Providence Health Plan

Providence Health Assurance

Healthcare Services: Medical, Pharmacy, Reimbursement, and Coding Policy Alerts

Number 112

November 1, 2025

This is the November 1, 2025 issue of the Providence Health Plans, Providence Health Assurance and Providence Plan Partners, Policy Alert to our providers. The focus of this update is to communicate to providers' new or revised Medical, Pharmacy, Reimbursement, and Coding policy changes. The Health Plan has a standard process to review all 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 subsequent 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 12/1/2025

Gender Affirming Surgical Interventions **MP32**	**Policy Updates:** • Added criteria regarding electrolysis, and hairline advancement/hair transplantation as explicitly medically necessary to affirm an individual's gender identity and reduce gender incongruence and dysphoria. **Codes/PA:** No changes to codes or PA.
Organic Acid Testing **MP254**	**Policy Updates:** Added Methylmalonic acid testing for suspicion of B12 deficiency as medically necessary in criterion I. **Codes/PA:** Added B12 deficiency dx codes to pair to pay with CPT 83921

Effective 1/1/2026

Allergen Subcutaneous Immunotherapy (SCIT)
 	
MP448
	Policy Updates: New commercial policy.
	Codes/PA: Changes to configuration include the following:
	• Codes 95120-95134 and 95144-95170
	  ○ For CPT 95165 only, apply a limit of up to 150 units/12-month period. Units billed in excess of this limit should deny u24
	  ○ Existing CES bundling edits should remain unchanged for the above codes. Additional codes are included in this policy with no change to configuration at this time, though future configuration may be considered at a later date.

Spinal Epidural Steroid Injections **MP14**	**Policy Updates:** Removed requirement allowing imaging from "onset of symptoms". Imaging must be within past 12 months. **Codes/PA:** No changes to codes or PA.
Genetic and Molecular Testing **MP215**	**Policy Updates:** • Added medically necessary criteria for connective tissue disorders • Cleaned up criteria language for criteria III, IX, XIII • Created criteria table of contents for easier access **Codes/PA:** Added 81410 and 81411 with no configuration changes
Meniscal Allograft Transplant and Other Meniscal Implants **MP150**	**Policy Updates:** • Based on health equity review, criteria around age limit has been updated to be more flexible with suggested age minimum and maximum instead of hard age cut offs. **Codes/PA:** No changes to codes.
Protein Biomarker and Genetic Testing for the Prostate (Company) **MP96**	**Policy Updates:** Added policy note and clarified criteria III and V. **Codes/PA:** No changes to codes or PA.
Intensity Modulated Radiation Therapy (IMRT) **MP444**	**New Company Medical Policy** • **Based on the American Society for Radiation Oncology guidelines (ASTRO) a new medical policy will consider IMRT for specific cancer indications medically necessary when criteria are met.** **Providers are not required to submit prior authorization, but should be billing for IMRT with a medically necessary diagnosis code as outlined by the policy.**

ARCHIVE

Effective 11/1/2025

Ganglion Impar Blocks (Company) **MP104**	**Policy Updates:** Archived policy due to low utilization. **Codes/PA:** No changes to codes or PA.

MEDICARE POLICIES

Effective 12/1/2025

Organic Acid Testing **MP363**	**Policy Updates:** No changes to criteria. In the absence of fully established Medicare coverage policy criteria, apply internal Company policy criteria. **Codes/PA:** Added DX codes D51.0-D51.9 as covered DXs for CPT 83921. No change to other code configuration.

Effective 1/1/2026

Allergen Subcutaneous Immunotherapy (SCIT) **MP449**	**Policy Updates:** New policy for Medicare Advantage. • Criteria used will vary by procedure and indication. Fully established coverage criteria will be applied when available, but in the absence of fully established coverage criteria by Medicare in a CMS manual, NCD, LCD, etc., either an out-of-area (OOA) LCD or internal Company coverage policy criteria may apply. ○ For services subject to the Novitas OOA LCD, information found in a CMS Final Rule FAQ states this approach is allowed, but certain requirements exist. Specifically, the MAO is required to treat this OOA LCD the same as we would any other "internal criteria" source, with a summary of evidence, list of sources/citations, as well as publicly publish the criteria we are using. **Codes/PA:** Changes to configuration include the following: • Codes 95120-95134 and 95144-95170 – Configuration added to:

	(1) deny if billed by NP, or with an -SA modifier, for Medicare LOB only (this is based on Medicare LCD and coverage manual guidelines) **and** (2) For CPT 95165 only, apply a limit of up to 150 units/12-month period. Units billed in excess of this limit should deny u24 • Existing CES bundling edits should remain unchanged for the above codes. Additional codes are included in this policy with no change to configuration at this time, though future configuration may be considered at a later date.
Intensity Modulated Radiation Therapy (IMRT) **MP445**	New Medicare Advantage Medical Policy • New policy for IMRT services. Since no NCD, LCD, etc. for our service area, coverage criteria are considered "not fully established." Therefore, the plan will use the Palmetto LCD for Medicare Advantage members. Providers are not required to submit prior authorization but should be billing for IMRT in accordance with the Palmetto LCA.

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 October 3, 2025
Go-Live Date: Thursday, January 01, 2026, unless otherwise noted

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Special Announcements

Preferred Biosimilar Product Changes

The committee has approved a policy change regarding the management of preferred product strategies for biosimilar products, which will allow these changes to be made as administrative changes (similar to the way traditional generics are managed).

- Denosumab: Prolia®/Xgeva® will no longer be covered options. Preferred biosimilar products will be as follows:
  - Commercial/Medicaid: Stoboclo®/Osenvelt® and Bildyos®/Bilprevda®
  - Medicare Part D: Jubbonti®/Wyost®
  - Medicare Part B: Stoboclo®/Osenvelt®, Bildyos®/ Bilprevda®, and Jubbonti®/Wyost®
- Rituximab: Ruxience® will no longer be covered. Riabni® will be added as a preferred biosimilar, along with Truxima®, for all lines of business
- Tocilizumab: Actemra® will no longer be covered; Tyenne® will be the preferred biosimilar
- Trastuzumab: Ontruzant® (trastuzumab-dttb) added as a preferred biosimilar option, along with Ogivri® (trastuzumab-dkst) and Trazimera® (trastuzumab-qyyp) for all lines of business
- Insulin glargine (Commercial): Lantus® will no longer be covered formulary option; insulin glargine-yfgn will be added to formulary

Ketamine coverage

- Per company policy, ketamine infusions are covered in inpatient settings; however, billing for outpatient use related to treatment of mental health disorders is not covered
- A new policy was created outlining when coverage would be approved in an outpatient setting

Infusion Therapy Site of Care transition periods

The policy was updated to change the transition periods for medications required to be administered at an approved site of care. Most medications will now allow for a one-time dose at an unapproved site of care to allow time for transition or getting prior authorization approved to continue at an approved site of care. Some medications do allow for longer transition periods, which are outlined in the policy.

New Drugs and Combinations:

1. **Acoltremon (Tryptyr) Droperette**
   a. **Indication**: **Indication**: For the treatment of dry eye disease (DED)
   b. **Decision**:

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

2. **Berdazimer sodium (Zelsuvmi) Gel (Gram)**
   a. **Indication**: For the topical treatment of molluscum contagiosum (MC) in adults and pediatric patients 1 year of age and older.
   b. **Decision**:

	Commercial	Medicaid	Medicare
Formulary Status*	Non-formulary	Non-formulary	Part D: Non-formulary Part B: N/A
Tier**	N/A	N/A	N/A

Affordable Care Act Eligible	N/A; Non-Formulary	N/A	N/A
Utilization Management Edits	Prior Authorization	Prior Authorization	N/A
Quantity Limit	None	None	None
* 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: podofilox 0.5% topical gel/solution			

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

PA PROGRAM NAME	Medications for Molluscum Contagiosum
MEDICATION NAME	berdazimer topical gel (Zelsuvmi) cantharidin 0.7% solution (Ycanth)
PA INDICATION INDICATOR	1 - All FDA-Approved Indications
OFF-LABEL USES	None
EXCLUSION CRITERIA	Use in combination with another treatment modality for molluscum contagiosum (such as cryotherapy, curettage, berdazimer, or cantharidin)
REQUIRED MEDICAL INFORMATION	For authorization, all the following must be met: 1. Patient's lesions have been present and unresolved for at least six (6) months 2. Patient has not already received the maximum duration of therapy for the affected area(s) (12 weeks for berdazimer and 4 treatments for cantharidin) 3. One of the following: a. Documentation that lesions are affecting patient's activities of daily life, for example severe pain or itching b. Patient is immunocompromised 4. Documentation that requested medication will not be used to treat lesions in or near the mouth, eyes, or mucosal tissue
AGE RESTRICTIONS	Zelsuvmi: May be approved for patients 1 year of age and older Ycanth: May be approved for patients 2 years of age and older
PRESCRIBER RESTRICTIONS	Must be prescribed by, or in consultation with, a dermatologist
COVERAGE DURATION	Authorization will be approved for 12 weeks.

3. **Ceftobiprole medocaril (Zevtera) Vial**
   a. **Indication**: For the treatment of:
      - Adult patients with Staphylococcus aureus bloodstream infection (bacteremia) (SAB), including those with right-sided infective endocarditis
      - Adult patients with acute bacterial skin and skin structure infections (ABSSSI)

- Adult and pediatric patients (3 months to less than 18 years old) with community-acquired bacterial pneumonia (CABP)

b. **Decision**:

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

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

PA PROGRAM NAME	Zevtera
MEDICATION NAME	Ceftobiprole medocaril sodium injection
PA INDICATION INDICATOR	1 - All FDA-Approved Indications
EXCLUSION CRITERIA	N/A
REQUIRED MEDICAL INFORMATION	For initial authorization: For methicillin-susceptible *Staphylococcus aureus* bloodstream infection (bacteremia) (SAB): Inadequate response to cefazolin and formulary anti-staphylococcal penicillins For methicillin-resistant *Staphylococcus aureus* bloodstream infection (bacteremia) (SAB): Inadequate response to vancomycin and daptomycin For acute bacterial skin and skin structure infections (ABSSSI): Inadequate response to combination of vancomycin and aztreonam For community-acquired bacterial pneumonia (CABP): Inadequate response to combination of vancomycin and ceftriaxone For reauthorization: Must meet initial authorization

AGE RESTRICTIONS	Age must be appropriate based on FDA-labeling
PRESCRIBER RESTRICTIONS	Must be prescribed by, or in consultation with, an infectious diseases specialist
COVERAGE DURATION	Initial authorization will be approved for a total of 14 days for ABSSSI and CABP and 42 days for SAB

4. **Garadacimab-gxii (Andembry Autoinjector) Auto Injct**
   a. **Indication**: For prophylaxis to prevent attacks of hereditary angioedema (HAE) in adult and pediatric patients aged 12 years and older.
   b. **Decision**:

