

Healthcare Services Medical & Pharmacy Policy Alerts

Number 266

January 1, 2022

This is the **January 1, 2022** issue of the Providence Health Plans, Providence Health Assurance and Providence Plan Partners, Medical and Pharmacy Policy Alert to our providers. The focus of this update is to communicate to providers' new or revised Medical or Pharmacy policy changes. The Health Plan has a standard process to review all Medical & Pharmacy Policies annually. Policies will be available for review on ProvLink and via the PHP website at: <https://healthplans.providence.org/providers/provider-support/medical-policy-pharmacy-policy-and-provider-information/>

The Provider Alert, Prior Authorization Requirements, and Medical policies are all available on ProvLink and through the link above.

MEDICAL POLICY COMMITTEE

MEDICAL

Effective 1/1/2022

<p>Intraoperative Monitoring (Medicare Only)</p>	<p>Policy Updates:</p> <ul style="list-style-type: none"> • New policy created addressing intraoperative neurophysiological monitoring (IOM), per the following Medicare guidance documents: <ul style="list-style-type: none"> ○ National Coverage Determination (NCD) for Electroencephalographic Monitoring During Surgical Procedures Involving the Cerebral Vasculature (160.8) • All other intraoperative monitoring services will be reviewed in accordance with the criteria of “Intraoperative Monitoring (All Lines of Business Except Medicare) – MP #295 <p>Codes/PA:</p> <ul style="list-style-type: none"> • As stated on the October 1st 2021, Provider Alert, this policy will be administered with UM techniques, including prior authorization. This policy will follow commercial policy criteria and coding configuration, per Medicare guidelines regarding coverage determinations when no appropriate Medicare guidance exists. • Configuration will include the following: <ul style="list-style-type: none"> ○ IOM codes (95940 and G0453) will be configured to pay when billed with certain diagnosis codes, which will be listed in the policy’s “Billing Guideline Appendix.” ○ IOM codes (95940 and G0453) will be configured to deny when billed with certain CPT codes (e.g. spinal cord stimulator placement, radiofrequency ablation) or when billed with certain dx codes for indications below L1/L2 or cervical surgery. ○ IOM codes (95940 and G0453) will require prior authorization when billed with any other diagnosis code
<p>Cochlear Implants and Auditory Brainstem Implants</p> <p>(All Lines of Business Except Medicare)</p>	<p>Policy Updates:</p> <ul style="list-style-type: none"> • Criteria liberalized to allow for cochlear implants in children and adults with profound unilateral hearing loss. • Billing Guidelines updated – termed codes removed and new codes added. <p>Codes/PA: No coding changes.</p>

MEDICAL

Effective 3/1/2022

<p>Back: Epidural Steroid Injections (All Lines of Business Except Medicare)</p>	<p>Policy Updates:</p> <ul style="list-style-type: none"> • New restriction to repeat injection requirements (criterion III.) – 50% relief from prior injection must have lasted a minimum of 6 weeks to be eligible for a subsequent injection. • Criteria VI.-VII. – per operations considerations, language has been clarified; no change in requirements. • Policy guideline added stating that conscious sedation, monitored anesthesia care, and intraoperative monitoring not allowed during ESI and will deny when billed with epidural steroid injections. • Policy guideline added clarifying that for patients who have had an initial injection and a subsequent change in history, exam or imaging, “initial injection” criteria should be used, not “repeat injection” criteria. <p>Codes/PA: Several codes removed from policy that have termed more than 12 months ago.</p>
<p>Surgical Site of Service</p>	<p>Policy Updates:</p> <ul style="list-style-type: none"> • Criteria added for total hip arthroplasty (THA) for inpatient settings. Criteria are based largely on current total knee arthroplasty criteria. • Two-part prior authorization process will be established: THA’s will be reviewed first for medical necessity per the “Hip: Total Joint Arthroplasty” policies, then if approved, for inpatient site of service, per this policy. • References to Medicare guidance documents added addressing site of service criteria. <p>Codes/PA:</p> <ul style="list-style-type: none"> • No coding changes; PA still required.
<p>Back: Implantable Spinal Cord and Dorsal Root Ganglion Stimulation (All Lines of Business Except Medicare)</p>	<p>Policy Updates:</p> <ul style="list-style-type: none"> • New medical necessity criteria added (VIII.-IX.) addressing the revision and replacement or spinal cord stimulator devices. • Language added to policy guidelines, specifying that intraoperative neurophysiological testing and monitoring (CPT: 95940; HCPCS: G0453) will deny as not medically necessary when billed with codes for spinal cord stimulator placement (CPT: 63650, 63655, 63663, 63664, 63685). <p>Codes/PA: No changes to coding or prior authorization.</p>
<p>Investigational and Non-Covered Medical</p>	<p>Policy Updates:</p> <ul style="list-style-type: none"> • Codes related to prosthetic paravalvular leak repair will deny as investigational and not covered. <p>Codes/PA:</p>

Technologies (All Lines of Business Except Medicare)	<ul style="list-style-type: none"> Codes 93590 and 93591 configured to deny as investigational Code 0662T and 0663T have been moved to “Cooling Devices” policy with no change to configuration.
Investigational and Non-Covered Medical Technologies (Medicare Only)	<p>Policy Updates:</p> <ul style="list-style-type: none"> Added CPT 93590, 93591, and 93592 to this policy, non-covered per Commercial policy criteria. <p>Codes/PA:</p> <ul style="list-style-type: none"> Added CPT codes 93590, 93591, and 93592 to this policy with E/I denial edit
Skin and Tissue Substitutes	<p>Policy Updates:</p> <ul style="list-style-type: none"> Amnioband Membrane and Allopatch now covered as medically necessary for diabetic foot ulcers when criteria are met. <p>Codes/PA: Code Q4151 configured to require PA (previously denied as investigational)</p>
Transcranial Magnetic Stimulation (All Lines of Business Except Medicare)	<p>Recommendation:</p> <ul style="list-style-type: none"> Added criteria specifying that patients must be 18 years of age or older to receive transcranial magnetic stimulation (TMS). This requirement is in line with the indications of use for all FDA-approved TMS devices, but had not previously been called out in the policy. <p>Codes/PA: No changes to configuration for these codes.</p>

VENDOR UPDATES

Updates to AIM Advanced Imaging Clinical Appropriateness Guideline

Effective for dates of service on and after March 13, 2022, 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

Updates by Guideline

Imaging of the Brain

- Acoustic neuroma – removed indication for CT brain and replaced with CT temporal bone
- Meningioma – new guideline establishing follow-up intervals
- Pituitary adenoma – removed allowance for CT following nondiagnostic MRI in macroadenoma

- Tumor, not otherwise specified – added indication for management; excluded surveillance for lipoma and epidermoid without suspicious features

Imaging of the Head and Neck

- Parathyroid adenoma – specified scenarios where surgery is recommended based on American Association of Endocrine Surgeons guidelines
- Temporomandibular joint dysfunction – specified duration of required conservative management

Imaging of the Heart

- Coronary CT Angiography Removed indication for patients undergoing evaluation for transcatheter aortic valve implantation/replacement who are at moderate coronary artery disease risk

Imaging of the Chest

- Pneumonia – removed indication for diagnosis of COVID-19 due to availability and accuracy of lab testing
- Pulmonary nodule – aligned with Lung-RADS for follow-up of nodules detected on lung cancer screening CT

Imaging of the Abdomen and Pelvis

- Uterine leiomyomata – new requirement for US prior to MRI; expanded indication beyond uterine artery embolization to include most other fertility-sparing procedures
- Intussusception – removed as a standalone indication
- Jaundice – added requirement for US prior to advanced imaging in pediatric patients
- Sacroiliitis – defined patient population in whom advanced imaging is indicated (predisposing condition or equivocal radiographs)
- Azotemia – removed as a standalone indication
- Hematuria – modified criteria for advanced imaging of asymptomatic microhematuria based on AUA guideline

