Providence Health Plan

Providence Health Assurance

Healthcare Services Medical & Pharmacy Policy Alerts

Number 88

November 1, 2023

This is the November 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 12/1/2023

New and Emerging Technologies and Other Non-Covered Services **MP23**	**Policy Updates:** Remove panels and associated codes from policy: • Molecular Microscope MMDx Heart Test • Molecular Microscope MMDx Kidney Test **Codes/PA:** Remove codes 0087U and 0088U from policy **OHP:** These changes do not apply to OHP. The Prioritized List and the Oregon Administrative Rules will be followed.
Radiofrequency Ablation of Tumors Outside the Liver **MP 67**	**Policy Updates:** Liberalize criteria (II and III), based on ACOG guideline, to allow for RFA of uterine fibroids. **Codes/PA:** Add PA to CPT 58674 and 0404T. **OHP:** These changes do not apply to OHP. The Prioritized List and the Oregon Administrative Rules will be followed.
Partial Thromboplastin Time **MP325**	**Policy Updates:** Updated pair to pay diagnosis list from CMS. **Codes/PA:** Updated pair to diagnosis list from CMS. **OHP:** These changes do not apply to OHP. The Prioritized List and the Oregon Administrative Rules will be followed.

Effective 1/1/2024

Automated Evacuation of the Meibomian Glands **MP30** *Previously: Eye: Automated Evacuation of the Meibomian Glands*	**Policy Updates:** Change denial language from investigational to not medically necessary. **Codes/PA:** Change denial type for 3 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.
Hearing Aids **MP261**	**Policy Updates:** Change denial language from investigational to not medically necessary for several non-covered hearing aid types. **Codes/PA:** Change denial type for 3 codes from investigational to not medically necessary. • V5095 - Semi-implantable middle ear hearing prosthesis • V5262- Hearing aid, disposable, any type, monaural • V5263 - Hearing aid, disposable, any type, binaural **OHP:** These changes do not apply to OHP. The Prioritized List and the Oregon Administrative Rules will be followed.
Osteochondral Allografts and Autografts for Cartilaginous Defects **MP149**	**Policy Updates:** Change denial language from investigational to not medically necessary **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.
Ganglion Impar Blocks **MP104**	**Policy Updates:** Update noncoverage position from investigational to not medically necessary when medical necessity criteria are not met. **Codes/PA:** No changes. Only unlisted code. **OHP:** These changes do not apply to OHP. The Prioritized List and the Oregon Administrative Rules will be followed.

Complementary and Alternative Medicine (CAM) Treatments **MP260**	**Policy Updates:** Change denial language from investigational to not medically necessary **Codes/PA:** Add code 0736T to policy for colonic lavage, continue to deny as not medically necessary. **OHP:** These changes do not apply to OHP. The Prioritized List and the Oregon Administrative Rules will be followed.
Sleep Disorder Treatment with Positive Airway Pressure **MP56** Previously: Sleep Disorder Treatment: Positive Airway Pressure	**Policy Updates:** Add criterion XX: Positive airway pressure for the treatment of upper airway resistance syndrome is considered not medically necessary. Definition of UARS in policy guidelines. **Codes/PA:** No changes to coding or PA. **OHP:** These changes do not apply to OHP. The Prioritized List and the Oregon Administrative Rules will be followed.
Sleep Disorder Treatment with Oral and Sleep Position Appliances **MP46** *Previously: Sleep Disorder Treatment: Oral and Sleep Position Appliances*	**Policy Updates:** Add criterion VII: Oral appliances for the treatment of upper airway resistance syndrome are considered not medically necessary. Definition of UARS in policy guidelines. **Codes/PA:** No changes to coding or PA. **OHP:** These changes do not apply to OHP. The Prioritized List and the Oregon Administrative Rules will be followed.
Implantable Spinal Cord and Dorsal Root Ganglion Stimulation **MP28** *Previously: Back: Implantable Spinal Cord and Dorsal Root Ganglion Stimulation (Company)*	**Policy Updates:** Add criterion II regarding repeat spinal cord stimulation trials. **Codes/PA:** Remove codes for StimRouter device - service is not a spinal cord stimulator and is currently addressed by the "Electrical Stimulation: Non-Covered Therapies" policy (CPT 64555, 64575, 64585). **OHP:** These changes do not apply to OHP. The Prioritized List and the Oregon Administrative Rules will be followed.

Electrical Stimulation Non-Covered Therapies **MP331**	**Policy Updates:** Add Reactiv8 as an example of peripheral nerve stimulation. **Codes/PA:** Change PNS code 64555 from requiring Prior Auth to denying as not medically necessary. **OHP:** These changes do not apply to OHP. The Prioritized List and the Oregon Administrative Rules will be followed.
Liposuction for Lipedema MP346	**Policy Updates:** Add criterion I.G clarifying that procedure must be performed by board-certified plastic surgeon. **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.
Rhinoplasty and Other Nasal Surgeries **MP 166**	**Policy Updates:** Add non-coverage criterion IV addressing low-dose radiofrequency to the nasal valve (e.g. VivAer). **Codes/PA:** No change to codes or configuration. **OHP:** These changes do not apply to OHP. The Prioritized List and the Oregon Administrative Rules will be followed.
Negative Pressure Wound Therapy **MP168**	**Policy Updates:** No change to criteria. **Codes/PA:** • For CPT codes 97605-97608, remove PA and add diagnosis code configuration based on a Noridian LCA. No changes to other codes in the policy or their respective configuration. • Following CMS, CPT codes 97605-97608 are considered medically necessary only when reported with an ICD-10 code found in the Wound Care LCA. **OHP:** These changes do not apply to OHP. The Prioritized List and the Oregon Administrative Rules will be followed.
Autologous Chondrocyte Implantation (ACI) for Cartilaginous Defects of the Knee	**Policy Updates:** • Title change without colon • Update age criteria to be more in alignment with other payers (15-55 instead of 18-55). Still must remain skeletally mature with closed growth plates.

MP137 *Formerly: Knee: Autologous Chondrocyte Implantation (ACI) for Cartilaginous Defects*	• Update noncoverage position from investigational to not medically necessary when medical necessity criteria are not met. **Codes/PA:** No coding changes needed- codes PA. **OHP:** These changes do not apply to OHP. The Prioritized List and the Oregon Administrative Rules will be followed.

MEDICARE

Effective 12/1/2023

Gene Expression Profile Testing for Melanoma **MP253**	**Policy Updates:** The MolDX Program Contractor *non-coverage* position found in the DEX Registry was retroactively changed to a potentially *covered* position for the DecisionDx® DiffDX™- Melanoma test for Medicare. According to MolDX directly, this test is now covered when LCD criteria are met as of 8/6/2023. Update policy to reflect this. No other changes made.. **Codes/PA:** • Code 0314U - Remove not medically necessary denial and add PA effective 8/6/2023. No claim adjustments required. • No changes to other codes or their configuration.
Genetic Testing for Thyroid Nodules *Previously: Genetic Testing: Thyroid Nodules* **MP40**	**Policy Updates:** • Update title (remove prefix and colon). • Remove outdated codes from "Criteria" table but add notes about code changes in "Billing Guidelines" section. • Remove criteria from prior to July 2023 (requests for services rendered prior to July 2023 should use prior versions of this policy, not the current version). *(NOTE: One LCD and LCA that were supposed to be effective 7/17/2023 were not implemented as expected, so the policy has been updated and the prior criteria source re-instated.)* • Add LCDs/LCAs to policy for testing in additional service areas. **Codes/PA:** • PLA code 0287U – Remove not medically necessary denial and re-add PA retroactively back to 8/1/2023 (as though the not medically necessary denial was never effective).

