Providence Health Plan

Providence Health Assurance

Healthcare Services Medical & Pharmacy Policy Alerts

Number 86

September 1, 2023

This is the September 1, 2023 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

MEDICAL

COMPANY POLICIES

Effective 9/1/2023

Back: Implantable Spinal Cord and Dorsal Root Ganglion Stimulation **MP28**	**Policy Updates:** • Liberalize coverage to allow dorsal root ganglion stimulation when criterion VI. are met. • Liberalize coverage to allow spinal cord stimulation for CRPS type II when criteria are met. **Codes/PA:** • No changes to codes or PA; relevant codes already require PA. **OHP:** OHP will follow the Company Policy above

Effective 10/1/2023

Genetic Testing: Whole Exome, Whole Genome and Proteogenomic Testing
 	
MP219
	Policy Updates: Inclusion of criteria for mitochondrial genome testing
	Codes/PA:
	• Inclusion of 81440 & 81465 as PA, inclusion of 81460 as no PA
	• For Q4 2023 code updates
	  • New codes- set to deny as NMN: 0410U, 0413U
	  • New code- set to PA: 0417U
	
	OHP: These changes do not apply to OHP. The Prioritized List and the Oregon Administrative Rules will be followed.

Effective 11/1/2023

Magnetic Resonance guided Focused Ultrasound Surgery (MRgFUS) **MP347**	**Policy Updates:** Update investigational noncoverage to NMN. **Codes/PA:** Update 0071T & 0072 from E/I to NMN. **OHP:** These changes do not apply to OHP. The Prioritized List and the Oregon Administrative Rules will be followed.
Apheresis (Therapeutic Pheresis) **MP305**	**Policy Updates:** Update investigational noncoverage to NMN. **Codes/PA:** Update 0071T & 0072 from E/I to NMN. **OHP:** These changes do not apply to OHP. The Prioritized List and the Oregon Administrative Rules will be followed
Inflammatory Bowel Disease: Serologic Testing and Therapeutic Monitoring **MP218**	**Policy Updates:** Change denial type from investigational to "not medically necessary." **Codes/PA:** Configure 0034U, 0169U, 0286U to deny as "not medically necessary." **OHP:** These changes do not apply to OHP. The Prioritized List and the Oregon Administrative Rules will be followed.
Bone-Anchored Hearing Aids **MP398**	**Policy Updates:** • Add prior authorization requirements to bone-anchored hearing aids (BAHAs), considered medically necessary when criteria are met. • Change denial type from "investigational" to "not medically necessary." **Codes/PA:** • Add prior authorization to multiple codes for BAHAs. • **OHP:** These changes do not apply to OHP. The Prioritized List and the Oregon Administrative Rules will be followed.
Genetic Testing: CADASIL Disease **MP238**	**Policy Updates:** Add criterion V: "Repeat testing of the same germline content for the same genetic information is considered not medically necessary." **Codes/PA:** No changes to coding or PA **OHP:** OHP will follow the Company Policy above

Non-small Cell Lung Cancer: Tumor Testing for Targeted Therapy **MP194**	**Policy Updates:** Criteria added for repeat testing (NMN) **Codes/PA:** No changes **OHP:** OHP will follow the Company Policy above
Genetic Testing: Whole Exome, Whole Genome and Proteogenomic Testing **MP219**	**Policy Updates:** Update MELAS code (81460) as PA for consistency with other mitochondrial genome testing codes (now all PA) **Codes/PA:** Update 81460 to PA **OHP:** These changes do not apply to OHP. The Prioritized List and the Oregon Administrative Rules will be followed.
High-Intensity Focused Ultrasound (HIFU) **MP199** Previously*: Prostate: High-Intensity Focused Ultrasound (HIFU)*	**Policy Updates:** • Remove "Prostate" from title to reflect policy's broadened scope. • Liberalize coverage to allow HIFU for pain palliation of pancreatic adenocarcinoma when criteria are met. • Change denial type from "investigational" to "not medically necessary." **Codes/PA:** No changes to codes/PA. **OHP:** These changes do not apply to OHP. The Prioritized List and the Oregon Administrative Rules will be followed

Providence Health Plan

Providence Health Assurance

MEDICARE

Effective 11/1/23

Bone-Anchored Hearing Aids **MP399**	**Policy Updates:** New Medicare Advantage medical policy. While Medicare generally excludes hearing aids, some hearing devices, such as osseointegrated implants and cochlear implants, are treated as prosthetics under the Medicare program. Apply Medicare guidance for the implantation of osseointegrated hearing devices (aka bone-anchored hearing aids or BAHA), as well as their replacement, upgrade and removal. ***NOTE:*** *Cochlear implant devices are addressed in a separate Medicare medical policy, while coverage of other hearing aids (e.g., air conduction and bone conduction) are managed via member supplemental benefits.* **Codes/PA:** Codes relevant to BAHA insertion, removal, and replacement will be added to the new policy, but not all will have configuration changes. These include: • CPT 69714, 69716, 69717, 69719, 69726, 69727, 69728, 69729, 69730 • HCPCS L8618, L8621, L8624, L8625, L8690, L8691, L8692, L8693, L8694 ****:*** *Some HCPCS codes may be used for components or accessories associated with* ***either*** *BAHA devices* ***OR*** *cochlear implants. Therefore, claim and PA data for these HCPCS codes may not represent true utilization for only BAHA devices, but rather, could represent utilization for items already managed using the cochlear implant medical policies. In addition, some codes do not require PA today and will continue to not require PA, even with this new policy (e.g., codes for replacement batteries, etc.).*
Diabetes: Blood Glucose Monitor and Supplies **MP276**	**Policy Updates:** No change to *existing* criteria, continue to use NCD 40.2, LCD L33822, and LCA A52464 for initial provision of blood glucose monitor and supplies. Add Medicare guidance for replacement of BGM and supplies, as described by Medicare Benefit Policy Manual, Chapter 15. While technically the criteria used for replacement requests today isn't changing, we will provide 60-day notice for the updated policy version. **Codes/PA:** No change to codes or configuration.
Walkers **MP211**	**Policy Updates:** Add Medicare guidance for replacement of walkers and components, as described by Medicare Benefit Policy Manual, Chapter 15. While technically the criteria used for replacement requests today isn't changing, we will provide 60-day notice for the updated policy version. **Codes/PA:** No change 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 August 4, 2023

Go-Live Date: Sunday, October 01, 2023, unless otherwise noted

Special Announcement: Please note that the health plan will be requiring the submission of National Drug Codes (NDCs) with all provider drug claims and hospital outpatient facility claims that are reported for reimbursement, effective November 1st 2023. The NDC must represent the code of the actual administered drug for the date of service. Please see the operational policy titled "Brand Drug Definition, Benefit Administration and Payment Policy (ORPTCOPS079)" for additional information.

NDCs are the industry standard identifier for drugs and provide full transparency to the medication administered. The NDC identifies the manufacturer, drug name, dosage, strength, package size and quantity. For purposes of this policy, a valid NDC number, NDC unit of measure and NDC units dispensed for the drug administered will be required for reimbursement of professional drug claims on a 1500 Health Insurance Claim Form (CMS-1500), the 837-professional transaction, a UB-04 Claim Form, or the 837i facility transaction.

