Providence Health Plan

Providence Health Assurance

Healthcare Services Medical & Pharmacy Policy Alerts

Number 81

April 1, 2023

This is the April 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 5/1/2023

Proton Beam Radiation Therapy **MP167**	**Policy Updates:** No changes to criteria **Codes/PA:** • Configure codes 77520, 77522, 77523, 77525 to pay with no PA when billed with dx code C61 in any position. Continue to require Prior Auth when billed with other dx codes. **OHP:** These changes do not apply to OHP. The Prioritized List and the Oregon Administrative Rules will be followed.

Effective 6/1/2023

Back: Stabilization Devices and Interspinous Spacers **MP19**	**Policy Updates:** Change denial from investigational to not medically necessary. **Codes/PA:** Change configuration of codes 22867, 22868, 22869, 22870, and C1821 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.
Cardiac: Left Atrial Appendage Devices	**Policy Updates:** Change denial from investigational to not medically necessary. **Codes/PA:** Change configuration of codes 33267, 33268, 33269 to deny as not medically necessary.

MP66	**OHP:** These changes do not apply to OHP. The Prioritized List and the Oregon Administrative Rules will be followed.
Genetic Testing: Hereditary Breast and Ovarian Cancer **MP143**	**Policy Updates:** Change to denial for non-covered genetic testing for hereditary breast and/or ovarian cancer gene mutation(s) from "investigational" to "not medically necessary." **Codes/PA:** 0102U, 0103U, 0131U, 0132U – change denials from "investigational" to "not medically necessary." **OHP:** These changes do not apply to OHP. The Prioritized List and the Oregon Administrative Rules will be followed.
Inflammatory Bowel Disease: Measurement of Antibodies to Immunosuppressive Therapies **MP237**	**Policy Updates:** Change denial from investigational to not medically necessary. **Codes/PA:** Change configuration of codes 80145, 80230, and 80280 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.
Ovarian Cancer: Multimarker Serum Testing **MP43**	**Policy Updates:** Change to denial for multianalyte serum biomarker testing from "investigational" to "not medically necessary." **Codes/PA:** 81500, 81503, 0003U, 0375U – change denials from "investigational" to "not medically necessary." **OHP:** These changes do not apply to OHP. The Prioritized List and the Oregon Administrative Rules will be followed.
Rhinoplasty and Other Nasal Surgeries **MP166**	**Policy Updates:** Change denial from investigational to not medically necessary. **Codes/PA:** Change configuration of codes 30468 and 30469 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.
Psychological and Neuropsychological Testing **MP274**	**Policy Updates:** Replace current criteria for non-computerized psychological testing, currently based on InterQual criteria, with criteria and documentation requirements taken from CMS (*Local Coverage Document, Psychological and Neuropsychological Testing* (L34646)) **Codes/PA:** No change to codes or configuration. **OHP:** These changes do not apply to OHP. The Prioritized List and the Oregon Administrative Rules will be followed.

Anesthesia Care with Diagnostic Endoscopy **MP105** *Previously All Lines of Business*	**Policy Updates:** • Remove Medicare lines of business from policy • Criterion II.C.2: Expand this criterion to include comorbidities such as neurological conditions, cardiac conditions, uncooperative or combative members, pregnancy, asthma, lung disease. • Remove STOP BANG score, which is a repetitive criterion that is already addressed in criterion II.C.4 • Edit criterion IV, clarifying that "average risk" means ASA Class 1 or 2 (defined in policy guidelines) and that this criterion does not include members who need ERCP. **Codes/PA:** Removing PA for Medicare **OHP:** These changes do not apply to OHP. The Prioritized List and the Oregon Administrative Rules will be followed.
Bariatric Surgery **MP41**	**Policy Updates:** • Criterion IV for adolescent bariatric surgery: ○ Add BMI equal to 140% or 120% of the 95th percentile for age and sex as an alternative to ≥ 40 kg/m^2 and 35.0-39.9 kg/m^2. ○ Remove Tanner Score criterion. ○ Add criterion requiring member to demonstrate enough emotional and cognitive maturity to provide informed consent for the procedure. ○ Add criterion that requires family support but not coercion for surgery. • Criterion VIII- add hiatal hernia as an example of an internal hernia. • Change denial language from investigational to not medically necessary in criteria VI and XII **Codes/PA:** Change denial for codes 43290 and 43291 from investigational to not medically necessary **OHP:** These changes do not apply to OHP. The Prioritized List and the Oregon Administrative Rules will be followed.
Prostate: Protein Biomarkers and Genetic Testing **MP96**	**Policy Updates:** • Change criteria for Oncotype DX Genomic Prostate Score Assay to allow for members with unfavorable intermediate or high-risk prostate cancer. • Combine criteria I-III to simplify language. • Add PanGIA Prostate to Criterion III as a non-covered test.

	Codes/PA: • Add code 0228U (for PanGIA Prostate) to policy to deny as not medically necessary • Change denial of codes 0339U and 0343U from investigational to not medically necessary **OHP:** These changes do not apply to OHP. The Prioritized List and the Oregon Administrative Rules will be followed.
Prostate: MRI-Transrectal Ultrasound (MRI-TRUS) Fusion Biopsy **MP89** *Previously All Lines of Business*	**Policy Updates:** • Remove Medicare lines of business from scope of policy (separate Medicare policy created) • Change criterion I to allow for initial biopsy with MRI TRUS fusion • Change denial language 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.
Ablative Procedures to Treat Back and Neck Pain **MP21** *Formerly "Back: Ablative Procedures to Treat Back and Neck Pain"*	**Policy Updates:** Update E/I indications for ablation to NMN **Codes/PA:** Change E/I indications to NMN. **OHP:** These changes do not apply to OHP. The Prioritized List and the Oregon Administrative Rules will be followed.
New and Emerging Technologies and Other Non-covered Services *Formerly Investigational and Non-Covered Medical Technologies* **MP23**	**Policy Updates:** Separating codes into E/I and NMN to align with new workflow. **Codes/PA:** • Several codes changed from E/I to NMN • C9745 removed from policy- removed from policy 7/2022 • 0115U- removed- on Respiratory Virals Panel policy • 0116U- removed- on Drug Testing for Therapeutic or Substance Use policy • 0398T removed- now on MRgFUS policy • 0720T removed- now on Electrical Stimulation Non-Covered Therapies • 0228U removed-moving to Prostate Biomarker policy 6/1

	• 0402T removed- on Eye: Corneal Collagen Cross-Linking • 0394T, 0025U, 0086U, 0087U, 0088U, 0095U, 0096U, 0164U, 0174U, 0546T, 55874, 64910, C9122, C9352, C9353, C9355, C9361, G0069, L8701, L8702- add as NMN. • 0480T, 0499T, 64912, 64913, K1031, K1032, K1033 - add to policy • Add 0559T, 0560T, 0561T, 0562T to CRW as E/I. • Re-add 0412T as NMN. Was removed in error 1/2022. **OHP:** These changes do not apply to OHP. The Prioritized List and the Oregon Administrative Rules will be followed.

