Providence Health Plan

Providence Health Assurance

Healthcare Services Medical & Pharmacy Policy Alerts

Number 90

January 1, 2024

This is the January 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 2/1/2024

Osteochondral Allografts and Autografts for Cartilaginous Defects **MP149**	**Policy Updates:** Updated graft sizes for alignment with other payors and available evidence. • Allograft: updated from "size defect of 2cm^2 or greater" to "size defect of 1cm^2 or greater" (Criterion I.D.1) • Autograft updated from "size defect 1-2.5cm^2" to "size defect 1-3 cm^2". (Criterion III.F.) **Codes/PA:** No coding changes- these codes PA. **OHP:** These changes do not apply to OHP. The Prioritized List and the Oregon Administrative Rules will be followed.

Effective 3/1/2024

Myoelectric Upper Limb Prosthesis **MP26**	**Policy Updates:** Change denial type from "investigational" to "not medically necessary." **Codes/PA:** • Add L9900 to coding table – not separately reimbursable. • Change L6026 configuration to "not medically necessary." **OHP:** These changes do not apply to OHP. The Prioritized List and the Oregon Administrative Rules will be followed.
Stem Cell Therapy for Orthopedic Applications **MP36**	**Policy Updates:** Change denial type from "investigational" to "not medically necessary." **Codes/PA:** • Add 0627T-0630T to coding table. • Change all codes' denial type "investigational" to "not medically necessary." **OHP:** These changes do not apply to OHP. The Prioritized List and the Oregon Administrative Rules will be followed.
Varicose Veins **MP182**	**Policy Updates:** Make the following changes to criteria: • Updated credentialing requirements for duplex scanning credentialing. • Update verbiage in VIII.C. • Add posterior accessory saphenous vein (PASV) and anterior accessory saphenous vein (AASV) to list of eligible veins for endovenous ablation (criteria VI.I-IX.) • Change session limits (criterion XIX.) to 3 allowed total sessions of treatment per leg per 12-month period when criteria are met. • Liberalize timeline for repeat venous studies following endovenous ablation to 3 weeks (previously 1 week) (note, criterion XXII.) **Codes/PA:** No changes to codes/PA. **OHP:** These changes do not apply to OHP. The Prioritized List and the Oregon Administrative Rules will be followed.
Spinal Epidural Steroid Injections **MP14**	**Policy Updates:** • Require that neurologic exam be conducted in person. The option for a telehealth exam was implemented during the COVID-19 PHE and is no longer appropriate. • Conservative care criteria in "Policy Guidelines" edited to match "Policy Criteria." ▪ Policy guidelines previously stated that care had to be within past year and via specific medications ▪ Policy criteria states that care had to be within the past 6-months via a broader range of medication.

Previously: *Back: Epidural Steroid Injections*	▪ Criteria have been in place since 2020, policy guidelines were added subsequently and were mistakenly not aligned. **Codes/PA:** No changes to codes/PA. **OHP:** These changes do not apply to OHP. The Prioritized List and the Oregon Administrative Rules will be followed.

MEDICARE

Effective 3/1/24

Stem Cell Therapy for Orthopedic Applications **MP372**	**Policy Updates:** No change to criteria, continue to apply Company medical policy criteria. The Company policy criteria changing from INV to NMN changes some of the generic language found in the Medicare version. Update "Policy Guidelines" to make a more robust argument if needed for appeals sent to MAXIMUS. **Codes/PA:** • No change to the configuration of codes **currently** in the policy. • Add 0627T-0630T and change from E/I to NMN. These codes are currently listed on the ATL NCL as being part of the *Back: Intradiscal* policy, but these codes were never actually added to the policy draft when they were released 1/ 2021.
Myoelectric Upper Limb Prosthesis **MP374**	**Recommendation:** • Continue to apply Company medical policy criteria for initial issue of myoelectric prosthetic of the upper limb. The Company policy criteria changing from INV to NMN changes some of the generic language found in the Medicare version. • Add replacement and repair criteria, which are based on CMS guidance. • Update "Policy Guidelines" **Codes/PA:** Add L9900 to the policy since it can be used with related supplies, but no change to the configuration of the code. No change to codes already in the policy or their configuration.

Varicose Veins **MP187**	**Recommendation:** • Add codes and direction in the "Criteria" table to direct to which specific procedure would be subject to which criterion in the LCD. • Change criteria for the KAVS procedure from Medicare LCD to Company criteria (not medically necessary). The LCD does not actually address this procedure. The NMN coverage position is consistent with the historical inclusion of this code in the now-retired LCD for *Additional Information Required for Coverage and Pricing for Category III CPT® Codes* (A55681). • Update "Policy Guidelines" section to support the changes made to the "Criteria" table. • Correct the companion LCA in the "Billing Guidelines" section. **Codes/PA:** Changes to codes and configuration is as follows: • 0524T – Remove PA and add NMN • S2202 – Currently has a NMN denial; however, this is NOT supported by medical policy, so it needs removed. Will allow Coding Policy (22.0) to address. • No changes to other codes in this policy or their configuration.

Reimbursement

Effective 1/1/24

Observation Status **RP69**	**Annual Review** **Recommendation:** Annual review, with minor updates to align with internal process changes which took place in September 2023 (no longer done concurrent, instead done post-service). **Reimbursement Methodology:** No change to reimbursement methodology. **MD/Other Feedback**: N/A **Effective date:** 1/1/2024 **Relevant References/CMS Guidance/OHP Guidance:** • Medicare Benefit Policy Manual, Chapter 1 - Inpatient Hospital Services Covered Under Part A, §10 - Covered Inpatient Hospital Services Covered Under Part A • Medicare Program Integrity Manual, Chapter 6 - Medicare Contractor Medical Review Guidelines for Specific Services, §6.5 - Medical Review of Inpatient Hospital Claims for Part A Payment