	Commercial	Medicaid	Medicare
Formulary Status*	Formulary	Non-formulary	Part D: Non-formulary Part B: N/A
Tier**	Tier 5 - Preferred Specialty	N/A	N/A
Affordable Care Act Eligible	N/A; Non-Formulary	N/A	N/A
Utilization Management Edits	Prior Authorization	Prior Authorization	N/A
Quantity Limit	1.2 mL per 28days	1.2 mL per 28days	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: Orladeyo, Haegarda, Takhzyro			

   c. **Prior Authorization Criteria for Commercial/Medicaid/Medicare Part B**: Added to Prophylactic Hereditary Angioedema Therapy Policy

5. **Linvoseltamab-gcpt (Lynozyfic) Vial**
   a. **Indication**: For the treatment of adult patients with relapsed or refractory (R/R) multiple myeloma (MM) who have received at least four prior lines of therapy, including a proteasome inhibitor, an immunomodulatory agent, and an anti-CD38 monoclonal antibody.
   b. **Decision**:

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

* 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: Elrexfio, Tecvayli, Talvey

c. **Prior Authorization Criteria for Commercial/Medicaid/Medicare Part B**: Added to T-Cell Therapy Policy

6. **Sebetralstat (Ekterly) Tablet**
   a. **Indication**: For the treatment of acute attacks of hereditary angioedema (HAE) in adult and pediatric patients aged 12 years and older.
   b. **Decision**:

	Commercial	Medicaid	Medicare
Formulary Status*	Formulary	Non-formulary	Part D: Non-formulary Part B: N/A
Tier**	Tier 6 - Non-Preferred Specialty	N/A	N/A
Affordable Care Act Eligible	No	N/A	N/A
Utilization Management Edits	Prior Authorization	Prior Authorization	N/A
Quantity Limit	4 tablets per 30 days	4 tablets per 30 days	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: Firazyr (Icatibant), Berinert, Kalbitor, Ruconest			

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

PA PROGRAM NAME	Acute Hereditary Angioedema therapy
MEDICATION NAME	Ekterly (Sebetralstat)
PA INDICATION INDICATOR	1 - All Food and Drug Administration (FDA) approved indications not otherwise excluded from the benefit.
OFF-LABEL USES	N/A

EXCLUSION CRITERIA	Concurrent use with other products indicated for the acute treatment of HAE attacks
REQUIRED MEDICAL INFORMATION	For initiation of therapy, all the following criteria (1-2) must be met: 1. Diagnosis of hereditary angioedema (HAE) as confirmed by one of the following: a. For HAE Type I and Type II, documentation of the following (per laboratory standard): i. Serum C4 below the lower limit of normal, **AND** ii. One of the following: 1) C1-Inhibitor (C1-INH) protein less than 50 percent of the lower limit of normal, or 2) C1-INH function less than 50 percent of the lower limit of normal b. For HAE with normal C1-INH or HAE Type III: i. Confirmed Factor 12 (FXII), angiopoietin-1 (ANGPT1), plasminogen (PLG), kininogen 1 (KNG1), or heparan sulfate-glucosamine 3-O sulfotransferase 6 (HS3ST6) gene mutation **OR** ii. Positive family history for HAE and attacks that lack response with high dose antihistamines or corticosteroids. 2. For coverage of Ekterly®, **Berinert®, Kalbitor®, brand Firazyr®, or Ruconest®** for members 18 years and older: Documentation of trial and failure or contraindication to generic icatibant For patients established on the requested therapy, all of the following criteria (1-2) must be met: 1. Documentation must be provided showing benefit of therapy with reduction of length and severity of HAE attack episodes 2. For coverage of **brand Firazyr®:** Documentation of trial and failure or contraindication to generic icatibant For quantities exceeding the formulary quantity limit: Documentation of frequent HAE attacks defined as greater than or equal to two attacks per month on average.
AGE RESTRICTIONS	Per FDA labeled indication
PRESCRIBER RESTRICTIONS	Must be prescribed by or consulted with an immunologist or allergist
COVERAGE DURATION	Initial authorization 6 months and reauthorization for 1 year
QUANTITY LIMIT	Berinert® - two injections per 30 days Ruconest® - two injections per 30 days Firazyr® - six injections (total of 18 mL) per 30 days Ekterly® - 4 tablets per 30 days

7. **Taletrectinib adipate (Ibtrozi) Capsule**
    a. **Indication**: For the treatment of adult patients with locally advanced or metastatic *ROS1*-positive (*ROS1*+) 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	Three capsules per day	Three capsules per day	Three capsules 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: Augtyro, Rozlytrek, Xalkori			

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

New Indications: - 4/1/2025- 5/31/2025

Therapies with Prior Authorization Policies (Non-oncology)

1. **DUPIXENT** (DUPILUMAB)
    a. New indication approved 04/18/2025:
        i. Treatment of adult and pediatric patients aged 12 years and older with chronic spontaneous urticaria (CSU) who remain symptomatic despite H1 antihistamine treatment.
    b. RECOMMENDATION: Inform prescribers via Medical Policy Alert. New indication reviewed and applicable policies updated at June 2025 P&T.

2. **FYLNETRA** (PEGFILGRASTIM-PBBK)
    a. New indication approved 04/23/2025:
        i. Patients with Hematopoietic Subsyndrome of Acute Radiation Syndrome: Indicated to increase survival in patients acutely exposed to myelosuppressive doses of radiation
    b. RECOMMENDATION: Inform prescribers via Medical Policy Alert. Update Commercial/Medicaid/Medicare Part B policy with new indication.

3. **NUCALA** (MEPOLIZUMAB)
   a. New indication approved 5/22/2025:
      i. Add-on maintenance treatment of adult patients with inadequately controlled chronic obstructive pulmonary disease (COPD) and an eosinophilic phenotype.
   b. **RECOMMENDATION:** Inform prescribers via Medical Policy Alert. For Commercial and Medicaid, new indication reviewed, and policy updated at October 2025 P&T annual policy review. Add new criteria to Medicare Part D policy.

Prior Authorization for **Medicare Part D**:

PA PROGRAM NAME	Respiratory Agents - Nucala
MEDICATION NAME	Nucala (mepolizumab)
PA INDICATION INDICATOR	All FDA-approved Indications
OFF-LABEL USES	N/A
EXCLUSION CRITERIA	Concurrent use with another therapeutic immunomodulator agent utilized for the same indication.
REQUIRED MEDICAL INFORMATION	No changes to criteria for other indications. For initial authorization for chronic obstructive pulmonary disease (COPD): 1. Diagnosis of COPD with an eosinophilic phenotype 2. The patient is currently being treated with AND will continue COPD control therapy (e.g., ICS, LABA, LAMA) in combination with the requested agent. Reauthorization for COPD requires: 1. Response to therapy, such as attainment and maintenance of remission or decrease in number of relapses and 2. The patient is currently being treated with, and will continue COPD control therapy in combination with the requested agent, or has an intolerance/ contraindication to standard COPD control therapy (e.g., ICS, LABA, LAMA).
AGE RESTRICTIONS	N/A
PRESCRIBER RESTRICTIONS	Medications must be prescribed by, or in consultation with the following specialists based on the diagnosis: 1. Asthma/COPD: respiratory specialist (such as a pulmonologist, immunologist, or allergist), 2. EGPA: pulmonologist, neurologist, or rheumatologist, 3. HES: hematologist, immunologist, pulmonologist, cardiologist, or neurologist, 4. CRSwNP: otolaryngologist, allergist, or pulmonologist.
COVERAGE DURATION	EGPA/HES/CRSwNP:Initial 6 mo/reauth 1 yr. Asthma/COPD: Initial 1 yr/reauth until no longer elig with plan

4. **RINVOQ** (UPADICITINIB)
   a. New indication approved 04/29/2025:
      i. Treatment of adults with giant cell arteritis.
   c. **RECOMMENDATION:** Inform prescribers via Medical Policy Alert. New indication reviewed and Commercial/Medicaid policy updated at October 2025 P&T annual policy review. No policy updates warranted for Medicare Part D.

5. **UPLIZNA** (INEBILIZUMAB-CDON)
   a. New indication approved 04/03/2025:
      i. Treatment of immunoglobulin G4-related disease (IgG4-RD) in adult patients.
   b. RECOMMENDATION: Inform prescribers via Medical Policy Alert. Update policy with new indication and add new criteria to Commercial/Medicaid and Medicare Part B policies.

Prior Authorization for **Commercial/Medicaid:**

PA PROGRAM NAME	Uplizna
MEDICATION NAME	Uplizna (inebilizumab)
COVERED USES	All FDA-Approved Indications
EXCLUSION CRITERIA	N/A
REQUIRED MEDICAL INFORMATION	**For all requests:** 1. Dose and frequency must be in accordance with FDA-approved labeling 2. The requested agent must not be given concurrently with another Complement Inhibitor (for example Ultomiris® or Empaveli®), or neonatal Fc receptor blocker (for example, Rystiggo®, Vyvgart®, Vyvgart Hytrulo®) **For initiation of therapy (new starts) for immunoglobulin G4-related disease (IgG4-RD), all of the following must be met:** 1. Confirmed diagnosis of IgG4-RD 2. Documentation of a history of IgG4-RD affecting at least 2 organ systems/sites 3. Documentation of current or recently experienced IgG4-RD flare requiring initiation or continuation of glucocorticoid treatment **For patients established on therapy (within the previous year) for IgG4-RD:** 1. Documentation of positive clinical response to therapy as defined by a reduction in the frequency of disease flares or reduction in need for glucocorticoid treatment
AGE RESTRICTIONS	May be approved for patients 18 and older
PRESCRIBER RESTRICTIONS	For IgG4-RD: Must be prescribed by, or in consultation with, a rheumatologist, immunologist, endocrinologist, nephrologist, hepatologist
COVERAGE DURATION	Initial approval for 3 months, with reauthorization for 1 year

Prior Authorizations for **Medicare Part B:**

PA PROGRAM NAME	Uplizna

MEDICATION NAME	Uplizna (inebilizumab)
COVERED USES	All FDA-Approved Indications
EXCLUSION CRITERIA	N/A
REQUIRED MEDICAL INFORMATION	**For all requests:** 1. Dose and frequency must be in accordance with FDA-approved labeling 2. The requested agent must not be given concurrently with another Complement Inhibitor (for example Ultomiris® or Empaveli®), or neonatal Fc receptor blocker (for example, Rystiggo®, Vyvgart®, Vyvgart Hytrulo®) **For initiation of therapy (new starts) for immunoglobulin G4-related disease (IgG4-RD), all of the following must be met:** 1. Confirmed diagnosis of IgG4-RD 2. Documentation of a history of IgG4-RD affecting at least 2 organ systems/sites 3. Documentation of current or recently experienced IgG4-RD flare requiring initiation or continuation of glucocorticoid treatment **For patients established on therapy (within the previous year) for IgG4-RD:** 2. Documentation of positive clinical response to therapy as defined by a reduction in the frequency of disease flares or reduction in need for glucocorticoid treatment
AGE RESTRICTIONS	May be approved for patients 18 and older
PRESCRIBER RESTRICTIONS	For IgG4-RD: Must be prescribed by, or in consultation with, a rheumatologist, immunologist, endocrinologist, nephrologist, hepatologist
COVERAGE DURATION	Initial approval for 3 months, with reauthorization for 1 year

6. **SUSVIMO** (RANIBIZUMAB)
   a. New indication approved 5/22/25
      i. Treatment of patients with Diabetic Retinopathy (DR) who have previously responded to at least two intravitreal injections of a Vascular Endothelial Growth Factor (VEGF) inhibitor medication.
   b. **RECOMMENDATION:** Inform prescribers via Medical Policy Alert. Update policy with new indication and update criteria for Commercial/Medicaid and Medicare Part B policies.

