Providence Health Plan

Providence Health Assurance

Healthcare Services Medical & Pharmacy Policy Alerts

Number 108

June 1, 2025

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

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

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

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

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

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

MEDICAL POLICY COMMITTEE

As of 05/30/25, Providence Health Plan is unable to accept records submitted on CDs or USB drives. Please reach out to the requesting department for updated submission methods.

Updated clinical practice guidelines for Providence Health Plan Provider partners
The clinical practice guidelines below have been provided by Health Share of Oregon and are intended to help doctors and medical providers stay informed about the standards of care Health Share follows in our region.

These guidelines are reviewed and approved by the Health Share Clinical Advisory Panel every two years.

The guidelines are meant to guide care for groups of people, but providers should still consider each person's unique needs when using them.

Please review the guidelines and implement when/where appropriate.

Health Share of Oregon | Clinical Practice Guidelines

Providence Health Plan

Providence Health Assurance

MEDICAL

COMPANY POLICIES

Effective 7/1/2025

Small Joint Surgery **MP438**	**New Policy** **Policy Updates:** Created new policy on various foot and ankle procedures: • Ankle arthrodesis • Ankle Arthroplasty • Bunionette Surgery • Hallux Valgus • Lesser Toe Deformity Surgery • Hallux Rigidus Surgery • First Metatarsophalangeal (MTP) Joint Arthrodesis • First MTP Joint Arthroplasty • Metatarsal Osteotomy **Codes/PA:** Added PA to 16 codes

Effective 8/1/2025

Allergy Testing **MP153**	**Policy Updates:** Updated billing guidelines to clarify frequency limits **Codes/PA:** No changes to codes
Glycated Hemoglobin and Glycated Protein Testing **MP267**	**Policy Updates:** Lab policy. No change to criteria, will continue to apply CMS NCD 190.21 for glycated hemoglobin/glycated protein testing. **Codes/PA:** Updated dx configuration per NCD 190.21 guidance to allow testing for diabetes and other specified disorders of pancreatic internal secretion.

Psychological and Neuropsychological Testing **MP274**	**Policy Updates:** No changes. **Codes/PA:** Added additional dx codes for dementia and cognitive disorders to the list of approved diagnoses for psychological and neuropsychological testing
Benign Skin Lesions **MP422**	**Policy Updates:** New policy approved at March 2025 MPC establishing pair-to-pay configuration for benign skin lesion removal, based on MD input and Noridian local coverage article (LCA). No change to policy or codes, but effective date has been moved back from 6/1/25 to 8/1/25 **Codes/PA**: No changes from March 2025 MPC - Add diagnosis code configuration to the relevant CPT codes.

Effective 9/1/2025

Total Knee Arthroplasty **MP418**	**Policy Updates:** Added criteria addressing partial knee arthroplasty, per EviCore and AAOS guidance. PKA procedures will now be subject to both medical necessity and inpatient site of service review. **Codes/PA:** Added CPT 27446 to policy; code currently only requires PA for inpatient sites of service. Change configuration to require PA across all sites of service.
Genetic Testing for Hereditary Breast, Ovarian, Pancreatic, and Prostate Cancer *Previously: Genetic Testing for Hereditary Breast, Ovarian, and Pancreatic Cancer* **MP143**	**Policy Updates:** • Changed title to include prostate cancer • Added criteria for prostate cancer, based on NCCN guidelines • Added Invitae Multi-Cancer Panel and Invitae Common Hereditary Cancer Panel as examples of non-covered panels in criterion VII. **Codes/PA:** No changes to codes or PA

Blood Counts **MP208**	**Policy Updates:** No recommended changes to criteria. **Codes/PA:** Updated pair to deny configurations with dx codes based on the Medicare Lab Manual.
Complementary and Alternative Medicine Treatments	**Policy Updates:** Added nerve blocks to list of "not medically necessary" procedures for behavioral health conditions (e.g. post-traumatic stress disorder). **Codes/PA:** Added CPT 64418 and 64510 to policy, and configured to deny when billed with dx codes for PTSD (F411, F4312, F4311, F4310).
Electrical Stimulation Non-Covered Therapies **MP331**	**Policy Updates:** Formatting changes; example devices added. **Codes/PA:** Added NMN configuration to two codes: E0743, A4544

ARCHIVE

Effective 7/1/2025

Blood Brain Barrier Disruption and Bypass **MP147**	**Policy Updates:** Archiving medical policy due to low utilization **Codes/PA:** Removed PA from 36215-36218 and NMN denial from 0947T. Codes will be allowed to process.

MEDICARE POLICIES

Effective 7/1/2025

Small Joint Surgery **MP439**	**New Medicare Advantage medical policy.** **Policy Updates:** In the absence of fully established Medicare coverage criteria for small joint procedures, the plan will use internal Company criteria. **Codes/PA:** Added PA to the codes addressed by this policy

Effective 8/1/2025

Benign Skin Lesions **MP423**	**Policy Updates:** New policy approved at March 2025 MPC establishing pair-to-pay configuration for benign skin lesion removal, based on Noridian local coverage article (LCA). No change to policy or codes, but effective date has been moved back from 6/1/25 to 8/1/25 **Codes/PA:** No changes from March 2025 MPC - Due to large numbers for overall utilization, add diagnosis code configuration to the relevant CPT codes, based on Noridian local coverage article (LCA).

Effective 9/1/2025

Spinal Fusion and Decompression Procedures **MP358**	**Policy Updates:** No change to criteria, continue to apply NCD, LCD or Company medical policy as directed. **Codes/PA:** 0275T and G0276: Updated diagnosis code configuration to add additional ICD-10 codes, as established by CMS. No change to other codes or their configuration.
Transcatheter Aortic Valve Replacement (TAVR) **MP221**	**Policy Updates:** No change to criteria. Continue to use NCD for TAVR. **Codes/PA:** CPTs don't require PA, but may be reviewed if billed with certain modifiers to ensure clinical registry criteria from the NCD are met. CPT 33370 didn't get this configuration added to it when the code was first developed (2022). Updating config for this code to align with the 3336X codes in the policy.

Effective 10/1/2025

Blepharoplasty, Blepharoptosis Repair, and Brow Lift **MP225**	**Policy Updates:** No change to criteria, continue to apply the Noridian LCD as directed. Added documentation requirements to the "Policy Guidelines" section. While the criteria are not changing, advanced provider notification is being given to advise that the CAP questionnaire will be updated to align more strictly with the Noridian LCD. **Codes/PA:** No change to codes or criteria.

ARCHIVE

Effective 7/1/25

Blood Brain Barrier Disruption and Bypass **MP335**	**Policy Updates:** Archiving medical policy. **Codes/PA:** Code and configuration changes are as follows: • Leave NMN denial on 0947T (will transfer this code to the MRgFUS policy). • Remove PA from 36215-36218. These codes will be allowed to process.
Prolotherapy **MP334**	**Policy Updates:** Archiving medical policy. **Codes/PA:** For M0076, transfer code to Medicare NET policy and keep NMN denial. All other codes are unlisted codes, which will continue to follow the unlisted code review process.

Effective 8/1/2025

Measurement of Antibodies to Immunosuppressive Therapies for Inflammatory Bowel Disease **MP345**	**Policy Updates:** Archiving this medical policy for Medicare LOB. **Codes/PA:** Remove NMN denial from codes.

CODING POLICY UPDATES

New Secondary Claims Editor	As previously published June 1, 2025, in the Healthcare Services Medical & Pharmacy Policy Alert: Effective August 4th, 2025, Providence Health Plan (PHP) and Providence Health Assurance (PHA) will be implementing a secondary claims editing tool that provides fast, accurate, and customized claims editing that is fully compliant with ever-changing coding and billing guidelines. The secondary claims editor uses robust technology and analytics to effectively review claims for billing errors prior to payment so you may see new edit codes on your explanation of payment. Providers/facilities may request a reconsideration of any findings in accordance with the PHP/PHA provider dispute process. New edits will initially apply to PHP/PHA Commercial Fully-Insured and Medicare products using industry standards sourced from the Centers for Medicare & Medicaid Services (CMS), the American Medical Association, and the ICD-10-CM manual. This new suite of edits will complement the systems currently in place.
NEW POLICY **Coding Policy 02.0 – Diagnosis Coding**	Coding Policy 02.0 (Diagnosis coding) establishes appropriate diagnosis coding requirements. PHP aligns with the ICD-10-CM Official Guidelines for Coding and Reporting by the Centers for Medicare and Medicaid Services (CMS) and the National Center for Health Statistics (NCHS), which provides clear direction on the proper reporting and sequencing of diagnosis codes. Coding edits are developed to promote the accuracy and efficiency of claims processing and reporting. Examples of diagnosis code related edits include, but are not limited to: A. Noncompliance with official guidelines B. Misuse of unspecified codes C. Inconsistencies between code sets Notably, this policy introduces a new coding edit for diagnosis codes indicating unspecified laterality. Effective for dates of service on or after August 4, 2025, claims including “unspecified” laterality diagnosis codes in either the first or second positions at either the claim or charge level will be denied. The new policy will be posted on ProvLink on or before August 8, 2025.