MEDICARE

Effective 6/1/23

Ablative Procedures to Treat Back and Neck Pain **MP13** ***Previously:*** *Back: Ablative Procedures to Treat Back and Neck Pain*	**Policy Updates:** No change to criteria in this Medicare policy, but because the Company policy criteria are changing from INV to NMN, this changes some of the generic language found in the Medicare version. **Codes/PA:** No changes to codes or configuration.
Bariatric Surgery **MP37**	**Policy Updates:** No change to criteria. The Medicare criteria is not changing, because some of criteria in the Company policy is changing from INV to NMN, this changes some of the generic language found in the Medicare version. **Codes/PA:** No changes to codes or configuration
Cardiac: Left Atrial Appendage Devices **MP74**	**Policy Updates:** No change to criteria in this Medicare policy, but because the Company policy criteria are changing from INV to NMN, this changes some of the generic language found in the Medicare version. **Codes/PA:** No changes to codes or configuration for Medicare (edits from E/I to NMN were changed in 2022).

Inflammatory Bowel Disease: Measurement of Antibodies to Immunosuppressive Therapies **MP345**	**Policy Updates:** No change to criteria in this Medicare policy, but because the Company policy criteria are changing from INV to NMN, this changes some of the generic language found in the Medicare version. **Codes/PA:** No changes to codes or configuration.
Rhinoplasty and Other Nasal Surgeries **MP247**	**Policy Updates:** No change to criteria in this Medicare policy, but because the Company policy criteria are changing from INV to NMN, this changes some of the generic language found in the Medicare version. **Codes/PA:** No changes to codes or configuration.
Prostate: MRI-Transrectal Ultrasound (MRI-TRUS) Fusion Biopsy **MP387**	**Policy Updates:** New Medicare policy, separating by line of business. No change to coverage criteria, continue to use Company medical policy criteria. *Note that with the 2023 annual review, Company criteria is changing from an INV denial to a NMN denial, which will also apply to Medicare plan members.* **Codes/PA:** No change to codes or configuration.
Advanced Diabetes Management Technology **MP25**	**Policy Updates:** Policy updates include the following: • Add replacement criteria. • Medicare coverage for CGMs has evolved quite a bit since 2017. During this update, recommend adding a visual aid to assist with understanding these changes and how Medicare expects these to be billed/reported. • Also of note, the COVID PHE is supposed to end 5/11/2023, so the temporary policy provision language will be updated to reflect this as well. **Codes/PA:** Codes and configuration changes are as follows: • Add A9279, E0782, E0783, and E0786 to policy. No change to configuration for any of these codes. Continue U09 denial for A9279 and No PA for E0782, E0783, and E0786. • Add S1030, S1031 to policy. • No change to other codes or configuration in the policy.
Prostate: Protein Biomarkers and Genetic Testing	**Policy Updates:** No change to criteria. Move one test from the Medicare NET policy to this policy (PanGIA Prostate; 0228U). Add summaries for both MolDX and non-MolDX service areas to assist with appeal write-ups. **Codes/PA:** Add 0228U to this policy, but no change to NMN denial. No changes to other codes/configuration.

MP95	
New and Emerging Technologies and Other Non-Covered Services **MP220**	**Policy Updates:** Remove 0228U for PanGIA Prostate test and transfer it to the *Prostate: Protein Biomarkers and Genetic Testing* policy. **Codes/PA:** Move 0228U from this policy to another policy, but no change to NMN denial. No changes to other codes/configuration.

VENDOR UPDATES

eviCore ASO Expansion

Please be aware that several Self-Funded Administrative Only (ASO) group plans will be adding the use of eviCore medical necessity reviews for outpatient rehabilitation, group and renewal dates provided below. Providers will need to request medical necessity review through eviCore healthcare for dates of service starting on plan renewal dates, as outlined below.
* Please note that Providence will continue to require a request to eviCore on all Commercial and Individual members.

For additional information, including eviCore's clinical guidelines and a complete list of services requiring medical necessity review, please visit: https://www.eviCore.com/healthplan/PHP or call the eviCore Client Provider Operations department at (800) 646-0418 (Option #4).

The following ASO plans become effective with the process outlined above on the following dates:
Effective 1/1/2023:

- Providence St. Joseph Health Groups (including Providence Health & Services, Swedish Health Services, Kadlec, Pacific Medical Centers, St. Joseph Health, and Covenant Health)
- Clackamas County
- COLLEGENET Inc
- Covenant Health

- Umpqua Health LLC
- Riverpoint Medical
- Marathon Coach
- Oregon Episcopal School
- SAIF Corporation

Effective 2/1/2023:

- Combined Transport, Inc.

Effective 4/1/2023:

- School District Trust

Effective 6/1/2023:

- Orthopedic and Fracture Clinic PC

Effective 8/1/2023

- Jet Industries

Effective 9/1/2023:

- Nosler

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

Pharmacy & Therapeutics (P&T) Committee

Oregon Region P&T Committee Meeting December 2, 2022
Go-Live Date: Wednesday, February 01, 2023, unless otherwise noted

Table of Contents:

New Drugs and Combinations:

1. **Betibeglogene autotemcel (Zynteglo) Plast. bag**
   a. **Indication**: For treatment of adult and pediatric patients with beta-thalassemia who require regular red blood cell transfusions
   b. **Decision**:

	Company	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, Company 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 Company/Medicaid/Medicare Part B**:

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

REQUIRED MEDICAL INFORMATION	For beta-thalassemia, Zynteglo® may be approved when all the following criteria are met: 1. Documented diagnosis of beta-thalassemia confirmed by genetic testing 2. Patient has transfusion-dependent disease defined as one of the following: a. History of transfusions of at least 100 mL/kg/year of packed red blood cells (pRBCs) b. Eight or more transfusions of pRBCs per year in the two years preceding therapy 3. Patient is clinically stable and eligible to undergo the pre-conditioning regimen and infusion regimen. 4. Patient does not have any of the following: a. Prior history of receiving a hematopoietic stem-cell transplant b. Prior history of receiving gene therapy for the requested indication c. Advanced liver disease (such as evidence of cirrhosis and/or persistent alanine aminotransferase, aspartate transferase or direct bilirubin values greater than three times the upper limit of normal) d. Evidence of severe iron overload [such as T2* less than 10 ms by magnetic resonance imaging (MRI) or other evidence of severe iron overload in the opinion of treating physician]
AGE RESTRICTIONS	Must be 4 years of age or older
PRESCRIBER RESTRICTIONS	Must be prescribed by, or in consultation with, a hematologist
COVERAGE DURATION	Authorization will be limited to one treatment course per lifetime

2. **Sodium phenylbutyrate-taurursodiol (Relyvrio) Powd pack**
   a. **Indication**: For the treatment of amyotrophic lateral sclerosis (ALS) in adults.
   b. **Decision**:

	Company	Medicaid	Medicare
Formulary Status*	Formulary	Formulary	Part D: Formulary Part B: N/A
Tier**	Tier 6 - Non-Preferred Specialty	N/A	Specialty
Affordable Care Act Eligible	N/A; Non-Formulary	N/A	N/A
Utilization Management Edits	Prior Authorization	Prior Authorization	Prior Authorization
Quantity Limit	56 packets/28 days	56 packets/28 days	56 packets/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, Company Tier 6 designation above means that the medication will be placed on the highest cost-sharing tier on the respective formulary(ies).
Formulary Alternatives: riluzole, edaravone (Radicava ORS®)

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

PA PROGRAM NAME	Relyvrio
MEDICATION NAME	Sodium phenylbutyrate/taurursodil (Relyvrio®)
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 (a-d) must be met: a. Documentation of diagnosis of amyotrophic lateral sclerosis (ALS) b. Documentation of baseline ALS Functional Rating Scale-Revised (ALSFRS-R) c. Forced vital capacity (FVC) greater than 60% of predicted (taken within the past three months) d. Documentation that patient is not dependent on invasive ventilation or tracheostomy 2. For patients established on therapy, all the following criteria (a-b) 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 b. Documentation that patient is not dependent on invasive ventilation or tracheostomy
AGE RESTRICTIONS	N/A
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.

d. **Prior Authorization Criteria for Medicare Part D:**

PA PROGRAM NAME	Relyvrio
MEDICATION NAME	Sodium phenylbutyrate/taurursodil (Relyvrio®)
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 (a-d) must be met: a. Documentation of diagnosis of amyotrophic lateral sclerosis (ALS) b. Documentation of baseline ALS Functional Rating Scale-Revised (ALSFRS-R) c. Forced vital capacity (FVC) greater than 60% of predicted (taken within the past three months) d. Documentation that patient is not dependent on invasive ventilation or tracheostomy 2. For patients established on therapy, all the following criteria (a-b) 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 b. Documentation that patient is not dependent on invasive ventilation or tracheostomy
AGE RESTRICTIONS	N/A
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.

3. **Oteseconazole (Vivjoa) Capsule**
   a. **Indication**: To reduce the incidence of recurrent vulvovaginal candidiasis (RVVC) in females with a history of RVVC who are NOT of reproductive potential.
   b. **Decision**:

	Company	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	18 capsules/4 months	18 capsules/4 months	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, Company Tier 6 designation above means that the medication will be placed on the highest cost-sharing tier on the respective formulary(ies).
Formulary Alternatives: oral fluconazole

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

PA PROGRAM NAME	Antifungal Agents
MEDICATION NAME	Oteseconazole (Vivjoa®)
REQUIRED MEDICAL INFORMATION	1. For recurrent vulvovaginal candidiasis (RVVC) (oteseconazole only) must meet all of the following criteria: a. Documentation that therapy is aligned with FDA approved indication (specifically, patient is a female who is NOT of reproductive potential) b. Documentation of compatible clinical symptoms (such as vulvovaginal irritation, burning, pruritus, characteristic discharge, or edema/erythema) c. Documentation of suggestive diagnosis by slide (10% KOH prep or saline mount) or fungal culture/histopathology d. Documented failure, intolerance, or contraindication to BOTH of the following: i. A 7- to 14-day topical azole course ii. An oral fluconazole course (specifically, oral fluconazole given every third day for a total of 3 doses)
COVERAGE DURATION	For recurrent vulvovaginal candidiasis (RVVC): initial authorization and reauthorization will be approved for six months.

d. **Prior Authorization Criteria for Medicare Part D:**

PA PROGRAM NAME	Antifungal Agents
MEDICATION NAME	Oteseconazole (Vivjoa®)
REQUIRED MEDICAL INFORMATION	For recurrent vulvovaginal candidiasis (RVVC) in females with a history of RVVC who are NOT of reproductive potential (oteseconazole only): a. Documentation of compatible clinical symptoms (such as vulvovaginal irritation, burning, pruritus, characteristic discharge, or edema/erythema), b. documentation of suggestive diagnosis by slide (10% KOH prep or saline mount) or fungal culture/histopathology, and c. documented failure, intolerance, or contraindication to both of the following: i. 7-14 day topical azole course and ii. An oral fluconazole course (specifically given every third day for a total of three doses)
COVERAGE DURATION	Recurrent vulvovaginal candidiasis (RVVC): initial/reauth 6 months.

4. **Olipudase alfa-rpcp (Xenpozyme) Vial**
   a. **Indication**: For the treatment of non-central nervous system (CNS) manifestations of acid sphingomyelinase deficiency (ASMD), also known as ASM-deficient Niemann-Pick disease, in adult and pediatric patients.
   b. **Decision**:

	Company	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, Company 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 Company/Medicaid/Medicare Part B**:

PA PROGRAM NAME	Enzyme Replacement Therapy
MEDICATION NAME	Olipudase alfa-rcpc (Xenpozyme)
PA INDICATION INDICATOR	1 - All FDA-Approved Indications
OFF-LABEL USES	N/A
EXCLUSION CRITERIA	N/A
REQUIRED MEDICAL INFORMATION	For initial authorization all the following must be met: 1. Documentation of FDA-labeled indication for the requested product **AND** 2. Dosing is within FDA-labeled guidelines AND For olipudase alfa (Xenpozyme®) only, the following additional criteria apply: a. Clinical presentation must be consistent with acid sphingomyelinase deficiency (ASMD) type B OR ASMD type A/B

	b. Spleen volume of six (6) multiples of normal (MN) or more for adults OR five (5) MN or more for those less than 18 years old c. For adults only, diffusing capacity of the lungs for carbon monoxide (DLco) equal to 70% or less of predicted normal value d. The following are excluded from coverage: i. Use of invasive ventilatory support, or noninvasive ventilatory support while awake for greater than 12 hours a day ii. Acute or rapidly progressive neurological abnormalities and/or genotypes associated with ASMD type A, meaning homozygous for SMPD1 gene mutations R496L, L302P, and fs330 or any combination of these three mutations Note: If request is for a non-FDA approved dose, medical rational must be submitted in support of therapy with a higher dose for the intended diagnosis (such as high-quality peer reviewed literature, accepted compendia or evidence-based practice guidelines) and exceptions will be considered on a case-by-case basis. **REAUTHORIZATION:** Both of the following must be met: 1. Documentation of successful response to therapy (e.g., disease stability or improvement in symptoms). a. For olipudase alfa (Xenpozyme) only, documentation of improvement in at least one of the following: spleen volume, liver volume, platelet count, DLco or forced vital capacity (FVC) 2. Dosing is within FDA-labeled guidelines Note: If request is for a non-FDA approved dose, medical rational must be submitted in support of therapy with a higher dose for the intended diagnosis (such as high-quality peer reviewed literature, accepted compendia or evidence-based practice guidelines) and exceptions will be considered on a case-by-case basis.