Oncologic Imaging

- National Comprehensive Cancer Network (NCCN) recommendation alignments for Breast Cancer, Hodgkin & Non Hodgkin Lymphoma, Neuroendocrine Tumor, Melanoma, Soft Tissue Sarcoma, Testicular Cancer, and Thyroid Cancers.
- Cancer Screening: new age parameters for Pancreatic Cancer screening; new content for Hepatocellular Carcinoma screening
- Breast Cancer: clinical scenario clarifications for Diagnostic Breast MRI and PET/CT

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 December 3, 2021

Go-Live Date: , February 01, 2022, unless otherwise noted

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New Drugs and Combinations:

1. Belzutifan (Welireg) Tablet

- a. **Indication:** For treatment of adult patients with von Hippel-Lindau (VHL) disease who require therapy for associated renal cell carcinoma (RCC), central nervous system (CNS) hemangioblastomas, or pancreatic neuroendocrine tumors (pNET), not requiring immediate surgery.
- b. **Decision:**

	Commercial	Medicaid	Medicare
Formulary Status*	Formulary	Formulary	Part D: Formulary Part B: N/A
Tier**	Tier 6 - Non-Preferred Specialty	N/A	Specialty
Affordable Care Act Eligible	N/A; Non-Formulary	N/A	N/A
Utilization Management Edits	Prior Authorization	Prior Authorization	Prior Authorization
Quantity Limit	N/A	N/A	N/A
* Recommendations for placement may differ between lines of business due to regulatory requirements.			

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

Formulary Alternatives: None

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

2. Olanzapine-samidorphan malate (Lybalvi) Tablet

a. **Indication:** For the treatment of:

- Schizophrenia in adults
- Bipolar I disorder in adults (1) for acute treatment of manic or mixed episodes as monotherapy and as adjunct to lithium or valproate or (2) maintenance monotherapy treatment

b. **Decision:**

	Commercial	Medicaid	Medicare
Formulary Status*	Formulary	Non-formulary	Part D: Formulary Part B: N/A
Tier**	Tier 4	N/A	Specialty
Affordable Care Act Eligible	N/A; Non-Formulary	N/A	N/A
Utilization Management Edits	Step Therapy	N/A	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: olanzapine, aripiprazole, ziprasidone, quetiapine

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

PA PROGRAM NAME	Antipsychotics Step Therapy
MEDICATION NAME	Lybalvi (olanzapine/samidorphan)
PA INDICATION INDICATOR	1 - All FDA-Approved Indications
OFF-LABEL USES	N/A
EXCLUSION CRITERIA	N/A
REQUIRED MEDICAL INFORMATION	The following criteria must be met:

	<p>For schizophrenia: Documented trial, failure, intolerance or contraindication to two formulary, generic antipsychotics (such as quetiapine, olanzapine, ziprasidone, risperidone, aripiprazole)</p> <p>For bipolar disorder: Documented trial, failure, intolerance or contraindication to two formulary, generic medications for bipolar disorder (such as lithium, quetiapine, lamotrigine, divalproex, aripiprazole, risperidone, olanzapine, ziprasidone)</p>
AGE RESTRICTIONS	N/A
PRESCRIBER RESTRICTIONS	N/A
COVERAGE DURATION	Authorization will be approved until no longer eligible with the plan, subject to formulary and/or benefit changes

d. Prior Authorization Criteria for Medicare Part D:

PA PROGRAM NAME	Antipsychotics
MEDICATION NAME	Lybalvi (olanzapine/samidorphane)
PA INDICATION INDICATOR	3 - All Medically-Accepted Indications
OFF-LABEL USES	N/A
EXCLUSION CRITERIA	N/A
REQUIRED MEDICAL INFORMATION	For schizophrenia or bipolar disorder: Documented trial, failure, intolerance or contraindication to two formulary, generic antipsychotics (e.g., quetiapine, olanzapine, ziprasidone, risperidone, aripiprazole).
AGE RESTRICTIONS	N/A
PRESCRIBER RESTRICTIONS	N/A
COVERAGE DURATION	Authorization will be approved until no longer eligible with the plan.

3. Mobocertinib succinate (Exkivity) Tablet

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, as detected by an FDA-approved test, who disease has progressed on or after platinum-based chemotherapy.

b. **Decision:**

	Commercial	Medicaid	Medicare
Formulary Status*	Formulary	Formulary	Part D: Formulary Part B: N/A
Tier**	Tier 6 - Non-Preferred Specialty	N/A	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: amivantamab-vmjw vial (Rybrevant®)			

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

4. Tisotumab vedotin-tftv (Tivdak) Vial

- a. **Indication:** For the treatment of adult patient with recurrent or metastatic cervical cancer with disease progression on or after chemotherapy
- b. **Decision:**

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

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

5. Odevixibat (Bilvay) Pel DSP CP

- a. **Indication:** For the treatment of pruritus in patients three months of age and older with progressive familial intrahepatic cholestasis (PFIC).

b. Decision:

	Commercial	Medicaid	Medicare
Formulary Status*	Non-formulary	Non-formulary	Part D: Non-formulary Part B: N/A
Tier**	N/A	N/A	N/A
Affordable Care Act Eligible	No	N/A	N/A
Utilization Management Edits	Prior Authorization	Prior Authorization	N/A
Quantity Limit	6 mg/day	6 mg/day	6 mg/day
<p>* 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).</p>			
Formulary Alternatives: ursodiol, cholestyramine, rifampin			

c. Prior Authorization Criteria for Commercial/Medicaid:

PA PROGRAM NAME	Bylvay
MEDICATION NAME	Bylvay
PA INDICATION INDICATOR	1 - All FDA-Approved Indications
OFF-LABEL USES	N/A
EXCLUSION CRITERIA	<ol style="list-style-type: none"> 1. Molecular genetic testing indicates PFIC type 2 with <i>ABCB11</i> variants encoding for nonfunction or absence of BSEP-3 protein 2. History of liver transplant 3. Decompensated cirrhosis
REQUIRED MEDICAL INFORMATION	<p>Progressive Familial Intrahepatic Cholestasis (PFIC) For initial authorization, all of the following must be met:</p> <ol style="list-style-type: none"> 1. Diagnosis of genetically confirmed PFIC type 1 or 2 (formerly known as Byler disease or syndrome) (note: gene mutations affiliated with PFIC include the <i>ATP8B1</i> gene, <i>ABCB11</i> gene, <i>ABCB4</i> gene, <i>TJP2</i> gene, <i>NR1H4</i> gene, and <i>MYO5B</i> gene) AND 2. Documentation of moderate-to-severe pruritis AND 3. Documentation that drug-induced pruritus has been ruled out AND 4. Documentation that serum bile acids are equal to or greater than 100 µmol/L AND 5. Documentation of trial and failure, contraindication, or intolerance to ALL of the following systemic medications for pruritis associated with cholestasis: <ol style="list-style-type: none"> a. Ursodiol AND b. Cholestyramine AND c. Rifampin

	For reauthorization: 1. Documentation of response to therapy defined as: a. Equal to or greater than 70% reduction in serum bile acids from baseline AND b. Improvement in pruritis
AGE RESTRICTIONS	N/A
PRESCRIBER RESTRICTIONS	Must be prescribed by, or in consultation with, a hepatologist or gastroenterologist
COVERAGE DURATION	Initial authorization will be approved for six months. Reauthorization will be approved for one year.

