Prior Authorization for Commercial/Medicaid:

PA PROGRAM NAME	BOTULINUM TOXIN
MEDICATION NAME	Botox (OnabotulinumtoxinA)
COVERED USES	4 - All FDA-Approved Indications, Some Medically-Accepted Indications
EXCLUSION CRITERIA	Botulinum toxin is considered cosmetic and is not covered for the treatment of glabellar lines and/or fine wrinkles on the face, or platysma bands associated with platysma muscle activity. • PrabotulinumtoxinA (Jeuveau®) will not be covered as it is only FDA approved for the treatment of glabellar lines and/or fine wrinkles on the face.

3. **LUMRYZ** (SODIUM OXYBATE)
    a. Previous Indication(s):
        i. Treatment of cataplexy or excessive daytime sleepiness (EDS) in adults with narcolepsy
    b. New indication approved 10/16/2024:
        i. Treatment of cataplexy or excessive daytime sleepiness (EDS) in patients 7 years of age and older with narcolepsy
    c. **RECOMMENDATION:** Inform prescribers via Medical Policy Alert. Update policy with new indication. No updates to criteria required.

4. **REPATHA** (EVOLOCUMAB)
    a. Previous Indication(s):
        i. In adults with established cardiovascular disease (CVD) to reduce the risk of myocardial infarction, stroke, and coronary revascularization
        ii. As an adjunct to diet, alone or in combination with other low-density lipoprotein cholesterol (LDL-C)-lowering therapies, in adults with primary hyperlipidemia, including heterozygous familial hypercholesterolemia (HeFH), to reduce LDL-C
        iii. As an adjunct to diet and other LDL-C-lowering therapies in pediatric patients aged 10 years and older with HeFH, to reduce LDL-C
        iv. As an adjunct to other LDL-C-lowering therapies in adults and pediatric patients aged 10 years and older with homozygous familial hypercholesterolemia (HoFH), to reduce LDL-C
    b. New indication approved 11/20/2024:
        i. To reduce the risk of major adverse cardiovascular (CV) events (CV death, myocardial infarction, stroke, unstable angina requiring hospitalization, or coronary revascularization) in adults with established cardiovascular disease
    c. **RECOMMENDATION:** Inform prescribers via Medical Policy Alert. Update policy with new indication. No updates to criteria required.

Therapies with Prior Authorization Policies (Oncology)

5. **FLUDARABINE PHOSPHATE**
    a. New indication(s) approved 11/19/2024:
        i. As a component of a combination regimen for the treatment of adults with B-cell chronic lymphocytic leukemia (CLL)
        ii. For the treatment of adults with B-cell CLL who have not responded to, or whose disease has progressed during treatment with at least one alkylating-agent containing regimen
    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. **OPDIVO** (NIVOLUMAB)
    a. New indication(s) approved 10/03/2024:
        i. Opdivo, in combination with platinum-doublet chemotherapy, for the neoadjuvant treatment of adult patients with resectable (tumors ≥4 cm or node positive) non-small cell lung cancer and no known epidermal growth factor receptor (EGFR) mutations or anaplastic lymphoma kinase (ALK) rearrangements, followed by single-agent Opdivo as adjuvant treatment after surgery.
    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. **SCEMBLIX** (ASCIMINIB HYDROCHLORIDE)
    a. New indication approved 10/29/2024:
        i. Treatment of adult patients with newly diagnosed Philadelphia chromosome-positive chronic myeloid leukemia (Ph+ CML) in chronic phase (CP).
    b. Revised indication approved 10/29/2024:
        ii. Treatment of adult patients with previously treated Philadelphia chromosome-positive chronic myeloid leukemia (Ph+CML) in chronic phase (CP).
    c. **RECOMMENDATION:** Inform prescribers via Medical Policy Alert. Prior authorization policy coverage criteria are based on recommendations from the National Comprehensive Cancer Network (NCCN); no updates to the policy are warranted.

8. **TRODELVY** (SACITUZUMAB GOVITECAN-HZIY)
    a. New indication(s) approved 11/22/2024:
        i. Locally advanced or metastatic urothelial cancer (mUC) who have previously received a platinum-containing chemotherapy and either programmed death receptor-1 (PD-1) or programmed death-ligand 1 (PDL1) inhibitor
            1) This indication is approved under accelerated approval based on tumor response rate and duration of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial.
    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.

