Providence Health Plan

Providence Health Assurance

Healthcare Services Medical & Pharmacy Policy Alerts

Number 106

May 1, 2025

This is the May 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.

Providence Health Plan

Providence Health Assurance

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.

MEDICAL

COMPANY POLICIES

Effective 6/1/2025

Thyroid Testing **MP206**	**Policy Updates:** Several new codes were added to pair-to-pay configuration per updates from CMS. **Codes/PA:** Updates to pair-to-pay configuration. We now allow the following when billed for thyroid testing: - E10.A0: Type 1 diabetes mellitus, presymptomatic, unspecified - E10.A1: Type 1 diabetes mellitus, presymptomatic, Stage 1 - E10.A2: Type 1 diabetes mellitus, presymptomatic, Stage 2 - L66.81: Central centrifugal cicatricial alopecia - L66.89: Other cicatricial alopecia - T45.AX1A: Poisoning by immune checkpoint inhibitors and immunostimulant drugs, accidental (unintentional), initial encounter - T45.AX2A: Poisoning by immune checkpoint inhibitors and immunostimulant drugs, intentional self-harm, initial encounter - T45.AX3A: Poisoning by immune checkpoint inhibitors and immunostimulant drugs, assault, initial encounter - T45.AX4A: Poisoning by immune checkpoint inhibitors and immunostimulant drugs, undetermined, initial encounter - T45.AX5A: Adverse effect of immune checkpoint inhibitors and immunostimulant drugs, initial encounter - Z92.26: Long-term (current) use of immunosuppressive drugs. **OHP:** These changes do not apply to OHP. The Prioritized List and the Oregon Administrative Rules will be followed.

Sleep Disorder Treatment with Oral and Sleep Position Appliances **MP46**	**Policy Updates:** • For patients with moderate OSA, the requirement that patients must undergo a CPAP trial before becoming eligible for a sleep oral appliance (OA) was removed. Trial requirement will continue for patients with severe OSA. **Codes/PA:** No changes **OHP:** These changes do not apply to OHP. The Prioritized List and the Oregon Administrative Rules will be followed.
Stem Cell Therapy for Orthopedic Indications **MP36**	**Policy Updates:** No changes. **Codes/PA:** Removed CPT 20939 from policy; code will deny "not medically necessary" per "Spinal Fusion and Decompression Procedures" policy. **OHP:** These changes do not apply to OHP. The Prioritized List and the Oregon Administrative Rules will be followed.
Total Shoulder Arthroplasty **MP430**	**Policy Updates:** Policy approved in March. Now adding CPT codes for revision arthroplasty to coding table. (CPT 23473, 23474) **Codes/PA**: Added PA to CPT 23473 and 23474 for medical necessity review **OHP:** These changes do not apply to OHP. The Prioritized List and the Oregon Administrative Rules will be followed.

Effective 7/1/2025

Knee Arthroscopy and Meniscal Repair	**New Policy** **Policy Updates:** New policy based on InterQual criteria for knee arthroscopy and arthroscopically assisted knee surgeries. **Codes/PA:** Prior authorization will be required as of 7/1/25 for all applicable CPT codes. **OHP:** These changes do not apply to OHP. The Prioritized List and the Oregon Administrative Rules will be followed.
Shoulder Arthroscopy and Open Procedures	**New Policy** **Policy Updates:** New policy for select arthroscopic and open procedures for the shoulder. These include: • Rotator cuff repair • Labral tear repair • Debridement • Capsulorrhaphy • Claviculectomy