6. Avalglucosidase alfa-ngpt (Nexviazyme) Vial

- a. **Indication:** For the treatment of patients one year of age and older with late-onset Pompe disease (lysosomal acid alpha-glucosidase [GAA] deficiency).
- b. **Decision:**

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

c. Prior Authorization Criteria for Commercial, Medicaid, and Medicare Part B:

PA PROGRAM NAME	Enzyme Replacement Therapy
MEDICATION NAME	Nexviazyme
PA INDICATION INDICATOR	1 - All FDA-Approved Indications
OFF-LABEL USES	N/A
EXCLUSION CRITERIA	N/A
REQUIRED MEDICAL INFORMATION	For initial authorization both of the following must be met: 1. Documentation of FDA-labeled indication (see Appendix) for the requested product AND

	<p>2. Dosing is within FDA-labeled guidelines (see Appendix).</p> <p>3. For avalglucosidase alfa (Nexviazyme) only: Patients weighing less than 30 kg must have a documented trial, failure, intolerance or contraindication to alglucosidase alfa (Lumizyme®)</p> <p>REAUTHORIZATION: Both of the following must be met:</p> <ol style="list-style-type: none"> 1. Documentation of successful response to therapy (e.g., disease stability or improvement in symptoms). 2. Dosing is within FDA-labeled guidelines <p>Note: If request is for a non-FDA approved dose, medical rationale must be submitted in support of therapy with a higher dose for the intended diagnosis (i.e., high-quality peer reviewed literature, accepted compendia or evidence-based practice guidelines) and exceptions will be considered on a case by case basis.</p>
AGE RESTRICTIONS	Nexviazyme: Approved for ages 1 year and older
PRESCRIBER RESTRICTIONS	Must be prescribed by or in consultation with a Hepatologist, Endocrinologist, Medical Geneticist, Cardiologist, Pulmonologist, or Bone and Mineral specialist
COVERAGE DURATION	Initial authorization will be approved for six months. Reauthorization will be approved for one year.
QUANTITY LIMITS	Initial dose approval will be based on patient's current weight. Increases in dose will require new authorization with patient's weight and relevant chart notes

New Indications:

Therapies with Prior Authorization Policies (Non-oncology)

1. ULTOMIRIS® (ravulizumab-ewvz)

a. Previous Indication(s):

- The treatment of adult patients with paroxysmal nocturnal hemoglobinuria (PNH)
- The treatment of adults and pediatric patients one month of age and older with atypical hemolytic uremic syndrome (aHUS) to inhibit complement-mediated thrombotic microangiopathy (TMA)

b. New indication approved 06/06/2021:

- The treatment of adult and pediatric patients one month of age and older with paroxysmal nocturnal hemoglobinuria (PNH)

c. RECOMMENDATION: Inform prescribers via Medical Policy Alert and update prior authorization criteria for Commercial, Medicare Part B, and Medicaid as outline below. No updated to criteria warranted for Medicare Part D

Prior Authorization for Commercial/Medicaid/Medicare Part B:

PA PROGRAM NAME	Ultomiris
MEDICATION NAME	Ultomiris
COVERED USES	1 - All FDA-Approved Indications
EXCLUSION CRITERIA	Concurrent therapy with another FDA-approved product for PNH, meaning Soliris® or Empaveli®

<p>REQUIRED MEDICAL INFORMATION</p>	<p>Paroxysmal Nocturnal Hemoglobinuria (PNH): Initial authorization all of the following must be met:</p> <ol style="list-style-type: none"> 1. Confirmed diagnosis of paroxysmal nocturnal hemoglobinuria (PNH) by Flow Cytometric Immunophenotyping (FCMI) using at least two independent flow cytometry reagents on at least two cell lineages (e.g., RBCs and WBCs) demonstrating that the patient's peripheral blood cells are deficient in glychosphatidylinositol (GPI)-linked proteins (which may include CD59, CD55, CD14, CD15, CD16, CD24, CD45, and CD64) <p>AND</p> <ol style="list-style-type: none"> 2. Severe disease as indicated by at least one of the following (a or b): <ol style="list-style-type: none"> a. Documented history of thrombosis, OR b. Documentation of at least 10% PNH type III red cells AND at least one of the following: <ol style="list-style-type: none"> i. Transfusion dependence (e.g., hemoglobin less than 7 g/dL or symptomatic anemia with hemoglobin less than 9 g/dL) ii. Disabling fatigue iii. End-organ complications iv. Frequent pain paroxysms (e.g., dysphagia or abdominal pain) v. Lactate dehydrogenase (LDH) levels greater than or equal to 1.5 times the upper limit of normal <p>AND</p> <ol style="list-style-type: none"> 3. Dose and frequency is in accordance with FDA-approved labeling <p>For patients currently on eculizumab (Soliris®) switching to ravulizumab (Ultomiris®) for PNH:</p> <ol style="list-style-type: none"> 1. Confirmed documentation of paroxysmal nocturnal hemoglobinuria (criteria 1 above) and severe disease (criteria 2 above). However, this can be based on patient's history prior to starting eculizumab. <p>AND</p> <ol style="list-style-type: none"> 2. Dose and frequency is in accordance with FDA-approved labeling <p>Reauthorization:</p> <ol style="list-style-type: none"> 1. Documentation of reduced LDH levels, reduced transfusion requirements, or improvement in PNH related symptoms 2. Dose and frequency is in accordance with FDA-approved labeling <p>Compliment-Mediated Hemolytic Uremic Syndrome (HUS) Initial authorization all of the following must be met:</p> <ol style="list-style-type: none"> 1. Diagnosis of non-infectious HUS (<i>i.e.</i> HUS is not due to infection with Shiga toxin-producing <i>Escherichia coli</i>) <p>AND</p> <ol style="list-style-type: none"> 2. Clinical presentation that includes: microangiopathic hemolytic anemia (hemoglobin less than 10 g/dL), thrombocytopenia (platelets less than 150), and acute kidney injury (elevations in serum creatinine) <p>AND</p>
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	<p>3. Complement dysregulation confirmed by genetic testing (e.g., mutations in complement regulatory genes: factor H (CFH), membrane cofactor protein (CD46), factor I (CFI), thrombomodulin (THBD), the activator genes: factor B (CFB) and C3 and autoantibodies to CFH)</p> <p>AND</p> <p>4. Prior or current treatment with plasma therapy (plasmapheresis or plasma infusions) OR medical rationale of why plasma therapy is not appropriate for member</p> <p>AND</p> <p>5. Dose and frequency is in accordance with FDA-approved labeling</p> <p>For patients currently on eculizumab (Soliris®) switching to ravulizumab (Ultomiris®)</p> <p>1. Confirmed documentation of <u>Complement-Mediated Hemolytic Uremic Syndrome (criteria 1, 2 and 3 above)</u>. However, this can be based on patient's history prior to starting eculizumab.</p> <p>AND</p> <p>2. Dose and frequency is in accordance with FDA-approved labeling</p> <p>Reauthorization for HUS:</p> <p>1. Documentation of improvement in at least two thrombotic microangiopathy endpoints, such as:</p> <ul style="list-style-type: none"> • Maintenance of platelet counts (i.e. improvements or reductions less than 25%) • Reductions in LDH • Reduction in number of needed plasmapheresis or plasma infusion events • Improvement in kidney function and reduction of dialysis <p>2. Dose and frequency is in accordance with FDA-approved labeling</p>
AGE RESTRICTIONS	For PNH: Approved for one month of age and older For aHUS: No age restriction
PRESCRIBER RESTRICTIONS	Must be prescribed by or in consultation with a nephrologist, hematologist or an oncologist
COVERAGE DURATION	Initial authorization for up to three months and reauthorization will be approved for up to one year.

2. NUCALA® (mepolizumab)

a. Previous Indication(s):

- Add-on maintenance treatment of patients with severe asthma aged six years and older, and with an eosinophilic phenotype
- The treatment of adult patients with eosinophilic granulomatosis with polyangiitis (EGPA)
- The treatment of adult and pediatric patients aged 12 years and older with hypereosinophilic syndrome (HES) for greater than or equal to six months without an identifiable non-hematologic secondary cause

b. New indication approved 07/29/2021

- Add-on maintenance treatment of adult patients 18 years and older with chronic rhinosinusitis with nasal polyps (CRSwNP)

- c. RECOMMENDATION: Inform prescribers via Medical Policy Alert and update prior authorization criteria for Commercial, Medicare Part B, Medicaid, and Medicare Part D as outlined below.