Providence Health Plan

Providence Health Assurance

Table of Contents:

New Drugs and Combinations:

1. **Omidubicel-onlv (Omisirge) Plast. Bag**
   a. **Indication**: For use in adults and pediatric patients 12 years and older with hematologic malignancies who are planned for umbilical cord blood transplantation following myeloablative conditioning to reduce the time to neutrophil recovery and the incidence of infection.
   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	None	None	None
* Recommendations for placement may differ between lines of business due to regulatory requirements. ** Medications will be placed on recommended tier above for the base formulary; tier placement for custom formulary(ies) will be based on designation above. For example, Commercial Tier 6 designation above means that the medication will be placed on the highest cost-sharing tier on the respective formulary(ies).			
Formulary Alternatives: N/A			

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

PA PROGRAM NAME	Omisirge

MEDICATION NAME	Omidubicel-onlv suspension (Omisirge®)
PA INDICATION INDICATOR	1 - All FDA-Approved Indications
OFF-LABEL USES	N/A
EXCLUSION CRITERIA	N/A
REQUIRED MEDICAL INFORMATION	A one-time authorization will be approved when the following criteria are met: 1. Documentation of provider determination that patient is eligible for allogeneic hematopoietic stem cell transplant 2. Patient has a hematologic malignancy planned for umbilical cord blood transplantation following myeloablative conditioning. 3. Documentation that patient does not have a matched related donor (MRD), matched unrelated donor (MUD), mismatched unrelated donor (MMUD), or haploidentical donor readily available. 4. Patient must not have received a prior allogeneic hematopoietic stem cell transplant
AGE RESTRICTIONS	12 years of age and older
PRESCRIBER RESTRICTIONS	Must be prescribed by, or in consultation with, an oncologist, immunologist, or hematologist
COVERAGE DURATION	Authorization will be limited to one treatment course per lifetime

2. **Retifanlimab-dlwr (Zynyz) Vial**
   a. **Indication**: For the treatment of adults patients with metastatic or recurrent locally advanced Merkel cell carcinoma (MCC).
      - This indication is approved under accelerated approval based on tumor response rate and duration of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trials

   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	20mL/28 days	20mL/28 days	20mL/28 days
* Recommendations for placement may differ between lines of business due to regulatory requirements.			

** Medications will be placed on recommended tier above for the base formulary; tier placement for custom formulary(ies) will be based on designation above. For example, Commercial Tier 6 designation above means that the medication will be placed on the highest cost-sharing tier on the respective formulary(ies).
Formulary Alternatives: Bavencio®, Keytruda®, Opdivo®

c. **Prior Authorization Criteria for Commercial/Medicaid**: Added to Oral Anti-Cancer Medications Policy

3. **Epcoritamab-bysp (Epkinly) Vial**
   a. **Indication**: For the treatment of adult patients relapsed or refractory diffuse large B-cell lymphoma (DLBCL), not otherwise specified, including DLBCL arising from indolent lymphoma, and high-grade B-cell lymphoma after two or more lines of systemic therapy.
   b. **Decision**:

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

   c. **Prior Authorization Criteria for Commercial/Medicaid**: Added to Injectable Anti-cancer Medications Policy
   d. **Prior Authorization Criteria for Medicare Part B**: Added to Injectable Anti-cancer Medications Prior Authorization and Step Therapy Policy

4. **Sparsentan (Filspari) Tablet**
   a. **Indication**: To reduce proteinuria in adults with primary immunoglobulin A nephropathy (IgAN) at risk of rapid disease progression, generally a urine protein-to-creatinine ratio (UPCR) ≥1.5 g/g.

- This indication is approved under accelerated approval based on a reduction of proteinuria. It has not been established whether sparsentan slows kidney function decline in patients with IgAN. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory clinical trial

b. **Decision**:

	Commercial	Medicaid	Medicare
Formulary Status*	Non-formulary	Non-formulary	Part D: Non-formulary Part B: N/A
Tier**	N/A	N/A	N/A
Affordable Care Act Eligible	N/A; Non-Formulary	N/A	N/A
Utilization Management Edits	Prior Authorization	Prior Authorization	N/A
Quantity Limit	2 tablets per day	2 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: Tarpeyo®, ACE/ARBs			

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

PA PROGRAM NAME	Filspari
MEDICATION NAME	Sparsentan tablet
PA INDICATION INDICATOR	1 - All FDA-Approved Indications
OFF-LABEL USES	N/A
EXCLUSION CRITERIA	• Patient is on dialysis or has undergone kidney transplant • Concurrent therapy with angiotensin receptor blockers, endothelin receptor antagonists, or aliskiren • History of serious side effect or allergic reaction to any angiotensin II antagonist or endothelin receptor antagonist, including sparsentan or irbesartan • Concurrent therapy with budesonide delayed-release capsule (Tarpeyo®) • Potassium greater than 5.5 mEq/L (5.5 mmol/L) • Chronic kidney disease (CKD) in addition to IgAN
REQUIRED MEDICAL INFORMATION	For initial authorization, all the following criteria must be met: 1. Diagnosis of primary immunoglobulin A nephropathy (IgAN), confirmed by biopsy

	2. Patient has been receiving a stable dose of an angiotensin-converting enzyme (ACE) inhibitor or angiotensin receptor blockers (ARB), at a maximally tolerated dose, with statement that ACE or ARB will be discontinued before sparsentan therapy is initiated 3. Patient is at high risk of disease progression with urine protein/creatinine ratio of at least 1.5g/g despite at least 90 days of supportive care including ACE or ARB 4. eGFR greater than or equal to 35 mL/min1.73m^2 Reauthorization: Documentation of positive response to therapy defined as improvement in proteinuria.
COVERAGE DURATION	Initial authorization and reauthorization will be approved for one year.
AGE RESTRICTION	Approved for patients aged 18 years and older
PRESCRIBER RESTRICTIONS	Must be prescribed by, or in consultation with, a nephrologist
QUANTITY LIMIT	60 tablets per 30 days

5. **Trientine tetrahydrochloride (Cuvrior) Tablet**
   a. **Indication**: For the treatment of adult patients with stable Wilson's disease who are de-coppered and tolerant to penicillamine.
   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	None	None	None
* Recommendations for placement may differ between lines of business due to regulatory requirements. ** Medications will be placed on recommended tier above for the base formulary; tier placement for custom formulary(ies) will be based on designation above. For example, Commercial Tier 6 designation above means that the medication will be placed on the highest cost-sharing tier on the respective formulary(ies).			
Formulary Alternatives: penicillamine, Depen®, trientine hydrochloride			

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

PA PROGRAM NAME	Trientine
MEDICATION NAME	Trientine tetrahydrochloride tablets (Cuvrior®)
PA INDICATION INDICATOR	1 - All FDA-Approved Indications
OFF-LABEL USES	None
EXCLUSION CRITERIA	• Cystinuria or rheumatoid arthritis
REQUIRED MEDICAL INFORMATION	For trientine hydrochloride: Confirmed diagnosis of Wilson's Disease For trientine tetrahydrochloride (Cuvrior®): The use of Cuvrior® (trientine tetrahydrochloride) for stable, de-coppered Wilson's disease in patients that are tolerant to penicillamine is not considered medically necessary and will not be covered due to the lack of clinical evidence with improved outcomes and safety. The use of Cuvrior® (trientine tetrahydrochloride) for initial therapy (de-coppering) in Wilson's disease is considered investigational and not covered.
AGE RESTRICTIONS	N/A
PRESCRIBER RESTRICTIONS	Must be prescribed by, or in consultation with, a gastroenterologist, hepatologist, or genetic specialist
COVERAGE DURATION	Initial authorization and reauthorization will be approved for one year.

6. **Leniolisib phosphate (Joenja) Tablet**
   a. **Indication**: For the treatment of activated phosphoinositide 3-kinase delta (PI3Kδ) syndrome (APDS) in adult and pediatric patients 12 years of age and older.
   b. **Decision**:

	Commercial	Medicaid	Medicare
Formulary Status*	Non-formulary	Non-formulary	Part D: Non-formulary Part B: N/A
Tier**	N/A	N/A	N/A
Affordable Care Act Eligible	N/A; Non-Formulary	N/A	N/A
Utilization Management Edits	Prior Authorization	Prior Authorization	N/A
Quantity Limit	Two tablets per day	Two tablets per day	
* Recommendations for placement may differ between lines of business due to regulatory requirements.			

