PROVIDENCE Health Plan

PROVIDENCE Health Assurance

Healthcare Services Medical & Pharmacy Policy Alerts

Number 273

August 1, 2022

This is the August 1, 2022 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.

MEDICAL POLICY COMMITTEE

MEDICAL

ALL LINES OF BUSINESS

Effective 10/1/2022

COVID-19 In Vitro Testing **MP350**	**New Policy** • Creation of a medical policy on COVID-19 testing, which is based on the federal coverage mandates: FFCRA and CARES Act. • The policy considers antigen, molecular, and serologic testing for the primary *diagnosis* of COVID-19 to be medically necessary, including the 8 OTC tests allowed per month* (per FFCRA). • Antigen, molecular and serologic testing that is <u>not</u> primarily intended to diagnose COVID-19 will be considered not medically necessary. • The policy indicates high frequency COVID-19 testing is subject to a medical necessity review to ensure the testing is in-line with the federal mandates. • The policy indicates testing/billing for COVID-19 testing of friends and family members is not medically appropriate (in accordance with regulations). *Not applicable to the Medicare line of business • **OHP:** Continue to follow the Prioritized List for coverage of COVID-19 In Vitro Testing

ALL LINES OF BUSINESS EXCEPT MEDICARE

Effective 10/1/2022

Respiratory Viral Panels **(All Lines of Business Except Medicare)** **MP256**	**Policy Updates:** Policy previously based on CMS guidance, which has been retired. Additional criteria changes as follows: • Patients must be at high risk for complications of respiratory infection • Testing must be used to guide or alter management **Codes/PA:** • No changes to codes/PA. **OHP:** No impact - no changes to existing PA requirements.
Urinary Incontinence Treatments (All Line of Business Except Medicare) **MP180**	**Policy Updates:** Clarified and streamlined conservative treatments/medications for each "may be medically necessary" treatment option. Standardization of language for these conservative measures. In addition to any requirements needed for a specific treatment, each treatment option has following criteria: may be medically necessary for patients who meet all of the following criteria: • Patient's symptoms limit activities of daily living; and • Failure, intolerance, or contraindication to conservative medical management; and • Patient has failed a trial of two different classes of medications (e.g. antimuscarinic/anticholinergics and beta-3 adrenoceptor agonists), unless contraindicated. **Codes/PA:** • No recommended changes to codes/PA **OHP:** No impact - no changes to existing PA requirements.
Wheelchairs and Power Vehicles (All Lines of Business Except Medicare) **MP140**	**Policy Updates:** • Add replacement criteria consistent with DMEPOS policy • Move references to Medicare guidance to policy guidelines.

	• Consolidate list of accessories or features that would be non-covered regardless of the wheelchair type • Minor formatting and wording edits to clarify criteria, simplify text, and fit PHP formatting • Remove sections of policy and billing guidelines to simplify policy **Codes/PA:** • Add 'not medically necessary' denial to codes E0968, E0969, E0980, E2610 (based on current criteria, these are always considered not medically necessary) **OHP:** These changes do not apply to OHP. Oregon Administrative Rules will be followed in regards to Wheelchairs and Power Vehicles.

Archive

Effective 9/1/2022

Eye: Retinopathy Telescreening (All Lines of Business Except Medicare) **MP185**	**Policy Updates:** • Archive policy due to low utilization/volume. **Codes/PA:** • Remove diagnosis code configuration from 92227 and set to pay with no PA. Remove NMN denial from codes 92228 & 92229 and set to pay with no PA. **OHP:** Archive applies to OHP

MEDICARE

Effective 9/1/2022

Fecal Incontinence Treatments (Medicare Only) **MP228**	**Policy Updates:** • No changes to criteria sources/references or intent, continue to use Medicare criteria when available and Commercial criteria when no Medicare guidance exists. Updated format for Medicare Only policies. **Codes/PA:** • Remove PA from L8680 and L8685-L8688 and add t07 denial per Medicare references. *This configuration change for these codes was presented for other policies in June*
Urinary Incontinence Treatments (Medicare Only) **MP231**	**Policy Updates:** • No changes to criteria sources/references or intent, continue to use Medicare criteria when available and Commercial criteria when no Medicare guidance exists. Updated format for Medicare Only policies. **Codes/PA:** • Remove PA from L8680 and L8685-L8688 and add t07 denial per Medicare references. *This configuration change for these codes was presented for other policies in June*
Wheelchair and Power Vehicles (Medicare Only) **MP300**	**Policy Updates:** No change to criteria sources or references but added some additional rows and notes to emphasize specific situations. Also added additional information to the *Policy Guidelines* section to assist with documentation requirements, replacement requests, and non-covered items which are non-covered, but for which rationale may be less clearly called out within the Medicare references. **Codes/PA:** • Codes E0968, E0969, E0980: Add NMN denial. • Codes E0970, E0994, E1227, E1228, E1296, E1297, E1298, and E2340-E2343: Add t07 denial (separate reimbursement not warranted per medical policy). ▪ The above changes are based on Medicare (LCA A52504).

Effective 10/1/22

Cardiac: External Ambulatory Electrocardiography (Medicare Only) **MP157**	**Policy Updates:** • The current *Cardiac: External Ambulatory Electrocardiography (Medicare Only)* policy references a Wisconsin (WPS) LCD and LCA; however, WPS is not the Medicare contractor (MAC) for our service area for **Part B** services. Noridian is our Part B MAC. • Due to the Noridian LCD and LCA (for our service area) being more limited in scope, it is recommended to use Commercial medical necessity criteria for any service not addressed by the NCD or LCD, following our established hierarchy. Due to the change in coverage criteria for MCOT and that our Commercial criteria are more restrictive, we will provide 60-day provider notification for this policy change. • Update format for Medicare Only policies. **Codes/PA:** Code and configuration changes are as follows: • 0295T-0298T: No configuration changes, but since these codes were deleted more than 12 months ago, removed them from the policy entirely. • No changes to any other codes in this policy.

REIMBURSEMENT

Effective 8/1/2022

Inpatient Readmissions UM54	**Recommendation:** • Added inverse statements to indicate that when unplanned criteria are not met the two IP admissions will be paid separately. • Added language to the billing guidelines indicating that if the combined about exceeds the DRG amount then the two stays will not be combined. **No changes to reimbursement methodology.**
Facility Supplies and Routine Services UM43	**Recommendation:** • Added several additional routine supplies/services and routine nursing services to the Policy Guidelines lists, which were all identified during our medium dollar review operations work.

	• Added a section on DMEPOS to the Policy Guidelines, as well. Medicare states that DMEPOS used during a Part A covered stay for hospital inpatients are included in the payment and are not separately billable. We saw several examples of DME being billed separately during our medium dollar review work, so adding these guidelines to the policy to support denial of these items as not separately reimbursable. **No changes to reimbursement methodology—routine supplies/services remain not separately reimbursable.**

Effective 10/1/2022

Preventable Adverse Events
UM 73.0
 	
**Replaces: UM73.0, UM76.0, UM77.0, UM79.0*
	Type of Update: New/Overhauled Reimbursement Policy
	Recommendation:
	• Recommend creation of this single reimbursement policy to replace the several UM policies that exist today for never events, hospital acquired conditions (HACs), and present on admission (POA) indicators.
	• Expanding the policy to address not only never events and HACs, but also other "preventable adverse events" which are not included in CMS' defined HAC indications.
	  • In addition to the CMS defined HACs, included a list of other preventable adverse events which are subject to post-service review in accordance with the reimbursement policy. These include:
	  • Surgical error (which could not have reasonably been prevented)
	  • Surgical site infections
	  • Nosocomial infections
	  • Error in the dosing or administration of a drug
	• No recommended changes to the reimbursement methodology for Never Events and HACs. We will continue to follow CMS reimbursement methodologies for each.
	• For the additional preventable adverse events, recommend following the HAC reimbursement methodology.
	Reimbursement Methodology:
	• Never Events: not reimbursable, including all professional, facility, and any other costs associated with a never event
	  • Providers and facilities are not to request reimbursement for costs associated with never events.
	  • Confirmed that CES is set-up to deny all claims billed with a never events modifier and diagnosis code (see policy Billing Guidelines for complete list of modifiers and diagnosis codes).
	• Hospital Acquired Conditions and other preventable adverse events: not reimbursable to the higher DRG. The claim will be processed as though the HAC or preventable adverse event is not present.
	  • Confirmed that CES is set-up to process HAC diagnosis codes and POA indicators based on CMS guidelines. All claims with POA indicator and associated HAC diagnosis code will pend to QMCX for processing.
	Complete list of diagnosis codes and POA indicators is available in Policy Guidelines

VENDOR UPDATES

InterQual

The ASAM Criteria® Powered by InterQual has Undergone a Name Change

Revision Summary	Product has been renamed to The ASAM Criteria® Navigator and required the notes at the subset level to reflect this name change. No changes have been made to the criteria.

