Providence Health Plan

Providence Health Assurance

Healthcare Services Medical & Pharmacy Policy Alerts

Number 279

February 1, 2023

This is the February 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 3/1/2023

Applied Behavior Analysis (All Lines of Business Except Medicare) **MP288** *Previously: Applied Behavior Analysis*	**Policy Updates:** • This is an administrative policy outlining the process and requirements for PA and medical necessity review for ABA • This will be a Company only policy now. Split out Medicare and removed the PA for Medicare. **Codes/PA:** Remove PA from all ABA codes for Medicare only **OHP:** These changes do not apply to OHP. The Prioritized List and the Oregon Administrative Rules will be followed.

Effective 4/1/2023

Computer Assisted Navigation for Musculoskeletal Procedures (All Lines of Business Except Medicare) **MP375**	**Policy Updates:** A new policy for computer assisted navigation for musculoskeletal procedures **Codes/PA: C**odes 20985, 0054T, and 0055T will deny as not medically necessary **OHP:** OHP will follow the Company Policy above
Investigational and Non-Covered Medical Technologies (All Lines of Business Except Medicare) **MP23**	**Policy Updates:** Removing and adding codes, see coding summary **Codes/PA:** • Add code 0499T, L8701, L8702, K1024, K1025, K1031, K1032, K1033 as investigational • Remove the following codes ○ Expired: 0190T, 0337T, 0406T, 0407T, 77422, C9122, J7401, 0125U-0128U, C9048, 0139U ○ 0100T, 0213T-0218T, 0351T-0354T, 0397T, 0424T-0443T, 0469T, 0472T, 0473T, 0481T, 0485T-0487T, 0489T, 0491T, 0493T, 0506T, 0508T, 0512T, 0515T-0522T, 0533T-0536T, 0544T, 0545T, 0547T, 0553T-0558T, 0568T ○ Already addressed in another policy: 0089U, 0090U, 0202U, 0203U, 0404T, 58674 **OHP:** These changes do not apply to OHP. The Prioritized List and the Oregon Administrative Rules will be followed.
Radiofrequency Ablation for Tumors Outside the Liver (All Lines of Business Except Medicare) **MP67** *Previously: Breast Surgery: Radiofrequency Ablation of Breast Tumors*	**Policy Updates:** • Breaking policy out by line of business • Expands current RFA of breast tumors policy to include all tumors outside the liver. • Added note directing users to the medical policy addressing Liver Tumor Treatments. • Cover RFA of tumors outside the liver when criteria are met for the following indications: ○ Thyroid carcinoma (NCCN criteria) ○ Kidney cancer (NCCN criteria) ○ Non-small cell lung cancer (NCCN criteria) ○ Pain palliation in patients with osteolytic bone metastases ○ Osteoid osteomas ○ Colon cancer (NCCN criteria)) • Add RFA for uterine fibroids to list of non-covered services **Codes/PA:**

	• Add PA to the following codes
	  ○ **20982**- Ablation therapy for reduction or eradication of 1 or more bone tumors (eg, metastasis) including adjacent soft tissue when involved by tumor extension, percutaneous, including imaging guidance when performed; radiofrequency
	  ○ **31641** - Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; with destruction of tumor or relief of stenosis by any method other than excision (eg, laser therapy, cryotherapy)
	  ○ **50542** - Laparoscopy, surgical; ablation of renal mass lesion(s), including intraoperative ultrasound guidance and monitoring, when performed
	  ○ **32998** - Ablation therapy for reduction or eradication of 1 or more pulmonary tumor(s) including pleura or chest wall when involved by tumor extension, percutaneous, including imaging guidance when performed, unilateral; radiofrequency
	  ○ **50592** - Ablation, one or more renal tumor(s), percutaneous, unilateral, radiofrequency
	• Moved codes specific to uterine fibroid ablation (0404T and 58674) from the IMT policy to this policy; changed configuration for these codes 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.