	• Lysis/capsular release • Biceps tenodesis and tenotomy **Codes/PA:** Prior authorization will be required as of 7/1/25 for all applicable CPT codes. **OHP:** These changes do not apply to OHP. The Prioritized List and the Oregon Administrative Rules will be followed.
Small Joint Surgery	**New Policy** **Policy Updates:** New policy for select small joint arthroscopic and open procedures. These include: • Ankle arthroplasty • Ankle arthroscopy • Foot/toe arthroplasties **Codes/PA:** Prior authorization will be required as of 7/1/25 for all applicable CPT codes. **OHP:** These changes do not apply to OHP. The Prioritized List and the Oregon Administrative Rules will be followed.
Elbow and Wrist Arthroplasty	**New Policy** **Policy Updates:** New policy based on InterQual criteria for elbow and wrist arthroplasty. **Codes/PA:** Prior authorization will be required as of 7/1/25 for all applicable CPT codes. **OHP:** These changes do not apply to OHP. The Prioritized List and the Oregon Administrative Rules will be followed.
Temporomandibular Joint (TMJ) Arthroplasty	**New Policy** **Policy Updates:** New policy based on InterQual criteria for temporomandibular joint (TMJ) arthroplasty. **Codes/PA:** Prior authorization will be required as of 7/1/25 for all applicable CPT codes. **OHP:** These changes do not apply to OHP. The Prioritized List and the Oregon Administrative Rules will be followed.
Vitamin D Assay Testing **MP94**	**Policy Updates:** Updated "Billing Guidelines" to clarify that at least one more specific dx code should be billed instead of E55.9 (vitamin D deficiency, unspecified), which will now be considered "not medically necessary" when billed alone. **Codes/PA:** Removed dx code E55.9 (vitamin D deficiency, unspecified) from pair-to-pay configuration with CPT 82306. **OHP:** These changes do not apply to OHP. The Prioritized List and the Oregon Administrative Rules will be followed.

Breast Reconstructive Surgery, Implant Management and Reduction Mammoplasty **MP58**	**Policy Updates:** ○ Criterion V - added criteria clarifying that replacement of cosmetically-placed implants is considered not medically necessary. ○ Criteria XI - added medical necessity criteria for gynecomastia surgery. **Codes/PA:** Added PA to CPT 19300 (surgery for gynecomastia) **OHP:** These changes do not apply to OHP. The Prioritized List and the Oregon Administrative Rules will be followed.
Cosmetic and Reconstructive Procedures **MP98**	**Policy Updates:** Removed gynecomastia from list of cosmetic procedures. Updated language in "notes" section of criteria; no substantive changes to content. **Codes/PA:** Removed CPT 19300 from policy; added PA per "Breast Reconstructive Surgery" policy. **OHP:** These changes do not apply to OHP. The Prioritized List and the Oregon Administrative Rules will be followed.
Ablative Procedures to Treat Back and Neck Pain **MP21**	**Policy Updates:** • Clarified note re: repeat diagnostic blocks: "Repeat diagnostic blocks are required if: More than 2 years have passed since the previous radiofrequency ablation (RFA); or there is uncertainty about the source of the recurrent pain." **Codes/PA:** No changes **OHP:** These changes do not apply to OHP. The Prioritized List and the Oregon Administrative Rules will be followed.
Sleep Disorder Treatment with Positive Airway Pressure **MP46**	**Policy Updates:** • The following indication is no longer eligible for home titration with APAP (criterion I.) or initial trial of CPAP/APAP (criterion IV.): excessive daytime sleepiness (defined as an Epworth Sleepiness Scale [ESS] score ≥ 10. • The following indication will now be eligible for home titration with APAP (criterion I.) or initial trial of CPAP/APAP (criterion IV.): parasomnias and periodic limb movement disorders. **Codes/PA:** No changes **OHP:** These changes do not apply to OHP. The Prioritized List and the Oregon Administrative Rules will be followed.

ARCHIVE

Effective 5/1/2025

Discography **MP11**	**Policy Updates:** Archived policy due to minimal utilization **Codes/PA:** Removed configuration from codes. **OHP:** These changes do not apply to OHP. The Prioritized List and the Oregon Administrative Rules will be followed.
Home Oxygen Equipment and Supplies **MP88**	**Policy Updates:** Archived policy due to low denials based on medical policy. **Codes/PA:** Removed NMN configuration from A4575 and E0446 **OHP:** These changes do not apply to OHP. The Prioritized List and the Oregon Administrative Rules will be followed.