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

9. **ABRYSVO** (RESPIRATORY SYNCYTIAL VIRUS VACCINE)
    a. Previous Indication(s):
        i. Active immunization of pregnant individuals at 32 through 36 weeks gestational age for the prevention of lower respiratory tract disease (LRTD) and severe LRTD caused by respiratory syncytial virus (RSV) in infants from birth through 6 months of age.

ii. Active immunization for the prevention of LRTD caused by RSV in individuals 60 years of age and older.

b. New indication(s) approved 10/22/2024:
   i. Active immunization for the prevention of lower respiratory tract disease (LRTD) caused by Respiratory Syncytial Virus (RSV) in individuals 18 through 59 years of age who are at increased risk for LRTD caused by RSV.

c. **RECOMMENDATION:** Inform prescribers via Medical Policy Alert. ACIP recommendations have not changed.

10. **BOTOX COSMETIC** (**ONABOTULINUMTOXINA**)
    a. Previous Indication(s):
       i. Temporary improvement in the appearance of moderate to severe glabellar lines associated with corrugator and/or procerus muscle activity in adult patients.
       ii. Temporary improvement in the appearance of moderate to severe lateral canthal lines associated with orbicularis oculi activity in adult patients.
       iii. Temporary improvement in the appearance of moderate to severe forehead lines associated with frontalis muscle activity in adult patients.
    b. New indication approved for Botox and Botox Cosmetic 10/18/2024:
       i. Temporary improvement in the appearance of moderate to severe platysma bands associated with platysma muscle activity in adult patients.
    c. **RECOMMENDATION:** Inform prescribers via Medical Policy Alert.

11. **FRAGMIN** (DALTEPARIN SODIUM)
    a. Previous Indication(s):
       i. Prophylaxis of ischemic complications in unstable angina and non-Q-wave myocardial infarction, when concurrently administered with aspirin therapy.
       ii. Prophylaxis of deep vein thrombosis (DVT), which may lead to pulmonary embolism (PE):
          1. In patients undergoing hip replacement surgery
          2. In patients undergoing abdominal surgery who are at risk for thromboembolic complications
          3. In medical patients who are at risk for thromboembolic complications due to severely restricted mobility during acute illness
       iii. Extended treatment of symptomatic venous thromboembolism (VTE) (proximal DVT and/or PE), to reduce the recurrence of VTE in adult patients with cancer. In these patients, the FRAGMIN therapy begins with the initial VTE treatment and continues for six months.
       iv. Treatment of symptomatic venous thromboembolism (VTE) to reduce the recurrence of VTE in pediatric patients 1 month of age and older.
       v. Limitations of Use: Fragmin is not indicated for the acute treatment of VTE.
    b. New indication(s) approved 10/15/2024:
       i. Treatment of symptomatic venous thromboembolism (VTE) to reduce the recurrence of VTE in pediatric patients from birth (gestational age at least 35 weeks).
    c. **RECOMMENDATION:** Inform prescribers via Medical Policy Alert.

12. **JYLAMVO** (METHOTREXATE)
    a. Previous Indication(s):
       i. Treatment of adults with acute lymphoblastic leukemia (ALL) as part of a combination chemotherapy maintenance regimen.
       ii. Treatment of adults with mycosis fungoides.
       iii. Treatment of adults with relapsed or refractory nonHodgkin lymphoma as part of a metronomic combination regimen.

iv. Treatment of adults with rheumatoid arthritis.
v. Treatment of adults with severe psoriasis.

b. New indication(s) approved 10/23/2024:
i. Treatment of pediatric patients with polyarticular juvenile idiopathic arthritis (pJIA).
ii. Treatment of pediatric patients with acute lymphoblastic leukemia (ALL) as part of a combination chemotherapy maintenance regimen.

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

13. **ZARXIO** (FILGRASTIM-SNDZ)
a. Previous Indication(s):
i. Decrease the incidence of infection, as manifested by febrile neutropenia, in patients with nonmyeloid malignancies receiving myelosuppressive anti-cancer drugs associated with a significant incidence of severe neutropenia with fever.
ii. Reduce the time to neutrophil recovery and the duration of fever, following induction or consolidation chemotherapy treatment of patients with acute myeloid leukemia (AML).
iii. Reduce the duration of neutropenia and neutropenia-related clinical sequelae, e.g., febrile neutropenia, in patients with nonmyeloid malignancies undergoing myeloablative chemotherapy followed by bone marrow transplantation (BMT).
iv. Mobilize autologous hematopoietic progenitor cells into the peripheral blood for collection by leukapheresis.
v. Reduce the incidence and duration of sequelae of severe neutropenia (e.g., fever, infections, oropharyngeal ulcers) in symptomatic patients with congenital neutropenia, cyclic neutropenia, or idiopathic neutropenia.

b. New indication(s) approved 10/22/2024:
i. Increase survival in patients acutely exposed to myelosuppressive doses of radiation (Hematopoietic Subsyndrome of Acute Radiation Syndrome (H-ARS)).

