Healthcare Services Medical & Pharmacy Policy Alerts

Number 262

September 1, 2021

This is the September 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.

Lab Management FAQ

Effective 11/1/2021, Providence Health Plan and Providence Health Assurance will institute additional CMS National Coverage Determinations (NCDs) of selected lab services for Medicare, commercial and individual plans.

Q: What is the CMS NCD coding policy manual?
A: The final rule, published in the Federal Register on November 23, 2001 (66 FR 58788), established the national coverage and administrative policies for clinical diagnostic laboratory services. It promoted Medicare program integrity and national uniformity, and simplified administrative requirements for clinical diagnostic services. A total of 23 lab NCDs for diagnostic lab testing services were established as part of this 2001 final rule.

For each of the 23 NCDs, the CMS NCD coding policy manual outlines ICD-10-CM codes that are medically necessary or do not support medical necessity. The coding policy manual also includes limitations to these lab testing services, such as frequency limits.

Q: What is a NCD for diagnostic laboratory testing?
A: A national coverage policy for diagnostic laboratory test(s) is a document stating CMS's policy with respect to the clinical circumstances in which the test(s) will be considered reasonable and necessary, and not screening, for Medicare purposes. Such a policy applies nationwide.

Q: How is Providence Health Plan and Providence Health Assurance implementing the NCDs for diagnostic laboratory testing and the CMS NCD coding policy manual?
A: Through medical policy, we will create new policies based on the NCDs for diagnostic laboratory testing and the CMS NCD coding policy manual. The CPT/HCPCS codes for the various lab testing services are configured to pay or deny (not medically necessary) based on the diagnosis codes outlined in the coding policy manual.

Q: What laboratory services will be affected by this change?
A: For Medicare, commercial, and individual lines of business, we will implement medical policies and coding configuration based on the CMS NCD coding policy manual for the following NCDs:

- Prostate Specific Antigen (NCD 190.31)
- Serum Iron Studies (NCD 190.18)
- Partial Thromboplastin Time (NCD 190.16)
- Hepatitis Panel/Acute Hepatitis Panel (NCD 190.33)

Q: When will the new policies and coding configuration take effect?

A: 11/1/2021 for Medicare, commercial, and individual plans. On this date, the medical policies will be accessible here: https://www.providencehealthplan.com/providers/medical-policy--rx-pharmacy-and-provider-information

Q: Where can I access the NCDs for diagnostic laboratory testing and the CMS NCD coding policy manual?
A: The NCDs are linked below. Within every NCD there is a section titled "**Covered Code Lists**". Under this section, you may download the most recent version of the CMS NCD coding policy manual.

- Prostate Specific Antigen (NCD 190.31)
- Serum Iron Studies (NCD 190.18)
- Partial Thromboplastin Time (NCD 190.16)
- Hepatitis Panel/Acute Hepatitis Panel (NCD 190.33)

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

MEDICAL POLICY COMMITTEE

MEDICAL

Effective 11/1/2021

Back: Percutaneous Vertebral Augmentation **MP196**	**Policy Updates** • No recommended changes to criteria. **Codes/PA:** Diagnosis codes C79.52 (secondary malignant neoplasm of bone marrow) and C90.01 (multiple myeloma in remission) will be added to list of diagnosis codes configured to pay with percutaneous vertebroplasty CPT codes.

MEDICAL

Effective 9/1/2021

Inflammatory Bowel Disease: Serologic Testing and Therapeutic Monitoring **MP218**	**Policy Updates** • Fecal calprotectin (FC) testing will be covered for management of inflammatory bowel disease: **Codes/PA:** Prior authorization will be required for CPT 81306 (NUDT15 gene analysis)

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

Vascular Imaging – 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 August 6, 2021
Go-Live Date: Friday, October 01, 2021, unless otherwise noted

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New Drugs and Combinations:

1. **Aducanumab (Aduhelm) Vial**
   a. **Indication**: For the treatment of Alzheimer's disease.
   b. **Decision**: Exclude from coverage until more information is available about the safety and efficacy of the product, and a full P&T review is completed
   c. **Prior Authorization Criteria**: N/A

2. **Loncastuximab tesirine-LPY (Zynlonta) Vial**
   a. **Indication**: Treatment of adult patients with relapsed or refractory large B-cell lymphoma after two or more lines of systemic therapy, including diffuse large B-cell lymphoma (DLBCL) not otherwise specified, DLBCL arising from low grade lymphoma, and high-grade B-cell lymphoma.
   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: Pharmacy- Xpovio®, Medical – Monjuvi®, Polivy®			

