PROVIDENCE Health Plan

PROVIDENCE Health Assurance

Healthcare Services Medical & Pharmacy Policy Alerts

Number 260

July 1, 2021

This is the July 1, 2021 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.

Special Medical Policy Alert

Effective 8/1/2021, PHP will cover additional services under the medical policy "Gender Affirming Surgical Interventions" for all lines of business. When policy criteria are met, many services previously considered "cosmetic" and not covered will be considered medically necessary and covered for members with a diagnosis of gender dysphoria. Examples may include but are not limited to: facial feminization, tracheal shave, electrolysis and rhinoplasty."

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

MEDICAL POLICY COMMITTEE

MEDICAL
Effective 9/1/2021
(Restrictions)

Allergy Testing (All Lines of Business Except Medicare) **MP153**	**Annual Update** **Policy Changes:** No recommended criteria changes. See below for information on frequency limit configurations. **Codes/PA:** Frequency limits for intracutaneous and percutaneous CPT codes were not correctly configured in 2017. Per the policy's stated intent, frequency limit will be a cumulative total of 70 units per calendar year across three percutaneous codes (CPT 95004, 95017 and 95018), and a cumulative total of 40 units per calendar year across three intracutaneous codes (CPT 95024, 95027, 95028). Configuration will be correctly established as of 9/1/2021.
Negative Pressure Wound Therapy (All Lines of Business Except Medicare) **MP168**	**Annual Update** • Continue to base policy on Medicare guidance for Negative Pressure Wound Therapy Pumps and DME. **Codes/PA:** • Adding code A9272 (disposable wound suction device) to policy to deny as not medically necessary.
Psychological and Neuropsychological Testing (All Lines of Business Except Medicare) **MP274**	**Interim Update** **Policy Changes:** • Criteria have been added which specify provider training and credentialing requirements for performing both psychological and neuropsychological testing. • Testing will be considered not medically necessary if these requirements are not met. **Codes/PA:** Psychological and neuropsychological testing codes will be configured to pay when billed with select provider speciality codes. These include: • Psychology • Developmental neuropsychology • Child/adolescent psychiatry • Psychiatry Claims billed with any other provider specialities will be denied as not medically necessary.

MEDICAL
Effective 7/1/2021
(Liberalizations)

Breast Surgery: Reduction Mammoplasty (All Lines of Business Except Medicare) **MP64**	**Annual Update** **Policy Changes:** • Liberalize criteria to allow reduction mammoplasty for the treatment of unilateral hypertrophy/macromastia. **Codes/PA:** No coding changes
Cardiac: Left Atrial Appendage Devices (All Lines of Business Except Medicare) **MP66**	**Annual Update** **Policy Changes:** • Watchman device for percutaneous left atrial appendage (LAA) closure: requirement for risk of stroke and systemic embolism of CHADS2 or CHA2DS2-VASc score of 1 has been eliminated and replaced with a requirement for "increased risk." **Codes/PA:** No coding changes

VENDOR UPDATES

Updates to AIM Advanced Imaging Clinical Appropriateness Guideline

Effective for dates of service on and after September 12, 2021, the following updates will apply to the AIM Advanced Imaging Clinical Appropriateness Guidelines. Part of the AIM guideline annual review process, these updates are focused on advancing efforts to drive clinically appropriate, safe, and affordable health care services

Advanced Imaging of the Spine – updates by section
Congenital vertebral defects
- New requirement for additional evaluation with radiographs

Scoliosis
- Defined criteria for which presurgical planning is indicated
- Requirement for radiographs and new or progressive symptoms for postsurgical imaging

Spinal dysraphism and tethered cord
- Diagnostic imaging strategy limiting the use of CT to cases where MRI cannot be performed

- New requirement for US prior to advanced imaging for tethered cord in infants age 5 months or less

Multiple sclerosis
- New criteria for imaging in initial diagnosis of MS

Spinal infection
- New criteria for diagnosis and management aligned with IDSA and University of Michigan guidelines

Axial spondyloarthropathy
- Defined inflammatory back pain
- Diagnostic testing strategy outlining radiography requirements

Cervical injury
- Aligned with ACR position on pediatric cervical trauma

Thoracic or lumbar injury
- Diagnostic testing strategy emphasizing radiography and limiting the use of MRI for known fracture
- Remove indication for follow-up imaging of progressively worsening pain in the absence of fracture or neurologic deficits

Syringomyelia
- Removed indication for surveillance imaging

Non-specific low back pain
- Aligned pediatric guidelines with ACR pediatric low back pain guidelines

Advanced Imaging of the Extremities– updates by section

Osteomyelitis or septic arthritis; myositis
- Removed CT as a followup to nondiagnostic MRI due to lower diagnostic accuracy of CT

Epicondylitis and Tenosynovitis – long head of biceps
- Removed due to lack of evidence supporting imaging for this diagnosis

Plantar fasciitis and fibromatosis
- Removed CT as a followup to nondiagnostic MRI due to lower diagnostic accuracy of CT
- Added specific conservative management requirements

Brachial plexus mass
- Added specific requirement for suspicious findings on clinical exam or prior imaging

Morton's neuroma
- Added requirements for focused steroid injection, orthoses, plan for surgery

Adhesive capsulitis
- Added requirement for planned intervention (manipulation under anesthesia or lysis of adhesions)

Rotator cuff tear; Labral tear – shoulder; Labral tear - hip
- Defined specific exam findings and duration of conservative management
- Recurrent labral tear now requires same criteria as an initial tear (shoulder only)

Triangular fibrocartilage complex tear
- Added requirement for radiographs and conservative management for chronic tear

Ligament tear – knee; meniscal tear

- Added requirement for radiographs for specific scenarios
- Increased duration of conservative management for chronic meniscal tears

Ligament and tendon injuries – foot and ankle

- Defined required duration of conservative management

Chronic anterior knee pain including chondromalacia patella and patellofemoral pain syndrome

- Lengthened duration of conservative management and specified requirement for chronic anterior knee pain

Intra-articular loose body

- Requirement for mechanical symptoms

Osteochondral lesion (including osteochondritis dissecans, transient dislocation of patella)

- New requirement for radiographs

Entrapment neuropathy

- Exclude carpal and cubital tunnel

Persistent lower extremity pain

- Defined duration of conservative management (6 weeks)
- Exclude hip joint (addressed in other indications)

Upper extremity pain

- Exclude shoulder joint (addressed in other indications)
- Diagnostic testing strategy limiting use of CT to when MRI cannot be performed or is nondiagnostic

Knee arthroplasty, presurgical planning

- Limited to MAKO and robotic assist arthroplasty cases

Perioperative imaging, not otherwise specified

- Require radiographs or ultrasound prior to advanced imaging

<u>Vascular Imaging</u> – updates by section

- Alternative non-vascular modality imaging approaches, where applicable

Hemorrhage, Intracranial

- Clinical scenario specification of subarachnoid hemorrhage indication.
- Addition of Pediatric intracerebral hemorrhage indication.

Horner's syndrome; Pulsatile Tinnitus; Trigeminal neuralgia

- Removal of management scenario to limit continued vascular evaluation

Stroke/TIA; Stenosis or Occlusion (Intracranial/Extracranial)

- Acute and subacute time frame specifications; removal of carotid/cardiac workup requirement for intracranial vascular evaluation; addition of management specifications
- Sections separated anatomically into anterior/posterior circulation (Carotid artery and Vertebral or Basilar arteries, respectively)

Pulmonary Embolism

- Addition of non-diagnostic chest radiograph requirement for all indications
- Addition of pregnancy-adjusted YEARS algorithm

Peripheral Arterial Disease

- Addition of new post-revascularization scenario to both upper and lower extremity PAD evaluation

For questions related to guidelines, please contact AIM via email at aim.guidelines@aimspecialtyhealth.com. Additionally, you may access and download a copy of the current and upcoming guidelines here.

