Providence Health Plan

Providence Health Assurance

Healthcare Services Medical & Pharmacy Policy Alerts

Number 97

August 1, 2024

This is the August 1, 2024 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 8/1/2024

Circulating Tumor Cell and DNA Assays for Cancer Management **MP122**	**Policy Updates:** Added the following indications for circulating tumor cell testing when criteria are met: ovarian cancer/fallopian tube cancer/primary peritoneal cancer; cervical cancer and occult primary cancer. **Codes/PA:** No changes to codes or PA **OHP:** These changes do not apply to OHP. The Prioritized List and the Oregon Administrative Rules will be followed

Effective 9/1/2024

Lipid Testing (Company) **MP304**	**Policy Updates:** No recommended changes to criteria **Codes/PA:** Added new pair to pay dx codes based on Medicare LAB NCD guidelines **OHP:** These changes do not apply to OHP. The Prioritized List and the Oregon Administrative Rules will be followed
Sleep Disorder Surgery **MP179**	**Policy Updates:** Updated Billing Guidelines to remove “investigational” denial language. **Codes/PA:** Updated dx code configuration for the following codes, changing denial type from “investigational” to “not medically necessary,” and applying configuration only to members 18 years of age and older: • Codes should continue to pay if billed with a dx code included in attached spreadsheet, but otherwise deny "not medically necessary." Edit should apply to members 18 years of age and older only ○ **42225** Palatoplasty for cleft palate; attachment pharyngeal flap ○ **42226** Lengthening of palate, and pharyngeal flap

	• Codes should deny u21 if billed with G4733 or G4739. All other diagnosis codes pay. Edit should only apply to members 18 years of age and older only. ○ **30140** Submucous resection inferior turbinate, partial or complete, any method ○ **30801** Ablation, soft tissue of inferior turbinates, unilateral or bilateral, any method (eg, electrocautery, radiofrequency ablation, or tissue volume reduction); superficial ○ **30802** Ablation, soft tissue of inferior turbinates, unilateral or bilateral, any method (eg, electrocautery, radiofrequency ablation, or tissue volume reduction); intramural (ie, submucosal) ○ **41530** Submucosal ablation of the tongue base, radiofrequency, 1 or more sites, per session ○ **42160** Destruction of lesion, palate or uvula (thermal, cryo or chemical) **OHP:** These changes do not apply to OHP. The Prioritized List and the Oregon Administrative Rules will be followed.
Negative Pressure Wound Therapy **MP168**	**Policy Updates:** No recommended changes to criteria. **Codes/PA:** • Remove PA from E2402. • Current pair-to-pay configuration for other codes will remain in place. **OHP:** These changes do not apply to OHP. The Prioritized List and the Oregon Administrative Rules will be followed.

Effective 10/1/2024

Urinary Dysfunction Treatments (Company) **MP180** *Previously: Urinary Incontinence Treatments*	**Policy Updates:** • Changed title to Urinary Dysfunction Testing • Added non obstructive urinary retention to criterion X for medically necessary indications for sacral nerve stimulation. **Codes/PA:** No changes to codes or PA **OHP:** These changes do not apply to OHP. The Prioritized List and the Oregon Administrative Rules will be followed.
Respiratory Viral Panels **MP256**	**Policy Updates: Recommendation:** Added 0225U to criterion III. as an example of an expanded panel considered not medically necessary. **Codes/PA:** Updated dx code configuration for targeted panels based on updated CMS guidance (LCA 58726) **OHP:** These changes do not apply to OHP. The Prioritized List and the Oregon Administrative Rules will be followed.

MEDICARE POLICIES

Effective 8/1/2024

Circulating Tumor Cell and DNA Assays for Cancer Management **MP306**	**Policy Updates:** Minor updates to criteria. Continue to apply Medicare references, or Company internal coverage criteria, as directed in the policy. Added Resolution ctDX Lung to this policy **(previously addressed in the Medicare Genetic and Molecular Testing policy)**. **Codes/PA:** For 0356U, removed NMN and added PA. Added 0179U (continue NMN denial). No change to other codes in the policy, or their configuration.
Clinical Trials, Studies and Registries **MP233**	**Policy Updates:** No significant changes to criteria, but propose clarifying revisions. • Rearranged some of the criteria, but no change to intent of coverage. As an MA plan, we cover some clinical trial and study services as the primary payer, and others we are secondary. This is per Medicare regulatory instruction, as well as member EOC language. • Added general information about clinical trials, study designs, etc. to Policy Guidelines section. • Reference Section 66.2 of Ch. 32 for CED topics that exceed CMS threshold for MA's to be primary payers (these are rare). • Correct description for Table 2. **Codes/PA:** No change to codes or configuration.

Effective 9/1/2024

Negative Pressure Wound Therapy **MP192**	**Policy Updates:** No change to criteria. Continue to apply Medicare criteria (NCD and LCD) as directed. **Codes/PA:** • Removed PA from E2402. • No changes to other codes in the policy or their current configuration.

Prostate Specific Antigen **MP320**	**Policy Updates:** Centers for Medicare and Medicaid Services (CMS) NCD Lab policy. No change to criteria, continue to apply CMS NCD 190.31 for prostate specific antigen (PSA) testing. **Codes/PA:** Updated diagnosis code configuration to add the following diagnosis codes to the pair to pay list. Z79810 Z79811 Z79818 Z79890 Z79899
Serum Iron Studies **MP322**	**Policy Updates:** Centers for Medicare and Medicaid Services (CMS) NCD Lab policy. No change to criteria, continue to apply CMS NCD 190.18 for serum iron study testing. **Codes/PA:** Updated diagnosis code configuration to add Z9884 to the pair to pay list.
Glycated Hemoglobin and Glycated Protein Testing **MP236**	**Policy Updates:** Centers for Medicare and Medicaid Services (CMS) NCD Lab policy. No change to criteria, continue to apply CMS NCD 190.21 for glycated hemoglobin and glycated protein testing. **Codes/PA:** Update diagnosis code configuration **for CPT 83036 only** to add Z131 to the pair to pay list. According to CMS, CPT 82985 is not impacted by this diagnosis code configuration update.

Archive

Effective 8/1/24

Tumor Treatment Fields Therapy for Glioblastoma **MP171**	**Policy :** Archive. Policy applies Noridian LCD for TTFT. However, due to low risk for over-utilization of this device, recommendation is to archive this policy for Medicare only. **Codes/PA:** No change to codes or configuration.

REIMBURSEMENT POLICIES

Effective 8/1/24

Incident-To Services **RP5**	**Interim Update** **Policy Update:** Changes include the following: • Clarified that incident to supervision requirements refer to direct supervision, not personal supervision. • Added notation to direct readers to the Policy Guidelines section of the policy for employment arrangements. • Added information regarding telehealth services and the incident to provision. • Added definition of "immediately available." • Updated table of "Supervision" definitions for "direct" and how through December 2024, this includes a virtual presence. • Added information regarding employment arrangements. • Revised paragraph regarding auxiliary personnel and billing 99211. *Note: These are meant to be liberalizations to current practices and the updated policy version will be effective 8/1/2024.* **Reimbursement Methodology:** Will now allow telehealth services to be billed as incident to and will consider a physician's virtual presence with audio and video technology to meet the "direct supervision" requirement through at least December 2024, per CMS instruction. **Relevant References/CMS Guidance:** • Centers for Medicare & Medicaid Services (CMS). Medicare Benefit Policy Manual, Chapter 15 - Covered Medical and Other Health Services, §60 - Services and Supplies Furnished Incident To a Physician's/NPP's Professional Service. • Centers for Medicare & Medicaid Services (CMS). Medicare Benefit Policy Manual, Chapter 15 - Covered Medical and Other Health Services, §§60.1-60.4. • Noridian web page for "Incident To Services." • National Coverage Determination (NCD). Physician's Office within an Institution Coverage of Services and Supplies Incident to a Physician's Services (70.3). • MLN Matters Number: SE0441. Centers for Medicare and Medicaid Services (CMS) Final Rule CMS-1784-F.
Associated Services and Related Claims **RP9**	**New Reimbursement policy** **Recommendation:** • New reimbursement policy for all lines of business ***EXCEPT OHP/Medicaid.*** • Policy advises which claims and services related to (or associated with) a non-covered principal (primary) service or procedure will also not be eligible for reimbursement. • Key elements of this policy include the following highlights:

	○ If the principal procedure, visit, service or durable medical equipment (DME) is denied (e.g., cosmetic, not medically necessary, benefit exclusion, etc.) by the Company, then related/associated services will also not be allowed coverage or reimbursement. ▪ Example: A non-covered surgery – the surgeon's claim is considered the primary claim, while claims from other providers (e.g., assistant surgeon, hospital, anesthesiologist, etc.) are considered related or associated claims. ▪ Example: Non-covered drug, implant or similar product – if a non-covered drug, implant, or product is provided, the administration, application, or implantation charge will also be non-covered. ▪ Example: Durable medical equipment – if a piece of equipment is not medically necessary, all accessories and related supplies used with the non-covered equipment will also be non-covered. ○ These denials will generally be for services rendered on the same date of service as the non-covered primary procedure, but there may be exceptions to this (e.g., a hospital claim spanning multiple days may be denied if a non-covered procedure is performed). Edits will be implemented in CES to operationalize this policy, but it can only be implemented for services on the same date. ○ Services or devices *unrelated* to the non-covered service/equipment may be considered for reimbursement. ○ If in the event reimbursement is made in error, recoupment efforts may take place. ○ This policy does **not** apply to complications that are otherwise medically necessary following a non-covered procedure when the complications occur after a member has been discharged from the hospital (e.g., a non-covered bariatric surgery leads to infection or a reoperation is required after discharge from the hospital). ○ This policy does **not** replace or supersede current practices or edits for services rendered within a global period of a prior procedure, as these may not be eligible for reimbursement for other reasons. ○ This policy does **not** replace or supersede CMS national correct coding initiative (NCCI) edits or medically unlikely edits (MUEs; daily maximum limits). ○ Some Commercial member benefit contracts call out benefit exclusions for services related to non-covered services, and individual member benefits will supersede this reimbursement policy. **Reimbursement Methodology:** • Phase I: For primary surgical procedure claims associated with a u21 (not medically necessary) denial on the **same claim**, this will be automated via an edit in CES. • Phase II (planned for Q4 2024): For primary procedure claims associated with a z80 (cosmetic) denial on the **same claim**, this will be automated via an edit in CES. • Phase III (planned for 2025): For related claims/associated services on **other claims**, this will be a manual process, and may not always be identified prior to payment. In these situations, claims may need to be reprocessed when appropriate. • *Unrelated* services or charges may be considered for reimbursement. • Because this automation is in CES, and OHP doesn't use CES, this policy will not apply to OHP LOB at this time. **Relevant References/CMS Guidance:**