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

3. **Dostarlimab-GXLY (Jemperli) Vial**
   a. **Indication**: For the treatment of adult patients with mismatch repair deficient (dMMR) recurrent or advanced endometrial cancer (EC), as determined by an FDA-approved test, that has progressed on or following prior treatment with a platinum-containing regimen.
   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- pembrolizumab (Keytruda®)			

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

4. **Amivantamab-VMJW (Rybrevant) Vial**
   a. **Indication**: For the treatment of adult patients with locally advanced or metastatic non-small cell lung cancer (NSCLC) with epidermal growth factor receptor (EGFR) exon 20 insertion mutations, whose disease has progressed on or after platinum-based chemotherapy
   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	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:			

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

5. **Sotorasib (Lumakras) Tablet**
   a. **Indication**: Treatment of adult patients with KRAS G12C-mutated locally advanced or metastatic non-small cell lung cancer (NSCLC), as determined by an FDA-approved test, who have received at least one prior systemic therapy.
   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			
* 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: Pharmacy: None Medical: Systemic chemotherapy, pembrolizumab			

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

6. **Infigratinib phosphate (Truseltiq) Capsule**
   a. **Indication**: For treatment of adults with unresectable locally advanced or metastatic cholangiocarcinoma.
   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			
* 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: Pemazyre			

c. **Prior Authorization Criteria**: **Prior Authorization Criteria for Commercial/Medicaid**: Added to Oral Anti-Cancer Medications Policy
d. **Prior Authorization Criteria**: Added the Anti-Cancer Agents Program

7. Ponesimod (Ponvory) Tablet / Tab DS PK

a. **Indication**: For the treatment of relapsing forms of multiple sclerosis (MS) in adults, to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease.
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
Specialty Medication	Yes	Yes	N/A
Affordable Care Act Eligible	N/A; Non-Formulary	N/A	N/A
Utilization Management Edits	N/A	N/A	N/A
Quantity Limit			
* Recommendations for placement may differ between lines of business due to regulatory requirements. ** Medications will be placed on recommended tier above for the base formulary; tier placement for custom formulary(ies) will be based on designation above. For example, Commercial Tier 6 designation above means that the medication will be placed on the highest cost-sharing tier on the respective formulary(ies).			
Formulary Alternatives:			

c. **Prior Authorization Criteria**: N/A

8. Dasiglucagon HCL (Zegalogue) Syringe and Auto Injct

a. **Indication**: Treatment of severe hypoglycemia in pediatric and adult patients with diabetes aged 6 years and above.

b. **Decision**:

	Commercial	Medicaid	Medicare
Formulary Status*	Formulary	Non-formulary	Part D: Non-formulary Part B: N/A
Tier**	Tier 3	N/A	N/A
Specialty Medication	No	No	N/A
Affordable Care Act Eligible	No	N/A	N/A
Utilization Management Edits	N/A	N/A	N/A
Quantity Limit	No	No	No
* 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: glucagon emergency kit, Gvoke®, Baqsimi®			

c. **Prior Authorization Criteria**: N/A

9. **Viloxazine HCL (Qelbree) Cap ER 24H**
   a. **Indication**: Viloxazine (Qelbree®) for treatment of Attention-Deficit Hyperactivity Disorder (ADHD) in pediatric patients 6 to 17 years of age.
   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
Specialty Medication	No	No	N/A
Affordable Care Act Eligible	N/A; Non-Formulary	N/A	N/A
Utilization Management Edits	N/A	N/A	N/A
Quantity Limit			
* Recommendations for placement may differ between lines of business due to regulatory requirements. ** Medications will be placed on recommended tier above for the base formulary; tier placement for custom formulary(ies) will be based on designation above. For example, Commercial Tier 6 designation above means that the medication will be placed on the highest cost-sharing tier on the respective formulary(ies).			
Formulary Alternatives: atomoxetine, clonidine extended-release, guanfacine extended-release			

c. **Prior Authorization Criteria**: N/A

10. Drospirenone-estetrol (Nextstellis) Tablet

a. **Indication**: DRSP/E4 oral tablet (Nextstellis®) is indicated for use by females of reproductive potential to prevent pregnancy. Drug may be less effective in females with a BMI greater than or equal to 30 kg/m^2.

b. **Decision**:

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

c. **Prior Authorization Criteria**: N/A

New Indications:

Therapies with Prior Authorization Policies (Non-oncology)

1. 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: Criteria for Commercial, Medicare Part B, and Medicaid were reviewed at June 2021 ORPTC. Criteria for Medicare Part D prior authorization policy will be updated as followed:

PA PROGRAM NAME	Arcalyst
MEDICATION NAME	Arcalyst
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): Diagnosis confirmed by: 1. Laboratory evidence of genetic mutation NLRP-3 (Nucleotide-binding domain, leucine rich family pyrin domain containing 3) or CIAS1 (Cold-induced auto-inflammatory syndrome-1), AND 2. Classic symptoms associated with FCAS or MWS (e.g., recurrent intermittent fever and rash typically associated with natural or artificial cold). For Deficiency of Interleukin-1 Receptor Antagonist (DIRA): 1. 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. Reauthorization: Documentation submitted of improvement of symptoms (such as fever, urticaria-like rash, arthralgia, myalgia, fatigue, and conjunctivitis for CAPS)
AGE RESTRICTIONS	N/A
PRESCRIBER RESTRICTIONS	Must be prescribed by, or in consultation with, a rheumatologist or nephrologist.
COVERAGE DURATION	Initial authorization and reauthorization will be approved for six months.

1. **ZIPSOR® (**diclofenac sodium)
   New indication approved 05/25/2021: For relief of mild to moderate acute pain in adult and pediatric patients 12 years of age and older
   RECOMMENDATION: Inform prescribers via Medical Policy Alert. No updates to criteria warranted.

2. **NURTEC® (**rimegepant)
   New indication approved 05/27/2021: Preventive treatment of episodic migraine in adults
   RECOMMENDATION: Inform prescribers via Medical Policy Alert and update prior authorization criteria for Commercial and Medicaid as outlined below. This drug is non-formulary for Medicare Part D, so no updates to criteria are warranted.

   Prior Authorization for Commercial/Medicaid:

PA PROGRAM NAME	Calcitonin gene-related peptide (CGRP) receptor antagonist for migraine prophylaxis
MEDICATION NAME	Nurtec
COVERED USES	1 - All FDA-Approved Indications
EXCLUSION CRITERIA	1. Concurrent use of a strong CYP3A4 inhibitor (e.g. ketoconazole, itraconazole, clarithromycin). 2. Concurrent use with a CGRP used for migraine prophylaxis.

REQUIRED MEDICAL INFORMATION	Initial authorization for **migraine prophylaxis (chronic and episodic)**: 1. Diagnosis of migraine headaches with at least four headache days per month **AND** 2. One of the following: a. Trial and inadequate response to at least six weeks of at least one prophylactic medication from one of the following categories: i. Anticonvulsants (i.e., divalproex, valproate, topiramate) ii. Beta-blockers (i.e., metoprolol, propranolol, timolol) iii. Antidepressants (i.e., amitriptyline, venlafaxine) b. Documented intolerance or contraindication to an anticonvulsant, a beta blocker, AND an antidepressant listed above **AND** 3. The patient has been evaluated for, and does not have, medication overuse headache 4. For non-preferred CGRP prophylactic agents (Ajovy®, Vyepti®, Nurtec®): Trial and failure, intolerance, or contraindication to two of the preferred CGRP agents (Aimovig® and Emgality®) 5. For patients established on botulinum toxin for migraine prophylaxis, combination therapy may be considered medically necessary if the following criteria are met: a. The patient has been established on, and adherent to botulinum toxin for at least six months and has a documented 30% reduction in headache days from baseline b. Patient continues to have at least four headache days per month with headaches lasting four hours or longer, despite use of botulinum toxin prophylaxis monotherapy c. Combination therapy is prescribed by, or in consultation with, a neurologist Reauthorization for all indications: Documented reduction in the severity or frequency of headaches.
AGE RESTRICTIONS	N/A
PRESCRIBER RESTRICTIONS	For cluster headaches: Must be prescribed by, or in consultation with, a headache specialist [*e.g.,* neurologist, pain management specialist, or specialist with United Council for Neurologic Subspecialties (UCNS)]
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

3. **ZEPOSIA® (**ozanimod)
New indication(s) approved 05/27/2021: Moderately to severely active ulcerative colitis (UC) in adults
RECOMMENDATION: Inform prescribers via Medical Policy Alert. New indication was reviewed at June 2021 ORPTC and policies were created.

4. **NOXAFIL®** (posaconzole)

New indication approved 05/31/2021:

- Noxafil is indicated for the prophylaxis of invasive Aspergillus and Candida infections in patients who are at high risk of developing these infections due to being severely immunocompromised, such as hematopoietic stem cell transplant (HSCT) recipients with graftversus-host disease (GVHD) or those with hematologic malignancies with prolonged neutropenia from chemotherapy as follows:
    1. Noxafil injection: adults and pediatric patients 2 years of age and older
    2. Noxafil delayed-release tablets: adults and pediatric patients 2 years of age and older who weigh greater than 40 kg
    3. Noxafil oral suspension: adults and pediatric patients 13 years of age and older
    4. Noxafil PowderMix for delayed-release oral suspension: pediatric patients 2 years of age and older (who weigh 40 kg or less)
- Oral suspension: treatment of oropharyngeal candidiasis (OPC), including OPC refractory (rOPC) to itraconazole and/or fluconazole in adult and pediatric patients ages 13 years and older

RECOMMENDATION: Inform prescribers via Medical Policy Alert. No updates to criteria warranted.