MEDICARE POLICIES

Effective 6/1/2025

Protein Biomarker and Genetic Testing for the Prostate **MP95**	**Policy Updates:** No change to criteria. **Codes/PA:** Due to high approval rates, recommend removal of PA for CPT 81542. All claims/PAs were submitted with a medically necessary dx code, and thus, no value to add dx code configuration. No change to configuration for other codes at this time.
Stem Cell Therapy for Orthopedic Applications **MP372**	**Policy Updates:** No change to criteria, continue to use Medicare coverage policy criteria when available, or Company criteria when no Medicare criteria exists, as directed by the policy. **Codes/PA:** Removed CPT 20939 from scope of policy
Total Shoulder Arthroplasty **MP523**	**Policy Updates:** New policy for total shoulder arthroplasty (TSA), initially approved in March. At the time, revision procedure and their associated codes were not included. As with initial TSA procedures, due to the absence of Medicare coverage policy for our service area (no NCD, no LCD), internal Company coverage criteria will be used, which is based on third-party vendor (InterQual®) criteria. **Codes/PA:** CPT 23473 and 23474: Added PA for all sites of service. No change to codes already in the policy and approved.

Effective 7/1/25

Knee Arthroscopy and Meniscal Repair	**New Policy** **Policy Updates:** New policy based on InterQual criteria for knee arthroscopy and arthroscopically assisted knee surgeries. **Codes/PA:** Prior authorization will be required as of 7/1/25 for all applicable CPT codes.
Shoulder Arthroscopy and Open Procedures	**New Policy** **Policy Updates:** New policy for select arthroscopic and open procedures for the shoulder. These include: • Rotator cuff repair • Labral tear repair • Debridement • Capsulorrhaphy • Claviculectomy • Lysis/capsular release • Biceps tenodesis and tenotomy **Codes/PA:** Prior authorization will be required as of 7/1/25 for all applicable CPT codes.
Small Joint Surgery	**New Policy** **Policy Updates:** New policy for select small joint arthroscopic and open procedures. These include: • Ankle arthroplasty • Ankle arthroscopy • Foot/toe arthroplasties **Codes/PA:** Prior authorization will be required as of 7/1/25 for all applicable CPT codes.
Elbow and Wrist Arthroplasty	**New Policy** **Policy Updates:** New policy based on InterQual criteria for elbow and wrist arthroplasty. **Codes/PA:** Prior authorization will be required as of 7/1/25 for all applicable CPT codes.
Temporomandibular Joint (TMJ) Arthroplasty	**New Policy** **Policy Updates:** New policy based on InterQual criteria for temporomandibular joint (TMJ) arthroplasty. **Codes/PA:** Prior authorization will be required as of 7/1/25 for all applicable CPT codes.

ARCHIVE

Effective 5/1/25

Discography **MP291**	**Policy Updates:** Archived policy. **Codes/PA:** Removed medical policy configuration from codes.
Home Oxygen Equipment and Supplies **MP292**	**Policy Updates:** Archived policy. **Codes/PA:** No change to code configuration. Transfered topical oxygen (O2) codes to NET policy for Medicare to continue NMN, and for all other codes, there is no configuration to update.

REIMBURSEMENT POLICIES

Effective 7/1/25

Inpatient Hospital Readmissions	**Reimbursement Policy Update** • For DRG and modified DRG reimbursed facilities, inpatient hospital readmissions **will be considered a continuation of the initial treatment** and **combined into a single DRG payment** when: o The readmission occurs less than 31 calendar days* from the date of the previous inpatient discharge (neither the day of discharge nor the day of admission is counted when determining whether a readmission has occurred); **and** o The admissions occurred at the *same,* acute, general, short-term hospital or *another* acute, general, short-term hospital that has the same Tax ID number, is under common ownership as the initial facility, and operates under the same facility contract; **and** ▪ Clinical review determines the readmission is for a same, similar, or related condition treated during the previous admission. • ***(Change) When these criteria are met, The Plan will combine readmissions regardless of whether it was due to premature discharge or could have been prevented. Readmissions for related conditions will be considered a continuation of treatment from the previous admission and combined into a single DRG payment.***

	• No other policy changes.