	• Medicare Benefit Policy Manual, Chapter 6 - Hospital Services Covered Under Part B, §20.6 - Outpatient Observation Services, "A. Outpatient Observation Services Defined • Medicare Claims Processing Manual, Chapter 4 - Part B Hospital (Including Inpatient Hospital Part B and OPPS), §290.1 - Observation Services Overview • Medicare Claims Processing Manual, Chapter 4 - Part B Hospital (Including Inpatient Hospital Part B and OPPS), 290.2.2 - Reporting Hours of Observation • Medicare Benefit Policy Manual, Chapter 1 - Inpatient Hospital Services Covered Under Part A, §10.2 - Hospital Inpatient Admission Order and Certification • Medicare Program Integrity Manual, Chapter 6 - Medicare Contractor Medical Review Guidelines for Specific Services, §6.5.2 - Conducting Patient Status Reviews of Claims for Medicare Part A Payment for Inpatient Hospital Admissions, A. Determining the Appropriateness of Part A Payment • Noridian web page for Inpatient to Outpatient Status Change • Noridian web page for Observation • Centers for Medicare & Medicaid Services. CMS Medicare Benefit Policy 100-02; Transmittal 42. • Oregon Health Authority (OHA). Health Systems Division: Medical Assistance Programs - Chapter 410. Division 125 HOSPITAL SERVICES. 410-125-0360. Definitions and Billing Requirements
Robotic Surgical Systems **RP1**	**Annual Review** **Recommendation:** Annual review, no changes. **Reimbursement Methodology:** No change to reimbursement methodology. **MD/Other Feedback**: N/A **Effective date:** 1/1/2024 **Relevant References/CMS Guidance:** • FDA website • Medicare National Correct Coding Initiative (NCCI) manual **OHP:** These changes do not apply to OHP. The Prioritized List and the Oregon Administrative Rules will be followed.

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Vendor Updates

Effective 4/14/24

Carelon (formerly AIM) Advanced Imaging Clinical Appropriateness Guidelines	**Changes to current criteria:** **Imaging of the Heart** • Cardiac CT: Cardiomyopathy: Added specificity to establish the basis for the suspicion of ARVD. This change aligns with Cardiac MRI guidelines. • Resting Transthoracic Echocardiography (TTE): Evaluation of ventricular function: New indications for evaluation of patients on mavacamten for treatment of HOCM **Imaging of the Abdomen and Pelvis** • Biliary tract dilatation or obstruction: Added indication for annual surveillance in Caroli disease/syndrome based on a 2022 guideline recommendation. • Diffuse liver disease: Removed indication for LiverMultiScan in hemochromatosis as there is insufficient evidence that this provides an advantage over standard MRI for this condition • Osteomyelitis: Added requirement for initial evaluation with radiographs in adult patients based on ACR appropriateness criteria. • Septic arthritis: Added requirement for initial radiographs in adult patients based on ACR appropriateness criteria Pancreatic mass, indeterminate cystic (IPMN/IPMT): For enlarging lesions in patients age 80 or greater, increased surveillance frequency to annually and removed endpoint of 4 years. • Pelvic floor disorders: Added indication for MRI (MR defecography preferred) in suspected pelvic organ prolapse based on ACR appropriateness criteria • Transplant-related imaging: Added indication for single CT abdomen or abdomen/pelvis prior to lung, kidney, or stem cell transplant to align with CT chest guidelines. **Imaging of the Brain** • Movement disorders (Adult only): Added indication for CT head for assessment of skull density prior to MRgFUS for essential tremor • Trauma: Added a 3-6 week follow up study in patients age 6 or younger with stable or inconclusive exam, due to difficulty in accurately assessing for changes in neurologic status • Acoustic neuroma: Added long-term follow-up intervals based on specialty society guidelines **Imaging of the Chest** • Perioperative or periprocedural evaluation, not otherwise specified: Added indication for CT chest to be used for planning of biopsy or placement of fiducial markers using navigational bronchoscopy **Imaging of the Head and Neck**

- Acoustic neuroma: Added long-term follow-up intervals based on specialty society guidelines
- Localized facial pain (including trigeminal neuralgia): Added MRI orbit/face/neck for this indication based on ACR criteria; some facilities use MRI face rather than brain for this condition

Oncologic Imaging

Cancer Screening

- Breast cancer screening: Addition of RAD51C or RAD51D and TK11 (Peutz-Jeghers syndrome) high-risk genetic mutations (NCCN alignment citing absolute risk of 20% or greater)
- Lung cancer screening: Clarification of asbestos-related lung disease as risk factor independent of smoking, aligned with original intent.
- Pancreatic cancer screening:_Alignment with NCCN recommended parameters; changes are overall expansive, except for:
  - Older start age (from 45 to 50) for certain genes (ATM, BRCA1, BRCA2, MLH1, MSH2, MSH6, EPCAM, PALB2, TP53)
  - Family history alone (relative requirement)

Breast Cancer

- CT chest, CT abdomen and pelvis: Added diagnostic workup allowance when metastatic disease is clinically suspected at presentation
- MRI Breast: Addition/clarification of surveillance scenarios aligned with NCCN/ACR considerations
- FDG-PET/CT: Added allowance for RT planning locoregional recurrence (e.g., confirmation of regional nodal involvement)
- 18F-fluoroestradiol (18F-FES) PET/CT: Added that it Is not indicated due to uncertain net benefit; low-level evidence, insufficient data on outcomes.

Cervical Cancer

- FDG-PET/CT: Update for follow-up of disease treated with either adjuvant RT or chemoradiation (NCCN alignment).

Hepatocellular and Biliary Tract Cancers

- FDG-PET/CT: Removed routine preop PET/CT for biliary tract cancers (NCCN alignment)
- FDG-PET/CT: Added management allowance when standard imaging cannot be done or is nondiagnostic (NCCN "consider" for equivocal finding)

Lung Cancer – Non-Small Cell

- FDG-PET/CT: Added management allowance when recurrence demonstrated by surveillance imaging (NCCN alignment)

Lung Cancer – Small Cell

- FDG-PET/CT: Clarification of initial staging allowance (NCCN alignment

Lymphoma – Non-Hodgkin and Leukemia

- FDG-PET/CT: NCCN alignment for interim restaging (allowed for DLBCL stage I-IV with or without bulky disease)

Melanoma

- Added surveillance option with MRI abdomen for liver metastases.