	• No changes to other codes in the policy or their configuration (policy title updates needed, but no changes to configuration).

Effective 1/1/24

Autologous Chondrocyte Implantation (ACI) for Cartilaginous Defects of the Knee *Previously: Knee: Autologous Chondrocyte Implantation (ACI) for Cartilaginous Defects* **MP355**	**Policy Updates:** • No change to criteria, continue to apply Company medical policy criteria. • The Company policy criteria changing from investigational to the not medically necessary changes some of • Update to title (remove prefix and colon). **Codes/PA:** No change to codes or configuration (some policy title updates needed, but no changes to configuration).
Automated Evacuation of the Meibomian Glands *Previously: Eye: Automated Evacuation of the Meibomian Glands* **MP366**	**Policy Updates:** • No change to criteria, continue to apply Company medical policy criteria. • The Company policy criteria changing from investigational to the not medically necessary changes some of the generic language found in the Medicare version. • Update to title (remove prefix and colon). • Updated "Policy Guidelines." **Codes/PA:** No change to codes or configuration (policy title updates needed, but no changes to configuration).
Osteochondral Allografts and Autografts for Cartilaginous Defects **MP357**	**Policy Updates:** • No change to criteria, continue to apply Company medical policy criteria. • The Company policy criteria changing from investigational to not medically necessary changes some of the generic language found in the Medicare version. • Updated "Policy Guidelines."

	Codes/PA: No change to codes or configuration
Complementary and Alternative Medicine (CAM) Treatments **MP327**	**Policy Updates:** • No change to criteria, continue to apply Medicare references, when available for the service in question, and Company medical policy criteria as indicated for services with no specific available Medicare guidance available. • The Company policy criteria changing from investigational to not medically necessary changes some of the generic language found in the Medicare version. • Updated "Policy Guidelines." **Codes/PA:** • Add 0736T to this policy (remove from NET, add to CAM – continue not medically necessary configuration). • No change to codes already in this policy or their configuration
New and Emerging Technologies and Other Non-Covered Services **MP220**	**Policy Updates:** No change to criteria table, only remove a code and relocate to the Medicare Complementary and Alternative Medicine (CAM) Treatments policy. **Codes/PA:** Remove 0736T from this policy and add to CAM policy. Continue not medically necessary denial. No changes to other codes in the policy or their respective configuration.
Negative Pressure Wound Therapy **MP192**	**Policy Updates:** No change to criteria table. However, due to confusion regarding criteria for services rendered in a setting *other than* a member's home and reported with CPT codes (rather than HCPCS codes for DME), added notes to clarify how coverage is determined. According to communication directly from Noridian, CPT codes 97605-97608 are considered medically necessary only when reported with an ICD-10 code found in the Wound Care LCA. **Codes/PA:** For CPT codes 97605-97608, remove PA and add diagnosis code configuration based on a Noridian LCA. No changes to other codes in the policy or their respective configuration.
Radiofrequency Ablation of Tumors Outside the Liver **MP377**	**Policy Updates:** Update to criteria for uterine fibroid (0404T/58674). When this policy was divided by line of business, Company policy criteria was not previously used for these services. Instead, they were allowed as medically necessary for Medicare plan members with no edits. At the time, we didn't use Company criteria before was because it previously was a full denial for all indications. However, since Commercial will have medically necessary criteria to allow coverage, the recommendation is to now use Company criteria for this service.

	Codes/PA: For CPT codes 0404T/58674, add PA. No changes to other codes in the policy or their respective configuration.

Reimbursement

Effective 11/15/23

Inpatient Hospital Readmissions **RP54**	**Reimbursement Policy Interim Update** **Background & Recommendation:** • Readmission reviews paused as of 6/1/23 • Recommendation: revert to combine reimbursement methodology with improved pend ○ Combine methodology and updated policy criteria **Effective Date:** 11/15/2023. Notice given 9/15/2023. **Reimbursement Methodology:** For DRG facilities, inpatient stays will be combined into single payment based on DRG with highest relative weight. For all facility types, readmissions will continue to deny if clinical review determines readmission was due to procedural complication or not medically necessary. **Relevant Medicare Guidelines:** • Centers for Medicare & Medicaid Services (CMS) Processing Manual, Chapter 3- Inpatient Hospital Billing, 40.2.5 • Chapter 4, Section 4240 (Readmission Review) of the Medicare Quality Improvement Organization (QIO) Manual. **OHP:** These changes do not apply to OHP. The Prioritized List and the Oregon Administrative Rules will be followed.

Providence Health Plan

Providence Health Assurance

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

Pharmacy & Therapeutics (P&T) Committee

Oregon Region P&T Committee Meeting October 6, 2023
Go-Live Date: Monday, January 01, 2024, unless otherwise noted

Table of Contents:

Special Announcements

Medicare Calendar-Year Formulary 2024 Changes

Annually, Medicare Part D plans are required to submit a formulary to the Centers for Medicare & Medicaid Services (CMS) for the upcoming calendar year. As part of this annual review, the formulary is reviewed in its entirety and changes are made based on the safety, comparative efficacy, and cost-effectiveness of therapies.

As of October 1st 2023 the CMS approved Providence Health Assurance CY2024 Medicare formularies are available for review on the Providence Health Assurance website: https://www.providencehealthplan.com/medicare/medicare-advantage-plans/formulary-list-of-approved-drugs

- Patients and providers are encouraged to review the formularies for changes to their medications prior to the new year

A high-level summary of changes for CY2024 include:

- Prior Authorization will be added to GLP-1 Agents (such as Ozempic/Rybelsus®, Trulicity®)
    - Criteria includes diagnosis of Type 2 diabetes

        - CMS statutorily excludes the coverage of drug used solely for the purpose of weight management
    - Patients currently using these therapies without confirmed diagnosis of diabetes will be notified and will require prior authorization to confirm eligibility of treatment
- Preferring generic respiratory inhalers on Tier 2 (please note than brand-name versions will no longer be covered)
    - Budesonide/formoterol furoate (generic for Symbicort®)
    - Fluticasone propionate/salmeterol (generic for Advair Diskus®)
    - Fluticasone propionate (generic for Flovent HFA®)
- Tier 1 Expansion – Several drugs have been moved to Tier 1, which has a very low cost-share ($0 for most patients)

Table 1. Medications being added to Tier 1 (not all inclusive)

Cardiovascular agents		**Diabetes Agents**	**Glaucoma Agents**
Ezetimibe tablets	Hydralazine	Glipizide ER/XL	Timolol maleate
Telmisartan tablets	Isosorbide mononitrate	Glipizide/metformin	Brimonidine 0.2%
Verapamil tablets	Spironolactone tablets		Dorzolamide 2%
Pravastatin tablets	Amiodarone tablet		Dorzolamide/timolol
Behavioral Health		**Other**	
Lithium carbonate	Duloxetine capsules	Estradiol tablets	Letrozole tablets
Buspirone tablets	Lamotrigine tablets	Donepezil tablet	Fluticasone nasal spray
Paroxetine tablets		Anastrozole tablet	ibuprofen