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

Pharmacy & Therapeutics (P&T) Committee

Oregon Region P&T Committee Meeting June 4, 2021
Go-Live Date: Sunday, August 01, 2021, unless otherwise noted

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New Drugs and Combinations:

1. **Vericiguat (Verquvo) Tablet**
   a. **Indication**: For the reduction of cardiovascular mortality and reduction of heart failure hospitalizations in adults with chronic, symptomatic heart failure and ejection fraction less than 45% following a hospitalization for heart failure or outpatient treatment with intravenous diuretics.
   b. **Decision**:

	Commercial	Medicaid	Medicare
Formulary Status*	Non-Formulary	Non-Formulary	Part D: Formulary Part B: N/A
Tier**	N/A	N/A	Non-preferred Drug
Specialty Medication	No	No	N/A

Affordable Care Act Eligible	No	N/A	N/A
Utilization Management Edits	Prior Authorization	Prior Authorization	Prior Authorization
Quantity Limit			
* Recommendations for placement may differ between lines of business due to regulatory requirements. ** Medications will be placed on recommended tier above for the base formulary; tier placement for custom formulary(ies) will be based on designation above. For example, Commercial Tier 6 designation above means that the medication will be placed on the highest cost-sharing tier on the respective formulary(ies).			
Formulary Alternatives: Corlanor® (ivabradine), SGLT-2 Inhibitors: Farxiga® (dapagliflozin), Jardiance® (empagliflozin)			

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

PA PROGRAM NAME	Verquvo
MEDICATION NAME	Verquvo™
PA INDICATION INDICATOR	1 - All FDA-Approved Indications
OFF-LABEL USES	N/A
EXCLUSION CRITERIA	N/A
REQUIRED MEDICAL INFORMATION	For chronic heart failure, all of the following criteria must be met: 1. Documentation of symptomatic heart failure (NYHA Class II-IV) with a left ventricular ejection fraction (LVEF) less than 45% 2. On maximally tolerated guideline-directed therapy including both of the following for at least six months, unless contraindicated or not tolerated: a. Beta-blocker (specifically carvedilol, metoprolol succinate, or bisoprolol) b. One of the following: i. Angiotensin-converting enzyme (ACE) inhibitor (such as lisinopril, enalapril) ii. Angiotensin II receptor blocker (ARB) (such as losartan, valsartan) iii. Angiotensin receptor-neprilysin inhibitor (ARNI) (sacubitril/valsartan), unless not tolerated or contraindicated, 3. On maximally tolerated therapy with the following for at least six months, as clinically appropriate: a. Aldosterone antagonists for patients with symptoms despite maximally tolerated therapy above b. Diuretic therapy for symptomatic patients with persistent volume overload 4. Documentation of clinical worsening of heart failure, defined as one of the following, despite maximal therapy as outlined above: a. Hospitalization for heart failure within the previous six months b. Need for outpatient intravenous diuretic therapy within the previous three months
AGE RESTRICTIONS	May be covered for adults 18 years of age and older

PRESCRIBER RESTRICTIONS	Must be prescribed by, or in consultation with, a cardiologist
COVERAGE DURATION	Authorization will be approved until no longer eligible with the plan, subject to formulary or benefit changes

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

PA PROGRAM NAME	Verquvo
MEDICATION NAME	Verquvo™
PA INDICATION INDICATOR	1 - All FDA-Approved Indications
OFF-LABEL USES	N/A
EXCLUSION CRITERIA	N/A
REQUIRED MEDICAL INFORMATION	1. Documentation of symptomatic heart failure (NYHA Class II-IV) with a left ventricular ejection fraction (LVEF) less than 45% 2. On maximally tolerated guideline-directed therapy including both of the following for at least six months, unless contraindicated or not tolerated: a. Beta-blocker (specifically carvedilol, metoprolol succinate, or bisoprolol) b. One of the following: i. Angiotensin-converting enzyme (ACE) inhibitor (such as lisinopril, enalapril) ii. Angiotensin II receptor blocker (ARB) (such as losartan, valsartan) iii. Angiotensin receptor-neprilysin inhibitor (ARNI) (sacubitril/valsartan), unless not tolerated or contraindicated, 3. Documentation of clinical worsening of heart failure, defined as one of the following, despite maximal therapy as outlined above: a. Hospitalization for heart failure within the previous six months b. Need for outpatient intravenous diuretic therapy within the previous three months
AGE RESTRICTIONS	May be covered for adults 18 years of age and older
PRESCRIBER RESTRICTIONS	Must be prescribed by, or in consultation with, a cardiologist
COVERAGE DURATION	Authorization will be approved until no longer eligible with the plan

2. **Trilaciclib dihydrochloride (Cosela) Vial**
   a. **Indication**: trilaciclib dihydrochloride to decrease incidence of chemotherapy-induced myelosuppression in adult patients when administered prior to a platinum/etoposide-containing regimen or topotecan-containing regimen for extensive-stage small cell lung cancer (ES-SCLC).
   b. **Decision**:

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

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

3. **Margetuximab-CMKB (Margenza) Vial**
   a. **Indication**: In combination with chemotherapy, for the treatment of adult patients with metastatic human epidermal growth factor receptor 2 protein (HER2)-positive breast cancer who have received two or more prior anti-HER2 regimens, at least one of which was for metastatic disease.
   b. **Decision**:

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

c. **Prior Authorization Criteria for Commercial/Medicaid**: Added to Injectable Anti-Cancer Medications Policy

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

4. **Melphalan flufenamide hydrochloride (Pepaxto) Vial**
   a. **Indication**: Melphalan flufenamide (Pepaxto®) is indicated in combination with dexamethasone, for the treatment of adult patients with relapsed or refractory multiple myeloma who have received at least four prior lines of therapy and whose disease is refractory to at least one proteasome inhibitor, one immunomodulatory agent, and one CD38-directed monoclonal antibody. This indication is approved under accelerated approval based on response rate. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trial(s).
   b. **Decision**:

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

   c. **Prior Authorization Criteria for Commercial/Medicaid**: Added to Injectable Anti-Cancer Medications Policy

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

5. **Umbralisib tosylate (Ukoniq) Tablet**
   a. **Indication**: the treatment of adult patients with relapsed or refractory marginal zone lymphoma (MZL) who have received at least one prior anti-CD20-based regimen, and for the treatment of adult patients with relapsed or refractory follicular lymphoma (FL) who have received at least three prior lines of therapy. Both indications are under accelerated approval based on overall response rate. Continued approval may be contingent upon verification and description of clinical benefit in a confirmatory trial.

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
Specialty Medication	Yes	Yes	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: Copiktra, Zydelig, Imbruvica, Revlimid			

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 Agents Program

6. **Tepotinib hcl (Tepmetko) Tablet**
   a. **Indication**: Treatment of adult patients with metastatic non-small cell lung cancer (NSCLC) harboring mesenchymal-epithelial transition (MET) exon 14 skipping alterations.
   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
Specialty Medication	Yes	Yes	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: Tabrecta			

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 Agents Program

7. **Tivozanib HCL (Fotivda) Capsule**
   a. **Indication**: Treatment of adult patients with relapsed or refractory advanced renal cell carcinoma (RCC) following two or more prior systemic therapies.
   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
Specialty Medication	No	No	N/A
Affordable Care Act Eligible	No	N/A	N/A
Utilization Management Edits	Prior Authorization	Prior Authorization	Prior Authorization
Quantity Limit	NA	NA	NA
* 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: sunitinib, sorafenib, everolimus, pazopanib			

   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 Agents Program

8. **Idecabtagene vicleucel (Abecma) Plast. Bag**
   a. **Indication**: Treatment of adult patients with relapsed or refractory multiple myeloma (RRMM) after four or more prior lines of therapy, including an immunomodulatory agent, a proteasome inhibitor, 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
Specialty Medication	Yes	Yes	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: Blenrep (medical)			

c. **Prior Authorization Criteria**:

PA PROGRAM NAME	CAR-T
MEDICATION NAME	Idecabtagene vicleucel (Abecma)
PA INDICATION INDICATOR	1 - All FDA-Approved Indications
OFF-LABEL USES	N/A
EXCLUSION CRITERIA	Previous treatment with chimeric antigen receptor therapy or other genetically modified T-cell therapy. Repeat administration of CAR-T therapy is considered experimental and investigational because the effectiveness of this approach has not been established.
REQUIRED MEDICAL INFORMATION	For all indications, the following criteria must be met: 1. Documentation of adequate bone marrow, cardiac, pulmonary and organ function (e.g., kidney) to minimize risks of serious adverse reactions (e.g., cytokine release syndrome) For multiple myeloma, **Abecma®** may be approved when all of the following criteria are met: 1. Confirmed diagnosis of multiple myeloma 2. Refractory or relapsed disease to four (4) or more prior lines of therapy. Prior therapy must have included an immunomodulatory agent, a proteasome inhibitor, and an anti-CD38 monoclonal antibody 3. Asymptomatic or minimally symptomatic with Eastern Cooperative Oncology Group (ECOG) performance status 0-1 4. No evidence of active infection (including hepatitis B or C, active graft vs. host disease)
AGE RESTRICTIONS	Approved for 18 years of age and older
PRESCRIBER RESTRICTIONS	Must be prescribed by, or in consultation with, an oncologist
COVERAGE DURATION	Two (2) months (limited to one (1) treatment course per lifetime, with four (4) doses of tocilizumab [Actemra®] at up to 800mg per dose).