Prostate Cancer

	• 18F Fluciclovine PET/CT or 11C Choline PET/CT, 68GaProstate-specific membrane antigen (PSMA) PET/CT or 18F-DCFPyL (piflufolastat or Pylarify) PET/CT • Addition of diagnostic workup/initial staging indication. • Specification of androgen-receptor pathway inhibitor treatment in alignment with Carelon Radiation Oncology guidelines. <u>Sarcomas of Bone/Soft Tissue</u> • FDG-PET/CT: Added allowance when standard imaging nondiagnostic or contraindicated (bone/soft tissue sarcoma). **Codes/PA:** No changes to codes or configuration. The full-text of the updated guidelines are already available on Carelon's website for providers to review Please submit your feedback to medicalbenefitsmanagement.guidelines@carelon.com

Providence Health Plan

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

Pharmacy & Therapeutics (P&T) Committee

Oregon Region P&T Committee Meeting December 1, 2023

Go-Live Date: Thursday, February 01, 2024, unless otherwise noted

Table of Contents:

New Drugs and Combinations:

1. **Nadofaragene firadenovec-vncg (Adstiladrin) Vial**
   a. **Indication**: For the treatment of adult patients with high-risk BCG-unresponsive non-muscle invasive bladder cancer (NMIBC) with carcinoma in situ (CIS) with or without papillary tumors
   b. **Decision**:

	Commercial	Medicaid	Medicare
Formulary Status*	Medical	Medical	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			
*Plans may differ in formulary status due to regulatory requirements			

** Medications will be placed in appropriate tiers for various formularies based on designation above. For example, non-preferred brand designation above means that the medication will be placed on the highest cost-sharing tier for branded medications on the respective formularies
Formulary Alternatives: Intravesical chemotherapy (valrubicin), Keytruda®

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

2. **Talquetamab-tgvs (Talvey) Vial**
   a. **Indication**: For the treatment of adult patients with relapsed or refractory multiple myeloma (RRMM) who have received at least four prior lines of therapy, including a proteasome inhibitor, an immunomodulatory agent and an anti-CD38 monoclonal antibody.
   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: Alternative **m**edical therapies include Tecvayli, Elrexfio, Carvykti, Abecma			

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

PA PROGRAM NAME	T Cell Therapy
MEDICATION NAME	Talvey

PA INDICATION INDICATOR	1 - All FDA-Approved Indications
EXCLUSION CRITERIA	Combination use of T-cell therapies included on this policy. For CAR T- cell therapy: Previous treatment with chimeric antigen receptor therapy (CAR-T). ~~or other genetically modified T-cell therapy.~~ Repeat administration is not considered medically necessary as ~~T-cell therapy is considered experimental and investigational because~~ the effectiveness of this approach has not been established.
REQUIRED MEDICAL INFORMATION	For Talvey, Tecvayli, Elrexfio initiation of therapy (new starts), all the following must be met: 1. Use must be for an indication supported by National Comprehensive Cancer Network (NCCN) guidelines with recommendation 2A or higher 2. 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 for Tecvayli, 0-2 for Talvey/Elrexfio or a written statement acknowledging that the patient is fit to tolerate therapy. 3. ~~No evidence of active systemic infection~~ 4. ~~Confirmed diagnosis of multiple myeloma~~ 5. ~~Refractory or relapsed disease to four or more prior lines of therapy. Prior therapy must have included an immunomodulatory agent, a proteasome inhibitor, and an anti-CD38 monoclonal antibody~~ For established on therapy, all the following must be met (Note: Medications obtained as samples, coupons, or any other method of obtaining medications outside of an established health plan benefit are NOT considered established on therapy): 1. Member is responding positively to therapy
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 Tecvayli, Talvey, Elrexfio: Initial authorization and reauthorization will be approved for 1 year and with up to four doses of tocilizumab (Actemra®) at up to 800 mg per dose

3. **Elranatamab-bcmm (Elrexfio) Vial**
   a. **Indication**: For the treatment of adult patients with relapsed or refractory multiple myeloma (RRMM) who have received at least four prior lines of therapy including a proteasome inhibitor, an immunomodulatory agent, and an anti-CD38 monoclonal antibody.
   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: Alternative **m**edical therapies include Tecvayli, Talvey, Carvykti, Abecma			

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

PA PROGRAM NAME	T Cell Therapy
MEDICATION NAME	Talvey
PA INDICATION INDICATOR	1 - All FDA-Approved Indications
EXCLUSION CRITERIA	Combination use of T-cell therapies included on this policy. For CAR T- cell therapy: Previous treatment with chimeric antigen receptor therapy (CAR-T). ~~or other genetically modified T-cell therapy.~~ Repeat administration is not considered medically necessary as ~~T-cell therapy is considered experimental and investigational because~~ the effectiveness of this approach has not been established.

REQUIRED MEDICAL INFORMATION	For Talvey, Tecvayli, Elrexfio initiation of therapy (new starts), all the following must be met: 1. Use must be for an indication supported by National Comprehensive Cancer Network (NCCN) guidelines with recommendation 2A or higher 2. 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 for Tecvayli, 0-2 for Talvey/Elrexfio or a written statement acknowledging that the patient is fit to tolerate therapy. ~~3. No evidence of active systemic infection~~ ~~4. Confirmed diagnosis of multiple myeloma~~ 5. ~~Refractory or relapsed disease to four or more prior lines of therapy. Prior therapy must have included an immunomodulatory agent, a proteasome inhibitor, and an anti-CD38 monoclonal antibody~~ For established on therapy, all the following must be met (Note: Medications obtained as samples, coupons, or any other method of obtaining medications outside of an established health plan benefit are NOT considered established on therapy): 1. Member is responding positively to therapy
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 Tecvayli, Talvey, Elrexfio: Initial authorization and reauthorization will be approved for 1 year and with up to four doses of tocilizumab (Actemra®) at up to 800 mg per dose