Coding Policy 06.0 – Multiple Procedure Reductions	Coding Policy 06.0 (Multiple Procedure Reductions) was updated to show procedure codes with a multiple procedure indicator of "5" on the Medicare Physician Fee Schedule (MPFS) are eligible for multiple procedure payment reductions. The Centers for Medicare and Medicaid Services (CMS) maintains a list of "always" and "sometimes" codes for physical therapy (PT), occupational therapy (OT), and speech-language pathology (SLP). The practice expense (PE) portion covers the costs of providing the service, such as equipment, supplies, and staff time. If a physical therapist provides two "always therapy" services during a single session, the first service is allowed at 100%, while the second service's PE component is reduced by 50%. The updated policy will be posted on ProvLink on or before August 8, 2025.
NEW POLICY **Coding Policy 06.2 – Multiple Diagnostic Service Reductions**	Coding Policy 06.2 (Multiple Diagnostic Service Reductions) replaces Coding Policy 99.0 (Reduction to Technical Component for Multiple Radiology Services) and updates multiple procedure payment reductions (MPPR) for diagnostic imaging, cardiovascular, and ophthalmology services to align with CMS methodologies. The new policy will be posted on ProvLink on or before August 8, 2025. • When two or more services with multiple procedure status indicator 4 are performed during the same session, a 50% reduction is applied to the TC portion and a 5% reduction is applied to the PC portion of the subsequent diagnostic imaging services. • When two or more services with multiple procedure status indicator 6 are performed during the same session, a 25% reduction is applied to the TC portion of all second and subsequent diagnostic cardiovascular service codes. • When two or more services with multiple procedure status indicator 7 are performed during the same session, a 20% reduction is applied to the TC portion of all second and subsequent diagnostic ophthalmology service codes.
Coding Policy 13.0 – Bundled or Adjunct Services	Coding Policy 13.0 (Bundled or Adjunct Services) was updated to reflect current PHP practice and explain that codes with Status Indicator T on the Medicare Physician Fee Schedule (MPFS) are bundled into payable services on the same date. Status T codes not specifically listed on this policy may be reimbursed if they are the sole payable service billed by the provider on the date of service. The updated policy will be posted on ProvLink on or before August 8, 2025.
Coding Policy 85.0 – Documentation Guidelines for Rehabilitation Therapy Services (Physical, Speech, and Occupational Therapy Services)	This policy was updated to clarify only one plan of care modifier may be reported per claim line. Facility claims must be submitted with the appropriate modifier and revenue code corresponding to the type of therapy performed. • Revenue Code 042X (physical therapy) lines may only contain modifier GP • Revenue code 43X (occupational therapy) lines may only contain modifier GO • Revenue code 44X (speech-language pathology) lines may only contain modifier GN The updated policy will be posted on ProvLink on or before August 8, 2025.

GENERAL CODING GUIDELINES

Adjacent Tissue Transfer with Mastectomy or	According to the National Correct Coding Initiative (NCCI) Policy Manual, Chapter 3: • Section J-2: Breast procedure codes include incision and closure.

Reconstructive Breast Procedures	• Section J-8: Breast reconstruction procedures (CPT codes 19357-19369) include adjacent tissue transfer (CPT codes 14000-14001). *CPT Assistant* (October 2017, p. 9 and February 2015, p. 10) further confirms that adjacent tissue transfer codes should not be reported with CPT codes 19301 or 19357–19369, as these services already include payment for the necessary flaps and/or closure. PHP will implement a coding edit to deny reimbursement for CPT codes 14000-14001 when billed with CPT codes 19301 or 19357-19369. These codes may only be reimbursed together if the adjacent tissue transfer is performed on a separate anatomical site unrelated to the breast procedure.

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

Pharmacy & Therapeutics (P&T) Committee

Oregon Region P&T Committee Meeting June 6, 2025
Go-Live Date: Friday, August 01, 2025, unless otherwise noted

Table of Contents:

New Drugs and Combinations:

1. **Axatilimab-csfr (Niktimvo) Vial**
    a. **Indication**: For the treatment of adult and pediatric patients with chronic graft-versus-host disease (cGVHD) weighing ≥40 kg after failure of at least two prior lines of systemic therapy.
    b. **Decision**:

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

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

PA PROGRAM NAME	Anti-Cancer Medications – Medical Benefit
MEDICATION NAME	Axatilimab-csfr (Niktimvo™)
PA INDICATION INDICATOR	1 - All FDA-Approved Indications
OFF-LABEL USES	N/A
EXCLUSION CRITERIA	N/A
REQUIRED MEDICAL INFORMATION	For initiation authorization: Use must be for an FDA approved indication or indication supported by National Comprehensive Cancer Network guidelines with recommendation 2A or higher For axatilimab (Niktimvo™), must meet of the following criteria: a. Documentation of trial and failure, intolerance, or contraindication to at least two prior lines of systemic therapy, including at least one of the following: belumosudil (Rezurock®), ibrutinib (Imbruvica®), or ruxolitinib (Jakafi®) b. Dose and frequency must be in accordance with FDA-approved labeling For patients established on therapy: 1. Documentation of adequate response to the medication must be provided 2. For axatilimab (Niktimvo™) only: Dose and frequency must be in accordance with FDA-approved labeling

AGE RESTRICTIONS	N/A
PRESCRIBER RESTRICTIONS	For axatilimab (Niktimvo™) only: Must be prescribed by, or in consultation with an oncologist, hematologist, or transplant specialist All others: Must be prescribed by, or in consultation with, an oncologist
COVERAGE DURATION	Authorization will be approved until no longer eligible with the plan, subject to formulary and/or benefit changes.

d. **Fitusiran sodium (Qfitlia) Pen Injctr & Vial**

2. **Indication**: For routine prophylaxis to prevent or reduce the frequency of bleeding episodes in adult and pediatric patients aged 12 years and older with hemophilia A or B with or without factor VIII or IX inhibitors.
   a. **Decision**:

	Commercial	Medicaid	Medicare
Formulary Status*	Medical	Medical	Part D: Non-formulary Part B: Medical
Tier**	N/A	N/A	N/A
Affordable Care Act Eligible	N/A; Non-Formulary	N/A	N/A
Utilization Management Edits	Prior Authorization	Prior Authorization	Prior Authorization
Quantity Limit	N/A	N/A	N/A
* Recommendations for placement may differ between lines of business due to regulatory requirements. ** Medications will be placed on recommended tier above for the base formulary; tier placement for custom formulary(ies) will be based on designation above. For example, Commercial Tier 6 designation above means that the medication will be placed on the highest cost-sharing tier on the respective formulary(ies).			
Formulary Alternatives: Hemophilia A: Advate®, Adynovate®, Afstyla®, Altuviiio®, Eloctate®, Esperoct®, Jivi®, Kogenate® FS, Kovaltry®, NovoEight®, Nuwiq®, Recombinate™, Xyntha®, Hemlibra®, Hympavzi™, Roctavian®, Alhemo® Hemophilia B: Alprolix®, BeneFix®, Idelvion®, Ixinity®, Rebinyn®, Rixubis®, Hympavzi™, Hemgenix®, Beqvez™, Alhemo®			

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

PA PROGRAM NAME	Hemophilia Prophylactic Agents
MEDICATION NAME	Fitusiran sodium (Qfitlia®) Marstacimab-hncq (Hympavzi™) Concizumab-mtci (Alhemo®)
PA INDICATION INDICATOR	1 - All FDA-Approved Indications
OFF-LABEL USES	N/A

