PROVIDENCE Health Plan

PROVIDENCE Health Assurance

Healthcare Services Medical & Pharmacy Policy Alerts

Number 258

May 1, 2021

This is the May 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.

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

MEDICAL POLICY COMMITTEE

Lab Management Medical Policies

Effective 6/1/2021*, Providence Health Plan will institute the Centers for Medicare & Medicaid (CMS) National Coverage Determination (NCD) Coding Policy Manual of selected lab services for 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 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 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:

- Blood Counts (NCD 190.15)
- Glycated Hemoglobin/Glycated Protein (NCD 190.21)
- Thyroid Testing (NCD 190.22)
- Lipids Testing (NCD 190.23)

In the future, we plan to implement all 23 diagnostic laboratory testing NCDs for all lines of business. Provider notice will be provided 60 days in advance of each implementation.

Q: When will the new policies and coding configuration take effect?
A: 6/1/2021* for commercial and individual plans. On this date, the medical policies will be accessible here: https://healthplans.providence.org/providers/provider-support/medical-policy-pharmacy-policy-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.

- Blood Counts (NCD 190.15)
- Glycated Hemoglobin/Glycated Protein (NCD 190.21)
- Thyroid Testing (NCD 190.22)
- Lipids Testing (NCD 190.23)

*Effective date subject to change to a later date. Will update proposed effective date here, if required.

Effective July 1, 2021

Ankle-Foot/Knee-Ankle-Foot Orthoses **(All Lines of Business Except Medicare)** **MP293**	**New Policy** New policy based on Medicare guidance documents: LCD: Ankle-Foot/Knee-Ankle-Foot Orthosis (L33686); and LCA: Ankle-Foot/Knee-Ankle-Foot Orthoses - Policy Article (A52457). **Codes/PA:** • Ankle foot orthosis (L4631, L4396, L3497) or replacement interface (L4392) will be covered when billed with diagnosis codes outlined in "Billing Guidelines" • One code (L2006 – microprocessor knee-ankle-foot orthosis) already requires PA per "Lower Limb Prosthesis" policy and will deny investigational per this policy; one code (A9283) already configured to deny not medically necessary; all other codes will pay without review
Ankle-Foot/Knee-Ankle-Foot Orthoses **(Medicare Only)** **MP294**	**New Policy** **Recommendation:** New policy based on Medicare guidance documents: LCD: Ankle-Foot/Knee-Ankle-Foot Orthosis (L33686); and LCA: Ankle-Foot/Knee-Ankle-Foot Orthoses - Policy Article (A52457). **Codes/PA:** • Ankle foot orthosis (L 4631, L4396, L3497) or replacement interface (L4392) will be covered when billed with diagnosis codes outlined in "Billing Guidelines" • One code (L2006 - knee-ankle-foot device) already requires PA; one code (A9283) already configured to deny not medically necessary. • All other codes will pay without review
Transcranial Magnetic Stimulation (All Lines of Business Except Medicare) **MP269**	**Interim Update** **Recommendation:** • Expanding requirements to allow psychiatrists and psychiatric nurse practitioners to order transcranial magnetic stimulation (TMS). • Adding requirement that psychiatrist or psychiatric nurse practitioner must oversee the administration of TMS. **Codes/PA:** No coding changes
Helicobacter pylori Serological Testing **MP303**	**New Policy** Create policy finding serological testing for H pylori infection not medically necessary and not covered. **Codes/PA:** Set code to deny as not medically necessary: 86677- Antibody; Helicobacter pylori

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.

Pharmacy & Therapeutics (P&T) Committee

Oregon Region P&T Committee Meeting April 2, 2021
Go-Live Date: Tuesday, June 01, 2021, unless otherwise noted

Table of Contents:

- New Drugs and Combinations
- Other Formulary Changes
- New Generic Medications
- Clinical Policy Changes
- New Indications Monitoring
- Drug Safety Monitoring

New Drugs and Combinations:

1. **Relugolix (Orgovyx) Tablet**
   a. **Indication**: Treatment of adult patients with advanced prostate cancer.
   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
Formulary Alternatives: No oral alternatives on the formulary			

   c. **Clinical Criteria**: Prior Authorization Criteria for Commercial/Medicaid (added to the existing Oral Anti-Cancer Medications Policy)

PA PROGRAM NAME	Oral Anti-Cancer Medications
MEDICATION NAME	Orgovyx™
PA INDICATION INDICATOR	3 - All Medically-Accepted Indications
OFF-LABEL USES	N/A

EXCLUSION CRITERIA	N/A
REQUIRED MEDICAL INFORMATION	For initial authorization: 1. Use must be for a FDA approved indication or indication supported by National Comprehensive Cancer Network guidelines with recommendation 2A or higher AND 2. For commercial members only, the following drug-specific criteria must be met: a. For ribociclib (Kisqali®) for advanced or metastatic breast cancer: Documented trial, failure, intolerance or contraindication to palbociclib (Ibrance®) or abemaciclib (Verzenio®) b. For talazoparib (Talzenna®) for recurrent or metastatic breast cancer: Documented trial, failure, intolerance or contraindication to olaparib (Lynparza®) For patients established on therapy: documentation of adequate response to the medication must be provided.
AGE RESTRICTIONS	N/A
PRESCRIBER RESTRICTIONS	Must be prescribed by, or in consultation, with an oncologist.
COVERAGE DURATION	Authorization may be reviewed annually to assess continued medical necessity and effectiveness of medication.

d. **Clinical Criteria**: Prior Authorization Criteria for Medicare Part D (added to the existing Anti-Cancer Agents PA Program)

PA PROGRAM NAME	Anti-Cancer Agents
MEDICATION NAME	Orgovyx™
PA INDICATION INDICATOR	3 - All Medically-Accepted Indications
OFF-LABEL USES	N/A
EXCLUSION CRITERIA	N/A
REQUIRED MEDICAL INFORMATION	Indications supported by National Comprehensive Cancer Network guidelines with recommendation 2A or higher.
AGE RESTRICTIONS	N/A

PRESCRIBER RESTRICTIONS	Must be prescribed by or in consultation with an oncologist, transplant specialist, or neurologist.
COVERAGE DURATION	Authorization will be approved until no longer eligible with the plan.