	• Medicare Benefit Policy Manual, Chapter 16 - General Exclusions From Coverage, §180 - Services Related to and Required as a Result of Services Which Are Not Covered Under Medicare; https://www.cms.gov/regulations-and-guidance/guidance/manuals/downloads/bp102c16.pdf. • Medicare Benefit Policy Manual, Chapter 1 - Inpatient Hospital Services Covered Under Part A, §120 - Services Related to and Required as a Result of Services Which Are Not Covered Under Medicare; https://www.cms.gov/regulations-and-guidance/guidance/manuals/downloads/bp102c01.pdf. • Medicare Benefit Policy Manual, Chapter 14 - Medical Devices, §40 - Services Related to and Required as a Result of Services Which are Not Covered Under Medicare; https://www.cms.gov/regulations-and-guidance/guidance/manuals/downloads/bp102c14.pdf.
Emergency Department Evaluation & Management Services **RP11**	**New Reimbursement Policy** **Recommendation:** • New reimbursement policy for ***Commercial and Medicare ONLY***. ***Does not apply to ASO and OHP/Medicaid.*** • When emergency department (ED) facilities or providers bill a high-level ED evaluation & management (E&M) code (99284 or 99285) with a low acuity non-emergent (LANE) diagnosis code, the claim will deny as not reimbursable due to the diagnosis code not supporting the E&M level. • Providers/facilities will need to rebill with a lower-level E&M or submit a reconsideration request with documentation that supports the need for the high-level E&M. • The diagnosis codes which do not support the higher-level E&M were compiled based on the American College of Emergency Physicians (ACEP) guidelines, other payer policies, and assessment by the Coding Policy Team. **Reimbursement Methodology:** Not reimbursable based on diagnosis code and CPT code pairing. Will create a specific denial code for the EOP that tells providers why it denied. *Note: this configuration will not apply to facilities reimbursed on a case-rate agreement.* **Relevant References/CMS Guidance:** • American College of Emergency Physicians (ACEP) ED Facility Level Coding Guidelines | LINK • Centers for Medicare and Medicaid Services (CMS). Federal Register / Vol. 72, No. 227 / Tuesday, November 27, 2007 / Rules and Regulations. LINK
High Dollar Drug Reviews **RP10**	**New Reimbursement policy** **Recommendation:** • New reimbursement policy for all lines of business ***EXCEPT OHP/Medicaid.*** • Facility claims billed with revenue code 0636 **and** when the billed charge for that line meets or exceeds $10,000 may be selected for high dollar drug review. • If the billed charge for the drug is marked up by 150% or more over the average sales price (ASP) or average wholesale price (AWP), the drug will be denied as not reimbursable, unless documentation supports the reasonableness of the charges submitted. • These reviews include consideration of the medical need for the drug, the quantity billed (ensuring it aligns with the documentation and how much was provided to the member), possible waste, and if excessive units are being reported. **Reimbursement Methodology:** Facility claims billed with revenue code 0636 **and** when the billed charge for that line meets or exceeds $10,000, it may be selected for high dollar drug review.

	Relevant References/CMS Guidance: CMS references state it is expected providers seek to minimize costs, that costs should not exceed what a prudent buyer would pay for an item, and that excess costs are not reimbursable by Medicare. CMS references include the following:
	• Medicare Claims Processing Manual, Chapter 17 - Drugs and Biologicals
	  ○ §10 - Payment Rules for Drugs and Biologicals
	  ○ §20.1 - MMA Drug Pricing - Average Sales Price
	  ○ §20.1.2 - Average Sales Price (ASP) Payment Methodology
	  ○ §20.1.3 - Exceptions to Average Sales Price (ASP) Payment Methodology
	  ○ §20.4 - Calculation of the AWP
	  ○ §90.3 - Hospital Outpatient Payment Under OPPS for New, Unclassified Drugs and Biologicals After FDA Approval But Before Assignment of a Product-Specific Drug or Biological HCPCS Code
	• Centers for Medicare and Medicaid Services (CMS) Provider Reimbursement Manual – Part 1, Chapter 21- Costs Related to Patient Care, §2102.1 Reasonable Costs
	• Quarterly CMS ASP Drug Pricing Files
	• CMS web page for MS-DRG Classifications and Software
	• Noridian web page for Drugs, Biologicals and Injections
	• Medicare Benefit Policy Manual, Chapter 15 – Covered Medical and Other Health Services, §50.4.2 - Unlabeled Use of Drug

VENDOR UPDATES

Effective 10/20/2024

Carelon

The following codes will require prior authorization through Carelon starting 10/20/24:

Included CPT Codes	Description	Modality	Procedure Name
78811	PET IMAGING LIMITED AREA CHEST HEAD/NECK	PET	Brain Imaging (PET Scan)
78814	PET IMAGING CT FOR ATTENUATION LIMITED AREA	PET	Brain Imaging (PET Scan)

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 June 7, 2024
Go-Live Date: Thursday, August 01, 2024, unless otherwise noted

Special Announcements

Granulocyte-Colony Stimulating Factors (G-CSF's)
Effective 9/1/24, the health plan will be implementing a preferred product strategy for Granulocyte-Colony Stimulating Factors (G-CSF's) for all lines of business

- Neulasta® and Fulphila® will be preferred products and available without prior authorization
- All other products will be non-preferred and require prior authorization for coverage
    - Criteria for coverage will require use of the preferred products or sufficient medical rationale for not using the preferred products

Ophthalmic Vascular Endothelial Growth Factor (VEGF) Inhibitors
The health plan will be changing the preferred product strategy for VEGF inhibitor for all lines of business

- Lucentis® will be added as a preferred agent in parity with the biosimilars Byooviz® and Cimerli®; these will not require prior authorization
- The new product Eyelea HD® will be non-preferred and require prior authorization.
    - Criteria for coverage will require use of the preferred products or sufficient medical rationale for not using the preferred products

Table of Contents:

New Drugs and Combinations:

1. **Exagamglogene autotemcel (Casgevy) Vial**

1. **Indication**: For the treatment of sickle cell disease (SCD) in adult and pediatric patients ≥ 12 years of age with recurrent vaso-occlusive crises (VOCs) AND the treatment of transfusion-dependent beta-thalassemia (TDT) in adults and pediatric patients ≥ 12 years of age.
2. **Decision**:

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

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

PA PROGRAM NAME	~~Zynteglo®~~ Gene Therapies for Hemoglobin Disorders
MEDICATION NAME	betibeglogene autotemcel (Zynteglo®) exagamglogene autotemcel (Casgevy®) lovotibeglogene autotemcel (Lyfgenia®)
PA INDICATION INDICATOR	1 – All FDA-Approved Indications
OFF-LABEL USES	N/A
EXCLUSION CRITERIA	N/A
REQUIRED MEDICAL INFORMATION	**For beta-thalassemia:** Zynteglo® or Casgevy® 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)~~ **For sickle cell disease:** Casgevy® or Lyfgenia® may be approved when all the following criteria are met: 1. Patient has a confirmed diagnosis of sickle cell disease with one of the following genotypes: ßS/ßS, ßS/ß0, ßS/ß+. The diagnosis may be confirmed with genetic testing results or provider attestation of genotype 2. Patient has experienced at least four vaso-occlusive events/crises (VOEs/VOCs) in the previous 24 months. A VOE/VOC is defined as an event requiring a visit to a medical facility for evaluation of acute pain, acute chest syndrome, acute splenic sequestration, acute hepatic sequestration, or priapism lasting greater than two hours 3. Patient is clinically stable and able to undergo the pre-infusion myeloablative chemotherapy regimen and gene therapy infusion regimen based on the assessment of the requesting provider 4. Documentation patient meets one of the following: a. Patient has experienced therapeutic failure of hydroxyurea despite use of a maximally tolerated dose for at least six months. Examples of therapeutic failure include incidence of one VOE/VOC or need for blood transfusion. b. Patient has had an intolerance or contraindication to hydroxyurea 5. Patient does not have any of the following: a. Prior history or receiving a hematopoietic stem-cell transplant b. Prior history of receiving gene therapy for the requested indication 6. For Lyfgenia®: all the following additional criteria must be met: a. The patient has a contraindication to Casgevy® (exagamglogene autotemcel) b. The patient does not have disease with more than two alpha-globin gene deletions
AGE RESTRICTIONS	For Casgevy® and Lyfgenia®: May be approved for patients aged 12 years or older For Zynteglo®: May be approved for patients aged 4 years 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. **Lovotibeglogene autotemcel (Lyfgenia) Plast. Bag**
    1. **Indication**: For the treatment of sickle cell disease (SCD) in adults and pediatric patients ≥12 years of age with history of vaso-occlusive events (VOEs).