Prior Authorization for **Commercial/Medicaid:**

PA PROGRAM NAME	Ophthalmic Vascular Endothelial Growth Factor (VEGF) Inibitors
MEDICATION NAME	Susvimo (ranibizumab)

COVERED USES	All FDA-Approved Indications
EXCLUSION CRITERIA	N/A
REQUIRED MEDICAL INFORMATION	**For initiation of therapy with the requested medication (new start):** 1. **Diabetic macular edema or diabetic retinopathy:** a. For faricimab (Vabysmo®), brolucizumab (Beovu®), and Eylea® HD, documentation that ALL of the following agents have been ineffective, not tolerated, or contraindicated or rationale is provided why therapy is not appropriate for the patient: i. Bevacizumab ii. Aflibercept (Eylea®) or aflibercept-ayyh (Pavblu®) iii. Ranibizumab (Lucentis®), ranibizumab-nuna (Byooviz®), or ranibizumab-eqrn (Cimerli®) b. For ranibizumab implant (Susvimo®), ~~for diabetic macular edema only~~ documentation that all of the following are met: i. Documentation that bevacizumab and aflibercept (Eylea®)/aflibercept-ayyh (Pavblu®) have been ineffective, not tolerated, or contraindicated or rationale is provided why therapy is not appropriate for the patient AND ii. Documentation of previous response to at least two intravitreal injections of ranibizumab (Lucentis®), ranibizumab-eqrn (Cimerli®), or ranibizumab-nuna (Byooviz®) AND iii. Documentation that increased risk of endophthalmitis associated with ranibizumab (Susvimo®) has been discussed with the patient **Reauthorization or continuation of therapy:** Documentation of positive response to therapy (such as stabilization or improvement in vision)
AGE RESTRICTIONS	N/A
PRESCRIBER RESTRICTIONS	Must be prescribed and administered by an ophthalmologist or retinal specialist
COVERAGE DURATION	Authorization will be approved until no longer eligible with the plan, subject to formulary or benefit changes

Prior Authorizations for **Medicare Part B:**

PA PROGRAM NAME	Ophthalmic Vascular Endothelial Growth Factor (VEGF) Inhibitors
MEDICATION NAME	Susvimo (ranibizumab)
COVERED USES	All FDA-Approved Indications

EXCLUSION CRITERIA	N/A
REQUIRED MEDICAL INFORMATION	For initiation of therapy with the requested medication (new start): 1. Diabetic macular edema or diabetic retinopathy: a. For faricimab (Vabysmo®), brolucizumab (Beovu®), and Eylea® HD, documentation that ALL of the following agents have been ineffective, not tolerated, or contraindicated or rationale is provided why therapy is not appropriate for the patient: i. Bevacizumab ii. Aflibercept (Eylea®) or aflibercept-ayyh (Pavblu®) iii. Ranibizumab (Lucentis®), ranibizumab-nuna (Byooviz®), or ranibizumab-eqrn (Cimerli®) b. For ranibizumab implant (Susvimo®), ~~for diabetic macular edema only~~ documentation that all of the following are met: i. Documentation that bevacizumab and aflibercept (Eylea®)/aflibercept-ayyh (Pavblu®) have been ineffective, not tolerated, or contraindicated or rationale is provided why therapy is not appropriate for the patient AND ii. Documentation of previous response to at least two intravitreal injections of ranibizumab (Lucentis®), ranibizumab-eqrn (Cimerli®), or ranibizumab-nuna (Byooviz®) AND iii. Documentation that increased risk of endophthalmitis associated with ranibizumab (Susvimo®) has been discussed with the patient **For patients established on therapy with the requested agent (within the previous year):** Documentation of positive response to therapy (such as stabilization or improvement in vision)
AGE RESTRICTIONS	N/A
PRESCRIBER RESTRICTIONS	Must be prescribed and administered by an ophthalmologist or retinal specialist
COVERAGE DURATION	Authorization will be approved until no longer eligible with the plan, subject to formulary or benefit changes

7. **ZORYVE FOAM** (ROFLUMILAST)
   a. New indication approved 5/22/25
      i. Treatment of plaque psoriasis of the scalp and body in adult and pediatric patients 12 years of age and older.
   b. **RECOMMENDATION:** Inform prescribers via Medical Policy Alert. Update Commercial and Medicaid policies with new indication and update criteria.
      Prior Authorization for **Commercial:**

PA PROGRAM NAME	Topical Agents for Skin Conditions
MEDICATION NAME	Zoryve foam (roflumilast)
COVERED USES	All FDA-Approved Indications
EXCLUSION CRITERIA	N/A
REQUIRED MEDICAL INFORMATION	**For initial authorization, must meet all the following indication-specific criteria:** 1. **For Plaque Psoriasis (PP) (Enstilar®, Wynzora®, Vtama®, Zoryve® cream/foam ~~only~~),** patient must meet both of the following criteria: a. Inadequate response to a sufficient trial (defined as two weeks or more of consistent use) of a high potency topical corticosteroid in combination with one of the following generic topicals: i. Calcipotriene product ii. Tazarotene 0.1% cream b. For Enstilar®/Wynzora®: Documentation of trial and failure (defined as two weeks or more of consistent use) of calcipotriene/betamethasone ointment (Taclonex®) or calcipotriene/betamethasone topical suspension (Taclonex® Scalp) **For reauthorization for all indications:** Must have documentation of response to therapy indicating improvement or stabilization of condition (e.g., reduced symptom and/or affected BSA)
AGE RESTRICTIONS	Age must be appropriate based on FDA-approved indication
PRESCRIBER RESTRICTIONS	Nonsegmental Vitiligo, Plaque Psoriasis, Seborrheic Dermatitis: Must be prescribed by, or in consultation with, a dermatologist
COVERAGE DURATION	Initial authorization will be approved for six months. Reauthorization will be approved until no longer eligible with the plan, subject to formulary or benefit changes.

Prior Authorizations for **Medicaid:**

PA PROGRAM NAME	Topical Agents for Skin Conditions
MEDICATION NAME	Zoryve foam (roflumilast)
COVERED USES	All FDA-Approved Indications
EXCLUSION CRITERIA	For Opzelura: Concurrent use with biologics, other Janus kinase (JAK) inhibitors, or potent immunosuppressants
REQUIRED MEDICAL INFORMATION	**For patients <21 years of age:**

	1. Documentation of covered disease severity as defined by one of the following: a. Documentation of severe disease as defined by both of the following: i. Documentation that patient is having functional impairment as indicated by one of the following: 1) Dermatology Life Quality Index (DLQI) of at least 11 2) Children's Dermatology Life Quality Index (CDLQI) of at least 13 3) Severe score on other validated tool ii. Documentation of one of the following: 1) At least 10% of body surface area involved 2) Hand, foot, face, or mucous membrane involvement b. 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. Documentation that the following indication-specific criteria: a. For mild to moderate plaque psoriasis (PP): Enstilar, Wynzora, Vtama cream, or Zoryve cream/foam may be covered if there is documentation of contraindication, intolerance, or failed trial of two of the following: i. Moderate to high-potency topical corticosteroid for at least 4 weeks ii. Topical vitamin D analogues (calcitriol, calcipotriene) for at least 4 weeks iii. Tazarotene for at least 8 weeks iv. Calcineurin inhibitor (tacrolimus, pimecrolimus) for at least 8 weeks b. For severe plaque psoriasis (PP): Enstilar, Wynzora, Vtama cream, or Zoryve cream/foam may be covered if there is documentation of contraindication, intolerance, or failed four-week trial of at least two different high to super-high potency topical corticosteroids c. For atopic dermatitis (AD): Eucrisa, Opzelura, Vtama or Zoryve 0.15% cream may be covered if there is documentation of contraindication, intolerance, or failed two-week trials of at least two different topical agents from one or both of the following categories i. Topical corticosteroids (e.g., mometasone, betamethasone, clobetasol) ii. Topical calcineurin inhibitors (e.g., tacrolimus) d. For Nonsegmental Vitiligo (NSV): Opzelura may be covered if there is an inadequate response, contraindication, or intolerance to at least two agents from the following categories:

	i. Topical calcineurin inhibitors (such as tacrolimus) for at least 3 months ii. Moderate- to high-potency topical corticosteroids (such as clobetasol 0.05%) for at least 2 months e. For Seborrheic Dermatitis (SD): Documentation of confirmed diagnosis **For adult patients ≥21 years of age:** 1. Documentation of severe disease as defined by both of the following: a. Documentation that patient is having functional impairment as indicated by one of the following: i. Dermatology Life Quality Index (DLQI) of at least 11 ii. Children's Dermatology Life Quality Index (CDLQI) of at least 13 iii. Severe score on other validated tool b. Documentation of one of the following: i. At least 10% of body surface area involved ii. Hand, foot, face, or mucous membrane involvement 2. Documentation that the following indication-specific criteria: a. For severe plaque psoriasis (PP): Enstilar, Wynzora, Vtama cream, or Zoryve cream/foam may be covered if there is documentation of contraindication, intolerance, or failed four-week trial of at least two different high to super-high potency topical corticosteroids b. For severe nonsegmental vitiligo (NSV): Opzelura may be covered if there is an inadequate response, contraindication, or intolerance to at least two agents from the following categories: i. Topical calcineurin inhibitors (such as tacrolimus) for at least 3 months ii. Moderate- to high-potency topical corticosteroids (such as clobetasol 0.05%) for at least 2 months **For reauthorization:** Must have documentation of response to therapy indicating improvement or stabilization of condition (e.g., reduced symptoms and/or affected BSA)
AGE RESTRICTIONS	Age must be appropriate based on FDA-approved indication
PRESCRIBER RESTRICTIONS	N/A
COVERAGE DURATION	Initial authorization will be approved for six months. Reauthorization will be approved until no longer eligible with the plan, subject to formulary or benefit changes.