9. **Etesevimab (Etesevimab EUA) Vial**
   a. **Indication**: Bamlanivimab and etesevimab administered together for the treatment of mild to moderate coronavirus disease 2019 (COVID-19) in adults and pediatric patients (12 years of age and older weighing at least 40 kg) with positive results of direct SARS-CoV-2 viral testing, and who are at high risk for progressing to severe COVID-19 and/or hospitalization
   b. **Decision**: N/A, Informational
   c. **Prior Authorization Criteria**: N/A

10. **Evinacumab-dgnb (Evkeeza) Vial**
    a. **Indication**: Adjunct therapy for homozygous familial hypercholesterolemia (HoFH).
    b. **Decision**:

	Commercial	Medicaid	Medicare
Formulary Status*	Medical	Medical	Part D: Non-formulary Part B: Medical
Tier**	N/A	N/A	N/A
Specialty Medication	No	No	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: ezetimibe, PCSK9 inhibitors			

    c. **Prior Authorization Criteria**:

PA PROGRAM NAME	Homozygous Familial Hypercholesterolemia (FH) Agents
MEDICATION NAME	Evinacumab-dgnb Injection (Evkeeza®)
PA INDICATION INDICATOR	1 - All FDA-Approved Indications
OFF-LABEL USES	N/A
EXCLUSION CRITERIA	• Pregnancy • Diagnosis of Heterozygous familial hypercholesterolemia (HeFH) or other hyperlipidemia disorders • Concomitant use of lomitapide
REQUIRED MEDICAL INFORMATION	For initial authorization, all of the following must be met: 1. Diagnosis of Homozygous Familial Hypercholesterolemia (HoFH) as evidenced by either genetic or clinical confirmation, as outlined below: a. Genetic confirmation: biallelic functional mutations in the low density lipoprotein receptor (LDLR), apolipoprotein B (apo B), or proprotein convertase subtilisin/kexin type 9 (PCSK9) genes b. Clinical confirmation defined as untreated total cholesterol greater than 500 mg/dL and one of the following: i. Presence of xanthomas before the age of 10 years ii. Untreated total cholesterol level greater than 250 mg/dL in both parents 2. Current use of all of the following therapies:

	a. High-intensity statin therapy, defined as atorvastatin 80mg daily or rosuvastatin 40mg daily, unless contraindicated or documented statin intolerance b. Ezetimibe, unless contraindicated or prior intolerance c. PCSK-9 inhibitor (e.g., evolocumab), unless contraindicated or prior intolerance 3. Documentation of LDL cholesterol levels greater than 100 mg/dL despite at least six (6) months of use of the therapies outlined above Initial reauthorization requires documentation of at least a 30% reduction in LDL cholesterol levels from pre-treatment levels
AGE RESTRICTIONS	May be covered for patients 12 years of age and older
PRESCRIBER RESTRICTIONS	Must be prescribed by, or in consultation with, a cardiologist, endocrinologist, or board certified lipidologist
COVERAGE DURATION	Initial authorization will be approved for six months. Reauthorization will be approved until no longer eligible with the plan, subject to formulary and/or benefit changes.

11. **Casimersen (Amondys-45) Vial**
    a. **Indication**: Treatment of Duchenne muscular dystrophy (DMD) in patients who have a confirmed mutation of the DMD gene that is amenable to exon 45 skipping.
        - This indication is approved under accelerated approval based on an increase in dystrophin production in skeletal muscle observed in patients treated with AMONDYS 45. Continued approval for this indication may be contingent upon verification of a clinical benefit in confirmatory trials

    b. **Decision**:

	Commercial	Medicaid	Medicare
Formulary Status*	Medical	Medical	Part D: Non-formulary Part B: Medical
Tier**	N/A	N/A	N/A
Specialty Medication	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: prednisone, deflazacort (Emflaza®)			

    c. **Prior Authorization Criteria**: Added to Exon-Skipping Therapies For Duchenne Muscular Dystrophy Policy

12. **Fosdenopterin hydrobromide (Nulibry) Vial**
    a. **Indication**: Indicated to reduce the risk of mortality in patients with molybdenum cofactor deficiency (MoCD) Type A.
    b. **Decision**:

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

PA PROGRAM NAME	Medications for Rare Indications
MEDICATION NAME	Nulibry (fosdenopterin)
PA INDICATION INDICATOR	1 - All FDA-Approved Indications
OFF-LABEL USES	N/A
EXCLUSION CRITERIA	N/A
REQUIRED MEDICAL INFORMATION	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 Nulibry®: Diagnosis of molybdenum cofactor deficiency (MoCD) Type A confirmed by a mutation in the *MOCS1* gene OR suspected molybdenum cofactor deficiency (MoCD) Type A 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 (e.g., high-quality peer reviewed literature, guidelines, other clinical information) Reauthorization Criteria: 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 (e.g., high-quality peer reviewed literature, guidelines, other clinical AND 3. For Nulibry®: Genetic testing to confirm mutation in the *MOCS1* gene (Nulibry® should be discontinued if the MoCD Type A diagnosis is not confirmed by genetic testing)

AGE RESTRICTIONS	N/A
PRESCRIBER RESTRICTIONS	Must be prescribed by, or in consultation with, a specialist in the respective disease state.
COVERAGE DURATION	Initial authorization will be approved for three months. Reauthorization will be approved for 12 months.

13. **Voclosporin (Lupkynis) Capsule**
    a. **Indication**: Indicated in combination with a background immunosuppressive therapy regimen for the treatment of adult patients with active lupus nephritis (LN).
        - Limitations of Use: Safety and efficacy of voclosporin have not been established in combination with cyclophosphamide. Use of voclosporin is not recommended in this situation.

    b. **Decision**:

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

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

PA PROGRAM NAME	Lupkynis®
MEDICATION NAME	Lupkynis® (voclosporin7.9 mg capsule)
PA INDICATION INDICATOR	1 - All FDA-Approved Indications
EXCLUSION CRITERIA	1. Estimated glomerular filtration rate (eGFR) less than 45 2. History of kidney transplant 3. Use in combination with benlimumab (Benlysta®)
REQUIRED MEDICAL INFORMATION	For active lupus nephritis, all of the following must be met: 1. Confirmed diagnosis of systemic lupus erythematosus (SLE) 2. Kidney biopsy with a histologic diagnosis of lupus nephritis classes III, IV, or V 3. Documentation of laboratory test results indicating that patient has presence of auto-antibodies for SLE, defined as one (1) of the following:

	a. Positive Antinuclear antibody (ANA) b. Positive anti-double-stranded DNA (anti-dsDNA) on two or more occasions, OR if tested by ELISA, an antibody level above laboratory reference range c. Positive anti-Smith (Anti-Sm) d. Positive anti-Ro/SSA and anti-La/SSB antibodies 4. Documented failure of an adequate trial (such as inadequate control with ongoing disease activity and/or frequent flares), contraindication, or intolerance to at least one of the following: a. Mycophenolate for induction followed by mycophenolate for maintenance, OR b. Cyclophosphamide for induction followed by azathioprine for maintenance 5. Documentation that patient will continue to receive standard therapy (e.g., corticosteroids, cyclophosphamide, mycophenolate, azathioprine) Reauthorization criteria: 1. Documentation currently receiving standard therapy active lupus nephritis 2. Documentation of a positive response to therapy based on one of the following: a. Improvement in urine protein/creatinine ratio (UPCR) (i.e. less than or equal to 0.5 mg/mg) and eGFR of at least 60 b. Decrease from baseline in eGFR of less than 20%
AGE RESTRICTIONS	Age 18 years and older
PRESCRIBER RESTRICTIONS	Must be prescribed by, or in consultation with, a nephrologist or rheumatologist
COVERAGE DURATION	Initial authorization will be approved for 6 months. Reauthorization will be approved for 12 months