Intraocular Lenses (IOLs)
 	
RP17
	New Reimbursement Policy
	Recommendation: New reimbursement policy for all lines of business except Medicaid/OHP to address inappropriate billing practices for Intraocular lenses (IOLs), as well as address the ineligibility of some IOLs as non-covered member benefits and educate providers on how to submit claims to still allow a portion of the costs.
	• This used to be part of a Payment Policy, which then was converted to what is now the *Facility Routine Supplies and Services* policy, but details specific to IOLs have been removed.
	• Two different issues have been observed regarding these services:
	  ○ **Benefits:** Certain IOLs are **not** covered for either Medicare Advantage or non-Medicare LOBs. The "not covered service" benefit configuration (NCSE) was accidentally removed back in 2022 and now the NCSE set-up will be put back on these codes.
	  ▪ Members may still obtain these premium IOLs if they choose, and the plan will pay the amount allowed for the conventional/standard types. However, the member is responsible for the difference.
	  ○ **Billing:** To align billing practices across all relevant LOBs with this benefit exclusion, billing expectations will follow Medicare, unless provider contract language indicates otherwise. This includes:
	  ▪ HCPCS codes V2787 and V2788 represent the astigmatism correcting and presbyopia correcting **function** of an intraocular lens, respectively. They do **not** represent an IOL in its entirety and should not be billed as such.
	  ▪ Physicians should not be billing for the IOL implant (V-code) when the procedure is performed at a **facility** (ASC or hospital), regardless of whether the facility bills the V-code or not. This practice is **not** allowed under Medicare. It is seen as a compliance issue because the cost of the IOL is already "packaged" into the ASC rate for the surgical procedure (in other words, the ASC and hospital rates for cataract surgery is increased by CMS to include the cost of an IOL, so when the physician *also* bills for these IOLs, PHP is essentially double paying for the implant).
	  ▪ By a surgeon reporting a V-code instead of or in addition to the professional cataract procedures they provided, this is not only a significant cost to the plan but also creates increased member liability amounts.
	  ▪ If patterns in other billing practices are observed in the future, then additional research, policy revisions, and possibly code configuration may address these.
	• **Policy Scope:** This policy does not address femto laser-assisted surgery (aka, femtosecond laser), nor does it include new technology IOLs (NTIOLs) (C1780).
	Reimbursement Methodology: Changes to current reimbursement methodology are addressed above, but in summary:
	• All claims are subject to member benefits.
	• Physicians performing cataract surgery with IOLs in a facility are not allowed to bill for the implant. They may only submit a claim for the cataract surgery they personally performed.
	• Facilities may submit claims for IOLs in the same manner they would bill Medicare, unless their contract indicates otherwise.

	• Some provider contracts may have pricing for V-codes included when there is no CMS pricing, but member benefit exclusions will take precedent over provider contract language. • HCPCS codes V2787 and V2788 represent the astigmatism correcting and presbyopia correcting **function** of an intraocular lens, respectively, so billed amounts should only be the difference in cost between the conventional IOLs and these premium IOLs. **Relevant CMS References:** • 2005 CMS Rulings, No. CMS-05-01 • 2007 CMS Rulings, No. CMS-1536-R • Medicare Claims Processing Manual, Ch. 20, §90 • Noridian Local Coverage Determination (LCD) for Cataract Surgery in Adults (L37027) • Medicare National Coverage Determination (NCD) for Intraocular Lenses (IOLs) (80.12) • Medicare Benefit Policy Manual, Ch. 16, §90 • CMS Recognized Presbyopia-Correcting (PC) IOLs and Astigmatism-Correcting (AC) IOLs. • CMS Pub 100-04, Transmittal 1430, CR5853 • Medicare Vision Services. MLN907165 • CMS Pub 100-04, Transmittal 1228, CR 5527 • Medlearn Matters Number: MM3927 • Medicare Claims Processing Manual, Ch. 32, §120 • Medicare Claims Processing Manual, Ch. 4, §240.3