Complementary and Alternative Medicine (All Lines of Business Except Medicare) **MP260**	**Policy Updates:** Added medical necessity criteria for therapeutic phlebotomy when billed with one of the diagnosis codes listed in the "Billing Guidelines." ○ This list of approved indications include: polycythemia vera, hemochromatosis, iron overload, erythrocytosis, porphyria. **Codes/PA:** • Configure CPT 99195 to pay only when billed with an approved diagnosis codes. If billed with a diagnosis code not on this list, CPT 99195 should deny as "not medically necessary." **OHP:** These changes do not apply to OHP. The Prioritized List and the Oregon Administrative Rules will be followed.
Genetic Testing: Non-Covered Genetic Panel Tests (All Lines of Business Except Medicare) **MP213**	**Policy Updates:** No changes to criteria. **Codes/PA:** • Add not medically necessary denial to 81320 - *PLCG2 (phospholipase C gamma 2) (eg, chronic lymphocytic leukemia) gene analysis, common variants (eg, R665W, S707F, L845F)*. Code is currently configured to PA. • For PLA code 0104U, need to also remove E/I edit for all lines of business retroactively effective to 10/1/2019

	OHP: OHP will follow the Company Policy above
Genetic Testing: Reproductive Planning and Prenatal Testing **(All Lines of Business Except Medicare)** **MP78**	**Policy Updates:** No changes to criteria. **Codes/PA:** Remove code 81320 - *PLCG2 (phospholipase C gamma 2) (eg, chronic lymphocytic leukemia) gene analysis, common variants (eg, R665W, S707F, L845F).* **OHP:** OHP will follow the Company Policy above

ARCHIVE

Effective 2/1/2023

Chelation Therapy for Non-Overload Conditions (All Lines of Business Except Medicare) **MP102**	**Policy Updates:** This policy will be archived, and the code configuration will be removed. **Codes/PA:** Remove diagnosis code configuration from codes M0300 and S9355. Address S code in Coding Policy 22.0

MEDICARE

Effective 3/1/23

Inflammatory Bowel Disease: Serologic Testing and Therapeutic Monitoring (Medicare Only) **MP344**	**Policy Updates:** No change to criteria. **Codes/PA:** Remove PA and add NMN denial to code 0203U. No changes to any other code in the policy.
Blood Counts (Medicare Only) **MP209**	**Policy Updates:** No changes to policy criteria. Continue to follow Medicare guidance for blood count testing. **Codes/PA:** Update diagnosis code configuration based on Medicare quarterly laboratory NCD edit changes. For Medicare, there will be multiple ICD-10 codes **added to deny.**
Glycated Hemoglobin and Glycated Protein Testing (Medicare Only) **MP236**	**Policy Updates:** No changes to policy criteria. Continue to follow Medicare guidance for glycated hemoglobin and protein testing. **Codes/PA:** Update diagnosis code configuration based on Medicare quarterly laboratory NCD edit changes.
Hepatitis Panel and Acute Hepatitis Panel Testing (Medicare Only) **MP324**	**Policy Updates:** No changes to policy criteria. Continue to follow Medicare guidance for hepatitis panel testing. **Codes/PA:** Update diagnosis code configuration based on Medicare quarterly laboratory NCD edit changes. For Medicare, ICD-10 codes **added to pay** should be: F1191 F1291 F1491 F1591 K7682
Partial Thromboplastin Time (PTT) (Medicare Only) **MP326**	**Policy Updates:** No changes to policy criteria. Continue to follow Medicare guidance for PTT testing. **Codes/PA:** Update diagnosis code configuration based on Medicare quarterly laboratory NCD edit changes. For Medicare, ICD-10 codes **added to pay** should be: K7682 S0633AA

	S0634AA S0635AA S0636AA S064XAA S065XAA S066XAA S0689AA S068A0A S068A1A S068A2A S068A3A S068A4A S068A5A S068A6A S068A7A S068A8A S068A9A S068AAA S069XAA T43655A

Effective 4/1/23

Complementary and Alternative Medicine (Medicare Only) **MP327**	**Policy Updates:** • In the absence of specific Medicare guidance, will apply Company criteria, which is to allow as medically necessary when billed with one of the diagnosis codes listed in the "Billing Guidelines." ○ This list of approved indications include: polycythemia vera, hemochromatosis, iron overload, erythrocytosis, porphyria. **Codes/PA:** • Configured CPT 99195 to pay only when billed with an approved diagnosis code. If billed with a diagnosis code **not** on this list, CPT 99195 should deny as "not medically necessary." • No changes to any other code in the policy.