4. **Niraparib tosylate abiraterone acetate (Akeega) Tablet**
   a. **Indication**: For the treatment of adult patients with deleterious or suspected deleterious BRCA-mutated (BRCAm) metastatic castration-resistant prostate cancer (mCRPC).
   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: Lynparza® (olaparib)/abiraterone, Talzenna® (talazoparib)/Xtandi® (enzalutamide)

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

5. **Momelotinib dihydrochloride (Ojjaara) Tablet**
   a. **Indication**: For the treatment of intermediate or high-risk myelofibrosis (MF), including primary MF or secondary MF [postpolycythemia vera (PV) and post-essential thrombocythemia (ET)], in adults with anemia.
   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	1/day	1/day	1/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: N/A			

   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. **Avacincaptad pegol sodium pf (Izervay) Vial**
   a. **Indication**: For the treatment of geographic atrophy (GA) secondary to age-related macular degeneration (AMD).
   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	4mg/30 days	4mg/30 days	4mg/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: Syfovre®			

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

PA PROGRAM NAME	Izervay
MEDICATION NAME	Avacincaptad pegol sodium vial
PA INDICATION INDICATOR	1 - All FDA-Approved Indications
OFF-LABEL USES	N/A
EXCLUSION CRITERIA	• Active ocular or periocular infections in the requested eye being treated • History of endophthalmitis, retinal detachments, or increased intraocular pressure in the requested eye being treated
REQUIRED MEDICAL INFORMATION	For initial authorization, all the following criteria must be met: 1. Documentation of diagnosis of geographic atrophy (GA) confirmed by clinical exam or diagnostic imaging (such as Color Fundus Photography, Fundus Autofluorescence, Near Infrared Reflectance Imaging, Optical Coherence Tomography) 2. Documentation that GA is secondary to age-related macular degeneration (AMD)

	3. If active choroidal neovascularization (CNV) present, documentation must be submitted attesting that treatment with the requested medication is medically necessary and appropriate monitoring of CNV will be conducted such as a comprehensive eye exam within three months of starting the requested therapy
AGE RESTRICTIONS	Age equal to or greater than 50 years of age.
PRESCRIBER RESTRICTIONS	Must be prescribed by, or in consultation with, an ophthalmologist.
COVERAGE DURATION	Initial authorization will be approved for one year. Reauthorization will not be allowed.

7. **Pozelimab-bbfg (Veopoz) Vial**
   a. **Indication**: For treatment of patients one year and older with CHAPLE disease (also known as CD55-deficient protein-losing enteropathy).
   b. **Decision**:

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

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

PA PROGRAM NAME	Medications for Rare Indications
MEDICATION NAME	Pozelimamb-bbfg (Veopoz)

PA INDICATION INDICATOR	1 - All FDA-Approved Indications
OFF-LABEL USES	N/A
EXCLUSION CRITERIA	For Veopoz: Combination use with eculizumab
REQUIRED MEDICAL INFORMATION	For initial authorization, both of the following must be met: 1. Confirmation of FDA-labeled indication (appropriate lab values and/or genetic tests must be submitted) a. For Veopoz®: Confirmation of CD55 loss-of-function mutation detected by genetic testing **AND** 2. Dosing is within FDA-labeled guidelines OR documentation has been submitted in support of therapy with a higher dose for the intended diagnosis such as high-quality peer reviewed literature, guidelines, other clinical information Reauthorization: 1. Documentation of successful response to therapy AND 2. Dosing is within FDA-labeled guidelines OR documentation has been submitted in support of therapy with a higher dose for the intended diagnosis such as high-quality peer reviewed literature, guidelines, other clinical information
AGE RESTRICTIONS	N/A
PRESCRIBER RESTRICTIONS	Must be prescribed by, or in consultation with a specialist in the respective disease state
COVERAGE DURATION	For Veopoz: Initial authorization and reauthorization will be approved for one year

8. **Rezafungin acetate (Rezzayo) Vial**
   a. **Indication**: For the treatment of candidemia and invasive candidiasis. Approval of this indication is based on limited clinical safety and efficacy data.
   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	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: caspofungin (Cancidas®), micafungin (Mycamine®), Eraxis® (anidulafungin)			

9. **Perfluorohexyloctane pf (Miebo) Drops Indication**:
    a. For the treatment of the signs and symptoms of dry eye disease (DED).
    b. **Decision**:

	Commercial	Medicaid	Medicare
Formulary Status*	Non-formulary	Non-formulary	Part D: Non-formulary Part B: N/A
Tier**	N/A	N/A	N/A
Affordable Care Act Eligible	No	N/A	N/A
Utilization Management Edits	N/A	N/A	N/A
Quantity Limit	6 mL per 30 days	6 mL per 30 days	6 mL 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: Xiidra®, Restasis®			

New Indications:

Therapies with Prior Authorization Policies (Non-oncology)

1. **Ezallor Sprinkle** (Rosuvastatin)
    a. New indication approved 08/04/2023:
        a. To reduce the risk of stroke, myocardial infarction, and arterial revascularization procedures in adults without established coronary heart disease who are at increased risk of cardiovascular (CV) disease based on age, hsCRP ≥2 mg/L, and at least one additional CV risk factor
        b. As an adjunct to diet to reduce LDL-C in adults with primary hyperlipidemia
        c. As an adjunct to diet to reduce low-density lipoprotein cholesterol (LDLC) and slow the progression of atherosclerosis in adults
        d. As an adjunct to diet to reduce LDL-C in adults and pediatric patients aged 8 years and older with heterozygous familial hypercholesterolemia (HeFH)
        e. As an adjunct to other LDL-C-lowering therapies, or alone if such treatments are unavailable, to reduce LDL-C in adults and pediatric patients aged 7 years and older with homozygous familial hypercholesterolemia (HoFH)
        f. As an adjunct to diet for the treatment of adults with:
            - Primary dysbetalipoproteinemia
            - Hypertriglyceridemia
    b. **RECOMMENDATION:** Inform prescribers via Medical Policy Alert.