- Examples of other drugs moved to lower tiers (lower cost-share)
    - Estradiol cream, patch, vaginal insert
    - Testosterone injection, gel
    - Candesartan
    - NSAIDs: naproxen, celecoxib, indomethacin,
    - Nurtec ODT®
- Examples of drugs being added to the formulary

  - Mounjaro® (requires prior authorization)
  - Xiidra®
  - Gemtesa®
  - Insulin glargine vial/pen
- Examples of drugs moved to higher tiers (higher cost-share)
  - Rhopressa®
  - Rocklatan®
  - Flovent Diskus®
  - Restasis®
  - Xtampza ER®
- Drugs Removed from Formulary, based on several reasons, including:
  - Preferred product changes (Onglyza®, Kombiglyze®)
  - A generic/biosimilar version has become available and was added to formulary in place of the brand/similar brands (Advair Diskus®, Symbicort®, Flovent HFA®)
  - Drugs that are considered a medical benefit, typically covered by Part B, and had no utilization under Part D in 2022
  - Drug is obsolete
  - Drug has safety concern or has been recalled from the market
  - More cost-effective alternatives or formulations available on the formulary (e.g., naproxen DR, metformin osmotic tablets)

CY2024 Part B Step Therapy:

Providence Health Assurance will continue to participate in the Centers for Medicare & Medicaid Services (CMS) Part B Step Therapy Program (ST) for CY2024.

- The ST program applies to drugs covered under the Part B benefit (outpatient healthcare administered medications)
- If a drug is part of the ST program, it requires a trial of a preferred drug to treat a medical condition before covering a non-preferred drug
  - Both preferred and non-preferred drugs may still be subject to prior authorization medical necessity criteria or quantity limits
- ST program requirements for preferred therapies will only be for members being initiated on therapy; patients established on the requested medication within the previous 365 days will not be subject to ST requirements
  - Prior authorization medical necessity criteria or quantity limits may still apply

Details of the Part B ST program are available on the Providence Health Assurance website at:
https://www.providencehealthplan.com/medicare/medicare-advantage-plans/formulary-list-of-approved-drugs

Smart RxAssist Copay Maximizer program

On January 1st, 2024, Providence Health Plan is expanding the program to all fully-insured Oregon non-HSA members. This program optimizes the use of manufacturer copay assistance on specialty medications.

- Captures the maximum benefit of manufacturer copay cards
- Reduces member copay responsibility to $0

As fully insured groups renew their PHP plans, the group will become eligible for the Smart Rx Assist program. For groups renewing 1/1/24, members who are on specialty medications that quality for manufacturer copay coupons will be mailed out letters on December 10th, 2024.

GLP-1/GIP changes for Commercial/Medicaid

On January 1st, 2024, GLP-1/GIP agents (such as Mounjaro®, Ozempic/Rybelsus®, and Trulicity®) will require prior authorization for patients newly starting on therapy. Criteria for coverage will require that patients have a diagnosis of type 2 diabetes and have need for therapy (such as inadequate response to metformin or insulin or comorbid conditions such as atherosclerotic cardiovascular disease).

New Drugs or Combinations:

1. **RFVIII FC-VWF-XTEN,BDD-EHTL (Altuviiio) Vial**
   a. **Indication**: Indicated for use in adults and children with hemophilia A for:
      - routine prophylaxis to reduce the frequency of bleeding episodes
      - on-demand treatment and control of bleeding episodes
      - perioperative management of bleeding
   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	-	-	-

* 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: Adynovate® (Factor VIII Long-Acting Recombinant, pegylated), Jivi® (Factor VIII Recombinant, PEGylated damactocog alfa pegol), Eloctate® (Factor VIII Recombinant Anti-hemophilic Factor Fc Fusion Protein), Esperoct® (Factor VIII Recombinant, glycopegylated), emicizumab (Hemlibra®)

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

PA PROGRAM NAME	Altuviiio
MEDICATION NAME	Antihemophilic factor (recombinant), Fc-VWF-XTEN fusion protein-ehtl
PA INDICATION INDICATOR	1 - All FDA-Approved Indications
EXCLUSION CRITERIA	Use for treatment of von Willebrand disease (VWD)

REQUIRED MEDICAL INFORMATION	For initial authorization:
	• Diagnosis of congenital FVIII deficiency (hemophilia A)
	• Use for one of the following indications:
	  • On-demand treatment and control of bleeding episodes
	  • Perioperative management of bleeding
	  • Routine prophylaxis to reduce the frequency of bleeding episodes
	• Documentation of patient weight
	• Appropriate dosing per FDA-approved or compendia-supported guidelines
	Reauthorization requires documentation of positive clinical response to therapy such as reduction in the number/severity of bleeds when use for routine prophylaxis

AGE RESTRICTIONS	N/A
PRESCRIBER RESTRICTIONS	Must be prescribed by or in consultation with a hematologist
COVERAGE DURATION	Initial authorization will be approved for six months Reauthorization will be approved until no longer eligible with the plan, subject to formulary and/or benefit changes.

2. **Nirsevimab-alip (Beyfortus) Syringe**
   - **a. Indication**: For the prevention of Respiratory Syncytial Virus (RSV) lower respiratory tract disease in:
     - Neonates and infants born during or entering their first RSV season.

- Children up to 24 months of age who remain vulnerable to severe RSV disease through their second RSV season

b. **Decision**:

	Commercial	Medicaid	Medicare
Formulary Status*	Medical	Medical	Part D: Non-formulary Part B: Medical
Tier**	ACA/Preventive	N/A	N/A
Affordable Care Act Eligible	Yes	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: Synagis®			

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

3. **Valoctocogene roxaparvovec-rvox (Roctavian) Vial**
   1. **Indication**: Indicated for the treatment of adults with severe hemophilia A (congenital factor VIII deficiency with factor VIII activity <1 IU/dL) without pre-existing antibodies to adeno-associated virus serotype 5 detected by an FDA-approved test
   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	No	N/A	N/A
Utilization Management Edits	Prior Authorization	Prior Authorization	Prior Authorization
Quantity Limit			
* Recommendations for placement may differ between lines of business due to regulatory requirements.			