2. **Tirbanibulin (Klisyri) Oint Pack**
   a. **Indication**: For the topical treatment of actinic keratosis of the face or scalp.
   b. **Decision**:

	Commercial	Medicaid	Medicare
Formulary Status*	Formulary	Non-formulary	Part D: Formulary Part B: N/A
Tier**	Tier 4	N/A	Specialty
Specialty Medication	No	No	N/A
Affordable Care Act Eligible	No	N/A	N/A
Utilization Management Edits	Prior Authorization	N/A	Prior Authorization
Quantity Limit	N/A	N/A	N/A
Formulary Alternatives: generic fluorouracil (0.5% cream, 5% cream, 5% solution, and 2% solution), generic imiquimod (5% cream pack and 3.75% cream pump)			

   c. **Clinical Criteria**: Prior Authorization Criteria for Commercial (added to the existing Actinic Keratosis Agents policy)

PA PROGRAM NAME	Actinic Keratosis Agents
MEDICATION NAME	Klisyri (tirbanibulin 1% ointment)
PA INDICATION INDICATOR	1 - All FDA-Approved Indications
OFF-LABEL USES	N/A
EXCLUSION CRITERIA	Treatment of basal cell carcinoma or other skin cancers
REQUIRED MEDICAL INFORMATION	1. For the treatment of Actinic Keratosis (AK): Documentation of trial and failure*, contraindication or intolerance to two (2) of the following formulary, generic topical agents: a. Diclofenac 3% gel b. 5-fluorouracil 2% or 5% cream/solution c. Imiquimod 5% cream *An adequate trial and failure is defined as failure to achieve clearance of AK lesion(s) after adherence to recommended treatment dosing and duration (see Table 1) **Reauthorization:**

	Requires documentation of a reduction in the number and/or size of lesions of AK and medical rationale for continuing therapy beyond recommended treatment course (see Table 1). 1. For the treatment of external genital and perianal warts/condyloma acuminate (Zyclara® 3.75% only): Documentation of trial and failure*, contraindication, or intolerance to formulary, generic imiquimod 5% cream. An adequate trial and failure is defined as failure to achieve total clearance of lesions after 16 weeks of therapy.
AGE RESTRICTIONS	N/A
PRESCRIBER RESTRICTIONS	Must be prescribed by, or in consultation with, a dermatologist.
COVERAGE DURATION	• Picato®/Tolak®/Carac®/Klisyri®: Initial authorization and reauthorization will be approved for one month • Zyclara®: Initial authorization and reauthorization will be approved for up to eight (8) weeks

3. **Cabotegravir-rilpivirine (Cabenuva) Suser Vial**
   a. **Indication**: A complete regimen for the treatment of HIV-1 infection in adults to replace the current antiretroviral regimen in those who are virologically suppressed (HIV-1 RNA less than 50 copies per mL) on a stable antiretroviral regimen with no history of treatment failure and with no known or suspected resistance to either cabotegravir or rilpivirine.
   b. **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			
Formulary Alternatives: Biktarvy®,Triumeq®, Juluca®, Dovato®, Atripla®, Genvoya®			

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

PA PROGRAM NAME	Cabenuva
MEDICATION NAME	Cabenuva®
PA INDICATION INDICATOR	1 - All FDA-Approved Indications
OFF-LABEL USES	N/A
EXCLUSION CRITERIA	N/A

REQUIRED MEDICAL INFORMATION	**For new starts:** 1. Patient must have a confirmed diagnosis of human immunodeficiency virus type -1 (HIV-1) 2. Patient has been stable and adherent with their current antiviral regimen for a minimum of six (6) months (adherence may be confirmed by pharmacy claims) 3. Patient has a recent viral HIV-1 RNA of less than 50 copies/mL on current oral antiviral regimen 4. Documentation that patient does not have a history of treatment failure **For continuation of therapy:** 1. Documentation that patient has been adherent with therapy 2. Documentation that patient has maintained a viral HIV-1 RNA of less than 50 copies/mL
AGE RESTRICTIONS	Must be at least 18 years of age
PRESCRIBER RESTRICTIONS	Must be prescribed by, or in consultation with, an infectious disease specialist
COVERAGE DURATION	Initial authorization for one (1) year. Reauthorization will be approved until no longer eligible with the plan, subject to formulary and/or benefit changes

4. **Lisocabtagene maraleucel (Breyanzi)**
   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 (including DLBCL arising from indolent lymphoma), high-grade B-cell lymphoma, primary mediastinal large B-cell lymphoma, and follicular lymphoma grade 3B. Limitations of Use: Lisocabtagene maraleucel is not indicated for the treatment of patients with primary central nervous system (CNS) lymphoma.
   b. **Decision**:

	Commercial	Medicaid	Medicare
Formulary Status*	Medical	Medical	Part D: Non-formulary Part B: Medical
Tier**	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			
Formulary Alternatives: Xpovio			

   c. **Clinical Criteria:** Prior Authorization Criteria for Commercial/Medicaid/Medicare Part B (added to the existing CAR-T Policy)

PA PROGRAM NAME	CAR-T
MEDICATION NAME	Breyanzi vial
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 relapsed or refractory large B-cell lymphoma, **Breyanzi®** may be approved when all of the following criteria are met: 1. Confirmed diagnosis of relapsed or refractory FDA approved large B-cell lymphomas 2. Refractory or relapse to two (2) or more prior treatment regimens. Prior therapy must have included the following unless otherwise not indicated/tolerated: a. An anthracycline containing chemotherapy regimen (e.g. doxorubicin), and b. Anti-CD20 monoclonal antibody (e.g. rituximab) 3. Asymptomatic or minimally symptomatic with Eastern cooperative oncology group (ECOG) performance status 0-1 4. Member does not have any of the following: a. Primary central nervous system (CNS) lymphoma b. Evidence of active or uncontrolled 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)