2. **Decision**:

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

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

PA PROGRAM NAME	~~Zynteglo®~~ Gene Therapies for Hemoglobin Disorders
MEDICATION NAME	betibeglogene autotemcel (Zynteglo®) exagamglogene autotemcel (Casgevy®) lovotibeglogene autotemcel (Lyfgenia®)
PA INDICATION INDICATOR	1 – All FDA-Approved Indications
OFF-LABEL USES	N/A
EXCLUSION CRITERIA	N/A
REQUIRED MEDICAL INFORMATION	**For beta-thalassemia:** Zynteglo® or Casgevy® 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: c. History of transfusions of at least 100 mL/kg/year of packed red blood cells (pRBCs) d. 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: e. Prior history of receiving a hematopoietic stem-cell transplant f. Prior history of receiving gene therapy for the requested indication g. 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)

	~~h. 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)~~ **For sickle cell disease:** Casgevy® or Lyfgenia® may be approved when all the following criteria are met: 1. Patient has a confirmed diagnosis of sickle cell disease with one of the following genotypes: ßS/ßS, ßS/ß0, ßS/ß+. The diagnosis may be confirmed with genetic testing results or provider attestation of genotype 2. Patient has experienced at least four vaso-occlusive events/crises (VOEs/VOCs) in the previous 24 months. A VOE/VOC is defined as an event requiring a visit to a medical facility for evaluation of acute pain, acute chest syndrome, acute splenic sequestration, acute hepatic sequestration, or priapism lasting greater than two hours 3. Patient is clinically stable and able to undergo the pre-infusion myeloablative chemotherapy regimen and gene therapy infusion regimen based on the assessment of the requesting provider 4. Documentation patient meets one of the following: a. Patient has experienced therapeutic failure of hydroxyurea despite use of a maximally tolerated dose for at least six months. Examples of therapeutic failure include incidence of one VOE/VOC or need for blood transfusion. b. Patient has had an intolerance or contraindication to hydroxyurea 5. Patient does not have any of the following: a. Prior history or receiving a hematopoietic stem-cell transplant b. Prior history of receiving gene therapy for the requested indication 6. For Lyfgenia®: all the following additional criteria must be met: a. The patient has a contraindication to Casgevy® (exagamglogene autotemcel) b. The patient does not have disease with more than two alpha-globin gene deletions
AGE RESTRICTIONS	For Casgevy® and Lyfgenia®: May be approved for patients aged 12 years or older For Zynteglo®: May be approved for patients aged 4 years 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

3. **Birch bark extract (Filsuvez) Gel (Gram)**
   a. **Indication**: For the treatment of wounds associated with dystrophic and junctional epidermolysis bullosa (DEB and JEB) in adult and pediatric patients 6 months of age and older.
   b. **Decision**:

	Commercial	Medicaid	Medicare
Formulary Status*	Non-formulary	Non-formulary	Part D: Non-formulary Part B: N/A
Tier**	N/A	N/A	N/A
Affordable Care Act Eligible	N/A; Non-Formulary	N/A	N/A
Utilization Management Edits	Prior Authorization	Prior Authorization	N/A
Quantity Limit	23.4 gram/day (1 single-use tube per day)	23.4 gram/day (1 single-use tube per day)	
* Recommendations for placement may differ between lines of business due to regulatory requirements. ** Medications will be placed on recommended tier above for the base formulary; tier placement for custom formulary(ies) will be based on designation above. For example, Commercial Tier 6 designation above means that the medication will be placed on the highest cost-sharing tier on the respective formulary(ies).			
Formulary Alternatives: None			

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

PA PROGRAM NAME	Topical Agents for Epidermolysis Bullosa
MEDICATION NAME	Filsuvez
PA INDICATION INDICATOR	1 – All FDA-Approved Indications
OFF-LABEL USES	N/A
EXCLUSION CRITERIA	1. Skin graft within the past three months 2. Current evidence or a history of squamous cell carcinoma in the area(s) that will undergo treatment 3. Combination therapy with Vyjuvek and Filsuvez
REQUIRED MEDICAL INFORMATION	Initial authorization requires all the following be met: 1. One of the following: a. For Vyjuvek: Diagnosis of dystrophic epidermolysis bullosa (EB) b. For Filsuvez: Diagnosis of dystrophic EB or junctional EB 2. Confirmed diagnosis by genetic testing. DEB is caused by mutations in the COL7A1 gene and JEB is caused by autosomal recessive mutations in the laminin-332 genes. 3. Treatment will be used on cutaneous wound(s) that are clean in appearance with adequate granulation tissue, excellent vascularization, and do not appear infected 4. Dosing is within FDA-labeled guidelines Reauthorization requires all the following be met:

	1. Documentation of successful response to therapy as indicated by complete wound healing or decrease in wound size 2. Patient continues to have incomplete wound closures that are clean in appearance with adequate granulation tissue, excellent vascularization, and do not appear infected 3. Dosing is within FDA-labeled guidelines
AGE RESTRICTIONS	Approved according to FDA approved labeling
PRESCRIBER RESTRICTIONS	Must be prescribed by, or in consultation with, a dermatologist or provider with experience in treating epidermolysis bullosa
COVERAGE DURATION	Initial authorization: 3 months. Reauthorization: 1 year

4. **Budesonide (Eohilia) Susp Packt**
   a. **Indication**: For the treatment of inflammation in eosinophilic esophagitis.
   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	N/A	N/A	N/A
Quantity Limit	168 packets/365 days	168 packets/365 days	N/A
* Recommendations for placement may differ between lines of business due to regulatory requirements. ** Medications will be placed on recommended tier above for the base formulary; tier placement for custom formulary(ies) will be based on designation above. For example, Commercial Tier 6 designation above means that the medication will be placed on the highest cost-sharing tier on the respective formulary(ies).			
Formulary Alternatives: Proton pump inhibitors: esomeprazole, lansoprazole, omeprazole, pantoprazole, rabeprazole Topical glucocorticosteroid: budesonide nebulizer, fluticasone meter dose inhaler			

5. **Donislecel-jujn (Lantidra) Plast. Bag**

a. **Indication**: For the treatment of adults with Type 1 diabetes who are unable to approach target HbA1c because of current repeated episodes of severe hypoglycemia despite intensive diabetes management and education. Use donislecel in conjunction with concomitant immunosuppression.

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

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

PA PROGRAM NAME	Lantidra
MEDICATION NAME	Lantidra
PA INDICATION INDICATOR	1 – All FDA-Approved Indications
OFF-LABEL USES	N/A
EXCLUSION CRITERIA	Pregnancy
REQUIRED MEDICAL INFORMATION	For initial authorization, all the following must be met: 1. Diagnosis of type 1 diabetes mellitus with a duration over five years 2. Documentation of recurrent, acute, and severe metabolic and potentially life-threatening complications requiring medical attention, as documented by at least one emergency room visit and/or hospitalization in the previous 12 months due to one of the following: a. Hyperglycemia; or b. Hypoglycemia; or c. Hypoglycemia unawareness associated with high risk of injury; or d. Ketoacidosis 3. The patient has experienced hypoglycemia, defined as documentation of at least one of the following in the previous 12 months: a. Recurrent hypoglycemic events, [defined as glucose less than 54mg/dL (3.0mmol/L)] that persist despite multiple attempts to adjust medication(s) and/or modify the diabetes treatment plan

	b. History of one hypoglycemic event [defined as glucose less than 54mg/dL (3.0mmol/L)] characterized by altered mental and/or physical state requiring third-party assistance for treatment of hypoglycemia c. Documentation of hypoglycemic unawareness associated with high risk of injury d. History of ketoacidosis 4. Consistent failure of exogenous insulin-based management, defined as inability to achieve sufficient glycemic control (HbA1c >8%) or recurrent hypoglycemia unawareness, despite aggressive conventional therapy (usually including insulin pump), including all of the following: a. Adjusting frequencies and amounts of insulin injected; and b. Taking multiple blood glucose measurements on a daily basis; and. c. Modifying diet and exercise; and d. Monitoring HbA1c levels For reauthorization of second infusion or third infusion, 1. Documentation that the patient has not achieved independence from exogenous insulin within one of the following: a. within one year of donislecel infusion, or b. within one year after losing independence from exogenous insulin after a previous donislecel infusion 2. Documentation that the patient has received no more than three donislecel infusions per the patient's lifetime
AGE RESTRICTIONS	May be approved for patients aged 18 and older.
PRESCRIBER RESTRICTIONS	Must be prescribed by, or in consultation with, an endocrinologist or transplant surgeon with experience in islet cell transplantation
COVERAGE DURATION	Initial authorization will be approved for 12 months. Reauthorization will be approved for 12 months.

6. **Eplontersen sodium (Wainua) Auto Inject**
   a. **Indication**: For the treatment of the polyneuropathy of hereditary transthyretin-mediated amyloidosis (hATTR-PN) in adults.
   b. **Decision**:

	Commercial	Medicaid	Medicare
Formulary Status*	Formulary	Formulary	Part D: Non-formulary Part B: N/A
Tier**	Tier 6 – Non-Preferred Specialty	N/A	N/A
Affordable Care Act Eligible	No	N/A	N/A

Utilization Management Edits	Prior Authorization	Prior Authorization	N/A
Quantity Limit	One 45-mg syringe/30 days	One 45-mg syringe/30 days	
* Recommendations for placement may differ between lines of business due to regulatory requirements. ** Medications will be placed on recommended tier above for the base formulary; tier placement for custom formulary(ies) will be based on designation above. For example, Commercial Tier 6 designation above means that the medication will be placed on the highest cost-sharing tier on the respective formulary(ies).			
Formulary Alternatives: Tegsedi			

c. **Prior Authorization Criteria for Commercial/Medicaid**: Added to Transthyretin (TTR) Lowering Agents policy

7. **Etrasimod arginine (Velsipity) Tablet**

a. **Indication**: For the treatment of moderately to severely active ulcerative colitis in adults.

b. **Decision**:

	Commercial	Medicaid	Medicare
Formulary Status*	Non-formulary	Non-formulary	Part D: Non-formulary Part B: N/A
Tier**	N/A	N/A	N/A
Affordable Care Act Eligible	N/A; Non-Formulary	N/A	N/A
Utilization Management Edits	Prior Authorization	Prior Authorization	N/A
Quantity Limit	1 tablet/day	1 tablet/day	N/A
* Recommendations for placement may differ between lines of business due to regulatory requirements. ** Medications will be placed on recommended tier above for the base formulary; tier placement for custom formulary(ies) will be based on designation above. For example, Commercial Tier 6 designation above means that the medication will be placed on the highest cost-sharing tier on the respective formulary(ies).			
Formulary Alternatives: Zeposia, adalimumab, Xeljanz, Rinvoq, Entyvio, Stelara, Simponi,			

c. **Prior Authorization Criteria for Commercial/Medicaid**: Added to Therapeutic Immunomodulators (TIMs) Policy as non-preferred.