Therapies with Prior Authorization Policies (Oncology)

8. **OPDIVO** (NIVOLUMAB)
    a. New indication(s) approved 04/08/25, 04/11/25:
        i. In combination with ipilimumab, for the first-line treatment of adult patients with unresectable or metastatic hepatocellular carcinoma.
        ii. In combination with ipilimumab, for the treatment of adult and pediatric patients 12 years and older with unresectable or metastatic microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) colorectal cancer
    b. **RECOMMENDATION:** Inform prescribers via Medical Policy Alert. Prior authorization policy coverage criteria are based on recommendations from the National Comprehensive Cancer Network (NCCN); no updates to the policy are warranted.

9. **WELIREG** (BELZUTIFAN)
    a. New indication(s) approved 5/14/25
        i. Treatment of adult and pediatric patients 12 years and older with locally advanced, unresectable, or metastatic pheochromocytoma or paraganglioma (PPGL).
    b. **RECOMMENDATION:** Inform prescribers via Medical Policy Alert. Prior authorization policy coverage criteria are based on recommendations from the National Comprehensive Cancer Network (NCCN); no updates to the policy are warranted.

10. **ZYNZ** (RETIFANLIMAB-DLWR)
    a. New indication(s) approved 5/15/25
        i. In combination with carboplatin and paclitaxel for the first-line treatment of adult patients with inoperable locally recurrent or metastatic squamous cell carcinoma of the anal canal (SCAC).
        ii. Single agent for the treatment of adult patients with locally recurrent or metastatic SCAC with disease progression on or intolerance to platinum-based chemotherapy.
    b. **RECOMMENDATION:** Inform prescribers via Medical Policy Alert. Prior authorization policy coverage criteria are based on recommendations from the National Comprehensive Cancer Network (NCCN); no updates to the policy are warranted.

Therapies Without Prior Authorization Policies

11. **DEXTENZA** (DEXAMETHASONE)
    a. New indication(s) approved 04/07/2025:
        i. Treatment of ocular itching associated with allergic conjunctivitis in adults and pediatric patients aged 2 years and older.
    b. **RECOMMENDATION:** Inform prescribers via Medical Policy Alert.

12. **ELIQUIS** (APIXABAN)
    a. New indication(s) approved 04/17/2025:
        i. Treatment of venous thromboembolism (VTE) and reduction in the risk of recurrent VTE in pediatric patients from birth and older after at least 5 days of initial anticoagulant treatment.
    b. **RECOMMENDATION:** Inform prescribers via Medical Policy Alert.

13. **POSFREA** (PALONOSETRON HYDROCHLORIDE)

a. New indication(s) approved 04/16/2025:
    i. In pediatric patients 1 month to less than 17 years of age for prevention of:
        a) Acute nausea and vomiting associated with initial and repeat courses of emetogenic cancer chemotherapy, including highly emetogenic cancer chemotherapy.

b. RECOMMENDATION: Inform prescribers via Medical Policy Alert.

14. **SIVEXTRO** (TIDEZOLID PHOSPHATE)
    a. New indication(s) approved 04/29/2025:
        i. Treatment of acute bacterial skin and skin structure infections (ABSSSI) caused by susceptible isolates of the following gram-positive microorganisms: *Staphylococcus aureus* (including methicillin-resistant [MRSA] and methicillin-susceptible [MSSA] isolates), *Streptococcus pyogenes*, *Streptococcus agalactiae*, *Streptococcus anginosus* Group (including *Streptococcus anginosus*, *Streptococcus intermedius*, and *Streptococcus constellatus*), and *Enterococcus faecalis*, in adult and pediatric patients (at least 26 weeks gestational age and weighing at least 1 kg).
    b. **RECOMMENDATION:** Inform prescribers via Medical Policy Alert.

New Indications - 6/1/2025- 7/31/2025:

Therapies with Prior Authorization Policies (Non-oncology)

1. **DUPIXENT** (DUPILUIMAB)
    a. New indication approved 06/18/2025:
        i. Treatment of adult patients with bullous pemphigoid (BP).
    b. **RECOMMENDATION:** For Commercial and Medicaid, new indication reviewed, and policy updated at October 2025 P&T annual policy review. Add new criteria to Medicare Part D policy.

Prior Authorization for **Medicare Part D**:

PA PROGRAM NAME	Dupixent
MEDICATION NAME	Dupixent (dupilumab)
PA INDICATION INDICATOR	All FDA-Approved Indications
OFF-LABEL USES	N/A
EXCLUSION CRITERIA	Concurrent use with another therapeutic immunomodulator agent utilized for the same indication.
REQUIRED MEDICAL INFORMATION	No changes to criteria for other indications. For initial authorization for bullous pemphigoid (BP): 1. The patient has a diagnosis of bullous pemphigoid (BP) Reauthorization for BP requires documentation of positive clinical response to therapy.
AGE RESTRICTIONS	N/A
PRESCRIBER RESTRICTIONS	Medications must be prescribed by, or in consultation with the following specialists based on the diagnosis: Asthma/COPD: respiratory specialist (such as a pulmonologist, immunologist, or allergist), AD: dermatologist,

	allergist, or immunologist, EOE: allergist or gastroenterologist, CRSwNP: otolaryngologist, allergist, or pulmonologist, PN: dermatologist, CSU: dermatologist, allergist, or immunologist, BP: dermatologist
COVERAGE DURATION	Asthma/COPD: Initial 1 yr/reauth until no longer elig with plan. BP: Initial/reauth 1 yr. Others: initial 6 mos/reauth 1 yr

2. **EMPAVELI** (PEGCETACOPLAN)
   a. New indication(s) approved 07/28/2025:
      i. Treatment of adult and pediatric patients aged 12 years and older with C3 glomerulopathy (C3G) or primary immune-complex membranoproliferative glomerulonephritis (IC-MPGN), to reduce proteinuria.
   b. **RECOMMENDATION:** Inform prescribers via Medical Policy Alert. Update policy with new indication and update criteria for Commercial/Medicaid and Medicare Part B policies.

Prior Authorization for **Commercial/Medicaid**:

PA PROGRAM NAME	Complement Inhibitors
MEDICATION NAME	Empaveli (pegcetacoplan)
PA INDICATION INDICATOR	All FDA-Approved Indications
OFF-LABEL USES	N/A
EXCLUSION CRITERIA	N/A

REQUIRED MEDICAL INFORMATION	**For ALL REQUESTS:** 1. Dose and frequency must be in accordance with FDA-approved labeling 2. The requested agent must not be given concurrently with another Complement Inhibitor (for example Ultomiris® or Empaveli®), or neonatal Fc receptor blocker (for example, Rystiggo®, Vyvgart®, Vyvgart Hytrulo®) **For Complement 3 Glomerulopathy (C3G), Fabhalta and Empaveli may be covered if the following criteria are met:** 1. Diagnosis of C3G confirmed by renal biopsy 2. Patient has been receiving a maximally tolerated dose of an angiotensin-converting enzyme (ACE) inhibitor, angiotensin receptor blockers (ARB), or stable dose of other antiproteinuric medications including mycophenolic acid, corticosteroids and mineralocorticoid receptor antagonists for at least 90 days prior to initiating Fabhalta therapy 3. Urine protein-to-creatinine ratio UPCR of 1.0 g/g or more 4. eGFR greater than or equal to 30 mL/min1.73m^2 **For patients established on the requested medication within the previous year, must meet the indication-specific criteria below:** 1. For C3G, documentation of positive response to therapy defined as improvement in proteinuria
AGE RESTRICTIONS	Age must be appropriate based on FDA-approved indication
PRESCRIBER RESTRICTIONS	Prescribed by, or in consultation with, a hematologist/oncologist or nephrologist
COVERAGE DURATION	Initial authorization for up to three months and reauthorization will be approved for up to one year.

Prior Authorization for **Medicare Part B**:

PA PROGRAM NAME	Complement Inhibitors
MEDICATION NAME	Empaveli (pegcetacoplan)
PA INDICATION INDICATOR	All FDA-Approved Indications
OFF-LABEL USES	N/A
EXCLUSION CRITERIA	N/A
REQUIRED MEDICAL INFORMATION	**For ALL REQUESTS:** 1. Dose and frequency must be in accordance with FDA-approved labeling

	2. The requested agent must not be given concurrently with another Complement Inhibitor (for example Ultomiris® or Empaveli®), or neonatal Fc receptor blocker (for example, Rystiggo®, Vyvgart®, Vyvgart Hytrulo®) **For Complement 3 Glomerulopathy (C3G), Empaveli may be covered if the following criteria are met:** 1. Diagnosis of C3G confirmed by renal biopsy 2. Patient has been receiving a maximally tolerated dose of an angiotensin-converting enzyme (ACE) inhibitor, angiotensin receptor blockers (ARB), or stable dose of other antiproteinuric medications including mycophenolic acid, corticosteroids and mineralocorticoid receptor antagonists for at least 90 days prior to initiating Fabhalta therapy 3. Urine protein-to-creatinine ratio UPCR of 1.0 g/g or more 4. eGFR greater than or equal to 30 mL/min1.73m^2 **For patients established on the requested medication within the previous year, must meet the indication-specific criteria below:** 2. For C3G, documentation of positive response to therapy defined as improvement in proteinuria
AGE RESTRICTIONS	Age must be appropriate based on FDA-approved indication
PRESCRIBER RESTRICTIONS	Prescribed by, or in consultation with, a hematologist/oncologist or nephrologist
COVERAGE DURATION	Initial authorization for up to three months and reauthorization will be approved for up to one year.

3. **GAMIFANT** (EMAPALUMAB-LZSG)
   a. New indication approved 06/27/2025
      i. Treatment of adult and pediatric (newborn and older) patients with HLH/macrophage activation syndrome (MAS) in known or suspected Still's disease, including systemic Juvenile Idiopathic Arthritis (sJIA), with an inadequate response or intolerance to glucocorticoids, or with recurrent MAS.
   b. **RECOMMENDATION:** Inform prescribers via Medical Policy Alert. Update policy with new indication for Commercial/Medicaid and Medicare Part B.

4. **KERENDIA** (FINERONONE)
   a. New indication(s) approved 07/11/2025
      i. Reduce the risk of cardiovascular death, hospitalization for heart failure, and urgent heart failure visits in adult patients with heart failure with left ventricular ejection fraction (LVEF) ≥ 40%.
   b. **RECOMMENDATION:** Inform prescribers via Medical Policy Alert. Update policy with new indication and update criteria for Commercial/Medicaid and Medicare Part D policies.

Prior Authorization for **Commercial/Medicaid**:

PA PROGRAM NAME	Kerendia
MEDICATION NAME	Kerendia (finerenone)

PA INDICATION INDICATOR	All FDA-Approved Indications
OFF-LABEL USES	N/A
EXCLUSION CRITERIA	N/A
REQUIRED MEDICAL INFORMATION	**One of the following must be met:** 1. **For chronic kidney disease associated with type 2 diabetes:** a. Patient has a diagnosis of chronic kidney disease associated with type 2 diabetes mellitus b. Member has tried and failed, or has a contraindication or intolerance to, a maximally tolerated Angiotensin Converting Enzyme inhibitor (such as lisinopril) or Angiotensin Receptor Blocker (such as losartan) 2. **For heart failure:** a. Patient has a diagnosis of heart failure with left ventricular ejection fraction (LVEF) greater than or equal to 40% b. Patient has been treated with diuretics within 30 days prior to start of requested therapy
AGE RESTRICTIONS	May be approved for patients aged 18 years and older
PRESCRIBER RESTRICTIONS	N/A
COVERAGE DURATION	Authorization will be approved until no longer eligible with the plan, subject to formulary and/or benefit changes.