** Medications will be placed on recommended tier above for the base formulary; tier placement for custom formulary(ies) will be based on designation above. For example, Commercial Tier 6 designation above means that the medication will be placed on the highest cost-sharing tier on the respective formulary(ies).
Formulary Alternatives: Hemlibra®, Adynovate®, Eloctate®, Esperoct®, Jivi®, Advate®, Afstyla®, Kovaltry®, NovoEight®, Nuwiq®, Xyntha®

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

PA PROGRAM NAME	~~Hemgenix®~~ Gene Therapy for Hemophilia
MEDICATION NAME	Hemgenix® Roctavian®
PA INDICATION INDICATOR	1 - All FDA-Approved Indications
OFF-LABEL USES	N/A
EXCLUSION CRITERIA	• Current or prior presence of Factor IX inhibitors (Hemgenix®) or Factor VIII inhibitors (Roctavian®) • HIV not controlled with antiviral therapy (CD4+ counts equal to 200/µL or by a viral load of greater than 200 copies/mL) • Active hepatitis B or C infection • Evidence of advanced liver fibrosis (Fibroscan score of 9 kPA or greater) • ALT, AST, total bilirubin, alkaline phosphatase, or creatinine greater than two times the upper limit of normal, unless evaluated by hepatology • Previous treatment with gene therapy for the same indication
REQUIRED MEDICAL INFORMATION	~~Hemgenix®~~Gene therapy may be approved when all the following criteria are met: 1. One of the following: a. For Hemgenix®: Diagnosis of severe or moderately severe hemophilia B, defined by Factor IX level less than 2 IU/dL or less than or equal to 2% of normal b. For Roctavian®: Diagnosis of severe hemophilia A, defined by Factor VIII level less than 1 IU/dL or less than or equal to 1% of normal 2. Patient is a biological male 3. One of the following: a. Patient is currently on a stable dose of ~~factor IX~~ prophylaxis therapy (has been receiving prophylaxis for 2 months of more) with greater than 150 exposure days of ~~factor IX~~ prophylaxis b. Current or historical life-threatening hemorrhage c. Documentation of repeated, serious spontaneous bleeding episodes 4. Patient is negative for Factor inhibitors, defined by a Factor inhibitor level assay less than 0.6 Bethesda units (BU) per mL. If initial test is positive, documentation of a subsequent negative test within 1-4 weeks will be allowed.

	5. Roctavian®: Patient is negative for pre-existing immunity to the AAV5 capsid as measured by AAV5 transduction inhibition or AAV5 total antibodies ~~Hemgenix®~~Gene therapy will be administered by or in consultation with a Hemophilia Treatment Center (HTC)
AGE RESTRICTIONS	May be approved for patients aged 18 years and older
PRESCRIBER RESTRICTIONS	Must be prescribed by, or in consultation with, an optometrist or ophthalmologist
COVERAGE DURATION	Initial authorization and reauthorization will be approved 3 months

4. **Vilobelimab (Gohibic [EUA]) Vial**
   a. **Indication**: For the use of vilobelimab for the treatment of COVID-19 in hospitalized adults when initiated within 48 hours of receiving invasive mechanical ventilation (IMV), or extracorporeal membrane oxygenation (ECMO). However, vilobelimab is not FDA-approved for this use.
   b. **Decision**: N/A - informational
   c. **Prior Authorization Criteria for Commercial/Medicaid/Medicare Part B/Medicare Part D**: N/A

5. **Quizartinib dihydrochloride (Vanflyta) Tablet**
   a. **Indication**: In combination with standard cytarabine and anthracycline induction and cytarabine consolidation, and as maintenance monotherapy following consolidation chemotherapy, for the treatment of adult patients with newly diagnosed acute myeloid leukemia (AML) that is FLT3 internal tandem duplication (ITD)-positive as detected by an FDA-approved test.
   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	No	N/A	N/A
Utilization Management Edits	Prior Authorization	Prior Authorization	Prior Authorization
Quantity Limit			

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

Formulary Alternatives: Midostaurin (Rydapt)

c. **Prior Authorization Criteria for Commercial/Medicaid**: Added to "Oral Anti-Cancer Medications" policy
d. **Prior Authorization Criteria for Medicare Part D**: Added to "Anti-Cancer Medications" policy

6. **Glofitamab-gxbm (Columvi) Vial** reviewed by Jessica Niculcea, PharmD.
   a. **Indication**: For the treatment of adult patients with relapsed or refractory diffuse large B-cell lymphoma, not otherwise specified (DLBCL, NOS) or large B-cell lymphoma (LBCL) arising from follicular lymphoma, 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. **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: Kymriah®, Yescarta®, Breyanzi®, Zynlonta®, Xpovio®, Epkinly®			

   c. **Prior Authorization Criteria for Commercial/Medicaid/Medicare Part B**: Added to "Injectable Anti-cancer Medications" policy

7. **Somapacitan-beco (Sogroya) Pen Injctr**
   a. **Indication**: For the replacement of endogenous growth hormone in pediatric patients aged 2.5 and older and adults with growth hormone deficiency.

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: Genotropin®, Norditropin®, Omnitrope®			

c. **Prior Authorization Criteria for Commercial/Medicaid**: Sogroya® will be added to the existing Human Growth Hormones policies for Commercial and Medicaid as a non-preferred agent. No changes to the existing criteria.

8. **Pegunigalsidase alfa-iwxj (Elfabrio) Vial**
   a. **Indication**: For the treatment of adults with confirmed Fabry disease.
   b. **Decision**:

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

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

c. **Prior Authorization Criteria for Commercial/Medicaid/Medicare Part B**: Added to "Enzyme Replacement Therapy" policy with addition of exclusion criteria for all agents on the policy: Concurrent use with another enzyme replacement therapy for treatment of the same indication.

9. **Fezolinetant (Veozah) Tablet**
   a. **Indication**: For the treatment of moderate to severe vasomotor symptoms due to menopause.
   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	One tablet per day	One tablet 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: Premarin®, estradiol, Vivele-dot®, Combipatch®, SSRIs, SNRIs			

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

10. **Lotilaner (Xdemvy) Ophthalmic Drops**
   a. **Indication**: For treatment of adult patients with Demodex blepharitis.
   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	-	-	-
* 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	Lotilaner (Xdemvy®)
MEDICATION NAME	Xdemvy 0.25% ophthalmic drop
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 criteria must be met: 1. Confirmed diagnosis of Demodex blepharitis, defined as presence of Demodex mites or presence of collarettes after one month trial of conventional therapy (such as eyelid scrubs, warm compresses) For reauthorization, the following must be met: Documentation of positive response to therapy (such as improvement of collarette, reduction of mites)
AGE RESTRICTIONS	May be approved for patients aged 18 years and older
PRESCRIBER RESTRICTIONS	Must be prescribed by, or in consultation with, an optometrist or ophthalmologist
COVERAGE DURATION	Initial authorization and reauthorization will be approved 3 months

11. **Sotagliflozin (Inpefa) Tablet**

a. **Indication**: To reduce the risk of cardiovascular death, hospitalization for heart failure, and urgent heart failure visit in adults with: heart failure or type 2 diabetes mellitus, chronic kidney disease, and other cardiovascular risk factors

b. **Decision**:

	Commercial	Medicaid	Medicare
Formulary Status*	Non-formulary	Formulary	Part D: Non-formulary Part B: N/A
Tier**	N/A	N/A	N/A
Affordable Care Act Eligible	No	N/A	N/A
Utilization Management Edits	N/A	Prior Authorization	N/A
Quantity Limit	60 tablets per 30 days	60 tablets per 30 days	
* Recommendations for placement may differ between lines of business due to regulatory requirements. ** Medications will be placed on recommended tier above for the base formulary; tier placement for custom formulary(ies) will be based on designation above. For example, Commercial Tier 6 designation above means that the medication will be placed on the highest cost-sharing tier on the respective formulary(ies).			
Formulary Alternatives: Farxiga®, Jardiance®, Invokana®			