8. **Iptacopan hcl (Fabhalta) Capsule**

a. **Indication**: For the treatment of adult patients with paroxysmal nocturnal hemoglobinuria (PNH).

b. **Decision**:

	Commercial	Medicaid	Medicare

Formulary Status*	Non-formulary	Non-formulary	Part D: Non-formulary Part B: N/A
Tier**	Tier 6 – Non-Preferred Specialty	N/A	
Affordable Care Act Eligible	No	N/A	N/A
Utilization Management Edits	Prior Authorization	Prior Authorization	N/A
Quantity Limit	2 capsules/day	2 capsules/day	N/A
* Recommendations for placement may differ between lines of business due to regulatory requirements. ** Medications will be placed on recommended tier above for the base formulary; tier placement for custom formulary(ies) will be based on designation above. For example, Commercial Tier 6 designation above means that the medication will be placed on the highest cost-sharing tier on the respective formulary(ies).			
Formulary Alternatives:			

c. **Prior Authorization Criteria for Commercial/Medicaid**: Added to Complement Inhibitor policy in parity with Soliris®.

9. **Lifileucel (Amtagvi) Plast. Bag**

a. **Indication**: For the treatment of adult patients with unresectable or metastatic melanoma previously treated with a PD-1 blocking antibody and if BRAF V600 mutation positive, a BRAF inhibitor with or without a MEK inhibitor. Also known as tumor-infiltrating lymphocyte (TIL) therapy.

b. **Decision**:

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

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

PA PROGRAM NAME	T-cell therapy
MEDICATION NAME	Lifileucel (Amtagvi)

PA INDICATION INDICATOR	1 – All FDA-Approved Indications
EXCLUSION CRITERIA	For Amtagvi: Previous treatment with Amtagvi therapy. Repeat administration is not considered medically necessary as the effectiveness of this approach has not been established.
REQUIRED MEDICAL INFORMATION	For all requests, the following criteria must be met: 1. Use must be for an indication supported by National Comprehensive Cancer Network (NCCN) guidelines with recommendation 2A or higher 2. Documentation of adequate bone marrow, cardiac, pulmonary and organ function (such as kidney, liver) 3. Provider attestation/documentation that the patient's functional status is sufficient to undergo treatment. This may include but is not limited to a documented Eastern Cooperative Oncology Group (ECOG) performance status of 0-1 or a written statement acknowledging that the patient is fit to tolerate therapy. 4. No evidence of active infection or inflammatory disorder (including hepatitis B or C, active graft vs. host disease)
AGE RESTRICTIONS	Age must be appropriate based on FDA-approved indication
PRESCRIBER RESTRICTIONS	Must be prescribed by, or in consultation with, an oncologist
COVERAGE DURATION	For chimeric antigen receptor (CAR) T-cell therapy and Amtagvi: Two months (limited to one treatment course per lifetime, with four doses of tocilizumab [Actemra®] at up to 800 mg per dose).

10. **Mirikizumab-mrkz (Omvoh) Pen Injctr – Vial**
    a. **Indication**: For the treatment of moderately to severely active ulcerative colitis in adults.
    b. **Decision**:

	Commercial	Medicaid	Medicare
Formulary Status*	Non-formulary	Non-formulary	Part D: Non-formulary Part B: N/A
Tier**	N/A	N/A	N/A
Affordable Care Act Eligible	N/A; Non-Formulary	N/A	N/A
Utilization Management Edits	Prior Authorization	Prior Authorization	N/A
Quantity Limit	2 pens/28 days	2 pens/28 days	N/A
* Recommendations for placement may differ between lines of business due to regulatory requirements. ** Medications will be placed on recommended tier above for the base formulary; tier placement for custom formulary(ies) will be based on designation above. For example, Commercial Tier 6 designation above means that the medication will be placed on the highest cost-sharing tier on the respective formulary(ies).			
Formulary Alternatives: Zeposia, adalimumab, Xeljanz, Rinvoq, Entyvio, Stelara, Simponi, infliximab			

    c. **Prior Authorization Criteria for Commercial/Medicaid**: Added to Therapeutic Immunomodulators (TIMs) Policy as non-preferred.

11. **Nedosiran sodium (Rivfloza) Syringe-Vial**

a. **Indication**: To lower urinary oxalate levels in children 9 years of age and older and adults with primary hyperoxaluria type 1 (PH1) and relatively preserved kidney function, e.g., eGFR ≥ 30 mL/min/1.73 m^2.

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	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**: Added to Hyperoxaluria Agents policy

12. **Taurolidine in heparin sodium (Defencath) Vial**

a. **Indication**: To reduce the incidence of catheter-related bloodstream infections (CRBSI) in adult patients with kidney failure receiving chronic hemodialysis (HD) through a central venous catheter (CVC).

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	N/A	N/A	N/A
Quantity Limit			
* Recommendations for placement may differ between lines of business due to regulatory requirements. ** Medications will be placed on recommended tier above for the base formulary; tier placement for custom formulary(ies) will be based on designation above. For example, Commercial Tier 6 designation above means that the medication will be placed on the highest cost-sharing tier on the respective formulary(ies).			

Formulary Alternatives: N/A

13. **Travoprost (Idose TR) Implant**

a. **Indication**: For the reduction of intraocular pressure (IOP) in patients with open-angle glaucoma (OAG) or ocular hypertension (OHT).

b. **Decision**:

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

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

PA PROGRAM NAME	~~Durysta®~~ Ophthalmic Prostaglandin Implants
MEDICATION NAME	Travoprost intracameral implant (iDose TR®)
PA INDICATION INDICATOR	1 – All FDA-Approved Indications
OFF-LABEL USES	None
EXCLUSION CRITERIA	N/A
REQUIRED MEDICAL INFORMATION	The following criteria must be met: 1. The patient is not receiving re-treatment of eye(s) previously treated with ~~bimatoprost intracameral implant (Durysta®)~~ the requested therapy 2. Trial and failure, intolerance or contraindication to at least two ophthalmic products (either as monotherapy or as concomitant therapy) from two different pharmacological classes, one of which is an ophthalmic prostaglandin (for example, bimatoprost, latanoprost, or travoprost)
AGE RESTRICTIONS	Approved for 18 years and older
PRESCRIBER RESTRICTIONS	Must be prescribed by an ophthalmologist
COVERAGE DURATION	Authorization will be approved for six months. Approval will be for a one-time use in each treated eye (one implant per treated eye, a total of two implants per patient)

14. **Vamorolone (Agamree) Oral Susp**

a. **Indication**: For the treatment of Duchenne muscular dystrophy (DMD) in patients aged two years of age and older.

b. **Decision**:

	Commercial	Medicaid	Medicare
Formulary Status*	Non-formulary	Non-formulary	Part D: Non-formulary Part B: N/A
Tier**	N/A	N/A	N/A
Affordable Care Act Eligible	N/A; Non-Formulary	N/A	N/A
Utilization Management Edits	Prior Authorization	Prior Authorization	N/A
Quantity Limit	7.5 mL (300 mg) per day	7.5 mL (300 mg) per day	N/A
* Recommendations for placement may differ between lines of business due to regulatory requirements. ** Medications will be placed on recommended tier above for the base formulary; tier placement for custom formulary(ies) will be based on designation above. For example, Commercial Tier 6 designation above means that the medication will be placed on the highest cost-sharing tier on the respective formulary(ies).			
Formulary Alternatives: Prednisone, deflazacort (Emflaza)			

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

PA PROGRAM NAME	~~Emflaza,~~ Corticosteroids for Duchenne Muscular Dystrophy
MEDICATION NAME	Vamorolone (Agamree) oral suspension
PA INDICATION INDICATOR	1 – All FDA-Approved Indications
OFF-LABEL USES	N/A
EXCLUSION CRITERIA	N/A
REQUIRED MEDICAL INFORMATION	Initial authorization: 1. Confirmed diagnosis of Duchenne Muscular Dystrophy by genetic testing (prescriber must provide genetic test to confirm diagnosis) 2. Documentation of one of the following: a. The patient has tried prednisone for at least six months and has experienced one of the following clinically significant adverse events: cushingoid appearance, central (truncal obesity), weight gain of at least 10% body weight over a 6-month period or diabetes and/or hypertension that is difficult to manage according to the prescribing physician OR b. The patient has tried prednisone and has experienced psychiatric/behavioral issues (such as abnormal behavior, aggression, or irritability) i. The psychiatric/behavioral issues persisted beyond the first six weeks of treatment with prednisone

	AND ii. A change in timing of prednisone administration (such as changing from morning to evening) has been attempted but was unsuccessful in resolving issues 3. For Agamree: Documentation of inadequate response (after at least three months of therapy), clinically significant adverse events (such as cataracts, growth delay, reduced bone density or bone fractures), or contraindication to deflazacort 4. The dose requested is within FDA labeled dosing based on the patient's weight (patient's weight must be provided) AND dose is given in most cost effective manner (such as rounding to appropriate tablet strength or use of suspension) Re-authorization: 1. Documentation of clinical benefit from therapy, such as improvement or stabilization of muscle strength or pulmonary function 2. The dose requested is within FDA labeled dosing based on the patient's weight (updated weight must be provided) AND dose is given in most cost effective manner (such as rounding to appropriate tablet strength or use of suspension)
AGE RESTRICTIONS	Two years of age and older
PRESCRIBER RESTRICTIONS	Must be prescribed by, or in consultation with a provider that specializes in the treatment of Duchenne muscular dystrophy (DMD) and/or neuromuscular disorders
COVERAGE DURATION	Initial authorization and reauthorization will be approved for one year.