5. **Oliceridine Fumarate (Olinvyk) Vial/PCA Vial**
   a. **Indication**: For the management of acute pain severe enough to require an intravenous opioid analgesic and for whom alternative treatments are inadequate.
   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	N/A	N/A	N/A
Quantity Limit			
Formulary Alternatives: N/A			

c. **Clinical Criteria**: N/A

6. **Setmelanotide acetate (Imcivree) Vial**
   a. **Indication**: setmelanotide (Imcivree®) for chronic weight management in adult and pediatric patients 6 years and older with obesity due to POMC, PCSK1, or LEPR deficiency confirmed by genetic testing demonstrating variants in POMC, PCSK1, or LEPR genes that are interpreted as pathogenic, likely pathogenic, or of uncertain significance (VUS).
   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			
Formulary Alternatives: None			

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

PA PROGRAM NAME	Imcivree
MEDICATION NAME	Imcivree
PA INDICATION INDICATOR	1 - All FDA-Approved Indications
EXCLUSION CRITERIA	Prior gastric bypass surgery resulting in less than 10% weight loss that was maintained
REQUIRED MEDICAL INFORMATION	Initial authorization: 1. Diagnosis of obesity, defined as either of the following: a. For adults: Body mass index (BMI) of greater than or equal to 30 b. For pediatrics: Greater than or equal to the 95th percentile using growth chart assessments, AND 2. Confirmation that obesity is due to a homozygous, or presumed compound heterozygous variant in at least one of the following genes, confirmed by genetic testing: proopiomelanocortin (POMC), proprotein convertase subtilisin/kexin type 1 (PCSK1), or leptin receptor (LEPR), AND

	3. Documentation of genetic testing demonstrating that the variants in POMC, PCSK1, or LEPR genes are interpreted as pathogenic, likely pathogenic, or of uncertain significance (VUS) Reauthorization: Documentation of response to therapy, as evidenced by: at least a 5% reduction in baseline body weight OR at least 5% reduction in baseline BMI for patients with continued growth potential
AGE RESTRICTIONS	May be approved for patients six (6) years of age and older
PRESCRIBER RESTRICTIONS	Must be prescribed by, or in consultation with, an endocrinologist, pediatric endocrinologist, or geneticist
COVERAGE DURATION	Initial authorization will be approved for four (4) months and reauthorization for one (1) year

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

PA PROGRAM NAME	Imcivree
MEDICATION NAME	Imcivree
PA INDICATION INDICATOR	1 - All FDA-Approved Indications
EXCLUSION CRITERIA	Prior gastric bypass surgery resulting in >10% weight loss that was maintained
REQUIRED MEDICAL INFORMATION	Initial authorization: 1. Diagnosis of obesity, defined as either of the following: a. For adults: Body mass index (BMI) of greater than or equal to 30 b. For pediatrics: Greater than or equal to the 95th percentile using growth chart assessments, AND 2. Confirmation that obesity is due to a homozygous, or presumed compound heterozygous variant in at least one of the following genes, confirmed by genetic testing: proopiomelanocortin (POMC), proprotein convertase subtilisin/kexin type 1 (PCSK1), or leptin receptor (LEPR), AND 3. Documentation of genetic testing demonstrating that the variants in POMC, PCSK1, or LEPR genes are interpreted as pathogenic, likely pathogenic, or of uncertain significance (VUS) Reauthorization: Documentation of response to therapy, as evidenced by: at least a 5% reduction in baseline body weight OR at least 5% reduction in baseline BMI for patients with continued growth potential
AGE RESTRICTIONS	N/A
PRESCRIBER RESTRICTIONS	Must be prescribed by, or in consultation with, an endocrinologist, pediatric endocrinologist, or geneticist
COVERAGE DURATION	Initial authorization will be approved for 4 months and reauthorization for one year

7. **Lonafarnib (Zokinvy) Capsule**
   a. **Indication**: For patients 12 months of age and older with a body surface area (BSA) of 0.39 m^2 and above:
      i. To reduce risk of mortality in Hutchinson-Gilford Progeria Syndrome
      ii. For treatment of processing-deficient Progeroid Laminopathies (PLs) with either:
         1. Heterozygous LMNA mutation with progerin-like protein accumulation
         2. Homozygous or compound heterozygous ZMPSTE24 mutations

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	Prior Authorization	Prior Authorization	N/A
Quantity Limit			
Formulary Alternatives: None			

c. **Clinical Criteria**: Prior Authorization Criteria for Commercial/Medicaid (added to Medications for Rare Indications)

PA PROGRAM NAME	Medications for Rare Indications (Orphan Drugs)
MEDICATION NAME	Zokinvy
PA INDICATION INDICATOR	1 - All FDA-Approved Indications
OFF-LABEL USES	N/A
EXCLUSION CRITERIA	N/A
REQUIRED MEDICAL INFORMATION	**Initial Authorization:** Both of the following must be met: 1. Confirmation of FDA-labeled indication (appropriate lab values and/or genetic tests must be submitted); **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:** Both of the following must be met: 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 information)
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 one (1) year and reauthorization may be reviewed annually to assess continued medical necessity and effectiveness of medication.

8. **Clascoterone (Winlevi) Cream**
   a. **Indication**: Treatment of acne vulgaris in patients 12 years of age or older.
   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	Prior Authorization	Prior Authorization	N/A
Quantity Limit	60 grams/30 days	60 grams/30 days	N/A
Formulary Alternatives: topical tretinoin, topical antibiotics with or without benzoyl peroxide (clindamycin lotion, erythromycin/benzoyl peroxide, clindamycin/benzoyl peroxide), oral antibiotics (minocycline, doxycycline), oral contraceptives			

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

PA PROGRAM NAME	Topical Androgen Receptor Inhibitors
MEDICATION NAME	Winlevi®
PA INDICATION INDICATOR	1 - All FDA-Approved Indications
OFF-LABEL USES	N/A
EXCLUSION CRITERIA	N/A
REQUIRED MEDICAL INFORMATION	1. Documented trial and failure of **ALL** of the following: a. A topical generic tretinoin gel or cream (any strength) b. A topical antibiotic* (e.g. clindamycin or erythromycin) c. A topical benzoyl peroxide product * Topical antibiotics should not be used alone due to risk of bacterial resistance; use in conjunction with benzoyl peroxide is recommended **AND** 2. For Medicaid only: Documentation that patient has one (1) of the following conditions (must be supported by chart notes): a. Acne Fulminans b. Acne Conglobata with recurrent abscesses or communicating sinuses c. Severe Cystic Acne with persistent or recurrent inflammatory nodules and cysts AND ongoing scarring
AGE RESTRICTIONS	Age 12 years and older
PRESCRIBER RESTRICTIONS	N/A
COVERAGE DURATION	Authorization will be approved until no longer eligible with the plan, subject to formulary and/or benefit changes