Prior Authorization for Commercial/Medicaid/Medicare Part B:

PA PROGRAM NAME	IL-5 Inhibitors
MEDICATION NAME	Nucala
COVERED USES	1 - All FDA-Approved Indications
EXCLUSION CRITERIA	Concurrent use with another therapeutic immunomodulator agent utilized for the same indication.
REQUIRED MEDICAL INFORMATION	<p>For initial authorization, must meet all of the following criteria:</p> <p>For eosinophilic asthma:</p> <ol style="list-style-type: none"> 1. Documentation of eosinophilic asthma by one of the following: <ol style="list-style-type: none"> a. A blood eosinophil count of greater than 150 cells/microliter in the past 12 months b. Past history of eosinophilic asthma if currently on daily maintenance treatment with oral glucocorticoids 2. Documentation of treatment with maximally tolerated dose of medium to high-dose inhaled corticosteroid plus an additional asthma controller (e.g., long-acting inhaled beta2-agonist, leukotriene receptor antagonist) and has been compliant to therapy in the past three months (<i>this may be verified by pharmacy claims information</i>) 3. Documentation of severe asthma with inadequate asthma control despite above therapy, defined as one of the following: <ol style="list-style-type: none"> a. Asthma Control Test (ACT) score less than 20 or Asthma Control Questionnaire (ACQ) score greater than or equal to 1.5 b. At least two asthma exacerbations requiring oral systemic corticosteroids in the last 12 months c. At least one asthma exacerbation requiring hospitalization, emergency room or urgent care visit <p>For Eosinophilic Granulomatosis with Polyangiitis (EGPA):</p> <ol style="list-style-type: none"> 1. Request is for Nucala® 2. Confirmed diagnosis of eosinophilic granulomatosis with polyangiitis (EGPA) 3. History or presence of asthma 4. Blood eosinophil level of at least 10% or an absolute eosinophil count of more than 1000 cells/microliter 5. Documentation of one of the following <ol style="list-style-type: none"> a. History of relapse requiring an increase in glucocorticoid dose, initiation or increase in other immunosuppressive therapy, or hospitalization in the previous two years while receiving at least 7.5 mg/day prednisone (or equivalent) <p>OR</p> b. Failure to achieve remission following a standard induction regimen administered for at least three months OR recurrence of symptoms of EGPA while tapering of glucocorticoids <ol style="list-style-type: none"> i. Standard treatment regimens include: prednisone [or equivalent] dosed at least 7.5 mg/day in combination with an immunosuppressant such as cyclophosphamide, azathioprine, methotrexate, or mycophenolate mofetil

	<p>For Hyperesoinophilic Syndrome (HES)</p> <ol style="list-style-type: none"> 1. Request is for Nucala® 2. Document of primary HES without an identifiable nonhematologic secondary cause such as parasitic infections, solid tumors, or T cell lymphoma 3. Blood eosinophil count of 1,000 cells/microliter or higher for at least six months 4. Documentation of use of HES therapy including one of the following in the past for the past 12 months: <ol style="list-style-type: none"> a. chronic or episodic oral corticosteroids (OCS) b. immunosuppressive therapy c. cytotoxic therapy 5. Documentation of at least two HES flares within the past 12 months (defined as HES-related worsening of clinical symptoms or blood eosinophil counts requiring an escalation in therapy) <p><u>Reauthorization</u> documentation of response to therapy, such as attainment and maintenance of remission or decrease in number of relapses</p> <p>For Adjunct Therapy for Chronic Rhinosinusitis with Nasal Polyp (CRSwNP), all the following must be met:</p> <ol style="list-style-type: none"> 1. The request is for Nucala® 2. Evidence of nasal polyposis by direct examination, endoscopy or sinus CT scan 3. Documentation of one of the following: <ol style="list-style-type: none"> a. Patient had an inadequate response to sinonasal surgery or is not a candidate for sinonasal surgery b. Patient has tried and had an inadequate response to, or has an intolerance or contraindication to, oral systemic corticosteroids 4. Patient has tried and had an inadequate response to a three month trial of intranasal corticosteroids (e.g., fluticasone) or has a documented intolerance or contraindication to ALL intranasal corticosteroids 5. Documentation that patient will continue standard maintenance therapy (e.g., nasal saline irrigation, intranasal corticosteroids) in combination with mepolizumab <p><u>Reauthorization for CRSwNP:</u> Documentation of positive clinical response to therapy such as symptom improvement</p>
AGE RESTRICTIONS	<p>Nucala®: Approved for six years of age or older for eosinophilic asthma, approved for 18 years of age and older for EGPA and CRSwNP and approved for 12 years of age and older for HES</p> <p>Cinqair®: Approved for 18 years of age or older</p> <p>Fasenra®: Approved for 12 years of age or older</p>
PRESCRIBER RESTRICTIONS	<p>For eosinophilic asthma: must be prescribed by or in consultation with an asthma specialist (such as a pulmonologist, immunologist, or allergist)</p> <p>For Eosinophilic Granulomatosis with Polyangiitis: must be prescribed by or in consultation with a pulmonologist, neurologist, or rheumatologist</p> <p>For hypereosinophilic syndrome (HES): must be prescribed by or in consultation with hematologist, immunologist, pulmonologist, cardiologist, or neurologist.</p>

	Chronic rhinosinusitis with nasal polyposis: Must be prescribed by, or in consultation with, an otolaryngologist, allergist, pulmonologist
COVERAGE DURATION	For EGPA and HES: Initial authorization and reauthorization will be approved for one year. For asthma: Initial authorization will be approved for one year and reauthorization will be approved until no longer eligible with the plan, subject to formulary or benefit changes For chronic rhinosinusitis with nasal polyposis: Initial authorization will be approved for six months. Reauthorization will be approved for one year.

Prior Authorization for Medicare Part D:

PA PROGRAM NAME	IL-5 Inhibitors
MEDICATION NAME	Nucala
PA INDICATION INDICATOR	1 - All FDA-Approved Indications
OFF-LABEL USES	N/A
EXCLUSION CRITERIA	Concurrent use with another therapeutic immunomodulator agent utilized for the same indication.
REQUIRED MEDICAL INFORMATION	<p>For initial authorization, must meet all of the following criteria: For eosinophilic asthma:</p> <ol style="list-style-type: none"> 1. Documentation of eosinophilic asthma by one of the following: <ol style="list-style-type: none"> a. A blood eosinophil count of greater than 150 cells/microliter in the past 12 months b. Past history of eosinophilic asthma if currently on daily maintenance treatment with oral glucocorticoids 2. Documentation of treatment with maximally tolerated dose of medium to high dose inhaled corticosteroid plus a long-acting inhaled beta2-agonist 3. Documentation of severe asthma with inadequate control such as frequent exacerbations requiring oral corticosteroids or hospitalizations or a poor asthma control scores (An ACT score less than 20 or an ACQ greater than or equal to 1.5). <p>For eosinophilic granulomatosis with polyangiitis (EGPA):</p> <ol style="list-style-type: none"> 1. Request is for mepolizumab (Nucala) 2. History or presence of asthma 3. Blood eosinophil level of at least 10% or an absolute eosinophil count of more than 1000 cells/microliter 4. At least two of the following clinical findings: <ol style="list-style-type: none"> a. Biopsy evidence of eosinophilic vasculitis b. Motor deficit or nerve conduction abnormality c. Pulmonary infiltrates d. Sinonasal abnormality e. Cardiomyopathy f. Glomerulonephritis g. Alveolar hemorrhage

- h. Palpable purpura
- i. Positive test for ANCA
- 5. Documentation of one of the following:
 - a. History of relapse requiring an increase in glucocorticoid dose, initiation or increase in other immunosuppressive therapy, or hospitalization in the previous two years while receiving at least 7.5 mg/day prednisone (or equivalent) OR
 - b. Failure to achieve remission following a standard induction regimen administered for at least three months OR recurrence of symptoms of EGPA while tapering of glucocorticoids. Standard treatment regimens include: prednisone (or equivalent) dosed at least 7.5 mg/day in combination with an immunosuppressant such as cyclophosphamide, azathioprine, methotrexate, or mycophenolate mofetil.

