Providence Health Plan

Providence Health Assurance

Healthcare Services Medical & Pharmacy Policy Alerts

Number 107

June 1, 2025

This is the June 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.

New Secondary Claims Editor

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.

REIMBURSEMENT POLICIES

Effective 8/4/25

DRG Validation

In addition to the secondary claims editor, beginning August 4th, 2025, for Commercial Fully-Insured and Medicare only, inpatient hospital stays reimbursed under a DRG payment methodology will be subject to either a pre-or-post payment validation review to confirm accurate coding and adherence to CMS and industry-standard coding rules. DRG audits will be based on claim information and medical records and will include, but are not limited to: coding accuracy (including diagnosis code and procedure code assignments), present on admission indicators, the sequencing of codes, verification of MCC and CC, and verification of the DRG assignment and associated payment.

If the DRG audit determines the billed DRG is not supported based on the claim information, medical records documentation, and/or industry-standard coding rules, then one of the following reimbursement methodologies will apply:

- For **pre-payment** reviews: the reimbursement will be adjusted to the appropriately assigned DRG.
- For **post-payment** reviews: overpayments will be recouped through standard payment recovery processes.

Facilities may request a reconsideration of any DRG validation findings in accordance with the Providence Health Plan/Providence Health Assurance provider dispute process.

MEDICAL

COMPANY POLICIES

Effective 7/1/2025

Shoulder Arthroscopy and Open Procedures **MP436**	**New Policy** **Policy Updates:** New policy for select arthroscopic and open procedures for the shoulder. Criteria include: • Rotator cuff repair • Labral tear repair • Debridement • Capsulorrhaphy

	• Claviculectomy • Lysis/capsular release • Biceps tenodesis and tenotomy **Codes/PA:** Added PA to 9 codes
Knee Arthroscopy and Meniscal Repair **MP434**	**New Policy** **Policy Updates:** New policy for knee arthroscopy and arthroscopically assisted knee surgeries based on InterQual criteria. **Codes/PA:** Added PA to the codes addressed by this policy.
Sleep Disorder Treatment with Positive Airway Pressure **MP56**	**Policy Updates:** Add parasomnias and periodic limb movement disorder to list of indications eligible for CPAP titration and initial trial. **Codes/PA:** No changes to codes/PA

Effective 8/1/2025

Benign Skin Lesions **MP422**	**New Policy** **Recommendation:** New policy establishing pair-to-pay configuration for benign skin lesion removal. **Codes/PA:** Added diagnosis code configuration to the relevant CPT codes. This policy was originally going to be made effective 6/1/25, but will now be effective 8/1/25
Alpha-Fetoprotein **MP406**	**Policy Updates:** No recommended changes to criteria. **Codes/PA:** Updated pair to pay diagnosis code list for 82105, based on CMS lab manual.
Prothrombin Time (PT) **MP412**	**Policy Updates:** No recommended changes to criteria. **Codes/PA:** Updated pair to pay diagnosis code list for 85610, based on CMS lab manual.
Bacterial Urine Cultures **MP408**	**Policy Updates:** No recommended changes to criteria. **Codes/PA:** Added three new dx codes to deny per CMS update.

Spinal Epidural Steroid Injections **MP14**	**Policy Updates:** Policy Guidelines – clarified that the patient must have been evaluated at least once, in-office, by the provider performing the injection before submitting a request for injection. **Codes/PA:** No changes to codes/PA
Human Chorionic Gonadotropin **MP 410**	**Policy Updates:** Added medical necessity criteria for HCG measurement to confirm pregnancy in patients undergoing IVF. **Codes/PA:** Added the following diagnosis codes to the policy's pair-to-pay configuration - O3680X0 (Pregnancy with inconclusive fetal viability, not applicable or unspecified) - 009891 (Supervision of other high risk pregnancies, first trimester - R338 (other retention of urine) - R339 (retention of urine, unspecified) - R34 (anuria) - N186 (end-stage renal disease)

ARCHIVE

Effective 8/1/2025

Irreversible Electroporation (IRE) (NanoKnife System) **MP154**	**Policy Updates:** Archived policy due to minimal utilization. **Codes/PA:** Removed configuration from codes.
Nerve Conduction Studies **MP129**	**Policy Updates:** Archived policy due to low utilization. **Codes/PA:** Removed configuration from codes.

MEDICARE POLICIES

Effective 7/1/2025

Knee Arthroscopy and Meniscal Repair **MP435**	**New Policy** **Policy Updates:** New Medicare Advantage medical policy. There is an NCD for arthroscopic knee debridement, but this service is excluded from the scope of our policy. In the absence of fully established Medicare coverage criteria for other knee arthroscopy and meniscal repair procedures internal Company criteria will be used **Codes/PA:** Added PA to the codes addressed by this policy.
Shoulder Arthroscopy and Open Procedures **MP437**	**New Policy** **Policy Updates:** New Medicare Advantage medical policy. In the absence of fully established Medicare coverage criteria for arthroscopic or open shoulder procedures internal Company criteria will be used. **Codes/PA:** Added PA to the codes addressed by this policy.

Effective 8/1/2025

Benign Skin Lesions **MP423**	**New Medicare Advantage medical policy** **Policy Updates:** New policy for Medicare Advantage. The Noridian local coverage determination (LCD) was used. **Codes/PA:** Added diagnosis code configuration to the relevant CPT codes, based on Noridian local coverage article (LCA). This policy was originally going to be made effective 6/1/25, but will now be effective 8/1/25
Next Generation Sequencing for Minimal Residual Disease Detection **MP111**	**Policy Updates:** Received notice on 4/8/2025 the clonoSEQ® Single Assay (0364U), a previously "not covered" test, was retroactively approved by MolDX as of 1/29/2025 and is now potentially covered when LCD criteria are met. (Other LCD and LCA requirements apply, OON provider, no provider contract language.) Updated to policy to reflect this change. **Codes/PA:** For CPT 0364U only, removed NMN denial and add PA. No change to other codes or their configuration.

ARCHIVE

Effective 5/6/25

External Ambulatory Electrocardiography **MP157**	**Archived. Transfer of services to Carlon Cardiology Program – Medicare Advantage** **Policy Updates:** Carelon is taking over the prior authorization and review process for these cardiology services. Since Carelon has their own criteria, the existing PHP medical policy is no longer required. Policy archived. **Codes/PA:** Configuration updates are as follows: • **Continue current PA requirement:** 0795T, 0796T, 0797T, 0801T, 0802T, 0803T, 0823T, 0825T, C1605, 33274 • **Removed current PA requirement:** 0804T, 0826T • **Added new PA requirement:** 0798T, 0799T, 0800T, 0824T, 33275
Implantable Loop Recorders **MP343**	**Archived. Transfer of services to Carlon Cardiology Program – Medicare Advantage** **Policy Updates:** Carelon is taking over the prior authorization and review process for these cardiology services. Since Carelon has their own criteria, the existing PHP medical policy is no longer required. Policy archived. **Codes/PA:** Configuration updates are as follows: • **Continue current PA requirement:** 93228, 93229 • **Removed current PA:** 0937T-0940T (Codes not included as any that will require PA with Carelon) • **All other codes:** No other codes in this policy have MP configuration, and it does not appear Carelon will require PA for them either, so no changes required.
Leadless Cardiac Pacemakers **MP425**	**Archived. Transfer of services to Carlon Cardiology Program – Medicare Advantage** **Policy Updates:** Carelon is taking over the prior authorization and review process for these cardiology services. Since Carelon has their own criteria, the existing PHP medical policy is no longer required. Policy archived. **Codes/PA:** Configuration updates are as follows: • **Continue current PA requirement:** 0795T, 0796T, 0797T, 0801T, 0802T, 0803T, 0823T, 0825T, C1605, 33274 • **Removed current PA requirement:** 0804T, 0826T • **Added new PA requirement:** 0798T, 0799T, 0800T, 0824T, 33275
Pelvic Congestion Syndrome **MP397**	**Archived. Transfer of services to Carlon Cardiology Program – Medicare Advantage** **Policy Updates:** Carelon is taking over the prior authorization and review process for these cardiology services. Since Carelon has their own criteria, the existing PHP medical policy is no longer required. Policy archived. **Codes/PA:** Removed diagnosis code pair-to-deny configuration for CPT 37241 and added PA, which will be reviewed by Carelon, using their criteria.

Effective 8/1/25

Irreversible Electroporation (IRE) (NanoKnife System) **MP393**	**Policy Updates:** Archived medical policy due to low utilization **Codes/PA:** 0600T, 0601T: Remove NMN denial. No change to other codes.
Nerve Conduction Studies **MP131**	**Policy Updates:** Archived due to low utilization **Codes/PA:** Configuration changes include the following: • For G0255, kept NMN denial since it is based on NCD and transfered to the NET policy. • For all other codes, removed any medical policy configuration and allowed codes to process according to member benefits, eligibility and provider contracts.