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

PA PROGRAM NAME	Lupkynis®
MEDICATION NAME	Lupkynis® (voclosporin7.9 mg capsule)
PA INDICATION INDICATOR	1 - All FDA-Approved Indications
EXCLUSION CRITERIA	1. Estimated glomerular filtration rate (eGFR) less than 45 2. History of kidney transplant 3. Use in combination with benlimumab (Benlysta®)
REQUIRED MEDICAL INFORMATION	For active lupus nephritis, all of the following must be met: 1. Confirmed diagnosis of systemic lupus erythematosus (SLE) 2. Kidney biopsy with a histologic diagnosis of lupus nephritis classes III, IV, or V 3. Documentation of laboratory test results indicating that patient has presence of auto-antibodies for SLE, defined as one (1) of the following: a. Positive Antinuclear antibody (ANA)

	b. Positive anti-double-stranded DNA (anti-dsDNA) on two or more occasions, OR if tested by ELISA, an antibody level above laboratory reference range c. Positive anti-Smith (Anti-Sm) d. Positive anti-Ro/SSA and anti-La/SSB antibodies 4. Documented failure of an adequate trial (such as inadequate control with ongoing disease activity and/or frequent flares), contraindication, or intolerance to at least one of the following: a. Mycophenolate for induction followed by mycophenolate for maintenance, OR b. Cyclophosphamide for induction followed by azathioprine for maintenance 5. Documentation that patient will continue to receive standard therapy (e.g., corticosteroids, cyclophosphamide, mycophenolate, azathioprine) Reauthorization criteria: 1. Documentation currently receiving standard therapy active lupus nephritis 2. Documentation of a positive response to therapy based on one of the following: a. Improvement in urine protein/creatinine ratio (UPCR) (i.e. less than or equal to 0.5 mg/mg) and eGFR of at least 60 b. Decrease from baseline in eGFR of less than 20%
AGE RESTRICTIONS	Age 18 years and older
PRESCRIBER RESTRICTIONS	Must be prescribed by, or in consultation with, a nephrologist or rheumatologist
COVERAGE DURATION	Initial authorization will be approved for 6 months. Reauthorization will be approved for one year

New Indications:

Therapies with Prior Authorization Policies (Non-oncology):

1. **XOLAIR®**
   omalizumab
   New indication approved 04/09/2021:
   - **Nasal polyps in adult patients 18 years of age and older with inadequate response to nasal corticosteroids, as add-on maintenance treatment**

   RECOMMENDATION: Inform prescribers via MD alert and update prior authorization criteria as follows:
   Criteria for Commercial, Medicare Part B, and Medicaid

PA PROGRAM NAME	**XOLAIR®**
MEDICATION NAME	XOLAIR® (Omalizumab injection)

PA INDICATION INDICATOR	1 - All FDA-Approved Indications
EXCLUSION CRITERIA	Concurrent use with another therapeutic immunomodulator agent utilized for the same indication
REQUIRED MEDICAL INFORMATION	For **asthma**, must meet all of the following criteria: 1. Diagnosis of moderate to severe persistent allergic asthma 2. IgE baseline levels greater than 30 IU/ml 3. Positive skin test to a common perennial aeroallergens 4. Documentation that in the past three months patient is adherent to a combination of a medium/high-dose inhaled corticosteroids and a long-acting inhaled beta2-agonist. (This may be verified by pharmacy claims information) 5. Documentation of inadequate asthma control despite above therapy, defined as one of the following: a. Asthma Control Test (ACT) score less than 20 or Asthma Control Questionnaire (ACQ) score greater than or equal to 1.5 b. At least two exacerbations requiring oral systemic corticosteroids in the last 12 months c. At least one exacerbation requiring hospitalization <u>Reauthorization</u> for asthma requires documentation of response to therapy, such as attainment and maintenance of remission or decrease in number of relapses For **chronic idiopathic urticaria**, must meet all of the following criteria: 1. Documentation that the condition is idiopathic and that secondary causes of urticaria (e.g. offending allergens, physical contact, etc.) have been ruled out **AND** 2. Trial and failure of a second-generation non-sedating H1 antihistamine (e.g., levocetirizine, loratadine, cetirizine, fexofenadine) **AND** 3. Trial and failure of one additional medication from the following classes: leukotriene receptor antagonists (e.g., montelukast), first generation H1 antihistamine (e.g., diphenhydramine), or histamine H2-receptor antagonist (e.g., famotidine, ranitidine) <u>Reauthorization</u> for chronic idiopathic urticaria will require documentation of response to therapy (e.g. reduction in flares or oral steroid dose). For **nasal polyps**, must meet all the following criteria: 1. Evidence of bilateral nasal polyposis by direct examination, endoscopy or sinus CT scan 2. Documentation of one (1) of the following:

	a. Patient had an inadequate response to sinonasal surgery or is not a candidate for sinonasal surgery b. Patient has tried and had an inadequate response to, or has an intolerance or contraindication to, oral systemic corticosteroids 3. Patient has tried and had an inadequate response to a three month trial of intranasal corticosteroids (e.g., fluticasone) or has a documented intolerance or contraindication to ALL intranasal corticosteroids 4. Documentation that patient will continue standard maintenance therapy (e.g., intranasal corticosteroids, nasal saline irrigation) in combination with omalizumab <u>Reauthorization</u> for nasal polyps requires documentation of positive clinical response to therapy such as symptom improvement
AGE RESTRICTIONS	Treatment of asthma: Approved for six years of age or older. Treatment of urticaria: Approved for twelve years of age or older. Treatment of nasal polyps: Approved for eighteen years of age or older.
PRESCRIBER RESTRICTIONS	Urticaria: Must be prescribed by, or in consultation with, a dermatologist, allergist or immunologist Asthma: Must be prescribed by, or in consultation with an asthma specialist (such as a pulmonologist, immunologist, or allergist) Nasal polyps: Must be prescribed by, or in consultation with, an otolaryngologist, allergist, pulmonologist or immunologist
COVERAGE DURATION	Urticaria and nasal polyps: Initial authorization will be for once year and reauthorization will be approved until no longer eligible with the plan, subject to formulary or benefit changes Asthma: Authorization will be approved until no longer eligible with the plan, subject to formulary or benefit changes

Criteria for Medicare Part D prior authorization policy will be updated as followed:

PA PROGRAM NAME	**XOLAIR®**
MEDICATION NAME	XOLAIR® (Omalizumab injection)
PA INDICATION INDICATOR	1 - All FDA-Approved Indications
EXCLUSION CRITERIA	N/A
REQUIRED MEDICAL INFORMATION	For asthma, must meet all of the following criteria: 1. Diagnosis of moderate or severe persistent allergic asthma, 2. IgE baseline levels greater than 30 IU/ml, 3. Positive skin test to common perennial aeroallergens, 4. Documentation of at least a 90-day trial of a combination of a high-dose inhaled

	corticosteroid and a long-acting inhaled beta2-agonist unless there is intolerance or contraindication to the medications, 5. Documentation of inadequate asthma control defined as one of the following: a. Asthma Control Test (ACT) score less than 20 or Asthma Control Questionnaire (ACQ) score greater than or equal to 1.5, b. At least two exacerbations requiring oral systemic corticosteroids in the last 12 months, or c. At least one exacerbation requiring hospitalization. Initial reauthorization for asthma will require documentation of response to therapy with at least one of the following: 1. Improvement in ACT or ACQ score, 2. Reduction in number of asthma exacerbations requiring oral systemic corticosteroids or hospitalization, or 3. Decrease in utilization of rescue medications (This may be verified by pharmacy claims information). Subsequent reauthorization requires documentation of continued benefit from therapy. For chronic idiopathic urticaria, must meet all of the following criteria: 1. Documentation that secondary causes of urticaria (e.g., offending allergens, physical contact, etc.) have been ruled out, 2. Trial and failure, intolerance, or contraindication to levocetirizine, and 3. Trial and failure of one additional medication from the following classes: leukotriene. For nasal polyps, must meet all the following criteria: 1. Evidence of nasal polyposis by direct examination, endoscopy or sinus CT scan, 2. Documentation that patient has had an inadequate response to (within the past 90 days), or has an intolerance, FDA labeled contraindication, or hypersensitivity to, oral systemic corticosteroids 3. Patient has had an inadequate response to a 3-month trial of intranasal corticosteroids (e.g., fluticasone) or has a documented intolerance, FDA labeled contraindication, or hypersensitivity to an intranasal corticosteroid 4. Documentation that patient will continue standard maintenance therapy (e.g., intranasal corticosteroids) in combination with the requested agent. Reauthorization for nasal polyps: 1. Documentation of positive clinical response to therapy, 2. Documentation that patient will continue standard maintenance therapy (e.g., intranasal corticosteroids) in combination with the requested agent, unless documented intolerance, FDA labeled contraindication, or hypersensitivity to such therapy.
AGE RESTRICTIONS	Asthma: 6 years of age and older. Urticaria: 12 years of age and older. Nasal polyps: 18 years of age or older.
PRESCRIBER RESTRICTIONS	Urticaria: Must be prescribed by, or in consultation with, a dermatologist, allergist or immunologist. Asthma: Must be prescribed by, or in consultation with an asthma specialist (such as a pulmonologist, immunologist, or allergist). Nasal polyps: Must be prescribed by, or in consultation with, an otolaryngologist, allergist, pulmonologist or immunologist
COVERAGE DURATION	Initial authorization will be approved for 6 months. Reauthorization will be approved for one year

2. **ACTEMRA®**
tocilizumab
New indication approved 03/04/2021:
- **Slowing the rate of decline in pulmonary function in adult patients with systemic sclerosis-associated interstitial lung disease (SSc-ILD)**