For hyperesoinophilic syndrome (HES):

1. Request is for mepolizumab (Nucala)
2. Document of primary HES without an identifiable nonhematologic secondary cause such as parasitic infections, solid tumors, or T cell lymphoma
3. Blood eosinophil count of 1,000 cells/mcL or higher for at least 6 months
4. Documentation of use of HES therapy including one of the following in the past for the past 12 months:
 - a. Chronic or episodic oral corticosteroids,
 - b. immunosuppressive therapy,
 - c. cytotoxic therapy
5. Documentation of at least two HES flares within the past 12 months (defined as HES-related worsening of clinical symptoms or blood eosinophil counts requiring an escalation in therapy)

Reauthorization requires documentation of response to therapy, such as attainment and maintenance of remission or decrease in number of relapses.

For Chronic Rhinosinusitis with Nasal Polyp (CRSwNP), all of the following:

1. Request is for mepolizumab (Nucala)
2. Evidence of nasal polyposis by direct examination, endoscopy or sinus CT scan,
3. Documentation that patient has had an inadequate response to (within the past 90 days), or has an intolerance, FDA labeled contraindication, or hypersensitivity to, oral systemic corticosteroids
4. Patient has had an inadequate response to a three month trial of intranasal corticosteroids (e.g., fluticasone) or has a documented intolerance, FDA labeled contraindication, or hypersensitivity to an intranasal corticosteroid
5. Documentation that patient will continue standard maintenance therapy (e.g., intranasal corticosteroids) in combination with the requested agent.

Reauthorization for CRSwNP:

1. Documentation of positive clinical response to therapy,
2. Documentation that patient will continue standard maintenance therapy (e.g., intranasal corticosteroids) in combination with the requested agent, unless documented intolerance, FDA labeled contraindication, or hypersensitivity to such therapy.

AGE RESTRICTIONS	Mepolizumab (Nucala): Approved for six years of age and older. Benralizumab (Fasenra): Approved for 12 years of age and older
PRESCRIBER RESTRICTIONS	For eosinophilic asthma: must be prescribed by or in consultation with an asthma specialist (such as a pulmonologist, immunologist, or allergist). For eosinophilic granulomatosis with polyangiitis: must be prescribed by or in consultation with a pulmonologist, neurologist, or rheumatologist Chronic rhinosinusitis with nasal polyposis: Must be prescribed by, or in consultation with, an otolaryngologist, allergist, or pulmonologist
COVERAGE DURATION	Initial authorization will be approved for six months, reauthorization will be approved for one year

3. XYWAV® (calcium, magnesium, potassium, and sodium oxybates)

a. Previous Indication(s):

- Treatment of cataplexy or excessive daytime sleepiness (EDS) in patients seven years of age and older with narcolepsy

b. New indication approved 08/12/2021:

- Idiopathic Hypersomnia (IH) in adults

c. RECOMMENDATION: Inform prescribers via Medical Policy Alert and update prior authorization criteria for Medicare Part D as outlined below. Idiopathic hypersomnia is a benefit exclusion for Commercial plans.

Prior Authorization for Medicare Part D:

PA PROGRAM NAME	Xyrem
MEDICATION NAME	Xywav
PA INDICATION INDICATOR	1 - All FDA-Approved Indications
OFF-LABEL USES	N/A
EXCLUSION CRITERIA	N/A
REQUIRED MEDICAL INFORMATION	For Narcolepsy: <ol style="list-style-type: none"> 1. Full nocturnal polysomnogram and a multiple sleep latency test showing mean onset to sleep less than 10 minutes AND 2. No other polysomnographic reasons to explain sleepiness AND 3. For adult patients: documentation of trial and failure, contraindication, or intolerance to modafinil AND armodafinil, unless the patient is diagnosed with cataplexy Reauthorization requires documentation that treatment has been effective. For idiopathic hypersomnia, all the following criteria must be met: <ol style="list-style-type: none"> 1. Diagnosis of idiopathic hypersomnia confirmed by sleep study

	<ol style="list-style-type: none"> 2. Documentation that sleepiness is not due to another medical, behavioral, or psychiatric disorder condition, including but not limited to: insufficient sleep (less than seven hours per night), depression, sedating medications, and sleep-related breathing disorders. 3. Documentation of excessive daytime sleepiness defined as an Epworth Sleepiness Scale (ESS) score greater than or equal to 12, or documentation of daily periods of irrepressible need to sleep/daytime lapses into sleep occurring for at least three months 4. Documentation of a 30-day trial and failure, intolerance, or contraindication to modafinil
AGE RESTRICTIONS	N/A
PRESCRIBER RESTRICTIONS	Must be prescribed by or in consultation with a sleep specialist or neurologist
COVERAGE DURATION	Initial authorization will be approved for six months, reauthorization will be approved for one year

4. JARDIANCE® (empagliflozin)

a. Previous Indication(s):

- As an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus
- To reduce the risk of cardiovascular death in adult patients with type 2 diabetes mellitus and established cardiovascular disease

b. New indication approved 08/18/2021:

- To reduce the risk of cardiovascular death plus hospitalization for heart failure in adults with heart failure and reduced ejection fraction

c. RECOMMENDATION: Inform prescribers via Medical Policy Alert and update prior authorization criteria for Medicaid as outlined below.

Prior Authorization for Medicaid

PA PROGRAM NAME	SGLT-2 Inhibitors
MEDICATION NAME	Jardiance
COVERED USES	1 - All FDA-Approved Indications
EXCLUSION CRITERIA	N/A
REQUIRED MEDICAL INFORMATION	<p>For type 2 diabetes, empagliflozin (Jardiance/Synjardy/Synjardy XR®) and dapagliflozin (Farxiga/Xigduo XR®) will be covered with trial (history of paid claim), intolerance, or contraindication to metformin. For all other SGLT-2 agents, all of the following criteria must be met:</p> <ol style="list-style-type: none"> 1. Documentation of trial and failure, contraindication or intolerance to metformin therapy at the maximum effective dose of 2000 mg/day. Trial and failure is defined as a hemoglobin A1c greater than 7% after at least three months of continuous therapy. <p>AND</p> <ol style="list-style-type: none"> 2. Documentation of a trial and failure, contraindication or intolerance to empagliflozin and dapagliflozin. Trial and failure is defined as a hemoglobin A1c greater than 7% after at least three months of continuous therapy. <p>AND</p> <ol style="list-style-type: none"> 3. A documented HbA1c, obtained within the last six months, which is greater than or equal to 7% and less than or equal to 10%.

	<p>For heart failure (with or without diabetes), dapagliflozin and empagliflozin may be covered if the following criteria are met:</p> <ol style="list-style-type: none"> 1. Documented diagnosis of heart failure with reduced ejection fraction (HFrEF) with New York Heart Association (NYHA) functional class II-IV 2. Documented left ventricular ejection fraction of less than or equal to 40% that has been present for at least two months <p>For chronic kidney disease:</p> <ol style="list-style-type: none"> 1. Dapagliflozin may be covered in adult patients (with or without diabetes) if the following criteria are met: <ol style="list-style-type: none"> a. Patient has a documented current estimated glomerular filtration rate (eGFR) of at least 25, but less than or equal to 75 mL/min/1.73m² (using CKD-EPI Formula) b. Urinary albumin-to-creatinine ratio (UACR) of at least 200 and less than or equal to 5000 mg/g c. Patient is currently taking a stable dose (at least four weeks) of maximum tolerated daily dose of one of the following, or intolerance/contraindication to both classes <ol style="list-style-type: none"> i. Angiotensin converting enzyme (ACE) inhibitor ii. Angiotensin receptor blocker (ARB) d. Patient does not have any of the following: Autosomal dominant or autosomal recessive polycystic kidney disease, lupus nephritis, or anti-neutrophil cytoplasmic antibody (ANCA)-associated vasculitis <p>Canagliflozin may be covered for patients with type 2 diabetes with a documented trial, intolerance of contraindication to dapagliflozin</p>
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

5. LEXETTE® (hablobetasol propionate)
 - a. Previous Indication(s):
 - For the topical treatment of plaque psoriasis in patients 18 years of age and older
 - b. New indication approved 08/18/2021:
 - For the topical treatment of plaque psoriasis in patients 12 years of age and older
 - c. RECOMMENDATION: Inform prescribers via Medical Policy Alert. No updates to criteria warranted.