9. **EUA COVID-19 Vac, AD26.COV2.S PF (Janssen COVID19 Vacc) Vial**
   a. **Indication**: Emergency use authorization (EUA) of the Janssen COVID-19 Vaccine for active immunization to prevent COVID-19 in individuals 18 years of age and older.
   b. **Decision**: N/A - Informational
   c. **Clinical Criteria**: N/A

10. **Vibegron (Gemtesa) Tablet**
   a. **Indication**: Treatment of adult patients with Overactive Bladder (OAB).
   b. **Decision**:

	Commercial	Medicaid	Medicare
Formulary Status*	Formulary	Formulary	Part D: Non-formulary Part B: N/A
Tier**	Tier 4	N/A	N/A
Specialty Medication	No	No	N/A
Affordable Care Act Eligible	No	N/A	N/A
Utilization Management Edits	Step Therapy	Step Therapy	N/A
Quantity Limit			
Formulary Alternatives: Mirbetriq®, oxybutynin, tolterodine, solifenacin, trospium			

   c. **Clinical Criteria**: Step Therapy Criteria for Commercial/Medicaid (added to Overactive Bladder Medications policy)

ST PROGRAM NAME	OVERACTIVE BLADDER MEDICATIONS
MEDICATION NAME	Gemtesa®
OFF-LABEL USES	N/A
EXCLUSION CRITERIA	N/A
REQUIRED MEDICAL INFORMATION	Trial, intolerance, or contraindication to: 1. One (1) of the following: oxybutynin or tolterodine, AND 2. Solifenacin 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

Other Formulary Changes:

Drug Name	Recommendation	Policy Name
Berotralstat hydrochloride (Orladeyo) Capsule	Add Quantity Limit 1 capsule per day	Prophylactic Hereditary Angioedema Therapy
Semglee (insulin glargine)	Add to Medicaid formulary as preferred long-acting insulin product Effective 5/1/2021	N/A
Basaglar (insulin glargine)	Remove from Medicaid formulary and retire step therapy Effective 8/1/2021	Insulins - Medicaid
Eszopiclone Tablet	Increase Quantity Limit for Commercial to 2 tablets per day	N/A
Famotidine/PF (Famotidine) Vial	Add to Medicare Part D formulary: Formulary, Tier 4	N/A
Methadone HCL Tablet/Tablet Sol	Remove Quantity Limit for Commercial and Medicare Part D: • Commercial: Formulary, Tier 2 • Medicare Part D: Formulary, Tier 2, Prior Authorization Effective 5/1/2021	N/A
Midodrine HCL Tablet	Add to Medicaid Formulary	N/A
Progesterone Vial	Add to Commercial and Medicaid formulary and remove Prior Authorization from Medical; • Commercial: Formulary, Tier 2 • Medicaid: Formulary • Medicare Part D: Non-Formulary • Medicare Part B: Covered	N/A
Methotrexate/PF (Reditrex) Syringe	New Dosage Form (syringe) and strength. • Non-Formulary for all lines of business	N/A
Ribavirin Capsule/Tablet	Remove from Specialty for Commercial and Medicaid. • Commercial Standard: Formulary, Tier 2 • Commercial Cost Based: Formulary, Tier 3	N/A
Fluoride (Sodium Fluoride) Drops	Add to Commercial Formularies:	N/A

	Formulary, ACA covered	
Levothyroxine Sodium (Thyquidity) Solution	New dosage form (solution) and strength (100mcg/5ml). • Non-Formulary for all lines of business	N/A
Calcipotriene/Betamethasone Dipropionate (Wynzora) Cream	New Dosage Form (cream). • Commercial/Medicaid: Non-Formulary, Prior Authorization • Medicare Part D: Non-Formulary	• Commercial/Medicaid: Enstilar/Taclonex/Taclonex Scalp • Medicare Part D: N/A
Cetirizine HCL (Zerviate) Droperette	Add to Commercial formulary. • Commercial: Formulary, Tier 4, Prior Authorization	Bepreve, Lastacaft, Pazeo, Zerviate
Ipratropium/Albuterol Sulfate (Combivent Respimat)	Increase Quantity Limit. • Commercial/Medicare Part D: Formulary, Tier 3, Quantity Limit (8 g per 30 days) • Medicaid: Formulary, Quantity Limit (8 g per 30 days)	N/A
Progesterone, Micronized (Endometrin) Insert	Down-tier for Commercial: • Commercial: Formulary, Tier 3, Prior Authorization	Vaginal Progesterone Formulations
• **Dapagliflozin (Farxiga)** • **Dapagliflozin/metformin (Xigduo XR)** • **Empagliflozin (Jardiance) Tablet** • **Empagliflozin/metformin (Synjardy)** • **Empagliflozin/ metformin (Synjardy XR)** • **Empagliflozin/ linagliptin (Glyxambi)** • **Empagliflozin/ linagliptin/metformin (Trijardy XR)**	Add to Custom Safe Harbor and Enhanced Preventative Lists for Commercial	SGLT-2 Inhibitors
Progesterone, Micronized (Endometrin) Insert	Down Tier for Commercial; Commercial: Formulary, Tier 3, Prior Authorization	Vaginal Progesterone Formulations
Ketorolac Tromethamine Drops	Add to Medicaid Formulary	N/A
Jelmyto (Mitomycin) Kit	Add to Injectable Anti-Cancer Medications policy. • Commercial/Medicaid/Medicare Part B: Medical Benefit, Prior Authorization • Medicare Part D: Non-Formulary	Injectable Anti-Cancer Medications