EXCLUSION CRITERIA	Concurrent use with prophylactic treatment for hemophilia (such as emicizumab-kxwh [Hemlibra®], marstacimab-hncq [Hympavzi™], or concizumab-mtci [Alhemo®])
REQUIRED MEDICAL INFORMATION	For initial authorization, all the following criteria must be met: 1. Use is for routine prophylaxis to prevent or reduce the frequency of bleeding episodes 2. One of the following (Hemophilia A OR Hemophilia B): a. For Marstacimab-hncq (Hympavzi™): i. Diagnosis of severe hemophilia A (congenital factor VIII deficiency) defined as pre-treatment factor VIII level less than 1 IU/dL or less than 1% of normal factor levels ii. Diagnosis of moderately severe to severe hemophilia B (congenital factor IX deficiency) defined as pre-treatment factor IX level less than 2 IU/dL or less than or equal to 2% of normal factor levels b. For Concizumab-mtci (Alhemo®): i. Diagnosis of hemophilia A (congenital factor VIII deficiency) ii. Diagnosis of hemophilia B (congenital factor IX deficiency) c. For Fitusiran (Qfitlia®): i. Diagnosis of hemophilia A (congenital factor VIII deficiency) ii. Diagnosis of hemophilia B (congenital factor IX deficiency) 3. For marstacimab-hncq (Hympavzi™) and concizumab-mtci (Alhemo®), patient has documentation of one of the following inhibitor titer levels: a. For Marstacimab-hncq (Hympavzi™), patient does not have inhibitors defined as one of the following: i. For Hemophilia A: factor VIII inhibitor titer less than 0.6 Bethesda units (BU) per mL ii. For Hemophilia B: factor IX inhibitor titer less than 0.6 Bethesda units (BU) per mL b. For Concizumab-mtci (Alhemo®), patient has inhibitors defined as one of the following: i. For Hemophilia A: factor VIII inhibitor titer greater than or equal to 0.6 Bethesda units (BU) per mL ii. For Hemophilia B: factor IX inhibitor titer greater than or equal to 0.6 Bethesda units (BU) per mL 4. For fitusiran (Qfitlia®), patient has documentation of all of the following criteria: a. Documentation of or prescriber attestation of antithrombin (AT) activity level equal to or greater than 60% prior to treatment initiation

	b. Documentation of or prescriber attestation of planned follow-up and monitoring with AT activity to adjust dose 5. Weigh 35 kg or more at treatment initiation for Marstacimab-hncq (Hympavzi™) OR weigh 25 kg or more at treatment initiation for Concizumab-mtci (Alhemo®) 6. Dose and frequency must be in accordance with FDA-approved labeling For reauthorization: 1. Documentation of response to therapy indicating a beneficial response (such as disease stability or a reduction in bleeding events, in the severity of bleeding episodes, in the number of bleeding events that required treatment, and/or in the number of spontaneous bleeds) 2. Dose and frequency must be in accordance with FDA-approved labeling 3. For Concizumab-mtci (Alhemo®), documentation of annual drug plasma concentration monitoring with appropriate dosage adjustments
AGE RESTRICTIONS	Age must be appropriate based on FDA-approved indication.
PRESCRIBER RESTRICTIONS	Must be prescribed by, or in consultation with, a hematologist
COVERAGE DURATION	Authorization and reauthorization will be approved for one year.

3. **Mirdametinib (Gomekli) Capsule and Tab Susp**
   a. **Indication**: For the treatment of adult and pediatric patients 2 years of age and older with neurofibromatosis type 1 (NF1) who have symptomatic plexiform neurofibromas (PN) not amenable to complete resection.
   b. **Decision**:

	Commercial	Medicaid	Medicare
Formulary Status*	Formulary	Formulary	Part D: Formulary Part B: N/A
Tier**	Tier 5 - 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	1 mg capsule, 1 mg tablet suspension: 8/day 2 mg capsule: 4/day	1 mg capsule, 1 mg tablet suspension: 8/day 2 mg capsule: 4/day	1 mg capsule, 1 mg tablet suspension: 8/day 2 mg capsule: 4/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: selumetinib

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

4. **Remestemcel-l-rknd (Ryoncil) Kit and Vial**
   a. **Indication**: For the treatment of steroid-refractory acute graft versus host disease (SR-aGvHD) in pediatric patients 2 months of age and older
   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: Ruxolitinib (Jakafi®)			

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

PA PROGRAM NAME	Anti-Cancer Medications – Medical Benefit
MEDICATION NAME	remestemcel-L-rknd suspension for intravenous infusion (Ryoncil®)
PA INDICATION INDICATOR	1 - All FDA-Approved Indications
OFF-LABEL USES	None
EXCLUSION CRITERIA	N/A
REQUIRED MEDICAL INFORMATION	For initiation of therapy (new starts): 1. Use must be for a FDA approved indication or indication supported by National Comprehensive Cancer Network guidelines with recommendation 2A or higher) 2. For Ryoncil®, must meet both of the following: a. For individuals ages 12 years and older: documented trial and failure, intolerance, or contraindication to Jakafi® (ruxolitinib) b. Dose and frequency must be in accordance with FDA-approved labeling

	For patients established on the requested product (within the previous year) for Ryoncil® requires documentation of one of the following: 1. Partial response (organ improvement of ≥1 stage without worsening of any other organ) or mixed response (organ improvement of ≥1 stage without worsening of any other organ) after four complete weeks of therapy 2. Recurrence of graft-versus-host-disease (GvHD) after an initial complete response
AGE RESTRICTIONS	N/A
PRESCRIBER RESTRICTIONS	For Ryoncil® only: Must be prescribed by, or in consultation with, an oncologist, hematologist, or transplant specialist All others: Must be prescribed by, or in consultation with, an oncologist
COVERAGE DURATION	For Ryoncil® only: Initial and reauthorization will be approved for 6 weeks All others: Authorization will be approved until no longer eligible with the plan, subject to formulary and/or benefit changes

5. **Vimseltinib (Romvimza) Capsule**
   a. **Indication**: For adult patients with symptomatic tenosynovial giant cell tumor (TGCT) for which surgical resection will potentially cause worsening functional limitation or severe morbidity.
   b. **Decision**:

	Commercial	Medicaid	Medicare
Formulary Status*	Formulary	Formulary	Part D: Formulary Part B: N/A
Tier**	Tier 6 - Non-Preferred Specialty	N/A	Specialty
Affordable Care Act Eligible	No	N/A	N/A
Utilization Management Edits	Prior Authorization	Prior Authorization	Prior Authorization
Quantity Limit	8 capsules per 28 days	8 capsules per 28 days	8 capsules per 28 days
* Recommendations for placement may differ between lines of business due to regulatory requirements. ** Medications will be placed on recommended tier above for the base formulary; tier placement for custom formulary(ies) will be based on designation above. For example, Commercial Tier 6 designation above means that the medication will be placed on the highest cost-sharing tier on the respective formulary(ies).			
Formulary Alternatives: Turalio			

New Indications:

The following information is gathered from the United States Food and Drug Administration (FDA) Approved Drug Products database from 2/1/2025– 3/31/2025

Therapies with Prior Authorization Policies (Non-oncology)

1. **AMVUTTRA** (VUTRISIRAN)
   a. Previous Indication(s):
      i. .Treatment of the polyneuropathy of hereditary transthyretin-mediated amyloidosis in adults
   b. New indication approved 3/20/2025:
      i. Treatment of the cardiomyopathy of wild-type or hereditary transthyretin-mediated amyloidosis in adults to reduce cardiovascular mortality, cardiovascular hospitalizations and urgent heart failure visits
   c. **RECOMMENDATION:** Inform prescribers via Medical Policy Alert. Update policy with new indication. Update criteria for Commercial, Medicaid, and Medicare Part B.