15. **Zilucoplan sodium (Zilbrysq) Syringe**

a. **Indication**: For the treatment of adult patients with generalized myasthenia gravis (gMG).

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	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**: Added to Complement Inhibitors Policy

New Indications:

Therapies with Prior Authorization Policies (Non-oncology)

1. **Xolair** (omalizumab)
    a. Previous Indication(s):
        a. Moderate to severe persistent asthma in adults and pediatric patients 6 years of age and older with a positive skin test or in vitro reactivity to a perennial aeroallergen and symptoms that are inadequately controlled with inhaled corticosteroids
        b. Chronic rhinosinusitis with nasal polyps (CRSwNP) in adult patients 18 years of age and older with inadequate response to nasal corticosteroids, as add-on maintenance treatment
        c. Chronic spontaneous urticaria (CSU) in adults and adolescents 12 years of age and older who remain symptomatic despite H1 antihistamine treatment
    b. New indication approved 02/16/2024:
        a. IgE-mediated food allergy in adult and pediatric patients aged 1 year and older for the reduction of allergic reactions (Type I), including anaphylaxis, that may occur with accidental exposure to one or more foods. To be used in conjunction with food allergen avoidance
    c. **RECOMMENDATION:** Inform prescribers via Medical Policy Alert. Policies are being updated as part of June P&T annual policy updates and will include review of this indication.

2. **Praluent** (alirocumab)
    a. Previous Indication(s):
        a. To reduce the risk of myocardial infarction, stroke, and unstable angina requiring hospitalization in adults with established cardiovascular disease
        b. As adjunct to diet, alone or in combination with other low-density lipoprotein cholesterol (LDL-C)-lowering therapies, in adults with primary hyperlipidemia, including heterozygous familial hypercholesterolemia (HeFH), to reduce LDL-C
        c. As an adjunct to other LDL-C-lowering therapies in adult patients with homozygous familial hypercholesterolemia (HoFH) to reduce LDL-C
    b. New indication approved 03/08/2024:
        a. As an adjunct to diet and other LDL-C-lowering therapies in pediatric patients aged 8 years and older with HeFH to reduce LDL-C
    c. **RECOMMENDATION:** Inform prescribers via Medical Policy Alert. Policies are being updated as part of June P&T annual policy updates and will include review of this indication.

3. **Spevigo** (spesolimab-SBZO)
    a. Previous Indication(s):
        a. Indicated for the treatment of generalized pustular psoriasis flares in adults

b. New indication approved 03/18/2024:
    a. Indicated for the treatment of generalized pustular psoriasis (GPP) in adults and pediatric patients 12 years of age and older and weighing at least 40 kg
c. **RECOMMENDATION:** Inform prescribers via Medical Policy Alert. Policies will be updated as part of August P&T annual review

4. **Ultomiris** (ravulizumab-cwvz)
    a. Previous Indication(s):
        a. The treatment of adult and pediatric patients one month of age and older with paroxysmal nocturnal hemoglobinuria (PNH)
        b. The treatment of adult and pediatric patients one month of age and older with atypical hemolytic uremic syndrome (aHUS) to inhibit complement-mediated thrombotic microangiopathy (TMA)
        c. The treatment of adult patients with generalized myasthenia gravis (gMG) who are anti-acetylcholine receptor (AchR) antibody-positive
    b. New indication approved 03/22/2024:
        a. The treatment of adult patients with neuromyelitis optica spectrum disorder (NMOSD) who are anti-aquaporin-4 (AQP4) antibody positive
    c. **RECOMMENDATION:** Inform prescribers via Medical Policy Alert. Policies are being updated as part of June P&T annual policy updates and will include review of this indication.

5. **Livmarli** (maralixibat chloride)
    a. Previous Indication(s):
        a. Indicated for the treatment of cholestatic pruritus in patients with Alagille syndrome (ALGS) 3 months of age and older
    b. New indication approved 03/13/2024:
        a. Indicated the treatment of cholestatic pruritus in patients 5 years of age and older with progressive familial intrahepatic cholestasis (PFIC)
    c. **RECOMMENDATION:** Inform prescribers via Medical Policy Alert. Update policy with new indication and policy criteria.

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

PA PROGRAM NAME	Cholestatic Pruritus Agents
PA INDICATION INDICATOR	1 – All FDA-Approved Indications
REQUIRED MEDICAL INFORMATION	c. For Progressive Familial Intrahepatic Cholestasis (PFIC): i. Documentation of genetically confirmed PFIC type 1 or 2 (formerly known as Byler disease or syndrome) (note: gene mutations affiliated with PFIC include the ATP8B1 gene, ABCB11 gene, ABCB4 gene, TJP2 gene, NR1H4 gene, and MYO5B gene) AND ii. For Livmarli®: Documentation that total serum bile acid is greater than three times ULN for age iii. For Bylvay®: Documentation that serum bile acids at least 100 micromol/L
AGE RESTRICTION	The patient's age must be within FDA labeling for the requested indication

6. **Xhance** (fluticasone propionate)
    a. Previous Indication(s):
        a. Indicated for the treatment of chronic rhinosinusitis with nasal polyps (CRSwNP) in adult patients 18 years of age or older
    b. New indication approved 03/15/2024:

a. Indicated for the treatment of:
    1. Chronic rhinosinusitis with nasal polyps (CRSwNP) in adults
    2. Chronic rhinosinusitis without nasal polyps (CRSsNP) in adults

c. **RECOMMENDATION:** Inform prescribers via Medical Policy Alert. Policies are being updated as part of June P&T annual policy updates and will include review of this indication.

7. **Nexletol; Nexlizet** (bempedoic acid; bempedoic acid and ezetimibe)
    a. Previous Indication(s):
        a. Indicated as an adjunct to diet and statin therapy for the treatment of primary hyperlipidemia in adults with heterozygous familial hypercholesterolemia (HeFH) or atherosclerotic cardiovascular disease, who require additional lowering of LDL-C
    b. New indication approved 03/22/2024:
        a. To reduce the risk of myocardial infarction and coronary revascularization in adults who are unable to take recommended statin therapy (including those not taking a statin) with:
            1. established cardiovascular disease (CVD), or
            2. a high risk for a CVD event but without established CVD
        b. As an adjunct to diet, in combination with other low-density lipoprotein cholesterol (LDL-C) lowering therapies, or alone when concomitant LDL-C lowering therapy is not possible, to reduce LDL-C in adults with primary hyperlipidemia, including heterozygous familial hypercholesterolemia (HeFH)
    c. **RECOMMENDATION:** Inform prescribers via Medical Policy Alert. Policies are being updated as part of June P&T annual policy updates and will include review of this indication.

Therapies with Prior Authorization Policies (Oncology)

1. **Rybrevant** (amivantamab-vmjw)
    a. New indication(s) approved 3/1/2024:
        i. In combination with carboplatin and pemetrexed for the first-line treatment of adult patients with locally advanced or metastatic non-small cell lung cancer (NSCLC) with epidermal growth factor receptor (EGFR) exon 20 insertion mutations, as detected by an FDA-approved test
    b. **RECOMMENDATION:** Inform prescribers via Medical Policy Alert. Prior authorization policy coverage criteria are based on recommendations from the National Comprehensive Cancer Network (NCCN); no updates to the policy are warranted.

2. **Onivyde** (irinotecan liposome injection)
    a. New indication(s) approved 2/13/2024:
        i. In combination with oxaliplatin, fluorouracil and leucovorin, for the first-line treatment of adult patients with metastatic pancreatic adenocarcinoma
    b. **RECOMMENDATION:** Inform prescribers via Medical Policy Alert. Prior authorization policy coverage criteria are based on recommendations from the National Comprehensive Cancer Network (NCCN); no updates to the policy are warranted.

3. **Tagrisso** (osimertinib)
    a. New indication(s) approved 2/16/2024:

i. In combination with pemetrexed and platinum-based chemotherapy, the first-line treatment of adult patients with locally advanced or metastatic NSCLC whose tumors have EGFR exon 19 deletions or exon 21 L858R mutations, as detected by an FDA-approved test

b. **RECOMMENDATION:** Inform prescribers via Medical Policy Alert. Prior authorization policy coverage criteria are based on recommendations from the National Comprehensive Cancer Network (NCCN); no updates to the policy are warranted.

4. **Opdivo** (nivolumab)
   a. New indication(s) approved 03/06/2024:
      i. Urothelial Carcinoma
         - Adult patients with unresectable or metastatic urothelial carcinoma, as firstline treatment in combination with cisplatin and gemcitabine
   b. **RECOMMENDATION:** Inform prescribers via Medical Policy Alert. Prior authorization policy coverage criteria are based on recommendations from the National Comprehensive Cancer Network (NCCN); no updates to the policy are warranted.