RECOMMENDATION: Inform prescribers via MD alert and update prior authorization criteria as follows: The criteria below will be added to the Required Medical Information and the Prescriber Restrictions of the following policies:

- MEDICALLY INFUSED THERAPEUTIC IMMUNOMODULATORS (TIMs) – Commercial and Medicare Part B
- THERAPEUTIC IMMUNOMODULATORS (TIMs) - Commercial
- THERAPEUTIC IMMUNOMODULATORS (TIMs) - Medicaid

REQUIRED MEDICAL INFORMATION	iv. For **systemic sclerosis (SSc-ILD)**, tocilizumab (Actemra®) may be covered if the following criteria are met: 1. Patient has interstitial lung disease, as evidence by high-resolution computed tomography (HRCT)
PRESCRIBER RESTRICTIONS	Systemic sclerosis-associated interstitial lung disease: pulmonologist or rheumatologist

3. FABRAZYME®

agalsidase beta

New indication approved 03/11/2021:

- **Treatment of adult and pediatric patients 2 years of age and older with confirmed Fabry disease**

RECOMMENDATION: Inform prescribers via MD alert. The FDA approved indications age limitations section for the Commercial, Medicaid and Medicare Part B Enzyme Replacement Therapy prior authorization policy will be updated with the current June P&T cycle. No policy criteria update needed.

4. TYVASO®

treprostinil

New indication approved 03/31/2021:

- **Pulmonary hypertension associated with interstitial lung disease (PH-ILD; WHO Group 3) to improve exercise ability. The study establishing effectiveness predominately included patients with etiologies of idiopathic interstitial pneumonia (IIP) (45%) inclusive of idiopathic pulmonary fibrosis (IPF), combined pulmonary fibrosis and emphysema (CPFE) (25%), and WHO Group 3 connective tissue disease (22%)**

RECOMMENDATION: Inform prescribers via MD alert. The FDA approved indications section for the Commercial, Medicaid, and Medicare Part B PAH prior authorization policies will be updated with the current June P&T cycle. No policy criteria update needed.

5. PRALUENT®

alirocumab

New indication approved 04/01/2021:

- **As an adjunct to other LDL-C-lowering therapies in adult patients with homozygous familial hypercholesterolemia (HoFH) to reduce LDL-C**

RECOMMENDATION: Inform prescribers via MD alert. The FDA approved indications section for the Commercial and Medicaid PCSK9-Inhibitor prior authorization policies will be updated. No policy criteria update needed.

6. MYRBETRIQ®

mirabegron extended-release tablet and granules

New indication approved 03/25/2021:

- **Treatment of neurogenic detrusor overactivity (NDO) in pediatric patients 3 years and older and weighing 35 kilograms or more.**

RECOMMENDATION: Inform prescribers via MD alert and update step therapy criteria to include new indication.

Criteria for the Commercial and Medicaid Step Therapy policy:

ST PROGRAM NAME	OVERACTIVE BLADDER MEDICATIONS
MEDICATION NAME	MYRBETRIQ® (mirabegron ER tablet)
PA INDICATION INDICATOR	1 - All FDA-Approved Indications
EXCLUSION CRITERIA	N/A
REQUIRED MEDICAL INFORMATION	Trial, intolerance, or contraindication to: 1. One (1) of the following: oxybutynin or tolterodine, AND 2. Solifenacin OR For Myrbetriq: Treatment is for neurogenic detrusor overactivity (NDO) in pediatric patients 3 years and older and weighing 35 kilograms or more Note: Contraindications to anticholinergic agents include delirium, dementia/cognitive impairment, preexisting issue with chronic constipation, urinary retention, gastric retention, or uncontrolled narrow-angle glaucoma.
AGE RESTRICTIONS	N/A
PRESCRIBER RESTRICTIONS	N/A
COVERAGE DURATION	Authorization will be approved until no longer eligible with the plan, subject to formulary or benefit changes

7. ARCALYST®

rilonacept

New indication approved 03/18/2021:

- **Treatment of recurrent pericarditis (RP) and reduction in risk of recurrence in adults and children 12 years and older**

RECOMMENDATION: Inform prescribers via MD alert and update prior authorization criteria as follows:

Criteria for the Commercial, Medicare Part B, and Medicaid

PA PROGRAM NAME	INTERLEUKIN – 1 INHIBITORS
MEDICATION NAME	ARCALYST® (rilonacept injection)
PA INDICATION INDICATOR	1 - All FDA-Approved Indications
EXCLUSION CRITERIA	N/A
REQUIRED MEDICAL INFORMATION	For Cryopyrin-Associated Periodic Syndrome (CAPS) including: Familial Cold Autoinflammatory Syndrome (FCAS) and Muckle-Wells Syndrome (MWS) confirmed by: 1. Laboratory evidence of genetic mutation NLRP-3 (Nucleotide-binding domain, leucine rich family (NLR) pyrin domain containing 3) or CIAS1 (Cold-Induced Auto-inflammatory Syndrome-1), **AND** 2. Classic symptoms associated with Familial Cold Auto-Inflammatory Syndrome (FCAS) or Muckle-Wells Syndrome (MWS) – recurrent intermittent fever and rash typically associated with natural or artificial cold **For Arcalyst® only:** For maintenance of remission of Deficiency of Interleukin-1 Receptor Antagonist (DIRA): 1. Diagnosis of Deficiency of Interleukin-1 Receptor Antagonist (DIRA) confirmed by laboratory evidence of genetic mutation in IL1RN (encodes for interleukin-1 receptor antagonist) 2. Current inflammatory remission of DIRA 3. Weight of at least 10 kg For recurrent pericarditis: 1. Diagnosis of recurrent pericarditis (RP) confirmed by an acute episode of pericarditis followed by a 4-6 week symptom free period prior to the next episode without an identified cause 2. Documentation trial and failure, contraindication or intolerance to NSAIDs or glucocorticoids **For Ilaris® only:**

	For Familial Mediterranean Fever (FMF), and all the following: 1. Documented trial and failure, contraindication or intolerance to colchicine, **AND** 2. Classic symptoms associated with FMF (febrile episodes, pain in the abdomen, chest, or arthritis of large joints). Diagnosis of Hyperimmunoglobulin D (Hyper-IgD) Syndrome (HIDS)/Mevalonate Kinase Deficiency (MKD) confirmed by: 1. Laboratory evidence of genetic mutation MVK (mevalonate kinase), **AND** 2. Classic symptoms associated with HIDs (abdominal pain; lymphadenopathy, aphthous ulcers). Diagnosis of Tumor Necrosis Factor (TNF) receptor Associated Periodic Syndrome (TRAPS) confirmed by: 1. Laboratory evidence of genetic mutation TNFRSF1A (tumor necrosis factor receptor super family), **AND** 2. Classic symptoms associated with TRAPs (abdominal pain, skin rash, musculoskeletal pain, eye manifestations). Diagnosis of Active Still's Disease including Systemic Juvenile Idiopathic Arthritis (SJIA) and Adult-Onset Still's Disease: 1. Documentation of trial and failure, intolerance, or contraindication to at least one conventional therapy (e.g., methotrexate, leflunomide, hydroxychloroquine, sulfasalazine) **AND** 2. Documentation of trial, failure, intolerance, or contraindication to both etanercept (Enbrel®) and adalimumab (Humira®)
AGE RESTRICTIONS	Arcalyst®: may be covered for patients aged 12 years and older with CAPS (which includes FCAS, MWS), treatment of recurrent pericarditis (RP), and reduction in risk of recurrence of pericarditis. Ilaris® may be covered for patients aged 4 years of age and older in patients with CAPS (which includes FCAS, MWS); Periodic Fever Syndromes including TRAPS, HIDS/MKD, and FMF Ilaris® may be covered for patients aged 2 years of age and older in patients with Active Systemic Juvenile Idiopathic Arthritis and Adult Onset Still's Disease (AOSD)
PRESCRIBER RESTRICTIONS	N/A
COVERAGE DURATION	Initial authorization will be approved for 6 months. Reauthorization will be approved for one year.

Therapies with Prior Authorization Policies (Oncology):

8. **BLINCYTO®**
   blinatumomab
   New indication approved 03/11/2021:
   - **Treatment of adults and children with relapsed or refractory CD19-positive B-cell precursor acute lymphoblastic leukemia (ALL).**

   RECOMMENDATION: Inform prescribers via MD alert. Prior authorization policy coverage criteria are based on recommendations from the National Comprehensive Cancer Network (NCCN) so no updates to the policy are warranted.