Computer Assisted Navigation for Musculoskeletal Procedures (Medicare Only) **MP376**	**Policy Updates:** New medical policy to address computer assisted navigation (CAN) with musculoskeletal or orthopedic surgical procedures. **Codes/PA:** Add NMN denials to 0054T, 0055T, and 20985.
Radiofrequency Ablation of Tumors Outside the Liver (Medicare Only) **MP377**	**Policy Updates:** New medical policy to address radiofrequency ablation (RFA) procedures of tumors outside of the liver (e.g., breast, kidney, thyroid, etc.). This policy was previously an all lines of business policy and was limited to RFA of breast tumors. At the same time as the change in scope to the existing policy, a separate Medicare policy is being developed. Continue to use Commercial criteria. **Exception** – Uterine fibroid ablation; CPT 0404T, 58674. These codes for uterine fibroid ablation procedures will be allowed to process without PA or review for Medicare. **Codes/PA:** Code and configuration changes are as follows: • **Codes 20982, 31641, 32998, 50542, 50592:** Add PA (No Medicare PAs in past two years, and only 13 Medicare claims, all for 31641 or 50592) • **Codes 0404T, 58674:** Remove any "new tech" denials or not covered benefit denials that are based on the "experimental/investigational" • All other codes are unlisted codes. Continue standard unlisted code review process.
Wireless Capsule for Gastrointestinal Motility Monitoring (Medicare Only) **MP378**	**Policy Updates:** New Medicare Advantage medical policy. Continue to use Commercial criteria with no Medicare guidance available. **Codes/PA:** Only one code in the policy, remove E/I denial and add NMN denial to CPT 91112.
NanoKnife System: Irreversible Electroporation (IRE) **MP154**	**Policy Updates:** No change to criteria. **Codes/PA:** Remove E/I denial from codes 0600T and 0601T and replace with NMN edits for Medicare Only.

Clinical Trials, Studies, and Registries (Medicare Only) **MP233**	**Policy Updates:** No change to criteria or guidelines. **Codes/PA:** Changing C9760 from E/I to NMN with modifier configuration.
Viscosupplementation (Medicare Only) **MP202**	**Policy Updates:** No change to criteria. **Codes/PA:** Continue diagnosis code configuration, but if not billed with medically necessary dx code, remove E/I denial from J-codes (J7320, J7321, J7322, J7323, J7324, J7326, J7327, J7328) and add NMN denial.
New and Emerging Technologies and Other Non-Covered Services (Medicare Only) **MP220**	**Policy Updates:** No change to criteria. **Codes/PA:** Code and/or configuration changes include the following: • Adding L8702 from CORE (and L8701) to this medical policy with NMN denial edits. • Adding K1024, K1025, K1031, K1032, and K1033 to the policy with NMN denial edits, consistent with Commercial changes. • Remove the following codes from the policy (consistent with Commercial changes): No Claims in 5 years: 0351T-0354T, 0397T, 0424T-0427T and 0431T-0436T, 0443T, 0481T, 0485T, 0486T, 0489T-0490T, 0506T, 0508T, 0512T, 0513T, 0515T-0522T, 0533T-0536T, 0547T, 0567T-0568T • No changes to other codes in the policy.

ARCHIVE

Effective 2/1/2023

Direct-to-Consumer and Over-the-Counter Testing (Medicare Only) **MP520**	**Policy Updates:** This policy will be archived. This service is a clear and direct member benefit exclusion. The member benefit contracts explicitly calls this out as not a covered benefit, so a medical policy isn't necessary. **Codes/PA:** No changes to codes or configuration. All codes in the policy are unlisted codes and they will continue unlisted code review as normal.

Chelation Therapy for Non-Overload Conditions (Medicare Only) **MP518**	**Policy Updates:** This policy will be archived **Codes/PA:** Changes to code configuration include the following: • G0068: Continue no medical policy edits, will not be addressed by any other medical policy. • M0300: Transfer to IMT policy, referencing NCD and continue NMN denial.

	• S9355: Remove diagnosis code configuration and allow Coding Policy 22.0 to take precedent

REIMBURSEMENT

Robotic Surgical Systems **UM1**	**Policy Update:** • New reimbursement policy addressing robotic surgical systems (computer-assisted navigation or CAN systems will be addressed in a separate *medical* policy). While the surgeries themselves may be medically necessary, separate allowance is not made for the surgeon's decision to use a robotic surgical system. • Proposed policy will state intraoperative use of robotic surgical systems (RAS) is not separately payable. **Codes/PA:** A t07 denial code (not separately payable per policy) will be added to HCPCS code S2900.