** Medications will be placed on recommended tier above for the base formulary; tier placement for custom formulary(ies) will be based on designation above. For example, Commercial Tier 6 designation above means that the medication will be placed on the highest cost-sharing tier on the respective formulary(ies).
Formulary Alternatives:

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

PA PROGRAM NAME	MEDICATIONS FOR RARE INDICATIONS
MEDICATION NAME	Joenja
PA INDICATION INDICATOR	1 - All FDA-Approved Indications
OFF-LABEL USES	N/A
EXCLUSION CRITERIA	None for Joenja
REQUIRED MEDICAL INFORMATION	For initial authorization, all the following must be met: 1. Confirmation of FDA-labeled indication (appropriate lab values and/or genetic tests must be submitted) AND 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 AND 3. Meet the following drug specific criteria as applicable: *** other drug specific criteria not included *** c. For Joenja®: i. Patient must weigh at least 45 kg AND ii. at least one measurable lymph node on computed tomography (CT) or magnetic resonance imaging (MRI) scan **Reauthorization Criteria:** The following must be met: 1. Documentation of successful response to therapy AND 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 AND 3. Meet the following drug specific criteria as applicable:

	a. For Nulibry®: Genetic testing to confirm mutation in the MOCS1 gene (Nulibry® should be discontinued if the MoCD Type A diagnosis is not confirmed by genetic testing) b. For Joenja®: Patient must weigh at least 45 kg
AGE RESTRICTIONS	Consistent with FDA approved labeling
PRESCRIBER RESTRICTIONS	Must be prescribed by, or in consultation with a specialist in the respective disease states
COVERAGE DURATION	Initial authorization will be approved for six months. Reauthorization will be approved for 12 months.
Quantity Limit	Joenja: two (2) tablets per day

7. **Tofersen (Qalsody) Vial**
   a. **Indication**: For the treatment of amyotrophic lateral sclerosis (ALS) in adults who have a mutation in the superoxide dismutase 1 (SOD1) gene.
   b. **Decision**:

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

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

PA PROGRAM NAME	Qalsody
MEDICATION NAME	Tofersen (Qalsody)
PA INDICATION INDICATOR	1 - All FDA-Approved Indications
OFF-LABEL USES	N/A
EXCLUSION CRITERIA	N/A

REQUIRED MEDICAL INFORMATION	1. For initiation of therapy, all the following criteria must be met: a. Documentation of diagnosis of amyotrophic lateral sclerosis (ALS) with mutation in the superoxide dismutase 1 (SOD1) gene b. Documentation of baseline ALS Functional Rating Scale-Revised (ALSFRS-R) c. Forced vital capacity (FVC) greater than or equal to 50% of predicted (taken within the past three months) d. Documentation of weakness attributable to ALS 2. For patients established on therapy, all the following criteria must be met: a. Documentation of a clinical benefit from therapy such as stabilization of disease or slowing of disease progression from pre-treatment baseline ALSFRS-R scores
AGE RESTRICTIONS	Patient age within FDA approved label
PRESCRIBER RESTRICTIONS	Must be prescribed by, or in consultation with, a neurologist with expertise in ALS
COVERAGE DURATION	Initial authorization will be approved for six months. Reauthorization will be approved for one year.

8. **Fecal microbiota, spores, live-brpk (Vowst)**
   a. **Indication**: To prevent the recurrence of *Clostridioides difficile* infection (CDI) in individuals 18 years of age and older following antibacterial treatment for recurrent CID (rCDI). This drug is not indicated for treatment of CDI.
   b. **Decision**:

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

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

PA PROGRAM NAME	Fecal Microbiota Agents
MEDICATION NAME	Vowst (fecal microbiota spores, live-brpk)
PA INDICATION INDICATOR	1 - All FDA-Approved Indications
OFF-LABEL USES	N/A
EXCLUSION CRITERIA	Treatment of CDI
REQUIRED MEDICAL INFORMATION	Authorization for the prevention of recurrence of *Clostridioides difficile* infection (CDI) requires all the following criteria be met: 1. Confirmed diagnosis of recurrent CDI, defined as two or more recurrences after a primary episode (greater than or equal to three total CDI episodes) within 12 months 2. Positive stool test for *C. difficile* within 30 days before prior authorization request 3. Member has completed or will have completed an appropriate antibiotic treatment regimen for recurrent CDI prior to administration as outlined in the package label 4. Current episode of CDI must be controlled (less than three unformed/loose stools/day for two consecutive days)
AGE RESTRICTIONS	Approved for ages 18 years and older
PRESCRIBER RESTRICTIONS	Must be prescribed by or in consultation with an infectious disease specialist or gastroenterology specialist
COVERAGE DURATION	Authorization will be approved for one treatment course.

9. **Zavegepant hcl (Zavzpret) Spray**
   a. **Indication**: For the acute treatment of migraine with or without aura 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	N/A; Non-Formulary	N/A	N/A
Utilization Management Edits	Prior Authorization	Prior Authorization	N/A
Quantity Limit	8 units per 30 days	8 units per 30 days	
* Recommendations for placement may differ between lines of business due to regulatory requirements.			

** Medications will be placed on recommended tier above for the base formulary; tier placement for custom formulary(ies) will be based on designation above. For example, Commercial Tier 6 designation above means that the medication will be placed on the highest cost-sharing tier on the respective formulary(ies).
Formulary Alternatives: Nurtec ODT®, triptans

c. **Prior Authorization Criteria for Commercial/Medicaid**: Added drug to Calcitonin Gene-Related Peptide (CGRP) Receptor Antagonists policy as a non-preferred agent for acute migraine treatment

10. **Beremagene geperpavec-svdt (Vyjuvek) Gel (ML)**
    a. **Indication**: For the treatment of wounds in dystrophic epidermolysis bullosa (DEB) with mutation(s) in the collagen type VII alpha 1 chain (*COL7A1*) gene.
    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	Four vials (10 mL) per 28 days	Four vials (10 mL) per 28 days	Four vials (10 mL) per 28 days
* Recommendations for placement may differ between lines of business due to regulatory requirements. ** Medications will be placed on recommended tier above for the base formulary; tier placement for custom formulary(ies) will be based on designation above. For example, Commercial Tier 6 designation above means that the medication will be placed on the highest cost-sharing tier on the respective formulary(ies).			
Formulary Alternatives: None			

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

PA PROGRAM NAME	Vyjuvek
MEDICATION NAME	Beremagene geperpavec-svdt gel (Vyjuvek®)
PA INDICATION INDICATOR	1 - All FDA-Approved Indications
OFF-LABEL USES	N/A
EXCLUSION CRITERIA	1. Skin graft within the past three months

	2. Current evidence or a history of squamous cell carcinoma in the area(s) that will undergo treatment
REQUIRED MEDICAL INFORMATION	Initial authorization requires all the following be met: 1. Diagnosis of dystrophic epidermolysis bullosa (DEB) 2. Documentation of mutation(s) in the collagen type VII alpha 1 chain (*COL7A1)* gene 3. Treatment will be used on a cutaneous wound or wounds that are clean in appearance with adequate granulation tissue, excellent vascularization, and do not appear infected 4. Dosing is within FDA-labeled guidelines Reauthorization requires all the following be met: 1. Documentation of successful response to therapy as indicated by complete wound healing or decrease in wound size 2. Patient continues to have incomplete wound closures that are clean in appearance with adequate granulation tissue, excellent vascularization, and do not appear infected 3. Dosing is within FDA-labeled guidelines
AGE RESTRICTIONS	May be approved for patients aged six months and older
PRESCRIBER RESTRICTIONS	Must be prescribed by, or in consultation with, a with a dermatologist or provider with experience in treating epidermolysis bullosa
COVERAGE DURATION	Initial authorization will be approved for six months. Reauthorization will be approved for one year.