5. **Spesolimab-sbzo (Spevigo) Vial**
   a. **Indication**: For the treatment of generalized pustular psoriasis (GPP) flares in adults.
   b. **Decision**:

	Company	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, Company Tier 6 designation above means that the medication will be placed on the highest cost-sharing tier on the respective formulary(ies).			
Formulary Alternatives: cyclosporine			

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

PA PROGRAM NAME	Spevigo®
MEDICATION NAME	Spevigo® injection
PA INDICATION INDICATOR	1 - All FDA-Approved Indications
OFF-LABEL USES	N/A
EXCLUSION CRITERIA	N/A
REQUIRED MEDICAL INFORMATION	For initial authorization, all of the following criteria must be met: 1. Diagnosis of generalized pustular psoriasis (GPP), confirmed by both of the following: a. Primary, sterile, macroscopically visible pustules on non-acral skin **AND** b. Pustulation is not restricted to psoriatic plaques 2. Presence of an acute flare of generalized pustular psoriasis of moderate to severe intensity, as defined by: a. Generalized Pustular Psoriasis Physician Global Assessment (GPPGA) total score of 3 or greater **AND** b. The presence of new or worsening pustules **AND** c. Generalized Pustular Psoriasis Physician Global Assessment (GPPGA) pustulation sub score of 2 or greater **AND** d. At least 5% of body surface area (BSA) with erythema and the presence of pustules 3. Dosing must be in accordance with FDA-approved labeling Requests for one additional dose may be approved one week after initial dose for treatment of the same flare if the following criteria are met: 1. Generalized Pustular Psoriasis Physician Global Assessment (GPPGA) total score of 2 or higher **AND**

	2. Generalized Pustular Psoriasis Physician Global Assessment (GPPGA) pustulation sub score of 2 or higher 3. Dosing must be in accordance with FDA-approved labeling For reauthorization, all of the following criteria must be met: 1. All criteria for initial authorization must be met **AND** 2. Documentation of a clinical response to prior treatment with spesolimab, defined as achieving a Generalized Pustular Psoriasis Physician Global Assessment (GPPGA) score of 0 or 1
AGE RESTRICTIONS	18 years and older
PRESCRIBER RESTRICTIONS	Must be prescribed by, or in consultation with, a dermatologist
COVERAGE DURATION	Authorization will be approved for two weeks, limited to one 900 mg (2 vials) infusion

6. **Vutrisiran sodium (Amvuttra) Syringe**
   a. **Indication**: For the treatment of the polyneuropathy of hereditary transthyretin-mediated amyloidosis (hATTR-PN) in adults.
   b. **Decision**:

	Company	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, Company Tier 6 designation above means that the medication will be placed on the highest cost-sharing tier on the respective formulary(ies).
Formulary Alternatives: patisiran (Onpattro ®), inotersen (Tegsedi®), diflunisal 500 mg tablet

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

PA PROGRAM NAME	Transthyretin (TTR) Lowering Agents
MEDICATION NAME	**Onpattro®** (patisiran intravenous injection) **Tegsedi®** (inotersen subcutaneous injection) **Amvuttra®** (vutrisiran subcutaneous injection)
PA INDICATION INDICATOR	1 - All FDA-Approved Indications
EXCLUSION CRITERIA	- New York Heart Association (NYHA) Heart Functional class III or IV ~~- Patients with type I or type II diabetes~~ ~~- Uncontrolled cardiac arrhythmia or unstable angina~~ - History of liver transplantation - Peripheral neuropathy attributed to causes other than hATTR - Used in combination with other agents for the treatment of transthyretin-mediated amyloidosis [such as Amvuttra® (vutrisiran), inotersen (Tegsedi®), patisiran (Onpattro®), or tafamidis (Vyndaqel®, Vyndamax®)]
REQUIRED MEDICAL INFORMATION	Reauthorization: 1. Documentation that patient is tolerating applicable therapy (vutrisiran (Amvuttra®), inotersen (Tegsedi®), or patisiran (Onpattro®))

New Indications:

Therapies with Prior Authorization Policies (Non-oncology)

1. **Orkambi® (**lumacaftor/ivacaftor)
    a. Previous Indication(s):
        a. ORKAMBI is a combination of lumacaftor and ivacaftor, a cystic fibrosis transmembrane conductance regulator (CFTR) potentiator, indicated for the treatment of cystic fibrosis (CF) in patients age **2 years and older** who are homozygous for the F508del mutation in the CFTR gene. If the patient's genotype is unknown, an FDA-cleared CF mutation test should be used to detect the presence of the F508del mutation on both alleles of the CFTR gene.
    b. New indication approved 09/02/2022:

a. ORKAMBI is a combination of ivacaftor, a cystic fibrosis transmembrane conductance regulator (CFTR) potentiator, and lumacaftor, indicated for the treatment of cystic fibrosis (CF) in patients aged **1 year and older** who are homozygous for the F508del mutation in the CFTR gene. If the patient's genotype is unknown, an FDA-cleared CF mutation test should be used to detect the presence of the F508del mutation on both alleles of the CFTR gene.

c. **RECOMMENDATION:** Inform prescribers via Medical Policy Alert. Update policy with new indication and update age restriction criteria in the Company/Medicaid policy. No changes needed to the Medicare Part D policy.
Prior Authorization for Company/Medicaid:

PA PROGRAM NAME	CFTR Modulators
MEDICATION NAME	Orkambi
AGE RESTRICTIONS	~~Ivacaftor (Kalydeco™): four months or older~~ ~~Lumacaftor/ivacaftor (Orkambi™): two years or older~~

2. **Dupixent® (**dupilumab)
   a. Previous Indication(s):
      a. For the treatment of adult and pediatric patients aged 6 months and older with moderate-to-severe AD whose disease is not adequately controlled with topical prescription therapies or when those therapies are not advisable. Can be used with or without topical corticosteroids.
      b. As an add-on maintenance treatment of adult and pediatric patients aged 6 years and older with moderate-to-severe asthma characterized by an eosinophilic phenotype or with oral corticosteroid dependent asthma
      c. As an add-on maintenance treatment in adult patients with inadequately controlled chronic rhinosinusitis with nasal polyposis (CRSwNP)
      d. For the treatment of adult and pediatric patients aged 12 years and older, weighing at least 40 kg, with eosinophilic esophagitis (EoE)
   b. New indication approved 09/28/2022:
      a. For the treatment of adult patients with prurigo nodularis (PN)
   c. **RECOMMENDATION:** Inform prescribers via Medical Policy Alert. Update policy with new indication and add new criteria
Prior Authorization for Company/Medicaid:

PA PROGRAM NAME	Dupixent
MEDICATION NAME	Dupixent
COVERED USES	1 - All FDA-Approved Indications
EXCLUSION CRITERIA	Concurrent use with another therapeutic immunomodulator agent utilized for the same indication (such as omalizumab, mepolizumab, benralizmab, reslizumab, upadacitinib)