6. BRIVIACT® (brivaracetam)
 - a. Previous Indication(s):
 - For the treatment of partial-onset seizures in patients four years of age and older
 - b. New indication approved 08/27/2021:
 - For the treatment of partial-onset seizures in patients one month of age and older

- c. RECOMMENDATION: Inform prescribers via Medical Policy Alert. No updates to criteria warranted.
7. STEGLATRO® (ertugliflozin)
- a. Previous Indication(s):
- Adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus.
 - Limitations of use: Not for the treatment of type 1 diabetes mellitus or diabetic ketoacidosis.
- b. New indication approved 09/17/2021:
- Limitations of use: Not recommended in patients with type 1 diabetes mellitus. It may increase the risk of diabetic ketoacidosis in these patients
- c. RECOMMENDATION: Inform prescribers via Medical Policy Alert. No updates to criteria warranted.
8. STEGLUJAN® (ertugliflozin and sitagliptin)
- a. Previous Indication(s):
- Adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus when treatment with both ertugliflozin and sitagliptin is appropriate.
 - Limitations of use: Not for the treatment of type 1 diabetes mellitus or diabetic ketoacidosis. Has not been studied in patients with a history of pancreatitis
- b. New indication approved 09/17/2021:
- Adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus
 - Limitations of use: Not for the treatment of type 1 diabetes mellitus or diabetic ketoacidosis. It may increase the risk of diabetic ketoacidosis in these patients
- c. RECOMMENDATION: Inform prescribers via Medical Policy Alert. No updates to criteria warranted.
9. SEGLUROMET® (ertugliflozin and metformin hydrochloride)
- a. Previous Indication(s):
- Adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus who are not adequately controlled on a regimen containing ertugliflozin or metformin, or in patients who are already treated with both ertugliflozin and metformin
 - Limitations of use: Not for the treatment of type 1 diabetes mellitus or diabetic ketoacidosis
- b. New indication approved 09/17/2021:
- Adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus
 - Limitations of use: Not for the treatment of type 1 diabetes mellitus or diabetic ketoacidosis. It may increase the risk of diabetic ketoacidosis in these patients.
- c. RECOMMENDATION: Inform prescribers via Medical Policy Alert.
10. REPATHA® (evolucumab)
- a. Previous Indication(s):

- To reduce the risk of myocardial infarction, stroke, and coronary revascularization in adults with established cardiovascular disease.
- As an adjunct to diet, alone or in combination with other lipid-lowering therapies (e.g., statins, ezetimibe), for treatment of adults with primary hyperlipidemia (including heterozygous familial hypercholesterolemia) to reduce low-density lipoprotein cholesterol (LDL-C)
- As an adjunct to diet and other LDL-lowering therapies (e.g., statins, ezetimibe, LDL apheresis) in patients with homozygous familial hypercholesterolemia (HoFH) who require additional lowering of LDL-C
- b. New indication approved 09/24/2021:
 - As an adjunct to diet and other LDL-C-lowering therapies in pediatric patients aged 10 years and older with HeFH, to reduce LDL-C
 - As an adjunct to other LDL-C-lowering therapies in adults and pediatric patients aged 10 years and older with homozygous familial hypercholesterolemia (HoFH), to reduce LDL-C
- c. RECOMMENDATION: Inform prescribers via Medical Policy Alert. No updates to criteria warranted.

Therapies with Prior Authorization Policies (Oncology)

11. PADCEV® (enfortumab vedotin-efjv)

- a. New indication(s) approved 07/09/2021:
 - For the treatment of adult patients with locally advanced or metastatic urothelial cancer who are ineligible for cisplatin-containing chemotherapy and have previously received one or more prior lines of therapy
- b. RECOMMENDATION: Inform prescribers via Medical Policy Alert. Prior authorization policy coverage criteria are based on recommendations from the National Comprehensive Cancer Network (NCCN); no updates to the policy are warranted.

12. DARZALEX FASPRO® (daratumumab and hyaluronidase-fihj)

- a. New indication(s) approved 07/09/2021:
 - Multiple myeloma in combination with pomalidomide and dexamethasone in patients who have received at least one prior line of therapy including lenalidomide and a proteasome inhibitor
- b. RECOMMENDATION: Inform prescribers via Medical Policy Alert. Prior authorization policy coverage criteria are based on recommendations from the National Comprehensive Cancer Network (NCCN); no updates to the policy are warranted.

13. KEYTRUDA® (pembrolizumab)

- a. New indication(s) approved 07/26/2021:
 - For triple-negative breast cancer (TNBC): for the treatment of patients with high-risk early-stage TNBC in combination with chemotherapy as neoadjuvant treatment, and then continued as a single agent as adjuvant treatment after surgery
- b. New indication(s) approved 08/10/2021:

- In combination with lenvatinib, for the first-line treatment of adult patients with advanced renal cell carcinoma (RCC)
- c. New indication(s) approved 08/30/2021:
 - For the treatment of patients with locally advanced or metastatic urothelial carcinoma who are not eligible for any platinum-containing chemotherapy or who have disease progression during or following platinum-containing chemotherapy or within 12 months of neoadjuvant or adjuvant treatment with platinum-containing chemotherapy
- d. RECOMMENDATION: Inform prescribers via Medical Policy Alert. Prior authorization policy coverage criteria are based on recommendations from the National Comprehensive Cancer Network (NCCN); no updates to the policy are warranted.

14. LENVIMA® (lenvatinib)

- a. New indication(s) approved 07/21/2021:
 - In combination with pembrolizumab, for the treatment of patients with advanced endometrial carcinoma (EC) that is not MSI-H or dMMR who have disease progression following prior systemic therapy in any setting and are not candidates for curative surgery or radiation
- b. New indication(s) approved 08/10/2021:
 - In combination with pembrolizumab, for the first line treatment of adult patients with advanced renal cell carcinoma (RCC)
- c. RECOMMENDATION: Inform prescribers via Medical Policy Alert. Prior authorization policy coverage criteria are based on recommendations from the National Comprehensive Cancer Network (NCCN); no updates to the policy are warranted.

15. OPDIVO® (nivolumab)

- a. New indication(s) approved 08/19/2021:
 - Adjuvant treatment of patients with urothelial carcinoma (UC) who are at high risk of recurrence after undergoing radical resection of UC
- b. RECOMMENDATION: Inform prescribers via Medical Policy Alert. Prior authorization policy coverage criteria are based on recommendations from the National Comprehensive Cancer Network (NCCN); no updates to the policy are warranted.

16. TIBSOVO® (ivosidenib)

- a. New indication(s) approved 08/25/2021:
 - Locally advanced or metastatic cholangiocarcinoma who have been previously treated
- b. RECOMMENDATION: Inform prescribers via Medical Policy Alert. Prior authorization policy coverage criteria are based on recommendations from the National Comprehensive Cancer Network (NCCN); no updates to the policy are warranted.

17. BRUKINSA® (zanubrutinib)

- a. New indication(s) approved 08/31/2021:
 - For the treatment of adult patients with Waldenstrom's macroglobulinemia (WM)
- b. New indication(s) approved 09/14/2021:

- For the treatment of adult patients with relapsed or refractory marginal zone lymphoma (MZL) who have received at least one anti-CD20-based regimen
- c. RECOMMENDATION: Inform prescribers via Medical Policy Alert. Prior authorization policy coverage criteria are based on recommendations from the National Comprehensive Cancer Network (NCCN); no updates to the policy are warranted.

18. CABOMETYX® (cabozantinib)

- a. New indication(s) approved 09/17/2021:
 - Adult and pediatric patients 12 years of age and older with locally advanced or metastatic differentiated thyroid cancer (DTC) that has progressed following prior VEGFR-targeted therapy and who are radioactive iodine-refractory or ineligible
- b. RECOMMENDATION: Inform prescribers via Medical Policy Alert. Prior authorization policy coverage criteria are based on recommendations from the National Comprehensive Cancer Network (NCCN); no updates to the policy are warranted.