New Indications:

Therapies with Prior Authorization Policies (Non-oncology)

1. **Tepezza** (Teprotumumab-TRBW)
    a. Previous Indication(s):
        a. Thyroid Eye Disease
    b. New indication approved 04/13/2023:
        a. Thyroid Eye Disease regardless of Thyroid Eye Disease activity or duration
    c. **RECOMMENDATION:** Inform prescribers via Medical Policy Alert. Update policy with new indication

2. **Hyrimoz** (Adalimumab-ADAZ)
    a. Previous Indication(s):
        a. Rheumatoid Arthritis

   b. Juvenile Idiopathic Arthritis
   c. Psoriatic Arthritis
   d. Ankylosing Spondylitis
   e. Crohn's Disease
   f. Ulcerative Colitis
   g. Plaque Psoriasis
b. New indication approved 04/14/2023:
   a. Moderate - severe hidradenitis suppurativa
c. **RECOMMENDATION:** Inform prescribers via Medical Policy Alert. Update policy with new indication

3. **Sogroya** (Somapacitan)
   a. Previous Indication(s):
      a. Replacement of endogenous growth hormone (GH) in adults with growth hormone deficiency (GHD)
   b. New indication approved 04/28/2023:
      a. Pediatric patients aged 2.5 years and older who have growth failure due to inadequate secretion of endogenous growth hormone (GH)
   c. **RECOMMENDATION:** Inform prescribers via Medical Policy Alert. New drug entity, full review scheduled for October P&T

4. **Kalydeco** (Ivacaftor)
   a. Previous Indication(s):
      a. Treatment of cystic fibrosis (CF) in patients age **4 months and older** who have one mutation in the CFTR gene that is responsive to ivacaftor potentiation based on clinical and/or in vitro assay data
   b. New indication approved 05/03/2023:
      a. Treatment of cystic fibrosis (CF) in patients age **1 month and older** who have at least one mutation in the CFTR gene that is responsive to ivacaftor potentiation based on clinical and/or in vitro assay data
   c. **RECOMMENDATION:** Inform prescribers via Medical Policy Alert. Update policy with new indication and add new criteria
      Prior Authorization for Commercial/Medicaid:

PA PROGRAM NAME	CFTR Modulators
MEDICATION NAME	Kalydeco
COVERED USES	1 - All FDA-Approved Indications

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

5. **Farxiga** (Dapagliflozin)
    a. Previous Indication(s):
        a. As an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus
        b. To reduce the risk of sustained eGFR decline, end-stage kidney disease, cardiovascular death, and hospitalization for heart failure in adults with chronic kidney disease at risk of progression
        c. To reduce the risk of hospitalization for heart failure in adults with type 2 diabetes mellitus and either established cardiovascular disease or multiple cardiovascular risk factors
    b. New indication approved 05/08/2023:
        a. To reduce the risk of cardiovascular death, hospitalization for heart failure, and urgent heart failure visit in adults with heart failure
    c. **RECOMMENDATION:** Inform prescribers via Medical Policy Alert. Update policy with new indication

6. **Rexulti** (Brexpiprazole)
    a. Previous Indication(s):
        a. Adjunctive treatment of major depressive disorder (MDD) in adults
        b. Treatment of schizophrenia in adults and pediatric patients ages 13 years and older
    b. New indication approved 05/10/2023:
        a. Treatment of agitation associated with dementia due to Alzheimer's disease
    c. **RECOMMENDATION:** Inform prescribers via Medical Policy Alert. Policy was updated with this new indication as part of its annual review and is in the consent agenda for review.

7. **Rinvoq** (Upadacitinib)
    a. Previous Indication(s):
        a. Rheumatoid arthritis
        b. Psoriatic arthritis
        c. Atopic dermatitis

   d. Ulcerative colitis
   e. Ankylosing spondylitis
   f. Non-radiographic axial spondyloarthritis
b. New indication approved 05/18/2023:
   a. Crohn's disease
c. **RECOMMENDATION:** Inform prescribers via Medical Policy Alert. Policy was updated previously with new indication.

8. **Zinplava** (Bezlotoxumab)
   a. Previous Indication(s):
      a. Reduce recurrence of Clostridium difficile infection (CDI) in patients **18 years of age or older** who are receiving antibacterial drug treatment of CDI and are at a high risk for CDI recurrence.
   b. New indication approved 05/26/2023:
      a. Reduce recurrence of Clostridium difficile infection (CDI) in adults and pediatric patients **1 year of age and older** who are receiving antibacterial drug treatment for CDI and are at a high risk for CDI recurrence.
   c. **RECOMMENDATION:** Inform prescribers via Medical Policy Alert. Update policy with new indication and add new criteria.
      Prior Authorization for Commercial/Medicaid/Medicare Part B:

PA PROGRAM NAME	Zinplava
MEDICATION NAME	Zinplava
COVERED USES	1 - All FDA-Approved Indications
AGE RESTRICTIONS	Approved for 1 years of age and older

Therapies with Prior Authorization Policies (Oncology)

9. **Keytruda** (Pembrolizumab)
   a. New indication(s) approved 04/03/2023:
      a. In combination with enfortumab vedotin, is indicated for the treatment of adult patients with locally advanced or metastatic urothelial carcinoma who are not eligible for cisplatin-containing 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. **Padcev** (Enfortumab Vedotin-EJFV)
    a. New indication(s) approved 04/03/2023:
        a. In combination with pembrolizumab for locally advanced or metastatic urothelial cancer (mUC) who are not eligible for cisplatin-containing 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.

11. **Polivy** (Polatuzumab Vedotin-PIIQ)
    a. New indication(s) approved 04/19/2023:
        a. In combination with a rituximab product, cyclophosphamide, doxorubicin, and prednisone (R-CHP) for the treatment of adult patients who have previously untreated diffuse large B-cell lymphoma (DLBCL), not otherwise specified (NOS) or high-grade B-cell lymphoma (HGBL) and who have an International Prognostic Index score of 2 or greater.
        b. In combination with bendamustine and a rituximab product for the treatment of adult patients with relapsed or refractory DLBCL, NOS, after at least two prior therapies.
    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. **Libtayo** (Cemiplimab-RWLC)
    a. New indication(s) approved 04/28/2023:
        a. Non-infectious intermediate, posterior, and panuveitis
        b. Cutaneous squamous cell carcinoma
    b. **RECOMMENDATION:** Inform prescribers via Medical Policy Alert. Prior authorization policy coverage criteria are based on recommendations from the National Comprehensive Cancer Network (NCCN); no updates to the policy are warranted.

13. **Ayvakit** (Avapritinib)
    a. New indication(s) approved 05/22/2023:
        a. Indolent systemic mastocytosis (ISM)
    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.

14. **Lynparza** (Olaparib)

a. New indication(s) approved 05/31/2023:
    a. In combination with abiraterone and prednisone or prednisolone for the treatment of adult patients with deleterious or suspected deleterious BRCA-mutated (BRCAm) metastatic castration resistant prostate cancer (mCRPC)
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

15. **Caldolor** (Ibuprofen)
    a. Previous Indication(s):
    Adults and pediatric patients **six months and older** for the
        a. Management of mild to moderate pain and the management of moderate to severe pain as an adjunct to opioid analgesics
        b. Reduction of fever
    b. New indication approved 05/11/2023:
    Adults and pediatric patients **three months and older** for the
        a. Management of mild to moderate pain and the management of moderate to severe pain as an adjunct to opioid analgesics
        b. Reduction of fever
    c. **RECOMMENDATION:** Inform prescribers via Medical Policy Alert.

16. **Breo Ellipta** (Fluticasone + Vilanterol)
    a. Previous Indication(s):
        a. Once-daily treatment of asthma in patients aged **18 years and older**
    b. New indication approved 05/12/2023:
        a. Maintenance treatment of asthma in patients aged **5 years and older**
    c. **RECOMMENDATION:** Inform prescribers via Medical Policy Alert.