VENDOR UPDATES

Effective 5/21/25

EviCore – Physical Therapy and Occupational Therapy	**Annual Update** **Updates:** - *Clinical Review Criteria: Physical Therapy and Occupational Therapy Services* -Updated Evicore to EviCore. Minor editorial changes. - *Definitions* - Minor editorial changes to definitions. Removal of Duplicative definition as is no longer applicable - *Criteria to Determine Medical Necessity for Skilled Physical/Occupational Therapy Care* - Minor editorial changes. Clarified that continuation of care needs to meet medical necessity as well as initiation of care. - *Rules, Coverage, Benefits and Mandates* - Simplified language and referenced EviCore CMS hierarchy - *Clinical Considerations* - Minor editorial changes to reduce redundant language that is already in definitions. Updated to align with most current literature. Removed outdated references. **Codes/PA:** No changes to codes or configuration.

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 April 4, 2025
Go-Live Date: Sunday, June 01, 2025, unless otherwise noted

Table of Contents:

New Drugs and Combinations:

1. **Suzetrigine (Journavx) Tablet**
   a. **Indication**: For the treatment of moderate to severe acute pain in adults.
   b. **Decision**:

	Commercial	Medicaid	Medicare
Formulary Status*	Non-Formulary	Non-Formulary	Part D: Non-Formulary Part B: N/A
Tier**	N/A	N/A	N/A
Affordable Care Act Eligible	No	N/A	N/A
Utilization Management Edits	Prior Authorization	Prior Authorization	N/A
Quantity Limit	7 tablets/75 days	7 tablets/75 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: ibuprofen, acetaminophen, oxycodone, hydrocodone/APAP			

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

PA PROGRAM NAME	Journavx®

MEDICATION NAME	suzetrigine tablets (Journavx®)
PA INDICATION INDICATOR	1 – All FDA-Approved Indications
OFF-LABEL USES	None
EXCLUSION CRITERIA	• Chronic pain • Concurrent use with opioid medications
REQUIRED MEDICAL INFORMATION	Diagnosis of moderate to severe acute pain.
AGE RESTRICTIONS	May be approved for patients ages 18 years and older
PRESCRIBER RESTRICTIONS	N/A
COVERAGE DURATION	Authorization will be approved for one month. No reauthorization.

2. **Zanidatamab-hrii (Ziihera) Vial**
   a. **Indication**: For the treatment of adults with previously treated, unresectable or metastatic HER2-positive immunohistochemistry (IHC) 3+ biliary tract cancer (BTC), as detected by an FDA-approved test.
   b. **Decision**:

	Commercial	Medicaid	Medicare
Formulary Status*	Medical	Medical	Part D: Non-formulary Part B: Medical
Tier**	N/A	N/A	N/A
Affordable Care Act Eligible	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: Medically-administered therapies: Fam-trastuzumab deruxtecan-nxki (IHC 3+), Trastuzumab + pertuzumab, Tucatinib + trastuzumab			

   c. **Prior Authorization Criteria for Commercial/Medicaid/Medicare Part B**: Added to Anti-Cancer Medications – Medical Benefit policy

3. **Zenocutuzumab-zbco (Bizengri) Vial**
   a. **Indication**: For the treatment of adults with advanced, unresectable, or metastatic non-small cell lung cancer (NSCLC) or pancreatic adenocarcinoma (PAC) harboring a neuregulin 1 (NRG1) gene fusion with disease progression on or after prior 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: None			

c. **Prior Authorization Criteria for Commercial/Medicaid/Medicare Part B**: Added to Anti-Cancer Medications – Medical Benefit policy

4. **Datopotamab deruxtecan-dlnk (Datroway) Vial**
   a. **Indication**: For the treatment of adult patients with unresectable or metastatic, hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative (IHC 0, IHC 1+ or IHC 2+/ISH-) breast cancer who have received prior endocrine-based therapy and chemotherapy for unresectable or metastatic disease.
   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: Trodelvy			

c. **Prior Authorization Criteria for Commercial/Medicaid/Medicare Part B**: Added to Anti-Cancer Medications – Medical Benefit policy

5. **Obecabtagene autoleucel (Aucatzyl) Plast. Bag**

a. **Indication**: For the treatment of adults with B-Cell precursor acute lymphoblastic leukemia (B-ALL) that is relapsed or refractory to prior treatment.
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	One administration per lifetime	One administration per lifetime	One administration per lifetime
* Recommendations for placement may differ between lines of business due to regulatory requirements. ** Medications will be placed on recommended tier above for the base formulary; tier placement for custom formulary(ies) will be based on designation above. For example, Commercial Tier 6 designation above means that the medication will be placed on the highest cost-sharing tier on the respective formulary(ies).			
Formulary Alternatives: brexucabtagene (Tecartus®), tisagenelecleucel (Kymriah®), blinatumomab (Blincyto®), inotuzumab ozogamicin (Besponsa®)			

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

6. **Treosulfan (Grafapex) Vial**
   a. **Indication**:
      - Use in combination with fludarabine as a preparative regimen for allogeneic hematopoietic stem cell transplantation (alloHSCT) in adult and pediatric patients 1 year of age and older with acute myeloid leukemia (AML).
      - Use in combination with fludarabine as a preparative regimen for allogeneic hematopoietic stem cell transplantation in adult and pediatric patients 1 year of age and older with myelodysplastic syndrome (MDS).
   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: busulfan with fludarabine

c. **Prior Authorization Criteria for Commercial/Medicaid/Medicare Part B**: Added to Anti-Cancer Medications – Medical Benefit policy

7. **Acoramidis hcl (Attruby) - Tablet**

a. **Indication**: For the treatment of cardiomyopathy of wild-type or variant/hereditary transthyretin-mediated amyloidosis (ATTR-CM) in adults.

b. **Decision**:

	Commercial	Medicaid	Medicare
Formulary Status*	Formulary	Formulary	Part D: Non-formulary Part B: N/A
Tier**	Tier 5 - 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 day	4 tablets 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: tafamidis (Vyndamax®, Vyndaqel®)			

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

PA PROGRAM NAME	Transthyretin (TTR) Stabilizing Agents ~~Tafamidis~~
MEDICATION NAME	Attruby oral tablet 356 mg Vyndamax oral capsule 61 mg Vyndaqel oral capsule 20 mg
PA INDICATION INDICATOR	1 - All FDA-Approved Indications
EXCLUSION CRITERIA	1. A New York Heart Association (NYHA) Heart Failure classification of IV 2. Used in combination with other agents for the treatment of transthyretin-mediated amyloidosis such as patisiran (Onpattro®), inotersen (Tegsedi®), vutrisiran (Amvuttra®), eplontersen (Wainua®), tafamidis (Vyndamax®, Vyndaqel®), or acoramidis (Attruby™) 3. For tafamidis: Prior liver transplantation ~~1. Implanted cardiac mechanical assist device such as left ventricular assist device (LVAD)~~
REQUIRED MEDICAL INFORMATION	Initial authorization: 1. Diagnosis of transthyretin mediated amyloid cardiomyopathy 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. For cardiomyopathy due to hereditary/variant amyloidosis: genetic testing confirming TTR mutation 2. Diagnosis of light chain (AL) amyloidosis EXCLUDED by monoclonal protein screen consisting of ALL the following: a. Serum free light chain (sLFC) assay b. Serum immunofixation electrophoresis (SIFE) c. Urine immunofixation electrophoresis (UIFE) 2. Documentation of New York Heart Association (NYHA) functional class I-III (functional class IV is excluded from coverage) 3. Documentation of clinical signs or symptoms of cardiomyopathy and/or heart failure such as dyspnea, fatigue, orthostatic hypotension, syncope, peripheral edema, elevated BNP or NT-BNP levels. Reauthorization requires documentation of a positive clinical response. Appropriate documentation may include evidence of slowing of clinical decline, reduced number of cardiovascular hospitalizations, or improvement or stabilization of the 6-minute walk test.
QUANTITY LIMIT	Acoramidis tablet (Attruby™): four tablets per day Tafamidis meglumine capsule (Vyndaqel®): four capsules per day Tafamidis capsule (Vyndamax®): one capsule per day

8. **Olezarsen sodium (Tryngolza) Auto Injct**
   a. **Indication**: Adjunct to diet to reduce triglycerides in adults with familial chylomicronemia syndrome (FCS).
   b. **Decision**:

	Commercial	Medicaid	Medicare
Formulary Status*	Non-formulary	Non-formulary	Part D: Non-formulary Part B: N/A
Tier**	N/A	N/A	N/A
Affordable Care Act Eligible	No	N/A	N/A
Utilization Management Edits	Prior Authorization	Prior Authorization	N/A
Quantity Limit	0.8 mL per 28 days	0.8 mL per 28 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: None

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

PA PROGRAM NAME	Tryngolza
MEDICATION NAME	Olezarsen (Tryngolza) injection
PA INDICATION INDICATOR	1 - All FDA-Approved Indications
EXCLUSION CRITERIA	N/A
REQUIRED MEDICAL INFORMATION	For initial authorization: Diagnosis of familial chylomicronemia syndrome (FCS) confirmed by genetic testing For reauthorization, must have documentation of benefit (such as a reduction in episodes of acute pancreatitis)
AGE RESTRICTIONS	Age must be appropriate based on FDA-approved indication
PRESCRIBER RESTRICTIONS	Must be prescribed by, or in consultation with, a specialist experienced in the treatment of familial chylomicronemia syndrome (FCS)
COVERAGE DURATION	Initial authorization will be approved for 6 months. Reauthorization will be approved for 12 months.
QUANTITY LIMIT	1 injector (0.8 mL) per 28 days

9. **Crinecerfont (Crenessity) Capsule & Solution**
   a. **Indication**: Adjunctive treatment to glucocorticoid replacement to control androgens in adults and pediatric patients 4 years of age and older with classic congenital adrenal hyperplasia (CAH).
   b. **Decision**:

	Commercial	Medicaid	Medicare
Formulary Status*	Non-formulary	Non-formulary	Part D: Non-formulary Part B: N/A
Tier**	N/A	N/A	N/A
Affordable Care Act Eligible	No	N/A	N/A
Utilization Management Edits	Prior Authorization	Prior Authorization	N/A
Quantity Limit	50 mg and 100 mg capsules: 2 per day 50 mg/mL solution: 2 mL per day	50 mg and 100 mg capsules: 2 per day 50 mg/mL solution: 2 mL 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: None

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

PA PROGRAM NAME	Medications for Rare Indications
MEDICATION NAME	Crinecerfont (Crenessity)
PA INDICATION INDICATOR	1 - All FDA-Approved Indications
EXCLUSION CRITERIA	N/A
REQUIRED MEDICAL INFORMATION	For Initial Authorization: 1. Diagnosis of classic CAH due to 21-hydroxylase deficiency (21-OHD) 2. Documentation that medication will be used concomitantly with glucocorticoid replacement therapy 3. Stable glucocorticoid dose (for at least 4 weeks) of greater than 13 mg/m2/day hydrocortisone equivalents for adults and greater than 12 mg/m2/day hydrocortisone equivalents for pediatric patients 4. For pediatric patients weighing at least 55 kg or patients weighing at least 20 kg if CYP3A4 dose adjustment is required: capsule formulation is requested or documentation is provided that patient is unable to swallow capsule whole. 5. Dosing is within FDA-labeled guidelines OR documentation has been submitted in support of therapy with a higher dose for the intended diagnosis such as high-quality peer reviewed literature, guidelines, other clinical information For reauthorization: 1. Documentation of benefit of therapy as evidence by improvement in symptoms, disease stabilization or lack of decline compared to the natural disease progression 2. Dosing is within FDA-labeled guidelines OR documentation has been submitted in support of therapy with a higher dose for the intended diagnosis such as high-quality peer reviewed literature, guidelines, other clinical information
AGE RESTRICTIONS	Age must be appropriate based on FDA-approved indication
PRESCRIBER RESTRICTIONS	Must be prescribed by, or in consultation with a specialist in the respective disease state.
COVERAGE DURATION	Initial authorization will be approved for six months. Reauthorization will be approved for 12 months
QUANTITY LIMITS	50 mg and 100 mg capsules: 2 per day; 50 mg/mL solution: 2 mL per day

10. **Concizumab-mtci (Alhemo) Pen Injctr**

a. **Indication**: For routine prophylaxis to prevent or reduce the frequency of bleeding episodes in adult and pediatric patients 12 years of age and older with:

- Hemophilia A (congenital factor VIII deficiency) with FVIII inhibitors
- Hemophilia B (congenital factor IX deficiency) with FIX inhibitors with paroxysmal nocturnal hemoglobinuria)

b. **Decision**:

	Commercial	Medicaid	Medicare
Formulary Status*	Medical	Medical	Part D: Non-formulary Part B: Medical
Tier**	N/A	N/A	N/A
Affordable Care Act Eligible	No	N/A	N/A
Utilization Management Edits	Prior Authorization	Prior Authorization	Prior Authorization
Quantity Limit	N/A	N/A	N/A
* Recommendations for placement may differ between lines of business due to regulatory requirements. ** Medications will be placed on recommended tier above for the base formulary; tier placement for custom formulary(ies) will be based on designation above. For example, Commercial Tier 6 designation above means that the medication will be placed on the highest cost-sharing tier on the respective formulary(ies).			
Formulary Alternatives: Hemophilia A: Advate®, Adynovate®, Afstyla®, Altuviiio®, Eloctate®, Esperoct®, Jivi®, Kogenate® FS, Kovaltry®, NovoEight®, Nuwiq®, Recombinate™, Xyntha®, Hemlibra®, Hympavzi™, Roctavian® Hemophilia B: Alprolix®, BeneFix®, Idelvion®, Ixinity®, Rebinyn®, Rixubis®, Hympavzi™, Hemgenix®, Beqvez™			

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

PA PROGRAM NAME	Anti-Tissue Factor Pathway Inhibitors
MEDICATION NAME	Concizumab-mtci (Alhemo®)
PA INDICATION INDICATOR	1 - All FDA-Approved Indications
OFF-LABEL USES	N/A
EXCLUSION CRITERIA	Use with other prophylactic therapies (such as emicizumab-kxwh)
REQUIRED MEDICAL INFORMATION	For initial authorization: 1. Use is for routine prophylaxis to prevent or reduce the frequency of bleeding episodes 2. Must meet criteria for one of the following (Hemophilia A **OR** Hemophilia B): a. Diagnosis of hemophilia A (congenital factor VIII deficiency) b. Diagnosis of hemophilia B (congenital factor IX deficiency) 3. Patient has documentation of inhibitors defined as one of the following: a. For Hemophilia A: factor VIII inhibitor titer greater than or equal to 0.6 Bethesda units (BU) per mL b. For Hemophilia B: factor IX inhibitor titer greater than or equal to 0.6 Bethesda units (BU) per mL 4. Weigh 25 kg or more at treatment initiation 5. Dose and frequency must be in accordance with FDA-approved labeling

	For reauthorization: 1. Documentation of response to therapy indicating a beneficial response (such as 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. Documentation of annual drug plasma concentration monitoring with appropriate dosage adjustments 3. Dose and frequency must be in accordance with FDA-approved labeling
AGE RESTRICTIONS	Age must be appropriate based on FDA-approved indication.
PRESCRIBER RESTRICTIONS	Must be prescribed by, or in consultation with, a hematologist
QUANTITY LIMIT	N/A
COVERAGE DURATION	Authorization and reauthorization will be approved for one year.

11. **Vanzacaftor calcium-tezacaftor-deutivacaftor (Alyftrek) Tablet**

a. **Indication**: For the treatment of cystic fibrosis (CF) in patients 6 years of age and older who have at least one *F508del* mutation or another responsive mutation in the cystic fibrosis transmembrane conductance regulator (*CFTR*) gene.