9. **SARCLISA®**
   isatuximab-irfc
   New indication approved 03/31/2021:
   - **In combination with carfilzomib and dexamethasone, for the treatment of adult patients with relapsed or refractory multiple myeloma who have received 1 to 3 prior lines of therapy**

   RECOMMENDATION: Inform prescribers via MD alert. Prior authorization policy coverage criteria are based on recommendations from the National Comprehensive Cancer Network (NCCN) so no updates to the policy are warranted.

10. **KEYTRUDA®**
    pembrolizumab
    New indication approved 03/22/2021:
    - **Treatment of patients with locally advanced or metastatic esophageal or gastroesophageal junction (GEJ) (tumors with epicenter 1 to 5 centimeters above the GEJ) carcinoma that is not amendable to surgical resection or definitive chemoradiation, in combination with platinum- and fluoropyrimidine-based chemotherapy. Additionally, the esophageal cancer section was updated with respect to the single agent indication for labeling consistency**

    RECOMMENDATION: Inform prescribers via MD alert. Prior authorization policy coverage criteria are based on recommendations from the National Comprehensive Cancer Network (NCCN) so no updates to the policy are warranted.

11. **LORBRENA®**
    lorlatinib
    New indication approved 03/03/2021:
    - **Treatment of adult patients with metastatic non-small cell lung cancer (NSCLC) whose tumors are anaplastic lymphoma kinase (ALK)-positive as detected by an FDA-approved test.**

RECOMMENDATION: Inform prescribers via MD alert. Prior authorization policy coverage criteria are based on recommendations from the National Comprehensive Cancer Network (NCCN) so no updates to the policy are warranted.

12. VYXEOS®

daunorubicin and cytarabine

New indication approved 03/30/2021:

- **Treatment of newly-diagnosed therapy-related acute myeloid leukemia (t-AML) or AML with myelodysplasia-related changes (AML-MRC) in pediatric patients ages 1 year and older**

RECOMMENDATION: Inform prescribers via MD alert. Prior authorization policy coverage criteria are based on recommendations from the National Comprehensive Cancer Network (NCCN) so no updates to the policy are warranted.

13. TRODELVY®

sacituzumab govitecan-hziy

New indication approved 04/07/2021:

- **Treatment of adult patients with unresectable locally advanced or metastatic triple-negative breast cancer (mTNBC) who have received two or more prior systemic therapies, at least one of them for metastatic disease**

RECOMMENDATION: Inform prescribers via MD alert. Prior authorization policy coverage criteria are based on recommendations from the National Comprehensive Cancer Network (NCCN) so no updates to the policy are warranted.

14. TECENTRIQ®

atezolizumab

New indication approved 04/13/2021:

- **Treatment of adult patients with locally advanced or metastatic urothelial carcinoma who have disease progression during or following any platinum-containing chemotherapy, or within 12 months of neoadjuvant or adjuvant chemotherapy**

RECOMMENDATION: Inform prescribers via MD alert. Prior authorization policy coverage criteria are based on recommendations from the National Comprehensive Cancer Network (NCCN) so no updates to the policy are warranted.

15. OPDIVO®

nivolumab

New indication approved 04/16/2021:

- **Treatment of unresectable or metastatic melanoma and disease progression following ipilimumab and, if BRAF V600 mutation positive, a BRAF inhibitor**

RECOMMENDATION: Inform prescribers via MD alert. Prior authorization policy coverage criteria are based on recommendations from the National Comprehensive Cancer Network (NCCN) so no updates to the policy are warranted.

Therapies without Prior Authorization Policies:

16. ZEPOSIA®

Ozanimod

New indication approved 05/27/2021

- **Moderately to severely active ulcerative colitis (UC) in adults**

RECOMMENDATION: Inform prescribers via MD alert and add prior authorization criteria as follows:

Prior Authorization Criteria for Commercial/Medicaid:

PA PROGRAM NAME	Zeposia
MEDICATION NAME	Ozanimod (Zeposia)
PA INDICATION INDICATOR	1 - All FDA-Approved Indications
OFF-LABEL USES	N/A
EXCLUSION CRITERIA	Concomitant use with another TIM agent (e.g., apremilast, adalimumab)
REQUIRED MEDICAL INFORMATION	Initial Authorization for **multiple sclerosis,** all of the following criteria must be met: 1. Must have one of the following confirmed diagnoses: a. Relapsing-remitting disease (RRMS) b. Secondary progressive multiple sclerosis (SPMS) c. Clinically isolated syndrome (CIS) 2. One of the following: a. Highly active disease, defined as both of the following: i. Two or more relapses in the previous year ii. One of the following: 1) The patient has at least 1 gadolinium enhancing lesion of MRI, OR 2) The patient has significant increase in T2 lesion load compared with a previous MRI The patient has been treated with at least three MS agents from different drug classes, OR 3) Documented inadequate response or intolerance to generic dimethyl fumarate or glatiramer, or contraindication to BOTH dimethyl fumarate and glatiramer 3. The prescriber has performed an electrocardiogram within six months prior to initiating treatment Initial Authorization for **ulcerative colitis (UC),** all of the following criteria must be met: 1. Documentation of moderately to severely active disease 2. Documentation of one of the following:

	a. Trial and failure, or intolerance to one of the following conventional therapies for UC: 6-mercaptopurine, azathioprine, balsalazide, corticosteroids, cyclosporine, mesalamine, or sulfasalazine, OR b. Documented FDA labeled contraindication to ALL of the therapies outlined above, OR c. Documentation of history of use of another therapeutic immunomodulatory (TIM) agent for the treatment of UC; TIM must be FDA labeled or compendia supported for the treatment of UC 3. Documentation of one of the following: a. Inadequate response or intolerance to two of the following preferred TIM agents: Humira (adalimumab), Stelara (ustekinumab), or Xeljanz (tofacitinib)/Xeljanz XR (tofacitinib extended release) b. FDA Labeled contraindication to ALL of the therapies outlined above 4. The prescriber has performed an electrocardiogram within six months prior to initiating treatment
AGE RESTRICTIONS	May be covered for adults 18 years of age and older
PRESCRIBER RESTRICTIONS	Must be prescribed by, or in consultation with, a neurologist (for MS) or gastroenterologist (for UC)
COVERAGE DURATION	Authorization will be approved until no longer eligible with the plan, subject to formulary or benefit changes

17. EXPAREL®

bupivacaine liposome injectable suspension

New indication approved 03/22/2021:

- **In patients 6 years of age and older for single-dose infiltration to produce postsurgical local analgesia**
- **In adults as an interscalene brachial plexus nerve block to produce postsurgical regional analgesia**

RECOMMENDATION: Inform prescribers via MD alert.

18. DIOVAN®

valsartan

New indication approved 04/19/2021:

- **Pediatric hypertension in children 1 year of age and older**

RECOMMENDATION: Inform prescribers via MD alert.

19. NATROBA®

spinosad

New indication approved 04/28/2021:

- **Topical treatment of scabies infestations in adult and pediatric patients 4 years of age and older**

RECOMMENDATION: Inform prescribers via MD alert.

Drug Safety Monitoring:

1. **Lamictal® (lamotrigine): Drug Safety Communication - Studies Show Increased Risk of Heart Rhythm Problems in Patients with Heart Disease**
   [Posted 3/31/2021]
   ISSUE:
   An FDA review of study findings showed a potential increased risk of heart rhythm problems, called arrhythmias, in patients with heart disease who are taking the seizure and mental health medicine Lamictal (lamotrigine). FDA wants to evaluate whether other medicines in the same drug class have similar effects on the heart and are also requiring safety studies on those medicines. FDA will update the public when additional information from these studies becomes available.

   FDA required these studies, called *in vitro* studies, to further investigate lamotrigines effects on the heart after FDA received reports of abnormal electrocardiographic (ECG) findings and some other serious problems. In some cases, problems including chest pain, loss of consciousness and cardiac arrest occurred. FDA first added information about this risk to the lamotrigine prescribing information and Medication Guides in October 2020, which has been updated.

   FDA RECOMMENDATION:
   Lamotrigine is used alone or with other medicines to treat seizures in patients 2 years and older. It may also be used as maintenance treatment in patients with the mental health condition bipolar disorder to help delay the occurrence of mood episodes such as depression, mania, or hypomania.

   Health care professionals should assess whether the potential benefits of lamotrigine outweigh the potential risk of arrhythmias for each patient. Laboratory testing performed at therapeutically relevant concentrations has shown that lamotrigine can increase the risk of serious arrhythmias, which can be life-threatening in patients with clinically important structural or functional heart disorders. Clinically important structural and functional heart disorders include heart failure, valvular heart disease, congenital heart disease, conduction system disease, ventricular arrhythmias, cardiac channelopathies such as Brugada syndrome, clinically important ischemic heart disease, or multiple risk factors for coronary artery disease. The risk of arrhythmias may increase further if used in combination with other medicines that block sodium channels in the heart. Other sodium channel blockers approved for epilepsy, bipolar disorder, and other indications should not be considered safer alternatives to lamotrigine in the absence of additional information.