Prior Authorization for Commercial/Medicaid/Medicare Part B:

PA PROGRAM NAME	Transthyretin (TTR) Lowering Agents
MEDICATION NAME	Amvuttra (vutrisiran)
COVERED USES	1 - All FDA-Approved Indications
EXCLUSION CRITERIA	1. A New York Heart Association (NYHA) Heart Failure classification of IV 2. A NYHA Heart Failure classification of III with a National Amyloidosis Centre ATTR stage of 3 (defined as an NT-proBNP level of >3000 pg per milliliter and an estimated glomerular filtration rate [eGFR] of <45 mL/min/1.73m^2 of body-surface area) 3. An eGFR of less than 30 mL/min/1.73m^2 4. A polyneuropathy disability score of IIIa, IIIb, or IV 5. Prior or concurrent use with other agents for the treatment of transthyretin-mediated amyloidosis such as patisiran (Onpattro®), inotersen (Tegsedi®), vutrisiran (Amvuttra®) or eplontersen (Wainua®)
REQUIRED MEDICAL INFORMATION	For Initial Authorization, the following indication-specific criteria must be met: A. **For Polyneuropathy of Hereditary Transthyretin-mediated Amyloidosis (hATTR),** eplontersen, inotersen, patisiran, or vutrisiran may be covered if all the following criteria are met: 1. Diagnosis of hereditary transthyretin-mediated amyloidosis (hATTR) with polyneuropathy 2. Documentation of a pathogenic TTR mutation

	3. Patient has a baseline polyneuropathy disability (PND) score of less than or equal to IIIB OR has a baseline familial amyloid polyneuropathy (FAP) stage of I or II 4. Baseline neuropathy impairment score (NIS) between 5 and 130 5. Demonstrate symptoms consistent with polyneuropathy of hATTR amyloidosis including at least two symptoms of peripheral sensorimotor polyneuropathy and/or autonomic neuropathy listed below: a. Peripheral sensorimotor polyneuropathy: tingling or increased pain in the hands, feet, hands and/or arms, loss of feeling in the hands and/or feet, numbness or tingling in the wrists, carpal tunnel syndrome, loss of ability to sense temperature, difficulty with fine motor skills, weakness in the legs, difficulty walking b. Autonomic neuropathy: orthostasis, abnormal sweating, sexual dysfunction, recurrent urinary tract infection, dysautonomia (constipation and/or diarrhea, nausea, vomiting, anorexia, early satiety) 6. For Tegsedi: Documentation of platelet count greater than 100 x 109/L 7. Dose and frequency are in accordance with FDA-approved labeling B. **For Cardiomyopathy of Wild-type or Hereditary Transthyretin-mediated Amyloidosis (ATTR-CM),** vutrisiran may be covered if all the following criteria are met: 1. Diagnosis of transthyretin mediated amyloid cardiomyopathy (hereditary/variant or wild-type) confirmed by one of the following: a. A positive radionuclide imaging scan, defined as showing Grade 2 or 3 cardiac uptake using one of the following radiotracers: i. 99m technetium-Pyrophosphate (99mTc-PYP) ii. 99m technetium (Tc)-labeled 3,3-diphosphono-1,2-propanodicarboxylic acid ((99mTc-DPD) iii. 99mTc-labeled hydroxymethylene diphosphonate (HMDP) b. A positive cardiac biopsy for transthyretin amyloid deposits c. A positive non-cardiac biopsy for transthyretin amyloid deposits and evidence of cardiac involvement by end-diastolic interventricular septal wall thickness greater than 12 mm (by echocardiogram or MRI) or suggestive cardiac MRI findings d. Genetic testing confirming transthyretin (TTR) mutation 2. History of heart failure with documentation of at least one prior hospitalization or current clinical sign and symptoms of volume overload or elevated intracardiac pressures warranting diuretic treatment (functional class IV is excluded from coverage)

	Reauthorization: **For Hereditary Transthyretin-mediated Amyloidosis (hATTR) with Polyneuropathy** 1. Documentation that patient is tolerating applicable therapy 2. Documented improvement or stabilization in polyneuropathy symptoms from baseline, defined as improvement or stabilization from baseline in the Neuropathy impairment score (NIS) **AND** at least one of the following measures: a. Baseline polyneuropathy disability (PND) score b. Familial amyloid polyneuropathy (FAP) stage **For Wild-type or Hereditary Transthyretin-mediated Amyloidosis (ATTR-CM) with Cardiomyopathy** Documentation of a positive clinical response (such as evidence of slowing clinical decline, reduced number of cardiovascular hospitalizations, or improvement or stabilization of the 6-minute walk test)
AGE RESTRICTIONS	Approved for patients 18 years of age and older
PRESCRIBER RESTRICTIONS	Prescribed by or in consultation with a neurologist, cardiologist, or a physician who specializes in the treatment of amyloidosis
COVERAGE DURATION	Initial authorization will be approved for six months. Reauthorization will be approved for 12 months.
QUANTITY LIMIT	Amvuttra® (vutrisiran): four syringes per year

2. **FABHALTA** (IPTACOPAN)
   a. Previous Indication(s):
      i. Treatment of adults with paroxysmal nocturnal hemoglobinuria (PNH)
      ii. The reduction of proteinuria in adults with primary immunoglobulin A nephropathy (IgAN) at risk of rapid disease progression, generally a urine protein-to-creatinine ratio (UPCR) ≥ 1.5 g/g
         1) This indication is approved under accelerated approval based on reduction of proteinuria. It has not been established whether FABHALTA slows kidney function decline in patients with IgAN. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory clinical trial
   b. New indication approved 3/20/2025:
      i. Treatment of adults with complement 3 glomerulopathy (C3G), to reduce proteinuria
   c. **RECOMMENDATION:** Inform prescribers via Medical Policy Alert. Update policy with new indication. Update criteria for Commercial and Medicaid.

Prior Authorization for Commercial/Medicaid:

PA PROGRAM NAME	Complement Inhibitors
MEDICATION NAME	Fabhalta (iptacopan)
COVERED USES	1 - 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 Initial Authorization**, the following indication-specific criteria must be met: 1. **For Complement 3 Glomerulopathy (C3G)**, Fabhalta may be covered if the following criteria are met: a. Diagnosis of C3G confirmed by renal biopsy b. 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 c. Urine protein-to-creatinine ratio UPCR of 1.0 g/g or more d. 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 a hematologist/oncologist or nephrologist
COVERAGE DURATION	Initial authorization for up to three months and reauthorization will be approved for up to one year
QUANTITY LIMIT	Fabhalta: two capsules per day

3. **RIVFLOZA** (NEDOSIRAN)

a. Previous Indication(s):
    i. To lower urinary oxalate levels in **children 9 years of age and older** and adults with primary hyperoxaluria type 1 (PH1) and relatively preserved kidney function, e.g., eGFR ≥ 30 mL/min/1.73 m^2
b. New indication approved 3/27/2025:
    i. To lower urinary oxalate levels in **children 2 years of age and older** and adults with primary hyperoxaluria type 1 (PH1) and relatively preserved kidney function, e.g., eGFR ≥ 30 mL/min/1.73 m^2
c. **RECOMMENDATION:** Inform prescribers via Medical Policy Alert. Update policy with new indication.

4. **SOLIRIS** (ECULIZUMAB)
    a. Previous Indication(s):
        i. Treatment of patients with paroxysmal nocturnal hemoglobinuria (PNH) to reduce hemolysis.
        ii. Treatment of patients with atypical hemolytic uremic syndrome (aHUS) to inhibit complement-mediated thrombotic microangiopathy.
        iii. Treatment of generalized myasthenia gravis (gMG) in adult patients who are anti-acetylcholine receptor (AchR) antibody positive.
        iv. Treatment of neuromyelitis optica spectrum disorder (NMOSD) in adult patients who are anti-aquaporin-4 (AQP4) antibody positive.
    b. New indication approved 02/28/2025:
        i. Treatment of generalized myasthenia gravis (gMG) in pediatric patients six years of age and older who are anti-acetylcholine receptor (AChR) antibody positive.
    c. **RECOMMENDATION:** Inform prescribers via Medical Policy Alert. Update policy with new indication.

5. **SUSVIMO** (RANIBIZUMAB)
    a. Previous Indication(s):
        i. Treatment of patients with Neovascular (wet) Age-related Macular Degeneration (AMD) who have previously responded to at least two intravitreal injections of a VEGF inhibitor.
    b. New indication approved 02/03/2025:
        i. Treatment of patients with diabetic macular edema (DME) who have previously responded to at least two intravitreal injections of a vascular endothelial growth factor (VEGF) inhibitor medication.
    c. **RECOMMENDATION:** Inform prescribers via Medical Policy Alert. New indication reviewed with June 2025 annual policy review.