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

Pharmacy & Therapeutics (P&T) Committee

Oregon Region P&T Committee Meeting June 3, 2022
Go-Live Date: Monday, August 01, 2022, unless otherwise noted

Special Reminders (information shared in prior medical policy alerts):

Pneumococcal Vaccinations

Based on the updated recommendations from the Advisory Committee on Immunization Practices (ACIP) for use of pneumococcal vaccinations, the following changes to coverage of these vaccines will be **effective 7/1/2022**:

- PCV15 (Vaxenuvance®) and PCV20 (Prevnar 20®) will be covered for one dose for adult patients. These vaccines are not be covered for patients less than 19 years of age.
- PCV13 (Prevnar 13®) will not be covered for patients over 19 years of age.
- PPSV23 (Pneumovax®) will require prior authorization for all patients. This vaccine will only be covered if the patient has a previous vaccination history with PCV15 or PCV13 while an adult. Second doses of PPSV23 may be covered subject to review

Self-Administered Drug Exclusions

- Some medications are injected into the body (IM and SC) by either a healthcare provider or directly by the patient or their caregiver
- There are benefits to requiring self-administration of some of these drugs including lower drug costs, lower administrative costs, convenience for patients, and on-going patient support through our specialty pharmacy providers. These types of drugs are added to a self-administered drug (SAD) exclusion list.
- A drug in the corresponding line of business SADs Exclusion List will be covered under the medical benefit for the initial 60-day treatment period to allow for proper healthcare provider training of self-administration and monitoring for adverse events. After the 60-day initial period, the drug will not be covered under the medical benefit ("incident-to" a healthcare provider visit), unless approved for on-going coverage.
- **Effective 8/1/2022** the following drugs will be added to the SADs exclusion list:
  - Stelara® syringe
  - Orencia® syringe and auto-injector
  - Fasenra® syringe and auto-injector (Pen)
  - Nucala® syringe and auto-injector
  - Actemra® syringe and auto-injector
  - Benlysta® subcutaneous administration with syringe and auto-injector

Infusion therapy Site of Care

- Drugs have been added to the Infusion therapy Site of Care policy
- **Effective 8/1/2022**, the following drugs will be required to be administered at an approved site of care unless and authorization has been granted for continued administration at an unapproved site of care:
  - Immune gamma globulin products (Asceniv®, Hyqvia®, Panzyga®, Cutaquig®)
  - Enzyme replacement therapies (Fabrazyme®, Lumizyme®, Nexviazyme®, Elaprase®, Mepsevii®, Vimizim®, Aldurazyme®)
    - For new starts only on enzyme replacement therapies- a longer transition time will be allowed to an approved site of care due to concerns for anaphylactic reactions
  - Denosumab (Prolia®, Xgeva®)
  - Radicava®
  - Onpattro®
  - Alpha-1 protenase inhibitos (Aralast NP®, Prolastin®, Zemaira®)
  - Tepezza®

- The most up-to-date list of approved site-of-care facilities/providers can be found at: https://www.providencehealthplan.com/-/media/providence/website/pdfs/providers/medical-policy-and-provider-information/pharmacy-policy/approved-site-of-care-facility-list.pdf

Table of Contents:

New Drugs and Combinations:

1. **Faricimab-svoa (Vabysmo®) Vial**
   a. **Indication**: For the treatment of patients with neovascular (wet) age-related macular degeneration (nAMD) and indicated for the treatment of patients with diabetic macular edema (DME)
   b. **Decision**:

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

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

PA PROGRAM NAME	Ophthalmic Vascular Endothelial Growth Factor (VEGF) Inhibitors
MEDICATION NAME	Beovu, Lucentis, Susvimo, Vabysmo
PA INDICATION INDICATOR	1 - All FDA-Approved Indications not otherwise excluded from the benefit
OFF-LABEL USES	N/A
EXCLUSION CRITERIA	N/A
REQUIRED MEDICAL INFORMATION	For **initiation of therapy** with the requested medication (new start): Must have one of the following diagnoses and meet any required criteria: a. **<u>Neovascular (wet) age-related macular degeneration (AMD):</u>** i. For ranibizumab (Lucentis®), faricimab (Vabysmo®) and brolucizumab (Beovu®): 1. Documentation that bevacizumab has been ineffective, not tolerated, or contraindicated or rationale is provided why therapy is not appropriate for the patient, AND 2. Documentation that aflibercept (Eylea®) or ranibizumab-nuna (Byooviz®) has been ineffective, not tolerated, or contraindicated or rationale is provided why therapy is not appropriate for the patient ii. For ranibizumab (Susvimo®): 1. Documentation that bevacizumab and aflibercept (Eylea®) have been ineffective, not tolerated, or contraindicated or rationale is provided why therapy is not appropriate for the patient, AND 2. Documentation of previous response to at least two intravitreal injections of ranibizumab (Lucentis®) or ranibizumab-nuna (Byooviz®), AND 3. Documentation that increased risk of endophthalmitis associated with ranibizumab (Susvimo®) implant has been discussed with the patient b. **<u>Diabetic macular edema or Diabetic retinopathy:</u>** i. For ranibizumab (Lucentis®) or faricimab (Vabysmo®): 1. Documentation that bevacizumab has been ineffective, not tolerated/contraindicated, or medical rationale is provided why therapy is not appropriate for member, AND 2. Documentation that aflibercept (Eylea®) or ranibizumab-nuna (Byooviz®) has been ineffective, not tolerated/contraindicated, or medical rationale is provided why therapy is not appropriate for member c. **<u>Macular edema following retinal vein occlusion:</u>** i. For ranibizumab (Lucentis®): 1. Documentation that bevacizumab has been ineffective, not tolerated/ contraindicated, or rationale is provided why therapy is not appropriate for the patient, AND

	2. Documentation that aflibercept (Eylea®) or ranibizumab-nuna (Byooviz®) has been ineffective, not tolerated/ contraindicated, or rationale is provided why therapy is not appropriate for the patient d. **Myopic Choroidal Neovascularization (mCNV):** i. For ranibizumab (Lucentis®): Documentation that ranibizumab-nuna (Byooviz®) has been ineffective, not tolerated, or contraindicated or rationale is provided why therapy with ranibizumab-nuna (Byooviz®) is not appropriate for the patient For **patients established on therapy** with the requested agent (within the previous year): Documentation of positive response to therapy (such as stabilization or improvement in vision)
AGE RESTRICTIONS	N/A
PRESCRIBER RESTRICTIONS	Must be prescribed and administered by an ophthalmologist or retinal specialist
COVERAGE DURATION	Authorization will be approved until no longer eligible with the plan, subject to formulary or benefit changes
QUANTITY LIMITS	Approval may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines and are subject to medical claims audits. (See Table 1 for dosing guidelines)

2. **Tebentafusp-tebn (Kimmtrak) Vial**
   a. **Indication**: For the treatment of HLA-A*02:01-positive adult patients with unresectable or metastatic uveal melanoma
   b. **Decision**:

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

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

3. **Ciltacabtagene autoleucel (Carvykti) Plast. Bag**
   a. **Indication**: For the treatment of adult patients with relapsed or refractory multiple myeloma, after four or more 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			
* 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: Blenrep (medical), Abecma (medical)			

   c. **Prior Authorization Criteria for Commercial/Medicaid/Medicare Part B**: Added to CAR-T policy