Therapies without Prior Authorization Policies:

5. **CUBICIN® (**DAPTOMYCIN)
   New indication(s) approved 05/05/2021:
   - Complicated skin and skin structure infections (cSSSI) in adult and pediatric patients (1 to 17 years of age)
   - Staphylococcus aureus bloodstream infections (bacteremia) in pediatric patients (1 to 1o 17 years of age)

   RECOMMENDATION: Inform prescribers via Medical Policy Alert.

6. **LYMPHOSEEK® (**technetium Tc 99m tilmanocept)
   New indication(s) approved 05/19/2021:
   - Lymphatic mapping using a handheld gamma counter to locate lymph nodes draining a primary tumor site in adult and pediatric patients age one month and older with solid tumors for which this procedure is a component of intraoperative management

   RECOMMENDATION: Inform prescribers via Medical Policy Alert.

Drug Safety Monitoring:

1. **Drug Name:** Ocaliva (obeticholic acid)
   Date Posted: 05-26-2021
    a. **Safety Alert Title:** Due to risk of serious liver injury, FDA restricts use of Ocaliva (obeticholic acid) in primary biliary cholangitis (PBC) patients with advanced cirrhosis
    b. **Link to more information:** https://www.fda.gov/drugs/drug-safety-and-availability/due-risk-serious-liver-injury-fda-restricts-use-ocaliva-obeticholic-acid-primary-biliary-cholangitis
    c. **What safety concern is FDA announcing?**

i. The U.S. Food and Drug Administration (FDA) is restricting the use of the liver disease medicine Ocaliva (obeticholic acid) in patients having primary biliary cholangitis (PBC) with advanced cirrhosis of the liver because it can cause serious harm. PBC is a rare, chronic disease affecting the ducts in the liver that carry bile, which helps with digestion. Some PBC patients with cirrhosis who took Ocaliva, especially those with evidence of advanced cirrhosis, developed liver failure, sometimes requiring liver transplant.
ii. Based on the original clinical trials, FDA believes the benefits of Ocaliva outweigh the risks for PBC patients who do not have advanced cirrhosis. We will continue to monitor and evaluate the clinical benefit and adverse events of Ocaliva and will communicate any new information to the public if it becomes available.

d. What is FDA doing?

i. We added a new Contraindication, FDA's strongest warning, to the Ocaliva prescribing information and patient Medication Guide stating that Ocaliva should not be used in PBC patients with advanced cirrhosis. Advanced cirrhosis is defined as cirrhosis with current or prior evidence of liver decompensation (e.g., encephalopathy, coagulopathy) or portal hypertension (e.g., ascites, gastroesophageal varices, persistent thrombocytopenia). We also revised the Boxed Warning, our most prominent warning, to include this information along with related warnings about this risk.

e. What should health care professionals do?

i. Health care professionals should determine before starting Ocaliva whether a patient with PBC has advanced cirrhosis as the medicine is contraindicated in these patients. Advanced cirrhosis is defined as cirrhosis with current or prior evidence of hepatic decompensation (e.g., encephalopathy, coagulopathy) or portal hypertension (e.g., ascites, gastroesophageal varices, persistent thrombocytopenia). Routinely monitor patients during Ocaliva treatment for progression of PBC with laboratory and clinical assessments to determine whether the medicine needs to be discontinued. Permanently discontinue Ocaliva in patients with cirrhosis who progress to advanced cirrhosis.
ii. Also monitor patients for clinically significant liver-related adverse reactions that may manifest as development of acute-on-chronic liver disease with nausea, vomiting, diarrhea, jaundice, scleral icterus, and/or dark urine. Permanently discontinue Ocaliva in patients developing these symptoms.

f. Health Plan Recommendation: Notify providers via Medical Policy Alert. PA policy changes needed (see policy updates below)

Commercial/Medicaid:

PA PROGRAM NAME	Gastrointestinal agents
MEDICATION NAME	Ocaliva

COVERED USES	1 - All FDA-Approved Indications
EXCLUSION CRITERIA	Use of non-alcoholic steatohepatitis (NASH), decompensated cirrhosis (e.g., Child-Pugh Class B or C) or a prior decompensation event, compensated cirrhosis with evidence of portal hypertension (e.g., ascites, gastroesophageal varices, persistent thrombocytopenia)
REQUIRED MEDICAL INFORMATION	**For the diagnosis of primary biliary cholangitis:** med diagnosis of primary biliary cholangitis as evidenced by two of the following criteria: a. Elevated alkaline phosphatase (ALP) [above the upper limit of normal (ULN) as defined by laboratory reference values] b. Presence of antimitochondrial antibody (AMA) c. Histologic evidence of primary biliary cirrhosis from liver biopsy **AND** f the following: a. Use of ursodiol for a minimum of six months and has had an inadequate response according to prescribing physician **AND** b. Documentation that the medication will be used in combination with ursodiol, unless patient is unable to tolerate ursodiol ~~**AND** Dose is appropriate based on an assessment of hepatic function (Child-Pugh class). If Child-Pugh B or C, start at 5mg once weekly (can be increased if needed to a maximum of 10mg twice weekly)~~ **Reauthorization Criteria:** 1. Maintenance of biochemical response [i.e. alkaline phosphatase (ALP) less than or equal to 1.67 times ULN, total bilirubin (tBili) less than or equal to ULN, and ALP decrease of at least 15%] 2. Documentation that ursodiol will be continued, if tolerated ~~3.~~ Hepatic function is assessed at least annually. ~~If Child-Pugh B or C, dose should not exceed 10mg twice weekly~~
AGE RESTRICTIONS	N/A
PRESCRIBER RESTRICTIONS	Must be prescribed by, or in consultation with, a gastroenterologist or hepatologist.
COVERAGE DURATION	Initial authorization will be approved for four months. Reauthorization will be approved for one year.

Medicare Part D:

PA PROGRAM NAME	Ocaliva
MEDICATION NAME	Ocaliva

PA INDICATION INDICATOR	3 - All Medically-Accepted Indications
OFF-LABEL USES	N/A
EXCLUSION CRITERIA	~~N/A~~ Decompensated cirrhosis (e.g., Child-Pugh Class B or C) or a prior decompensation event, compensated cirrhosis with evidence of portal hypertension (e.g., ascites, gastroesophageal varices, persistent thrombocytopenia)
REQUIRED MEDICAL INFORMATION	1. Confirmed diagnosis of Primary Biliary Cirrhosis with two of three of the following criteria are met: a. Elevated alkaline phosphatase (greater than upper limit of normal [ULN]), b. Presence of antimitochondrial antibody (AMA) (titer greater than or equal to 1:40), c. Liver biopsy consistent with primary biliary cirrhosis AND 2. Both of the following: a. Use of ursodiol for a minimum of 6 months and failure to achieve: ALP less than or equal to 1.5 X ULN, AST less than or equal to 1.5 X ULN, and total bilirubin (tBili) less than or equal to ULN. If laboratory reference values for ALP are not available, the values used in a clinical trial may be used for this assessment (ULN = 117 U/L for women, 129 U/L for men). AND b. Documentation that ursodiol will be continued unless there were intolerable adverse effects with ursodiol AND ~~3. Dose is appropriate based on an assessment of hepatic function (Child-Pugh class). If Child-Pugh B or C, start at 5 mg once weekly (can be increased if needed to a maximum of 10mg twice weekly).~~ Reauthorization: 1. Maintenance of biochemical response (ie. alkaline phosphatase (ALP) less than or equal to 1.67 times ULN, total bilirubin (tBili) less than or equal to ULN, and an ALP decrease of at least 15%) 2. Documentation that ursodiol will be continued, if tolerated 3. Hepatic function is assessed at least annually. ~~If Child-Pugh B or C, dose should not exceed 10mg twice weekly)~~
AGE RESTRICTIONS	N/A
PRESCRIBER RESTRICTIONS	Must be prescribed by, or in consultation with, a gastroenterologist or hepatologist.
COVERAGE DURATION	Initial authorization will be approved for four months. Reauthorization will be approved for one year.

Other Formulary Changes:

Drug Name	Recommendation	Policy Name
Ezetimibe/Rosuvastatin Calcium (Roszet) Tablet	New combination; • Commercial/Medicaid: Non-Formulary, add Prior Authorization • Medicare Part D: Non-Formulary	• Commercial/Medicaid: New Medications and Formulations without Established Benefit • Medicare Part D: N/A
Brand Silver Sulfadiazine (SSD) Cream	• Commercial: Change Brand from Tier 4 to Tier 2 • Medicaid: Add Brand to formulary • Medicare Part D: Add Brand to Formulary, Tier2	N/A
Tetrabenazine (Xenazine) Tablet	• Commercial: Move generic to Tier 5	VMAT2 Inhibitors
Amantadine HCL (Osmolex ER) Tab BP 24H	Remove from Commercial and Medicaid formularies	N/A
Methylphenidate HCL (Jornay PM) CPDR ER SP	• Commercial: Add Quantity Limit (1 CPDR ER SP per day)	N/A
Fluoxetine HCL Tablet	• Commercial: Add Prior Authorization	New Medications and Formulations without Established Benefit
Meperidine HCL (Demerol)	Remove from Commercial and Medicaid formulary	N/A
Apomorphine HCL (Apokyn) Cartridge	• Commercial: Remove from Formulary	N/A
• **Solriamfetol HCL (Sunosi) Tablet** • • **Pitolisant HCL (Wakix) Tablet** • • **Sodium oxybate (Xyrem)** • **Sodium,calcium,mag,pot oxybate (Xywav) Solution**	• Commercial: Add to Formulary, Tier 4 • Commercial: Add to Formulary, Tier 5 • Medicaid: Remove from Formulary	Narcolepsy Agents
Levodopa (Inbrija) CD-Cap w/Dev	• Commercial/Medicaid: Add Quantity Limit (10 inhalation capsules per day) • Medicare Part D: Add Quantity Limit (FDA max 10 inhalation capsules per day)	N/A

Vortioxetine (Trintellix) tablet	• Add to Commercial Formulary, Tier 4	

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**
Valbenazine tosylate (Ingrezza) Capsule	New strength (60mg). Line extend with Ingrezza capsule; • Commercial/Medicaid: Non-Formulary, Specialty, Prior Authorization, Quantity Limit (1 capsule per day) • Medicare Part D: Formulary, Tier 5, Prior Authorization, Quantity Limit (1 capsule per day)	VMAT2 Inhibitors
Risankizumab-rzaa (Skyrizi) Syringe	New dosage form (syringe). Line extend with Skyrizi; • Commercial: Formulary, Tier 5, Prior Authorization, Quantity Limit (1 ml per 84 days) • Medicaid: Non-Formulary, Specialty, Prior Authorization, Quantity Limit (1 ml per 84 days) • Medicare Part D: Formulary, Tier 5, Prior Authorization	Therapeutic Immunomodulators
Risankizumab-rzaa (Skyrizi Pen) Pen Injctr	New dosage form (pen). Line extend with Skyrizi; • Commercial: Formulary, Tier 5, Prior Authorization, Quantity Limit (1 ml per 84 days) • Medicaid: Non-Formulary, Specialty, Prior Authorization, Quantity Limit (1 ml per 84 days) • Medicare Part D: Formulary, Tier 5, Prior Authorization	Therapeutic Immunomodulators
Florbetaben F-18 (Neuraceq) Vial	New entity; Medical. Line extend as Medical; • Non-formulary for all lines of business, covered medical benefit	N/A
Bupivacaine/Meloxicam (Zynrelef) Soler Vial	New combination; Medical. Line extend as Medical; • Non-formulary for all lines of business, covered medical benefit	N/A
Oritavancin diphosphate (Kimyrsa) Vial	New strength. Line extend with Orbactiv; • Medical benefit for all lines of business	N/A
Elexacaftor/Tezacaftor/Ivacaftor (Trikafta) Tablet SEQ	Line extend with existing strength; • Commercial/Medicare Part D: Formulary, Tier 5, Prior Authorization, Quantity Limit (3 tablets per day)	CFTR Modulators

	• Medicaid: Formulary, Prior Authorization, Quantity Limit (3 tablets per day)	
Lipase/Protease/Amylase (Pancreaze) Capsule DR	New strength (37K-97.3K). Line extend with existing strengths; • Non-formulary for all lines of business	N/A
Dupilumab (Dupixent pen) Pen Injctr	New dosage form. Line Extend with existing strengths; • Commercial/Medicare Part D: Formulary, Tier 5, Prior Authorization, Quantity Limit (2.28 mL per 28 days) • Medicaid: Non-Formulary, Specialty, Prior Authorization, Quantity Limit (2.28 mL per 28 days)	Dupixent
Avapritinib (Ayvakit) Tablet	New strength. Line extend with existing strength; • Commercial: Formulary, Tier 6, Prior Authorization • Medicaid: Non-Formulary, Specialty, Prior Authorization • Medicare Part D: Formulary, Tier 5, Prior Authorization	• Commercial/Medicaid: Oral Anti-Cancer Medications • Medicare Part D: Anti-Cancer Agents

New Generics:

NEW GENERICS		
Drug Name	**Action Taken**	**Policy Name**
Isotretinoin Capsule	First generic (Absorica). 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
Calcitonin,Salmon,Synthetic (Calcitonin-Salmon) Vial	First generic (Miacalcin). Line extend with Miacalcin; • Commercial Standard: Formulary, Tier 2, Prior Authorization • Commercial Cost-Based: Formulary, Tier 4, Prior Authorization • Medicaid: Non- Formulary, Prior Authorization • Medicare Part D: Non- Formulary	• Commercial/Medicaid: Miacalcin • Medicare Part D: N/A
Tiopronin Tablet	First generic; Line extend with brand Thiola; • Commercial: Formulary, Tier 6, Prior Authorization • Medicaid: Non-Formulary, Specialty, Prior Authorization • Medicare Part D: Formulary, Tier 5, Prior Authorization	Thiola, Thiola EC
Arformoterol Tartrate Vial/Neb	First generic (Brovana). Line extend as generic; • Commercial Standard: Formulary, Tier 2, Quantity Limit (4 ml per day)	N/A

	• Commercial Cost-Based: Formulary, Tier 4, Quantity Limit (4 ml per day) • Medicaid/Medicare Part D: Non-Formulary	
Carboprost Tromethamine Ampul	First generic. Line extend with Hemabate; • Medical benefit for all lines of business	N/A
Lopinavir-ritonavir Tablet	Line Extend with Kaletra; • Commercial Standard: Formulary, Tier 2 • Commercial Cost-Based: Formulary, Tier 3 • Medicaid: Formulary • Medicare Part D: Formulary, Tier 5	N/A
Rufinamide Tablet	First generic (Banzel). Line extend as generic; • Commercial Standard: Formulary, Tier 2, Step Therapy • Medicaid: Formulary, Step Therapy • Medicare Part D: Formulary Tier 5, Prior Authorization	• Commercial/Medicaid: Antiepileptic Medications Step Therapy • Medicare Part D: Antiepileptic Agents
Bepotastine besilate Drops	First generic (Bepreve). Line extend as generic; • Commercial Standard: Formulary, Tier 2, Prior Authorization • Commercial Cost-Based: Formulary, Tier 4, Prior Authorization • Medicaid: Non-Formulary • Medicare Part D: Non-Formulary	• Commercial: Bepreve, Lastacaft, Zerviate • Medicaid/Medicare Part D: N/A
Etravirine Tablet	New generic. Line extend with Intelence; • Commercial Standard: Formulary, Tier 2 • Commercial Cost-Based: Formulary Tier 3 • Medicaid: Formulary • Medicare Part D: Formulary, Tier 5	N/A
Formoterol Fumarate Vial-Neb	First generic (Perforomist). Line extend; • Commercial: Formulary, Tier 3 • Medicaid: Non-Formulary • Medicare Part D: Formulary, Tier 5	N/A

Drug Utilization Review:

1. **Antiepileptic Therapies**
    a. **Decision:**
        i. **All Policies**

- Align restrictions to say neurologists

ii. **Epidiolex, Fintepla, Diacomit Policies**
- Align drug trial and failure of drugs for Dravet Syndrome to two of the following: valproate, clobazam, or topiramate
- Allow continued coverage for patients established and having benefit

iii. **Epidiolex**
- Update trial and failure drugs by indication with first-line therapies

iv. **Seizure Rescue Drugs Policy**
- Remove requirement for clonazepam ODT

v. **Qudexy XR, Trokendi XR Policy**
- Add requirement of generic topiramate ER prior to approval of brand Qudexy and Trokendi
- Add requirement of IR topiramate back to the Medicaid policy

vi. **Remove step therapy**
- Oxcarbazepine ER (Oxtellar XR)
- Lamotrigine ER (Commercial)
- Lacosamide (Vimpat)

vii. **Move to Tier 3 (commercial)**
- Lacosamide (Vimpat)

viii. **Retire Individual Policies and Add to New Drugs and Formulations without Established Benefit Policy**
- Lamotrigine ODT (Commercial)
- Sympazan

CY2022 Part B Step Therapy:

1. Effective January 1, 2022, Providence Health Assurance will be participating in the Centers for Medicare & Medicaid Services (CMS) Part B Step Therapy Program (ST).
2. The ST program requires a trial of a preferred drug to treat a medical condition before covering a non-preferred drug. Both preferred and non-preferred drugs may still be subject to prior authorization or quantity limits.
3. Clinical policies were updated to ensure the ST program only applies to patients new to therapy. If a patient has taken a non-preferred drug over the previous 365 days, switching to the preferred drug is not required. The following clinical policies were updated:
    a. Injectable Anti-Cancer Agents – Medicare Part B
    b. Adakveo – Medicare Part B
    c. Oxlumo – Medicare Part B
    d. Durysta – Medicare Part B
    e. Signifor LAR – Medicare Part B
    f. IL-5 Inhibitors - Medicare Part B
    g. Soliris - Medicare Part B
    h. Vyepti – Medicare Part B

i. Prevymis – Medicare Part B
j. Interleukin- inhibitors – Medicare Part B
k. Tysabri – Medicare Part B
l. Medically Infused Therapeutic Immunomodulators (TIMs) - Medicare Part B
m. Somatostatin Analogs - Medicare Part B
n. Xolair - Medicare Part B
o. Rituximab – Medicare Part B
p. Acute Hereditary Angioedema Therapy – Medicare Part B
q. Ophthalmic Vascular Endothelial Growth Factor (VEGF) Inhibitors - Medicare Part B
r. Testosterone Replacement – Medicare Part B
s. Prophylactic Hereditary Angioedema Therapy - Medicare Part B
t. Lemtrada – Medicare Part B
u. Uplizna – Medicare Part B