5. **Besponsa** (inotuzumab ozogamicin)
   a. New indication(s) approved 03/06/2024:
      i. Treatment of relapsed or refractory CD22-positive B-cell precursor acute lymphoblastic leukemia (ALL) in adult and pediatric patients 1 year and older
   b. **RECOMMENDATION:** Inform prescribers via Medical Policy Alert. Prior authorization policy coverage criteria are based on recommendations from the National Comprehensive Cancer Network (NCCN); no updates to the policy are warranted.

6. **Brukinsa** (zanubrutinib)
   a. New indication(s) approved 03/07/2024:
      i. Relapsed or refractory follicular lymphoma (FL), in combination with obinutuzumab, after two or more lines of systemic therapy. This indication is approved under accelerated approval based on response rate and durability of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial
   b. **RECOMMENDATION:** Inform prescribers via Medical Policy Alert. Prior authorization policy coverage criteria are based on recommendations from the National Comprehensive Cancer Network (NCCN); no updates to the policy are warranted.

7. **Iclusig** (ponatinib)
   a. New indication(s) approved 03/19/2024:
      i. Philadelphia Chromosome-Positive Acute Lymphoblastic Leukemia (Ph+ ALL):
         - Newly diagnosed Ph+ ALL, in combination with chemotherapy. This indication is approved under accelerated approval based on minimal residual disease (MRD)-negative complete remission (CR) at the end of induction. Continued approval for this indication may be contingent upon verification of clinical benefit in a confirmatory trial(s)
         - As monotherapy in Ph+ ALL for whom no other kinase inhibitors are indicated or T315I-positive Ph+ ALL
      ii. Chronic Myeloid Leukemia (CML):
         - Chronic phase (CP) CML with resistance or intolerance to at least two prior kinase inhibitors
         - Accelerated phase (AP) or blast phase (BP) CML for whom no other kinase inhibitors are indicated

- T315I-positive CML (chronic phase, accelerated phase, or blast phase)

Limitations of Use: ICLUSIG is not indicated and is not recommended for the treatment of patients with newly diagnosed CP-CML

b. **RECOMMENDATION:** Inform prescribers via Medical Policy Alert. Prior authorization policy coverage criteria are based on recommendations from the National Comprehensive Cancer Network (NCCN); no updates to the policy are warranted.

Therapies Without Prior Authorization Policies

1. **Creon, Pertzye, Zenpep, Pancreaze** (pancrelipase)
   a. Previous Indication(s):
      i. Indicated for the treatment of exocrine pancreatic insufficiency due to cystic fibrosis, chronic pancreatitis, pancreatectomy, or other conditions
   b. New indication approved 02/28/2024:
      i. Indicated for the treatment of exocrine pancreatic insufficiency in adult and pediatric patients
   c. **RECOMMENDATION:** Inform prescribers via Medical Policy Alert.

2. **Ziextenzo** (pegfilgrastim-bmez)
   a. Previous Indication(s):
      i. Decrease the incidence of infection, as manifested by febrile neutropenia, in patients with non-myeloid malignancies receiving myelosuppressive anti-cancer drugs associated with a clinically significant incidence of febrile neutropenia
   b. New indication approved 02/28/2024:
      i. Increase survival in patients acutely exposed to myelosuppressive doses of radiation (Hematopoietic Subsyndrome of Acute Radiation Syndrome)
   c. **RECOMMENDATION:** Inform prescribers via Medical Policy Alert.

3. **Cefazolin In Plastic Container**
   a. Previous Indication(s):
      i. Treatment of the following infections caused by susceptible isolates of the designated microorganisms in adult and pediatric patients for whom appropriate dosing with this formulation can be achieved:
         1. Respiratory tract infections
         2. Urinary tract infections
         3. Skin and skin structure infections
         4. Biliary tract infections
         5. Bone and joint infections
         6. Genital infections
         7. Septicemia
         8. Endocarditis
      ii. Perioperative prophylaxis in adults for whom appropriate dosing with this formulation can be achieved
   b. New indication approved 02/01/2024:
      i. Perioperative prophylaxis in adults and pediatric patients aged 10 to 17 years old for whom appropriate dosing with this formulation can be achieved
   c. **RECOMMENDATION:** Inform prescribers via Medical Policy Alert.

4. **Biktarvy** (bictegravir, emtricitabine, tenofovir alafenamide)
    a. Previous Indication(s):
        i. Indicated as a complete regimen for the treatment of HIV-1 infection in adults and pediatric patients weighing at least 14 kg who have no antiretroviral treatment history or to replace the current antiretroviral regimen in those who are virologically suppressed (HIV-1 RNA less than 50 copies per mL) on a stable antiretroviral regimen with no history of treatment failure and no known substitutions associated with resistance to the individual components of BIKTARVY
    b. New indication approved 02/23/2024:
        i. Indicated as a complete regimen for the treatment of HIV-1 infection in adults and pediatric patients weighing at least 14 kg:
            1. who have no antiretroviral treatment history or
            2. to replace the current antiretroviral regimen in those who are virologically suppressed (HIV-1 RNA less than 50 copies per mL) on a stable antiretroviral regimen with no known or suspected substitutions associated with resistance to bictegravir or tenofovir
    c. **RECOMMENDATION:** Inform prescribers via Medical Policy Alert.

5. **Veklury** (remdesivir)
    a. Previous Indication(s):
        i. Indicated for the treatment of coronavirus disease 2019 (COVID-19) in adults and pediatric patients (28 days of age and older and weighing at least 3 kg) who are:
            1. Hospitalized, or
            2. Not hospitalized and have mild-to-moderate COVID-19, and are at high risk for progression to severe COVID-19, including hospitalization or death
    b. New indication approved 02/23/2024:
        i. Indicated for the treatment of coronavirus disease 2019 (COVID-19) in adults and pediatric patients (birth to less than 18 years of age weighing at least 1.5 kg) who are:
            1. Hospitalized, or
            2. Not hospitalized and have mild-to-moderate COVID-19, and are at high risk for progression to severe COVID-19, including hospitalization or death
    c. **RECOMMENDATION:** Inform prescribers via Medical Policy Alert.

6. **Definity** (perflutren lipid microsphere)
    a. Previous Indication(s):
        i. Indicated for use in patients with suboptimal echocardiograms to opacify the left ventricular chamber and to improve the delineation of the left ventricular endocardial border
    b. New indication approved 03/01/2024:
        i. Indicated, after activation, for use in adult and pediatric patients with suboptimal echocardiograms to opacify the left ventricular chamber and to improve the delineation of the left ventricular endocardial border
    c. **RECOMMENDATION:** Inform prescribers via Medical Policy Alert.

7. **Xofluza** (baloxavir marboxil)
    a. Previous Indication(s):
        i. Treatment of acute uncomplicated influenza in patients who have been symptomatic for no more than 48 hours and who are:
            1. otherwise healthy adults and pediatric patients 5 years of age and older
                OR
            2. adults and pediatric patients 12 years of age and older who are at highrisk of developing influenza-related complications
        ii. Post-exposure prophylaxis of influenza in patients 5 years of age and older following contact with an individual who has influenza
    b. New indication approved 03/01/2024:
        i. Treatment of acute uncomplicated influenza in patients 5 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
    c. **RECOMMENDATION:** Inform prescribers via Medical Policy Alert.

8. **Edurant** (rilpivirine)
    a. Previous Indication(s):
        i. Indicated in combination with other antiretroviral agents for the treatment of HIV-1 infection in treatment-naïve patients 12 years of age and older and weighing at least 35 kg with HIV-1 RNA less than or equal to 100,000 copies/mL
            1. Limitation of Use:
                a. More EDURANT treated subjects with HIV-1 RNA greater than 100,000 copies/mL at the start of therapy experienced virologic failure (HIV-1 RNA ≥50 copies/mL) compared to EDURANT treated subjects with HIV-1 RNA less than or equal to 100,000 copies/mL
        ii. Indicated in combination with VOCABRIA (cabotegravir), for short-term treatment of HIV-1 infection in adults and adolescents 12 years and older and weighing at least 35 kg who are virologically suppressed (HIV-1 RNA less than 50 copies/mL) on a stable regimen with no history of treatment failure and with no known or suspected resistance to either cabotegravir or rilpivirine
    b. New indication approved 03/01/2024:
        i. Indicated in combination with other antiretroviral agents for the treatment of HIV-1 infection in treatment-naïve patients **2 years of age** and older and weighing at least **14 kg** with HIV-1 RNA less than or equal to 100,000 copies/mL
    c. **RECOMMENDATION:** Inform prescribers via Medical Policy Alert.

9. **Vemlidy** (tenofovir alafenamide)
    a. Previous Indication(s):
        i. Indicated for the treatment of chronic hepatitis B virus infection in adults and pediatric patients 12 years of age and older with compensated liver disease
    b. New indication approved 03/27/2024:

i. Indicated for the treatment of chronic hepatitis B virus infection in adults and pediatric patients 6 years of age and older and weighing at least 25 kg with compensated liver disease

c. **RECOMMENDATION:** Inform prescribers via Medical Policy Alert.

Drug Safety Monitoring:

FDA Drug Safety Communications

There were no drug safety communications reported during this period.