Prior Authorization for **Medicare Part D**:

PA PROGRAM NAME	Kerendia
MEDICATION NAME	Kerendia (finerenone)
PA INDICATION INDICATOR	All FDA-approved indications
OFF-LABEL USES	N/A
EXCLUSION CRITERIA	N/A
REQUIRED MEDICAL INFORMATION	**For initiation of therapy, all the following must be met:** **For chronic kidney disease associated with type 2 diabetes:** 1. Patient has a diagnosis of type 2 diabetes, AND 2. Patient has evidence of diabetic nephropathy, AND 3. Documentation that patient is on a maximally tolerated Angiotensin Converting Enzyme inhibitor (such as lisinopril) or an Angiotensin Receptor Blocker (such as losartan), unless all agents in these classes are contraindicated, AND 4. Documentation of trial, contraindication, or intolerance to a Sodium Glucose Cotransporter-2 inhibitor (such as empagliflozin or dapagliflozin). **For heart failure:** 1. Patient has a diagnosis of heart failure with left ventricular ejection fraction (LVEF) greater than or equal to 40%, 2. Patient has been treated with diuretics within 30 days prior to start of requested therapy.

AGE RESTRICTIONS	Approved for patients 18 years of age and older
PRESCRIBER RESTRICTIONS	N/A
COVERAGE DURATION	Authorization will be approved until no longer eligible with the plan

5. **NEMLUVIO** (NEMOLIZUMAB-ILTO)
    a. New indication approved 06/26/2025:
        i. Treatment of adults and pediatric patients 12 years of age and older with moderate-to-severe atopic dermatitis in combination with topical corticosteroids and/or calcineurin inhibitors when the disease is not adequately controlled with topical prescription therapies.
    b. **RECOMMENDATION:** Inform prescribers via Medical Policy Alert. For Commercial and Medicaid, new indication reviewed, and policy updated at October 2025 P&T annual policy review.

6. **OTEZLA** (APREMILAST)
    a. Treatment of adult patients and pediatric patients 6 years of age and older and weighing at least 20 kg with active psoriatic arthritis.
    b. **RECOMMENDATION:** Inform prescribers via Medical Policy Alert. For Commercial and Medicaid, new indication reviewed, and policy updated at October 2025 P&T annual policy review.

7. **RIABNI** (RITUXIMAB-ARRX)
    a. New indication approved 06/09/2025:
        i. Treatment of adult patients with moderate to severe pemphigus vulgaris.
    b. **RECOMMENDATION:** Inform prescribers via Medical Policy Alert. Update Commercial/Medicaid and Medicare Part B policies with new indication.

8. **RUXIENCE** (RITUXIMAB-PVVR)
    a. New indication approved 06/09/2025:
        i. Treatment of adult patients with moderate to severe pemphigus vulgaris.
    b. **RECOMMENDATION:** Inform prescribers via Medical Policy Alert. Update Commercial/Medicaid and Medicare Part B policies with new indication.

9. **SKYTROFA** (LONAPEGSOMATROPIN-TCGD)
    a. New indication approved 7/25/25
        i. Replacement of endogenous growth hormone in adults with growth hormone deficiency (GHD).
    b. **RECOMMENDATION:** Inform prescribers via Medical Policy Alert. Update Commercial and Medicaid policy with new indication.

10. **TRUXIMA** (RITUXIMAB-ABBS)
    a. New indication approved 06/09/2025:
        i. Treatment of adult patients with moderate to severe pemphigus vulgaris.
    b. **RECOMMENDATION:** Inform prescribers via Medical Policy Alert. Update Commercial/Medicaid and Medicare Part B policies with new indication.

Therapies with Prior Authorization Policies (Oncology)

11. **KEYTRUDA** (PEMBROLIZUMAB)
    a. New indication(s) approved 06/18/2025:
        i. For adults with resectable locally advanced head and neck squamous cell carcinoma (HNSCC) whose tumors express PD-L1.
    b. **RECOMMENDATION:** Inform prescribers via Medical Policy Alert. Prior authorization policy coverage criteria are based on recommendations from the National Comprehensive Cancer Network (NCCN); no updates to the policy are warranted.

12. **MONJUVI** (TAFASITAMAB-CXIX)
    a. New indication(s) approved 06/18/2026:
        i. In combination with a rituximab product and lenalidomide, for the treatment of adult patients with previously treated follicular lymphoma (FL).
    b. **RECOMMENDATION:** Inform prescribers via Medical Policy Alert. Prior authorization policy coverage criteria are based on recommendations from the National Comprehensive Cancer Network (NCCN); no updates to the policy are warranted.

13. **NUBEQA** (DAROLUTAMIDE)
    a. New indication(s) approved 06/03/2025:
        i. Treatment of adult patients with non-metastatic castration-resistant prostate cancer (nmCRPC).
    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

14. **AMYVID** (FLORBETAPIR F-18)
    a. New indication(s) approved 06/23/2025:
        i. Indicated for positron emission tomography (PET) of the brain to estimate amyloid beta neurotic plaque density in adults with cognitive impairment for selection of patients who are indicated for amyloid beta-directed therapy as described in the prescribing information of the therapeutic products.
    b. **RECOMMENDATION:** Inform prescribers via Medical Policy Alert.

15. **HARLIKU** (NITISINONE)
    a. New indication(s) approved 06/10/2025:
        i. indicated for the reduction of urine homogentisic acid (HGA) in adult patients with alkaptonuria (AKU).
    b. **RECOMMENDATION:** Inform prescribers via Medical Policy Alert.

16. **NEURACEQ** (FLORBETABEN F-18)
    a. New indication(s) approved 06/23/2025:
        i. Indicated for positron emission tomography (PET) of the brain to estimate amyloid beta neurotic plaque density in adults with cognitive impairment for selection of patients who are indicated for amyloid beta-directed therapy as described in the prescribing information of the therapeutic products.
    b. **RECOMMENDATION:** Inform prescribers via Medical Policy Alert.

17. **TYBOST** (COBICISTAT)
    a. New indication(s) approved 06/20/2025:
        i. Indicated to increase systemic exposure of atazanavir or darunavir (once daily dosing regimen) in combination with other antiretroviral agents in the treatment of HIV-1 infection in adults and in pediatric patients weighing at least 14 kg.
    b. **RECOMMENDATION:** Inform prescribers via Medical Policy Alert.

Drug Safety Monitoring 4/1/2025– 5/31/2025:

FDA Drug Safety Communications

1. **Drug Name:** Cetirizine and levocetirizine (Zyrtec, Xyzal, and other trade names)
    - **Date Posted: 05/16/2025**
    - **Safety Alert Title:** FDA requires warning about rare but severe itching after stopping long-term use of oral allergy medicines cetirizine or levocetirizine (Zyrtec, Xyzal, and other trade names)
    - **Link to more information:** FDA requires warning about rare but severe itching after stopping long-term use of oral allergy medicines cetirizine or levocetirizine (Zyrtec, Xyzal, and other trade names) | FDA
    - **What safety concern is FDA announcing?**
        - The U.S. Food and Drug Administration (FDA) is warning that patients stopping the oral allergy medicines cetirizine (Zyrtec) or levocetirizine (Xyzal) after long-term use may experience rare but severe itching. These medicines are available in prescription and over-the-counter (OTC) forms. The itching, also called pruritus, has been reported in patients who used these medicines daily, typically for at least a few months and often for years. Patients did not experience itching before starting the medicines. Reported cases were rare but sometimes serious, with patients experiencing widespread, severe itching that required medical intervention. As a result, the FDA is revising the prescription cetirizine and levocetirizine prescribing information to include a new warning about this risk. The FDA will subsequently request that manufacturers add a warning about pruritus to the Drug Facts Label of the OTC versions.
    - **What is FDA doing?**
        - Prescriber information has been updated to include this warning.
        - OTC manufacturers have also been informed to include this new warning.
        - FDA will follow up with further information when it becomes available.
    - **What should health care professionals do?**
        - Providers should discuss the risk of pruritus after stopping cetirizine or levocetirizine after long term use.
        - Symptoms have shown to resolve after restarting the medication and for patients who taper off the medication.

Drug Recalls/Market Withdrawals

1. **Drug Name:** Ropivacaine Hydrochloride injection USP 500mg/100ml IV bag
    - **Date of Recall:** 04/18/2025
    - **Reason for recall:** Product may contain an inert fiber identified as polypropylene fibers from the IV bag

- **Link to more information:** Amneal Pharmaceutical LLC Issues a Nationwide Recall of Ropivacaine Hydrochloride Injection, USP 500mg/100mL, Due to the Potential Presence of Particulate Matter | FDA
- **Health Plan Recommendation:** Notify providers via Medical Policy Alert.

2. **Drug Name:** Endurance Boost
   - **Date of Recall:** 05/06/2025
   - **Reason for recall:** Product was found to have propoxyphenylsildenafil (a sildenafil analogue) and sildenafil.
   - **Link to more information:** **EnShiShiXiangNiShangMaoYouXianGongSi Issues Voluntary Nationwide Recall of ENDURANCE BOOST WITH HORNY GOAT WEED Capsules Due To Presence of Undeclared Propoxyphenylsildenafil and Sildenafil | FDA**
   - **Health Plan Recommendation:** Notify providers via Medical Policy Alert.

3. **Drug Name:** Unavy Acidio Hialuronico (30 caplets/850 mg) and Umovy Acidio Hialuronico (30 caplets/850 mg)
   - **Date of Recall:** 05/22/2025
   - **Reason for recall:** Product was found to contain traces of drug ingredients diclofenac, dexamethasone and omeprazole.
   - **Link to more information:** UMARY- USA.COM Issues Voluntary Nationwide Recall of UNAVY ÁCIDO HIALURÓNICO Caplets and UMOVY ÁCIDO HIALURÓNICO Caplets Due to the Presence of Undeclared Drug Ingredients Dexamethasone, Diclofenac and Omeprazole | FDA
   - **Health Plan Recommendation:** Notify providers via Medical Policy Alert.