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

Drug Safety Monitoring:

The following information is gathered from the United States Food and Drug Administration (FDA) database from 10/1/2024 – 11/30/2024

FDA Drug Safety Communications
None

Drug Recalls/Market Withdrawals

1. **Drug Name:** Ascorbic Acid Solution for Injection
- **Date of Recall:** 10/10/2024
- **Reason for recall:** Presence of glass particulates

- **Link to more information:** https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/staska-pharmaceuticals-inc-issues-voluntary-nationwide-recall-ascorbic-acid-solution-injection
- **Health Plan Recommendation:** Notify providers via Medical Policy Alert.

2. **Drug Name:** AK Forte Dietary Supplement
   - **Date of Recall:** 10/16/2024
   - **Reason for recall:** Product is tainted with diclofenac, dexamethasone, and methocarbamol
   - **Link to more information:** https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/ca-naturistics-issues-voluntary-nationwide-recall-ak-forte-tablets-con-ortiga-y-omega-3-due-presence
   - **Health Plan Recommendation:** Notify providers via Medical Policy Alert.
3. **Drug Name:** ZoomMax and ZapMax Capsules
   - **Date of Recall:** 11/04/2024
   - **Reason for recall:** Product is tainted with sildenafil
   - **Link to more information:** https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/boulla-llc-issues-voluntary-nationwide-recall-zoommax-and-zapmax-capsules-due-presence-undeclared
   - **Health Plan Recommendation:** Notify providers via Medical Policy Alert.
4. **Drug Name:** VitalityXtra and PeakMax Capsules
   - **Date of Recall:** 11/04/2024
   - **Reason for recall:** VitalityXtra is tainted with sildenafil and PeakMax with sildenafil and diclofenac
   - **Link to more information:** https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/vitalityvita-issues-voluntary-nationwide-recall-vitalityxtra-and-peakmax-capsules-due-presence
   - **Health Plan Recommendation:** Notify providers via Medical Policy Alert.
5. **Drug Name:** Clonazepam Orally Disintegrating Tablets, USP (C-IV)
   - **Date of Recall:** 11/21/2024
   - **Reason for recall:** Mislabeled with the incorrect strength on the carton
   - **Link to more information:** https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/endo-expands-voluntary-recall-clonazepam-orally-disintegrating-tablets-usp-c-iv-due-potential
   - **Health Plan Recommendation:** Notify providers via Medical Policy Alert.
6. **Drug Name:** UMARY Hyaluronic Acid tablets
   - **Date of Recall:** 11/21/2024
   - **Reason for recall:** The product contains undeclared diclofenac and omeprazole
   - **Link to more information:** https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/mxbbb-issues-voluntary-nationwide-recall-umary-acid-hyaluronic-due-presence-diclofenac-and
   - **Health Plan Recommendation:** Notify providers via Medical Policy Alert.

Safety-related Labelling Updates

7. **Drug Name:** Glucagon-like peptide-1 receptor agonist (GLP-1 RA) products
    a. **Date of Update:** 10/01/2024-11/30/2024
    b. **Reason for update:** This information pertains to the serious risk of pulmonary aspiration for patients undergoing elective surgeries or procedures requiring general anesthesia or deep sedation
    c. **Link to label:** https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2024/125469Orig1s061,%20s062ltr.pdf
    d. **Health Plan Recommendation:** Notify providers via Medical Policy Alert
8. **Drug Name:** Ilaris (canakinumab)
    a. **Date of Update:** 11/01/2024
    b. **Reason for update:** Risk of drug reaction with eosinophilia and systemic symptoms (DRESS)
    c. **Link to label:** https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2024/125319Orig1s110ltr.pdf
    d. **Health Plan Recommendation:** Notify providers via Medical Policy Alert
9. **Drug Name:** Leqembi (lecanemab-irmb)
    a. **Date of Update:** 11/14/2024
    b. **Reason for update:** Risk of symptoms of amyloid-related imaging abnormalities (ARIA) mimicking symptoms of ischemic stroke and the increased risk of ARIA in patients with baseline factors of pretreatment microhemorrhages or superficial siderosis
    c. **Link to label:** https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2024/761269Orig1s008ltr.pdf
    d. **Health Plan Recommendation:** Notify providers via Medical Policy Alert
10. **Drug Name:** Lunsumio (mosunetuzumab)
    a. **Date of Update:** 11/22/2024
    b. **Reason for update:** Warning/Precaution of Hemophagocytic Lymphohistiocytosis
    c. **Link to label:** https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2024/761263Orig1s005ltr.pdf
    d. **Health Plan Recommendation:** Notify providers via Medical Policy Alert
11. **Drug Name:** Sunlenca (lenacapavir)
    a. **Date of Update:** 11/25/2024
    b. **Reason for update:** Improper administration (intradermal injection) and associated serious injection site reactions, including necrosis and ulcer
    c. **Link to label:** https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2024/215973Orig1s006,215974Orig1s008ltr.pdf
    d. **Health Plan Recommendation:** Notify providers via Medical Policy Alert