2. **Abrilada** (Adalimumab-AFZB)
    a. New indication approved 08/16/2023:
        a. Uveitis
    b. **RECOMMENDATION:** Inform prescribers via Medical Policy Alert. Medication will be reviewed once available on the market.

3. **Ingrezza** (Valbenazine tosylate)
    a. New indication approved 06/05/2023:
        a. Chorea associated with Huntington's disease
    b. **RECOMMENDATION:** Inform prescribers via Medical Policy Alert. Update policy with new indication and add new criteria.

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

PA PROGRAM NAME	VMAT2 Inhibitors
MEDICATION NAME	Ingrezza
PA INDICATION INDICATOR	1 - All FDA-Approved Indications
REQUIRED MEDICAL INFORMATION	1. For chorea associated with Huntington disease [tetrabenazine (Xenazine®) or deutetrabenazine (Austedo® and Austedo® XR) or valbenazine (Ingrezza®)] a. Initiation of therapy requires all the following must be met:

	i. Diagnosis of Huntington Disease confirmed by all the following: 1. DNA testing showing CAG expansion of 36 or higher, AND 2. Family history (if known), AND 3. Classic presentation (choreiform movements, psychiatric problems, and dementia), AND ii. Documentation that chorea is causing functional impairment, AND iii. For deutetrabenazine (Austedo® and Austedo® XR) and valbenazine (Ingrezza®): Documented trial (of at least eight weeks) and failure or intolerance to tetrabenazine. b. For reauthorization: Documented benefit of therapy, as evidence by improved function through reduction in choreiform movements.

4. **Ilaris** (canakinumab)
   a. New indication approved 08/25/2023:
      a. Gout flares in adults in whom non-steroidal anti-inflammatory drugs (NSAIDs) and colchicine are contraindicated, are not tolerated, or do not provide an adequate response, and in whom repeated courses of corticosteroids are not appropriate
   b. **RECOMMENDATION:** Inform prescribers via Medical Policy Alert. Update policy with new indication and add new criteria.

Prior Authorization Criteria for **Commercial**:

PA PROGRAM NAME	Interleukin-1 Inhibitor
MEDICATION NAME	Ilaris
PA INDICATION INDICATOR	1 - All FDA-Approved Indications
REQUIRED MEDICAL INFORMATION	3. One of the following: a. For patients already established on the requested agent: i. Documentation of positive response to therapy (e.g., improvement or stabilization of clinical symptoms of disease) b. For patients not established on the requested agent, must meet ALL of the following criteria according to their diagnosis: viii. Gout flares (Ilaris only) 1. Classic symptoms associated with gout flares (monoarticular inflammation, severe pain, redness, swelling) 2. Confirmed diagnosis, defined as one of the following: a. Presence of uric acid crystals in inflamed synovial fluid, joint, or tophus

	b. Score greater or equal to 8 on gout clinical diagnostic rule 3. Documentation of inadequate response to therapy with all the following on contraindication/intolerance to all therapies: a. Colchicine (at least three days) b. Nonsteroidal anti-inflammatory drugs (NSAIDs) (at least one week) c. Corticosteroid therapy (at least one week)

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

PA PROGRAM NAME	Interleukin-1 Inhibitor – Medicare Part B
MEDICATION NAME	Ilaris
PA INDICATION INDICATOR	1 - All FDA-Approved Indications
REQUIRED MEDICAL INFORMATION	1. For initiation of therapy (new starts), must meet the indication-specific criteria outlined below: f. Gout flares 1. Classic symptoms associated with gout flares (monoarticular inflammation, severe pain, redness, swelling) 2. Confirmed diagnosis, defined as one of the following: a. Presence of uric acid crystals in inflamed synovial fluid, joint, or tophus b. Score greater or equal to 8 on gout clinical diagnostic rule 3. Documentation of inadequate response to therapy with all the following on contraindication/intolerance to all therapies: a. Colchicine (at least three days) b. Nonsteroidal anti-inflammatory drugs (NSAIDs) (at least one week) c. Corticosteroid therapy (at least one week)

5. **Reblozyl** (luspatercept-AAMT)
   a. New indication approved 08/28/2023:
      a. Anemia without previous erythropoiesis stimulating agent use (ESA-naïve) in adult patients with very low- to intermediate-risk myelodysplastic syndromes (MDS) who may require regular red blood cell (RBC) transfusions
   b. **RECOMMENDATION:** Inform prescribers via Medical Policy Alert. Update policy with new indication and add new criteria.

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

PA PROGRAM NAME	Reblozyl
MEDICATION NAME	Reblozyl

PA INDICATION INDICATOR	1 - All FDA-Approved Indications
REQUIRED MEDICAL INFORMATION	For initiation of therapy (new starts) for **myelodysplastic syndrome (MDS)**, all the following must be met (supporting documentation required): 1. Symptomatic anemia, defined as a pretreatment or pretransfusion Hgb level less than or equal to 11 g/dL 2. A score of very low to intermediate risk based on the Revised International Prognostic Scoring System 3. Patient requires RBC transfusions of at least two units every eight weeks 4. Meets one of the following (a or b): a. Ring sideroblasts greater than or equal to 15% or ring sideroblasts greater than or equal to 5% and less than 15% with a SF3B1 mutation b. Both of the following: i. Ring sideroblasts <15% (or ring sideroblasts <5% with an SF3B1 mutation) ii. Endogenous erythropoietin level less than 500 mU/mL

6. **Jardiance** (Empagliflozin)
    a. New indication approved 09/21/2023:
        a. To reduce the risk of sustained decline in eGFR, end-stage kidney disease, cardiovascular death, and hospitalization in adults with chronic kidney disease at risk of progression
    b. **RECOMMENDATION:** Inform prescribers via Medical Policy Alert. Update policy with new indication.

7. **Yusimry** (Adalimumab-AQVH)
    a. New indication approved 09/13/2023:
        a. Uveitis
    b. **RECOMMENDATION:** Inform prescribers via Medical Policy Alert. Update policy with new indication.