19. JAKAFI® (ruxolitinib)

- a. New indication(s) approved 09/22/2021:
 - Chronic graft-versus-host disease after failure of one or two lines of systemic therapy in adult and pediatric patients 12 years and older
- b. RECOMMENDATION: Inform prescribers via Medical Policy Alert. Prior authorization policy coverage criteria are based on recommendations from the National Comprehensive Cancer Network (NCCN); no updates to the policy are warranted.

20. TASIGNA® (nilotinib)

- a. New indication(s) approved 09/23/2021:
 - Pediatric patients greater than or equal to one year of age with Ph+ CML-CP and CML-AP resistant or intolerant to prior tyrosine-kinase inhibitor (TKI) therapy
- b. RECOMMENDATION: Inform prescribers via Medical Policy Alert. Prior authorization policy coverage criteria are based on recommendations from the National Comprehensive Cancer Network (NCCN); no updates to the policy are warranted.

21. ERBITUX® (cetuximab)

- a. New indication(s) approved 09/24/2021:
 - In combination with encorafenib, for the treatment of adult patients with metastatic colorectal cancer (CRC) with a BRAF V600E mutation, as detected by an FDA-approved test, after prior therapy.
- b. RECOMMENDATION: Inform prescribers via Medical Policy Alert. Prior authorization policy coverage criteria are based on recommendations from the National Comprehensive Cancer Network (NCCN); no updates to the policy are warranted.

Therapies Without Prior Authorization Policies

22. MIRENA® (levonorgestrel-releasing intrauterine system)

- a. Previous Indication(s):

- Prevention of pregnancy for up to six years
- Treatment of heavy menstrual bleeding for women who choose to use intrauterine contraception as their method of contraception for up to five years
- b. New indication(s) approved 08/11/2021:
 - Prevention of pregnancy for up to seven years
- c. RECOMMENDATION: Inform prescribers via Medical Policy Alert.

23. XARELTO® (rivaroxaban)

- a. Previous Indication(s):
 - To reduce risk of stroke and systemic embolism in nonvalvular atrial fibrillation
 - for treatment of deep vein thrombosis (DVT)
 - for treatment of pulmonary embolism (PE)
 - for reduction in the risk of recurrence of DVT or PE
 - for the prophylaxis of DVT, which may lead to PE in patients undergoing knee or hip replacement surgery
 - for prophylaxis of venous thromboembolism (VTE) in acutely ill medical patients
 - to reduce the risk of major cardiovascular events in patients with chronic coronary artery disease (CAD) or peripheral artery disease (PAD)
- b. New indication(s) approved 08/23/2021:
 - To reduce the risk of major thrombotic vascular events in patients with peripheral artery disease (PAD), including patients after recent lower extremity revascularization due to symptomatic PAD
- c. RECOMMENDATION: Inform prescribers via Medical Policy Alert.

24. INVEGA HAFYERA® (paliperidone palmitate)

- a. New indication(s) approved 08/30/2021:
 - Indicated for the treatment of schizophrenia in adults after they have been adequately treated with:
 - Once-a-month paliperidone palmitate extended-release injectable suspension (e.g., Invega Sustenna) for at least four months or
 - An every three month paliperidone palmitate extended-release injectable suspension (e.g., Invega Trinza) for at least one three-month cycle
- b. RECOMMENDATION: Inform prescribers via Medical Policy Alert.

Therapies With Indication(s) Removed

25. ISTODAX® (Romidepsin)

- a. Previous Indication(s):
 - Treatment of cutaneous T-cell lymphoma (CTCL) in adult patients who have received at least one prior systemic therapy
 - Treatment of peripheral T-cell lymphoma (PTCL) in adult patients who have received at least one prior therapy

- b. New indication(s) removed 07/30/2021:
 - Treatment of peripheral T-cell lymphoma (PTCL) in adult patients who have received at least one prior therapy
- c. RECOMMENDATION: Inform prescribers via Medical Policy Alert.

Drug Safety Monitoring:

FDA Drug Safety Communications

1. **Drug Name:** Janus Kinase (JAK) Inhibitors

- **Date Posted:** 09-01-2021
- **Safety Alert Title:** FDA requires warnings about increased risk of serious heart-related events, cancer, blood clots, and death for JAK inhibitors that treat certain chronic inflammatory conditions
- **Link to more information:** <https://www.fda.gov/drugs/drug-safety-and-availability/fda-requires-warnings-about-increased-risk-serious-heart-related-events-cancer-blood-clots-and-death>
- **What safety concern is FDA announcing?**
 - Based on a completed U.S. Food and Drug Administration (FDA) review of a large, randomized safety clinical trial, we have concluded there is an increased risk of serious heart-related events such as heart attack or stroke, cancer, blood clots, and death with the arthritis and ulcerative colitis medicines Xeljanz and Xeljanz XR (tofacitinib). This trial compared Xeljanz with another type of medicine used to treat arthritis called tumor necrosis factor (TNF) blockers in patients with rheumatoid arthritis. The trial's final results also showed an increased risk of blood clots and death with the lower dose of Xeljanz. A [prior drug safety communication](#) based upon earlier results from this trial, reported an increased risk of blood clots and death only seen at the higher dose.
 - We are requiring new and updated warnings for two other arthritis medicines in the same drug class as Xeljanz, called Janus kinase (JAK) inhibitors, Olumiant (baricitinib) and Rinvoq (upadacitinib). Olumiant and Rinvoq have not been studied in trials similar to the large safety clinical trial with Xeljanz, so the risks have not been adequately evaluated. However, since they share mechanisms of action with Xeljanz, FDA considers that these medicines may have similar risks as seen in the Xeljanz safety trial.
 - Two other JAK inhibitors, Jakafi (ruxolitinib) and Inrebic (fedratinib), are not indicated for the treatment of arthritis and other inflammatory conditions and so are not a part of the updates being required to the prescribing information for Xeljanz, Xeljanz XR, Olumiant, and Rinvoq. Jakafi and Inrebic are used to treat blood disorders and require different updates to their prescribing information. If FDA becomes aware of any additional safety information or data that warrants updates to the prescribing information for these medicines, we may take further action and will alert the public.
- **What is FDA doing?**
 - We are requiring revisions to the Boxed Warning, FDA's most prominent warning, for Xeljanz/Xeljanz XR, Olumiant, and Rinvoq to include information about the risks of serious heart-related events, cancer, blood clots, and death. Recommendations for health care professionals will include consideration of the benefits and risks for the individual patient prior to initiating or continuing therapy. In addition, to ensure the benefits of these three medicines outweigh the risks in patients who receive them, we are limiting all approved uses to certain patients who have not responded or cannot tolerate

one or more TNF blockers. Changes will also be made to several sections of the prescribing information and to the patient [Medication Guide](#).

- **What should health care professionals do?**
 - Health care professionals should consider the benefits and risks for the individual patient prior to initiating or continuing therapy with Xeljanz/Xeljanz XR, Olumiant, or Rinvoq. This is particularly the case in patients who are current or past smokers, those with other cardiovascular risk factors, those who develop a malignancy, and those with a known malignancy other than a successfully treated nonmelanoma skin cancer. Reserve these medicines for patients who have had an inadequate response or intolerance to one or more TNF blockers. Counsel patients about the benefits and risks of these medicines and advise them to seek emergency medical attention if they experience signs and symptoms of a heart attack, stroke, or blood clot.
- **Health Plan Recommendation:** Notify providers via Medical Policy Alert.

Drug Recalls/Market Withdrawals

Drug Name: Ruzurgi® (amifampridine)

- **Date of Recall:** September 13, 2021
- **Reason for recall:** Exceeds Specification for Total Yeast and Mold Counts
- **Link to more information:** <https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/jacobus-pharmaceutical-company-inc-issues-voluntary-worldwide-recall-ruzurgir-amifampridine-10-mg>
- **Health Plan Recommendation:** Notify providers via Medical Policy Alert.

Drug Name: Chantix® (varenicline)

- **Date of Recall:** September 16, 2021
- **Reason for recall:** N-nitroso-varenicline above acceptable daily intake level
- **Link to more information:** <https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/pfizer-expands-voluntary-nationwide-recall-include-all-lots-chantixr-varenicline-tablets-due-n>
- **Health Plan Recommendation:** Notify providers via Medical Policy Alert. The health plan took action by mailing member and provider specific letter to advise those who may be affected by the recall.