4. **Pacritinib citrate (Vonjo) Capsule**
   a. **Indication**: For the treatment of adults with intermediate or high-risk primary or secondary (post-polycythemia vera or post-essential thrombocythemia) myelofibrosis (MF) with a platelet count below 50 × 10^9/L
   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	4 tablets/day	4 tablets/day	4 tablets/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: Jakafi® (ruxolitinib), Inrebic® (fedratinib), hydroxyurea, peginterferon alpha-2a

c. **Prior Authorization Criteria for Commercial/Medicaid**: Added to Antineoplastics Agents Oral Anti-Cancer Medications policy
   - Allowing for prescriber of hematologist for this medication

d. **Prior Authorization Criteria for Medicare Part D**: Added to Anti-Cancer Agents program

5. **Nivolumab-Relatlimab-rmbw (Opdualag) Vial**
   a. **Indication**: For the treatment of adult and pediatric patients 12 years of age or older with untestable or metastatic melanoma
   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: Pembrolizumab (Keytruda), nivolumab (Opdivo), ipilimumab (Yervoy)			

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

6. **Tezepelumab-ekko (Tezspire) Syringe**
   a. **Indication**: For the add-on maintenance treatment of adult and pediatric patients aged 12 years and older with severe asthma
   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: Other biologics for asthma, although most are limited to use in allergic asthma: omalizumab (Xolair®), mepolizumab (Nucala®), benralizumab (Fasenra®), reslizumab (Cinqair®), dupilumab (Dupixent®)

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

PA PROGRAM NAME	Tezspire
MEDICATION NAME	Tezepelumab-ekko 210 mg subcutaneous injection
PA INDICATION INDICATOR	1 - All FDA-Approved Indications
OFF-LABEL USES	N/A
EXCLUSION CRITERIA	Concurrent use with another therapeutic immunomodulator agent utilized for the same indication
REQUIRED MEDICAL INFORMATION	1. For patients initiating therapy, all the following criteria must be met: a. Documentation of treatment with maximally tolerated high-dose inhaled corticosteroid plus an inhaled long-acting beta-2 agonist and has been adherent to therapy in the past three months (*this may be verified by pharmacy claims information*), b. Documentation of severe asthma with inadequate asthma control despite above therapy, defined as one of the following i. Asthma Control Questionnaire (ACQ) score greater than equal to 1.5, ii. At least two asthma exacerbations require oral corticosteroids for at least three days in last 12 months, iii. At least one asthma exacerbation requiring hospitalization, emergency room or urgent care visit c. For patients with eosinophilic asthma or steroid -dependent asthma: Documented trial and failure, intolerance, or contraindication to therapy with dupilumab (Dupixent®)
AGE RESTRICTIONS	12 years of age and older
PRESCRIBER RESTRICTIONS	Must be prescribed by or in consultation with an asthma specialist (such as a pulmonologist, immunologist, or allergist)
COVERAGE DURATION	Authorization will be approved until no longer eligible with the plan, subject to formulary and/or benefit changes

7. **Levoketoconazole (Recorlev) Tablet**
   a. **Indication**: For the treatment of endogenous hypercortisolemia in adult patients with Cushing's syndrome for whom surgery is not an option or has not been curative
   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	8 tablets per day	8 tablets per day	FDA MAX: 8 tablets per day
* Recommendations for placement may differ between lines of business due to regulatory requirements. ** Medications will be placed on recommended tier above for the base formulary; tier placement for custom formulary(ies) will be based on designation above. For example, Commercial Tier 6 designation above means that the medication will be placed on the highest cost-sharing tier on the respective formulary(ies).			
Formulary Alternatives: ketoconazole			

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

PA PROGRAM NAME	Pituitary Disorder Therapies
MEDICATION NAME	Recorlev
PA INDICATION INDICATOR	4 - All FDA-Approved Indications, Some Medically-Accepted Indications
OFF-LABEL USES	N/A
EXCLUSION CRITERIA	N/A
REQUIRED MEDICAL INFORMATION	For initiation of therapy, must meet indication-specific criteria below: **Criteria listed are only for Cushing's syndrome, other criteria in the policy will remain the same. For Cushing's syndrome, levoketoconazole may be covered if all the following criteria are met: 1. Diagnosis of endogenous Cushing's syndrome 2. Documentation that patient is not a candidate for surgery, or previous surgery has not been curative 3. Documentation of baseline urinary free cortisol 4. Documentation of baseline liver enzyme function tests 5. Documentation of adequate trial and failure of oral ketoconazole, defined as minimal to no improvement in urinary free cortisol concentrations after at least three months of therapy

	For patients established on therapy, documentation of a positive clinical response must be provided. Appropriate documentation may include: • For acromegaly, a reduction or normalization of IGF-1/GH level for same age and sex or reduction in tumor size • For Cushing's syndrome, documentation of positive response to therapy, evidenced by a decrease in urinary free cortisol from baseline • For Cushing's disease, clinically meaningful reduction and maintenance in late-night salivary cortisol or 24-hour urinary free cortisol levels, or improvement in signs or symptoms of the disease • For diarrhea, an improvement in the number of diarrhea episodes • For carcinoid tumors, an improvement in the number of diarrhea and flushing episodes
AGE RESTRICTIONS	N/A
PRESCRIBER RESTRICTIONS	N/A
COVERAGE DURATION	Initial authorization and reauthorization will be approved for one year.

8. **Sutimlimab-jome (Enjaymo) Vial**
   a. **Indication**: For adult patients, with cold agglutinin disease, to decrease the need for red blood cell transfusions
   b. **Decision**:

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

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

PA PROGRAM NAME	Enjaymo
MEDICATION NAME	Sutimlimab injection

PA INDICATION INDICATOR	1 - All FDA-Approved Indications
EXCLUSION CRITERIA	N/A
REQUIRED MEDICAL INFORMATION	For initiation of therapy (new start), all the following must be met: 1. Diagnosis of primary cold agglutinin disease (CAD) by all the following: a. Chronic hemolysis b. Positive direct antiglobulin (Coombs) test for C3d c. Cold agglutinin titer of 1:64 or higher at 4 degrees Celsius d. Presence of one or more symptom associated with CAD such as symptomatic anemia, acrocyanosis, Raynaud's phenomenon, hemoglobinuria 2. History of blood transfusion within the previous six months 3. Hemoglobin of 10 g/dL or less 4. Dose and frequency are in accordance with FDA-approved labeling For patients established on therapy, all the following must be met: 1. Diagnosis of cold agglutinin disease 2. Documentation of successful response to therapy defined as an increase in hemoglobin level or reduced transfusion requirements 3. 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 hematologist or an oncologist
COVERAGE DURATION	Initial authorization will be approved for six months. Reauthorization will be approved for a year

9. **Mitapivat sulfate (Pyrukynd) Tab DS PK**
   a. **Indication**: For the treatment of hemolytic anemia in adults with pyruvate kinase (PK) deficiency
   b. **Decision**:

	Commercial	Medicaid	Medicare
Formulary Status*	Formulary	Formulary	Part D: Formulary Part B: N/A
Tier**	Tier 5 - 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	2 tablets per day	2 tablets per day	2 tablets per day
* Recommendations for placement may differ between lines of business due to regulatory requirements.			

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

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

PA PROGRAM NAME	Mitapivat (Pyrukynd®)
MEDICATION NAME	Pyrukynd® tablet
PA INDICATION INDICATOR	1 - All FDA-Approved Indications
OFF-LABEL USES	N/A
EXCLUSION CRITERIA	None
REQUIRED MEDICAL INFORMATION	For initial authorization, the following criteria must be met: 1. Diagnosis of pyruvate kinase deficiency (PKD) (ICD-10 d55.21). Must include evidence supporting diagnosis, such as: a. Documentation of markers of chronic hemolytic anemia (such as low hemoglobin, low haptoglobin, elevated bilirubin, and elevated reticulocytes) and evidence of family history of PKD), **OR** b. Documentation of pyruvate kinase enzyme activity below the lower limit of normal per the laboratory standard (actual laboratory results must be included), **OR** c. Documentation of at least two mutant alleles in the *PKLR* gene 2. Hemoglobin less than or equal to 10 mg/dL taken within the previous three months For reauthorization, ONE of the following criteria must be met: 1. Increase in hemoglobin (Hb) of at least 1.5 mg/dL from pre-treatment level **OR** 2. Documentation of a reduction in transfusion burden from prior to treatment
AGE RESTRICTIONS	18 years or older
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 for one year.