Drug Safety Monitoring 5/1/2025– 7/31/2025:

FDA Drug Safety Communications

1. **Drug Name:** Transderm Scop/Scopolamine Transdermal patch
   - **Date Posted:** 06/18/2025
   - **Safety Alert Title:** FDA adds warning about serious risk of heat-related complications with antinausea patch Transderm Scōp (scopolamine transdermal system)
   - **Link to more information:** https://www.fda.gov/drugs/drug-safety-and-availability/fda-adds-warning-about-serious-risk-heat-related-complications-antinausea-patch-transderm-scop
   - **What safety concern is FDA announcing?**
     - The U.S. Food and Drug Administration (FDA) is warning that the antinausea patch Transderm Scōp (scopolamine transdermal system) can increase body temperature and cause heat-related complications, resulting in hospitalization or even death in some cases. Most cases occurred in children 17 years and younger and in adults 60 years and older, who may be sensitive to body temperature control disturbances. As a result, the Transderm Scōp prescribing information will be revised to include a warning and other information about this risk.
     - Most reports of hyperthermia that resulted in serious harm occurred when the Transderm Scōp was used in children 17 years and younger. Transderm Scōp is not FDA-approved for any use in children but is sometimes prescribed “off-label” (which means that it is not an FDA-approved use) to manage excessive drooling in children with cerebral palsy or other neurologic disorders.

- Hyperthermia occurred most often within 72 hours after the Transderm Scōp patch was applied to patients' bodies for the first time. The Transderm Scōp patch can affect the body's ability to maintain a stable internal temperature, leading to a rise in core body temperature. It can also reduce sweating, which may cause increases in body temperature. Severe cases may lead to heat-related complications, such as confusion, loss of consciousness, coma, or death.
- Hyperthermia may be exacerbated when patients are in warm environmental temperatures and when they are using external heat sources, such as a heated blanket.

- **What is FDA doing?**
  - Requiring the addition of a new warning and other information to the Transderm Scōp prescribing information and patient information leaflet about the risk of hyperthermia resulting in serious harm. These revisions include information to help reduce this risk, particularly in children and older adult patients. It instructs patients to remove the Transderm Scōp patch if their body temperature increases or if they are not sweating in warm environmental temperatures and to contact their health care professional if they are experiencing symptoms.
- **What should health care professionals do?**
  - Discuss the risk of hyperthermia and associated serious harms with patients when prescribing the Transderm Scōp patch, especially in children and older adult patients who may be more susceptible to the anticholinergic effects of thermoregulatory disruption. Instruct patients to remove the patch and to contact their health care professional if they experience hyperthermia symptoms, including increased body temperature or reduced sweating in warm environmental temperatures.
  - Make patients aware that after they remove the Transderm Scōp patch, symptoms of hyperthermia may persist because the absorbed medicine will remain in the body for a period of hours to days.
- **Health Plan Recommendation:** Notify providers via Medical Policy Alert.

2. **Drug Name:** Extended-Release Stimulant Drug Class
   - **Date Posted:** 6/30/2025
   - **Safety Alert Title:** FDA requires expanded labeling about weight loss risk in patients younger than 6 years taking extended-release stimulants for ADHD
   - **Link to more information:** https://www.fda.gov/drugs/drug-safety-and-availability/fda-requires-expanded-labeling-about-weight-loss-risk-patients-younger-6-years-taking-extended
   - **What safety concern is FDA announcing?**
     - The U.S. Food and Drug Administration (FDA) is revising the labeling of all extended-release stimulants indicated to treat attention-deficit/hyperactivity disorder (ADHD) - including certain formulations of amphetamine and methylphenidate - to warn about the risk of weight loss and other adverse reactions (side effects) in patients younger than 6 years taking these medications.
     - Although extended-release stimulants are not approved for children younger than 6 years, health care professionals can prescribe them "off label" to treat ADHD.
     - FDA has found that patients younger than 6 years taking extended-release stimulants have a greater risk of weight loss and other side effects than older children taking the same medication at the same dosage. The Agency assessed data from clinical trials of extended-release formulations of amphetamine and methylphenidate for ADHD treatment. This analysis found that patients younger than 6 years have higher plasma exposures (i.e., higher levels of the drug in their bodies) and higher rates of side effects than older children. In particular, clinically significant weight loss (at least 10% decrease in the Centers for Disease Control and Prevention (CDC) weight percentile) was observed in both short- and long-term studies with

extended-release stimulants. For these reasons, the benefits of extended-release stimulants may not outweigh the risks of these products in patients younger than 6 years with ADHD.

- **What is FDA doing?**
  - Requiring a Limitation of Use section in the prescribing information of all extended-release stimulants that includes a statement about the higher plasma exposures and higher rates of adverse reactions in children younger than 6 years. Manufacturers of extended-release stimulants that do not have a Limitation of Use section in the labeling will be required to add one about this risk. Manufacturers of extended-release stimulants that already have a Limitation of Use section will be required to revise the labeling to ensure consistent messaging across the drug class.
- **What should health care professionals do?**
  - Health care professionals should be aware that extended-release stimulants are not indicated to treat ADHD in children younger than 6 years because these products have a greater risk of weight loss and other adverse reactions than in older children taking the same dose of the same medication. If a child younger than 6 years is taking an extended-release stimulant and experiencing weight loss or other adverse events, consider stopping the medication and/or switching to an alternative treatment (e.g., immediate-release stimulant). Health care professionals should monitor the child's growth and development and provide necessary interventions to mitigate weight loss. Health care professionals may prescribe other ADHD medications (e.g., immediate-release stimulants) or provide information about behavioral ADHD therapies.
- **Health Plan Recommendation:** Notify providers via Medical Policy Alert.

3. **Drug Name:** Opioid Pain Medication Class
   - **Date Posted:** 07/31/2025
   - **Safety Alert Title:** FDA is requiring opioid pain medicine manufacturers to update prescribing information regarding long-term use
   - **Link to more information:** https://www.fda.gov/drugs/drug-safety-and-availability/fda-requiring-opioid-pain-medicine-manufacturers-update-prescribing-information-regarding-long-term
   - **What safety concern is FDA announcing?**
     - Results of post marketing safety studies 3033-1 and 3033-2, showed new quantitative estimates of the risks of addiction, abuse, misuse, fatal and non-fatal overdose in patients taking opioid analgesics long-term.
   - **What is FDA doing?**
     - FDA is updating prescribing information for opioid pain medications to remove the phrase “extended-treatment” period.
     - Increasing emphasis on increased risk of serious harm with higher doses and prolonged therapy.
     - Requiring further labeling regarding extended-release/long-acting opioid pain medications should only be used when alternative therapies such as immediate release pain medications.
   - **What should health care professionals do?**
     - Providers should continue to assess severity, source, and impact of pain on their quality of life.
     - Professionals should also continue to focus on non-pharmaceutical and non-interventional targeted treatments that address the patient's pain.
     - Continue to establish lowest effective dose for pain management with the shortest duration possible.
     - Report side effects involving opioid pain medications to FDA MedWatch program.
   - **Health Plan Recommendation:** Notify providers via Medical Policy Alert.

Drug Recalls/Market Withdrawals

4. **Drug Name:** Amneal/Sulfamethoxazole/Trimethoprim Tablets USP 400mg/800mg
   - **Date of Recall:** 06/04/2025
   - **Reason for recall:** Microbial contamination
   - **Link to more information:** https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/amneal-pharmaceutical-llc-issues-nationwide-recall-sulfamethoxazole-trimethoprim-tablets-usp-400
   - **Health Plan Recommendation:** Notify providers via Medical Policy Alert.

5. **Drug Name:** Zicam and Orajel/Cold Remedy Nasal Swabs, Nasal AllClear Swabs, Baby Teething Swabs
   - **Date of Recall:** 06/06/2025
   - **Reason for recall:** Microbial contamination
   - **Link to more information:** https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/church-dwight-co-inc-issues-voluntary-nationwide-recall-zicamr-cold-remedy-nasal-swabs-zicamr-nasal
   - **Health Plan Recommendation:** Notify providers via Medical Policy Alert.

6. **Drug Name:** Sandoz Cefazolin for Injection USP, 1gm vial
   - **Date of Recall:** 06/27/2025
   - **Reason for recall:** Potential presence of penicillin g potassium injection vial
   - **Link to more information:** https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/sandoz-inc-issues-voluntary-nationwide-recall-one-lot-cefazolin-injection-due-product-mispackaging
   - **Health Plan Recommendation:** Notify providers via Medical Policy Alert.

7. **Drug Name:** Sucralfate 1 gram tablet
   - **Date of Recall:** 07/11/2025
   - **Reason for recall:** Nostrum Labs has filed for bankruptcy and started a voluntary recall of Sucralfate Tablets USP 1 gram, all lots within expiry, as a result of the bankruptcy. All lots of 1 gm sucralfate with expiry, manufactured by Nostrum Labs after June 2023.
   - **Link to more information:** https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/nostrum-laboratories-inc-issues-voluntary-nationwide-recall-sucralfate-tablets-usp-1-gram-within
   - **Health Plan Recommendation:** Notify providers via Medical Policy Alert.

Other Formulary Changes:

Journavx Drug Utilization Review

a. **Indication**: For the treatment of moderate to severe acute pain in adults.

b. **Decision**:

	Commercial	Medicaid	Medicare
Formulary Status*	Non-formulary	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	N/A	N/A
Quantity Limit	7/75	5/30	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:			

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

PA PROGRAM NAME	Journavx
MEDICATION NAME	Journavx
PA INDICATION INDICATOR	1 - All FDA-Approved Indications
OFF-LABEL USES	None
EXCLUSION CRITERIA	• Use for chronic pain or sciatica • Concurrent use with opioid medications
REQUIRED MEDICAL INFORMATION	**REQUIRED MEDICAL INFORMATION:** 1. **One of the following:** a. Diagnosis of moderate to severe acute pain b. Member has a surgical procedure scheduled within the next 30 days that is expected to result in moderate to severe acute pain, such as an invasive procedure that affects vital tissues or organs and requires longer recovery periods (for example, open-heart surgery, organ transplant, reconstructive surgery, knee or hip joint replacement, cesarean section) 2. **Medicaid quantity limit exception requests must also meet both of the following:** a. Patient has not already received 14 days of therapy for the same indication b. Documentation that the patient is failing to receive adequate pain relief from, or has contraindications to, both acetaminophen and a non-steroidal anti-inflammatory agent (such as ibuprofen)
AGE RESTRICTIONS	May be approved for patients aged 18 years and older
PRESCRIBER RESTRICTIONS	N/A
COVERAGE DURATION	Initial authorization will be approved for one month. No reauthorization.