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	3 tablets per day	3 tablets per day	3 tablets per day
* Recommendations for placement may differ between lines of business due to regulatory requirements. ** Medications will be placed on recommended tier above for the base formulary; tier placement for custom formulary(ies) will be based on designation above. For example, Commercial Tier 6 designation above means that the medication will be placed on the highest cost-sharing tier on the respective formulary(ies).			
Formulary Alternatives: Trikafta®			

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

PA PROGRAM NAME	CFTR Modulators
MEDICATION NAME	• Ivacaftor (Kalydeco®) • Lumacaftor/Ivacaftor (Orkambi®) • Tezacaftor/Ivacaftor (Symdeko™) • Elexacaftor/Tezacaftor-ivacaftor (Trikafta™) • Vanzacaftor/Tezacaftor/Deutivacaftor (Alyftrek®):

PA INDICATION INDICATOR	1 - All FDA-Approved Indications
OFF-LABEL USES	N/A
EXCLUSION CRITERIA	N/A
REQUIRED MEDICAL INFORMATION	For vanzacaftor/Tezacaftor/Deutivacaftor (Alyftrek®): Diagnosis of cystic fibrosis with documentation of at least one F508del mutation in the CFTR gene or a mutation in the CFTR gene that is responsive to vanzacaftor- tezacaftor-ivacaftor based on in vitro data (See Appendix 4 and/or package insert)
AGE RESTRICTIONS	• Ivacaftor (Kalydeco®): one month or older • Lumacaftor/Ivacaftor (Orkambi®): one year or older • Tezacaftor/Ivacaftor (Symdeko™): six years or older • Elexacaftor/Tezacaftor-ivacaftor (Trikafta™): two years or older • Vanzacaftor/Tezacaftor/Deutivacaftor (Alyftrek®): six years or older
PRESCRIBER RESTRICTIONS	Must be prescribed by or in consultation with a pulmonologist or provider at a Cystic Fibrosis Center.
COVERAGE DURATION	Authorization will be approved until no longer eligible with the plan, subject to formulary or benefit changes

d. **Prior Authorization Criteria for Medicare Part D:** Added to CFTR Modulators prior authorization policy

12. **Eladocagene exuparvovec-tneq (Kebilidi) Vial**

a. **Indication**: For the treatment of adult and pediatric patients with aromatic L-amino acid decarboxylase (AADC) deficiency.

b. **Decision**:

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

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

PA PROGRAM NAME	Medications for Rare Indications

MEDICATION NAME	Eladocagene exuparvovec-tneq (Kebilidi)
PA INDICATION INDICATOR	1 - All FDA-Approved Indications
EXCLUSION CRITERIA	N/A
REQUIRED MEDICAL INFORMATION	For initial authorization: 1. Genetic confirmation of biallelic mutations in the DDC gene
AGE RESTRICTIONS	Age must be appropriate based on FDA-approved indication
PRESCRIBER RESTRICTIONS	Must be prescribed by, or in consultation with a specialist in the respective disease state.
COVERAGE DURATION	Authorization is limited to one treatment course per lifetime. Approval duration will be for 12 weeks.

New Indications:

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

from 12/1/2024– 1/31/2025

Therapies with Prior Authorization Policies (Non-oncology)

1. **OMVOH (MIRIKIZUMAB-MRKZ)**
   a. Previous Indication(s):
      i. Treatment of moderately to severely active ulcerative colitis in adults
   b. New indication approved 01/15/2025:
      i. Treatment of moderately to severely active Crohn's disease in adults
   c. **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	Omvoh (mirikizumab-mrkz)
COVERED USES	1 - All FDA-Approved Indications
REQUIRED MEDICAL INFORMATION	A. For moderate to severe non-fistulizing **Crohn's disease**, preferred adalimumab products (Humira® Simlandi®, Hadlima®, adalimumab-adaz¥ and adalimumab-aaty¥), ustekinumab (Stelara®), risankizumab-rzaa (Skyrizi®), subcutaneous vedolizumab (Entyvio® Pen) may be covered. Other therapies may be covered as outlined below: 1) 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 (Humira® Simlandi®, Hadlima®, adalimumab-adaz and adalimumab-aaty) b. Ustekinumab (Stelara®) c. Risankizumab-rzaa (Skyrizi®) d. Subcutaneous vedolizumab (Entyvio® Pen)

2. **OZEMPIC (SEMAGLUTIDE)**
   a. Previous Indication(s):
      i. An adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus
      ii. To reduce the risk of major adverse cardiovascular events in adults with type 2 diabetes mellitus and established cardiovascular disease
   b. New indication approved 01/28/2025:
      i. To reduce the risk of sustained eGFR decline, end-stage kidney disease and cardiovascular death in adults with type 2 diabetes mellitus and chronic kidney disease
   c. **RECOMMENDATION:** Inform prescribers via Medical Policy Alert. New indication reviewed with April 2025 annual policy review.

3. **SPRAVATO (ESKETAMINE)**
   a. Previous Indication(s):
      i. Indicated, in conjunction with an oral antidepressant, for the treatment of:
         1) Treatment-resistant depression (TRD) in adults
         2) Depressive symptoms in adults with major depressive disorder (MDD) with acute suicidal ideation or behavior
   b. New indication approved 01/17/2025:
      i. Indicated for the treatment of:
         1) Treatment-resistant depression (TRD) in adults, as monotherapy or in conjunction with an oral antidepressant
         2) Depressive symptoms in adults with major depressive disorder (MDD) with acute suicidal ideation or behavior in conjunction with an oral antidepressant
   c. **RECOMMENDATION:** Inform prescribers via Medical Policy Alert. Update policy with new indication. Update criteria requiring concomitant antidepressant use to only apply to MDD with acute suicidal ideation for Commercial/Medicaid/Medicare Part B/Medicare Part D.

Prior Authorization for Commercial/Medicaid/Medicare Part B:

PA PROGRAM NAME	Spravato
MEDICATION NAME	Spravato (esketamine nasal spray)
REQUIRED MEDICAL INFORMATION	For initiation of therapy, all the following criteria (1-4) must be met: 1. Confirmed diagnosis of one of the following: a. For treatment-resistant depression (TRD), clinical documentation must be provided that outlines the patient evaluation. TRD is defined as use of the following regimens (i and ii) for the current depressive episode:

	i. Inadequate response to at least three oral antidepressants in two different therapeutic classes for at least eight weeks of treatment at a therapeutic dose for major depressive disorder (MDD). ii. Inadequate response to augmentation therapy (i.e., two antidepressants with different mechanisms of action used concomitantly or an antidepressant and a second-generation antipsychotic, lithium, thyroid hormone, or anticonvulsant used concomitantly). b. For MDD with acute suicidal ideation or behavior, documentation must be provided that patient has current suicidal ideation with intent defined as both of the following: i. Patient has thoughts, even momentarily, of self-harm with at least some intent or awareness that they may die as a result, or member thinks about suicide, and ii. Patient intends to act on thoughts of killing themselves. 2. Baseline score from one of the following standardized depression rating scales confirming severe depression: a. Patient Health Questionnaire-9 (PHQ-9) score of at least 20 b. Hamilton Depression Scale (HAMD17) score of at least 24 c. Quick Inventory of Depressive Symptomatology, Clinician-Rated (QIDS-C16) score of at least 16 d. Montgomery Asberg Depression Rating Scale (MADRS) total score of at least 28 3. For MDD with acute suicidal ideation or behavior: Documentation that esketamine (Spravato®) will be used in combination with oral antidepressant therapy 4. Dosing is in accordance with the United States Food and Drug Administration approved labeling For patients established on therapy for MDD, **all** the following criteria must be met: 1. Documentation of sustained clinical improvement from baseline in depression symptoms, documented by depression rating scores 2. For MDD with acute suicidal ideation or behavior: Documentation that esketamine (Spravato®) will be used in combination with oral antidepressant therapy

	3. Dosing is in accordance with the United States Food and Drug Administration approved labeling Reauthorization requests for MDD with acute suicidal ideation or behavior will not be covered. Patient must meet criteria for initiation of therapy in TRD.

Prior Authorization for Medicare Part D:

PA PROGRAM NAME	Spravato
MEDICATION NAME	Spravato (esketamine nasal spray)
REQUIRED MEDICAL INFORMATION	For initiation of therapy, all the following criteria (1-4) must be met: 1. Confirmed diagnosis of one of the following (a or b): a. Treatment-resistant depression (TRD), defined as use of BOTH of the following regimens for the current depressive episode (clinical documentation must be provided that outlines the patient evaluation): i. Inadequate response to at least three oral antidepressants in two different therapeutic classes for at least eight weeks of treatment at a therapeutic dose for major depressive disorder (MDD) **AND** ii. Inadequate response to augmentation therapy (i.e., two antidepressants with different mechanisms of action used concomitantly or an antidepressant and a second-generation antipsychotic, lithium, thyroid hormone, or anticonvulsant used concomitantly) b. For MDD with acute suicidal ideation or behavior, defined as BOTH of the following (clinical documentation must be provided that outlines the patient evaluation): i. Patient has thoughts about suicide, or thoughts of self-harm with at least some intent or awareness that they may die as a result **AND** ii. Patient intends to act on thoughts of killing themselves 2. Baseline score from one of the following standardized depression rating scales confirming severe depression: a. Patient Health Questionnaire-9 (PHQ-9) score of at least 20 b. Hamilton Depression Scale (HAMD17) score of at least 24

	c. Quick Inventory of Depressive Symptomatology, Clinician-Rated (QIDS-C16) score of at least 16 d. Montgomery Asberg Depression Rating Scale (MADRS) total score of at least 28 3. For MDD with acute suicidal ideation or behavior: Documentation that esketamine (Spravato) will be used in combination with oral antidepressant therapy 4. Dosing is in accordance with the United States Food and Drug Administration approved labeling NOTE: For MDD with suicidal ideation or behavior, initial authorization will be approved for four weeks. Reauthorization requests for MDD with acute suicidal ideation or behavior will not be covered. Patient must meet criteria for initiation of therapy in TRD.