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

PA PROGRAM NAME	Mitapivat (Pyrukynd®)
MEDICATION NAME	Pyrukynd® tablet

PA INDICATION INDICATOR	1 - All FDA-Approved Indications
OFF-LABEL USES	N/A
EXCLUSION CRITERIA	None
REQUIRED MEDICAL INFORMATION	For initial authorization, the following criteria must be met: 1. Diagnosis of pyruvate kinase deficiency (PKD) (ICD-10 d55.21). Must include evidence supporting diagnosis, such as: a. Documentation of markers of chronic hemolytic anemia (such as low hemoglobin, low haptoglobin, elevated bilirubin, and elevated reticulocytes) and evidence of family history of PKD), **OR** b. Documentation of pyruvate kinase enzyme activity below the lower limit of normal per the laboratory standard (actual laboratory results must be included), **OR** c. Documentation of at least two mutant alleles in the *PKLR* gene 2. Hemoglobin less than or equal to 10 mg/dL taken within the previous three months For reauthorization, ONE of the following criteria must be met: 1. Increase in hemoglobin (Hb) of at least 1.5 mg/dL from pre-treatment level **OR** 2. Documentation of a reduction in transfusion burden from prior to treatment
AGE RESTRICTIONS	18 years or older
PRESCRIBER RESTRICTIONS	Must be prescribed by, or in consultation with, a hematologist
COVERAGE DURATION	Initial authorization for six months, reauthorization for one year.

10. **Plasminogen, human-tvmh (Ryplazim) Vial**
    a. **Indication**: For the treatment of patients with plasminogen deficiency (PLGD) type 1 (hypoplasminogenemia)
    b. **Decision**:

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

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

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

PA PROGRAM NAME	Ryplazim
MEDICATION NAME	Plasminogen, human-tvmh (Ryplazim®) vial
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. Diagnosis of plasminogen deficiency type 1 confirmed by one of the following: a. Genetic testing (biallelic pathogenic variants in PLG gene), or b. Confirmed hypoplasminogenemia (reduced plasminogen protein levels and functional activity) 2. Documentation of plasminogen activity level of 45% or lower of laboratory standard within the previous six months 3. Documentation of clinical signs and symptoms of the disease (such as ligneous conjunctivitis, gingivitis, tonsillitis, abnormal wound healing) For initial reauthorization, the following criteria must be met: 1. Documented positive response to therapy, defined as improvement in lesion number/size or improved function from baseline For subsequent reauthorization, the following criteria must be met: 1. Documentation of no new or recurring lesions 2. Documentation that trough plasminogen activity levels are maintained at least 10% above baseline trough levels (indicating absence of anti-plasminogen antibodies)
AGE RESTRICTIONS	N/A
PRESCRIBER RESTRICTIONS	Must be prescribed by, or in consultation with, a geneticist, hematologist, pulmonologist, ophthalmologist, and/or pediatric subspecialist
COVERAGE DURATION	Initial authorization and reauthorization will be approved for six months.

11. **Thymus tissue-agdc (Rethymic)**
    a. **Indication**: For immune reconstitution in pediatric patients with congenital athymia
        - Limitations of Use: Allogenic processed thymus tissue is not indicated for the treatment of patients with severe combined immunodeficiency (SCID)
    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	42 slices (~55,000 mm^2)	42 slices (~55,000 mm^2)	42 slices (~55,000 mm^2)
* Recommendations for placement may differ between lines of business due to regulatory requirements. ** Medications will be placed on recommended tier above for the base formulary; tier placement for custom formulary(ies) will be based on designation above. For example, Commercial Tier 6 designation above means that the medication will be placed on the highest cost-sharing tier on the respective formulary(ies).			
Formulary Alternatives: N/A			

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

PA PROGRAM NAME	Rethymic
MEDICATION NAME	Allogenic processed thymus tissue-agdc implant (Rethymic®)
PA INDICATION INDICATOR	1 - All FDA-Approved Indications
OFF-LABEL USES	N/A
EXCLUSION CRITERIA	• Patients with severe combined immunodeficiency (SCID) • Patients with heart surgery anticipated within four weeks prior to, or three months after, treatment • Patients with pre-existing cytomegalovirus (CMV) infection or human immunodeficiency virus (HIV) infection • Repeat administration of allogenic processed thymus tissue implant or previous history of thymus transplant • Patients over 18 years of age
REQUIRED MEDICAL INFORMATION	For authorization of a one-time implant, all the following must be met: 1. Diagnosis of congenital athymia confirmed by all the following criteria:

	a. Absence of genetic markers of severe combined immunodeficiency (SCID) b. Flow cytometry, defined as one of the following: i. Less than 50 naïve T cells/mm3 in the peripheral blood ii. Less than 5% of total T cells being naïve in phenotype c. One of the following: i. Genetic defect associated with congenital athymia [such as 22q11.2 deletion syndrome, forkhead box protein N1 (FOXN1) deficiency] ii. CHARGE syndrome 2. Documentation that infection control measures, including immunoprophylaxis, will be maintained until thymic function is established (immune reconstitution sufficient to protect from infection is unlikely to develop until 6-12 months after treatment) 3. Attestation from provider of absence of comorbidities, in the opinion of the treating clinician, that are reasonably likely to result in severe complications, including death, from administration of allogeneic processed thymus tissue 4. Dose will not exceed 42 slices
AGE RESTRICTIONS	N/A
PRESCRIBER RESTRICTIONS	Must be prescribed by, or in consultation with, a pediatric immunologist.
COVERAGE DURATION	Authorization will be for one dose per lifetime. Repeat administration will not be covered

12. **Tick-borne encephallitis vaccine (Ticovac) Syringe**
    a. **Indication**: For active immunization to prevent tick-borne encephalitis. Ticovac® is approved for use in individuals 1 year of age and older
    b. **Decision**:

	Commercial	Medicaid	Medicare
Formulary Status*	Medical	Medical	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	Covered only for groups with a travel benefit	N/A	N/A
Quantity Limit	4 doses per lifetime	4 doses per lifetime	4 doses per lifetime
* Recommendations for placement may differ between lines of business due to regulatory requirements.			

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

New Indications:

Therapies with Prior Authorization Policies (Non-oncology)

1. **XIGDUO XR® (**dapagliflozin and metformin HCl extended-release)
    a. Previous Indication(s):
        a. indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus.
        b. Dapagliflozin is indicated in adults with type 2 diabetes mellitus to reduce the risk of hospitalization for heart failure in adults with type 2 diabetes mellitus and established cardiovascular disease or multiple cardiovascular risk factors.
    b. New indication approved 02/03/2022:
        a. Dapagliflozin is indicated to reduce: the risk of cardiovascular death and hospitalization for heart failure in adults with heart failure (NYHA class II-IV) with reduced ejection fraction
    c. **RECOMMENDATION:** Inform prescribers via Medical Policy Alert. Policy was reviewed for April P&T, no updates to criteria warranted.

2. **CABENUVA® (**cabotegravir and rilpivirine extended-release injectable suspension;)
    a. Previous Indication(s):
        a. indicated as a complete regimen for the treatment of HIV-1 infection in adults to replace the current antiretroviral regimen in those who are virologically suppressed (HIV-1 RNA <50 copies/mL) on a stable antiretroviral regimen with no history of treatment failure and with no known or suspected resistance to either cabotegravir or rilpivirine
    b. New indication approved 03/29/2022:
        a. indicated as a complete regimen for the treatment of HIV-1 infection in adults and adolescents 12 years of age and older and weighing at least 35 kg to replace the current antiretroviral regimen in those who are virologically suppressed (HIV-1 RNA <50 copies/mL) on a stable antiretroviral regimen with no history of treatment failure and with no known or suspected resistance to either cabotegravir or rilpivirine
    c. **RECOMMENDATION:** Inform prescribers via Medical Policy Alert and update prior authorization criteria for Commercial, Medicaid, and Medicare Part B as outlined below.
        Prior Authorization for Commercial/Medicaid/Medicare Part B:

PA PROGRAM NAME	Cabenuva
MEDICATION NAME	Cabenuva
COVERED USES	1 - All FDA-Approved Indications