High-Dollar Charge Validation Using Facility CDM	**New Reimbursement Policy**
	Policy Update:
	• Providence Health Plan reserves the right to reprice high-dollar facility services when submitted charges do not align with the facility's Charge Description Master (CDM).
	• Items or services may be selected for high-cost review when **both** of the following (A. and B.) criteria are met:
	  ○ Billed on an inpatient or outpatient facility claim with supporting revenue codes, CPT, and/or HCPCS codes; **and**
	  ○ The billed charges for the item or service meets or exceeds $10,000.
	• If the billed charges for the items or services selected for review based on criterion II. exceed the pricing listed on the facility CDM, the **reimbursement will be reduced to the facility CDM pricing**.
	  ○ *In order to be considered for reimbursement, a corrected claim or additional facility documentation to support the reasonableness of the charges submitted will be required.*

Inpatient Acuity Level	**New Reimbursement Policy** **Policy Update:** • Claims for inpatient stays may be subject to clinical review to determine if the appropriate acuity level was used throughout the duration of the stay. • The policy is based on the following clinical and billing/coding guidelines:

	1. Nates, J. L., Nunnally, M., Kleinpell, R., Blosser, S., Goldner, J., Birriel, B., Fowler, C. S., Byrum, D., Miles, W. S., Bailey, H., & Sprung, C. L. (2016). ICU Admission, Discharge, and Triage Guidelines: A framework to enhance clinical operations, development of institutional policies, and further research. *Critical Care Medicine*, *44*(8), 1553–1602. 2. InterQual® 2024 Level of Care Criteria - Acute Adult. 3. *(NICU only)* National Uniform Billing Committee (NUBC) Official UB-04 Data Specifications Manual; 2025 e-book. • If clinical review determines an acuity level is not supported by the documentation, **room and board reimbursement will be reduced** using one of the following methods: A. If the lower acuity level is already reported on the itemized statement for the inpatient stay, the reimbursement for each day of the unsupported high-acuity level will be reduced to this amount; **or** B. If the lower acuity level is not already reported on the itemized statement for the inpatient stay, the reimbursement for each day of the unsupported high-acuity level will be reduced by a pre-determined percentage based on average revenue code reimbursement rates for that facility.

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

Providence Health Plan

Providence Health Assurance

Table of Contents:

- New Drugs and Combinations
- New Indications Monitoring
- Drug Safety Monitoring
- Other Formulary Changes
- Clinical Policy Changes

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) • 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	Therapeutic Immunomodulators (TIMS)
Ustekinumab-kfce (Yesintek) Syringe/Vial	New Biosimilar for Stelara® • 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 Part D: Non-Formulary Effective: 7/1/2025	
• **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 • Medicare Part D: Non-Formulary • Medicare Part B: Medical Benefit, Prior Authorization	Anti-Cancer Medications - Medical Benefit
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;	N/A

	• Non-formulary for all lines of business	
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: Non-Formulary, Prior Authorization • Medicare Part D: Non-Formulary	• Commercial/Medicaid: Vuity • Medicare Part D: N/A
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;	N/A

	• Commercial: Formulary, Tier 2 • Medicaid: Formulary • Medicare Part D: Formulary, Tier 2	
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** • **Lybalvi (olanzapine/samidorphan) tablet** • **Cobenfy (xanomeline/trospium chloride) capsule**	Commercial: Move to Tier 3 (from Tier 4), Prior Authorization and Quantity Limits continue to apply	Antipsychotics

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: Therapeutic Immunomodulators (TIMS) • Medicare Part D: N/A

NEW DRUGS / COMBINATIONS / STRENGTHS / DOSAGE FORMS		
Drug Name	**Action Taken**	**Policy Name**
	• Commercial/Medicaid: Non-Formulary, Prior Authorization, Quantity Limit (2 mL per 56 days), Specialty • Medicare Part D: Non-Formulary	
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 • Medicare Part D: Non- Formulary	N/A
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