Drug Recalls/Market Withdrawals

1. **Drug Name:** TING® 1% Tolnaftate Athlete's Foot Spray Antifungal Spray Liquid
   - **Date of Recall:** 2/2/2024
   - **Reason for recall:** Presence of benzene
   - **Link to more information:** https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/insight-pharmaceuticals-issues-voluntary-nationwide-recall-tingr-1-tolnaftate-athletes-foot-spray
   - **Health Plan Recommendation:** Notify providers via Medical Policy Alert

2. **Drug Name:** Arize brand male enhancement capsules
   - **Date of Recall:** 2/5/2024
   - **Reason for recall:** Products contain undeclared Nortadalafil
   - **Link to more information:** https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/today-world-issues-voluntary-nationwide-recall-all-lots-arize-herbal-dietary-supplement-capsules-due
   - **Health Plan Recommendation:** Notify providers via Medical Policy Alert

3. **Drug Name:** Sustain and Schwinnng brand male enhancement capsules
   - **Date of Recall:** 2/5/2024
   - **Reason for recall:** Products contain undeclared Tadalafil and Nortadalafil
   - **Link to more information:** https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/today-world-issues-voluntary-nationwide-recall-all-lots-sustain-and-schwinnng-brand-dietary
   - **Health Plan Recommendation:** Notify providers via Medical Policy Alert

4. **Drug Name:** Equate Lubricant Eye Ointment (Mineral Oil 42.5%, White Petrolatum 57.3%, Lanolin Alcohols), Equate Stye Lubricant Eye Ointment (Mineral Oil 31.9%, White Petrolatum 57.7%, Microcrystalline Wax, Stearic Acid, Wheat Germ Oil), CVS Health Lubricant Eye Ointment (Mineral Oil 31.9%, White Petrolatum 57.7%, Microcrystalline Wax, Stearic Acid Wheat Germ Oil, Lubricant PM Ointment
   - **Date of Recall:** 2/26/2024

- **Reason for recall:** Due to Potential Lack of Sterility Assurance
- **Link to more information:** https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/brassica-pharma-pvt-ltd-issues-voluntary-nationwide-recall-equate-lubricant-eye-ointment-equate-stye
- **Health Plan Recommendation:** Notify providers via Medical Policy Alert

5. **Drug Name:** Par Pharmaceutical Treprostinil 20mg/20mL Injection
   - **Date of Recall:** 3/12/2024
   - **Reason for recall:** Potential Presence of Silicone Particulate Matter
   - **Link to more information:** https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/par-pharmaceutical-issues-voluntary-nationwide-recall-one-lot-treprostinil-injection-due-potential
   - **Health Plan Recommendation:** Notify providers via Medical Policy Alert

6. **Drug Name:** Pyramid Wholesale dietary supplements for sexual enhancement (multiple brands)
   - **Date of Recall:** 3/20/2024
   - **Reason for recall:** Undeclared Sildenafil and/or Tadalafil
   - **Link to more information:** https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/pyramid-wholesale-issues-recall-various-brands-products-sold-dietary-supplements-sexual-enhancement
   - **Health Plan Recommendation:** Notify providers via Medical Policy Alert

7. **Drug Name:** Amneal Vancomycin Hydrochloride for Oral Solution, USP, 250 mg/5mL
   - **Date of Recall:** 3/27/2024
   - **Reason for recall:** Super potent due to bottles being overfilled
   - **Link to more information:** https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/amneal-pharmaceuticals-llc-issues-nationwide-voluntary-recall-vancomycin-hydrochloride-oral-solution
   - **Health Plan Recommendation:** Notify providers via Medical Policy Alert

8. **Drug Name:** Eugia brand Methocarbamol Injection, USP 1000 mg/10 mL (100mg/mL) (Single Dose Vial)
   - **Date of Recall:** 3/28/2024
   - **Reason for recall:** Device & Drug Safety – Presence of Particulate Matter
   - **Link to more information:** https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/eugia-us-llc-fka-auromedics-pharma-llc-issues-voluntary-nationwide-recall-methocarbamol-injection
   - **Health Plan Recommendation:** Notify providers via Medical Policy Alert

Providence Health Plan

Providence Health Assurance

Other Formulary Changes:

Drug Name	Action Taken	Policy Name
Palovarotene (Sohonos) Capsule	Correction from April 2024 P&T: • Medicare Part D: Non-Formulary without Prior Authorization	N/A
Tiopronin Tablet DR	First generic drug (Thiola EC). Line extend as generic; • Commercial: Formulary, Tier 6 • Medicaid: Non-Formulary, Specialty • Medicare Part D: Non-Formulary	N/A
Apomorphine hcl Cartridge	Add to Commercial Formulary, Tier 5	N/A
Fesoterodine fumarate Tab ER 24h	Add to Commercial Formulary; • Commercial Standard: Tier 2 • Commercial Dynamic: Tier 4	N/A
Testosterone undecanoate (Kyzatrex) Capsule	Remove from Commercial and Medicaid formularies Effective 09/01/2024	N/A
• **Nirsevimab-alip (Beyfortus)** • **Palivizumab (Synagis)**	Remains covered medical benefit for all lines of business	N/A
Nevirapine Oral Susp	Add to Commercial Formulary; Commercial Standard: Tier 2 Commercial Dynamic: Tier 4	N/A
Secukinumab (Cosentyx) Vial	New strength (125mg/5ml), dosage form (vial) and route (Intravenous); • Medical Benefit, Prior Authorization for all lines of business	• Commercial: Medically Infused Therapeutic Immunomodulators (Tims) – Comm • Medicaid: Therapeutic Immunomodulators (TIMS) – Medicaid • Medicare Part B: Medically Infused Therapeutic Immunomodulators (TIMs) Prior Authorization and Step Therapy Policy – Medicare Part B

Drug Name	Action Taken	Policy Name
Vedolizumab (Entyvio Pen) Pen Injctr	New route (subcutaneous), strength (108mg/0.68ml), and dosage Form (Pen Injctr); • Commercial/Medicaid: Non-Formulary, Prior Authorization, Quantity Limit (1.36 mL per 28 days) • Medicare Part D: Non-Formulary	• Commercial/Medicaid: Therapeutic Immunomodulators • Medicare Part D: N/A
Tramadol hcl Tablet	New strength (25mg); • Non-Formulary for all lines of business	N/A
Sitagliptin (Zituvio) Tablet	New authorized generic (Januvia); • Commercial: Non-Formulary, Step Therapy • Medicaid: Non-Formulary, Step Therapy • Medicare Part D: Non-Formulary	• Commercial/Medicaid: DPP-4 Inhibitors • Medicare Part D: N/A
Bepotastine besilate (Bepreve) Drops	Remove from Commercial formulary	N/A
Cetirizine hcl (Zerviate) Droperette	Remove from Commercial formulary	N/A
Auvi-Q, Epipen, Epipen Jr, Symjepi	• Commercial/Medicaid: Increase quantity limit to 4 pens (2 packs of 2) per 90 days	N/A
Pirfenidone 267 mg Capsule	Add to formulary: • Commercial: Formulary, Tier 5, Prior Authorization, Quantity Limit (6 capsules per day) • Medicaid: Formulary, Prior Authorization, Quantity Limit (6 capsules per day)	Esbriet, Ofev, Pirfenidone tablets
Pirfenidone (Esbriet) 267 mg and 534 mg Tablets	Remove from Commercial and Medicaid Formulary Effective 09/01/2024	Esbriet, Ofev, Pirfenidone tablets
• **Sitagliptin (Januvia) Tablet** • **Sitagliptin/metformin (Janumet/Janumet XR) Tablet**	Commercial: Move to Tier 3 from Tier 4	DPP-4 Inhibitors
• **Bempedoic acid (Nexletol) Tablet**	• Commercial: Add to Formulary, Tier 4 • Medicaid: Add to Formulary	Nexletol, Nexlizet

Drug Name	Action Taken	Policy Name
• **Bempedoic acid/ezetimibe (Nexlizet) Tablet**		
Mepolizumab (Nucala) Auto Injct / Syringe	Add to Medicaid formulary	IL-5 Inhibitors
Mepolizumab (Nucala) Vial	Remove from Commercial and Medicaid formulary (covered under the medical benefit with prior authorization)	IL-5 Inhibitors
• **Ciclesonide (Omnaris) Spray/Pump** • **Beclomethasone dipropionate (Qnasl) Spray** • **Ciclesonide (Zetonna) Spray**	Remove from Commercial formulary	N/A
• **Flunisolide (37asalide) 0.025% nasal spray** • **Mometasone (Nasonex) 50 mcg nasal spray**	Commercial Dynamic: Move to Tier 2 from Tier 3	N/A
Dapagliflozin Tablet	Authorized generic (Farxiga). • Commercial: Non-Formulary • Medicaid: Formulary • Medicare Part D: Non-Formulary, Quantity Limit (1 tablet per day)	N/A
• **Novolog/Novolog Mix** • **Novolin R, N, 70/30** • **Fiasp**	Added to Commercial Formulary, Tier 3 Effective 07/01/2024	N/A

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

INFORMATIONAL ONLY

NEW DRUGS / COMBINATIONS / STRENGTHS / DOSAGE FORMS		
Drug Name	**Action Taken**	**Policy Name**
Pemetrexed disodium (Pemrydi RTU) Vial	New entity. Line extend as covered medical benefit for all lines of business	N/A
Nirogacestat hydrobromide (Ogsiveo) Tablet	New strength. Line extend with Ogsiveo 50mg tablet; • Commercial: Formulary, Tier 6, Prior Authorization • Medicaid: Formulary, Prior Authorization • Medicare Part D: Formulary, Tier 5, Prior Authorization	Anti-Cancer Medications – Self-Administered
Emicizumab-kxwh (Hemlibra) Vial	New strength. Line extend with other Hemlibra; • Commercial/Medicaid: Medical Prior Authorization • Medicare Part D: Non-Formulary • Medicare Part B: Prior Authorization	Hemlibra

NEW GENERICS		
Drug Name	**Action Taken**	**Policy Name**
Nitroglycerin Oint.	First generic drug (Rectiv). Line extend as generic; • Commercial Standard: Formulary, Tier 2 • Commercial Dynamic: Formulary, Tier 4 • Medicaid: Non-Formulary • Medicare Part D: Formulary, Tier 4	N/A
Citric acid/sodium citrate (Oral Citrate) Solution	First generic drug (Oracit). Line extend as generic; • Non-Formulary for all lines of business	N/A
Carbinoxamine Maleate Tablet	First generic drug (Ryvent). Line extend as generic;	• Commercial/Medicaid: New Medications and