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

8. **Lonsurf** (trifluridine/tipiracil)
    a. New indication(s) approved 08/02/2023:
        a. As a single agent or in combination with bevacizumab, is indicated for the treatment of adult patients with metastatic colorectal cancer previously treated with fluoropyrimidine-, oxaliplatin- and irinotecan-based chemotherapy, an anti-VEGF biological therapy, and if RAS wild-type, an anti-EGFR therapy.

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.

9. **Tafinlar** (dabrafenib)
    a. New indication(s) approved 08/31/2023:
        a. Treatment of adult and pediatric patients 1 year of age and older with unresectable or metastatic solid tumors with BRAF V600E mutation who have progressed following prior treatment and have no satisfactory alternative treatment options. This indication is approved under accelerated approval based on overall response rate (ORR) and duration of response (DoR). Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial(s)
    b. **RECOMMENDATION:** Inform prescribers via Medical Policy Alert. Prior authorization policy coverage criteria are based on recommendations from the National Comprehensive Cancer Network (NCCN); no updates to the policy are warranted.

10. **Mekinist** (trametinib)
    a. New indication(s) approved 08/31/2023:
        a. Treatment of adult and pediatric patients 1 year of age and older with unresectable or metastatic solid tumors with BRAF V600E mutation who have progressed following prior treatment and have no satisfactory alternative treatment options. This indication is approved under accelerated approval based on overall response rate (ORR) and duration of response (DoR). Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial(s)
    b. **RECOMMENDATION:** Inform prescribers via Medical Policy Alert. Prior authorization policy coverage criteria are based on recommendations from the National Comprehensive Cancer Network (NCCN); no updates to the policy are warranted.

11. **Bosulif** (bosutinib monohydrate)
    a. New indication(s) approved 09/26/2023:
        a. Adult and pediatric patients 1 year of age and older with chronic phase Ph+ chronic myelogenous leukemia (CML), newly-diagnosed or resistant or intolerant to prior therapy
    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. **Temodar (temozolomide)**
    a. New indication(s) approved 09/14/2023:
        i. Newly diagnosed glioblastoma concomitantly with radiotherapy and then as maintenance treatment
        ii. Anaplastic astrocytoma

- Adjuvant treatment of adults with newly diagnosed anaplastic astrocytoma
- Treatment of adults with refractory anaplastic astrocytoma

b. **RECOMMENDATION:** Inform prescribers via Medical Policy Alert. This medication does not require prior authorization, so no updates to policies are warranted

2. **Daxxify** (DaxibotulinumtoxinA-lanm)
   a. New indication approved 08/11/23:
      i. Treatment of cervical dystonia in adult patients
   b. **RECOMMENDATION:** Inform prescribers via Medical Policy Alert. Update new indication and add new criteria.

PA PROGRAM NAME	Botulinum Toxin
MEDICATION NAME	Daxxify (DaxibotulinumtoxinA-lanm)
PA INDICATION INDICATOR	1 - All FDA-Approved Indications
REQUIRED MEDICAL INFORMATION	5. DaxibotulinumtoxinA-lanm (Daxxify®) may covered for the following indications: a. Moderate to severe glabellar lines associated with corrugator and/or procerus muscle activity in adults b. Cervical dystonia in adults

Drug Safety Monitoring:

FDA Drug Safety Communications

There were no drug safety communications reported during this period.

Drug Recalls/Market Withdrawals

1. **Drug Name:** INMAR Supply Chain Solutions: Numerous human food, animal (pet) food, medical devices, and drug products
   - **Date of Recall:** 08/23/2023
   - **Reason for recall:** Potential Salmonella contamination and presence of rodent activity at the distribution center & temperature abuse
   - **Link to more information:** https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/inmar-supply-chain-solutions-llc-issues-voluntary-recall-product-stored-its-arlington-texas-facility
   - **Health Plan Recommendation:** Notify providers via Medical Policy Alert

2. **Drug Name:** MSM Eye Drops - 5% Solution, 15% Solution, Castor Oil, 5% MIST Drops
   - **Date of Recall:** 08/26/2023
   - **Reason for recall:** Bacterial and Fungal Contamination
   - **Link to more information:** https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/dr-bernes-whole-health-products-issues-voluntary-nationwide-recall-dr-bernes-msm-drops-5-and-15
   - **Health Plan Recommendation:** Notify providers via Medical Policy Alert

3. **Drug Name:** Digoxin Tablets USP, 0.125mg and 0.25mg
   - **Date of Recall:** 08/31/2023
   - **Reason for recall:** Label Mix-Up
   - **Link to more information:** https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/marlex-pharmaceuticals-inc-issues-voluntary-nationwide-recall-digoxin-tablets-usp-0125mg-and-digoxin
   - **Health Plan Recommendation:** Notify providers via Medical Policy Alert

4. **Drug Name:** WEFUN Brand Dietary Supplement with undeclared Sildenafil
   - **Date of Recall:** 09/05/2023
   - **Reason for recall:** Undeclared drug, Sildenafil
   - **Link to more information:** https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/hua-da-trading-inc-dba-wefun-inc-issues-voluntary-nationwide-recall-wefun-capsules-due-presence
   - **Health Plan Recommendation:** Notify providers via Medical Policy Alert

5. **Drug Name:** TheraBreath Kids Strawberry Splash Oral Rinse
   - **Date of Recall:** 09/08/2023
   - **Reason for recall:** Device & Drug Safety/Microbial Contamination
   - **Link to more information:** https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/church-dwight-issues-voluntary-nationwide-recall-one-specific-lot-therabreath-strawberry-splash-kids
   - **Health Plan Recommendation:** Notify providers via Medical Policy Alert

6. **Drug Name:** Sandimunne Oral Solution (cyclosporine oral solution, USP) 100 mg/mL
   - **Date of Recall:** 09/11/2023
   - **Reason for recall:** Crystal formation which could potentially result in incorrect dosing
   - **Link to more information:** https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/novartis-issues-voluntary-nationwide-recall-one-lot-sandimmuner-oral-solution-cyclosporine-oral
   - **Health Plan Recommendation:** Notify providers via Medical Policy Alert