   Recommendation: Notify via MD alert

2. **Benzedrex® (propylhexedrine): Drug Safety Communication - FDA Warns that Abuse and Misuse of the Nasal Decongestant Causes Serious Harm**
   [Posted 3/25/2021]

ISSUE:
The FDA is warning that the abuse and misuse of the over-the-counter (OTC) nasal decongestant propylhexedrine can lead to serious harm such as heart and mental health problems. Some of these complications, which include fast or abnormal heart rhythm, high blood pressure, and paranoia, can lead to hospitalization, disability, or death. Reports of individuals abusing and misusing propylhexedrine have increased in recent years. Propylhexedrine is safe and effective when used as directed.

FDA is requesting that all manufacturers of OTC propylhexedrine nasal decongestant inhalers consider product design changes that support its safe use. For example, modifying the product to create a physical barrier that would make tampering with the device and abusing the propylhexedrine inside more difficult. In addition, decreasing the amount of medicine the device contains could also reduce the risk of serious side effects if abused or misused. FDA continues to evaluate this safety issue and will determine if additional FDA actions are needed.

FDA RECOMMENDATION:
Propylhexedrine is a nasal decongestant that is available OTC in an inhaler. It is used short term to temporarily relieve nasal congestion due to colds, hay fever, or other upper respiratory allergies. It works by reducing swelling and inflammation of the mucous membrane lining of the nose. Health Care Professionals should be aware that some individuals are abusing or misusing propylhexedrine, particularly using it by routes other than nasal inhalation, which can result in serious cardiac and psychiatric adverse events or death. In the event of a suspected overdose, attempt to determine whether a patient used propylhexedrine alone or with other substances. There is no specific reversal agent in cases of acute intoxication, so symptomatic and supportive care should be provided.

Recommendation: Notify via MD alert

Other Formulary Changes:

Drug Name	Recommendation	Policy Name
Loteprednol etabonate (Eysuvis) Drops Susp	**Loteprednol etabonate (Eysuvis) Drops Susp**	N/A
Azelastine HCL Spray/Pump	• Commercial Standard: Formulary, Tier2 • Commercial Cost-Based: Formulary, Tier 3 • Medicaid: Non-Formulary, Prior Authorization • Medicare Part D: Formulary, Tier 3	• Commercial/Medicare Part D: N/A • Medicaid: Intranasal Allergy Medications – Medicaid
Mannitol (Bronchitol) Cap w/Dev	New route (Inhalation), dosage form (Cap w/dev), and strength (40mg); • Non-formulary for all lines of business	N/A

Cefixime Susp Recon	Add to Medicaid formulary EFFECTIVE: 07/01/2021	N/A
Cyclophosphamide Tablet	Returning drug; • Commercial: Formulary, Tier 4 • Medicaid: Formulary • Medicare Part D: Formulary, Tier 4	N/A
Desloratadine Tablet	• Medicaid: Add Prior Authorization, keep Non-Formulary	Second and Third generation antihistamines - Medicaid
Levetiracetam (Elepsia XR)Tab ER 24H	New strengths (1000 mg, 1500 mg); • Commercial/Medicaid: Non-Formulary, Prior Authorization • Medicare Part D: Non-Formulary	• Commercial/Medicaid: New Medications and Formulations without Established Benefit • Medicare Part D: N/A
Loteprednol etabonate (Lotemax) 0.5% Oint	Remove brand from Medicaid formulary	N/A
Loteprednol etabonate (Lotemax SM) 0.38% Drops Gel	Remove brand from Commercial and Medicaid formularies	N/A
Loteprednol etabonate 0.5% Drops Gel and Drops Susp	• Commercial Standard: Add to Formulary, Tier 2 • Commercial Cost-Based: Add to Formulary, Tier 4 • Medicaid: Remove from Formulary • Medicare Part D: Add to Formulary, Tier 3	N/A
Siponimod (Mayzent) Tab DS PK	• Commercial/Medicare Part D: Formulary, Tier 5 • Medicaid: Formulary, Specialty	N/A
Oxycodone HCL/acetaminophen (Prolate) Solution	New strength (10mg-300mg/5ml); • Commercial/Medicaid: Non-Formulary, Quantity Limit (90 MME) • Medicare Part D: Non-Formulary	N/A
Ursodiol (Reltone) Capsule	New strengths (200mg, 400mg); • Non-Formulary for all lines of business	N/A
Lanreotide acetate (Somatuline Depot) Syringe	• Commercial/ Medicare Part B: Medical Benefit, Prior Authorization • Medicaid: Non-Formulary, Prior Authorization	Somastatin Analogs

	• Medicare Part D: Non-Formulary EFFECTIVE: 09/01/2021	
Solifenacin succinate (Vesicare LS) Oral Susp	New dosage form (susp) and strength (5mg/5ml); • Non-Formulary for all lines of business	N/A
Zileuton (Zyflo) Tablet	• Commercial/Medicaid: Non-Formulary, Prior Authorization • Medicare Part D: Non-Formulary	• Commercial/Medicaid: Zyflo CR • Medicare Part D: N/A
Azelaic acid cream (Azelex) Cream	Remove from Commercial formulary	N/A
Azilsartan medoxomil (Edarbi) Tablet Azilsartan med/chlorthalidone (Edarbyclor) Tablet	Remove from Commercial formulary EFFECTIVE: 09/01/2021	N/A
Calcipotriene/ betamethasone (Taclonex Scalp) Suspension	Add to Medicaid formulary	Enstilar, Taclonex, Taclonex Scalp
Tafluprost/PF (Zioptan) Droperette	• Commercial: Formulary, Tier 4, Step Therapy, Quantity Limit (1 droperette per day) • Medicaid: Non-Formulary, Step Therapy, Quantity Limit (1 droperette per day) • Medicare Part D: Non-Formulary	• Commercial/Medicaid: Anti-Glaucoma Agents Step Therapy • Medicare Part D: N/A
Bimatoprost Drops	• Commercial Cost-Based: Change from Tier 4 to Tier 3 • Medicare Part D: Change from Tier 4 to Tier 3	• Commercial: Lumigan Step Therapy • Medicare Part D: N/A

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**
Trastuzumab-QYYP (Trazimera) Vial	New strength. Line extend with Trazimera 420mg; • Commercial/Medicaid/Medicare Part B: Medical Benefit, Prior Authorization	Injectable Anti-Cancer Medications

	• Medicare Part D: Non-Formulary	
Enzalutamide (Xtandi) Tablet	New dosage form (Tablet) and Strength (40 mg and 80 mg). Line extend with Xtandi capsule; • Commercial/Medicare Part D: Formulary, Tier 5, Prior Authorization • Medicaid: Formulary, Specialty, Prior Authorization	Oral Anti-Cancer Medications
Tasimelteon (Hetlioz LQ) Oral Susp	New dosage form (suspension) and strength (4mg/ml). Line extend with Hetlioz capsule; • Commercial: Formulary, Tier 6, Prior Authorization, Quantity Limit (5 ml per day) • Medicaid: Formulary, Specialty, Prior Authorization, Quantity Limit (5 ml per day) • Medicare Part D: Formulary, Tier 5, Prior Authorization, Quantity Limit (5 ml per day)	Hetlioz
Aripiprazole (Abilify Mycite) Tabsenstpd / Tabsensstr	New Dosage Form (Starter/Maint Kits). Line extend with Abilify Mycite; • Commercial/Medicaid: Non-Formulary, Prior Authorization • Medicare Part D: Formulary, Tier 5	• Commercial/Medicaid: New Medications and Formulations without Established Benefit • Medicare Part D: N/A

New Generics:

NEW GENERICS		
Drug Name	**Action Taken**	**Policy Name**
Hydrocodone Bitartrate ER (Hydrocodone Bitartrate) Tab ER 24H	First generic (Hysingla ER). Line extend as generic;	• Commercial/Medicaid: Long Acting Opioids • Medicare Part D: N/A

	• Commercial: Non-Formulary, Prior Authorization, Quantity Limit (1 Tab ER per Day) • Medicaid: Non-Formulary, Prior Authorization, Quantity Limit (90 MME per day) • Medicare Part D: Non-Formulary	
Brinzolamide Drops Susp	First Generic (Azopt). Line extend as generic; • Commercial Standard: Formulary, Tier 2 • Commercial Cost-Based: Formulary, Tier 4 • Medicaid: Formulary • Medicare Part D: Formulary, Tier 4	N/A
Tazarotene Foam	First Generic (Fabior). Line extend as generic; • Non-formulary for all lines of business	N/A
Pregabalin ER (Pregabalin) Tab ER 24H	First Generic (Lyrica CR). Line extend as generic; • Commercial/Medicaid: Non-Formulary, Prior Authorization, Quantity Limit (1 tab per day) • Medicare Part D: Non-Formulary	• Commercial/Medicaid: New Medications and Formulations without Established Benefit • Medicare Part D: N/A

Clinical Policy Changes:

Policy Name	Summary of Change
Aczone Step Therapy	Updated covered uses to all medically accepted indications.
Alpha-1 Proteinase Inhibitors	Changed initial authorization to one year. Added positive response to therapy as reauthorization criteria. Removed phenotype SZ as high risk for low levels of serum alpha-1 antitrypsin (ATT) and development of lung disease as evidence is mixed (i.e., SZ phenotype must provide documentation of low levels of AAT).
Benlysta	Addition of concurrent use of Lupkynis to the exclusion criteria.