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

PA PROGRAM NAME	SGLT-2 Inhibitors
MEDICATION NAME	Sotagliflozin (Inpefa®)
PA INDICATION INDICATOR	1 - All FDA-Approved Indications
OFF-LABEL USES	N/A
EXCLUSION CRITERIA	N/A
REQUIRED MEDICAL INFORMATION	Empagliflozin (Jardiance/Synjardy/Synjardy XR®), canagliflozin (Invokana/Invokamet®), dapagliflozin (Farxiga/Xigduo XR®), and sotagliflozin (Inpefa®) may be covered if the following criteria are met: 1. One of the following: a. History of paid claim for metformin b. For type 2 diabetes, documentation of trial, intolerance, or contraindication to metformin c. For patient without type 2 diabetes, documentation of FDA-labeled indication for use for the requested medication

	2. Documentation of estimated glomerular filtration rate (eGFR), measured within the last 12 months, showing the product is not contraindicated
AGE RESTRICTIONS	N/A
PRESCRIBER RESTRICTIONS	N/A
COVERAGE DURATION	Authorization will be approved until no longer eligible with the plan, subject to formulary and/or benefit changes

12. **Rozanolixizumab-noli (Rystiggo) Vial**

a. **Indication**: For the treatment of generalized myasthenia gravis (gMG) in adult patients who are anti-acetylcholine receptor (AChR) or anti-muscle-specific tyrosine kinase (MuSK) antibody positive.

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: pyridostigmine, prednisone, azathioprine, mycophenolate, cyclosporine			

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

PA PROGRAM NAME	~~Vyvgart~~ FcRn antagonists
MEDICATION NAME	Vyvgart Vyvgart Hytrulo Rystiggo
PA INDICATION INDICATOR	1 - All FDA-Approved Indications

OFF-LABEL USES	None
EXCLUSION CRITERIA	N/A
REQUIRED MEDICAL INFORMATION	For Generalized Myasthenia Gravis (gMG), all the following must be met (1-5): 1. Anti-acetylcholine receptor (anti-AChR) antibody positive OR anti-muscle-specific tyrosine kinase (MuSK) (Rystiggo® only) 2. One of the following: a. For Vyvgart®: • Myasthenia Gravis Foundation of America (MGFA) Clinical Classification Class II to IV • Myasthenia Gravis - Activities of Daily Living (MG-ADL) total score of five or greater b. For Rystiggo®: • Myasthenia Gravis Foundation of America (MGFA) Clinical Classification Class II to IVa • Myasthenia Gravis - Activities of Daily Living (MG-ADL) total score of three or greater (with 3 or greater points from non-ocular symptoms) 3. Failure with treatment of one of the following over the course of at least 12 months, unless intolerance or contraindication to all therapies: a. At least TWO immunosuppressive agents (such as azathioprine, methotrexate, cyclosporine, mycophenolate, corticosteroids, tacrolimus, cyclophosphamide, or rituximab) OR b. ONE immunosuppressive therapy and required at least four infusions/year of either intravenous immunoglobulin (IVIG), or plasmapheresis/plasma exchange (PLEX) ~~History of failure of at least two immunosuppressive agents over the course of at least 12 months (such as azathioprine, methotrexate, cyclosporine, mycophenolate, corticosteroids) or has an intolerance or contraindication to these therapies~~ 4. Dose and frequency are in accordance with FDA-approved labeling Reauthorization for Generalized Myasthenia Gravis (gMG), all the following must be met (1-2): 1. Documentation of improvement in MG-ADL by at least two points from baseline 2. Dose and frequency are in accordance with FDA-approved labeling
AGE RESTRICTIONS	May be approved for patients aged 18 years and older
PRESCRIBER RESTRICTIONS	Must be prescribed by, or in consultation with, a neurologist or rheumatologist
COVERAGE DURATION	Initial authorization will be approved for six months. Reauthorization will be approved for one year.

13. **Nirmatrelvir-ritonavir (Paxlovid [EUA]) Tab DS PK**

a. **Indication**: Used to treat mild-to-moderate coronavirus disease 2019 (COVID-19) in adults who are at high risk for progression to severe COVID-19, including hospitalization or death.
   - Paxlovid® is not approved for use as pre-exposure or post-exposure treatment for prevention of COVID-19.
   - The FDA has issued an EUA for the treatment of mild-to-moderate COVID-19 in children (12 years of age and older weighing at least 88 pounds [40 kg]) who are at high risk for progression to severe COVID-19, including hospitalization or death.

b. **Decision**:

	Commercial	Medicaid	Medicare
Formulary Status*	Formulary	Formulary	Part D: Formulary Part B: N/A
Tier**	Tier 4	N/A	Non-preferred Drug
Affordable Care Act Eligible	No	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			

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

Other Changes - All changes were approved as outlined below.

New Indications:

Therapies with Prior Authorization Policies (Non-oncology)

1. **Abrilada** (Adalimumab-AFZB)
   a. Previous Indication(s):
      a. Rheumatoid Arthritis
      b. Juvenile Idiopathic Arthritis

   c. Psoriatic Arthritis
   d. Ankylosing Spondylitis
   e. Crohn's Disease
   f. Ulcerative Colitis
   g. Plaque Psoriasis
b. New indication approved 06/14/2023:
   a. Hidradenitis Suppurativa
c. **RECOMMENDATION:** Inform prescribers via Medical Policy Alert. Update policy with new indication.

2. **Hadlima** (Adalimumab-BWWD)
   a. Previous Indication(s):
      a. Rheumatoid Arthritis
      b. Juvenile Idiopathic Arthritis
      c. Psoriatic Arthritis
      d. Ankylosing Spondylitis
      e. Crohn's Disease
      f. Ulcerative Colitis
      g. Plaque Psoriasis
   b. New indication approved 06/26/23; 07/11/2023 respectively:
      a. Hidradenitis Suppurativa
      b. Uveitis
   c. **RECOMMENDATION:** Inform prescribers via Medical Policy Alert. Update policy with new indication.

3. **Amjevita** (Adalimumab-ATTO))
   a. Previous Indication(s):
      a. Rheumatoid Arthritis
      b. Juvenile Idiopathic Arthritis
      c. Psoriatic Arthritis
      d. Ankylosing Spondylitis
      e. Crohn's Disease
      f. Ulcerative Colitis

   g. Plaque Psoriasis
   h. Hidradenitis Suppurativa
b. New indication approved 07/12/2023:
   a. Uveitis
c. **RECOMMENDATION:** Inform prescribers via Medical Policy Alert. Update policy with new indication.

4. **Cyltezo** (Adalimumab-ADBM)
   a. Previous Indication(s):
      a. Rheumatoid Arthritis
      b. Juvenile Idiopathic Arthritis
      c. Psoriatic Arthritis
      d. Ankylosing Spondylitis
      e. Crohn's Disease
      f. Ulcerative Colitis
      g. Plaque Psoriasis
   b. New indication approved 06/30/2023:
      a. Uveitis
   c. **RECOMMENDATION:** Inform prescribers via Medical Policy Alert. Update policy with new indication.

5. **Prevymis** (Letermovir)
   a. Previous Indication(s):
      i. Prophylaxis of cytomegalovirus (CMV) infection and disease in adult CMV seropositive recipients [R+] of an allogeneic hematopoietic stem cell transplant (HSCT)
   b. New indication approved 06/05/2023:
      a. Prophylaxis of cytomegalovirus (CMV) disease in adult kidney transplant recipients at high risk (Donor CMV seropositive/Recipient CMV seronegative [D+/R-])
   c. **RECOMMENDATION:** Inform prescribers via Medical Policy Alert. Update policy with new indication and add new criteria.