4. The following operational policies were updated to outline requirements of the ST program
   a. Charter and Conflict of Interest Review
   b. Expedited Coverage Determination and Timeframes – Medicare
   c. Medicare Part D Prior Authorization and Step Therapy Criteria
   d. Pharmaceutical Product Review
   e. Standard Coverage Determination Timeframes
   f. Standard Coverage Determinations, Exceptions, and Reopening

Clinical Policy Changes:

PHP CLINICAL POLICIES – MAJOR CHANGES	
Policy Name	**Summary of Change**
Amifampridine	Changed criteria to require symptomatic disease rather than disease affecting activities of daily living (ADL's).
Antipsychotics Step Therapy	Added ziprasidone to trial and failure options.
Botulinum Toxin	The covered indications were updated based on package labeling and review of literature. Achalasia and laryngeal dystonia are recommended to be eligible for coverage for Botox®
Dupixent	Clarified wording of reauthorization criteria for atopic dermatitis.
Evrysdi	Quantity limit was added to ensure appropriate dose is used.
Extavia	Policy was updated to require generic dimethyl fumarate or glatiramer plus an additional trial of a preferred agent for multiple sclerosis.
Hetlioz, Hetlioz LQ	For Non-24-Hour Sleep-Wake Disorder (Non-24), updated criteria to require symptomatic disease rather than disease affecting ADL's.
Horizant	Coverage duration was increased from one year to until no longer eligible with the plan.

Insomnia Agents – Commercial	Removed prior authorization from ramelteon and added to policy criteria as a trial and failure option. Ramelteon is available as generic and provides a non-controlled/different mechanism of action alternative for policy trial and failure options.
Insomnia Agents – Medicaid	Updated quantity limits for all sleep agents on policy to allow dosing per FDA label and to align with Oregon Health Authority recent changes.
Lemtrada	Policy clarified to state trial and failure of generic dimethyl fumarate.
Long-Acting Stimulant Medications - Medicaid	Add quantity limit to Jornay PM®. Removed Zenedi® from policy, as this is a short-acting formulation.
Long-Acting Stimulant Medications Quantity Limit	Added quantity limit to Jornay PM®
Mavenclad	Policy was updated to clarify covered uses and prerequisite therapy requirements.
Nuedexta	Added diagnosis to criteria to be explicit in what uses are covered. Added exclusion criteria to align with contraindications to therapy on package labeling
Nuplazid	Changed wording from "delirium" to "dementia-related psychosis", as this is the language used in the package labeling.
Ongentys Step Therapy	Changed covered uses to "all medically accepted indication" instead of "FDA approved indications"
Spinraza	Added exclusion for concomitant use with risdiplam (Evrysdi)
Spravato	Policy was updated to include PHQ-9 as an acceptable clinical rating scale for severe depression. Also, clarified that prerequisite therapy should be tried within the previous two years.
Tysabri	Policy clarified to state trial and failure of generic dimethyl fumarate.
VMAT2 Inhibitors	Policy criteria updated to clarify drugs covered for each condition. For Tardive Dyskinesia (TD), replaced AIMS score with documentation of moderate to severe TD that is causing functional impairment. In addition, removed requirement of other medications (clonazepam, amantadine, and ginko biloba) and require use of generic tetrabenazine prior to other costly agents (off-label use supported in drug compendia).
Xyrem, Xywav	Renamed policy to "Narcolepsy Agents" and combined with Wakix® and Sunosi®. Sunosi® was added as prerequisite therapy for Wakix® and Xyrem/Xywav® for the indication of excessive daytime sleepiness in narcolepsy without cataplexy. Wakix® will be preferred over Xyrem/Xywav® for narcolepsy with cataplexy.
Zolgensma	Added exclusion for concomitant use of risdiplam (Evrysdi®) therapy to align with other spinal muscular atrophy (SMA) policies

Retired Policies

- Apomorphine
- Brisdelle
- Osmolex ER
- Vimpat

- Wakix – combined with Xyrem/Xywav as “Narcolepsy Agents”
- Zulresso
- Sunosi – combined with Xyrem/Xywav as “Narcolepsy Agents”