Drug Name	Action Taken	Policy Name

Adbry (tralokinumab-ldrm) syringe and auto-injector	Add to Commercial formulary in parity with preferred agents • Commercial: Tier 5, Prior Authorization, Quantity Limit (2 mL/28 days)	Therapeutic Immunomodulators
• **Alecensa (alectinib)** • **Alunbrig (brigatinib)** • **Lorbrena (lorlatinib)** • **Xalkori (crizotinib)**	Commercial: Down tier from Tier 6 to Tier 5	Anti-Cancer Medications - Self-Administered
• **Amjevita (adalimumab-atto)** • **Adalimumab-fkjp** • **Simlandi (adalimumab-ryvk)**	Add to Medicaid formulary as preferred product in parity with Humira: • Medicaid: Formulary, Prior Authorization, Quantity Limit (2 doses per 28 days)	Therapeutic Immunomodulators
Breyna (budesonide/formoterol) inhaler	Added to Core Preventive List	N/A
Brilinta (ticagrelor)	Brand product removed from Core PLUS Preventive List. Generic added to Core Preventive List	N/A
Brynovin (sitagliptin) solution	New dosage form. Non-formulary for all lines of business	N/A
Cosentyx (secukinumab) syringe and pen injector	Remove from Medicaid formulary (non-preferred on Preferred Drug List) • Non-formulary, Prior Authorization, Quantity limit (2 doses per 28 days)	Therapeutic Immunomodulators
Fasenra (benralizumab) Pen	Remove from Medicaid formulary (non-preferred on Preferred Drug List) • Non-formulary, Prior Authorization, Quantity limit (1 mL per 56 days)	Therapeutic Immunomodulators
Harliku (nitisinone) tablet	New formulation. Non-formulary for all lines of business	N/A
Hydrocodone/acetaminophen 10-300 mg/ 15 mL solution	New dosage. Non-formulary for all lines of business	N/A
Hymrioz (adalimumab-adaz) syringe and pen injector	Remove from Medicaid formulary (non-preferred on Preferred Drug List) • Non-formulary, Prior Authorization, Quantity limit (2 doses per 28 days)	Therapeutic Immunomodulators
Leucovorin calcium 5 mg Tablet	• Commercial: Formulary, Tier 2, Step Therapy, Quantity Limit (3 tablets per day) • Medicaid: Formulary, Step Therapy, Quantity Limit (3 tablets per day)	Leucovorin

	• Medicare Part D: Formulary Tier 3	
Leucovorin calcium 25 mg Tablet	• Commercial: Formulary, Tier 2, Step Therapy, Quantity Limit (2 tablets per day) • Medicaid: Non-Formulary, Step Therapy, Quantity Limit (2 tablets per day) • Medicare Part D: Formulary Tier 3	Leucovorin
Leucovorin calcium Tablet (10mg; 15mg)	• Commercial: Formulary, Tier 2, Step Therapy, Quantity Limit (3 tablets per day) • Medicaid: Non-Formulary, Step Therapy, Quantity Limit (3 tablets per day) • Medicare Part D: Formulary Tier 3	Leucovorin
Liraglutide pen injector	Generic for Victoza. Add to formulary: • Commercial Standard: Formulary, Tier 2, Prior Authorization, Quantity Limit (9 mL per 30 days) • Commercial Dynamic: Formulary, Tier 3, Prior Authorization, Quantity Limit (9 mL per 30 days) • Medicaid: Formulary, Prior Authorization, Quantity Limit (9 mL per 30 days) • Medicare Part D: Formulary, Tier 3, Prior Authorization, Quantity Limit (9 mL per 30 days)	GIP and GLP-1 Receptor Agonists
Lopressor (metoprolol tartrate) 10 mg/mL oral solution	New dosage form. Non-formulary for all lines of business	N/A
Metformin 500 mg extended-release tablet (Glumetza)	Add to Commercial and Medicaid formulary • Commercial: Formulary, Tier 1 • Medicaid: Formulary	N/A
Nifedipine ER tablet	Added to Core Preventive List	N/A
Nilotinib tartrate capsule	New brand. Brand Tasigna already available • Commercial: Formulary, Tier 6, Prior Authorization, Quantity Limit (4 capsules per day) • Medicaid: Non-Formulary, Prior Authorization, Quantity Limit (4 capsules per day) • Medicare Part D: Formulary, Tier 5, Prior Authorization, Quantity Limit (4 capsules per day)	• Commercial/Medicaid: Anti-cancer medications – self administered • Medicare Part D: Anti-cancer agents
Opsumit	• Commercial: Down tier to Tier 5	Pulmonary Hypertension

	• Medicaid: Add to Formulary	
Otezla (apremilast) tablet	Add to Medicaid formulary as preferred product: • Medicaid: Formulary, Prior Authorization, Quantity Limit (2 tablets per day)	Therapeutic Immunomodulators
Oxandrolone (Oxandrin) tablet	Remove from Commercial formulary	N/A
Paromomycin sulfate (Humatin) Capsule	Remove from Commercial formulary	N/A
Penicillamine 250 mg Capsule	• Commercial: Down tier from Tier 5 to Tier 4 • Medicare Part D: Add to Formulary, Tier 4	N/A
Penicillamine 250 mg Tabet	Remove from Commercial formulary	N/A
Pirfenidone 267 mg Tablet	Add to formulary • Commercial: Formulary, Tier 5, Prior Authorization, Quantity Limit (three tablet per day) • Medicaid: Formulary, Prior Authorization, Quantity Limit (three tablet per day) • Medicare Part D: Formulary, Tier 5, Prior Authorization, Quantity Limit (9 tablets per day)	• Commercial/Medicaid: Ofev, Pirfenidone • Medicare Part D: Pulmonary Fibrosis Agents
Taltz (ixekizumab) syringe and auto-injector	Add to Medicaid formulary as preferred product: • Medicaid: Formulary, Prior Authorization, Quantity Limit (One injection per 28 days)	Therapeutic Immunomodulators
Tyvaso DPI	Remove from Commercial and Medicaid formularies	Pulmonary Hypertension
Veozah (fezolinetant) tablet	Add to Commercial formulary: Tier 4, Prior Authorization, Quantity Limit (one tablet per day)	Veozah
Vyvgart Hytrulo (efgartigimod-hyaluronidase-qvfc) syringe	New formulation. • Commercial: Formulary, Tier 6, Prior Authorization • Medicaid: Formulary, Prior Authorization • Medicare Part D: Formulary, Tier 5, Prior Authorization	FcRN Antagonists
Xeljanz (tofacitinib) tablet	Add to Medicaid formulary as preferred product: Formulary, Prior Authorization, Quantity Limit (tablet: 2 tablets per day; oral solution: 10 mL per day; ER tablets: one per day)	Therapeutic Immunomodulators
Xifaxan (rifaximin) tablet	Remove from Medicaid formulary.	Xifaxan

Xolair (benralizumab) syringe and auto-injector	Remove from Medicaid formulary (non-preferred on Preferred Drug List): Non-formulary, Prior Authorization, Quantity limit (one dose per 28 days)	Therapeutic Immunomodulators
Ycanth (cantharidin) 0.7% solution	Add prior authorization. Medical benefit for all lines of business	Medications for Molluscum Contagiosum
Yutrepia	• Commercial: Formulary, Tier 6, Prior Authorization • Medicaid: Non-Formulary, Prior Authorization, Specialty • Medicare Part D: Formulary, Tier 5, Prior Authorization	Pulmonary Hypertension
Zepbound (tirzepatide)	Add to Medicaid formulary: Formulary, Prior Authorization, Quantity Limit (Four injections per 28 days)	Weight Management Medications
Zusduri (mitomycin) kit	New formulation. Medical benefit with Prior Authorization for all lines of business	Anti-Cancer Medications - Medical Benefit

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

Drugs released from 6/13/2025 – 7/25/2025

INFORMATIONAL ONLY

NEW DRUGS / COMBINATIONS / STRENGTHS / DOSAGE FORMS		
Drug Name	**Action Taken**	**Policy Name**
Desogestrel/e.estradiol/iron (Averi) Tablet	New formulation. Line extend with ACA birth control; • Commercial: Preventive • Medicaid: Formulary • Medicare Part D: Non-Formulary	N/A
Crinecerfont (Crenessity) Capsule	New strength (25 mg). Line extend with Crenessity 50mg, 100mg strengths; • Commercial/Medicaid: Non- Formulary, Prior Authorization, Quantity Limit (2 capsules per day), Specialty	• Commercial/Medicaid: Medications for Rare Indications • Medicare Part D: N/A

NEW DRUGS / COMBINATIONS / STRENGTHS / DOSAGE FORMS		
Drug Name	**Action Taken**	**Policy Name**
	• Medicare Part D: Non- Formulary	
Tesamorelin acetate (Egrifta WR) Kit	New strength (11.6 mg). Line extend with Egrifta SV 2 mg subcutaneous solution; • All lines of business: Commercial/Medicaid: Non-Formulary • Medicare Part D: Non-Formulary	N/A
Iloperidone (Fanapt Titration Pack B) Tab DS PK	New packaging. Line extend as/with Fanapt Titration Pack A; • Commercial: Formulary, Tier 4, Prior Authorization, Quantity Limit (12 tablets per 365 days) • Medicaid: Non-Formulary (Covered by OMAP, 7-11 carve-out) • Medicare Part D: Formulary, Tier 4, Prior Authorization, Quantity Limit (12 tablets per 365 days)	• Commercial/Medicare Part D: Antipsychotics • Medicaid: N/A
Iloperidone (Fanapt Titration Pack C) Tab DS PK	New packaging. Line extend as/with Fanapt Titration Pack A; • Commercial: Formulary, Tier 4, Prior Authorization, Quantity Limit (8 tablets per 365 days) • Medicaid: Non-Formulary (Covered by OMAP, 7-11 carve-out) • Medicare Part D: Formulary, Tier 4, Prior Authorization, Quantity Limit (8 tablets per 365 days)	• Commercial/Medicare Part D: Antipsychotics • Medicaid: N/A
Alpha-1-proteinase inhibitor (Glassia) Vial	New strengths (4 g/200 mL; 5 g/250 mL). Line extend with Glassia; • Medical Benefit, Prior Authorization for all lines of business	Alpha-1 Proteinase Inhibitors
Ustekinumab-srlf (Imuldosa) Vial	New biosimilar. Line extend with non-Preferred Stelara biosimilar; • Medical Benefit, Prior Authorization for all lines of business	• Commercial/Medicare Part B: Medically Infused Therapeutic Immunomodulators • Medicaid: Therapeutic Immunomodulators (Tims)