Prior Authorization Criteria for **Commercial**:

PA PROGRAM NAME	Prevymis

MEDICATION NAME	Prevymis
PA INDICATION INDICATOR	1 - All FDA-Approved Indications
REQUIRED MEDICAL INFORMATION	1. All the following must be met for the prevention of cytomegalovirus (CMV) infection and disease: a. Member is within 100 days post hematopoietic stem cell transplant (HSCT) transplant or 200 days post kidney transplant b. CMV Recipient positive c. If IV letermovir is being requested, rationale for not using oral formulation must be provided (such as patient is unable to swallow)

Prior Authorization Criteria for **Medicare Part B**:

PA PROGRAM NAME	Prevymis – Medicare Part B
MEDICATION NAME	Prevymis
PA INDICATION INDICATOR	1 - All FDA-Approved Indications
REQUIRED MEDICAL INFORMATION	1. All the following must be met for the prevention of cytomegalovirus (CMV) infection and disease: a. Member is within 100 days post hematopoietic stem cell transplant (HSCT) transplant or 200 days post kidney transplant b. CMV Recipient positive c. If IV letermovir is being requested, rationale for not using oral formulation must be provided (such as patient is unable to swallow) 2. For member established on therapy (within the previous year): Documentation of response to therapy and member is within 100 days post hematopoietic stem cell transplant (HSCT) transplant or 200 days post kidney transplant

6. **Linzess** (Linaclotide)
    a. Previous Indication(s):
        a. Irritable bowel syndrome with constipation (IBS-C)
        b. Chronic idiopathic constipation (CIC)
    b. New indication approved 06/12/2023:
        a. Functional constipation (FC) in pediatric patients 6 to 17 years of age
    c. **RECOMMENDATION:** Inform prescribers via Medical Policy Alert. Update policy with new indication and add new criteria.

Prior Authorization Criteria for **Commercial**:

PA PROGRAM NAME	Constipation Agents
MEDICATION NAME	Linzess
PA INDICATION INDICATOR	1 - All FDA-Approved Indications

REQUIRED MEDICAL INFORMATION	For patients not established on the requested product must meet ALL the following indication-specific criteria: i. **For chronic idiopathic constipation (CIC)** or **Functional constipation (FC)**: a. Documentation of two or more of the following occurring over the last three months: 1) Fewer than three spontaneous bowel movements per week 2) Straining during defecations 3) Lumpy or hard stools (Bristol Stool Form Scale 1-2) 4) Sensation of incomplete evacuation 5) Sensation of anorectal obstruction/blockage 6) Manual maneuvers to facilitate defecations (e.g., digital evacuation, support of the pelvic floor) b. Screen for constipation-inducing medications and medical rationale provided for continuing these medications, if applicable c. Inadequate response or contraindication to a reasonable trial (at least two weeks treatment) to ALL the following: 1) Regular use of dietary fiber supplementation (e.g., cereal, citrus, fruits or legumes) or use of bulking agents (e.g., psyllium or methylcellulose taken with adequate fluids) 2) A stimulant laxative (e.g., senna, bisacodyl) 3) Routine laxative therapy, with a different mechanism of action than the laxative(s) listed above (e.g., lactulose, Miralax®) 4) For CIC only: Lubiprostone (Amitiza®)
COVERAGE DURATION	For CIC, FC or IBS: Authorization will be approved until no longer eligible with the plan, subject to formulary or benefit changes

7. **Bylvay** (Odevixibat)
   a. Previous Indication(s):
      a. Treatment of pruritus in patients 3 months of age and older with progressive familial intrahepatic cholestasis (PFIC)
   b. New indication approved 06/13/2023:
      a. Treatment of cholestatic pruritus in patients 12 months of age and older with alagille syndrome (ALGS)
   c. **RECOMMENDATION:** Inform prescribers via Medical Policy Alert. Update policy with new indication.

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

PA PROGRAM NAME	Cholestatic Pruritus Agents
MEDICATION NAME	Bylvay
PA INDICATION INDICATOR	1 - All FDA-Approved Indications
EXCLUSION CRITERIA	1. History of liver transplant 2. Decompensated cirrhosis 3. History of surgical interruption of enterohepatic circulation, such as partial external biliary diversion surgery (For Livmarli® only)

	4. Molecular genetic testing indicates PFIC type 2 with ABCB11 variants encoding for nonfunction or absence of BSEP-2, protein (For Bylvay® only)
REQUIRED MEDICAL INFORMATION	For initial authorization, all the following criteria must be met: 1. Documentation of moderate-to-severe pruritus AND 2. Documentation that drug-induced pruritis has been ruled out 3. Documentation of trial and failure, contraindication, or intolerance to ALL of the following systemic medications for pruritis associated with cholestasis: a. Ursodiol b. Cholestyramine c. Rifampin 4. Indication-specific criteria, as outlined below: a. For cholestatic pruritus in patients with confirmed diagnosis of Alagille syndrome (ALGS), the following criteria must be met: 1) Bylvay®: Individual has a serum bile acid concentration above the upper limit of the normal reference range for the reporting laboratory

8. **Jardiance** (Empagliflozin); **Synjardy, Synjardy XR** (Empagliflozin; Metformin hydrochloride)
    a. Previous Indication(s):
        a. To reduce the risk of cardiovascular death and hospitalization for heart failure in adults with heart failure.
        b. To reduce the risk of cardiovascular death in adults with type 2 diabetes mellitus and established cardiovascular disease.
        c. As an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus.
    b. New indication approved 06/20/2023:
        a. As an adjunct to diet and exercise to improve glycemic control in adults and **pediatric patients aged 10 years and older** with type 2 diabetes mellitus.
    c. **RECOMMENDATION:** Inform prescribers via Medical Policy Alert. Update policy with new indication.

<u>Therapies with Prior Authorization Policies (Oncology)</u>

1. **Talzenna** (Talazoparib tosylate)
    a. New indication(s) approved 06/20/2023:
        i. In combination with enzalutamide for the treatment of adult patients with homologous recombination repair (HRR) gene-mutated metastatic castration-resistant prostate cancer (mCRPC)
    b. **RECOMMENDATION:** Inform prescribers via Medical Policy Alert. Prior authorization policy coverage criteria are based on recommendations from the National Comprehensive Cancer Network (NCCN); no updates to the policy are warranted.
2. **Jemperli** (Dostarlimab-GXLY)
    a. New indication(s) approved 07/31/2023:

i. Endometrial cancer
- In combination with carboplatin and paclitaxel, followed by JEMPERLI as a single agent, is indicated for the treatment of adult patients with primary advanced or recurrent endometrial cancer (EC) that is mismatch repair deficient (dMMR).
- As a single agent, is indicated for the treatment of adult patients with dMMR recurrent or advanced endometrial cancer, as determined by an FDA-approved test, that has progressed on or following prior treatment with a platinum-containing regimen in any setting and are not candidates for curative surgery or radiation.

ii. Mismatch Repair Deficient Recurrent or Advanced Solid Tumors
- As a single agent, is indicated for the treatment of adult patients with dMMR recurrent or advanced solid tumors, as determined by an FDA-approved test, that have progressed on or following prior treatment and who have no satisfactory alternative treatment options.