EXCLUSION CRITERIA	N/A
REQUIRED MEDICAL INFORMATION	For new starts: 1. Patient must have a confirmed diagnosis of human immunodeficiency virus type -1 (HIV-1) 2. Patient has been stable and adherent with their current antiviral regimen for a minimum of six months (adherence may be confirmed by pharmacy claims) 3. Patient has a recent viral HIV-1 RNA of less than 50 copies/mL on current oral antiviral regimen 4. Documentation that patient does not have a history of treatment failure For continuation of therapy: 1. Documentation that patient has been adherent with therapy 2. Documentation that patient has maintained a viral HIV-1 RNA of less than 50 copies/mL
AGE RESTRICTIONS	May be approved for patients aged 12 years and older

3. **JARDIANCE® (**empagliflozin)
    a. Previous Indication(s):
        a. As an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus
        b. To reduce the risk of cardiovascular death in adults with type 2 diabetes mellitus and established cardiovascular disease
        c. To reduce the risk of cardiovascular death plus hospitalization for heart failure in adults with heart failure and reduced ejection fraction
    b. New indication approved 02/24/2022
        a. To reduce the risk of cardiovascular death and hospitalization for heart failure in adults with heart failure
    c. **RECOMMENDATION:** Inform prescribers via Medical Policy Alert and update prior authorization criteria for Medicaid as outlined below:
        Prior Authorization for Medicaid:

PA PROGRAM NAME	SGLT-2 inhibitors
MEDICATION NAME	Jardiance
COVERED USES	1 - All FDA-Approved Indications

REQUIRED MEDICAL INFORMATION	For **heart failure** (with or without diabetes), dapagliflozin and empagliflozin may be covered if the following criteria are met: 1. For dapagliflozin only: a. Documented diagnosis of heart failure with reduced ejection fraction (HFrEF) with New York Heart Association (NYHA) functional class II-IV b. Documented left ventricular ejection fraction of less than or equal to 40% that has been present for at least two (2) months 2. For empagliflozin only: a. Documented diagnosis of heart failure with New York Heart Association (NYHA) functional class II-IV

4. **RINVOQ® (**upadacitinib)
    a. Previous Indication(s):
        a. Adults with moderately to severely active rheumatoid arthritis who have had an inadequate response or intolerance to one or more TNF blockers
        b. Adults with active psoriatic arthritis who have had an inadequate response or intolerance to one or more TNF blockers
        c. Adults and pediatric patients 12 years of age and older with refractory, moderate to severe atopic dermatitis whose disease is not adequately controlled with other systemic drug products, including biologics, or when use of those therapies are inadvisable.
    b. New indication approved 03/16/2022:
        a. Adults with moderately to severely active ulcerative colitis who have had an inadequate response or intolerance to one or more TNF blockers
    c. **RECOMMENDATION:** Inform prescribers via Medical Policy Alert. Prior authorization policy for Commercial was updated by chair vote and included with the June 2022 P&T meeting materials. No updates to Medicaid or Medicare part D criteria warranted.

5. **SMOFLIPID® (**lipid injectable emulsion)
    a. Previous Indication(s):
        a. in adults as a source of calories and essential fatty acids for parenteral nutrition when oral or enteral nutrition is not possible, insufficient, or contraindicated
    b. New indication approved 03/22/2022:

a. in adult and pediatric patients, including term and preterm neonates, as a source of calories and essential fatty acids for parenteral nutrition when oral or enteral nutrition is not possible, insufficient, or contraindicated

c. **RECOMMENDATION:** Inform prescribers via Medical Policy Alert and no updates to criteria warranted.

6. **FINTEPLA® (**fenfluramine)
   a. Previous Indication(s):
      a. for the treatment of seizures associated with Dravet syndrome in patients 2 years of age and older
   b. New indication approved 03/25/2022:
      a. for the treatment of seizures associated with Dravet syndrome and Lennox-Gastaut syndrome in patients 2 years of age and older
   c. **RECOMMENDATION:** Inform prescribers via Medical Policy Alert. Other recommendations may include:
      - Update policy with new indication
      - Update policy with new indication and add new criteria
      - Other change of clinical significance (discretionary)
      - If no policy- be sure to review with preceptor about whether to add a policy

      Prior Authorization for Commercial/Medicaid/Medicare Part B:

PA PROGRAM NAME	Fintepla
MEDICATION NAME	Fintepla
COVERED USES	1 - All FDA-Approved Indications
REQUIRED MEDICAL INFORMATION	For New Starts: 1. Documentation that the patient has one of the following: a. seizures associated with Dravet syndrome (DS) b. seizures associated with Lennox-Gastaut syndrome (LGS) 2. Documented trial, failure, intolerance, or contraindication to two of the following: a. For DS: Clobazam, valproate/valproic acid, or topiramate b. For LGS: lamotrigine, valproate/valproic acid, topiramate, or rufinamide For Patients Established on therapy: Documentation of positive response to therapy such as a decrease in seizure frequency or intensity since beginning therapy

Prior Authorization for Medicare Part D:

PA PROGRAM NAME	Fintepla
MEDICATION NAME	Fintepla
PA INDICATION INDICATOR	3 - All Medically-Accepted Indications
REQUIRED MEDICAL INFORMATION	Initial authorization: 1. Documentation that patient has one of the following: a. Seizure associated with Dravet syndrome (DS) b. Seizure associated with Lennox-Gastaut syndrome (LGS) 2. Documented trial, failure, intolerance, or contraindication to one of the following: a. For DS: clobazam, valproate/valproic acid, topiramate b. For LGS: lamotrigine, valproate/valproic acid, topiramate, or rufinamide

Therapies with Prior Authorization Policies (Oncology)

7. **KEYTRUDA® (**pembrolizumab)
   a. New indication(s) approved 03/21/22:
      i. Endometrial carcinoma: as a single agent, for the treatment of patients with advanced endometrial carcinoma that is MSI-H or dMMR, as determined by an FDA-approved test, who have disease progression following prior systemic therapy in any setting and are not candidates for curative surgery or radiation

   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.

8. **OPDIVO® (**nivolumab)
   a. New indication(s) approved 03/04/2022:
      i. Non-small cell lung cancer (NSCLC): adult patients with resectable (tumors ≥4 cm or node positive) non-small cell lung cancer in the neoadjuvant setting, in combination with platinum-doublet chemotherapy
   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. **LYNPARZA® (**olaparib)
   a. New indication(s) approved 03/11/2022:

i. for the adjuvant treatment of adult patients with deleterious or suspected deleterious gBRCAm human epidermal growth factor receptor 2 (HER2)-negative high risk early breast cancer who have been treated with neoadjuvant or adjuvant chemotherapy. Select patients for therapy based on an FDA-approved companion diagnostic for Lynparza

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

Therapies Without Prior Authorization Policies

10. **VOCABRIA® (**cabotegravir)
    a. Previous Indication(s):
        i. HIV-1 Treatment: In combination with EDURANT (rilpivirine) for short-term treatment of HIV-1 infection in adults who are virologically suppressed (HIV-1 RNA < 50 copies/mL) on a stable antiretroviral regimen with no history of treatment failure and with no known or suspected resistance to either cabotegravir or rilpivirine
        ii. HIV-1 Pre-exposure Prophylaxis: Indicated in at-risk adults and adolescents weighing at least 35 kg for short-term pre-exposure prophylaxis (PrEP) to reduce the risk of sexually acquired HIV-1 infection. Individuals must have a negative HIV-1 test prior to initiating VOCABRIA for HIV-1 PrEP
        iii. Vocabria may be used as:
            1. oral lead-in to assess the tolerability of cabotegravir prior to administration of CABENUVA (cabotegravir extended-release injectable or suspension; rilpivirine extended-release injectable suspension) for HIV-1 treatment or APRETUDE (cabotegravir extended-release injectable suspension) for HIV-1 PrEP
            2. oral therapy for patients who will miss planned injection dosing with CABENUVA for HIV-1 treatment or APRETUDE for HIV-1 PrEP
    b. New indication(s) approved 03/29/2022:
        iv. HIV-1 Treatment: in combination with EDURANT (rilpivirine) for short-term treatment of HIV-1 infection in adults and adolescents 12 years of age and older and weighing at least 35 kg who are virologically suppressed (HIV-1 RNA < 50 copies/mL) on a stable antiretroviral regimen with no history of treatment failure and with no known or suspected resistance to either cabotegravir or rilpivirine
    c. **RECOMMENDATION:** Inform prescribers via Medical Policy Alert.