17. **Lexapro** (Escitalopram Oxalate)
    a. Previous Indication(s):
        a. Acute and maintenance treatment of major depressive disorder in adults and in adolescents 12 to 17 years of age
        b. Acute treatment of Generalized Anxiety Disorder (GAD) in **adults**
    b. New indication approved 05/12/2023:

   a. Generalized anxiety disorder (GAD) in **adults and pediatric patients 7 years of age and older**
c. **RECOMMENDATION:** Inform prescribers via Medical Policy Alert. Update policy with new indication

18. **Ultravist** (Iopromide)
   a. Previous Indication(s):
      a. Cerebral arteriography and peripheral arteriography in adults
      b. Coronary arteriography and left ventriculography, visceral angiography, and aortography in adults
      c. Excretory urography in adults and pediatric patients aged 2 years and older
      d. Contrast Computed Tomography (CT) of the head and body (intrathoracic, intra-abdominal, and retroperitoneal regions) for the evaluation of neoplastic and non-neoplastic lesions in adults and pediatric patients aged 2 years and older
   b. New indication approved 05/25/2023:
      a. Contrast mammography to visualize known or suspected lesions of the breast in adults, as an adjunct following mammography and/or ultrasound
      b. Radiographic evaluation of cardiac chambers and related arteries in pediatric patients aged 2 years and older
   c. **RECOMMENDATION:** Inform prescribers via Medical Policy Alert.

19. **Injectafer** (Ferric Carboxymaltose)
   a. Previous Indication(s):
      iron deficiency anemia (IDA) in:
      a. Adult and pediatric patients 1 year of age and older who have either intolerance or an unsatisfactory response to oral iron.
      b. Adult patients who have non-dialysis dependent chronic kidney disease.
   b. New indication approved 05/31/2023:
      a. Iron deficiency in adult patients with heart failure and New York Heart Association class II/III to improve exercise capacity.
   c. **RECOMMENDATION:** Inform prescribers via Medical Policy Alert.

Therapies with Indication(s) Removed

1. **Imbruvica** (Ibrutinib)
   a. **Indication(s) removed 05/18/2023:**
      i. Mantle cell lymphoma (MCL) who have received at least one prior therapy

ii. Marginal zone lymphoma (MZL) who require systemic therapy and have received at least one prior anti-CD20-based therapy
iii. 560mg strength tablet

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.

Drug Safety Monitoring:

FDA Drug Safety Communications

1. **Drug Name:** Prescription opioid
   - **Date Posted:** 04/13/2023
   - **Safety Alert Title:** Updates prescribing information for all opioid pain medicines to provide additional guidance for safe use.
   - **Link to more information:** https://www.fda.gov/drugs/drug-safety-and-availability/fda-updates-prescribing-information-all-opioid-pain-medicines-provide-additional-guidance-safe-use
   - **What safety concern is FDA announcing?**
     - FDA has determined that extended-release/long-acting (ER/LA) opioid pain medicines have unique risks and should be used only for those with severe and persistent pain. They also determined a new warning is needed about opioid-induced hyperalgesia (OIH), which is when an opioid that is prescribed and taken for pain relief causes an increase in pain (called hyperalgesia) or an increased sensitivity to pain (called allodynia). Although OIH can occur at any opioid dosage, it may occur more often with higher doses and longer-term use. This condition can be difficult to recognize and may result in increased opioid dosages that could worsen symptoms and increase the risk of respiratory depression.
   - **What is FDA doing?**
     - We are requiring several updates to the prescribing information for both immediate-release (IR) and extended release/long acting (ER/LA) opioid pain medicines. This includes stating for all opioid pain that the risk of overdose increases as the dose increases. The updates to IR opioids state these products should not be used for an extended period unless the pain remains severe enough to require them and alternative treatments continue to be inadequate, and that many acute pain conditions treated in the outpatient setting require no more than a few days of an opioid pain medicine. This may include pain occurring with several surgical conditions or musculoskeletal injuries. We are also updating the approved use for

ER/LA opioid pain medicines to recommend they be reserved for severe and persistent pain that requires an extended treatment period with a daily opioid pain medicine and for which alternative treatment options are inadequate. In addition, we are adding a new warning about opioid-induced hyperalgesia (OIH) for both IR and ER/LA opioid pain medicines. This includes information describing the symptoms that differentiate OIH from opioid tolerance and withdrawal.

- **What should health care professionals do?**
  - If the patient's pain is severe enough to require an opioid pain medicine and alternative treatment options are insufficient, prescribe the lowest effective dose of an IR opioid for the shortest duration of time to reduce the risks associated with these products. Reserve increasing to higher doses only when lower doses are inadequate and the benefits of using a higher dose outweigh the substantial risks. Many acute pain conditions, such as pain occurring with several surgical procedures or musculoskeletal injuries, require no more than a few days of an IR opioid pain medicine. Reserve ER/LA opioid pain medicines only for severe and persistent pain that requires an extended treatment period with a daily opioid pain medicine and for which alternative treatment options are inadequate. Advise patients about the risk of OIH and tell them to never increase the opioid dosage without first consulting a health care professional, because this could worsen the pain and increase the risk of respiratory depression.
- **Health Plan Recommendation:** Notify providers via Medical Policy Alert

2. **Drug Name: Prescription stimulants**
   - **Date Posted: 05/11/23**
   - **Safety Alert Title: Misuse, abuse, addiction, and overdose of prescription stimulants.**
   - **Link to more information:** https://www.fda.gov/drugs/drug-safety-and-availability/fda-updating-warnings-improve-safe-use-prescription-stimulants-used-treat-adhd-and-other-conditions
   - **What safety concern is FDA announcing?**
     - Prescription stimulants can be an important treatment option for disorders for which they are indicated. However, even when prescribed to treat an indicated disorder, their use can lead to misuse or abuse. Misuse and abuse, also called nonmedical use, can include taking your own medicine differently than prescribed or using someone else's medicine. For this reason, sharing prescription stimulants with those for whom they are not prescribed is an important concern and a major contributor to nonmedical use and addiction. Misuse and abuse of prescription stimulants can result in overdose and

death, and this risk is increased with higher doses or unapproved methods of taking the medicine such as snorting or injecting.

- **What is FDA doing?**
  - We are requiring the Boxed Warning, FDA's most prominent warning, to be updated and we are adding other information to the prescribing information for all prescription stimulants. We are adding information that patients should never share their prescription stimulants with anyone, and the Boxed Warning information will describe the risks of misuse, abuse, addiction, and overdose consistently across all medicines in the class. The Boxed Warning also will advise heath care professionals to monitor patients closely for signs and symptoms of misuse, abuse, and addiction.
- **What should health care professionals do?**
  - Assess patient risk of misuse, abuse, and addiction before prescribing stimulant medicines. Counsel patients not to share their prescribed stimulant with anyone else. Educate patients and their families on these serious risks, proper storage of the medicine, and proper disposal of any unused medicine. Throughout treatment, regularly assess and monitor them for signs and symptoms of nonmedical use, addiction, and potential diversion, which may be evidenced by more frequent renewal requests than warranted by the prescribed dosage.
- **Health Plan Recommendation:** Notify providers via Medical Policy Alert

Drug Recalls/Market Withdrawals

1. **Drug Name:** Pro Power Knight Plus, NUX, Dynamite Super
   a. **Date of Recall:** 04/26/2023
   b. **Reason for recall:** Product contains undeclared tadalafil and sildenafil
   c. **Link to more information:** https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/gear-isle-issues-voluntary-nationwide-recall-pro-power-knight-plus-nux-male-enhancement-and-dynamite
   d. **Health Plan Recommendation:** Notify providers via Medical Policy Alert

2. **Drug Name:** FENTANYL Buccal Tablets CII
   a. **Date of Recall:** 04/28/2023
   b. **Reason for recall:** Safety updates were omitted in the Product Insert/Medication Guide (MG)

c. **Link to more information:** https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/teva-initiates-voluntary-nationwide-recall-specific-lots-fentanyl-buccal-tablets-cii-due-labeling
d. **Health Plan Recommendation:** Notify providers via Medical Policy Alert