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.

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

1. **Spy Agent Green Kit (Indocyanine Green)**
   a. Previous Indication(s):
      i. Visualization of vessels (micro- and macro-vasaculature), blood flow and tissue perfusion before, during and after vascular, gastrointestinal, organ transplant, plastic, micro- and reconstructive surgeries, including general minimally invasive surgical procedures, in adults and pediatric patients aged 1 month and older.
      ii. Visualization of extrahepatic biliary ducts in adults and pediatric patients aged 12 to 17 years.
      iii. Visualization of lymph nodes and lymphatic vessels during lymphatic mapping in adults with cervical and uterine cancer.
   b. New indication(s) approved 06/05/2023:
      i. Visualization of extrahepatic biliary ducts in adults and pediatric patients aged **12 years and older.**
      ii. Visualization of lymph nodes and lymphatic vessels during lymphatic mapping in adults with breast cancer.
   c. **RECOMMENDATION:** Inform prescribers via Medical Policy Alert.

2. **Triumeq, Triumeq PD** (Abacavir sulfate; Dolutegravir sodium; Lamivudine)
   a. Previous Indication(s):
      i. Treatment of HIV-1 infection in adults and in pediatric patients weighing at least 10 kg

   b. New indication approved 06/15/2023:
      i. Treatment of HIV-1 infection in adults and in pediatric patients **aged at least 3 months and weighing at least 6 kg**
   c. **RECOMMENDATION:** Inform prescribers via Medical Policy Alert.
3. **Liletta** (Levonorgestrel)
   a. Previous Indication(s):
      i. Prevention of pregnancy for up to 8 years
   b. New indication approved 06/29/2023:
      i. Treatment of heavy menstrual bleeding for up to 5 years in patients who choose to use intrauterine contraception as their method of contraception; replace after the end of the fifth year if continued treatment of heavy menstrual bleeding is needed
   c. **RECOMMENDATION:** Inform prescribers via Medical Policy Alert.

Therapies with Indication(s) Removed

1. **Eligard Kit** (Leuprolide acetate)
   a. Indication(s) removed 07/20/2023:
      i. For the **"palliative"** treatment of advanced prostate cancer
   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.

Drug Safety Monitoring:

The following information is gathered from the United States Food and Drug Administration (FDA) database from **6/1/2023–7/31/2023**

FDA Drug Safety Communications

There were no drug safety communications reported during this period.

Drug Recalls/Market Withdrawals

1. **Drug Name:** Dronabinol
   - **Date of Recall:** 06/14/2023
   - **Reason for recall:** Packaging may contain incorrect product due to labeling mix-up

- **Link to more information:** https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/harvard-drug-group-llc-issues-voluntary-nationwide-recall-dronabinol-capsules-usp-25-mg-and
- **Health Plan Recommendation:** Notify providers via Medical Policy Alert

2. **Drug Name:** Albuterol Sulfate Inhalation Aerosol
   - **Date of Recall:** 07/07/2023
   - **Reason for recall:** Failure to deliver the recommended dose
   - **Link to more information:** https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/cipla-issues-voluntary-nationwide-recall-six-batches-albuterol-sulfate-inhalation-aerosol-90-mcg-200
   - **Health Plan Recommendation:** Notify providers via Medical Policy Alert

3. **Drug Name:** Tydemy oral contraceptive
   - **Date of Recall:** 07/31/2023
   - **Reason for recall:** Out of Specification Results
   - **Link to more information:** https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/lupin-pharmaceuticals-inc-issues-voluntary-nationwide-recall-2-lots-tydemytm-drospirenone-ethinyl
   - **Health Plan Recommendation:** Notify providers via Medical Policy Alert

Other Formulary Changes:

OTHER FORMULARY CHANGES		
Drug Name	**Action Taken**	**Policy Name**
Clindamycin phos/benzoyl perox 1.2%-2.5% gel w/pump	Add to formularies: • Commercial: Formulary, Tier 2 • Medicaid: Formulary, Prior Authorization	Medicaid: Acne Medications
Penicillamine 250 mg capsule	Add to Commercial formulary, Tier 5	N/A
Enspryng (satralizumab-mwge) syringe	Add to Medicaid formulary with Prior Authorization	Enspryng
Gelclair (potassium sorbate/ hydroxyethylcellulose/ povidone/ hyaluronic) oral gel packets	Add to formularies: • Commercial: Formulary, Tier 4, Quantity limit (3 packets per day) • Medicaid: Formulary, Quantity limit (3 packets per day)	N/A

Sympazan (clobazam) film	Remove from formulary for Commercial and Medicaid	New Medications and Formulations without Established Benefit
Advair Diskus (fluticasone propionate/salmeterol xinafoate) inhaler	Remove Brand from Commercial formulary. Add generic to Commercial formulary, Tier 2	N/A
Symbicort (budesonide/formoterol fumarate) inhaler	Remove Brand from Commercial formulary. Add generic to Commercial formulary, Tier 2	N/A
Flovent HFA (fluticasone propionate)	Remove Brand from Commercial formulary. Add generic to Commercial formulary, Tier 2	N/A
Flovent Diskus (fluticasone propionate)	Remove from Commercial formulary	N/A
Alvesco	Remove from Commercial formulary	N/A
Clenpiq (sodium picosulfate/ magnesium oxide/ citric acid) solution	Bowel prep agent to be covered as ACA for patients 45 years of age and older	N/A
Peg 3350/ sodium sulfate/ sod chloride/ KCl/ ascorbate sod/ vit C powder packet (generic for Moviprep)	Bowel prep agent to be covered as ACA for patients 45 years of age and older	N/A
Plenvu (Peg 3350/ sodium sulfate/ sod chloride/ KCl/ ascorbate sod/ vit C) powder packet	Bowel prep agent to be covered as ACA for patients 45 years of age and older	N/A
sodium sulfate/ potassium sulfate/ magnesium sulfate prep kit (generic for Suprep)	Bowel prep agent to be covered as ACA for patients 45 years of age and older	N/A
Sutab (sodium sulfate/ potassium sulfate/ magnesium sulfate) tablet	Bowel prep agent to be covered as ACA for patients 45 years of age and older	N/A
Tezspire (tezepelumab-ekko) syringe and pen injector	Add to Commercial formulary, Tier 5 with Prior Authorization	Tezspire
Victoza (liraglutide) pen injector	Remove from Commercial formulary (non-preferred GLP-1 inhibitor)	GIP/GLP-1 Receptor Agonists
Desvenlafaxine succinate 100 mg tablet ER	Commercial: change quantity limit from one per day to four per day	N/A
Buprenorphine HCl/naloxone HCl (Suboxone) 8/2 mg film	All lines of business: change quantity limit from three per day to four per day	N/A
Hadlima (adalimumab-bwwd)	New biosimilar • Commercial: Formulary, Tier 5, Prior Authorization, Quantity Limit (2 injections per 28 days) • Medicaid: Non-Formulary, Prior Authorization, Quantity Limit (2 injections per 28 days) • Medicare Part D: Formulary, Tier 5, Prior Authorization	Therapeutic Immunomodulators
• **Hymrioz citrate free (adalimumab-adaz)**	New biosimilar	Therapeutic Immunomodulators