6. **TREMFYA** (GUSELKUMAB)
    a. Previous Indication(s):
        i. Moderate-to-severe plaque psoriasis who are candidates for systemic therapy or phototherapy
        ii. Active psoriatic arthritis
        iii. Moderately to severely active ulcerative colitis
    b. New indication approved 3/20/2025:
        i. Moderately to severely active Crohn's disease
    a. **RECOMMENDATION:** Inform prescribers via Medical Policy Alert. Update policy with new indication. Update criteria for Commercial. No criteria updates required for Medicaid.

Prior Authorization for **Commercial**:

PA PROGRAM NAME	Therapeutic immunomodulators (TIMs)
MEDICATION NAME	Tremfya (guselkumab)
COVERED USES	1 - All FDA-Approved Indications
REQUIRED MEDICAL INFORMATION	For moderate to severe Crohn's disease, Preferred adalimumab products (Simlandi®, Hadlima®, adalimumab-adaz and adalimumab-aaty), preferred ustekinumab products (Selarsdi®, Steqeyma®, and Yesintek®), guselkumab (Tremfya®), risankizumab-rzaa (Skyrizi®), subcutaneous vedolizumab (Entyvio® Pen) may be covered for initial authorization. Other therapies may be covered as outlined below: Upadacitinib (Rinvoq®) requires trial and failure (after at least three months of therapy), intolerance, or contraindication to one TNF inhibitor 1. Certolizumab (Cimzia®) requires trial and failure (after at least three months of therapy), intolerance, or contraindication to a preferred adalimumab product (Simlandi®, Hadlima®, adalimumab-adaz and adalimumab-aaty) 2. Mirikisumab (Omvoh®) requires a trial and failure (after at least three months of therapy), intolerance, or contraindication to **one** of the following agents: a. Preferred adalimumab products (Simlandi®, Hadlima®, adalimumab-adaz and adalimumab-aaty) b. Preferred ustekinumab products (Selarsdi®, Steqeyma®, and Yesintek®) c. Risankizumab-rzaa (Skyrizi®) d. Subcutaneous vedolizumab (Entyvio® Pen) e. Guselkumab (Tremfya®) 3. All other therapies require trial and failure (after at least three months of therapy), intolerance, or contraindication to both of the following: a. A preferred adalimumab product (, Simlandi®, Hadlima®, adalimumab-adaz and adalimumab-aaty) b. One of the following: Preferred ustekinumab product (Selarsdi®, Steqeyma®, and Yesintek®), risankizumab-rzaa (Skyrizi®), upadacitinib (Rinvoq®), subcutaneous vedolizumab (Entyvio® Pen), guselkumab (Tremfya®)

7. **TYENNE** (TOCILIZUMAB-AAZG)
   a. Previous Indication(s):

i. Adult patients with moderately to severely active rheumatoid arthritis who have had an inadequate response to one or more Disease-Modifying Anti-Rheumatic Drugs (DMARDs).
ii. Adult patients with giant cell arteritis.
iii. Patients 2 years of age and older with active polyarticular juvenile idiopathic arthritis.
iv. Patients 2 years of age and older with active systemic juvenile idiopathic arthritis.

b. New indication approved 02/28/2025:
i. Adults and pediatric patients 2 years of age and older with chimeric antigen receptor (CAR) T cell-induced severe or life-threatening cytokine release syndrome.
ii. Hospitalized adult patients with coronavirus disease 2019 (COVID-19) who are receiving systemic corticosteroids and require supplemental oxygen, non-invasive or invasive mechanical ventilation, or extracorporeal membrane oxygenation (ECMO).

c. **RECOMMENDATION:** Inform prescribers via Medical Policy Alert. Update policy with new indication.

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

8. **ADCETRIS** (BRENTUXIMAB VEDOTIN)
a. New indication(s) approved 02/11/2025:
i. In combination with lenalidomide and a rituximab product for the treatment of adult patients with relapsed or refractory large B-cell lymphoma (LBCL), including diffuse large B-cell lymphoma (DLBCL) not otherwise specified (NOS), DLBCL arising from indolent lymphoma, or high-grade B-cell lymphoma (HGBL), after two or more lines of systemic therapy who are not eligible for autologous hematopoietic stem cell transplantation (auto-HSCT) or chimeric antigen receptor (CAR) T-cell therapy.
b. **RECOMMENDATION:** Inform prescribers via Medical Policy Alert. Prior authorization policy coverage criteria are based on recommendations from the National Comprehensive Cancer Network (NCCN); no updates to the policy are warranted.

9. **CABOMETYX (CABOZANTINIB)**
a. New indication(s) approved 3/26/2025:
i. Treatment of adult and pediatric patients 12 years of age and older with previously treated, unresectable, locally advanced or metastatic, well-differentiated pancreatic neuroendocrine tumors
ii. Treatment of adult and pediatric patients 12 years of age and older with previously treated, unresectable, locally advanced or metastatic, well-differentiated extra-pancreatic neuroendocrine tumors
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. **IMFINZI (DURVALUMAB)**
a. New indication(s) approved 3/28/2025:
i. In combination with gemcitabine and cisplatin as neoadjuvant treatment, followed by single agent IMFINZI as adjuvant treatment following radical cystectomy, for the treatment of adult patients with muscle invasive bladder cancer (MIBC)
b. **RECOMMENDATION:** Inform prescribers via Medical Policy Alert. Prior authorization policy coverage criteria are based on recommendations from the National Comprehensive Cancer Network (NCCN); no updates to the policy are warranted.

11. **PLUVICTO (LUTETIUM LU 177 VIPIVOTIDE TETRAXETAN)**
    a. New indication(s) approved 3/28/2025:
        i. Treatment of adult patients with prostate-specific membrane antigen (PSMA)-positive metastatic castration-resistant prostate cancer (mCRPC) who have been treated with androgen receptor pathway inhibitor (ARPI) therapy, and
            1) are considered appropriate to delay taxane-based chemotherapy, or
            2) have received prior taxane-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.

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

12. **BAQSIMI** (GLUCAGON) NASAL POWDER
    a. Previous Indication(s):
        i. Treatment of severe hypoglycemia in adult and pediatric patients with diabetes ages 4 years and above
    b. New indication approved 3/17/2025:
        i. Treatment of severe hypoglycemia in adults and pediatric patients aged **1 year and older** with diabetes
    c. **RECOMMENDATION:** Inform prescribers via Medical Policy Alert.

13. **FUROSCIX** (FUROSEMIDE)
    a. Previous Indication(s):
        i. Treatment of congestion due to fluid overload in adults with chronic heart failure
    b. New indication approved 3/6/2025:
        i. Treatment of edema in adult patients with chronic heart failure or chronic kidney disease, including the nephrotic syndrome
    c. **RECOMMENDATION:** Inform prescribers via Medical Policy Alert.

14. **GVOKE** (GLUCAGON) AND GVOKE VIALDX (GLUCAGON)
    a. Previous Indication(s):
        i. Treatment of severe hypoglycemia in pediatric and adult patients with diabetes ages 2 years and above
    b. New indication approved 3/14/2025:
        i. For subcutaneous use for the treatment of severe hypoglycemia in adult and pediatric patients aged 2 years and older with diabetes
        ii. For intravenous use as a diagnostic aid during radiologic examinations to temporarily inhibit movement of the gastrointestinal tract in adult patient
    c. **RECOMMENDATION:** Inform prescribers via Medical Policy Alert.

15. **NEFFY** (EPINEPHRINE)
    a. Previous Indication(s):
        i. Indicated for emergency treatment of type I allergic reactions, including anaphylaxis, in adult and pediatric patients who weigh 30 kg or greater
    b. New indication approved 3/5/2025:

i. Indicated for emergency treatment of type I allergic reactions, including anaphylaxis, in adult and pediatric patients **4 years of age** and older who **weigh 15 kg or greater**.

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

16. **ODEFSEY** (EMTRICITABINE, RILPIVIRINE, TENOFOVIR)
    a. Previous Indication(s):
        i. Treatment of HIV-1 infection in patients weighing at least 35kg as initial therapy in those with no antiretroviral treatment history with HIV-1 RNA less than or equal to 100,000 copies per mL; or to replace a stable antiretroviral regimen in those who are virologically suppressed (HIV-1 RNA less than 50 copies per mL) for at least 6 months with no history of treatment failure and no known substitutions associated with resistance to the individual components of Odefsey.
    b. New indication(s) approved 02/19/2025:
        i. Treatment of HIV-1 infection in adult and pediatric patients weighing at least 25kg: as initial therapy in those with no antiretroviral treatment history with HIV-1 RNA less than or equal to 100,000 copies/mL; or to replace a stable antiretroviral regimen in those who are virologically-suppressed (HIV-1 RNA less than 50 copies/mL) for at least 6 months with no history of treatment failure and no known substitutions associated with resistance to the individual components of Odefsey.
    c. **RECOMMENDATION:** Inform prescribers via Medical Policy Alert.