REQUIRED MEDICAL INFORMATION	**For Prurigo Nodularis (PN):** 1. For initiation of therapy, all the following must be met a. Diagnosis of PN for at least 3 months b. Documentation of severe or very severe itch with a Worst-Itch Numeric Rating Scale (WI-NRS) score of 7 or greater c. Documentation of at least 20 PN lesions in total on both legs and/or both arms and/or trunk d. Patient had an inadequate response to, or has an intolerance or contraindication to all of the following therapies: a. Standard topical antipruritic agents (such as menthol and camphor, oatmeal baths, pramoxine, and calamine lotion) b. First-generation oral antihistamine, tricyclic antidepressant, or selective serotonin reuptake inhibitor for the purpose of controlling itching c. Moderate to high potency topical corticosteroid for at least two weeks (such as clobetasol 0.05%, betamethasone dipropionate 0.05%, triamcinolone 0.5%) 2. For reauthorization for PE: documentation of positive clinical response to therapy, including reduced number of PN nodules and decreased severity of itching.
AGE RESTRICTIONS	The patient's age must be within FDA labeling for the requested indication
PRESCRIBER RESTRICTIONS	• Prurigo Nodularis: Must be prescribed by, or in consultation with, a dermatologist
COVERAGE DURATION	For atopic dermatitis, chronic rhinosinusitis with nasal polyposis, eosinophilic esophagitis, and prurigo nodularis: Initial authorization will be approved for six months. Reauthorization will be approved for one year.

Prior Authorization for Medicare Part D:

PA PROGRAM NAME	Dupixent
MEDICATION NAME	Dupixent
PA INDICATION INDICATOR	1 - All FDA-Approved Indications

EXCLUSION CRITERIA	Concurrent use with another therapeutic immunomodulator agent utilized for the same indication.
AGE RESTRICTIONS	N/A
PRESCRIBER RESTRICTIONS	Atopic dermatitis, prurigo nodularis: Must be prescribed by, or in consultation with, a dermatologist, allergist or immunologist.
COVERAGE DURATION	Asthma: until no longer eligible with the plan. All other indications: initial/reauth 1 yr
OTHER CRITERIA:	For Prurigo Nodularis (PN), all the following: a. Diagnosis of PN for at least 3 months, b. Documentation of severe or very severe itch, c. Documentation of at least 20 PN lesions in total on both legs and/or both arms and/or trunk. d. Patient has had an inadequate response to at least 2 weeks of moderate to high topical corticosteroids (such as clobetasol, betamethasone dipropionate, triamcinolone) Reauthorization for PN: documentation of positive clinical response to therapy, such as reduced number of PN nodules and decreased severity of itching.

3. **Firdapse® (**amifampridine)
    a. Previous Indication(s):
        a. For the treatment of Lambert-Eaton myasthenic syndrome (LEMS) in adults
    b. New indication approved 09/29/2022:
        a. For the treatment of Lambert-Eaton myasthenic syndrome (LEMS) in adults and pediatric patients **6 years of age and older**
    c. **RECOMMENDATION:** Inform prescribers via Medical Policy Alert. Update Company/Medicaid policy with new indication and modified age restriction. No changes needed to the Medicare Part D policy.
    Prior Authorization for Company/Medicaid:

PA PROGRAM NAME	Firdapse
MEDICATION NAME	Firdapse
AGE RESTRICTIONS	~~N/A.~~ The patient's age must be within FDA labeling for the requested indication.

4. **Myfembree® (**relugolix, estradiol, and norethindrone acetate)
    a. Previous Indication(s):

a. For the management of heavy menstrual bleeding associated with uterine leiomyomas (fibroids) in premenopausal women.

b. New indication approved 08/05/2022:
   a. For the management of moderate to severe pain associated with endometriosis

c. **RECOMMENDATION:** Inform prescribers via Medical Policy Alert. Update policy with new indication and add Myfembree to criteria for pain associated with endometriosis
Prior Authorization for Company/Medicaid:

PA PROGRAM NAME	GNRH Antagonists
MEDICATION NAME	Myfembree
COVERED USES	1 - All FDA-Approved Indications
EXCLUSION CRITERIA	
REQUIRED MEDICAL INFORMATION	For endometriosis (Orilissa® and Myfembree® only): Initial Authorization 1. Documentation that patient has moderate to severe pain associated with endometriosis AND 2. Documentation that patient has failed a three-month trial of hormonal contraceptives unless they are not tolerated, or contraindicated

Therapies with Prior Authorization Policies (Oncology)

a. **Imbruvica® (**ibrutinib)
   i. New indication(s) approved 08/24/2022:
      - Adult and pediatric patients age 1 year and older with chronic graft versus host disease (cGVHD) after failure of one or more lines of systemic therapy
   ii. **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.

b. **Lynparza® (**olaparib)
   i. Indication Withdrawn 8/26/2022:
      - For the treatment of adult patients with deleterious or suspected deleterious germline BRCA-mutated (gBRCAm) advanced ovarian cancer who have been treated with three or more prior lines of chemotherapy. Select patients for therapy based on an FDA-approved companion diagnostic for Lynparza
        - Indication was voluntarily withdrawn due to subgroup analysis of the SOLO3 trial showing patients treated with Lynparza saw a 33% greater risk of death than controls who received standard chemotherapy.

https://www.biospace.com/article/astrazeneca-merck-pull-lynparza-indication-heralding-more-trouble-for-parp-inhibitors/

ii. **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.

c. **Pemazyre® (**pemigatinib)
   i. New indication(s) approved 08/26/2022:
      - For the treatment of adults with relapsed or refractory myeloid/lymphoid neoplasms (MLNs) with FGFR1 rearrangement.
   ii. **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.

d. **Retevmo® (**selpercatinib)
   i. New indication(s) approved 09/21/2022:
      - For Adult patients with locally advanced or metastatic non-small cell lung cancer (NSCLC) with a rearranged during transfection (RET) gene fusion, **as detected by an FDA-approved test**
      - Adult patients with locally advanced or metastatic solid tumors with a RET gene fusion that have progressed on or following prior systemic treatment or who have no satisfactory alternative treatment options
   ii. **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.

e. **Tabrecta® (**capmatinib)
   i. New full indication(s) approved 08/10/2022, previously approved under accelerated approval:
      - For the treatment of adult patients with metastatic non-small cell lung cancer (NSCLC) whose tumors have a mutation that leads to mesenchymal-epithelial transition (MET) exon 14 skipping as detected by an FDA-approved test.
   ii. **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.

f. **Enhertu® (**am-trastuzumab deruxtecan-nxki)
   i. New indication(s) approved 08/11/2022:
      - For adult patients with unresectable or metastatic non-small cell lung cancer (NSCLC) whose tumors have activating HER2 (ERBB2) mutations, as detected by an FDA-approved test, and who have received a prior systemic therapy
   ii. **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.

g. **Imfinzi® (**durvalumab)
   i. New indication(s) approved 09/02/2022:
      - In combination with gemcitabine and cisplatin, as treatment of adult patients with locally advanced or metastatic biliary tract cancer (BTC)
   ii. **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

a. **Xofluza® (**baloxavir marboxil)
   i. Previous Indication(s):
      - Treatment of acute uncomplicated influenza in patients **12 years of age and older** who have been symptomatic for no more than 48 hours and who are:
        - Otherwise healthy, or
        - At high risk of developing influenza-related complications.
      - Post-exposure prophylaxis of influenza in patients 12 years of age and older following contact with an individual who has influenza.
   ii. New indication(s) approved 08/11/2022:
      - Treatment of acute uncomplicated influenza in patients who have been
      - symptomatic for no more than 48 hours and who are:
        - Otherwise healthy adults and pediatric patients **5 years of age and older**, OR
        - Adults and pediatric **patients 12 years of age and older** who are at high risk of developing influenza-related complications.
      - Post-exposure prophylaxis of influenza in patients **5 years of age and older** following contact with an individual who has influenza.
   iii. **RECOMMENDATION:** Inform prescribers via Medical Policy Alert.