Bepreve, Lastacaft, Pazeo, Zerviate	Changed covered uses to all medically-accepted indications. Removed Pazeo from policy as product is to be discontinued. Product will remain non-formulary.
Botulinum Toxin	Criteria were added to establish medical necessity criteria for the use of Botox® in combination with prophylactic calcitonin gene related peptide (CGRP) receptor antagonists. Additionally added reauthorization criteria for successful response to Botox® for migraine prophylaxis.
Buprenorphine	Prior Authorization removed for commercial lines of business due to regulatory requirements.
Bystolic	Changed covered uses to all medically-accepted indications.
Calcitonin Gene-Related Peptide Receptor (CGRP) Antagonists for Migraine Prophylaxis - Medicaid	Criteria were updated to align with criteria approved by the Oregon Health Authority.
Calcitonin Gene-Related Peptide Receptor (CGRP) Antagonists for Migraine Prophylaxis	Updated criteria to allow for coverage of combination of botulinum toxin and CGRPs for prophylaxis when medically necessary. Removed prescriber restrictions for chronic migraine.
CFTR Modulators	Added quantity limit of two granule packets per day for Orkambi. This was already attached to the product but not listed on the policy.
Corlanor	The policy criteria was updated to include a relatively new indication for pediatric patients with heart failure due to dilated cardiomyopathy (DCM).
Daliresp	Remove provider restriction and exclusion criteria for hepatic impairment. Add trial duration to be at least 60 days. Add option to allow for coverage without trial of ICS in combination with LAMA/LABA in patients with low likelihood of response (blood eosinophils less than 100 cells/microliter) to align with the Global initiative for chronic Obstructive Lung Disease (GOLD) guidelines. Changed reauthorization duration to lifetime.
Enstilar, Taclonex, Taclonex Scalp, Wynzora	Added ointment formulation as an option for trial and failure criteria of calcipotriene. In addition, updated trial and failure of betamethasone to high potency steroid to allow for other formulations that may be better suited for scalp application (e.g., clobetasol solution/shampoo).
Esbriet, Ofev	Change initial and reauthorization duration to one year; updated idiopathic pulmonary fibrosis (IPF) diagnosis criteria to include option for biopsy supported

	probably or indeterminate UIP on HRCT to better align with the American Thoracic Society IPF diagnosis guidelines.
Gonadotropin Releasing Hormone Agonists	HealthShare of Oregon has decided to prefer Vantas® (histrelin acetate 50 mg implant) for providing transgender services.
IL-5 Inhibitors	For eosinophilic asthma changed combination of ICS with a LABA to ICS and any additional inhaled asthma controller to align with FDA labeling and study population in approval trials. Updated authorization duration for eosinophilic granulomatosis with polyangiitis and hyperesosinophilic syndrome to 12 months and changed reauthorization for asthma to lifetime.
Infertility and Related Medications	Updated criteria to assess that the medications are being used for a covered benefit (infertility treatments are not covered for many plans). Additionally, preferred products have been chosen and will be required before coverage of non-preferred therapies.
Injectable Anti-Cancer Medications	Policy was updated to clarify non-preferred and preferred trastuzumab and bevacizumab products.
Juxtapid	Update criteria to align with new therapy for homozygous familial hypercholesterolemia (HoFH) called evinocumab.
Ketorolac Intramuscular Injection	Updated policy to clarify that the five day limit is per treatment course.
Krystexxa	Updated the criteria to align with the 2020 American College of Rheumatology Guideline for the Management of Gout. This medication is recommended to be used only in patients that have failed other urate lowering therapy and continue to have symptomatic chronic gout.
Long-Acting Stimulant Medications - Medicaid	Updated to clarify the intention of the changes made at April ORPTC.
Lumigan Step Therapy	Renamed policy to Anti-Glaucoma Agents and added Vyzulta and Zioptan to the policy.

Luxturna	Updated authorization duration from four weeks to 12 weeks to reduce repeat requests if treatment was not able to occur right away. Still one treatment course per eye per lifetime.
Medically Infused Therapeutic Immunomodulators (Tims) - Comm	Updated age restrictions to clarify that coverage is only approved for patients within the FDA label.
Nexletol, Nexlizet	Clarified language around statin intolerance, added option for endocrinologist or lipid specialist as prescriber as may be the class for familial hypercholesterolemia, changed initial authorization to one year.
Nucynta & Nucynta ER	Quantity limit section added.
Ophthalmic Vascular Endothelial Growth Factor (VEGF) Inhibitors	Removed the brand name Avastin® from the policy criteria as there are now biosimilar products. Policy now uses the generic name bevacizumab only as all compounded bevacizumab products will count toward trial and failure.
Oxaydo, Roxybond	Policy name to be changed to Oxaydo. Roxybond removed from policy as drug has been discontinued. Added criteria to require a least one non-opioid therapy prior to approval unless request is for active cancer pain. Increased initial authorization from six months to one year. Update quantity limit section to refer to the maximum allowable opioid dose policy.
Oxymorphone (Opana)	Updated criteria to require trial failure of IR morphine sulfate and oxycodone for all indications (previously was not required for active cancer pain. Increased reauthorization length to lifetime. Update quantity limit section to reflect cumulative dose policy.
Pediatric Analgesics	Update criteria to require trial of an over the counter cough and cold product if the requesting a product for cough.
• **Pulmonary Arterial Hypertension – Commercial** • **Pulmonary Arterial Hypertension - Part B**	Updated FDA indication of Tyvaso for pulmonary hypertension associated with interstitial lung disease (PH-ILD; WHO Group 3) to improve exercise ability.
Reyvow	Added history of hemiplegic or basilar migraine as a contraindication to the use of triptans. Increased quantity limit of 100 mg tablets to eight per month (200 mg max per headache, max four headaches per month).
Rituximab	Policy was updated to clarify non-preferred and preferred rituximab products.

Soliris	Removed requirement for genetic testing and prior use of plasma therapy for complement mediated hemolytic uremic syndrome. Kidney Disease - improving global outcomes (KDIGO) recommend all patients with a clinical diagnosis of atypical HUS be eligible for treatment with a complement inhibitor and genetic testing should not delay treatment. 50-70% of participants in approval trials had confirmed genetic mutation. KDIGO states all patients with clinical diagnosis should be eligible for eculizumab with plasma therapy as alternative.
Somastatin Analogs	New policy
Tafamidis	Update initial authorization duration to one year as study endpoints assessed after 30 months. Remove requirement of documented baseline 6-minute walk test or Kansas City Cardiomyopathy Questionnaire-Overall Summary.
Trelegy Ellipta - Step Therapy - Medicaid	Changed covered uses to all medically accepted indications. Updated step therapy to be any dual therapy combination not just combination inhalers to align with Oregon Health Plan PA criteria.
Therapeutic Immunomodulators – Comm	Updated age restrictions to clarify that coverage is only approved for patients within the FDA label.
Topical Antibiotics Step Therapy	Updated covered uses to all medically accepted indications to align with all other step therapy policies.
Trelegy Ellipta - Step Therapy – Medicaid	Changed covered uses to all medically accepted indications. Updated step therapy to be any dual therapy combination not just combination inhalers to align with Oregon Health Plan PA criteria.
Xhance	Updated duration of approval and added reauthorization criteria to assess response to therapy.
Xolair	Added new indication for nasal polyps. Policy criteria aligned closely with Dupixent criteria for nasal polyps. Increased reauthorization duration of urticaria to lifetime. For asthma, added medium dose ICS (in addition to high dose ICS) with a long-acting inhaled beta2-agonist as required prior medication therapy requirements to align with the Global Initiative for Asthma (GINA) 2021 updated guidelines.
Zinplava	Added requirement patient is on standard of care antibiotics for reauthorization.