4. **VTAMA** (TAPINAROF)
    a. Previous Indication(s):
        i. Topical treatment of plaque psoriasis in adults
    b. New indication approved 12/12/2024:
        i. Topical treatment of atopic dermatitis in adult and pediatric patients 2 years of age and older
    c. **RECOMMENDATION:** Update Topical Agents for Skin Conditions Commercial & Medicaid policies with new indication. Inform prescribers via Medical Policy alert. No updates to criteria required.

5. **IMCIVREE** (SETMELANOTIDE ACETATE)
    a. Previous Indication(s):
        i. Chronic weight management in adult and pediatric patients 6 years of age and older with monogenic or syndromic obesity due to:
            1) Pro-opiomelanocortin (POMC), proprotein convertase subtilisin/kexin type 1 (PCSK1), or leptin receptor (LEPR) deficiency as determined by an FDA-approved test demonstrating variants in POMC, PCSK1, or LEPR genes that are interpreted as pathogenic, likely pathogenic, or of uncertain significance (VUS)
            2) Bardet-Biedl syndrome (BBS)
    b. New indication approved 12/20/2024:
        i. Chronic weight management in adult and pediatric patients 2 years of age and older with monogenic or syndromic obesity due to:
            1) Pro-opiomelanocortin (POMC), proprotein convertase subtilisin/kexin type 1 (PCSK1), or leptin receptor (LEPR) deficiency as determined by an FDA-approved test demonstrating variants in POMC, PCSK1, or LEPR genes that are interpreted as pathogenic, likely pathogenic, or of uncertain significance (VUS)
            2) Bardet-Biedl syndrome (BBS)
    c. **RECOMMENDATION:** Update Medications for Rare Indications Commercial & Medicaid policy with new indication. Inform prescribers via Medical Policy alert. No updates to criteria required.

6. **ZEPBOUND** (TIRZEPATIDE)
   a. Previous Indication(s):
      i. Reduction of excess body weight and maintenance of weight reduction long term in adults with obesity or adults with overweight in the presence of at least one weight-related comorbid condition, in combination with a reduced-calorie diet and increased physical activity
   b. New indication approved 12/20/2024:
      i. Treatment of moderate to severe obstructive sleep apnea (OSA) in adults with obesity, in combination with a reduced-calorie diet and increased physical activity
   c. **RECOMMENDATION:** Update Weight Management Medications Commercial & Medicaid policies with new indication and add new criteria. Inform prescribers via Medical Policy alert.

Prior Authorization for Commercial:

PA PROGRAM NAME	Weight Management Medications
MEDICATION NAME	Zepbound (tirzepatide)
COVERED USES	1 - All FDA-Approved Indications
REQUIRED MEDICAL INFORMATION	For initiation of therapy for obstructive sleep apnea (Zepbound only): 1. Diagnosis of obesity as defined by body mass index (BMI) of at least 30 kg/m^2 2. Diagnosis of obstructive sleep apnea as defined by both of the following a. Polysomnography (PSG) or home sleep apena test b. Apnea-hypopnea index (AHI; the number of apneas and hypopneas during an hour of sleep) greater than or equal to 15 events per hour prior to initiation of pharmacotherapy For continuation of therapy, all of the following criteria must be met: 1. Patient has previous authorization for coverage with the plan or attestation from provider that coverage was provided through another health plan (new start to this plan). Note: Medications obtained as samples, coupons, or any other method of obtaining medications outside of an established health plan benefit are NOT considered established on therapy. 2. For Zepbound for obstructive sleep apnea: i. Patient has clinical benefit from the requested agent (such as reduction in AHI)

Prior Authorization for Medicaid:

PA PROGRAM NAME	Weight Management Medications

MEDICATION NAME	Zepbound (tirzepatide)
COVERED USES	1 - All FDA-Approved Indications
REQUIRED MEDICAL INFORMATION	For initiation of therapy in adults over age 21 for obstructive sleep apnea (Zepbound only): 1. Patient does not have diabetes (screening to have occurred within the previous year). Note, for patients with diabetes a GLP-1 agent indicated for diabetes should be considered 2. Diagnosis of obesity as defined by body mass index (BMI) of at least 30 kg/m^2 3. Diagnosis of moderate to severe obstructive sleep apnea as defined by the following: a. Apnea-hypopnea index (AHI; the number of apneas and hypopneas during an hour of sleep) greater than or equal to 15 events per hour prior to initiation of pharmacotherapy 4. Patient previously tried a weight loss treatment plan administered by a health care provider (such as diet and exercise program, nutritional counseling, and/or a calorie restricted diet) for a time period of at least three months within the previous six-month timeframe For continuation of therapy, all the following criteria must be met (Note: Medications obtained as samples, coupons, or any other method of obtaining medications outside of an established health plan benefit are NOT considered established on therapy): 1. Patient is continuing with a weight loss treatment plan (such as diet and exercise program, nutritional counseling, and/or a calorie restricted diet) 2. For patients less than 21 years of age, patient has lost at least 1% of BMI from baseline or maintained at least a 1% BMI weight loss 3. For patients 21 years of age and older, Wegovy® may be continued if all the following criteria must be met: a. Patient has established cardiovascular disease (e.g., history of myocardial infarction, stroke, or symptomatic peripheral arterial disease) b. Patient achieved and maintained at least a 5% weight loss from baseline body weight while on the requested medication 4. For patients 21 years of age and older, Zepbound® may be continued if all the following criteria must be met: a. Patient has clinical benefit from the requested agent (such as reduction in AHI)

Therapies with Prior Authorization Policies (Oncology)

7. **CALQUENCE (ACALABRUTINIB)**
    a. New indication(s) approved 01/16/2025:
        i. In combination with bendamustine and rituximab for the treatment of adult patients with previously untreated mantle cell lymphoma (MCL) who are ineligible for autologous hematopoietic stem cell transplantation (HSCT)
    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.

8. **ENHERTU (FAM-TRASTUZUMAB DERUXTECAN-NXKI)**
    a. New indication(s) approved 01/27/2025:
        i. Treatment of adult patients with unresectable or metastatic hormone receptor (HR)-positive, HER2-low (IHC 1+ or IHC 2+/ISH-) or HER2-ultralow (IHC 0 with membrane staining) breast cancer, as determined by an FDA-approved test, that has progressed on one or more endocrine therapies in the metastatic setting
    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. **LUMAKRAS (SOTORASIB)**
    a. New indication(s) approved 01/16/2025:
        i. KRAS G12C-mutated Metastatic Colorectal Cancer (mCRC) In combination with panitumumab, for the treatment of adult patients with KRAS G12C-mutated mCRC as determined by an FDA approved-test, who have received prior fluoropyrimidine-, oxaliplatin- and irinotecan-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.

10. **VECTIBIX (PANITUMUMAB)**
    a. New indication(s) approved 01/16/2025:
        i. Treatment of KRAS G12C-mutated Metastatic Colorectal Cancer (mCRC)*
            1) In combination with sotorasib, for the treatment of adult patients with KRAS G12C-mutated mCRC, as determined by an FDA-approved test, who have received prior treatment with fluoropyrimidine-, oxaliplatin-, and irinotecan-based chemotherapy
        ii. Limitations of Use: Vectibix is not indicated for the treatment of patients with RAS-mutant mCRC unless used in combination with sotorasib in KRAS G12C-mutated mCRC. Vectibix is not indicated for the treatment of patients with mCRC for whom RAS mutation status is unknown
    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. **IMFINZI** (DURVALUMAB)
    a. New indication(s) approved 12/04/2024:
        i. Treatment of adult patients with limited-stage small cell lung cancer (LS-SCLC) whose disease has not progressed following concurrent platinum-based chemotherapy and radiation therapy (cCRT) as a single agent

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. **BRAFTOVI** (ENCORAFENIB)
    a. New indication(s) approved 12/20/2024:
        i. Treatment of patients with metastatic colorectal cancer (CRC) with a BRAF V600E mutation, as detected by an FDA-approved test, in combination with cetuximab and mFOLFOX6
    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

13. **INVOKANA** (CANAGLIFLOZIN); **INVOKAMET** (CANAGLIFLOZIN AND METFORMIN); **INVOKAMET XR** (CANAGLIFLOZIN AND METFORMIN)
    a. Previous Indication(s):
        i. As an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus
        ii. To reduce the risk of major adverse cardiovascular events in adults with type 2 diabetes mellitus and established cardiovascular disease
        iii. To reduce the risk of end-stage kidney disease, doubling of serum creatinine, cardiovascular death, and hospitalization for heart failure in adults with type 2 diabetes mellitus and diabetic nephropathy with albuminuria
    b. New indication(s) approved 12/18/2024:
        i. As an adjunct to diet and exercise to improve glycemic control in pediatric patients aged 10 years and older with type 2 diabetes mellitus
    c. **RECOMMENDATION:** Inform prescribers via Medical Policy Alert.