Other Formulary Changes:

Drug Name	Recommendation	Policy Name
Amlodipine/valsartan/ HCTZ Tablet	Remove from Medicaid formulary	N/A
Aurlumyn (iloprost tromethamine) 100 mcg/mL vial	Covered medical benefit for all lines of business	N/A
Carbamazepine 200 mg chewable tablet	Non-formulary for all lines of business	N/A

Drug Name	Recommendation	Policy Name
Danziten (nilotinib tartrate) tablet	New strength/dosage form. Line extend with Tasigna • Commercial: Formulary, Tier 6, Prior Authorization • Medicaid: Covered by DMAP • Medicare Part D: Formulary, Tier 5, Prior Authorization	• Commercial/Medicaid: Anti-Cancer Medications - Self-Administered • Medicare Part D: Anti-cancer agents
Dexamethasone intensol Drops	Add to Commercial and Medicare Part D Formularies, Tier 2	N/A
Doxepin HCl Tablet	Medicaid: Remove Prior Authorization and Quantity Limit	N/A
Emtricitabine/tenofov alafenam (Descovy) Tablet	Add to formulary: • Commercial: Formulary, Tier 3 • Medicaid: Formulary	Descovy
Erlotinib tablet	Move to Tier 5 for Commercial	Anti-Cancer Medications - Self-Administered
Esomeprazole packets	Add to Commercial formulary, Tier 2	
• **Fluvastatin ER tablet** • **Fluvastatin capsule** • **Pitavastatin tablet** • **Quinapril/HCTZ** • **Candesartan/HCTZ** • **Telmisartan/HCTZ** • **Olmesartan/ amlodipine/ HCTZ** • **Amlodipine/atorvastatin**	Add to Medicare Part D formulary, Tier 2 Effective 12/15/2024	N/A
• **Guaifenesin Tablet** • **Guaifenesin ER tablet**	Add to Medicaid formulary	N/A
• **Hydrocodone-acetaminophen 2.5/325 mg tablet** • **Hydrocodone-acetaminophen 10-325 per 15 mL solution**	Add to Formulary • Commercial: Formulary, tier 2 • Medicaid: Formulary • Medicare Part D: Formulary, tier 3	N/A
• **K-Phos Neutral (potassium and sodium phosphate)** • **K-Phos Original (potassium phosphate, monobasic)**	Add to Formulary • Commercial: Formulary, tier 2 • Medicaid: Formulary	N/A
Mesalamine 4 g/60 mL enema	Add quantity limit to Medicaid of 60 mL per day	N/A
Myrbetriq (mirabegron) tablet and suspension	Retire step therapy and change formulary status as follows:	N/A

Drug Name	Recommendation	Policy Name
	• Commercial: Move to tier 3 and add quantity limit (1 tablet per day or 10 mL per day) • Medicaid: Remove from formulary and add quantity limit (1 tablet per day or 10 mL per day)	
Naproxen DR 500 mg tablet	Remove from Commercial and Medicaid formulary	N/A
Opipza (aripiprazole) film	New formulation • Commercial: Non-Formulary, Quantity Limit (3 films per day) • Medicaid: Covered by DMAP • Medicare Part D: Non-Formulary	N/A
Pavblu (aflibercept-ayyh)	Biosimilar for Eylea. Covered medical benefit for all lines of business	N/A
Nirmatrelvir/ritonavir (Paxlovid) Tab DS PK	Commercial: Move to Tier 3	N/A
Pentazocine/naloxone	Remove from Medicaid formulary	N/A
Quinapril/HCTZ	Add Medicare formulary, Tier 2	
Sacubitril/valsartan tablet	Authorized generic for Entresto • Commercial: Non-Formulary • Medicaid: Formulary • Medicare Part D: Non-Formulary	N/A
Sodium chloride 3% nebulizer vial	Add to Medicaid formulary	N/A
Telmisartan/amlodipine	Add to Medicare Part D formulary, Tier 3 Effective 12/15/2024	N/A
Testosterone cypionate 200 mg/mL syringe	New formulation. Covered medical benefit for all lines of business	N/A
Yonsa (abiraterone submicronized)	Remove from Medicaid formulary	Anti-Cancer Medications - Self-Administered