11. **Methotrexate Injection**
    a. Previous Indication(s):
        i. adults and pediatric patients with acute lymphoblastic leukemia (ALL) as part of a combination chemotherapy regimen
        ii. adults with relapsed or refractory non-Hodgkin lymphoma as part of a combination chemotherapy regimen
        iii. adults and pediatric patients with Burkitt lymphoma as part of a combination chemotherapy regimen
        iv. adult and pediatric patients with osteosarcoma as part of a combination chemotherapy regimen
    b. New indication(s) approved 03/10/2022:
        v. adult and pediatric patients with non-Hodgkin lymphoma
    c. **RECOMMENDATION:** Inform prescribers via Medical Policy Alert.

12. **EDURANT® (**rilpivirine)
    a. Previous Indication(s):
        i. in combination with other antiretroviral agents for the treatment of HIV-1 infection in treatment-naïve patients 12 years of age and older and weighing at least 35 kg with HIV-1 RNA less than or equal to 100,000 copies/mL
        ii. indicated in combination with VOCABRIA (cabotegravir), for short-term treatment of HIV-1 infection in adults who are virologically suppressed (HIV-1 RNA less than 50 copies/mL) on a stable regimen with no history of treatment failure and with no known or suspected resistance to either cabotegravir or rilpivirine
    b. New indication(s) approved 03/29/2022:
        iii. indicated in combination with VOCABRIA (cabotegravir), for short-term treatment of HIV-1 infection in adults and adolescents 12 years and older and weighing at least 35 kg who are virologically suppressed (HIV-1 RNA less than 50 copies/mL) on a stable regimen with no history of treatment failure and with no known or suspected resistance to either cabotegravir or rilpivirine
    c. **RECOMMENDATION:** Inform prescribers via Medical Policy Alert.

13. **TRIUMEQ/TRIUMEQ PD ® (**abacavir, dolutegravir, lamivudine)
    a. Previous Indication(s):
        i. indicated for the treatment of HIV-1 infection in adults and in pediatric patients weighing at least 40 kg
    b. New indication(s) approved 03/30/2022:
        i. indicated for the treatment of HIV-1 infection in adults and in pediatric patients weighing at least 10 kg
    c. **RECOMMENDATION:** Inform prescribers via Medical Policy Alert.

<u>Therapies With Indication(s) Removed</u>

14. **KEYTRUDA® (**pembrolizumab)
    a. Indication(s) removed 02/04/2022:
        i. Gastric cancer: as a single agent for the treatment of patients with recurrent locally advanced or metastatic gastric or GEJ adenocarcinoma whose tumors express PD-L1 (CPS ≥1) as determined by an FDA-approved test, with disease progression on or after 2 or more prior lines of therapy including fluoropyrimidine- and platinum-containing chemotherapy and if appropriate, HER2/neu-targeted 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.

15. **ZYDELIG® (**idelalisib)
    a. Indication(s) removed 02/18/2022:
        i. Relapsed follicular B-cell non-Hodgkin lymphoma (FL) in patients who have received at least two prior systemic therapies.

ii. Relapsed small lymphocytic lymphoma (SLL) in patients who have received at least two prior systemic therapies.

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.

16. **Methotrexate Injection**
    a. Indication(s) removed 03/10/2022:
        i. adults and pediatric patients with Burkitt lymphoma as part of a combination chemotherapy regimen
    b. **RECOMMENDATION:** Inform prescribers via Medical Policy Alert. No updates to policy are warranted.

Drug Safety Monitoring:

FDA Drug Safety Communications

1. **Drug Name:** Umbralisib (Ukoniq®)
    - **Date Posted:** 2-3-2022
    - **Safety Alert Title:** FDA investigating possible increased risk of death with lymphoma medicine Ukoniq (umbralisib)
    - **Link to more information:** https://www.fda.gov/drugs/development-approval-process-drugs/fda-investigating-possible-increased-risk-death-lymphoma-medicine-ukoniq-umbralisib
    - **What safety concern is FDA announcing?**
        - The U.S. Food and Drug Administration (FDA) is investigating a possible increased risk of death with the cancer medicine Ukoniq (umbralisib) approved to treat two specific types of lymphomas, which are cancers that affect the body's immune system. We determined that initial findings from a clinical trial evaluating Ukoniq to treat a related type of cancer found a possible increased risk of death in patients taking the medicine. Because of the seriousness of this safety concern and the similarities between the two types of cancer for which this drug is approved and the type of cancer that was studied in the clinical trial, we are alerting patients and health care professionals that we are re-evaluating this risk against the benefits of Ukoniq for its approved uses
    - **What is FDA doing?**
        - We are continuing to evaluate the results from the clinical trial called UNITY. FDA may also hold a future public meeting to discuss these findings and explore the continued marketing of Ukoniq. We have also suspended enrollment of new patients in other ongoing clinical trials of Ukoniq while we continue to review the UNITY findings. We will communicate our final conclusions and recommendations when we have completed our review or have more information to share
    - **What should health care professionals do?**
        - Health care professionals should review patients' progress on Ukoniq and discuss with them the risks and benefits of continuing Ukoniq in the context of other available treatments.
    - **Health Plan Recommendation:** Notify providers via Medical Policy Alert.

2. **Drug Name:** Iodine-containing contrast media
    - **Date Posted:** 3-30-2022
    - **Safety Alert Title:** FDA recommends thyroid monitoring in babies and young children who receive injections of iodine-containing contrast media for medical imaging
    - **Link to more information:** https://www.fda.gov/drugs/drug-safety-and-availability/fda-recommends-thyroid-monitoring-babies-and-young-children-who-receive-injections-iodine-containing
    - **What safety concern is FDA announcing?**
        - Based on our recent review of published studies, the U.S. Food and Drug Administration (FDA) is recommending that newborns and children through 3 years old have follow-up thyroid monitoring within 3 weeks after receiving injections of contrast media containing iodine, also called "contrast dye," for X-rays and other medical imaging procedures. Our review showed that underactive thyroid or a temporary decrease in thyroid hormone levels were uncommon. However, the conditions should be identified and treated early when needed to prevent potential future complications. Newborns, particularly those born premature, and children in their first 3 years with underlying conditions such as heart issues may be at higher risk for problems of the thyroid, a gland in the neck that releases hormones that help control many of the body's functions.
    - **What is FDA doing?**
        - We have approved a new warning to the prescribing information for the entire class of iodinated contrast media (ICM) injections and monitoring recommendations for children 3 years or younger. The warning describes the risk of underactive thyroid or a temporary decrease in thyroid hormone levels. These risks and recommendations pertain to ICM given as an injection through an artery or vein.
    - **What should health care professionals do?**
        - Health care professionals should perform appropriate monitoring of patients from birth through 3 years for the possibility of hypothyroidism or a temporary decrease in thyroid hormone levels following exposure to ICM. Consider evaluating thyroid function within 3 weeks, especially in term and preterm neonates and children with some underlying conditions. If thyroid dysfunction is detected, treat and monitor thyroid function as clinically needed to avoid future cognitive and other developmental disabilities
        - Certain pediatric patients are at an increased risk, including those who are newborns or have very low birth weight, prematurity, or the presence of cardiac or other conditions such as those requiring care in neonatal or pediatric intensive care units. Patients with cardiac conditions may be at greatest risk since they often require high doses of contrast during invasive cardiac procedures.
    - **Health Plan Recommendation:** Notify providers via Medical Policy Alert.

Drug Recalls/Market Withdrawals

1. **Drug Name:** Accuretic (quinapril HCl/hydrochlorothiazide), quinapril and hydrochlorothiazide, and quinapril/hydrochlorothiazide
    - **Date of Recall:** March 22, 2022
    - **Reason for recall:** Presence of a nitrosamine, N-nitroso-quinapril in certain lots of the medication

- **Link to more information:** https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/pfizer-voluntary-nationwide-recall-lots-accuretic-quinapril-hclhydrochlorothiazide-quinapril-and
- **Health Plan Recommendation:** Notify providers via Medical Policy Alert.