Loteprednol etabonate Drops Gel	First Generic (Lotemax) • Commercial: Non-Formulary • Medicaid: Formulary • Medicare Part D: Non-Formulary	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**
Ravulizumab-cwvz (Ultomiris) Vial	New Strength (300mg/3ml). Line extend with Ultomiris 300mg/30ml; • Commercial/Medicaid: Medical Benefit, Prior Authorization • Medicare Part D: Non-Formulary • Medicare Part B: Medical Benefit, Prior Authorization Effective 2/1/2021	Ultomiris
Sofosbuvir/velpatasvir (Epclusa) Tablet	New Strength (200mg/50mg). Line extend with Epclusa (400mg/100mg); • Commercial: Formulary, Tier 5, Prior Authorization • Medicaid: Non-Formulary, Specialty, Prior Authorization Effective 2/1/2021	• Commercial: Hepatitis C - Direct Acting Antivirals – Commercial • Medicaid: Hepatitis C - Direct Acting Antivirals - Medicaid
Clinimix IV Soln	New Strengths. Line extend with Clinimix; • Commercial/Medicaid: Medical Benefit, Prior Authorization • Medicare Part D: Non-Formulary • Medicare Part B: Medical Benefit, Prior Authorization Effective 2/1/2020	• Commercial/Medicaid: Total Parenteral Nutrition (TPN) • Medicare Part B: Total Parenteral Nutrition (TPN) – Medicare Part B
Epoetin alfa-epbx (Retacrit) Vial	New Strength (20000/2ml). Line extend with Retacrit; • Commercial: Formulary, Tier 6, Prior Authorization • Medicaid: Formulary, Prior Authorization • Medicare Part D: Formulary, Tier 4, Prior Authorization	• Commercial/Medicaid/Medicare Part D: Erythropoiesis Stimulating Agents (ESAs) • Medicare Part B: Erythropoiesis Stimulating Agents (ESAs) – Medicare Part B

	• Medicare Part B: Medical Benefit, Prior Authorization	
Pegfilgrastim-apgf (Nyvepria) Syringe	Biosimilar to Neulasta. Line extend with Neulasta; • Commercial/Medicare Part D: Formulary, Tier 5 • Medicaid: Formulary	N/A
Diphtheria,pertus(acell), tetanus/hepb/polio/hib conj-meng/pf (Vaxelis) Syringe / Vial	New Combination; Line extend with TDAP vaccines; • Commercial; Formulary, Preventive, Quantity Limit (1.5 mL per lifetime) • Medicaid: Non-Formulary • Medicare Part D: Formulary, Tier 3	N/A
Fluoroestradiol f-18 (Cerianna) Vial	New Entity; Medical; Line extend as Medical; • Commercial/Medicaid: Medical Benefit, Prior Authorization • Medicare Part D: Non-Formulary • Medicare Part B: Medical Benefit, Prior Authorization	N/A
Rituximab-arrx (Riabni) Vial	Biosimilar to Rituxan. Line extend with Rituxan; • Commercial/Medicaid: Medical Benefit, Prior Authorization • Medicare Part D: Non-Formulary • Medicare Part B: Medical Benefit, Prior Authorization	Rituximab

New Generics:

NEW GENERICS		
Drug Name	**Action Taken**	**Policy Name**
Rufinamide Oral Susp	First generic (Banzel). Line extend as generic; • Commercial Standard: Formulary, Tier 2, Step Therapy • Commercial Cost Based: Formulary, Tier 4, Step Therapy • Medicaid: Formulary, Step Therapy • Medicare Part D: Formulary, Tier 5, Prior Authorization	• Commercial/Medicaid: Antiepileptic Medications • Medicare Part D: Antiepileptic Agents

Icosapent ethyl 1 gram Capsule	First Generic (Vascepa). Line extend as generic; • Commercial Standard: Formulary, Tier 2, Prior Authorization • Commercial Cost Based: Formulary, Tier 3, Prior Authorization • Medicaid: Formulary, Prior Authorization • Medicare Part D: Formulary, Tier 3, Prior Authorization	Vascepa
Timolol maleate Droperette	First Generic (Timoptic). Line extend as generic; • Non-formulary for all lines of business	N/A
Norethindrone acetate-ethinyl estradiol/ferrous fumarate (Gemmily) Capsule	Line extend with noreth-estradiol-FE; • Commercial: Formulary, Preventive • Medicaid: Non-Formulary • Medicare Part D: Formulary, Tier 4	N/A
Levothyroxine sodium (Levothyroxine) Capsule	First Generic (Tirosint). Line extend as generic; • Non-formulary for all lines of business	N/A
Estradiol (Lyllana) Patch TDSW	Line extend with generic Minivelle; • Commercial Standard: Formulary, Tier 2 • Commercial Cost Based: Formulary, Tier 3 • Medicaid: Formulary • Medicare Part D: Formulary, Tier 4	N/A
Ethynodiol diacetate-ethinyl estradiol (Zovia) Tablet	Line extend with other generic Zovia; • Commercial: Formulary, Preventive • Medicaid: Formulary • Medicare Part D: Formulary, Tier 2	N/A
Alvimopan Capsule	First Generic (Entereg). Line extend as generic; • Non-Formulary for all lines of business	N/A
Ivermectin Lotion	First Generic (Sklice). Line extend as generic; • Commercial Standard: Formulary, Tier 2 • Commercial Cost Based: Formulary, Tier 4 • Medicaid/Medicare Part D: Non-Formulary	N/A
Nitazoxanide Tablet	First Generic (Alinia). Line extend as generic; Generic;	• Commercial/Medicaid: Alinia • Medicare Part D: N/A