NEW DRUGS / COMBINATIONS / STRENGTHS / DOSAGE FORMS		
Drug Name	**Action Taken**	**Policy Name**
Ustekinumab-srlf (Imuldosa) Syringe	New biosimilar. Line extend with non-Preferred Stelara biosimilar; • Commercial/Medicaid: Non-Formulary, Prior Authorization, Quantity Limit (45 mg/0.5 mL: 0.5 mL per 84 days; 90 mg/mL: 1 mL per 84 days) • Medicare Part D: Non-Formulary	• Commercial/Medicaid: Therapeutic Immunomodulators (TIMS) • Medicare Part D: N/A
Finerenone (Kerendia) Tablet	New strength (40 mg). Line extend with other Kerendia strengths; • Commercial: Formulary, Tier 4, Prior Authorization, Quantity Limit (1 tablet per day) • Medicaid: Formulary, Prior Authorization, Quantity Limit (1 tablet per day) • Medicare Part D: Formulary, Tier 3, Prior Authorization, Quantity Limit (1 tablet per day)	Kerendia
Ustekinumab-ttwe (Pyzchiva) Vial	New biosimilar. Line extend with non-preferred Stelara biosimilar; • Commercial/Medicaid: Non-Formulary, Prior Authorization, Quantity Limit (0.5 mL per 84 days) • Medicare Part D: Non-Formulary	• Commercial/Medicaid: Therapeutic Immunomodulators (TIMS) • Medicare Part D: N/A
Guselkumab (Tremfya Pen Induction PK-Crohn) Pen Injctr	New MedID. Line extend with Tremfya 100 mg/mL subcutaneous syringe; • Commercial: Formulary, Tier 5, Prior Authorization, Quantity Limit (2 mL per 28 days) • Medicaid: Non-Formulary, Prior Authorization, Quantity Limit (2 mL per 28 days) • Medicare Part D: Formulary, Tier 5, Prior Authorization, Quantity Limit (24 mL per 365 days)	Therapeutic Immunomodulators (TIMS)
Sotatercept-csrk (Winrevair [2 Pack]) Kit	New packaging. Line extend with Winrevair 60mg; • Commercial: Formulary, Tier 6, Prior Authorization, Quantity Limit (1 kit per 21 days)	Pulmonary Hypertension

NEW DRUGS / COMBINATIONS / STRENGTHS / DOSAGE FORMS		
Drug Name	**Action Taken**	**Policy Name**
	• Medicaid: Formulary, Prior Authorization, Quantity Limit (1 kit per 2142 days) • Medicare Part D: Formulary, Tier 5, Prior Authorization, Quantity Limit (1 kit per 21 days)	
Lenacapavir sodium (Yeztugo) Tablet	New MedID. Line extend with Sunlenca; HIV Pre-exposure prophylaxis medication • Commercial: Preventive • Medicaid: Formulary • Medicare Part D: Formulary, Tier 5, Quantity Limit (10 tablets per 365 days)	N/A
Lenacapavir sodium (Yeztugo) Vial	New MedID. Line extend with Sunlenca (medical); HIV Pre-exposure prophylaxis medication • Medical benefit for all lines of business; covered in full for Commercial	N/A
Tirzepatide (Zepbound) Vial	New dosage form (vial). Line extend with Zepbound; • Commercial Standard: Formulary, Tier 3, Prior Authorization, Quantity Limit (2 ml per 28 days) • Commercial Dynamic: 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	• Commercial/Medicaid: Weight Management Medications • Medicare Part D: N/A
		•

NEW GENERICS		
Drug Name	**Action Taken**	**Policy Name**
Estradiol/norethindrone acet (Abigale) Tablet	New Generic. Line extend as generic Activella; • Commercial Standard: Formulary, Tier 2 • Commercial Dynamic: Formulary, Tier 3 • Medicaid: Formulary • Medicare Part D: Formulary, Tier 2	N/A
Fidaxomicin Tablet	First generic drug (Dificid). Line extend as generic;	N/A

	• Commercial Standard: Formulary, Tier 2, Quantity Limit (20 tablets per 30 days) • Commercial Dynamic: Formulary, Tier 4, Quantity Limit (20 tablets per 30 days) • Medicaid: Formulary, Quantity Limit (20 tablets per 30 days) • Medicare Part D: Formulary, Tier 5, Quantity Limit (20 tablets per 10 days)	
Fluticasone furoate Blst w/dev	Authorized generic drug (Arnuity Ellipta). Line extend as non-preferred; • Non-Formulary for all lines of business	N/A
Norethindrone (Orquidea) Tablet	New Generic. Line extend with other generics; • Commercial: Preventive • Medicaid: Formulary • Medicare Part D: Formulary, Tier 3	N/A
Rivaroxaban Susp Recon	First generic drug (Xarelto). Line extend as non-preferred; • Commercial/Medicaid: Non-Formulary • Medicare Part D: Non-Formulary	N/A
Sacubitril-Valsartan Tablet	First generic drug (Entresto). Line extend as generic; • Commercial Standard: Formulary, Tier 2 • Commercial Dynamic: Formulary, Tier 3 • Medicaid: Formulary • Formulary, Tier 3, Quantity Limit (24 mg-26 mg: 3 tablets per day; 49 mg-51 mg/97 mg-103 mg: 2 tablets per day)	N/A
Sertraline hcl 150 mg and 200 mg Capsule	First generic drug (sertraline hcl). Line extend as generic; • Commercial: Non-Formulary, Prior Authorization • Medicaid/Medicare Part D: Non-Formulary	• Commercial: New Medications and Formulations without Established Benefit • Medicaid/Medicare Part D: N/A
Topiramate 25 mg/mL Solution	First generic drug (Eprontia). Line extend as generic; • Commercial/Medicaid: Non-Formulary • Medicare Part D: Formulary, Tier 4	N/A

Clinical Policy Changes:

MAJOR CHANGES	
Policy Name	**Summary of Change**
Antipsychotics	Clarifying duration of four weeks for prerequisite therapy requirements
Complement Inhibitors	Added policy criteria for primary IgA nephropathy for Fabhalta®.
Continuous Glucose Monitors for Personal Use	• Added criteria to allow for individuals with type 1 diabetes regardless of insulin use. • Updated quantity limits for the sensors to align with sensors duration. • Updated replacement of reader/receiver criteria to align with Medicare policy. • Autopay already set up for patients with claims for insulin; however, added age edits so will only pay if they meet the FDA-approved minimum age.
Continuous Glucose Monitors for Personal Use - Medicare Part B	• Updated quantity limits for the sensors to align with sensors duration. • Updated replacement of reader/receiver criteria due to change in Medicare benefit manual language.
• **FcRn Antagonists** • **FcRn Antagonists Prior Authorization and Step Therapy Policy - Medicare Part B**	• Changed trial and failure criteria for Myasthenia Gravis to one drug from two classes: AChE inhibitors, corticosteroids, non-steroidal immunosuppressive agents • Added criterion for medically-administered products require medical rational why self-administered Vyvgart Hytrulo is not appropriate
Formulary and Quantity Limit Exceptions	Clarified this policy applies to pharmacy benefit drugs only as there will be a separate quantity limit policy for medical drugs (new policy).
GIP and GLP-1 Receptor Agonists	Liraglutide (generic for Victoza®) added as co-preferred product.
• **Interleukin-1 Inhibitors** • **Interleukin-1 Inhibitors Prior Authorization and Step Therapy – Medicare Part B**	Added criteria that dosing and frequency must be in accordance with FDA labeling.
Ketamine	New policy created to clarify coverage of intravenous ketamine is limited to FDA-approved treatments related to anesthesia. The health plan does not cover IV ketamine for behavioral health disorders.
Lupkynis	Added lab requirement (eGFR and urinary protein to creatine ratio) to the initial auth to allow assessment of treatment response at reauth. Clarified wording to the reauth criteria.
Medical Necessity – Medicaid	Updated coverage duration to address quantity limit exception authorization duration.
Medical Drug Quantity Limit Exceptions	New policy to outline criteria for coverage of medically administered medications above FDA or compendia-supported dosing regimens.
• **Medically Administered Multiple Sclerosis Agents** • **Medically Administered Multiple Sclerosis Agents Prior Authorization and Step Therapy Policy – Medicare Part B**	Added step through Ocrevus IV for Ocrevus Zunovo.
• **Medically Infused Therapeutic Immunomodulators (Tims) – Comm**	Updated preferred agents, coverage durations, prescriber restrictions, defined response to therapy, changed reauthorization to established, updated criteria, added durations for trial and failure.

• **Medically Infused Therapeutic Immunomodulators (TIMs) Prior Authorization and Step Therapy Policy - Medicare Part B**	
Medications For Rare Indications	Added Procsybi to policy, updated criteria to Aqneursa and Miplyffa, removed Niemann-Pick disease type C indication from Opfolda and added it to Zevaskyn.
New Medications and Formulations without Established Benefit	Several agents were removed from this policy due to no longer being available on the market, or due to generic availability and costs more aligned with current formulary options.
Oral Rinses	Gelx and Caphosol removed from policy as obsolete.
Rezurock (now Medications for Graft-versus-Host-Disease)	• Changed name to Medications for Graft-versus-Host-Disease and added Niktimvo and Ryoncil (these medications were previously on the anti-cancer policy) • Added quantity limit exception criteria requiring medical rationale why patient cannot switch to Jakafi or Imbruvica instead of dose escalation on these medications • Will also have separate policy for Medicare Part B (with same criteria, not included in packet)
Saphnelo	Prescriber restrictions updated to include providers with experience treating systemic lupus erythematosus (SLE)
Self-Administered Drugs (SAD)	List of applicable medications was updated to clarify when transition period would be allowed vs requiring self-administration at initiation of therapy.
• **Therapeutic Immunomodulators (TIMS) – Comm** • **Therapeutic Immunomodulators (TIMS) - Medicaid**	Updated preferred agents, coverage durations, prescriber restrictions, defined response to therapy, changed reauthorization to established, updated criteria, added durations for trial and failure.
• **Tysabri** • **Tysabri Prior Authorization and Step Therapy Policy - Medicare Part B**	Trail and failure of Entyvio added to Crohn's criteria to align with TIMs policy. Additionally, add in a one year timeframe for negative JCV antibody testing as patients on Tysabri should be getting JCV antibody testing at least every 6 months even if previous test was negative.
Veozah	New policy – this medication is required to be added to Commercial formulary due to state regulations. Therefore policy was created to ensure appropriate utilization of more cost-effective therapies prior to use of this agent.
Weight Management Medications	Added metabolic dysfunction-associated steatohepatitis criteria, added exclusion for combination with another weight loss agent, and clarified BMI requirements for other indications.
Weight Management Medications - Medicaid	Added criteria for metabolic dysfunction-associated steatohepatitis and updated/clarified other criteria to align with Oregon Health Authority criteria
Xifaxan	This medication is no longer covered by Oregon Medicaid. The health plan will maintain coverage for hepatic encephalopathy despite this state change.
Zeposia	Preferred agents updated in the ulcerative colitis policy criteria to mirror preferred agents in the Therapeutic Immunomodulators policy.

Deferred Policies: The following policies reviews are being deferred, to December 2025 ORPTC, for further evaluation	
Benefit Exception - Member-Pay-Difference	Multiple Sclerosis Agents
Complement Inhibitors Prior Authorization and Step Therapy Policy - Medicare Part B	Non-Preferred Fumarate Products
Compounded Drugs	Rethymic
Diabetic Durable Medical Equipment (DME)	Sylvant
Enspryng	Therapies for Duchenne Muscular Dystrophy
Gene Therapy for Hemophilia	Trientine
Lemtrada	• Uplizna • Uplizna Prior Authorization and Step Therapy Policy - Medicare Part B
Lemtrada Prior Authorization and Step Therapy Policy - Medicare Part B	Xiaflex
Medications For Rare Indications Prior Authorization Policy - Medicare Part B	Zeposia - Medicaid

Retired Policies:

Procysbi - Medication added to Medications for Rare Indications Po