2. **Drug Name:** Orphenadrine citrate 100 mg extended release (ER)
   - **Date of Recall:** March 21, 2022
   - **Reason for recall:** Presence of a Nitrosamine Impurity in certain lots of the medication
   - **Link to more information:** https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/sandoz-inc-issues-nationwide-recall-13-lots-orphenadrine-citrate-100-mg-extended-release-tablets-due
   - **Health Plan Recommendation:** Notify providers via Medical Policy Alert.

Other Formulary Changes:

Drug Name	Recommendation	Policy Name
Ranibizumab (Susvimo) Vial	New route (Implant) and strength (10mg/0.1ml); • Commercial/Medicaid: Medical Benefit, Prior Authorization • Medicare Part D: Non-Formulary • Medicare Part B: Medical Benefit, Prior Authorization	• Commercial/Medicaid/Medicare Part B: Ophthalmic Vascular Endothelial Growth Factor (VEGF) Inhibitors • Medicare Part D: N/A
Ranibizumab-nuna (Byooviz®)	New biosimilar; • Medical benefit for all lines of business	N/A
Tralokinumab-ldrm (Adbry) Syringe	Correction from April 2022 P&T: • Medicare Part B: Prior Authorization	Adbry
Fluticasone propionate/ salmeterol (Advair HFA) HFA AER AD	Remove from Medicaid formulary Effective 09/01/2022	N/A
Atomoxetine hcl Capsule	Down-tier; • Commercial Cost-Based: Formulary, Tier 2 • Medicare Part D: Formulary, Tier 3 Effective 07/01/2022	N/A
Cabozantinib s-malate (Cabometyx) Tablet	Add quantity limit (1 capsule per day) to Commercial and Medicaid Effective 09/01/2022	N/A
Citalopram hydrobromide (Citalopram HBR) Capsule	New dosage form (capsule) and strength (30 mg); • Non-formulary for all lines of business	N/A

Dextroamphetamine-amphet er Cap ER 24H	Down-tier for Commercial Cost Based: Tier 2, Quantity Limit (5, 10, 15, 30 mg - 1 capsule per day) (20 mg – 2 capsules per day) Effective 07/01/2022	Long-acting Stimulants Quantity Limit
Baclofen (Fleqsuvy) Oral Susp	New dosage form (suspension); • Non-Formulary for all lines of business	N/A
Fluoxetine hcl Tablet	Add to formulary for Commercial, remove Prior Authorization; • Commercial Standard: Formulary, Tier 2 • Commercial Cost-Based: Formulary, Tier 4 Effective 07/01/2022	N/A
• **Methylphenidate ER Tablet ER** • **Methylphenidate HCL CD CPBP**	Down tier for Commercial Cost-Based; Tier 2, Quantity Limit (1 tablet per day) Effective 07/01/2022	N/A
Ergotamine tartrate/caffeine (Migergot) Supp.Rect	Remove from Commercial and Medicaid formularies Effective 09/01/2022	N/A
• **Omnipod GENERATION 4, 5, AND 6 Intro Kit** • **Omnipod GENERATION 4, 5, AND 6 Pods**	• Add to Medicare Part D Formulary: Tier 4, Prior Authorization, Quantity Limit (1 kit per 365 days) • Add to Medicare Part D: Formulary: Tier 4, Quantity Limit (10 pods per 30 days) Effective 06/01/2022	Disposable Insulin Pumps
Insulin glargine-yfgn [Semglee (YFGN)] Cartridge/Vial	Remove Brand Semglee from Medicaid formulary Effective 09/01/2022	N/A
Dimethyl fumarate Capsule DR	• Commercial Standard: Change from Tier 5 to Tier 2 • Commercial Cost-Based: Change from Tier 5 to Tier 3 • Medicare Part D: Change from Tier 5 to Tier 3	N/A
Tretinoin/benzoyl peroxide (Twyneo) Cream (G)	New combination (tretinoin/benzoyl peroxide); • Non-formulary for all lines of business	N/A
Naloxone hcl (Zimhi) Syringe	New Strength (5mg/0.5ml); • Commercial: Formulary, Tier 2 • Medicaid: Formulary • Medicare Part D: Formulary, Tier 3	N/A

Almotriptan malate Tablet	Remove from Commercial formulary Effective 09/01/2022	N/A
Frovatriptan succinate Tablet	Remove from Commercial and Medicaid formularies Effective 09/01/2022	N/A
MITE,D.FARINAE-D.PTERONYSSINUS (Odactra)	Remove from Medicaid formulary	N/A
Grass pollen- timothy, std (Grastek) Tab SL	Remove from Medicaid formulary	N/A
GR POL-ORC/SW VER/RYE/KENT/TIM (Oralair) Tab Subl	Remove from Medicaid formulary	N/A
Weed pollen- short ragweed (Ragwitek) Tab SL	Remove from Medicaid formulary	N/A
Everolimus disperz (Afinitor Disperz) Tablet	Remove from Commercial and Medicaid formularies Effective 09/01/2022	Oral Anti-Cancer Medications

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

Providence Health Plan Pharmacy Operational Policy ORPTCOPS062

NEW DRUGS / COMBINATIONS / STRENGTHS / DOSAGE FORMS		
Drug Name	**Action Taken**	**Policy Name**
Emtricitabine/tenofovir alafenamide fumarate (Descovy) Tablet	New strength (120/15mg). Line extend with Descovy 200/25mg; • Commercial/Medicaid: Non-Formulary, Prior Authorization • Medicare Part D: Formulary, Tier 5	• Commercial/Medicaid: Descovy • Medicare Part D: N/A
Filgrastim-ayow (Releuko) Syringe	Biosimilar to Neupogen. Line extend with Neupogen; • Commercial/Medicare Part D: Formulary, Tier 5 • Medicaid: Formulary, Specialty	N/A
Lorazepam (Loreev XR) Cap ER 24H	New strength (1.5 mg). Line extend with other Loreev XR; • Non-formulary for all lines of business	N/A
Siponimod (Mayzent) Tab DS PK & Tablet	New strengths (0.25 mg(7) / 1 mg). Line extend with other Mayzent strengths;	N/A

	• Commercial/Medicare Part D: Formulary, Tier 5, Quantity Limit (1 mg – one tablet per day) • Medicaid: Formulary, Quantity Limit (1 mg – one tablet per day)	
Antihemoph.FVIII,HEK B-delete (Nuwiq) Vial	New strength [1500(+/-)]. Line extend with other Nuwiq strengths; • Medical benefit for all lines of business	N/A
Upadacitinib (Rinvoq) Tab ER 24H	New strength (45mg). Line extend with other Rinvoq strengths; • Commercial: Formulary, Tier 5, Prior Authorization, Quantity Limit (1 tab per day) • Medicaid: Formulary, Prior Authorization, Quantity Limit (1 tab per day) • Medicare Part D: Formulary, Tier 5, Prior Authorization	Therapeutic Immunomodulators (TIMS)
Semaglutide (Ozempic) Pen Injctr	New strength (8mg/ml). Line extend with Ozempic; • Commercial: Formulary, Tier 3, Quantity Limit (3 ml per 28 days) Step Therapy • Medicaid: Formulary, Quantity Limit (3 ml per 28 days) Step Therapy • Medicare Part D: Formulary, Tier 3	• Commercial: GLP-1 Receptor Agonists Step Therapy Policy - Comm • Medicaid: GLP-1 Receptor Agonists Step Therapy Policy – Medicaid • Medicare Part D: N/A
Testosterone undecanoate (Tlando) Capsule	New strength (112.5 mg). Line extend with Jatenzo; • Commercial/Medicaid: Non-Formulary, Prior Authorization • Medicare Part D: Non-Formulary	• Commercial/Medicaid: Testosterone Replacement Therapy (TRT) • Medicare Part D: N/A
Abacavir sulfate/dolutegravir sodium/lamivudine (Triumeq PD) Tab Susp	New dosage form (tab susp) and strength (60/5/30mg). Line extend with Triumeq; • Commercial: Formulary, Tier 3 • Medicaid: Formulary • Medicare Part D: Formulary, Tier 5	N/A
Leuprolide mesylate (Camcevi) Syringe	New formulation (syringe) and strength (42mg). Line extend with Lupron Depot; • Commercial/Medicaid: Medical Benefit, Prior Authorization • Medicare Part D: Formulary, Tier 5	• Commercial/Medicaid: Gonadotropin Releasing Hormone Agonists • Medicare Part D: N/A