17. **ODACTRA** (DERMATOPHAGOIDES FARINAE AND DERMATOPHAGOIDES PTERONYSSINUS)
    a. Previous Indication(s):
        i. An allergen extract indicated as immunotherapy for the treatment of house dust mite (HDM)-induced allergic rhinitis, with or without conjunctivitis, confirmed by positive in vitro testing for IgE antibodies to Dermatophagoides farinae or Dermatophagoides pteronyssinus house dust mites or by positive skin testing to licensed house dust mite allergen extracts. ODACTRA is approved for use in individuals 12 through 65 years of age.
    b. New indication(s) approved 02/27/2025:
        i. An allergen extract indicated as immunotherapy for the treatment of house dust mite (HDM)-induced allergic rhinitis, with or without conjunctivitis, confirmed by positive in vitro testing for IgE antibodies to Dermatophagoides farinae or Dermatophagoides pteronyssinus house dust mites or by positive skin testing to licensed house dust mite allergen extracts. ODACTRA is approved for use in individuals 5 through 65 years of age.
    c. **RECOMMENDATION:** Inform prescribers via Medical Policy Alert.

18. **PREZCOBIX (DARUNAVIR AND COBICISTAT)**
    a. Previous Indication(s):
        i. Treatment of HIV-1 infection in treatment-naïve and treatment-experienced adults and pediatric patients **weighing at least 40 kg** with no darunavir resistance-associated substitutions (V11I, V32I, L33F, I47V, I50V, I54L, I54M, T74P, L76V, I84V, L89V)
    b. New indication approved 3/21/2025:
        i. Treatment of HIV-1 in treatment-naïve and treatment-experienced adults and pediatric patients **weighing at least 25 kg** with no darunavir resistance-associated substitutions (V11I, V32I, L33F, I47V, I50V, I54L, I54M, T74P, L76V, I84V, L89V)
    c. **RECOMMENDATION:** Inform prescribers via Medical Policy Alert.

19. **SYNJARDY (EMPAGLIFLOZIN AND METFORMIN HYDROCHLORIDE) AND SYNJARDY XR (EMPAGLIFLOZIN AND METFORMIN HYDROCHLORIDE EXTENDED-RELEASE)**
    a. Previous Indication(s):
        i. SYNJARDY:
            1) Adjunct to diet and exercise to improve glycemic control in adults and pediatric patients aged 10 years and older with type 2 diabetes mellitus
        ii. SYNJARDY XR:
            1) Adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus
        iii. Empagliflozin:
            1) Empagliflozin, when used as a component of SYNJARDY or SYNJARDY XR, is indicated in adults with type 2 diabetes mellitus to reduce the risk of:
                a. Cardiovascular death in adults with established cardiovascular disease
                b. Cardiovascular death and hospitalization for heart failure in adults with heart failure
        iv. Limitations of Use:
            1) Not recommended for use to improve glycemic control in patients with type 1 diabetes mellitus. It may increase the risk of diabetic ketoacidosis in these patients
            2) Because of the metformin HCl component, the use of SYNJARDY or SYNJARDY XR is limited to patients with type 2 diabetes mellitus for all indications
    b. New indication approved 3/7/2025:
        i. Empagliflozin:
            1) Empagliflozin, when used as a component of SYNJARDY or SYNJARDY XR, is indicated in adults with type 2 diabetes mellitus to reduce the risk of:
                a. Sustained decline in eGFR, end-stage kidney disease, cardiovascular death, and hospitalization in adults with chronic kidney disease at risk of progression
        ii. Limitations of Use:
            1) Empagliflozin, when used as a component of SYNJARDY or SYNJARDY XR, is not recommended for the treatment of chronic kidney disease in patients with polycystic kidney disease or patients requiring or with a recent history of intravenous immunosuppressive therapy or greater than 45 mg of prednisone or equivalent for kidney disease. Empagliflozin is not expected to be effective in these populations
    c. **RECOMMENDATION:** Inform prescribers via Medical Policy Alert.

20. **TNKASE** (TENECTEPLASE)
    a. Previous Indication(s):
        i. Reduce the risk of death associated with acute ST elevation myocardial infarction (STEMI).
    b. New indication(s) approved 02/28/2025:
        i. For the treatment of acute ischemic stroke (AIS) in adults.

RECOMMENDATION: Inform prescribers via Medical Policy Alert.

Drug Safety Monitoring:

The following information is gathered from the United States Food and Drug Administration (FDA) database

from 2/1/2025 – 3/31/2025

FDA Drug Safety Communications: None

Drug Recalls/Market Withdrawals

1. **Drug Name:** Potassium Chloride Injection, 20 mEq and 10 mEq
   - **Date of Recall:** 02/14/2025
   - **Reason for recall:** Bags of potassium chloride Injection 20 mEq have incorrect overwrap labels which state POTASSIUM CHLORIDE Inj. 10 mEq
   - **Link to more information:** https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/icu-medical-issues-nationwide-recall-potassium-chloride-injection-20-meq-and-potassium-chloride
   - **Health Plan Recommendation:** Notify providers via Medical Policy Alert.

2. **Drug Name:** ChloraPrep Clear 1 mL applicator skin preparation product (Lot Number: 3200240, Expiration: 6/30/2026)
   - **Date of Recall:** 02/18/2025
   - **Reason for recall:** Potential for fungal contamination under certain environmental conditions allowing the growth of Aspergillus penicillioides
   - **Link to more information:** https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/bd-announces-voluntary-worldwide-recall-one-lot-chlorapreptm-clear-1-ml-applicators-due-fungal
   - **Health Plan Recommendation:** Notify providers via Medical Policy Alert.

3. **Drug Name:** Vitality male enhancement dietary supplement capsules
   - **Date of Recall:** 02/20/2025
   - **Reason for recall:** Undeclared Sildenafil and Tadalafil
   - **Link to more information:** https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/one-source-nutrition-inc-issues-voluntary-nationwide-recall-vitality-capsules-due-presence
   - **Health Plan Recommendation:** Notify providers via Medical Policy Alert.

4. **Drug Name:** SinuCleanse Soft Tip Squeeze Bottle Nasal Wash System
   - **Date of Recall:** 02/25/2025
   - **Reason for recall:** Microbial contamination of the product with Staphylococcus aureus (S. aureus)
   - **Link to more information:** https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/ascent-consumer-products-inc-issues-voluntary-nationwide-recall-sinucleanse-soft-tip-squeeze-bottle
   - **Health Plan Recommendation:** Notify providers via Medical Policy Alert.

5. **Drug Name:** Phenylephrine 40 mg added to 0.9% Sodium Chloride 250 mL in 250 mL excel bags
   - **Date of Recall:** 02/25/2025
   - **Reason for recall:** Due to visible black particulate matter
   - **Link to more information:** https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/central-admixture-pharmacy-services-caps-issues-nationwide-recall-phenylephrine-40-mg-added-09
   - **Health Plan Recommendation:** Notify providers via Medical Policy Alert.