Drug Safety Monitoring:

FDA Drug Safety Communications

No drug safety communications to report for this period

Drug Recalls/Market Withdrawals

1. **Drug Name:** Wonder Pill Capsules
   - **Date of Recall:** 9/28/2022
   - **Reason for recall:** Undeclared tadalafil

- **Link to more information:** https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/proper-trade-llcmy-stellar-lifestyle-issues-voluntary-nationwide-recall-wonder-pill-capsules-due
- **Health Plan Recommendation:** Notify providers via Medical Policy Alert.

2. **Drug Name:** Propofol Injection Emulsion, USP
   i. **Date of Recall:** 08/22/2022
   ii. **Reason for recall:** Potential presence of visible particulate
   iii. **Link to more information:** https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/hospira-issues-voluntary-nationwide-recall-one-lot-propofol-injectable-emulsion-containing-benzyl
   iv. **Health Plan Recommendation:** Notify providers via Medical Policy Alert.
3. **Drug Name:** Magnesium Citrate Saline Laxative Oral Solution
   i. **Date of Recall:** 08/04/2022
   ii. **Reason for recall:** Microbial contamination with Gluconacetobacter liquefaciens in multiple brand names, recall expanded to additional lots
   iii. **Link to more information:** https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/vi-jon-llc-expands-voluntary-worldwide-recall-all-flavors-and-lots-within-expiry-magnesium-citrate
   iv. **Health Plan Recommendation:** Notify providers via Medical Policy Alert.
4. **Drug Name:** Milk of Magnesia, Magnisium Hydroxide/Aluminum Hydroxide/Simethicone Oral Suspension
   i. **Date of Recall:** 08/04/2022
   ii. **Reason for recall:** Microbial contamination
   iii. **Link to more information:** https://www.fda.gov/drugs/drug-safety-and-availability/drug-recalls
   iv. **Health Plan Recommendation:** Notify providers via Medical Policy Alert.
5. **Drug Name:** Launch Sequence Aphrodisia and Euphoria Capsules
   i. **Date of Recall:** 08/03/2022
   ii. **Reason for recall:** Product contains tadalafil
   iii. **Link to more information:** https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/loud-muscle-science-llc-issues-voluntary-recall-launch-sequence-capsules-due-presence-undeclared
   iv. **Health Plan Recommendation:** Notify providers via Medical Policy Alert.
6. **Drug Name:** SANGTER Energy Supplement, 3000mg
   i. **Date of Recall:** 08/02/2022
   ii. **Reason for recall:** Product contains undeclared sildenafil
   iii. **Link to more information:** https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/distributor-rfr-llc-voluntary-nationwide-recall-sangter-energy-supplement-due-presence-undeclared
   iv. **Health Plan Recommendation:** Notify providers via Medical Policy Alert.

Providence Health Plan

Providence Health Assurance

Other Formulary Changes:

Drug Name	Recommendation	Policy Name
Dextromethorphan hbr/ bupropion hcl (Auvelity) Tab IR ER	New combination; • Company: Formulary, Tier 6, Step Therapy, Quantity Limit (two tablets per day) • Medicaid: Non-Formulary (covered by DMAP) • Medicare Part D: Formulary, Tier 5, Step Therapy, FDA Max (two tablets per day) Effective: 12/28/2022 (protected class)	• Company/Medicare Part D: Antidepressants Step Therapy Policy • Medicaid: N/A
Allopurinol 200 mg tablet	New strength; non-formulary for all lines of business	N/A
Budesonide 3 mg DR capsule	Down tier; • Company Dynamic: Tier 3	N/A
Pirfenidone Tablet	Down-tier generic and add Quantity Limit • Company: Tier 5, Quantity Limit (three tablets per day) • Medicaid: Formulary, Quantity Limit (three tablets per day) Effective: 03/01/2023	Esbriet/Ofev
Pirfenidone (Esbriet) Capsule	Non-preferred agent • Company/Medicaid: Remove from formulary, add Quantity Limit (three tablets per day) Effective: 03/01/2023	Esbriet/Ofev
Propranolol hcl (Hemangeol) Solution	Company: Add to Formulary, Tier 4, Specialty	N/A
Insulin degludec (Insulin Degludec Pen [U-100]) Insuln Pen	New generic product for Tresiba®: Non-formulary for all lines of business	N/A
Methocarbamol Tablet	New strength (1000 mg); • Company/Medicaid: Non-Formulary, Prior Authorization	• Company/Medicaid: New Medications and Formulations without Established Benefit

	• Medicare Part D: Non-Formulary	• Medicare Part D: N/A
Sodium chloride for inhalation (Nebusal) Vial-Neb	Add to Company and Medicaid formularies • Company: Tier 4 • Medicaid: Formulary	N/A
Orlistat Capsule	Authorized generic (Xenical); • Company Standard: Formulary, Tier 4 (only for those with coverage for weight loss medications) • Non-Formulary for all other lines of business	N/A
Sodium thiosulfate (Pedmark) Vial	New strength (12.5g/100ml); • Medical Benefit, Prior Authorization for all lines of business	Injectable Anti-Cancer Medications
Sodium phenylbutyrate (Pheburane) Granules	New dosage form (granules) and strength (483 mg/g); • Company/Medicaid: Non-Formulary, Prior Authorization, Specialty • Medicare Part D: Non-Formulary	• Company/Medicaid: Medications For Rare Indications - Orphan Drugs • Medicare Part D: N/A
Bismuth subcitrate/ metronidazole/tetracycline (Pylera) capsule	Add Quantity Limit for Company: 120 capsules per 28 days	N/A
Omeprazole/amoxicillin / rifabutin (Talicia) capsule	Add to Company Formulary: Tier 4, Quantity Limit 168 capsules per 28 days	N/A
Omeprazole/clarithromycin / amoxicillin (Omeclamox) capsule	Change Company formulary status: Tier 4 (from Tier 3), add Quantity Limit One pack per 28 days	• N/A
Sevelamer Carbonate Powder Pack	Add to Step Therapy Program for Company and Medicaid: Effective: 03/01/2023	• Company/Medicaid: Phosphate Binders Step Therapy Policy
Sevelamer Carbonate Tablet	Down-tier generic • Company Dynamic: Down tier from Tier 3 to Tier 2 • Medicare Part D: From Tier 4 to Tier 3	N/A