3. **Drug Name:** Advil
   a. **Date of Recall:** 05/04/2023
   b. **Reason for recall:** Product was stored outside of labeled temperature requirements
   c. **Link to more information:** https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/family-dollar-initiating-voluntary-recall-certain-over-counter-drug-products-because-products-have
   d. **Health Plan Recommendation:** Notify providers via Medical Policy Alert

4. **Drug Name:** Drugs from Akorn Operating Company LLC
   a. **Date of Recall:** 05/04/2023
   b. **Reason for recall:** As a result of a bankruptcy, the firm is removing several products from the market due to the discontinuation of the Quality program which would result in the company's inability to assure that products meet the identity, strength, quality, and purity
   c. **Link to more information:** https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/update-akorn-issues-voluntary-nationwide-recall-various-human-and-animal-drug-products-within-expiry
   d. **Health Plan Recommendation:** Notify providers via Medical Policy Alert

5. **Drug Name:** G-SUPRESS DX
   a. **Date of Recall:** 05/19/2023
   b. **Reason for recall:** Device & Drug Safety/Mislabeling
   c. **Link to more information:** https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/novis-pr-llc-issues-voluntary-recall-g-supress-dx-pediatric-drops-due-incorrect-packaging
   d. **Health Plan Recommendation:** Notify providers via Medical Policy Alert

6. **Drug Name:** EuroMedica, Terry Naturally (Dietary Supplement)
   a. **Date of Recall:** 04/22/2023
   b. **Reason for recall:** Undeclared milk

c. **Link to more information:** https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/europharma-inc-issues-voluntary-allergy-alert-undeclared-milk-terry-naturallyr-bioactive-vitamin-btm
d. **Health Plan Recommendation:** Notify providers via Medical Policy Alert

Other Formulary Changes:

Drug Name	Action Taken	Policy Name
Diclofenac Potassium Tablet	• Commercial: Add to Formulary, Tier 2 • Medicaid Add to Formulary • Medicare Part D: Add to Formulary Tier 3	N/A
• **Codeine Phosphate/Guaifenesin (Guaifenesin AC) 10-100mg/5 Liquid** • **Codeine Phosphate/Guaifenesin (Guaifenesin-Codeine) 10-100mg/5; 20-200/10 Liquid** • **Pseudoephed/Codeine/Guaifen (Virtussin DAC and Guaifenesin DAC) 30-10-100 Syrup**	Remove from Commercial formulary Effective 11/1/2023	N/A
Levocarnitine Solution	• Commercial Standard: Add to Formulary, Tier 2 • Commercial Dynamic: Add to Formulary, Tier 3 • Medicaid: Add to Formulary	N/A
Thyroid,Pork (Adthyza) Tablet	Add to formulary: • Commercial/Medicare Part D: Formulary, Tier 4 • Medicaid: Formulary	N/A
Deutetrabenazine (Austedo XR) 6mg; 24mg Tab ER 24H	New dosage form (tab ER 24H) and strength (6mg, 24mg); • Commercial: Formulary, Tier 6, Prior Authorization, Quantity Limit (2 tablets per day) • Medicaid: Formulary, Prior Authorization, Quantity Limit (2 tablets per day)	VMAT2 Inhibitors

	• Medicare Part D: Formulary, Tier 5, Prior Authorization, Quantity Limit (2 tablets per day)	
Deutetrabenazine (Austedo XR) 12mg Tab ER 24H	New dosage form (tab ER 24H) and strength (12mg); • Commercial: Formulary, Tier 6, Prior Authorization, Quantity Limit (3 tablets per day) • Medicaid: Formulary, Prior Authorization, Quantity Limit (3 tablets per day), Specialty • Medicare Part D: Formulary, Prior Authorization, Quantity Limit (3 tablets per day), Specialty	VMAT2 Inhibitors
Tetrabenazine (Xenazine) Tablet	• Medicare Part D: Down tier to Tier 3	VMAT2 Inhibitors
Chloroprocaine hcl/pf (Iheezo) Droper Gel	New strength (3%) and dosage form (dropper gel) • Commercial/Medicaid/Medicare Part B: Medical benefit • Medicare Part D: Non-Formulary	N/A
Sildenafil citrate (Liqrev) Oral Susp	New dosage form (oral susp); • Commercial/Medicaid: Non-Formulary, Prior Authorization • Medicare Part D: Non-Formulary	• Commercial/Medicaid: New Medications and Formulations without Established Benefit • Medicare Part D: N/A
Sodium oxybate (Lumryz) Pack ER GR	New strengths (4.5g, 6g, 7.5g, 9g) and dosage form (pack er gr); • Commercial: Formulary, Tier 6, Prior Authorization, Quantity Limit (1 pack per day) • Medicaid: Non-Formulary, Prior Authorization, Quantity Limit (1 pack per day) • Medicare Part D: Non-Formulary	• Commercial/Medicaid: Narcolepsy Agents • Medicare Part D: N/A
Sodium phenylbutyrate (Olpruva) Pelet Pack	New strengths (2g, 3g, 4g, 5g, 6g, 6.67g) and dosage form (pelet pack); • Commercial/Medicaid: Non-Formulary, Prior Authorization, Quantity Limit (1 kit per 30 days) • Medicare Part D: Non-Formulary	• Commercial/Medicaid: Medications for Rare Indications • Medicare Part D: N/A
Risperidone (Uzedy) Suser Syr	New strengths (50mg/0.14ml, 75mg/0.21ml, 100mg/0.28ml, 125mg/0.35ml, 150mg/0.42ml, 200mg/0.56ml, 250mg/0.7ml);	N/A

	• Commercial/Medicaid: Medical Benefit • Medicare Part D: Non-Formulary • Medicare Part B: Medical, covered	
Methylphenidate Patch TD24	Add to Medicaid formulary to align with Oregon Health Authority	N/A
Dextroamphetamine sulfate capsule ER	Remove from Medicaid formulary	N/A
Opicapone (Ongentys) Capsule	Commercial/Medicaid: Remove from Formulary add Quantity Limit (1 capsule per day) Effective 11/1/2023	N/A
Ramelteon (Rozerem) Tablet	Add generic to Medicaid formulary with Prior Authorization and Quantity Limit (1 tablet per day)	Insomnia Agents – Medicaid
• **Adalimumab-fkjp(cf)** • **Adalimumab-adbm (Cyltezo(CF))** • **Adalimumab-fkjp (Hulio(CF))** • **Adalimumab-aacf (Idacio(CF))** • **Adalimumab-aqvh (Yusimry(CF))**	Commercial/Medicaid: Non-Formulary, Prior Authorization, Quantity Limit (2 injections per 28 days)	• Commercial: Therapeutic Immunomodulators (TIMS) • Medicaid: TIMS – Medicaid
MELATONIN • **1 mg, 3 mg, 5 mg, Tablet** • **1 mg/ml Liquid**	Add to Medicaid formulary for patients less than 21 years of age.	N/A

Niraparib tosylate (Zejula)
• **Capsule**
• **Tablet**
	New strength (100 mg, 200 mg, & 300mg) and dosage Form (tablet). Line extend with Zejula 100mg capsule; Add quantity limits
	• 100 mg, 200 m, and 300 mg tablet:
	  ○ Commercial/Medicaid/: Add Quantity Limit (1 tablet per day)
	• 100 mg capsule:
	  ○ Commercial/Medicaid/Medicare Part D: Add Quantity Limit (2 capsules per day)
		• Commercial/Medicaid: Oral Anti-Cancer Medications
		• Medicare Part D: Anti-Cancer Agents Program

Vilazodone (Viibryd®)	Commercial (Dynamic): Move to Tier 2 from Tier 4	N/A
Vyvanse (lisdexamfetamine)	Remove from Medicaid formulary	