	• Commercial Standard: Formulary, Tier 2, Prior Authorization, Quantity Limit (2 Tablets per day) • Commercial Cost Based: Formulary, Tier 3, Prior Authorization, Quantity Limit (2 Tablets per day) • Medicaid: Non-Formulary, Prior Authorization, Quantity Limit (2 Tablets per day) • Medicare Part D: Formulary, Tier 5, Quantity Limit (6 Tablets per 30 days)	
Norgestimate-ethinyl estradiol (Nymyo) Tablet	Line extend with Ortho-Cyclen generics; • Commercial: Formulary, Preventive • Medicaid: Formulary • Medicare Part D: Formulary, Tier 2	N/A
Meloxicam, submicronized (Meloxicam) Capsule	First Generic (Vivlodex). 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
Abiraterone acetate Tablet	First Generic (Zytiga). Line extend as generic; • Commercial: Formulary, Tier 6, Prior Authorization • Medicaid: Formulary, Specialty, Prior Authorization • Medicare Part D: Formulary, Tier 5, Prior Authorization	• Commercial/Medicaid: Oral Anti-Cancer Medications • Medicare Part D: Anti-Cancer Agents
Asenapine maleate Tab Subl	First Generic (Saphris). Line extend as generic; Brand: • Commercial Standard: Formulary, Tier 2, Step Therapy • Commercial Cost Based: Formulary, Tier 4, Step Therapy • Medicaid: Non-Formulary (covered by DMAP) • Medicare Part D: Formulary, Tier 4, Prior Authorization	• Commercial: Antipsychotics Step Therapy • Medicare Part D: Antipsychotics

Norethindrone acetate-ethinyl estradiol/ferrous fumarate (Merzee) Capsule	Line extend with noreth-estradiol-FE; • Commercial: Formulary, Preventive • Medicaid: Non-Formulary • Medicare Part D: Formulary, Tier 4	N/A

Clinical Policy Changes:

PHP CLINICAL POLICIES – MAJOR CHANGES	
Policy Name	**Summary of Change**
Adult Long-Acting Stimulant Medications - Medicaid	Policy was updated to reflect that criteria may apply to pediatrics as well (for non-preferred agents and quantity limitations)
Brineura	Policy reworded for clarification, but the intention remains similar.
calcitonin gene-related peptide Receptor Antagonists for Acute Migraine Treatment	Added history of hemiplegic or basilar migraine to list of contraindications to triptan therapy and updated prescriber restrictions from neurologist to any headache specialist.
CAR-T	Updated previous drug trial criteria for relapsing large B-cell lymphoma to align with National Comprehensive Cancer Network guidelines and updated prescriber restrictions to those whom are enrolled in REMS program.
Constipation Agents	Follow-up from December 2020 P&T meeting - per committee request, updated adequate duration trial of pre-requisite drugs per gastroenterology consult.
• **Continuous Glucose Monitors (CGMs) for Personal Use** • **CGMs for Personal Use - Medicaid** • **Disposable Insulin Pumps**	Removed requirement related to diabetes education, as this was an operational burden for the review team. Most patients have met this, but it is not well documented in chart notes and a lot of effort is being made to determine whether this criterion is met.
Disposable Insulin Pumps	Removed requirement related to diabetes education, as this was an operational burden for the review team. Most patients have met this, but it is not well documented in chart notes and a lot of effort is being made to determine whether this criterion is met.
Enzyme Replacement Therapy	Clarified wording for dosing requirement to be within FDA approved labeling or supported by high-quality literature.
Galafold	Add nephrologist to allowed prescriber specialty
GLP-1 Agonists	Updated policy to include duration of treatment for metformin to align with American Diabetes Association recommendation to reassess and modify treatment every three (3) to six (6) months.
GLP-1 Agonists - Medicaid	Updated policy to include duration of treatment for metformin to align with American Diabetes Association recommendation to reassess and modify treatment every three (3) to six (6) months. In addition, updated non-preferred drugs to include exenatide.
Human Growth Hormones for Adults	Removed exclusion statement "treatment for isolated growth hormone deficiency (GHD)," as this may be the case for certain genetic or congenital defects that require treatment. Removed criteria for “suspected GHD” as this is typically considered idiopathic; patients will be required to meet biochemical laboratory values as outlined in the criteria. Added gastroenterologist as a prescriber for

	coverage of short bowel syndrome. Updated reauthorization dosing to not be more than product specific max weight-based dosing. Clarified that FDA-labeled indications other than GHD may be covered for Medicaid (previous exclusion for treatment in adults for all indications).
Human Growth Hormones for Pediatrics	Updated criteria for treatment of Small for Gestational Age (SGA) with failure of catch-up growth to align with a consensus statement of the International Societies of Pediatric Endocrinology and the Growth Hormone Research Society and the International Classification of Pediatric Endocrine Diagnoses (ICPED).
Injectable Anti-Cancer Agents	Updated to reflect preferred biosimilars for trastuzumab (Ogivri® and Kanjinti®) and bevacizumab (Mvasi® and Zirabev®). These agents will be required to be used prior to coverage of the reference products (Herceptin® and Avastin®) and the subcutaneous product (Herceptin Hylecta®). Effective 7/1/2021 for Commercial and Medicaid Effective 1/1/2022 for Medicare Part B
Kuvan	Reauthorization criteria simplified according to package insert and extended from one year to until no longer eligible with the plan.
Medical Nutrition - Commercial	Criteria was added for patients with severe milk protein allergy and this indication was removed as an exclusion. A small proportion of infants with this allergy have a severe form that does require supplementation with an elemental nutritional product.
Nocdurna, Noctiva	Noctiva® has been removed from this policy as drug is no longer being made. Policy name changed to Nocdurna®.
Non-Preferred Fumarate Products	Policy was updated to be prior authorization (instead of step therapy) due to complexity of review for medical necessity of the non-preferred agents.
Palynziq	Quantity limit and reauthorization criteria updated to reflect new maximum daily dose of 60mg (from 40mg) once daily.
Rituximab	Updated to reflect preferred biosimilars for rituximab (Ruxience® and Truxima®) These agents will be required to be used prior to coverage of the reference products (Rituxan®) and the subcutaneous product (Rituxan Hycela®). Effective 7/1/2021 for Commercial and Medicaid Effective 1/1/2022 for Medicare Part B
SGLT-2 Inhibitors - Medicaid	The criteria related to the use of canagliflozin in chronic kidney disease was updated to improve operational considerations for the review of the medication.
Signifor LAR	1. Broaden definition of persistent disease after surgery to include biochemical markers in addition to clinical symptoms. 2. Add lanreotide as a trial and failure option in addition to octreotide as both recommended as first line medications in the Endocrine Society 2017 Consensus Statement.
Somavert	1. Change initial criteria to reflect persistent disease after surgery or ineligibility to surgery alone as this is the first-line treatment according to the Endocrine Society. 2. Added lanreotide as a trial and failure option in addition to octreotide as both recommended as first line medications in the Endocrine Society 2017 Consensus Statement.
Strensiq	Removed Medicare Part B from policy as this medication is on the self-administration drug exclusion list.