14. **GEMTESA** (VIBEGRON)
    a. Previous Indication(s):
        i. Treatment of overactive bladder (OAB) with symptoms of urge urinary incontinence, urgency, and urinary frequency in adults
    b. New indication(s) approved 12/18/2024:
        i. Treatment of overactive bladder (OAB) with symptoms of urge urinary incontinence, urgency, and urinary frequency in adult males on pharmacological therapy for benign prostatic hyperplasia (BPH)
    c. **RECOMMENDATION:** Inform prescribers via Medical Policy Alert.

15. **ARIXTRA** (FONDAPARINUX SODIUM)
    a. Previous Indication(s):
        i. Prophylaxis of deep vein thrombosis (DVT) in adults, which may lead to pulmonary embolism (PE):
            1) in patients undergoing hip fracture surgery, including extended prophylaxis;
            2) in patients undergoing hip replacement surgery;
            3) in patients undergoing knee replacement surgery;
            4) in patients undergoing abdominal surgery who are at risk for thromboembolic complications.
        ii. Treatment of acute deep vein thrombosis in adults when administered in conjunction with warfarin sodium

iii. Treatment of acute pulmonary embolism in adults when administered in conjunction with warfarin sodium when initial therapy is administered in the hospital

b. New indication(s) approved 12/23/2024:
   i. Treatment of venous thromboembolism in pediatric patients aged 1 year or older weighing at least 10 kg
c. **RECOMMENDATION:** Inform prescribers via Medical Policy Alert.

Drug Safety Monitoring:

The following information is gathered from the United States Food and Drug Administration (FDA) database from **12/1/2024– 1/31/2025**

FDA Drug Safety Communications

1. **Drug Name:** Ocaliva (obeticholic acid)
   - **Date Posted:** 12/12/2024
   - **Safety Alert Title:** Serious liver injury being observed in patients without cirrhosis taking Ocaliva (obeticholic acid) to treat primary biliary cholangitis: Monitor liver tests often for early identification of worsening liver function
   - **Link to more information:** https://www.fda.gov/drugs/drug-safety-and-availability/serious-liver-injury-being-observed-patients-without-cirrhosis-taking-ocaliva-obeticholic-acid-treat
   - **What safety concern is FDA announcing?**
     - Based on its review of postmarket clinical trial data, the U.S. Food and Drug Administration (FDA) identified cases of serious liver injury among patients being treated for primary biliary cholangitis (PBC) with Ocaliva (obeticholic acid) who did not have cirrhosis of the liver. We previously identified that PBC patients with advanced cirrhosis were at risk of serious liver injury when taking Ocaliva and updated the prescribing information to restrict its use in these patients. FDA's review of this required clinical trial found that some cases of liver injury in patients without cirrhosis resulted in liver transplant. This risk was notably higher for patients taking Ocaliva compared with a placebo, a pill without any active medicine.
   - **What is FDA doing?**
     - FDA restricted the use of Ocaliva in patients who have PBC with advanced cirrhosis of the liver in 2021 because it can cause serious harm in those patients, adding a new Contraindication to the Ocaliva prescribing information and patient Medication Guide. However, our recent review of case reports submitted to FDA* found that some patients with PBC and advanced cirrhosis were still taking the medicine despite these restrictions.
     - We are notifying health care professionals and patients of this new safety information, and that frequent liver test monitoring is necessary to identify worsening liver function and ensure appropriate discontinuation of Ocaliva. The agency will continue to monitor the medicine's safety and will follow up if additional information becomes available.
   - **What should health care professionals do?**
     - Monitor liver tests frequently in patients being treated with Ocaliva to detect and address worsening liver function early. Based on the current data, it is not clear if this monitoring will be sufficient to address the risk of serious liver injury. Discontinue Ocaliva treatment with any evidence of liver disease progression or if efficacy is not established. Explain the signs and symptoms of worsening liver injury to patients receiving Ocaliva and direct them to contact you immediately if they develop any signs or symptoms of worsening liver injury.

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

2. **Drug Name:** Copaxone, Glatopa (glatiramer acetate)
   - **Date Posted:** 01/22/2025
   - **Safety Alert Title:** FDA adds Boxed Warning about a rare but serious allergic reaction called anaphylaxis with the multiple sclerosis medicine glatiramer acetate (Copaxone, Glatopa): Treat immediately if symptoms worsen or do not go away shortly after an injection
   - **Link to more information:** https://www.fda.gov/drugs/drug-safety-and-availability/fda-adds-boxed-warning-about-rare-serious-allergic-reaction-called-anaphylaxis-multiple-sclerosis
   - **What safety concern is FDA announcing?**
     - The U.S. Food and Drug Administration (FDA) is warning about the risk of a rare but serious allergic reaction with the medicine glatiramer acetate (Copaxone, Glatopa), which is used to treat patients with multiple sclerosis (MS). This serious allergic reaction, called anaphylaxis, can occur at any time while on treatment, after the first dose or after doses administered months or years after starting the medicine. For most patients who experienced anaphylaxis with glatiramer acetate use, the symptoms appeared within one hour of injection. In some cases, anaphylaxis resulted in hospitalization and death.
     - The initial symptoms of anaphylaxis can overlap with those of a common reaction called immediate post-injection reaction that is temporary and can start soon after a shot is given. While immediate post-injection reaction is common, anaphylaxis is rare and its symptoms are typically more severe, worsen over time, and require treatment. Patients experiencing a reaction after the medicine is administered should seek immediate medical attention if the symptoms are more than mild, get worse over time, or do not go away within a brief time. We are adding a new Boxed Warning about this risk to the glatiramer acetate prescribing information and patient Medication Guide.
   - **What is FDA doing?**
     - We are adding the risk of anaphylaxis to a new Boxed Warning, FDA's most prominent warning, and to the Warnings and Precautions section of the glatiramer acetate prescribing information. These warnings include information that anaphylaxis can occur at any time, from as early as after the first dose or after doses administered years after starting the medicine. We are also adding new recommendations for patients and health care professionals about the critical importance of quickly recognizing and treating symptoms of anaphylaxis. The updated prescribing information also instructs patients to stop taking the medicine and seek immediate medical attention by going to an emergency room or calling 911 if symptoms of anaphylaxis occur.
   - **What should health care professionals do?**
     - Health care professionals should be aware that fatal anaphylaxis has occurred with glatiramer acetate, including years after treatment has been initiated and that the symptoms of these rare anaphylactic events may overlap with those of common immediate post-injection reactions. Symptoms such as flushing, chest pain, palpitations, anxiety, shortness of breath, rash, or hives typically occur within minutes after an injection and are generally transient, self-limited, and resolve without specific treatment within 30 minutes. Those associated with anaphylaxis are typically more severe, worsen, or last longer, requiring urgent medical attention.
     - Educate patients on the signs and symptoms of anaphylaxis and immediate post-injection reactions. Instruct them to seek immediate medical attention by going to an emergency room or calling 911 if they experience any symptoms of anaphylaxis, and to contact their prescriber if they experience an immediate post-injection reaction. Do not restart the medicine in patients who experience anaphylaxis unless a clear alternative etiology is identified.
   - **Health Plan Recommendation:** Notify providers via Medical Policy Alert.

Drug Recalls/Market Withdrawals

1. **Drug Name:** Nhan Sam Tuyet Lien Truy Phong Hoan dietary supplement capsules
   - **Date of Recall:** 12/12/2024
   - **Reason for recall:** Unapproved drug with undeclared Furosemide, Dexamethasone and Chlorpheniramine
   - **Link to more information:** https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/buy-herbalcom-issues-voluntary-nationwide-recall-nhan-sam-tuyet-lien-truy-phong-hoan-capsules-due
   - **Health Plan Recommendation:** Notify providers via Medical Policy Alert.

2. **Drug Name:** Force Forever dietary supplement tablets
   - **Date of Recall:** 12/16/2024
   - **Reason for recall:** Undeclared diclofenac and dexamethasone
   - **Link to more information:** https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/gnmart-inc-issues-voluntary-nationwide-recall-force-forever-due-undeclared-drug-ingredients
   - **Health Plan Recommendation:** Notify providers via Medical Policy Alert.