Other Formulary Changes:

Drug Name	Action Taken	Policy Name
	•	•
Tretinoin Gel (Gram)	Add to Medicaid formulary, Prior Authorization for ages 21 years and above	Acne Medications – Medicaid
Corticotropin (Cortrophin) 40/0.5 mL & 80 unit/mL gel Syringe	New formulation; • Commercial: Formulary Tier 6, Prior Authorization • Medicaid: Non- Formulary, Prior Authorization, Specialty • Medicare Part D: Non- Formulary	• Commercial/Medicaid: HP Acthar Gel • Medicare Part D: N/A
Fenofibric Acid (Fibricor) 35, and 105 mg tablet	Remove from Commercial and Medicaid formularies Effective: 09/01/2025	N/A
Chenodiol (Ctexli) Tablet	New entity; • Commercial: Formulary Tier 6, Prior Authorization • Medicaid: Non-Formulary, Prior Authorization, Specialty • Medicare Part D: Non- Formulary	• Commercial/Medicaid: Chenodal • Medicare Part D: N/A
Hydrochlorothiazide (Inzirqo) Susp Recon	New formulation; • Non-Formulary for all lines of business	N/A
Ivermectin Tablet	New strength (6mg); • Non-Formulary for all lines of business	N/A
Melphalan hcl (Ivra) Vial	New strength (90 mg/mL); • Commercial/Medicaid: Medical Benefit, Prior Authorization • Medicare Part D: Non-Formulary • Medicare Part B: Prior Authorization	Anti-Cancer Medications - Medical Benefit

Metaxalone Tablet	New strength (650 mg); Non-Formulary for all lines of business	N/A
Apomorphine hcl (Onapgo) Cartridge	New strength (98 mg/20mL); • Commercial/Medicaid: Non-Formulary, Specialty • Medicare Part D: Non-Formulary • Medicare Part B: Not Covered	N/A
Trazodone hcl (Raldesy) Solution	New Formulation; • Commercial/Medicaid: Non-Formulary • Medicaid: Formulary, Tier 4	N/A
Rizatriptan benzoate/meloxicam (Symbravo) Tablet	New combination; • Non-Formulary for all lines of business	N/A
Terazosin hcl (Tezruly) Solution	New formulation; • Non-Formulary for all lines of business	N/A
Diazoxide choline (Vykat XR) Tab ER 24h	New formulation; • Non-Formulary for all lines of business	N/A
Hydroxyurea (Xromi) Solution	New formulation; • Non-Formulary for all lines of business	N/A
Benzgalantamine gluconate (Zunveyl) Tablet DR	New entity; Non-Formulary for all lines of business	N/A
Lebrikizumab-lbkz (ebglyss pen) pen injctr	Add to Commercial formulary: Tier 5, Prior Authorization, Quantity Limit (2 mL per 28 days)	Therapeutic Immunomodulators (TIMS)
Pirfenidone 267 mg Tablet	Add generic to Formulary: • Commercial: Tier 5, Prior Authorization, Quantity Limit (6 tablets per day) • Medicaid: Formulary, Prior Authorization, Quantity Limit (6 tablets per day)	Ofev, Pirfenidone
Lomitapide (Juxtapid) Capsule	Remove from Medicaid formulary	N/A
Ambrisentan (Letairis) Tablet	• Commercial/Medicaid: Add Quantity Limit (1 tablet per day) Effective 09/01/2025	Pulmonary Hypertension
Nemolizumab-ilto (Nemluvio) Pen Injctr	Add to Commercial Formulary, Tier 5, Prior Authorization, Quantity Limit (one injection per 28 days)	Therapeutic Immunomodulators (TIMS)
Becaplermin (Regranex) Gel (Gram)	Remove from Commercial/Medicaid formularies	Regranex

Antiretroviral Drugs for HIV	Positive formulary changes: • Add to Commercial/Medicaid formularies: Cimduo® (lamuvidine/TDF) and Isentress® (raltegravir) chewable tablets Negative Commercial/Medicaid formulary changes - Effective 1/1/2026: • Quantity limit addition: maraviroc 150 mg tablet (2 tablets per day) • Remove from formulary: all zidovudine products Negative tiering changes Commercial dynamic formulary - Effective 1/1/2026: • Tier 2 to Tier 3: abacavir tablet • Tier 2 to Tier 4: abacavir solution, atazanavir 150- 200- and 300mg, emtricitabine 200mg, Kaletra® 200/50mg and 100/25mg • Tier 3 to Tier 4: Aptivus®, Complera®, darunavir 600 and 800mg, Edurant® 25mg, Emtriva® solution, etravirine 100 and 200mg, Intelence® 25mg, Isentress® (powder pack, 400mg, 600mg), maraviroc 150mg and 300mg, nevirapine ER 100mg and 400mg, Norvir® powder pack, Prezista® (75 and 150mg, 100mg/mL oral suspension), atazanavir powder pack, Selzentry® solution, Tybost® 150mg, Viracept® 250mg and 625mg, Viread® (40mg scoop powder, 150mg, 200mg, and 250mg)	N/A

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

Drugs released from: 02/21/2025 - 04/04/2025

INFORMATIONAL ONLY

NEW DRUGS / COMBINATIONS / STRENGTHS / DOSAGE FORMS		
Drug Name	**Action Taken**	**Policy Name**
Clobazam Enfit Syringe	New dosage form (10 mg/4 ml oral syringe). Line extend with clobazam 2.5mg/ml suspension; • Commercial Standard: Formulary, Tier 2 • Commercial Dynamic: Formulary, Tier 4 • Medicaid: Formulary • Medicare Part D: Formulary, Tier 4	N/A
Epinephrine (Neffy) Spray	New strength (1 mg/spray). Line extend with Neffy 2mg; • Commercial/Medicaid: Non-Formulary, Quantity Limit (2 sprays per 30 days) • Medicare Part D: Non-Formulary	N/A
Revumenib citrate (Revuforj) Tablet	New strength (25 mg). Line extend with Revuforj 110mg, 116mg strengths; • Commercial: Formulary, Tier 6, Prior Authorization, Quantity Limit (2 tablets per day) • Medicaid: Formulary, Prior Authorization, Quantity Limit (2 tablets per day), Specialty • Medicare Part D: Formulary, Tier 5, Prior Authorization, Quantity Limit (2 tablets per day)	Anti-Cancer Medications - Self-Administered
Selinexor (Xpovio) Tablet	New GCN. Line extend with Xpovio; • Commercial: Formulary, Tier 6, Prior Authorization, Quantity Limit (4 tablets per 28 days) • Medicaid: Formulary, Prior Authorization, Quantity Limit (4 tablets per 28 days), Specialty • Medicare Part D: Formulary, Tier 5, Prior Authorization, Quantity Limit (4 tablets per 28 days)	Anti-Cancer Medications - Self-Administered
Concizumab-mtci (Alhemo Pen) Pen Injctr	New strength (300 mg/3 ml). Line extend with Alhemo strengths; • Commercial/Medicaid: Medical Benefit, Prior Authorization • Medicare Part D: Non-Formulary	Hemophilia Prophylactic Agents

NEW DRUGS / COMBINATIONS / STRENGTHS / DOSAGE FORMS		
Drug Name	**Action Taken**	**Policy Name**
	• Medicare Part B: Prior Authorization	
Mirikizumab-mrkz (Omvoh) Pen Injctr & Syringe	New strengths (200 mg/2mL; 300 mg/3mL). Line extend with other Omvoh strengths; • Commercial: Formulary, Tier 5, Prior Authorization, Quantity Limit (one injection per 28 days) • Medicaid: Non-Formulary, Prior Authorization, Quantity Limit (one injection per 28 days), Specialty • Medicare Part D: Non-Formulary	• Commercial/Medicaid: Therapeutic Immunomodulators (TIMS) • Medicare Part D: N/A
Adalimumab-ryvk (Simlandi (CF)) Autoinjkit	New GCN. Line extend with other Simlandi; • Commercial: Formulary, Prior Authorization, Quantity Limit (0.8 mL per 28 days) • Medicaid: Formulary, Prior Authorization, Quantity • Limit (0.8 mL per 28 days), Specialty • Medicare Part D: Formulary, Tier 5, Prior Authorization, Quantity Limit (0.8 mL per 28 days)	• Commercial/Medicaid: Therapeutic Immunomodulators (TIMS) • Medicare Part D: N/A
Guselkumab (Tremfya) Pen Injctr	New strength (100 mg/ml). Line extend with Tremfya Pen 200 mg/2 mL; • Commercial/Medicare Part D: Formulary, Tier 5, Prior Authorization, Quantity Limit (1 mL per 56 days) • Medicaid: Non- Formulary, Prior Authorization, Quantity Limit (1 mL per 56 days), Specialty	Therapeutic Immunomodulators (TIMS)
Ustekinumab-aekn (Selarsdi) Vial	New strength (130mg/26mL) and dosage form (vial). Line extend with preferred biosimilar; • Commercial/Medicaid: Medical Benefit, Prior Authorization • Medicare Part D: Non-Formulary • Medicare Part B: Prior Authorization	• Commercial/Medicaid: Medically Infused Therapeutic Immunomodulators • Medicare Part B: Medically Infused Therapeutic Immunomodulators (TIMs) Prior Authorization and Step Therapy Policy
Tirzepatide (Zepbound) Vial	New formulation. Line extend with other Zepbound strengths;	• Commercial/Medicaid: Weight Management Medications