Tadalafil (Tadliq) Oral Susp	New dosage form (oral susp); • Company/Medicaid: Non-Formulary, Prior Authorization • Medicare Part D: Non-Formulary	• Company/Medicaid: New Medications and Formulations without Established Benefit • Medicare Part D: N/A
Tolmetin Sodium Tablet	Remove from Company and Medicaid formularies (obsolete agent)	N/A
Zonisamide (Zonisade) Oral Susp	New dosage form. Add to Medicare Part D Formulary, Tier 4	N/A
Roflumilast (Zoryve) Cream (G)	New route (topical), dosage form (cream) and strength (0.3%); • Company/Medicaid: Non-Formulary, Prior Authorization, Quantity Limit (60 grams per 30 days) • Medicare Part D: Non-Formulary	• Company/Medicaid: Vtama • Medicare Part D: N/A
Dexlansoprazole (Dexilant) Cap DR MP	Remove from Company formulary	N/A
Avatrombopag maleate (Doptelet) Tablet	Remove from Medicaid formulary	• Medicaid: Thrombocytopenia Medications
• **BRAND Epclusa® tablets and pellet packets**	Remove from Company and Medicaid formularies Effective: 01/01/2023	• Company: Hepatitis C - Direct Acting Antivirals • Medicaid: Hepatitis C - Direct Acting Antivirals – Medicaid
• **BRAND Harvoni® tablets and pellet packets**	Remove from Company and Medicaid formularies Effective: 01/01/2023	• Company: Hepatitis C - Direct Acting Antivirals • Medicaid: Hepatitis C - Direct Acting Antivirals – Medicaid
Sodium Zirconium Cyclosilicate (Lokelma) Powd Pack	Retire prior authorization and add to formulary: • Company: Tier 3 • Medicaid: Formulary • Medicare part D: Tier 3	N/A
Patiromer Calcium Sorbitex (Veltassa) Powder Pack	Retire prior authorization and add to formulary: • Company: Tier 3 • Medicaid: Formulary • Medicare part D: Tier 3	N/A

Glecaprevir/Pibrentasvir (Mavyret) Pellet Pack	Remove from Medicaid formulary	Medicaid: Hepatitis C - Direct Acting Antivirals – Medicaid
Lusutrombopag (Mulpleta) Tablet	Remove from Medicaid formulary	Thrombocytopenia Medications
Ketoconazole (Nizoral) Tablet	Add to Company Formulary: • Company Standard: Tier 2 • Company Dynamic: Tier 4	N/A
• **Sofosbuvir (Sovaldi) Pellet Pack and Tablet** • **Ombita/Paritap/Ritonavir/ Dasabuvir (Viekira Pak) Tab DS PK** • **Elbasvir/Grazoprevir (Zepatier) Tablet**	Non-preferred agents; remove from Company formulary Effective: 01/01/2023	Hepatitis C - Direct Acting Antivirals
Sofosbuvir/Velpatas/ Voxilaprevir (Vosevi) Tablet	Non-preferred agent • Company: Change from Tier 5 to Tier 6 • Medicaid: Remove from Formulary Effective: 01/01/2023	• Company: Hepatitis C - Direct Acting Antivirals • Medicaid: Hepatitis C - Direct Acting Antivirals – Medicaid

	Company	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, Company Tier 6 designation above means that the medication will be placed on the highest cost-sharing tier on the respective formulary(ies).			
Formulary Alternatives: patisiran (Onpattro ®), inotersen (Tegsedi®), diflunisal 500 mg tablet			

The formulary status for the following drugs was line extended in accordance with

Providence HealthPlan Pharmacy Operational Policy ORPTCOPS062

NEW DRUGS / COMBINATIONS / STRENGTHS / DOSAGE FORMS		
Drug Name	**Action Taken**	**Policy Name**
Lumateperone tosylate (Caplyta) Capsule	Correction from October 2022 P&T: • Company/Medicare Part D: Add Quantity Limit (1 capsule per day)	• Company: Antipsychotics Step Therapy Policy • Medicare Part D: Antipsychotics Program
Indigotindisulfonate sodium (Bludigo) Ampul	New route (Ampule). Line extend with Indigo; • Medical benefit for all lines of business	N/A
Lumacaftor/Ivacaftor (Orkambi) Gran Pack	New strength (75-94 mg). Line extend with Orkambi 100-125 mg; • Company/Medicare Part D: Formulary, Tier 5, Prior Authorization, Quantity Limit (two packets per day) • Medicaid: Formulary, Specialty, Prior Authorization, Quantity Limit (two packets per day)	CFTR Modulators
Doxycycline hyclate (Doryx MPC) Tablet DR	New strength (60mg). Line extend with Doryx MPC 120 mg; • Company/Medicaid: Non-Formulary, Prior Authorization • Medicare Part D: Non-Formulary	• Company/Medicaid: New Medications and Formulations without Established Benefit • Medicare Part D: N/A
Ibrutinib (Imbruvica) Oral Susp	New dosage form (oral susp). Line extend with Imbruvica; • Company: Formulary, Tier 6, Prior Authorization • Medicaid: Formulary, Specialty, Prior Authorization • Medicare Part D: Formulary, Tier 5, Prior Authorization	Oral Anti-Cancer Medications
Ranibizumab-eqrn (Cimerli) Vial	Interchangeable with Lucentis. Line extend with Lucentis;	• Company/Medicaid: Ophthalmic Vascular Endothelial Growth Factor (VEGF) Inhibitors

	• Company/Medicaid: Medical Benefit, Prior Authorization • Medicare Part D: Non-Formulary • Medicare Part B: Medical Benefit, Prior Authorization & Step Therapy	• Medicare Part B: Ophthalmic Vascular Endothelial Growth Factor (VEGF) Inhibitors - Medicare Part B
Dalteparin Sodium, Porcine (Fragmin) Vial	New strength (10000U/4ml). Line extend with Fragmin; • Company: Formulary, Tier 6, Self-Administered Drug Exclusion • Medicaid: Non- Formulary, Self-Administered Drug Exclusion • Medicare Part D: Formulary, Tier 5	Self-Administered Drug (SAD) Exclusion

New Generics:

Drug Name	Action Taken	Policy Name
Tazarotene Gel (Gram)	First generic (Tazorac). Line extend as generic; • Company/Medicaid: Non-Formulary • Medicare Part D: Formulary, Tier 4, Prior Authorization	• Company/Medicaid: N/A • Medicare Part D: Topical Retinoid Products
Lenalidomide Capsule	First generic (Revlimid). Line extend as generic; • Company: Formulary, Tier 5, Prior Authorization • Medicaid: Formulary, Specialty, Prior Authorization • Medicare Part D: Formulary, Tier 5, Prior Authorization	Oral Anti-Cancer Medications
Icosapent Ethyl Capsule	First generic (Vascepa). Line extend as generic; • Company Standard: Formulary, Tier 2, Prior Authorization	Vascepa