7. **Drug Name:** Sucralfate Oral Suspension 1g/10mL
   - **Date of Recall:** 09/22/2023
   - **Reason for recall:** Potential contamination with Bacillus cereus
   - **Link to more information:** https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/vistapharm-llc-issues-voluntary-nationwide-recall-sucralfate-oral-suspension-1g10ml-due-microbial
   - **Health Plan Recommendation:** Notify providers via Medical Policy Alert

8. **Drug Name:** Brexafemme
   - **Date of Recall:** 09/28/2023
   - **Reason for recall:** Potential cross contamination with non-antibacterial beta-lactam drug substance
   - **Link to more information:** https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/scynexis-issues-voluntary-nationwide-recall-brexafemmer-ibrexafungerp-tablets-due-potential-cross
   - **Health Plan Recommendation:** Notify providers via Medical Policy Alert

Other Formulary Changes:

OTHER FORMULARY CHANGES		
Drug Name	**Action Taken**	**Policy Name**
Propranolol hcl (Hemangeol) Solution	• Commercial: Move from Tier 4 to Tier 3	• N/A
Latanoprost/pf (Iyuzeh) Droperette	New dosage form (droperette); • Commercial/Medicaid: Non-Formulary, Step Therapy, Quantity Limit (1 droperette per date) • Medicare Part D: Non-Formulary	• Commercial/Medicaid: Anti-Glaucoma Agents Step Therapy Policy • Medicare Part D: N/A
Lacosamide (Motpoly Xr) Cap ER 24h	New dosage form (Cap ER 24H); • Commercial: Non-Formulary, Quantity Limit (1 capsule per day) • Medicaid: Non-Formulary (DMAP) • Medicare Part D: Non-Formulary	• N/A
Dronabinol Capsule / Solution	Add quantity limit • Commercial/Medicaid: Quantity Limit (2 capsules per day; 4 mL per day for solution)	• N/A
Rifamycin sodium (Aemcolo) Tablet DR	Update quantity limit • Commercial/Medicaid: Quantity Limit to 1 claim per year	• N/A
Kanjinti (trastuzumab-anns)	• Change to non-preferred biosimilar for all lines of business	• Injectable Anti-cancer Medications

Trazimera (trastuzumab-qyyp)	• Change to preferred biosimilar for all lines of business	• Injectable Anti-cancer Medications

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**
Fluticasone furoate/vilanterol trifenatate (Breo Ellipta) Blst w/Dev	New strength (50/25mcg). Line extend with other Breo Ellipta; • Commercial: Formulary, Tier 3 • Medicaid: Non-Formulary • Medicare Part D: Formulary, Tier 3 Quantity Limit (60 per 30 days)	N/A
Aflibercept (Eylea HD) Vial	New strength (8mg/0.07ml). Line extend as medical with Eylea 2mg/0.05ml; • Medical benefit for all lines of business	N/A
Potassium chloride (Pokonza) Packet	New dosage form (packet). Line extend with other potassium packets; • Non-Formulary for all lines of business	N/A
Isavuconazonium sulfate (Cresemba) Capsule	New strength. Line extend with existing Cresemba; • Commercial: Formulary, Tier 6, Prior Authorization • Medicaid: Formulary, Prior Authorization, Specialty • Medicare Part D: Formulary, Tier 5, Prior Authorization	Antifungal Agents
Insulin aspart (niacinamide)/pump cartridge (Fiasp Pumpcart) Cartridge	New dosage form (cartridge). Line extend with Fiasp cart; • Commercial: Non-Formulary, Prior Authorization • Medicaid/Medicare Part D: Non- Formulary	• Commercial: Non-Preferred Insulins • Medicaid/Medicare Part D: N/A
Adalimumab-adaz (Hyrimoz) Syringe / Pen Injctr	New strength. Line extend as non-preferred biosimilar to Humira;	• Commercial/Medicaid: Therapeutic Immunomodulators (TIMS)

	• Commercial/Medicaid: Non-Formulary, Prior Authorization, Quantity Limit (1.6 mL per 28 days) Specialty • Medicare Part D: Non-Formulary	• Medicare Part D: N/A
Adalimumab-afzb (Abrilada(CF)) 20mg/0.4ml Syringekit	Humira Biosimilar. Line extend with non-preferred Humira biosimilars; • Commercial/Medicaid: Non-Formulary, Prior Authorization, Quantity Limit (0.8 mL per 28 days) Specialty • Medicare Part D: Non-Formulary	• Commercial/Medicaid: Therapeutic Immunomodulators (TIMS) • Medicare Part D: N/A
Adalimumab-afzb (Abrilada(CF)) 40mg/0.8ml Syringekit / Pen IJ Kit	Humira Biosimilar. Line extend with non-preferred Humira biosimilars; • Commercial/Medicaid: Non-Formulary, Prior Authorization, Quantity Limit (1.6 mL per 28 days) Specialty • Medicare Part D: Non-Formulary	• Commercial/Medicaid: Therapeutic Immunomodulators (TIMS) • Medicare Part D: N/A

NEW GENERICS		
Drug Name	**Action Taken**	**Policy Name**
Brimonidine tartrate Drops	First generic drug (Alphagan P). Line extend as generic; • Commercial Standard: Formulary, Tier 2 • Commercial Dynamic: Standard: Formulary, Tier 4 • Medicaid: Non- Formulary • Medicare Part D: Formulary, Tier 3	• N/A
Dextroamphetamine-Amphet ER CPTP 24hr	First generic drug ((Mydayis). Line extend as generic; • Commercial/Medicaid: Non- Formulary, Quantity Limit (1 capsule per day) • Medicare Part D: Non- Formulary	• N/A
Levonorg-eth estrad-fe bisglyc Tablet	First generic drug (Balcoltra). Line extend as generic; • Commercial: Preventative • Medicaid/Medicare Part D: Non-Formulary	• N/A
Lisdexamfetamine Dimesylate Tab Chew	First generic drug. Line extend as generic; • Comm: Formulary, Tier 2, Quantity Limit (1 tablet per day	• N/A