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**
Axtle (pemetrexed dipotassium) vial	New salt form. Line extend with Alimta® as covered medical benefit for all lines of business	N/A
Erzofri (paliperidone palmitate) syringe	New formulation. Line extend with Invega Sustenna. • Commercial/Medicaid: Covered medical benefit	N/A

NEW DRUGS / COMBINATIONS / STRENGTHS / DOSAGE FORMS		
Drug Name	**Action Taken**	**Policy Name**
	• Medicare Part D: Formulary, Tier 5, Quantity Limit (0.25 mL per 28 days) • Medicare Part B: Covered medical benefit	
Augtyro (repotrectinib) 160 mg capsule	New strength. Line extend with Line extend with Augtryo 40mg capsule. • Commercial: Formulary, Tier 6, Prior Authorization, Quantity Limit (two capsules per day) • Medicaid: Formulary, Prior Authorization, Quantity Limit (two capsules per day) • Medicare Part D: Formulary, Tier 5, Prior Authorization Quantity Limit (two capsules per day)	• Commercial/Medicaid: Anti-Cancer Medications - Self-Administered • Medicare Part D: Anti-cancer agents
Lumakras (sotorasib) 240mg tablet	New strength. Line extend with Line extend with Lumakras 120 mg capsule. • Commercial: Formulary, Tier 6, Prior Authorization • Medicaid: Formulary, Prior Authorization • Medicare Part D: Formulary, Tier 5, Prior Authorization Quantity Limit (four tablets per day)	• Commercial/Medicaid: Anti-Cancer Medications - Self-Administered • Medicare Part D: Anti-cancer agents
Ryzumvi (phentolamine mesylate/pf) 0.75 % droperette	New formulation. Line extend as covered medical benefit for all lines of business	N/A
Freestyle Libre 2 plus sensor (blood-glucose sensor)	New product. Line extend with Freestyle Libre sensors: Preferred diabetic supply for all lines of business with Quantity Limit of 2 sensors per 28 days	
Adalimumab-adaz 20 mg/0.2 mL syringe	New product. Line extend as preferred Humira biosimilar • Commercial: Formulary, Tier 5, Prior Authorization, Quantity Limit (0.4 mL per 28 days) • Medicaid: Formulary, Prior Authorization, Quantity Limit (0.4 mL per 28 days) • Medicare Part D: Formulary, Tier 5, Prior Authorization	Therapeutic Immunomodulators
Ebglyss (lebrikizumab-lbkz) 250 mg/2mL syringe	New dosage form; Line extend with Ebglyss Pen Injctr • Commercial: Non-Formulary, Prior Authorization, Quantity Limit (2 mL per 28 days) • Medicaid: Non-Formulary, Prior Authorization, Quantity Limit (2 mL per 28 days) • Medicare Part D: Non-Formulary	Interleukin-13 inhibitors

NEW DRUGS / COMBINATIONS / STRENGTHS / DOSAGE FORMS		
Drug Name	**Action Taken**	**Policy Name**
Emrosi (minocycline) 40 mg capsule	New strength. Line extend with minocycline ER tablets • Commercial/Medicaid: Non-Formulary, Prior Authorization • Medicare Part D: Non-Formulary	New Medications and Formulations without Established Benefit
Simlandi (adalimumab-ryvk) 40 mg/0.4 mL syringe kit	New product. Line extend as preferred Humira biosimilar • Commercial: Formulary, Tier 5, Prior Authorization, Quantity Limit (0.8 mL per 28 days) • Medicaid: Formulary, Prior Authorization, Quantity Limit (0.8 mL per 28 days) • Medicare Part D: Formulary, Tier 5, Prior Authorization	Therapeutic Immunomodulators

New Generics:

Drug Name	Action Taken	Policy Name
Avanafil tablet	First generic drug (Stendra). Line extend as generic. Non-formulary for all lines of business	N/A
Dicyclomine 10 mg/mL ampule	First Generic Drug (Bentyl). Line extend as generic. Covered medical benefit for all lines of business	N/A
Hydrocortisone 2.5% solution	First generic drug (Texacort). Line extend as generic • Commercial (Standard): Formulary, Tier 2 • Commercial (Dynamic): Formulary. Tier 4 • Medicaid/Medicare: Non-Formulary	N/A
Nypozi (filgrastim-txid) syringe	New biosimilar for neupogen. Line extend with Neupogen • Commercial: Formulary, Tier 5; also covered medical benefit • Medicaid: Formulary; also covered medical benefit • Medicare Part D: Non-Formulary • Medicare part B: Covered	N/A
Timolol 0.5% drops	First generic drug (Betimol). Line extend as generic • Commercial (Standard): Formulary, Tier 2 • Commercial (Dynamic): Formulary. Tier 4 • Medicaid: Formulary • Medicare: Formulary, Tier 4	N/A

Hercessi (trastuzumab-strf) vial	New biosimilar for Herceptin. Line extend as non-preferred biosimilar • Commercial/Medicaid/Medicare Part B: Medical Benefit, Prior Authorization • Medicare Part D: Non-Formulary	Anti-Cancer Medications - Medical Benefit
Exenatide pen injector	First generic drug (Byetta). Line extend as generic • Commercial/Medicaid: Non-Formulary, Prior Authorization, Quanitty Limit 2.4 mL per 30 days) • Medicare Part D: Non-Formulary	GLP-1 Receptor Agonists
Edaravone 60 mg/100mL infusion bottle	New generic for Radicava. Line extend as generic: medical benefit with prior authorization for all lines of business	Radicava, Radicava ORS

Clinical Policy Changes:

MAJOR CHANGES	
Policy Name	**Summary of Change**
• **Anti-Cancer Medications - Medical Benefit** • **Anti-Cancer Medications Prior Authorization and Step Therapy Policy - Medicare Part B**	Several therapies will be moved to the "T-Cell" policy (Columvi, Blincyto, Epkinly, Imdelltra, Kimmtrak, and Lunsumio).
Benefit Exception - Member-Pay-Difference	This is a new policy to outline criteria for when higher cost-shares may be waived for using a brand medication when a generic is available. This policy was approved by chair vote for 1/1/25 implementation.
Dupixent	Add criteria for new indication Chronic Obstructive Pulmonary Disease.
Filspari	Updated quantity limit to align with approved label dosing. Updated exclusion criteria to align with package insert list of contraindications.
• **Gonadotropin Releasing Hormone Agonists** • **Gonadotropin Releasing Hormone Agonists - Medicare Part B**	Added criteria for premenstrual syndrome. Will allow several therapies to pay paired with diagnosis codes for prostate cancer.
• **Hormone Replacement Therapy** • **Hormone Replacement Therapy Prior Authorization and Step Therapy Policy - Medicare Part B**	Policy was updated based on feedback from committee members to update policy name and language related to gender incongruence.Also billing information was updated to clarify coverage of drugs and administration codes.
• **Hyperoxaluria Agents**	Update required medical criteria to remove fluid intake requirement.

• **Hyperoxaluria Agents Prior Authorization and Step Therapy Policy – Medicare Part B**	
Infusion Therapy Site of Care	Several intravenously administered iron products were removed from the policy due to operational burden.
Medical Necessity - Medicaid	Updated quantity exception criteria to require quantity to be both safe and ensure appropriate tablet is used instead of either or. Updated coverage duration to align duration with the drug prior authorization policy, if applicable.
• **Medical Nutrition – Commercial** • **Medical Nutrition – Medicaid** • **Medical Nutrition – Medicare Part B**	Policy coding material was updated to clarify that certain B-codes require prior authorization to limit fraud, waste, and abuse concerns.
• **Provenge** • **Provenge Prior Authorization Policy - Medicare Part B**	Clarified coverage duration language
• **Rituximab** • **Rituximab Prior Authorization and Step Therapy Policy - Medicare Part B**	Added criteria for Thrombotic Thrombocytopenic Purpura (TTP) to policy; clarified severity criteria for vasculitis indication.
T-Cell Therapy	Added bi-specific T-Cell engager (BiTE) antibodies to the policy, which brings all BiTEs into one policy and allows restriction to appropriate authorization lengths. Clarified policy exclusions.
Weight Management Medications	Policy was updated to clarify continuation of therapy criteria based on clinical trials and BMI requirements.