New Generics:

Drug Name	Action Taken	Policy Name
Baclofen Solution	First generic (Ozobax). Line extend as generic; • Non-formulary for all lines of business	N/A
Digoxin Tablet	First generic (Lanoxin). Line extend as generic; Non-formulary for all lines of business; • Non-formulary for all lines of business	N/A
Lenalidomide Capsule	First Generic (Revlimid). Line extend as generic; • Commercial: Formulary, Tier 5, Prior Authorization • Medicaid: Formulary, Specialty, Prior Authorization • Medicare Part D: Formulary, Tier 5, Prior Authorization	• Commercial/Medicaid: Oral Anti-Cancer Medications • Medicare Part D: Anti-Cancer Agents
Lacosamide Tablet	First generic (Vimpat). Line extend as generic; • Commercial Standard: Formulary, Tier 2 • Commercial Cost-Based: Formulary, Tier 3 • Medicaid: Formulary • Medicare Part D: Formulary, Tier 4, Step Therapy, Quantity Limit (2 tablets per day)	• Commercial/Medicaid: N/A • Medicare Part D: Antiepileptic Agents
Lacosamide Vial	First generic (Vimpat vial). Line extend as generic; • Commercial/Medicaid: Medical Benefit • Medicare Part D: Non-Formulary	N/A
Paclitaxel Protein-Bound Vial	Authorized generic. Line extend as generic; • Commercial/Medicaid: Medical Benefit • Medicare Part D: Non-formulary	• Commercial/Medicaid: Injectable Anti-Cancer Medications • Medicare Part B: Injectable Anti-Cancer Medications- Medicare Part B
Apomorphine hcl Cartridge	First generic (Apokyn). Line extend as generic; • Commercial/Medicaid: Non-Formulary, Specialty • Medicare Part D: Formulary, Tier 5	N/A
Isosorbide dinit-hydralazine Tablet	Marketed under NDA (Bidil). 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

Clinical Policy Changes:

MAJOR CHANGES	
Policy Name	**Summary of Change**
Anti-Glaucoma Agents	Changed wording on covered uses from N/A to all medically accepted indications not otherwise excluded from the benefit.
Benlysta	Updated policy so new members established on therapy do not need to meet initial criteria.
CFTR Modulators	Age restrictions updated to meet FDA approved indications.
Disposable Insulin Pumps	V-go and the new Omnipod 5 were added to this policy. V-go will require use of Omnipod prior to coverage.

Dupixent	Updated criteria to align with contract requirements
	• For atopic dermatitis:
	  ○ Diagnostic criteria were updated to align with the Oregon health Authority
	  ○ Updated prerequisite therapy to allow for either trial of systemic immunosuppressants or trial of BOTH topical steroids and topical calcineurin inhibitors
	• For asthma:
	  ○ Diagnostic criteria for eosinophilic asthma was updated to include more definitions
	  ○ Updated requirement for an additional controller medication (on top of inhaled corticosteroid) to include a long-acting beta-2 agonists (LABA), leukotriene receptor antagonist, or long-acting muscarinic antagonist (LAMA) instead of only allowing a LABA.
	Effective 06/13/2022

Elidel, Protopic - Medicaid	Added reauthorization criteria
Immune Gamma Globulin (IgG)	Removed trial and failure of prophylactic antibiotics.
Infusion Therapy Site of Care	The drug list was updated to reflect contracts for approved sites of care.
Intranasal Allergy Medications - Medicaid	Updated covered uses section to clarify coverage based on the Oregon Health Services Commission listed on the Prioritized List of Health Care Services
Ketoconazole tablets	Updated criteria to allow for coverage in enogenous Cushing's syndrome
Krystexxa	Added language clarifying that maximum medically appropriate doses of xanthine oxidase and uricosuric agents must be tried.
Medically Infused Therapeutic Immunomodulators – Commercial and Medicare Part B	Vedolizumab (Entyvio®) was added as a co-preferred agent with infliximab biosimilars (Renflexis® and Inflectra®) for Crohn's disease Effective 7/1/2022
Narcolepsy Agents	Developed criteria for Xywav in the setting of idiopathic hypersomnia. Criteria aligns with the respected clinical trial, International Classification of Sleep Disorders guidance, and American Academy of Sleep Medicine treatment guidelines.

Nexletol, Nexlizet	Removed provider restrictions
Non-Preferred Insulins	Adding duration for required trial and failure of preferred insulins.
Oral Anti-Cancer Medications	Criterion was added to establish medical necessity for everolimus tablets for oral suspension (generic for Afinitor Disperz®), as this formulation is only warranted in certain cases and is much more costly than the generic everolimus tablets (generic for Afinitor®). Additionally, quantity limits were added to support dose optimization.
Osteoanabolic Therapies	Add criteria for use of teriparatide beyond two years based on new labeling.
PCSK9 Inhibitors – Commercial and Medicaid	Removed provider restrictions
Pulmonary Arterial Hypertension	1. Updated diagnosis criteria for mPAP from 25 mmHg to greater than or equal to 20 mmHg to align with current recommendations from the 6th World Symposium on Pulmonary Hypertension Task Force. 2. Changed authorization to until no longer eligible with the plan.
Pulmonary Arterial Hypertension - Part B	1. Updated diagnosis criteria for mPAP from 25 mmHg to greater than or equal to 20 mmHg to align with current recommendations from the 6th World Symposium on Pulmonary Hypertension Task Force. 2. Changed authorization to until no longer eligible with the plan.
Reyvow	Updated initial criteria to include "intolerance of two triptan entities," separated trial and failure requirements by line of business, and removed prescriber requirements to align with other anti-migraine drug therapy policies (e.g., CGRP).
Scenesse	Updated diagnostic criteria to align with The Porphyrias Consortium that notes "the diagnosis of EPP/XLP is established biochemically by demonstrating increased protoporphyrin in red blood cells, with a predominance of metal-free protoporphyrin rather than zinc protoporphyrin."
Soliris	For neuromyelitis optica spectrum disorder (NMOSD) will require trial of rituximab and an additional therapy (Enspryng or Uplizna) prior to approval of Soliris. Changed based on high cost of Soliris and feedback from expert opinion.
Soliris - Medicare Part B	For neuromyelitis optica spectrum disorder (NMOSD) will require trial of rituximab and an additional therapy (Enspryng or Uplizna) prior to approval of Soliris. Changed based on high cost of Soliris and feedback from expert opinion.
Tafamidis	Clarified wording surrounding reauthorization criteria. Need to provide documentation of positive response but specific criteria (such as 6-minute walk test) not required.
Therapeutic Immunomodulators – Comm	Criteria were updated to reflect new FDA approved indications.
Therapeutic Immunomodulators – Medicaid	Vedolizumab (Entyvio®) was added as a co-preferred agent with infliximab biosimilars (Renflexis® and Inflectra®) for Crohn's disease Effective 7/1/2022

Triptan Quantity Limit	Updated initial criteria to allow a Calcitonin Gene-Related Peptide (CGRP) Receptor Antagonist as a trial option.
Vascepa	Atherosclerotic cardiovascular disease (ASCVD) low density lipoprotein (LDL) requirement or less than or equal to 100 mg/dL has been removed from policy criteria to align with Oregon Health Authority prior authorization policy.
VEGF Inhibitors	Aflibercept (Eylea® and ranibizumab-nuna (Byooviz®) will no longer require prior authorization. Other non-preferred products will require trial of 1) bevacizumab and 2) aflibercept (Eylea®) or ranibizumab-nuna (Byooviz®)

RETIRED POLICIES	
Koselugo	Combined with to Oral Anti-Cancer Medications policy
Sublingual Immunotherapy with Allergen-specific Pollen Extracts (SLIT)	Retired due to appropriate utilization
Dihydroergotamine	Retired due to low utilization of medications
Northera	Retired due to low risk of overutilization and generic availability
Triptans Step Therapy	Retired due to cost-effective agents on the formulary and more costly agents will be removed from the formulary (frovatriptan and almotriptan)