3. **Drug Name:** Fouzee SugarLin Herbal Formula Herbal Dietary Supplement capsules
   - **Date of Recall:** 12/16/2024
   - **Reason for recall:** Unapproved drug with undeclared metformin and glyburide
   - **Link to more information:** https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/shoppers-plaza-issues-voluntary-nationwide-recall-fouzee-sugarlin-herbal-formula-due-presence
   - **Health Plan Recommendation:** Notify providers via Medical Policy Alert.

4. **Drug Name:** Adrenalin® Chloride Solution (EPINEPHrine nasal solution, USP)
   - **Date of Recall:** 12/20/2024
   - **Reason for recall:** Unapproved drug misbranded with a misleading label
   - **Link to more information:** https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/endo-usa-inc-issues-voluntary-nationwide-recall-adrenalinr-chloride-solution-epinephrine-nasal
   - **Health Plan Recommendation:** Notify providers via Medical Policy Alert.

5. **Drug Name:** Systane Lubricant Eye Drops Ultra PF, Single Vials On-the-Go, 25 count (Lot 10101)
   - **Date of Recall:** 12/21/2024
   - **Reason for recall:** Fungal contamination
   - **Link to more information:** https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/alcon-laboratories-issues-voluntary-nationwide-recall-one-1-lot-systane-lubricant-eye-drops-ultra-pf

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

6. **Drug Name:** one lot of PROGRAF® 0.5mg (tacrolimus) and one lot of ASTAGRAF XL® 0.5mg (tacrolimus extended-release) capsules
   - **Date of Recall:** 12/23/2024
   - **Reason for recall:** Bottles may contain empty capsules
   - **Link to more information:** https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/astellas-pharma-us-inc-issues-voluntary-nationwide-recall-one-lot-prografr-05mg-tacrolimus-and-one
   - **Health Plan Recommendation:** Notify providers via Medical Policy Alert.

7. **Drug Name:** Phenylephrine hydrochloride Injection, USP, 10 mg/ mL (Pharmacy Bulk Package; lot number 24020027; Expiry Date 12/2025)
   - **Date of Recall:** 01/24/2025
   - **Reason for recall:** Potential foreign material
   - **Link to more information:** https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/provepharm-inc-issues-voluntary-nationwide-recall-one-lot-phenylephrine-hydrochloride-injection-usp
   - **Health Plan Recommendation:** Notify providers via Medical Policy Alert.

8. **Drug Name:** Fentanyl Transdermal System 25 mcg/h transdermal patches (Lot 108319; Expiry Date 04/2027)
   - **Date of Recall:** 01/31/2025
   - **Reason for recall:** There is potential that patches could be multi-stacked, adhered one on top of the other, in a single product pouch.
   - **Link to more information:** https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/alvogen-issues-voluntary-nationwid-recall-one-lot-fentanyl-transdermal-system-25-mcgh-due-defective
   - **Health Plan Recommendation:** Notify providers via Medical Policy Alert.

Other Formulary Changes:

OTHER FORMULARY CHANGES		
Drug Name	**Action Taken**	**Policy Name**
Stelara (ustekinumab)	Remove from Commercial formulary Effective: 7/1/2025	Therapeutic Immunomodulators (TIMS)
• **Ustekinumab-aekn (Selarsdi) Syringe** • **Ustekinumab-aekn (Steqeyma) Syringe**	New Biosimilars for Stelara®; preferred products • Commercial: Formulary, Tier 5, Prior Authorization, Quantity Limit (one dose every 84 days)	Therapeutic Immunomodulators (TIMS)

	• Medicaid: Formulary, Specialty, Prior Authorization, Quantity Limit (one dose every 84 days) • Medicare: Formulary, Tier 5, Prior Authorization, Quantity Limit (one dose every 84 days) Effective: 7/1/2025	
Ustekinumab-kfce (Yesintek) Syringe/Vial	New Biosimilar for Stelara® • Commercial: Formulary, Tier 5, Prior Authorization, Quantity Limit (one dose every 84 days) • Medicaid: Formulary, Specialty, Prior Authorization, Quantity Limit (one dose every 84 days) • Medicare Part D: Non-Formulary Effective: 7/1/2025	Therapeutic Immunomodulators (TIMS)
• **Ustekinumab-auub (Wezlana) Syringe/Vial** • **Ustekinumab-aauz (Otulfi) Syringe** • **Ustekinumab-ttwe (Pyzchiva) Syringe** • **Ustekinumab ("unbranded" Stelara) Syringe & Vial**	New Biosimilars for Stelara®; Non-preferred products • Commercial/Medicaid: Non-Formulary, Specialty, Prior Authorization, Quantity Limit (one dose every 84 days) • Medicare Part D: Non-Formulary Effective: 7/1/2025	Commercial/Medicaid: Therapeutic Immunomodulators (TIMS)
Humira (adalimumab)	Remove from Commercial formulary Effective: 8/1/2025	Therapeutic Immunomodulators (TIMS)
• **Lantus 100/ml Vial** • **Lantus Solostar, Basaglar Kwikpen U-100 100/ml (3) Insuln Pen**	Add brand Lantus to Medicaid formulary Effective: 3/1/2025	N/A
Nitrofurantoin 25 mg/5 ml Oral Susp	• Commercial Standard: Formulary, Tier 2 • Commercial Dynamic: Formulary, Tier 4 • Medicaid: Formulary • Medicare Part D: Formulary, Tier 4	N/A
• **Tafamidis (Vyndamax) Capsule** • **Tafamidis meglumine (Vyndaqel) Capsule**	• Commercial: Change from Tier 6 to Tier 5	Tafamidis
Bortezomib (Boruzu) Vial	New formulation; • Commercial/Medicaid: Medical Benefit, Prior Authorization	Anti-Cancer Medications - Medical Benefit

	• Medicare Part D: Non-Formulary • Medicare Part B: Medical Benefit, Prior Authorization	
Esomeprazole magnesium Suspdr Pkt	First generic drug; • Commercial Standard: Formulary, Tier 2 • Commercial Dynamic: Formulary, Tier 4 • Medicaid/Medicare Part D: Non-Formulary	N/A
Labetalol hcl 400 mgTablet	New strength; • Non-formulary for all lines of business	N/A
Metformin hcl Tablet	New strength; • Non-formulary for all lines of business	N/A
Metronidazole 125 mg Tablet	New strength; • Non-formulary for all lines of business	N/A
Ocrelizumab-hyaluronidase-ocsq (Ocrevus Zunovo) Vial	New entity; • Commercial/Medicaid: Medical Benefit, Prior Authorization • Medicare Part D: Non-Formulary • Medicare Part B: Medical Benefit, Prior Authorization:	Medically Administered Multiple Sclerosis Agents
Letermovir (Prevymis) Pellet Pack	New formulation; • Commercial: Formulary, Tier 6, Prior Authorization, Quantity Limit (4 pellet packs per day) • Medicaid: Formulary, Specialty, Quantity Limit (4 pellet packs per day) • Medicare Part D: Formulary, Tier 6, Prior Authorization, Quantity Limit (4 pellet packs per day)	Prevymis
Prucalopride succinate Tablet	First Generic Drug (Motegrity); • Commercial: Formulary, Tier 4, Prior Authorization • Medicaid: Non- Formulary, Prior Authorization • Medicare Part D: Non- Formulary Effective: 5/1/2025	Constipation Agents
Pilocarpine hcl (Qlosi) Droperette	New entity;	• Commercial/Medicaid: Vuity • Medicare Part D: N/A

	• Commercial/Medicaid: Non-Formulary, Prior Authorization • Medicare Part D: Non-Formulary	
Adalimumab-ryvk (Simlandi(CF)) Syringekit	New Formulation; • Commercial: Formulary, Tier 5, Prior Authorization, Quantity Limit (two syringes per 28 days) • Medicaid: Formulary, Specialty, Prior Authorization, Quantity Limit (two syringes per 28 days) • Medicare: Non-Formulary	Commercial/Medicaid: Therapeutic Immunomodulators (TIMS)
Topiramate Cap Sprink	New strength; • Commercial: Formulary, Tier 2 • Medicaid: Formulary • Medicare Part D: Formulary, Tier 2	N/A
Tramadol hcl 75 mg Tablet	New strength; • Non-formulary for all lines of business	N/A
Vigabatrin (Vigafyde) Solution	New formulation; • Commercial/Medicaid: Non-Formulary, Specialty • Medicare Part D: Formulary, Tier 5, Step Therapy, Quantity Limit (30 mL per day)	N/A
Corticotropin (Acthar Selfject) Pen Injctr	Remove from Medicaid formulary	HP Acthar Gel
Tesamorelin acetate (Egrifta SV) Vial	Remove from Commercial and Medicaid formularies	N/A
• **Semaglutide (Ozempic) Pen Injector** • **Semaglutide (Rybelsus) Tablet**	Remove from Medicaid formulary (non-preferred products)	GIP and GLP-1 Receptor Agonists
Sitagliptin (Zituvio) Tablet	• Commercial: Add to Formulary, Tier 2, Quantity Limit (1 tablet per day) • Medicaid: Add to Formulary, Quantity Limit (1 tablet per day)	N/A
Imatinib (Imkeldi) oral solution	New Formulation • Commercial/Medicaid: Non-Formulary, Prior Authorization • Medicare Part D: Non-Formulary	Anti-Cancer Medications – Self-Administered
• **Vraylar (cariprazine) capsule** • **Rexulti (brexpiprazole) tablet**	Commercial: Move to Tier 3 (from Tier 4), Prior Authorization and Quantity Limits continue to apply	Antipsychotics