Tepezza	The criteria requiring two-week trial of steroids has been updated. Steroids will not be required for patients with sight-threatening disease, given that a trial of steroids could delay care and patient could lose their eye sight.
Testosterone Replacement Therapy (TRT)	Policy simplified to require trial and failure of preferred testosterone products. Removed statement that testosterone implant is not covered for Medicaid, as insertion of pellets is now covered. Updated position statement and removed benefit exclusion criteria that no longer applies.
Therapeutic Immunomodulators - Comm	Policy was updated to meet contractual requirements - Simponi® (golimumab) must step through Humira® (adalimumab) for ulcerative colitis indication.
Tolvaptan	Updated coverage duration for Samsca to clarify that 30 day approval is per treatment course. Added information in the position statement about the SALTWATER extension trial.
Tysabri	Updated criteria to define highly active or aggressive disease to aid clinical reviewers. In addition, the prerequisite therapy changed from trial of two disease-modifying therapies to trial of one.

New Indications:

1. **NPLATE®**
   Romiplostim
   New indication approved 01/28/21:
   - To increase survival in adults and in pediatric patients (including term neonates) acutely exposed to myelosuppressive doses of radiation (Hematopoietic Syndrome of Acute Radiation Syndrome [HSARS]).

   RECOMMENDATION: Inform prescribers via MD alert. Criteria for Commercial, Medicare Part B, and Medicaid prior authorization policy will be updated as followed:

REQUIRED MEDICAL INFORMATION	For immune thrombocytopenia, all of the following must be met: 1. A diagnosis of immune thrombocytopenia (ITP), **AND** 2. Patient is at risk for bleeding with a platelet count of less than or equal to 30,000 cells per microliter, **AND** 3. Treatment by at least one of the following was ineffective or not tolerated: a. Systemic corticosteroids, OR b. Immune globulin, OR c. Splenectomy For Hematopoietic Syndrome of Acute Radiation Syndrome [HSARS], all of the following must be met: 1. Documentation of acute exposure to radiation, **AND** 2. Documentation of myelosuppression defined as leukopenia, thrombocytopenia, or anemia

2. **BOTOX®**
   OnabotulinumtoxinA
   New indication approved 02/09/2021:
   - Treatment of pediatric neurogenic detrusor over activity

   RECOMMENDATION: Inform prescribers via MD alert. The FDA approved indications section for the Commercial/Medicaid and Medicare Part B botulin toxin prior authorization policies will be updated with the current April P&T cycle.

3. **HUMIRA®**
   Adalimumab
   New indication approved 02/24/2021:
   - Treatment of moderately to severely active ulcerative colitis to include pediatric patients 5 years of age and older

   RECOMMENDATION: Inform prescribers via MD alert. The FDA approved indications section for the Commercial, Medicaid and Medicare Part B TIMs prior authorization policies will be updated with the current April P&T cycle.

4. **GOCOVRI®**
   Amantadine hydrochloride
   New indication approved 02/01/2021:
   - Adjunctive treatment to levodopa/carbidopa in patients with Parkinson's disease experiencing "off" episodes

   RECOMMENDATION: Inform prescribers via MD alert. On the New drugs and Formulations without Established Benefit Policy, formulary alternatives such as generic amantadine IR and Osmolex ER are still appropriate. No change to policy warranted.

5. **CARBAGLU®**
   Carglumic acid
   New indication approved 01/22/2021:
   - In pediatric and adult patients as:
     - Adjunctive therapy to standard of care for the treatment of acute hyperammonemia due to propionic acidemia (PA) or methylmalonic acidemia (MMA).

   RECOMMENDATION: Inform prescribers via MD alert. On the Medications for Rare Indications (Orphan Drugs) policy which requires confirmation of a FDA-labeled indication. No changes to policy are warranted.

Therapies with Prior Authorization Policies (Oncology):

6. **DARZALEX FASPRO®**
   Daratumumab and hyaluronidase-fihj
   New indication approved 01/11/2021:
   - For treatment of adult patients with multiple myeloma in combination with bortezomib, thalidomide, and dexamethasone in newly diagnosed patients who are eligible for autologous stem cell transplant

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

7. **ENHERTU®**
Fam-trastuzumab deruxtecan-nxki
New indication approved 01/15/2021:
- Adult patients with locally advanced or metastatic HER2-positive gastric or gastroesophageal junction adenocarcinoma who have received a prior trastuzumab-based regimen.

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

8. **OPDIVO®**
Nivolumab
New indication approved 01/22/2021:
- Advanced renal cell carcinoma, as a first-line treatment in combination with cabozantinib

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

9. **XALKORI®**
Crizotinib
New indication approved 01/14/2021:
- Pediatric patients 1 year of age and older and young adults with relapsed or refractory, systemic anaplastic large cell lymphoma (ALCL) that is ALKpositive. Limitations of use: The safety and efficacy of Xalkori have not been established in older adults with relapsed or refractory, systemic ALK-positive ALCL.

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

10. **CABOMETYX®**
Cabozantinib s-malate
New indication approved 01/22/2021:
- Patients with advanced renal cell carcinoma, as a first-line treatment in combination with nivolumab.