Providence Health Plan

Providence Health Assurance

The formulary status for the following drugs was line extended in accordance with Providence Health Plan Pharmacy Operational Policy ORPTCOPS062
Drugs released from May 6, 2023 to June 24, 2023
INFORMATIONAL ONLY

NEW DRUGS / COMBINATIONS / STRENGTHS / DOSAGE FORMS		
Drug Name	**Action Taken**	**Policy Name**
Aripiprazole (Abilify Asimtufii) Suser Syr	New strengths (720mg/2.4ml and 960mg/3.2ml). Line extend with Abilify Maintena; • Commercial/Medicaid: Medical Benefit • Medicare Part D: Formulary, Tier 5 • Medicare Part B: Medical Benefit	• N/A
Buprenorphine (Brixadi) Soler Syr	New strength (8mg/0.16). Line extend with Sublocade; • Commercial/Medicaid/Medicare Part B: Medical benefit • Medicare Part D: Non-Formulary	• N/A
Pegfilgrastim-cbqv (Udenyca Autoinjector) Auto Injct	New dosage Form (Auto-Inject). Line extend with Udenyca (Subcut); • Commercial: Formulary, Tier 5 • Medicaid: Formulary, Specialty • Medicare Part D: Formulary, Tier 5	• N/A
Ivacaftor (Kalydeco) Gran Pack	New strength (13.4 mg). Line extend with Kalydeco granules pkts; • Commercial: Formulary, Tier 6, Prior Authorization, Quantity Limit (2 packets per day) • Medicaid: Formulary, Prior Authorization, Quantity Limit (2 packets per day), Specialty • Medicare Part D: Formulary, Tier 5, Prior Authorization, Quantity Limit (2 packets per day)	• CFTR Modulators

Trametinib dimethyl sulfoxide (Mekinist) Soln Recon	New strength (0.05 mg/ml) and dosage form (soln recon). Line extend with Mekinist tablets; • Commercial: Formulary, Tier 6, Prior Authorization • Medicaid: Formulary, Prior Authorization, Specialty • MAPD: Formulary, Tier 5, Prior Authorization	• Commercial/Medicaid: Oral Anti-Cancer Medications • Medicare Part D: Anti-Cancer Agents Program
Dabrafenib mesylate (Tafinlar) Tab Susp	New strength (10mg) and dosage form (tab susp). Line extend with Tafinlar capsule; • Commercial: Formulary, Tier 6, Prior Authorization • Medicaid: Formulary, Prior Authorization, Specialty • MAPD: Formulary, Tier 5, Prior Authorization	• Commercial/Medicaid: Oral Anti-Cancer Medications • Medicare Part D: Anti-Cancer Agents Program
Talazoparib tosylate (Talzenna) Capsule	New strength (0.1 mg, 0.35 mg). Line extend with Talzenna strengths; • Commercial: Formulary, Tier 6, Prior Authorization • Medicaid: Formulary, Prior Authorization, Specialty • Medicare Part D: Formulary, Tier 5, Prior Authorization	• Commercial/Medicaid: Oral Anti-Cancer Medications • Medicare Part D: Anti-Cancer Agents Program
Adalimumab-atto (Amjevita(CF)) Syringe	New strength (10mg/0.2ml). Line extend with other Amjevita strengths; • Commercial: Formulary, Tier 5, Prior Authorization, Quantity Limit (1.6 ml per 28 days) • Medicaid: Non-Formulary, Prior Authorization, Quantity Limit (1.6 ml per 28 days), Specialty Medicare Part D: Non-Formulary	• Commercial: Therapeutic Immunomodulators (TIMS) • Medicaid: Therapeutic Immunomodulators (TIMS) - Medicaid 1. Medicare Part D: N/A

Ozanimod hydrochloride (Zeposia) Cap DS PK	New route, form, & strength for existing brand: Line extend with Zeposia starter kits; • Comm: Formulary, Tier 5, Prior Authorization • Medicaid: Formulary, Prior Medicare: Non-Formulary	• Commercial: Therapeutic Immunomodulators (TIMS) • Medicaid: Zeposia

New Generics:

GENERIC DRUGS		
Drug Name	**Action Taken**	**Policy Name**
Methsuximide Capsule	First generic (Celontin). Line extend as generic; • Commercial Standard: Formulary, Tier 2 • Commercial Dynamic: Formulary, Tier 4 • Medicaid: Formulary • Medicare Part D: Formulary, Tier 4	N/A
Gefitinib Tablet	First generic (Iressa). Line extend as generic; • Commercial: Formulary, Tier 5, Prior Authorization, Quantity Limit (1 tablet per day) • Medicaid: Formulary, Prior Authorization, Quantity Limit (1 tablet per day), Specialty • Medicare Part D: Formulary, Tier 5, Prior Authorization, Quantity Limit (1 tablet per day)	• Commercial/Medicaid: Oral Anti-Cancer Medications • Medicare Part D: Anti-Cancer Agents Program

Clinical Policy Changes:

PHARMACY CLINICAL POLICIES – MAJOR CHANGES	
Policy Name	**Summary of Change**
Anti-Amyloid Monoclonal Antibodies	Updated criteria for Medicare to align with CMS guidance.
Antidepressants Step Therapy Policy	Removed vilazodone from the policy due to availability of low-cost generic formulation.
Antiepileptic Medications Step Therapy Policy	Updated criteria to indicate only a trial of prerequisite therapy, as automated step therapy programs do not assess for "failure."

Antipsychotics Step Therapy Policy	Changed policy from Step Therapy to Prior Authorization policy, requiring FDA approved indication for all requests.
Brand Over Generic	Four medications were added to this policy: Gilenya®, Aubagio®, Copaxone®, Ampyra®
Botulinum Toxin	Added criteria for reauthorization to ensure response to therapy. For chronic anal fissures, removing requirement related to surgery as the guidelines from the American College of Gastroenterology and the American Society of Colon and Rectal Surgeons recommend that botulinum toxin can be used second line after topical therapies and prior to surgery. For severe axillary hyperhidrosis, clarified topical agent that must be tried is aluminum chloride hexahydrate (Drysol. For overactive bladder in adults and neurologic detrusor overactivity, added beta-3 adrenoceptor agonist (e.g., mirabegron) as option for pharmaceutical trial and failure. Removed all "experimental and investigational" wording and replaced with "not considered medically necessary". Added criteria for evaluation of off-label uses.
Calcitonin Gene-Related Peptide (CGRP) Receptor Antagonists	Clarified language for quantity limit requests for acute migraine treatment to require documentation of use of any migraine prophylactic therapy. Quantity limit added to Vyepti.
Calcitonin Gene-Related Peptide (CGRP) Receptor Antagonists - Medicaid	Updated criteria to align with Oregon Health Authority guidance. Specifically, removed history of cluster headache frequency and confirmation of specific number of headache reduction on reauthorization. Removed exclusion criteria as it is outlined in initial criteria. Clarified language for quantity limit requests for acute migraine treatment to require documentation of use of any migraine prophylactic therapy.
Diabetic Durable Medical Equipment (DME)	Removed restriction on test strips for users of continuous glucose monitors.
Diacomit	Updated coverage duration for initial authorization to 12 months and removed prerequisite therapy criteria.
Dupixent	For asthma: 1. Updated trial and failure criteria to clarify duration of use of conventional therapies, 2. Updated severity criteria, defining duration in which exacerbations must have occurred which aligns with clinical trials and added additional definitions of severity, 3. Clarified reauthorization criteria language to require documentation of improvement or stabilization of condition.
Epidiolex	Updated coverage duration for initial authorization to 12 months. Reduced requirement of prerequisites therapies to one agent for Dravet syndrome and tuberous sclerosis complex.
Fintepla	Updated coverage duration for initial authorization to 12 months.
IL-5 Inhibitors	For asthma: 1. Updated trial and failure criteria to clarify duration of use of conventional therapies, 2. Updated severity criteria, defining duration in which exacerbations must have occurred which aligns with clinical trials and added additional definitions of severity, 3. Updated age restrictions language to require age be within FDA label, 4. Clarified reauthorization criteria language to require documentation of improvement or stabilization of condition.