• Lybalvi (olanzapine/samidorphan) tablet • Cobenfy (xanomeline/trospium chloride) capsule		

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

INFORMATIONAL ONLY

NEW DRUGS / COMBINATIONS / STRENGTHS / DOSAGE FORMS		
Drug Name	**Action Taken**	**Policy Name**
Bimekizumab-bkzx (Bimzelx) Auto Injct / Syringe	New strength. Line extend with Bimzelx Autoinjector; • Commercial/Medicaid: Non-Formulary, Prior Authorization, Quantity Limit (2 mL per 56 days), Specialty • Medicare Part D: Non-Formulary	• Commercial/Medicaid: Therapeutic Immunomodulators (TIMS) • Medicare Part D: N/A
Nivolumab-hyaluronidase-nvhy (Opdivo Qvantig) Vial	New entity. Line extend with Opdivo; • Commercial/Medicaid: Medical Benefit, Prior Authorization • Medicare Part D: Non-Formulary • Medicare Part B: Medical Benefit, Prior Authorization	Anti-Cancer Medications - Medical Benefit
Fenoprofen calcium (Fenopron) Capsule	New Med ID. Line Extend with Nalfon; • Non-Formulary for all lines of business	N/A
Risdiplam (Evrysdi) Tablet	New formulation. Line extend with Evrysdi; • Commercial/Medicaid: Non-Formulary, Prior Authorization, Specialty • Medicare Part D: Non-Formulary	• Commercial/Medicaid: Therapies for Spinal Muscular Atrophy • Medicare Part D: N/A
Norethindrone-e.estradiol-iron (Feirza) Tablet	New MedID. Line extend with other generics; • Commercial: Formulary, Tier 2 • Medicaid: Formulary • Medicare Part D: Non-Formulary	N/A
Peanut allergen powder-dnfp (Palforzia) Cap Sprink	New strength. Line extend with Palforzia; • Commercial/Medicaid: Non-Formulary, Prior Authorization • Medicare Part D: Non-Formulary	• Commercial/Medicaid: Palforzia • Medicare Part D: N/A
Ethynodiol d-ethinyl estradiol (Valtya) Tablet	New MedID. Line extend with other generics; • Commercial: Formulary, Tier 2 • Medicaid: Formulary	N/A

NEW DRUGS / COMBINATIONS / STRENGTHS / DOSAGE FORMS		
Drug Name	**Action Taken**	**Policy Name**
	• Medicare Part D: Non- Formulary	
Patiromer calcium sorbitex (Veltassa) Powd Pack	New strength. Line extend with Veltassa; • Commercial/Medicare Part D: Formulary, Tier 3 • Medicaid: Formulary	N/A

New Generics:

NEW GENERICS		
Drug Name	**Action Taken**	**Policy Name**
Memantine hcl-donepezil hcl ER Cap Spr 24	First generic drug. Line extend with Namzaric; • Commercial/Medicaid: Non-Formulary • Medicare Part D: Formulary, Tier 4, Quantity Limit (one capsule per day	• N/A
Levetiracetam Tab Susp	First generic drug (Spritam). Line extend with Spritam; • Commercial/Medicaid: Non-Formulary, Prior Authorization • Medicare Part D: Formulary, Tier 4, Step Therapy	• Commercial/Medicaid: New Medications and Formulations without Established Benefit • Medicare Part D: Antiepileptic Agents
Lactulose Packet	First generic drug (KRISTALOSE). Line extend as generic; • Non-Formulary for all lines of business	• N/A

Clinical Policy Changes:

PHARMACY CLINICAL POLICIES – MAJOR CHANGES	
Policy Name	**Summary of Change**
Anti-Cancer Medications - Medical Benefit	Step criteria added to policy for bortezomib (Boruzu) requests to step through bortezomib (Velcade) due to similar efficacy/safety, but higher cost of Boruzu.
Anti-Cancer Medications - Self-Administered	Added exception to Ibrance criteria (requiring step therapy) when used with Itovebi in alignment with FDA labeling.

Antipsychotics	Updated criteria to only require trial and failure of one atypical antipsychotic prior to coverage. Added additional criteria for Fanapt® to require and additional trial of two brand atypical antipsychotic agents.
Disposable Insulin Pumps	Preferred pumps (Ominpod) will now automatically process at point-of-sale with history of claims for rapid- or short-acting insulin claims.
DPP-4 Inhibitors Step Therapy Policy	Criteria were updated to prefer any generic DPP-4 inhibitor prior to coverage of branded products. Added quantity limits and an exclusion for use in combination with GLP-1 therapies (such as semaglutide).
Fertility and Related Medications	Clomiphene removed from policy as it will be reviewed as non-formulary (for medical necessity) to allow for coverage of compendial supported indications outside of fertility.
GIP and GLP-1 Receptor Agonists	Removed trial and failure of metformin and clarified diagnostic criteria for type 2 diabetes (such as history of A1C >6.5%). Added exclusions for autoimmune diabetes and concomitant use with dipeptidyl peptidase-4 inhibitors and other GIP/GLP agonists.
GnRH Antagonists	Updated prerequisite therapy criteria, removed undiagnosed abnormal uterine bleeding exclusion, and added exclusion for using multiple therapies due to lack of evidence for long-term use.
Human Growth Hormones - Medicaid	Updated growth hormone stimulation test requirements for diagnosing pediatrics growth hormone deficiency.
Infusion Therapy Site of Care	Removed drugs from the policy: Camcevi, Eligard, Lupron Depot, and Fensolvi
Kerendia	Remove laboratory requirements and trial of sodium glucose co-transporter-2.
• **Medical Hormone Therapy Policy** • **Medical Hormone Therapy Prior Authorization and Step Therapy Policy – Medicare Part B**	Added indication of delayed puberty for testosterone pellet (Testopel®) which may be covered after failure of testosterone enanthate.
Medical Nutrition – Commercial	Removed exclusion for use of oral nutritional products, as if patients meet medical necessity criteria, coverage for any nutritional products would be allowed.
Medical Nutrition – Medicaid	Updated Medicaid covered indications to include select physical and intellectual disabilities.
Osteoanabolic Agents Prior Authorization and Step Therapy Policy - Medicare Part B	Added exclusion for concurrent use of similar agents.
Palynziq	Decreased reauthorization duration from long-term authorization (until no longer eligible with the plan, subject to formulary and/or benefit changes) to one year.
Self-Administered Drugs (SAD) Policy	Several drugs added to this policy: Zymfentra, Takhzyro, Ebglyss, Nemluvio, Tryngolza, Yorvipath, Winrevair, Tofidence, Stegeyma, Entyvio Pen, and Zilbrysq.
Spravato	Updated billing and coding information for clarity.
Tolvaptan	Revised diagnostic criteria for rapidly progressive disease per new 2025 KDIGO ADPKD guidelines.
Tzield	Updated exclusion criteria as well as updated policy criteria to have more clear language and to align with Oregon Health Plan criteria.
Vaginal Progesterone Formulations	Updated criteria for secondary amenorrhea to require a trial of formulary progestins approved for secondary amenorrhea (such as medroxyprogesterone, norethindrone).
Vijoice	Simplified diagnostic criteria to require genetic mutation OR onset/overgrowth/spectrum of isolated features, clarified provider specialist options.

Yorvipath Policy	Removed criteria requiring recent normal vitamin D and albumin-adjusted serum calcium levels, as patients who cannot achieve albumin-adjusted serum calcium greater than or equal to 7.8 mg/dL are those most likely to benefit from therapy.

Retired Policies:

Policy Name	Summary of Change
Apidra	Policy retired due to low risk of inappropriate utilization.
Egrifta	Policy retired and medication removed from the formulary due to low utilization for rare disease state.
Revcovi	Retired policy and added drug to the Enzyme Replacement Therapy policy. Adding prior authorization to Medicare