NEW DRUGS / COMBINATIONS / STRENGTHS / DOSAGE FORMS		
Drug Name	**Action Taken**	**Policy Name**
	• 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	• Medicare Part D: N/A

NEW GENERICS		
Drug Name	**Action Taken**	**Policy Name**
Auranofin Capsule	First generic drug (Ridaura). Line extend as generic; • Commercial: Formulary, Tier 6 • Medicaid: Non-Formulary, Specialty • Medicare Part D: Non-Formulary	• N/A
Memantine HCL-Donepezil HCL ER Cap SPR 24	First generic drug (Namzaric). Line extend as generic; • Commercial/Medicaid: Non-Formulary • Medicare Part D: Formulary, Tier 4, Quantity Limit (1 capsule per day)	• N/A
Mercaptopurine Oral Susp	First generic drug (Purixan). Line extend as generic; • Commercial: Formulary, Tier 2, Specialty • Medicaid: Formulary, Specialty • Medicare Part D: Formulary Tier 5	• N/A
Nilotinib hcl (Tasigna) Capsule	First generic drug (Tasigna). Line extend as generic; • Commercial: Formulary, Tier 6, Prior Authorization, Quantity Limit (4 capsules per day)	• Anti-Cancer Medications - Self-Administered

	• Medicaid: Formulary, Tier 6, Prior Authorization, Quantity Limit (4 capsules per day), Specialty • Medicare Part D: Formulary, Tier 5, Prior Authorization, Quantity Limit (4 capsules per day)	
Clobetasol Propionate Cream (G)	First generic drug (Impoyz). Line extend as generic; • Commercial/Medicaid: Non-Formulary, Prior Authorization • Medicare Part D: Non-Formulary	• Commercial/Medicaid: New Medications and Formulations without Established Benefit • Medicare Part D: N/A
Ferric Citrate Iron Tablet	First generic drug (Auryxia). Line extend as generic; • Commercial Standard: Formulary, Tier 2, Step Therapy • Commercial Dynamic: Formulary, Tier 4, Step Therapy • Medicaid: Formulary, Step Therapy • Medicare Part D: Formulary, Tier 5	• Commercial/Medicaid: Phosphate Binders Step Therapy Policy • Medicare Part D: N/A
Octreotide Acetate ER Vial	First generic drug (Sandostatin LAR Depot). Line extend generic; • Commercial/Medicaid: Medical Benefit, Prior Authorization • Medicare Part D: Non-Formulary, Medicare Part B: Prior Authorization, Step Therapy	• Commercial/Medicaid: Pituitary Disorder Therapies • Medicare Part B: Somatostatin Analogs Prior Authorization and Step Therapy Policy

Clinical Policy Changes:

PHARMACY CLINICAL POLICIES – MAJOR CHANGES	
Policy Name	**Summary of Change**
Anti-Cancer Medications - Medical Benefit	Clarified that utilization of preferred products/biosimilars are required for patients established on therapy as well as for new starts.
Benefit Exception - Member-Pay-Difference	Criteria were clarified for determining medical necessity of a brand-name formulation over a generic equivalent.

Benlysta	Expand age in pediatric patients with Systemic Lupus Erythematosus (SLE).
Camzyos	Added reauthorization criteria that Left ventricular ejection fraction (LVEF) must be 50% or greater to align with package labeling.
CFTR Modulators	Clarified quantity limit for new drug Alyftrek.
Denavir, Xerese, Zovirax Cream	Medicaid criteria updated to include coverage in immunocompromised patients and those taking immunosuppressants. Treatment of cold sore in immunocompetent patients is an unfunded diagnosis.
Formulary and Quantity Limits Exception	Updated criteria related to quantity exceptions to assess appropriateness of medical drug dose and frequency due to future implementation of claims editing.
Geographic Atrophy Agents	Reauthorization criteria added for Izervay (avacincaptad pegol intravitreal solution) as the package labeling has been updated to allow therapy beyond 12 months. Additionally, reauthorization criteria has been updated to align with clinical trials.
• **Homozygous Familial Hypercholesterolemia (HoFH) Agents** **Homozygous Familial Hypercholesterolemia (HoFH) Agents Prior Authorization Policy - Medicare Part B**	Update criteria to align with 2023 European Atherosclerosis Society Consensus Statement on Homozygous Familial Hypercholesterolemia.
• **Hyperhidrosis Agents**	Added reauthorization criteria.
• **Immune Gamma Globulin (IGG)** • **Immune Gamma Globulin (IGG) Prior Authorization and Step Therapy Policy - Medicare Part B**	Indication for B-cell chronic lymphocytic leukemia has been expanded to secondary hypoimmunodeficiency in patients with hematologic malignancy or cancer patients receiving therapies that affect B-cell function. Consolidated criteria for immune thrombocytopenic purpura. Updated reauthorization criteria for pediatric autoimmune neuropsychiatric disorders (PANDAS).
• **Intranasal Allergy Medications – Medicaid**	Updated coverage duration for members aged under 21 years old, as coverage criteria is more restrictive for adults.
• **Lodoco**	Decreased coverage duration to one year, added quantity limit, updated criteria to clarify definition of clinical atherosclerotic cardiovascular disease, and allowed approval for patients with multiple risk factors for cardiovascular disease to align with FDA indication. Split criteria that is specific to Commercial members only
• **Ofev, Pirfenidone**	Due to changes in pricing, added pirfenidone 267 mg tablet to policy and increased quantity limit to align with pirfenidone 267 mg capsule.
• **Ohtuvayre** • **Ohtuvayre Prior Authorization and Step Therapy Policy – Medicare Part B**	Removed language for quantity limit duration of approval as any approvals for a quantity limit exception will align with the duration of the approval for the drug.
• **Ophthalmic Prostaglandin Implants**	Clarified that iDose is exclude from coverage, as the administration procedure is not covered per the medical benefit policy.

• **Ophthalmic Prostaglandin Implants Prior Authorization and Step Therapy Policy - Medicare Part B**	
• **Ophthalmic Vascular Endothelial Growth Factor (VEGF) Inhibitors** • **Ophthalmic Vascular Endothelial Growth Factor (VEGF) Inhibitors Prior Authorization and Step Therapy Policy - Medicare Part B**	Susvimo added to Diabetic Macular Edema policy criteria as Susvimo is now FDA approved for this indication.
• **Oxervate**	Removed trial and failure requirements for Medicaid to align with the Oregon Health Authority (OHA) and added optometrist as a prescriber option.
• **Pulmonary Hypertension**	Added a quantity limit for ambrisentan (Letairis)
• **Pulmonary Hypertension Prior Authorization Policy - Medicare Part B**	Changed policy to a Part B Step Therapy policy due to criteria requirements with Winrevair.
• **Saphnelo**	Removed lab requirements for the diagnosis of SLE and updated first-line therapies to align with current standard of practice.
• **Therapies for Resistant Hypertension**	Added endocrinologist to prescriber restrictions.
• **Transthyretin (TTR) Stabilizing Agents**	Removed NYHA class IV exclusion since criteria already requires class I-III
• **Upneeq**	Coverage duration for reauthorization reduced to 12 months to assess continued benefit of therapy.

RETIRED PHARMACY CLINICAL POLICIES	
Policy Name	**Summary of Change**
• **Cibinqo** • **Dupixent** • **Dupixent – Medicaid** • **IL-5 Inhibitors** • **Interleukin (IL)-13 Inhibitors** • **Interleukin (IL)-31 Inhibitors** • **Tezspire** • **Xolair**	Drugs moved to Therapeutic Immunomodulators (TIMS) Policy. Dupixent criteria updated to add coverage for new indication (Chronic Spontaneous Urticaria) in parity with omalizumab (Xolair).

• **Il-5 Inhibitors Prior Authorization and Step Therapy – Medicare Part B** • **Tezspire Prior Authorization and Step Therapy Policy - Medicare Part B** • **Xolair Prior Authorization and Step Therapy Policy – Medicare Part B**	Drugs moved to Medically Infused Therapeutic Immunomodulators (TIMs) Prior Authorization and Step Therapy Policy – Medicare Part B
Palforzia	Due to low utilization.
Topical Agents for Epidermolysis Bullosa	Drugs moved to Medications for Rare Indications policy.
Zinplava	Product has been discontinued.