VENDOR UPDATES

Name Change for AIM and Beacon	AIM and Beacon are undergoing a name change to Carelon, effective 3/1/2023

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 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**:

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

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

	Commercial	Medicaid	Medicare
Formulary Status*	Formulary	Formulary	Part D: Formulary Part B: N/A
Tier**	Tier 6 - Non-Preferred Specialty	N/A	Specialty
Affordable Care Act Eligible	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, 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: riluzole, edaravone (Radicava ORS®)			

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

	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	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, 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: oral fluconazole			

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

	Commercial	Medicaid	Medicare
Formulary Status*	Medical	Medical	Part D: Non-formulary Part B: Medical
Tier**	N/A	N/A	N/A
Affordable Care Act Eligible	N/A; Non-Formulary	N/A	N/A
Utilization Management Edits	Prior Authorization	Prior Authorization	Prior Authorization
Quantity Limit	N/A	N/A	N/A
* Recommendations for placement may differ between lines of business due to regulatory requirements. ** Medications will be placed on recommended tier above for the base formulary; tier placement for custom formulary(ies) will be based on designation above. For example, Commercial Tier 6 designation above means that the medication will be placed on the highest cost-sharing tier on the respective formulary(ies).			
Formulary Alternatives: None			

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

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**:

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

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

	Commercial	Medicaid	Medicare
Formulary Status*	Medical	Medical	Part D: Non-formulary Part B: Medical
Tier**	N/A	N/A	N/A
Affordable Care Act Eligible	N/A; Non-Formulary	N/A	N/A
Utilization Management Edits	Prior Authorization	Prior Authorization	Prior Authorization
Quantity Limit	N/A	N/A	N/A
* Recommendations for placement may differ between lines of business due to regulatory requirements. ** Medications will be placed on recommended tier above for the base formulary; tier placement for custom formulary(ies) will be based on designation above. For example, Commercial Tier 6 designation above means that the medication will be placed on the highest cost-sharing tier on the respective formulary(ies).			
Formulary Alternatives: patisiran (Onpattro ®), inotersen (Tegsedi®), diflunisal 500 mg tablet			

   c. **Prior Authorization Criteria for Commercial/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 Commercial/Medicaid policy. No changes needed to the Medicare Part D policy.
    Prior Authorization for Commercial/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 Commercial/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 Commercial/Medicaid policy with new indication and modified age restriction. No changes needed to the Medicare Part D policy.
Prior Authorization for Commercial/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 Commercial/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.

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

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.

Other Formulary Changes:

Drug Name	Recommendation	Policy Name
Dextromethorphan hbr/ bupropion hcl (Auvelity) Tab IR ER	New combination; • Commercial: 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)	• Commercial/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; • Commercial Dynamic: Tier 3	N/A
Pirfenidone Tablet	Down-tier generic and add Quantity Limit • Commercial: 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 • Commercial/Medicaid: Remove from formulary, add Quantity Limit (three tablets per day) Effective: 03/01/2023	Esbriet/Ofev
Propranolol hcl (Hemangeol) Solution	Commercial: 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); • 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 chloride for inhalation (Nebusal) Vial-Neb	Add to Commercial and Medicaid formularies • Commercial: Tier 4 • Medicaid: Formulary	N/A
Orlistat Capsule	Authorized generic (Xenical); • Commercial 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); • Commercial/Medicaid: Non-Formulary, Prior Authorization, Specialty • Medicare Part D: Non-Formulary	• Commercial/Medicaid: Medications For Rare Indications - Orphan Drugs • Medicare Part D: N/A
Bismuth subcitrate/ metronidazole/tetracycline (Pylera) capsule	Add Quantity Limit for Commercial: 120 capsules per 28 days	N/A

Omeprazole/amoxicillin / rifabutin (Talicia) capsule	Add to Commercial Formulary: Tier 4, Quantity Limit 168 capsules per 28 days	N/A
Omeprazole/clarithromycin / amoxicillin (Omeclamox) capsule	Change Commercial 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 Commercial and Medicaid: Effective: 03/01/2023	• Commercial/Medicaid: Phosphate Binders Step Therapy Policy
Sevelamer Carbonate Tablet	Down-tier generic • Commercial 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); • 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
Tolmetin Sodium Tablet	Remove from Commercial 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%); • Commercial/Medicaid: Non-Formulary, Prior Authorization, Quantity Limit (60 grams per 30 days) • Medicare Part D: Non-Formulary	• Commercial/Medicaid: Vtama • Medicare Part D: N/A
Dexlansoprazole (Dexilant) Cap DR MP	Remove from Commercial formulary	N/A
Avatrombopag maleate (Doptelet) Tablet	Remove from Medicaid formulary	• Medicaid: Thrombocytopenia Medications
• **BRAND Epclusa® tablets and pellet packets**	Remove from Commercial and Medicaid formularies Effective: 01/01/2023	• Commercial: Hepatitis C - Direct Acting Antivirals • Medicaid: Hepatitis C - Direct Acting Antivirals – Medicaid
• **BRAND Harvoni® tablets and pellet packets**	Remove from Commercial and Medicaid formularies	• Commercial: Hepatitis C - Direct Acting Antivirals