	• Commercial/Medicaid: Non-Formulary, Prior Authorization • Medicare Part D: Non-Formulary	Formulations without Established Benefit • Medicare Part D: N/A
Adalimumab-ryvk (Adalimumab-RYVK [CF]) Autoinjkit and Syringekit	New Humira biosimilar. Line extend with non-preferred Humira biosimilars; • Commercial/Medicaid: Non-Formulary, Prior Authorization, Quantity Limit (2 syringe kit per 28 days) • Medicare Part D: Non-Formulary	Therapeutic Immunomodulators (TIMS)
Adalimumab-aaty (Yuflyma [CF]) Syringekit	New BLA: Line extend with other Yuflyma; • Commercial/Medicaid: Non-Formulary, Prior Authorization, Quantity Limit (2 syringe kit per 28 days), Specialty • Medicare Part D: Non-Formulary	Therapeutic Immunomodulators (TIMS)

Clinical Policy Changes:

MAJOR CHANGES	
Policy Name	**Summary of Change**
Actinic Keratosis Agents	Remove prior authorization on fluorouracil 4% cream (Tolak®) and removed prescriber restriction for treatment of genital warts.
Adbry	For Commercial: Removed daily/twice daily application requirement for topicals For Medicaid: Clarified members needs trial of four weeks of prerequisite therapy.
Benlysta	Simplified diagnostic criteria and updated prerequisite therapies based on the latest guideline updates. Removed the requirement to use standard therapy in reauthorization criteria based on provider feedback.
Calcitonin Gene-Related Peptide (CGRP) Receptor Antagonists	Removed exclusion of combination therapy for acute treatments, as the risk of exacerbating medication overuse headache has not been well established with CGRPs.

	This criterion has caused a lot of operational burden and member/provider dissatisfaction.
Camzyos	Removed requirement for providing documentation/imaging to support diagnosis. Updated conventional therapy based on guideline recommendations.
Cibinqo	For Commercial: Updated requirement of trial of upadacitinib (Rinvoq®) to dupilumab (Dupixent®) and removed daily/twice daily application requirement for topicals For Medicaid: Clarified members needs trial of four (4) weeks of prerequisite therapy.
• **Complement Inhibitors** • **Complement Inhibitors Prior Authorization and Step Therapy Policy – Medicare Part B**	New policy combining criteria for Soliris®, Ultomiris®, and Empaveli®. Aligned criteria for all agents, updated exclusion to not allow with another complement inhibitor OR an Fc receptor antagonist. Soliris® will required use of more cost-effective agents for overlapping indications.
Corlanor	Clarified definition of inappropriate sinus tachycardia and that postural orthostatic tachycardia syndrome should be ruled out. Slightly reworded crtieria for guideline directed medical therapy (intent did not change).
Denavir, Sitavig, Xerese, Zovirax	Retired prior authorization on acyclovir 5% ointment. Removed references to Sitavig®, as this drug is no longer available on the market.
DPP-4 Inhibitors	Changed policy to a step therapy policy; claims for non-preferred therapies will require trial of saxagliptin or alogliptin for coverage.
Esbriet, Ofev, Pirfenidone tablets	Remove brand Esbriet and pirfenidone 267 mg and 534 tablets, as these drugs are non-preferred behind the pirfenidone 267 mg capsules.
Granulocyte-Colony Stimulating Factor (G-CSF) Policy	New policy and preferred product strategy. Preferred pegfilgrastim products (Neulasta® and Fulphila®) will continue to be available without prior authorization. Non-preferred products will require prior authorization and use of preferred products. Effective 09/01/2024
• **Homozygous Familial Hypercholesterolemia (FH) Agents** • **Homozygous FH Agents – Medicare Part B**	Updated policy language clarify dosage range for defining high-intensity statins.
• **IL-5 Inhibitors** • **Il-5 Inhibitors Prior Authorization and Step Therapy – Medicare Part B**	Updated diagnostic criteria to remove lab values measured while patient on high doses of steroids or oral steroids as it is presumed that eosinophilic level would be lower if on steroids.

Intranasal Allergy Medications – Medicaid	Xhance was added to the policy and language around covered diagnosis was clarified.
Medications for Rare Indications	Policy criteria for urea cycle disorders was updated to require use of Pheburane® (sodium phenylbutyrate pellets) prior to coverage of Ravicti® or Olpruva®
Nexletol, Nexlizet	1. Added new indication of cardiovascular risk reduction in both primary and secondary prevention, 2. Removed PCSK-9 inhibitors as a prerequisite, 3. Re-worded statin intolerance definition to align with our other policies such as PCSK-9 inhibitors.
• **Ophthalmic Vascular Endothelial Growth Factor (VEGF) Inhibitors** • **Ophthalmic VEGF Inhibitors Prior Authorization and Step Therapy Policy – Medicare Part B**	Changed preferred product strategy. Eyelea HD® will be non-preferred and Lucentis® (along with biosimilars Byooviz® and Cimerli®) will be preferred for the respective indications. Preferred agents do not require prior authorization.
Oxervate	Reduced number of required failed conventional therapies.
• **PCSK9 Inhibitors – Commercial** • **PCSK9 Inhibitors – Medicaid**	Updated age restriction criteria and new indication for Praluent.
Pulmonary Hypertension	Clarified that pulmonary capillary wedge pressure/left ventricular end diastolic pressure is used for diagnosis of pulmonary arterial hypertension or WHO group 1 only. Removed criteria for brand Tracleer tablets and Letairis as these are reviewed using the brand over generic policy. Added exclusion of idiopathic pulmonary fibrosis for ambrisentan due to contraindication in package insert.
Pulmonary Hypertension Prior Authorization Policy – Medicare Part B	Clarified that pulmonary capillary wedge pressure/left ventricular end diastolic pressure is used for diagnosis of pulmonary arterial hypertension or WHO group 1 only.
Second and Third Generation Antihistamines – Medicaid	Updated criteria to add comorbid conditions for patients under age 21 to align with Oregon Health Authority.
Syfovre	Rename policy to Geographic Atrophy Agents and add Izervay.
Tafamidis	Clarified the need for documentation of New York Heart Association class. Updated concurrent drug exclusion criteria to include the two new drugs for transthyretin-mediated amyloidosis polyneuropathy.
Tezspire	Clarified that coverage of medication when being administered by a healthcare provider would only be approved for short duration, as this medication is required to be self-administered. Clarified prescriber restrictions apply for initial and subsequent authorizations.

Tezspire – Medicare Part B	Clarified prescriber restrictions apply for initial and subsequent authorizations.
• **Therapeutic Immunomodulators** • **Therapeutic Immunomodulators – Medicaid**	Added criteria for new self-administered vedolizumab (Entyvio®) product. Updated FDA indications for upadacitinib (Rinvoq®).
• **Topical Agents for Skin Conditions** • **Topical Agents for Skin Conditions – Medicaid**	New policy combining criteria from multiple agents (Eucrisa®, Zoryve®, Wynzora®, Enstilar®, and Vtama®)
Upneeq	Minor update to policy criteria for documentation of superior visual field deficit criteria listing Leicester Peripheral Field Test as an example of documentation.
Vascepa	Updated wording surrounding statin use requirement to align with other policies requiring statin therapy. Intent to optimize statin therapy for ASCVD risk reduction has not changed.
Xdemvy	Updated trial and failure meds based on the latest guideline updates.
• **Xolair** • **Xolair – Medicare Part B**	Updated trial and failure duration for urticaria indication to align with the European Academy of Allergy and Clinical Immunology Guidelines. Criteria added for newly approved indication, IgE-mediated food allergy.

MEDICAL REIMBURSEMENT POLICIES	
Policy Name	**Summary of Change**
Medical Drug Reimbursement Policy: Outpatient and Inpatient	New Policy

RETIRED POLICIES	
Policy Name	**Summary of Change**
Bepreve, Zerviate	Bepreve and Zerviate will be removed from the formulary and criteria for coverage is outlined in the “Formulary and Quantity Limit Exceptions” policy.
Corticosteroid and Vitamin D Analogues	Remove prior authorization for Taclonex and moved remaining drugs (Wynzora and Enstilar) to new policy “Topical Agents for Skin Conditions”
Empaveli	Drug moved to new combined “Complement Inhibitors” policy.

Eucrisa	Drugs were moved to new combined "Topical Agents for Skin Conditions" policy.
Intranasal Medications – Commercial	Policy retired due to low utilization- formulary nasal steroids include flunisolide, fluticasone, mometasone.
Izervay	Drug combined with Syfovre policy.
Opzelura	Drugs were moved to new combined "Topical Agents for Skin Conditions" policy.
Quantity Limits of Epinephrine Auto-Injector	Retire policy due to low utilization of policy, will continue to manage utilization with epinephrine quantity limit.
• **Soliris** • **Soliris Prior Authorization and Step Therapy Policy – Medicare Part B**	Drug moved to new combined "Complement Inhibitors" policy
• **Topical Antibiotics Step Therapy Policy**	Retired prior authorization due to low risk for inappropriate utilization
• **Ultomiris** • **Ultomiris Prior Authorization and Step Therapy Policy – Medicare Part B**	Drug moved to new combined "Complement Inhibitors" policy.
• **Verkazia**	Retired prior authorization. The medication is non-formulary and criteria for coverage is outlined in the "Formulary and Quantity Limit Exceptions" policy.
• **Verquvo**	Retire policy due to low risk of inappropriate use or over utilization. The medication is non-formulary and criteria for coverage is outlined in the "Formulary and Quantity Limit Exceptions" policy.
• **Vtama, Zoryve**	Drugs were moved to new policy "Topical Agents for Skin Conditions"
• **Xhance**	Retire Xhance policy due to low utilization. Other nasal steroids are available on formulary (such as fluticasone).