	• Company Dynamic: Formulary, Tier 3, Prior Authorization • Medicaid: Formulary, Prior Authorization • Medicare Part D: Formulary, Tier 3, Prior Authorization	
Estradiol Gel Packet	First generic (Divigel). Line extend as generic; • Non-formulary for all lines of business	N/A
Fingolimod hcl (Fingolimod) Capsule	First generic (Gilenya). Line extend as generic; • Company: Formulary, Tier 5, Quantity Limit (one capsule per day) • Medicaid: Formulary, Specialty, Quantity Limit (one capsule per day) • Medicare Part D: Formulary, Tier 5	N/A
Clonidine hcl (Clonidine HCL ER) Tab ER	Authorized generic (Nexiclon). Line extend as generic; • Company/Medicaid: Non-Formulary, Prior Authorization • Medicare Part D: Non-Formulary	• Company/Medicaid: New Medications and Formulations without Established Benefit • Medicare Part D: N/A
Cetrorelix acetate Kit	First generic (Cetrotide). Line extend as generic; • Company: Non-Formulary, Prior Authorization • Medicaid: Non-Formulary, Prior Authorization • Medicare Part D: Non-Formulary	• Company/Medicaid: Fertility and Related Medications • Medicare Part D: N/A
Roflumilast Tablet	First generic (Daliresp). Line extend as generic; • Company Standard: Formulary, Tier 2, Prior Authorization • Company Dynamic: Formulary, Tier 4, Prior Authorization	Daliresp

	• Medicaid: Non-Formulary, Prior Authorization • Medicare Part D: Formulary, Tier 4, Prior Authorization	

Clinical Policy Changes:

MAJOR CHANGES	
Policy Name	**Summary of Change**
Acute Hereditary Angioedema Therapy	Policy criteria for patients established on the requested therapy has been updated to require trial and failure of generic icatibant for requests for brand Firazyr® requests.
Aemcolo	Removed exclusion criteria to align policy with Oregon Health Authority criteria.
Albenza, Emverm	Clarified that infectious disease specialist prescribing would only be required if laboratory confirmation of parasitic infection is not available.
Alinia	Changed criteria for *C. parvum* infection to align with updated package labeling.
Chenodal	Criteria updated to include dose optimization criteria. For Medicaid, gallstones without cholecystitis is below the line, so a requirement for evidence of cholecystitis was added.
Constipation Agents	Updated criteria for chronic idiopathic constipation to resemble Rome IV diagnostic criteria more closely.
Empaveli	For Paroxysmal Nocturnal Hemoglobinuria, added “increase or stabilization of hemoglobin levels” as option for successful response to therapy at reauthorization. Added criteria for patients switching from eculizumab (Soliris®) or ravulizumab-CWVZ (Ultomiris®)
Enjaymo	Defined some of the criteria, added note that medications obtained as samples, coupons, other methods outside established health plan are not considered established on therapy.
Erythropoiesis Stimulating Agents (ESAs)	Added Mircera to policy, removed exclusion of anemia due to treatment for hepatitis C.
ESAs - Medicare Part B	
Formulary and Quantity Limit Exceptions	Added criteria for quantity limit reviews to allow for denials related to dose optimization.
Gattex	Updated to allow patients established on therapy to get continued coverage if they have a documented response to therapy.

Hepatitis C - Direct Acting Antivirals	Clarified preferred products for the Company line of business and that coverage of non-preferred regimens will require rationale for use over preferred formulary alternative regimens.
Hepatitis C - Direct Acting Antivirals - Medicaid	Update criteria to align with Oregon Health Authority Risk Corridor requirements. Prior authorization be removed on preferred therapies for treatment naïve patients. Additionally, life expectancy and hep B requirements were removed.
Lotronex	Re-worded criteria to clarify irritable bowel syndrome must be chronic (lasting at least six months) and not that severe symptom must have been occurring for at least six months.
Mepron	Expand prescriber restriction to allow review by infectious disease specialist, pulmonologist, hematologist, and oncologist.
Ocaliva	Increased trial duration for ursodiol from six months to 12 months.
Phosphate Binders Step Therapy Policy	Sevelamer carbonate powder packets were added to the policy due to large discrepancies in cost between these and carbonate tablets.
Prevymis	Updated criteria to align with FDA label and recommendations from the American Society for Transplantation and Cellular Therapy guideline. Retire prior authorization for Medicaid to align with Oregon Health Authority's preferred drug list.
Prevymis - Medicare Part B	
Pyrukynd	Changed criteria to initiation of therapy and for patients established on therapy, gave specific timeframes for documentation for patients established on therapy criteria.
Reblozyl	Removed minimum hemoglobin requirement for beta-thalassemia, updated criteria for myelodysplastic syndrome to align with NCCN guidelines.
Self-Administered Drug (SAD) Exclusion Policy	Drugs were added to the policy and criteria were clarified regarding prior history of anaphylaxis and appropriateness of medical administration for patients with needle phobia.
Soolantra Step Therapy Policy	Remove specific strength from metronidazole prerequisite.
Tavneos	Remove kidney and liver function criteria, remove cirrhosis as exclusion, remove requirement for reduction in glucocorticoid use from reauthorization criteria.
Thrombocytopenia Medications	Updated criteria for hematopoietic syndrome of acute radiation syndrome to align with FDA label, added indication specific criteria for hepatitis C associated thrombocytopenia.
Thrombocytopenia Medications - Medicare Part B	Updated criteria for hematopoietic syndrome of acute radiation syndrome to align with FDA label.
Ultomiris	For Paroxysmal Nocturnal Hemoglobinuria, added “increase or stabilization of hemoglobin levels” as option for successful response to therapy at reauthorization. Also added criteria
Ultomiris - Medicare Part B	

	for patients switching from pegcetacoplan (Empaveli®). For generalized myasthenia gravis, added criteria for patients switching from eculizumab (Soliris®).
Xermelo	Removed criteria requiring trial of short-acting somatostatin analogs and loperamide to align with National Comprehensive Cancer Network (NCCN) and North American Neuroendocrine Society (NANETS) guidelines. Changed requirement of 4+ bowel movements/day to “uncontrolled diarrhea.”
Xifaxan	Removed trial of loperamide for irritable bowel syndrome with diarrhea (IBS-D) to align with guidelines, changed maximum to three courses per rolling 6-month period.

RETIRED POLICIES	
Ketoconazole Tablets	Due to low utilization and is similarly priced to other formulary generic antifungal medications such as fluconazole
Mircera	Added Mircera to Erythropoiesis Stimulating Agents policy
Potassium Lowering Agents	Due low utilization and low risk of inappropriate utilization
Proton Pump Inhibitors Step Therapy Policy	All agents on this policy with be non-formulary and require trial of formulary agents prior to approval
Rukobia, Trogarzo	Due to low utilization and low risk of inappropriate utilization