	Effective: 01/01/2023	• Medicaid: Hepatitis C - Direct Acting Antivirals – Medicaid
Sodium Zirconium Cyclosilicate (Lokelma) Powd Pack	Retire prior authorization and add to formulary: • Commercial: Tier 3 • Medicaid: Formulary • Medicare part D: Tier 3	N/A
Patiromer Calcium Sorbitex (Veltassa) Powder Pack	Retire prior authorization and add to formulary: • Commercial: 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 Commercial Formulary: • Commercial Standard: Tier 2 • Commercial 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 Commercial formulary Effective: 01/01/2023	Hepatitis C - Direct Acting Antivirals
Sofosbuvir/Velpatas/ Voxilaprevir (Vosevi) Tablet	Non-preferred agent • Commercial: Change from Tier 5 to Tier 6 • Medicaid: Remove from Formulary Effective: 01/01/2023	• Commercial: Hepatitis C - Direct Acting Antivirals • Medicaid: Hepatitis C - Direct Acting Antivirals – Medicaid

	Commercial	Medicaid	Medicare
Formulary Status*	Medical	Medical	Part D: Non-formulary Part B: Medical
Tier**	N/A	N/A	N/A

Affordable Care Act Eligible	N/A; Non-Formulary	N/A	N/A
Utilization Management Edits	Prior Authorization	Prior Authorization	Prior Authorization
Quantity Limit	N/A	N/A	N/A
* Recommendations for placement may differ between lines of business due to regulatory requirements. ** Medications will be placed on recommended tier above for the base formulary; tier placement for custom formulary(ies) will be based on designation above. For example, Commercial Tier 6 designation above means that the medication will be placed on the highest cost-sharing tier on the respective formulary(ies).			
Formulary Alternatives: 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: • Commercial/Medicare Part D: Add Quantity Limit (1 capsule per day)	• Commercial: 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; • Commercial/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; • Commercial/Medicaid: Non-Formulary, Prior Authorization	• Commercial/Medicaid: New Medications and Formulations without Established Benefit • Medicare Part D: N/A

	• Medicare Part D: Non-Formulary	
Ibrutinib (Imbruvica) Oral Susp	New dosage form (oral susp). Line extend with Imbruvica; • Commercial: 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; • Commercial/Medicaid: Medical Benefit, Prior Authorization • Medicare Part D: Non-Formulary • Medicare Part B: Medical Benefit, Prior Authorization & Step Therapy	• Commercial/Medicaid: Ophthalmic Vascular Endothelial Growth Factor (VEGF) Inhibitors • 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; • Commercial: 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; • Commercial/Medicaid: Non-Formulary • Medicare Part D: Formulary, Tier 4, Prior Authorization	• Commercial/Medicaid: N/A • Medicare Part D: Topical Retinoid Products

Lenalidomide Capsule	First generic (Revlimid). Line extend as generic; • Commercial: 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; • Commercial Standard: Formulary, Tier 2, Prior Authorization • Commercial Dynamic: Formulary, Tier 3, Prior Authorization • Medicaid: Formulary, Prior Authorization • Medicare Part D: Formulary, Tier 3, Prior Authorization	Vascepa
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; • Commercial: 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; • 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
Cetrorelix acetate Kit	First generic (Cetrotide). Line extend as generic;	• Commercial/Medicaid: Fertility and Related Medications

	• Commercial: Non-Formulary, Prior Authorization • Medicaid: Non-Formulary, Prior Authorization • Medicare Part D: Non-Formulary	• Medicare Part D: N/A
Roflumilast Tablet	First generic (Daliresp). Line extend as generic; • Commercial Standard: Formulary, Tier 2, Prior Authorization • Commercial Dynamic: Formulary, Tier 4, Prior Authorization • Medicaid: Non-Formulary, Prior Authorization • Medicare Part D: Formulary, Tier 4, Prior Authorization	Daliresp

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) **ESAs - Medicare Part B**	Added Mircera to policy, removed exclusion of anemia due to treatment for hepatitis C.
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 Commercial 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 **Prevymis - Medicare Part B**	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.
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 for patients switching from pegcetacoplan (Empaveli®). For generalized myasthenia gravis, added criteria for patients switching from eculizumab (Soliris®).
Ultomiris - Medicare Part B	
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