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

11. **LIBTAYO®**
Cemiplimab-RWLC
New indication approved 02/09/2021 and 02/22/2021:

- Treatment of patients with metastatic basal cell carcinoma (mBCC) previously treated with a hedgehog pathway inhibitor or for whom a hedgehog pathway inhibitor is not appropriate.
- First-line treatment of patients with non-small cell lung cancer (NSCLC) whose tumors have high PD-L1 expression [Tumor Proportion Score (TPS) ≥50%] as determined by and FDA-approved test, with no EGFR, ALK or ROS1 aberrations, and is:
  • locally advanced where patients are not candidates for surgical resection or • metastatic

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. ZIRABEV®

Bevacizum-BVZR

New indication approved 02/09/2021:

- In combination with carboplatin and paclitaxel, followed by Zirabev as a single agent, for the treatment of patients with stage III or IV epithelial ovarian, fallopian tube, or primary peritoneal cancer following initial surgical resection;
- In combination with paclitaxel, pegylated liposomal doxorubicin, or topotecan for treatment of patients with platinum-resistant, recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer who received no more than 2 prior chemotherapy regimens; and
- In combination with carboplatin and paclitaxel or with carboplatin and gemcitabine, followed by Zirabev as a single agent, for the treatment of patients with platinum sensitive recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer.

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

13. LIBTAYO®

Cemiplimab-RWLC

New indication approved 02/22/21:

- First-line treatment of patients with non-small cell lung cancer (NSCLC) whose tumors have high PD-L1 expression [Tumor Proportion Score (TPS) ≥50%] as determined by and FDA-approved test, with no EGFR, ALK or ROS1 aberrations, and is:
  - locally advanced where patients are not candidates for surgical resection
    or
  - metastatic
- For the treatment of patients with locally advanced BCC (laBCC) previously treated with a hedgehog pathway inhibitor or for whom a hedgehog pathway inhibitor is not appropriate.
- For the treatment of patients with metastatic BCC (mBCC) previously treated with a hedgehog pathway inhibitor or for whom a hedgehog pathway inhibitor is not appropriate.
  - The mBCC indication is approved under accelerated approval based on tumor response rate and durability of response. Continued approval for mBCC may be contingent upon verification and description of clinical benefit.

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

Therapies without Prior Authorization Policies:

14. **CEFAZOLIN IN PLASTIC CONTAINER®**
Cefazolin Sodium
New indication approved 02/01/2021:
- Treatment of the following infections caused by susceptible isolates of the designated microorganisms in adult and pediatric patients for whom appropriate dosing with this formulation can be achieved:
  - Respiratory tract infections;
  - Urinary tract infections;
  - Skin and skin structure infections;
  - Biliary tract infections;
  - Bone and joint infections;
  - Genital infections;
  - Septicemia;
  - Endocarditis
- Perioperative prophylaxis in adults for whom appropriate dosing with this formulation can be achieved

RECOMMENDATION: Inform prescribers via MD alert.

15. **ENTRESTO®**
SACUBITRIL; VALSARTAN
New indication approved 02/16/2021:
- To reduce the risk of cardiovascular death and hospitalization for heart failure in adult patients with chronic heart failure. Benefits are most clearly evident in patients with left ventricular ejection fraction (LVEF) below normal
- For the treatment of symptomatic heart failure with systemic left ventricular systolic dysfunction in pediatric patients aged one year and older. ENTRESTO reduces NT-proBNP and is expected to improve cardiovascular outcomes

RECOMMENDATION: Inform prescribers via MD alert.

16. **SPRITAM®**
Levetiracetam oral tablet for suspension
New indication approved 01/19/2021:
- Partial-onset seizures in patients 4 years of age and older weighing more than 20 kg
- Adjunctive therapy for the treatment of:
  - Myoclonic seizures in patients 12 years of age and older with juvenile myoclonic epilepsy
  - Primary generalized tonic-clonic seizures in patients 6 years of age and older with idiopathic generalized epilepsy

RECOMMENDATION: Inform prescribers via MD alert.

17. **RAPIVAB®**
Peramivir
New indication approved 01/28/2021:
- Treatment of acute uncomplicated influenza in patients 6 months and older who have been symptomatic for no more than two days

RECOMMENDATION: Inform prescribers via MD alert.

18. **EDURANT®**
Rilpivirine hydrochloride
New indication approved 01/21/2021:
- In combination with VOCABRIA (cabotegravir), for short-term treatment of HIV-1 infection in adults who are virologically suppressed (HIV-1 RNA less than 50 copies/mL) on a stable regimen with no history of treatment failure and with no known or suspected resistance to either cabotegravir or rilpivirine

RECOMMENDATION: Inform prescribers via MD alert

Drug Safety Monitoring:

1. **Xeljanz, Xeljanz XR (tofacitinib): Drug Safety Communication - Initial Safety Trial Results Find Increased Risk of Serious Heart-related Problems and Cancer with Arthritis and Ulcerative Colitis Medicine**
[Posted 2/4/2021]

ISSUE:
The FDA is alerting the public that preliminary results from a safety clinical trial show an increased risk of serious heart-related problems and cancer with the arthritis and ulcerative colitis medicine Xeljanz, Xeljanz XR (tofacitinib) compared to another type of medicine called tumor necrosis factor (TNF) inhibitors. FDA required the safety trial, which also investigated other potential risks including blood clots in the lungs and death. Those final results are not yet available.

In February 2019 and July 2019, FDA warned that interim trial results showed an increased risk of blood clots and death with the higher 10 mg twice daily dosage, and as a result, approved a *Boxed Warning* to the tofacitinib prescribing information. The clinical trial is now complete and initial results show a higher occurrence of serious heart-related events and cancer in rheumatoid arthritis (RA) patients treated with both doses of tofacitinib compared to patients treated with a TNF inhibitor. FDA is awaiting additional results from the trial.

FDA RECOMMENDATION:
Tofacitinib was approved in 2012 to treat adults with RA who did not respond well to the medicine methotrexate. In 2017, FDA approved tofacitinib to treat patients with a second condition that causes joint pain and swelling, psoriatic arthritis (PsA), who did not respond well to methotrexate or other similar medicines. In 2018, FDA approved the medicine to treat ulcerative colitis,

which is a chronic, inflammatory disease affecting the colon. Tofacitinib works by decreasing the activity of the immune system; an overactive immune system contributes to RA, PsA, and ulcerative colitis.

Patients should not stop taking tofacitinib without first consulting with your health care professionals, as doing so may worsen your condition. Health care professionals should consider the benefits and risks of tofacitinib when deciding whether to prescribe or continue patients on the medicine. Continue to follow the recommendations in the tofacitinib prescribing information.

Recommendation: Notify via MD alert