Il-5 Inhibitors – Medicare Part B	For asthma: 1. Updated diagnostic and trial and failure criteria to align with GINA 2023 guidelines, 2. Updated severity criteria, defining duration in which exacerbations must have occurred which aligns with clinical trials and added additional definitions of severity, 3. Updated age restrictions language to require age be within FDA label.
Infusion Therapy Site of Care	Several drugs were added to the mandatory site of care list.
Insomnia Agents - Medicaid	Added ramelteon as another preferred medication to align with Oregon Health Authority preferred drug list. Coverage of non-preferred therapy requires trial of generic ramelteon and either generic zopiclone or generic eszopiclone. Clarified that melatonin will not be covered for adults 21 years of age and older.
• **Lemtrada** • **Lemtrada - Medicare Part B**	Updated criteria to require documentation of highly active disease, inadequate response to ocrelizumab (Ocrevus®), and have trial of one of the generic medications currently available: dimethyl fumarate, glatiramer, fingolimod, or teriflunomide.
Long Acting Opioids	Clarified requirement of around-the-clock short-acting opioid therapy prior to approval of long-acting opioid therapy. Also clarified definition of established on therapy and requirements for patients switching to a different long-acting opioid product.
Long-Acting Stimulant Medications Quantity Limit	Policy was updated to include Medicaid and Medicaid specific provider restriction for Quantity Limits was added and allowance for continuation of established patients for up to 90 days to allow time for consult with mental health provider.
Maximum Allowable Opioid Dose - Comm	Added requirement that patients have been provided with prescription for naloxone when established on doses exceeding 90 milligram morphine equivalents.
• **Medically Administered Multiple Sclerosis Agents** • **Medically Administered Multiple Sclerosis Agents – Medicare Part B**	New policy for injectable multiple sclerosis agents (Ocrevus®, Briumvi®); patients initiating therapy on brand-name multiple sclerosis agents will be required to either have highly active disease, previously used at least three different therapies, or have trial of one of the generic medications currently available: dimethyl fumarate, glatiramer, fingolimod, or teriflunomide.
Multiple Sclerosis Agents	New policy for brand-name self-administered multiple sclerosis agents (Avonex®, Rebif®, Plegridy®, Betaseron®, Extavia®, Mavenclad®, Kesimpta®, Mayzent®, Ponvory®); patients initiating therapy on brand-name multiple sclerosis agents will be required to either have highly active disease, previously used at least three different therapies, or have trial of one of the generic medications currently available: dimethyl fumarate, glatiramer, fingolimod, or teriflunomide.
Narcolepsy Agents	Updated narcolepsy criteria to clarify that if requesting medication for the treatment of excessive daytime sleepiness (even in those with a history of cataplexy), trial of prerequisite and preferred agents still applies. Treatment of cataplexy in narcolepsy does not require trial of modafinil/armodafinil, stimulant or Sunosi®. Added new extended release drug formulation of sodium oxybate (Lumryz®) to policy in parity with Xyrem® and Xywav®. Added criteria for when coverage of combination therapy with

	Sunosi® and other agents would be considered. Added new extended release drug formulation of sodium oxybate (Lumryz®) to policy in parity with Xyrem® and Xywav®.
PCSK9 Inhibitors - Commercial	Updated policy that only provider attestation is required (instead of "documented evidence") of previous statin use.
Pediatric Analgesics	Clarified wording that for commercial members all over-the-counter (OTC) formulations, even those that are placed on prescription-only status as required by state or local laws, are a benefit exclusion.
Qudexy XR, Trokendi XR	Removed prescriber restrictions from migraine therapy criteria to align with other migraine therapy policies (such as CGRP antagonists).
Rebyota	Renaming policy to include all fecal microbiota agents. Updated policy criteria to align with FDA label and clinical trials of both Vowst and Rebyota.
Reyvow	Updated trial and failure criteria to only require a trial of two oral formulary triptans to align with Oregon Health Authority guidance and current Calcitonin Gene-Related Peptide Antagonist policies.
Savella	Added criteria for patients established on therapy.
SGLT-2 Inhibitors - Medicaid	Added criteria for coverage of non-preferred therapy, ertugliflozin, for type 2 diabetes.
Spravato	Limit coverage duration for Major Depressive Disorder with Acute Suicidal Ideation to four weeks with no reauthorization. Patients using for this specific indication will have to meet criteria for treatment-resistant depression for continuation of therapy.
Tezspire	For asthma: 1. Updated trial and failure criteria to align with GINA 2023 guidelines, 2. Updated severity criteria, defining duration in which exacerbations must have occurred which aligns with clinical trials and added additional definitions of severity, 3. Updated exclusion criteria to specify which drug classes are not allowed to be used in combination with requested agent, 4. Removed requirement of Dupixent for steroid dependent asthma as FDA label does not specify asthma type, 5. Updated age restrictions language to require age be within FDA label.
Tezspire - Medicare Part B	For asthma: 1. Updated trial and failure criteria to align with GINA 2023 guidelines, 2. Updated severity criteria defining duration in which exacerbations must have occurred (which aligns with clinical trials) and added additional definitions of severity, 3. Updated exclusion criteria to specify which drug classes are not allowed to be used in combination with requested agent, 4. removed requirement of Dupixent for steroid dependent asthma as FDA label does not specify asthma type, 5. Added reauthorization criteria for patients established on therapy, 6. Updated age restrictions language to require age be within FDA label.
Therapeutic Immunomodulators	Several Humira® (adalimumab) biosimilar products launched and have been added to the policy as either preferred [Amjevita® (standard list price) and Hadlima®] or non-preferred.

• **Tysabri** • **Tysabri – Medicare Part B**	Updated criteria to require that patients initiating therapy will be required to either have highly active disease, previously used at least three different therapies, or have trial of one of the generic medications currently available: dimethyl fumarate, glatiramer, fingolimod, or teriflunomide.
VMAT2 Inhibitors	Added Austedo XR® (deutetrabenazine extended-release) to the policy with quantity limitations. Removed reference to reserpine in the exclusion criteria, as this drug is banned in the U.S.. Minor update to diagnostic criteria related to genetic testing.
Vyepti - Medicare Part B	Clarified exclusion criteria verbiage and added Nurtec as a preferred drug for the trial and failure criteria requirements. Quantity limit added.
Xolair	For asthma: 1. Updated trial and failure criteria to align with GINA 2023 guidelines, 2. Updated severity criteria, defining duration in which exacerbations must have occurred which aligns with clinical trials and added additional definitions of severity, 3. Updated age restrictions language to require age be within FDA label, 4. Clarified reauthorization criteria language to require documentation of improvement or stabilization of condition.
Xolair – Medicare Part B	For asthma: 1. Updated trial and failure criteria to align with GINA 2023 guidelines, 2. Updated severity criteria, defining duration in which exacerbations must have occurred which aligns with clinical trials and added additional definitions of severity, 3. Updated age restrictions language to require age be within FDA label
• **Zeposia** • **Zeposia - Medicaid**	Updated criteria to require that patients initiating therapy will be required to either have highly active disease, previously used at least three different therapies, or have trial of one of the generic medications currently available: dimethyl fumarate, glatiramer, fingolimod, or teriflunomide.
Ztalmy	Updated coverage duration for initial authorization to 12 months. Reduced requirement of prerequisites therapies to one agent and removed adjunct therapy requirement

RETIRED POLICIES	
Policy Name	**Summary of Change**
Ongentys Step Therapy Policy	Policy retired and drug removed from the formulary due to very low utilization and low risk of inappropriate use.