	• Medicaid: Non-Formulary • Medicare Part D: Formulary, Tier 4, Quantity Limit (1 tablet per day)	
Tretinoin Microsphere Gel w/Pump	First generic drug (Retin-A Micro Pump). Line extend as generic; • Commercial/Medicaid: Non-Formulary, Prior Authorization • Medicare Part D: Non-Formulary	• Commercial/Medicaid: New Medications and Formulations without Established Benefit • Medicare Part D: N/A
Pazopanib hcl Tablet	First generic drug (Votrient). Line extend as generic; • Commercial: Formulary, Tier 5, Prior Authorization • Medicaid: Formulary, Prior Authorization, Specialty • Medicare Part D: Formulary, Tier 5, Prior Authorization	• Commercial/Medicaid: Oral Anti-Cancer Medications • Medicare Part D: Anti-Cancer Agents

Clinical Policy Changes:

MAJOR CHANGES	
Policy Name	**Summary of Change**
• **Acute Hereditary Angioedema Therapy** • **Acute Hereditary Angioedema Therapy - Medicare Part B**	Added exclusion for use of multiple agents for acute treatment and clarified icatibant prerequisite therapy will only be required for adult patients.
Antifungal Agents	Updated criteria based on new guidelines: Aspergillus/Candida prophylaxis for HIV/AIDS for secondary prophylaxis for patients with frequent or severe recurrences only, not for primary prophylaxis
Cablivi	Specified treatment extension criteria to define persistent severe genetic deficiency as ADAMTS13 activity less than 10% or 10 IU/dL
Constipation Agents - Medicaid	Removed Zelnorn (obsolete), updated coverage duration for patient under 21 years of age to one year or until member reaches age 21, whichever is shortest.
Empaveli	Redefined severe disease as symptomatic hemolytic PNH with LDH greater than 1.5 time the upper limit of normal (ULN) plus one additional finding.
Enjaymo	1) Removed requirement that the person must have had a blood transfusion within the past six months as updated indication now includes those with cold agglutinin diseases that are not transfusion dependent. 2) Added exclusion criteria that use must not be for treatment of cold-induced symptoms of cold agglutinin disease as these are caused by red blood cell (RBC) agglutination not complement-mediated (Enjaymo mechanism of action).

	3) Updated documentation of successful response to therapy to also include improvement in markers of hemolysis or symptoms.
• **Erythropoiesis Stimulating Agents (ESAs)** • **ESAs - Medicare Part B**	Preoperative use in patients scheduled for cardiac surgery added as medically accepted indication as per guidance from guidelines. Criteria updated for hemoglobin levels to be drawn up to 45 days prior to initiation of therapy.
GIP/GLP-1 Receptor Agonists Step Therapy Policy	This is on hold – notification will be provided well in advance of when this will be implemented. Policy will be changed to a prior authorization instead of step therapy. This is due to a high risk for off-label use for weight loss (without diabetes diagnosis), which is a benefit exclusion for most plans.
Hemgenix	Updated criteria required for confirmation of diagnosis for Hemgenix, allowing historical diagnosis of severe hemophilia or provider attestation.
Hemlibra	Coverage duration updated to until no longer eligible with the plan upon initial authorization.
• **Hepatitis C - Direct Acting Antivirals** • **Hepatitis C - Direct Acting Antivirals - Medicaid**	Removed Viekira Pak (obsolete) and made minor edits to criteria and coverage duration.
• **Injectable Anti-Cancer Medications** • **Injectable Anti-Cancer Medications - Medicare Part B**	Updated preferred biosimilar products for trastuzumab. Kanjinti® will no longer be preferred and Trazimera® will be preferred.
Livtencity	Added exclusion of coadministration with ganciclovir or valganciclovir.
Lotronex	Removed loperamide requirement due to conflicting guideline recommendations.
Medications For Rare Indications	Age restriction updated to align with FDA-approved indication(s). Clarified criteria regarding confirmation of diagnosis and prerequisite therapy.
• **Prevymis** • **Prevymis - Medicare Part B**	Add nephrologist as prescriber option and clarified that therapy must be started within 28 days for stem cell transplants or seven days for kidney transplant. Updated kidney transplant criteria to required that patient is seronegative (if seropositive donor). Increased duration of approval to 200 days for all indications; however, for stem cell transplants the patients must have evidence of high risk for late disease.
Prophylactic Hereditary Angioedema Therapy	Clarified quantity limitation for Takhzyro.
Pyrukynd	Changed criteria to allow low hemoglobin levels OR transfusion dependence.
Reblozyl	1) Updated myelodysplastic syndrome (MDS) criteria to allow for newly approved indication, 2) Simplified diagnosis criteria for beta thalassemia, 3) Updated prescriber restrictions to hematologist / oncologist, 4) Removed exclusion criteria as not FDA labeled contraindication, 5) changed wording to allow for continuation of therapy for patients new to the health plan.
Syfovre	History of choroidal neovascularization (CNV) removed from exclusion criteria but added medical necessity criteria for patients with active CNV. Exclusion criteria updated to state exclusion criteria is pertinent to requested eye being treated.
Tavneos	Updated reauthorization coverage duration from 6 months to 12 months.

Thrombocytopenia Medications - Medicare Part B	Updated with oncologic indications criteria, updated criteria for Immune Thrombocytopenia based on CMS LCD L38268.
• **Ultomiris** • **Ultomiris - Medicare Part B**	Criteria regarding symptomatic hemolytic PNH simplified to align with the market.
Viberzi	Remove trial and failure of loperamide, add all contraindications to exclusion criteria.
Xermelo	Removed prescriber restriction.
Xifaxan	Added requirement for combination with lactulose for hepatic encephalopathy, and added requirement for azithromycin or fluoroquinolone to Traveler's Diarrhea criteria.

RETIRED	
Aemcolo	Due to low risk of inappropriate utilization
Antimalarial Agents	Due to low utilization
Dronabinol	Due to low risk of overutilization and availability of low-cost generic capsules
GIP and GLP-1 Receptor Agonists Step Therapy Policy – Medicaid	Combined with Commercial policy
Ivermectin	Due to low utilization
Mepron	Due to low risk of inappropriate utilization