• **Yuflyma citrate free (adalimumab-aaty)**	Commercial/Medicaid: Non-Formulary, Prior Authorization, Quantity Limit (2 injections per 28 days)	

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**
Olipudase alfa-rpcp (Xenpozyme) Vial	New strength (4mg). Line extend with Xenpozyme 20mg vial; • Commercial/Medicaid: Medical Benefit, Prior Authorization, Specialty • Medicare Part D: Non-Formulary • Medicare Part B: Medical Benefit, Prior Authorization	• Commercial/Medicaid: Enzyme Replacement Therapy • Medicare Part B: Enzyme Replacement Therapy Prior Authorization and Step Therapy Policy
Abrysvo **Arexvy**	RSV Vaccines; Covered in full for all patients aged 60 and above	N/A
Austedo XR (deutetrabenazine) titration pack	New to market brand: New strength (6-12-24mg). Line extend with Austedo XR; • Commercial: Formulary, Tier 6, Prior Authorization, Quantity Limit (1 claim/365 days) • Medicaid: Formulary, Prior Authorization, Quantity Limit (1 claim/365 days) • Medicare Part D: Formulary, Tier 5, Prior Authorization	VMAT-2 Inhibitors
Cosentyx (secukinumab) 300 mg/2mL pen injector	New strength (300mg pen). Line extend with Cosentyx; • Commercial: Formulary, Tier 5, Prior Authorization, Quantity Limit (2 injections per 28 days) • Medicaid: Formulary, Prior Authorization, Quantity Limit (2 injections per 28 days) • Medicare Part D: Formulary, Tier 5, Prior Authorization	Therapeutic Immunomodulators

NEW GENERICS		
Drug Name	**Action Taken**	**Policy Name**
Plerixafor Vial	First generic drug (Mozobil). Line extend as medical; • Medical benefit for all lines of business	• N/A
• **Saxagliptin hcl Tablet** • **Saxagliptin hcl/metformin hcl (Saxagliptin-Metformin ER) TBMP 24HR**	First generic drug (Onglyza). Line extend as generic; • Commercial Standard: Formulary, Tier 2, Prior Authorization • Commercial Dynamic: Formulary, Tier 4, Prior Authorization • Medicaid: Formulary, Prior Authorization • Medicare Part D: Formulary, Tier 4, Prior Authorization	• DPP-4 Inhibitors

Clinical Policy Changes:

MAJOR CHANGES	
Policy Name	**Summary of Change**
Brand Over Generic	Added Esbriet tablets, Letairis, Tracleer tablets, Syprine
Compounded Drugs	Clarified that over-the-counter (OTC) medications are excluded from coverage according to the respective benefit. Added drugs to the Appendix to reflect updated 503A and 503B bulk lists from the FDA.
Continuous Glucose Monitors for Personal Use - Medicare Part B	Updated age restriction criteria and removed Freestyle Libre 3 exclusion criteria to align with CMS guidance.
Continuous Glucose Monitors for Personal Use	Updated age restriction criteria.
Enspryng	Remove ophthalmologist from prescriber restrictions and removed requirement to rule out alternate diagnoses (reduce operational burden and better align with market). Added drug to formulary for Medicaid to align with Oregon Health Authority Preferred Drug List.
Hemgenix	Criteria added to define testing and Factor IX inhibitor requirements. Will be adding Roctavian® to policy; updated name to Gene Therapy for Hemophilia.
• **Interleukin -1 Inhibitors - Medicare Part B** • **Interleukin -1 Inhibitors**	Update coverage duration for initial authorization to 12 months.
Long-Acting Stimulant Medications Quantity Limit	Medicaid changes made to align with Oregon Health Authority criteria: 1. patients on doses higher than the max FDA approved dose were either initiated on a lower dose and titrated up or regimen was developed in consultation with a mental health specialist, 2. remove exclusion for only once or twice daily dosing. No changes to Commercial requirements.

Lupkynis	Removed requirement for systemic lupus erythematosus confirmation as redundant (histologic diagnosis of lupus nephritis is sufficient). Removed exclusion criteria of kidney transplant and estimated Glomerular Filtration Rate (eGFR) of at least 45 as not true contraindications to therapy; Specified that combination therapy must be with mycophenolate and corticosteroid to align with package insert and inclusion criteria for clinical trials.
Medically Infused Therapeutic Immunomodulators (TIMS) – Commercial/Medicare Part B	Updated medical necessity criteria for immune checkpoint inhibitors to align with National Comprehensive Cancer Network guidelines and added medical necessity criteria for coverage of sarcoidosis.
New Medications and Formulations without Established Benefit	Removed Acanya® (clindamycin/benzoyl peroxide 1.2%/2.5% gel) and Cuprimine® (penicillamine capsules) due to generic availability and similar costs as formulary agents. Reduced quantity limit on Kadian® (morphine sulfate ER capsules) to two per day in alignment with package insert. Removed obsolete drugs.
Oral Rinses	Added Gelclair® product to formulary with quantity limitation and requiring step through this for other products for mucositis
Saphnelo	Minor update to diagnostic criteria to remove duplicative prescriber restrictions.
Sylvant	Updated criteria to align with National Comprehensive Cancer Network (NCCN) guideline support beyond FDA indication.
Therapeutic Immunomodulators (TIMS) - Comm	Updated conventional therapy requirement options to align with clinical guidelines. Added prescriber restrictions for atopic dermatitis and clarified preferred products based on new indications approved by the FDA.
Therapeutic Immunomodulators (TIMS) - Medicaid	Removed conventional therapy requirement for inflammatory bowel disease and updated those for plaque psoriasis. Updated medical necessity criteria for immune checkpoint inhibitors to align with National Comprehensive Cancer Network guidelines and added medical necessity criteria for coverage of sarcoidosis.
Transthyretin (TTR) Lowering Agents	Criteria regarding symptoms of polyneuropathy of hATTR amyloidosis simplified for ease of review. Cardiologist added to prescriber restrictions to align with Oregon Health Authority.
Trientine	Removed brand-name Syprine® from commercial formulary and added to brand over generic policy. For coverage of brand-name Syprine®, requires documentation that patient will be using generic trientine. Updated coverage duration for reauthorization to until no longer eligible with the plan. Updated to requires prescriber restrictions only for initial authorization.
Uplizna - Medicare Part B	Removed ophthalmologist from prescriber restrictions and removed requirement to rule out alternate diagnoses (reduce operational burden and better align with market).
Uplizna	Removed ophthalmologist from prescriber restrictions and removed requirement to rule out alternate diagnoses (reduce operational burden and better align with market). Added drug to formulary for Medicaid to align with Oregon Health Authority Preferred Drug List.
Vyvgart - Medicare Part B	Added several agents as options for prerequisite therapy (such as tacrolimus, rituximab, and cyclophosphamide immunoglobulin, and plasmapheresis) based on guideline recommendations.
Vyvgart	Updated name to FcRn antagonists; will be adding new therapeutic agents to this policy as they become available

RETIRED	
Lucemyra Step Therapy Policy	Policy was retired due to low utilization