Other Formulary Changes:

Drug Name	Action Taken	Policy Name
Butalbital/acetaminophen/ caffeine 50/300/40 mg Capsule	<p>Correction from October P&T:</p> <ul style="list-style-type: none"> • This will remain Non-Formulary for Medicare Part D and Medicaid 	<ul style="list-style-type: none"> • Medicaid: New Medications and Formulations without Established Benefit • Medicare Part D: N/A

<p>Dexlansoprazole (Dexilant)</p> <p>Rabeprazole (Aciphex Sprinkle)</p> <p>Esomeprazole strontium</p> <p>Esomeprazole (Nexium) packet</p>	<ul style="list-style-type: none"> Remove prior authorization for Medicaid; this will remain Non-formulary 	<ul style="list-style-type: none"> N/A
<p>Fidoxamicin (Dificid) 200 mg tablet</p>	<p>Step Therapy policy will be retired. Add quantity limit for Commercial and Medicaid:</p> <ul style="list-style-type: none"> Commercial: Formulary, Tier 4, Quantity Limit (20 tablet per 30 days) Medicaid: Formulary, Tier 4, Quantity Limit (20 tablet per 30 days) 	<ul style="list-style-type: none"> N/A
<p>Fidoxamicin (Dificid) 40 mg/mL suspension</p>	<p>Step Therapy policy will be retired. Add quantity limit for Commercial and Medicaid:</p> <ul style="list-style-type: none"> Commercial: Formulary, Tier 4, Quantity Limit (136 mL per 30 days) Medicaid: : Formulary, Tier 4, Quantity Limit (136 mL per 30 days) 	<ul style="list-style-type: none"> N/A
<p>Hydroxychloroquine Sulfate Tablet</p>	<p>New strength;</p> <ul style="list-style-type: none"> Commercial/Medicare Part D: Formulary, Tier 2 Medicaid: Formulary 	<ul style="list-style-type: none"> N/A
<p>Ivermectin tablet</p>	<ul style="list-style-type: none"> Add prior authorization for all lines of business to ensure not being used for COVID 	<ul style="list-style-type: none"> Ivermectin
<p>Insulin Glargine-YFGN (Semglee (YFGN)) Vial</p>	<p>New entity; interchangeable biosimilar for Lantus® that will be preferred for Commercial starting 1/1/2022</p> <ul style="list-style-type: none"> Commercial: Formulary, Tier 3 Medicaid: Non-Formulary Medicare Part D: Non-Formulary 	<ul style="list-style-type: none"> N/A
<p>Insulin Glargine-YFGN Insulin Pen and vial</p>	<p>New entity; interchangeable biosimilar for Lantus® that will be preferred for Commercial and Medicaid starting 1/1/2022</p> <ul style="list-style-type: none"> Commercial: Formulary, Tier 3 Medicaid: Formulary Medicare Part D: Non-Formulary 	<ul style="list-style-type: none"> N/A

Insulin glargine (Lantus)	<ul style="list-style-type: none"> Remove from Commercial formulary, effective 1/1/2022 	<ul style="list-style-type: none"> N/A
Paliperidone Palmitate (Invega Hafyera) Syringe	<p>New Dosing regimen and strengths (1560 mg/5 ml; 1092 mg/3.5 ml);</p> <ul style="list-style-type: none"> Commercial/Medicaid: Medical Benefit Medicare Part D: Formulary, Tier 5 	<ul style="list-style-type: none"> N/A
Lorazepam (Loreev XR) Cap ER 24h	<p>New dosage form (Cap ER 24h);</p> <ul style="list-style-type: none"> Non-Formulary for all lines of business 	<ul style="list-style-type: none"> N/A
Dihydroergotamine Mesylate (Trudhesa) Spray/Pump	<p>New strength;</p> <ul style="list-style-type: none"> Commercial/Medicaid: Non-Formulary, Quantity Limit (8 ml per 30 days) Medicare Part D: Non-Formulary 	<ul style="list-style-type: none"> 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
Nivolumab (Opdivo) Vial	<p>New strength (120mg/12ml). Line extend with Opdivo;</p> <ul style="list-style-type: none"> Medical benefit, Prior Authorization for all lines of business 	<ul style="list-style-type: none"> Injectable anti-cancer medications
Zinc sulfate/cupric sulfate/manganese sulfate/selenium (Multrys) Vial	<p>New strength (1000-60ml). Line extend with Tralement;</p> <ul style="list-style-type: none"> Non-Formulary for all lines of business 	<ul style="list-style-type: none"> N/A
Glecaprevir/Pibrentasvir (Mavyret) Pelet Pack	<p>New dosage form (Pelet Pack) and strength (50-20mg). Line extend with Mavyret;</p> <ul style="list-style-type: none"> Commercial: Formulary, Tier 5, Prior Authorization Medicaid: Non-Formulary, Prior Authorization Medicare Part D: Non-Formulary 	<ul style="list-style-type: none"> Commercial: Hepatitis C - Direct Acting Antivirals Medicaid: Hepatitis C - Direct Acting Antivirals – Medicaid Medicare Part D: N/A
Dupilumab (Dupixent) Syringe	<p>New Strength (100mg/0.67ml). Line extend with Dupixent;</p> <ul style="list-style-type: none"> Commercial: Formulary Tier 5, Prior Authorization, Quantity Limit (4 ml per 28 days) 	<ul style="list-style-type: none"> Dupixent

	<ul style="list-style-type: none"> • Medicaid: Non-Formulary, Specialty, Prior Authorization, Quantity Limit (4 ml per 28 days) • Medicare Part D Formulary Tier 5, Prior Authorization 	
Sulfacetamide sodium (Plexion NS) Shampoo	New dosage form (shampoo); Line extend with Plexion; <ul style="list-style-type: none"> • Non-Formulary for all lines of business 	<ul style="list-style-type: none"> • N/A

New Generics:

Drug Name	Action Taken	Policy Name
Enalapril maleate Solution	Correction from October P&T: <ul style="list-style-type: none"> • Commercial Standard: Change from Tier 4 to Tier 2 • Commercial Cost-Based: Change from Tier 2 to Tier 4 	<ul style="list-style-type: none"> • N/A
Nebivolol hcl 2.5, 5, 10, 20 mg Tablet	First generic (Bystolic). Line extend as generic; <ul style="list-style-type: none"> • Commercial Standard: Formulary, Tier 2, Step Therapy • Commercial Cost-Based: Formulary Tier 4, Step Therapy • Medicaid: Non-Formulary, Step Therapy • Medicare Part D: Formulary, Tier 4, Step Therapy 	<ul style="list-style-type: none"> • Bystolic Step Therapy
Difluprednate Drops	First generic (Durezol). Line extend as generic; <ul style="list-style-type: none"> • Commercial Standard: Formulary, Tier 2 • Commercial Cost-Based: Formulary Tier 4 • Medicaid: Non-Formulary • Medicare Part D: Formulary, Tier 4 	<ul style="list-style-type: none"> • N/A
Ezetimibe/rosuvastatin calcium (Rosuvastatin-ezetimibe) Tablet	Authorized Generic (Roszet). Line extend as generic; <ul style="list-style-type: none"> • Commercial/Medicaid: Non-Formulary, Prior Authorization • Medicare Part D: Non-Formulary 	<ul style="list-style-type: none"> • Commercial/Medicaid: New Medications and Formulations without Established Benefit • Medicare Part D: N/A
Azathioprine Tablet	First Generic (Azasan). Line extend as generic; <ul style="list-style-type: none"> • Non-formulary for all lines of business 	<ul style="list-style-type: none"> • N/A
Everolimus	First Generic (Afinitor); Line extend as generic: <ul style="list-style-type: none"> • Commercial: Formulary, Tier 6, Prior Authorization • Medicaid: Formulary, Prior Authorization 	<ul style="list-style-type: none"> • Oral Anti-Cancer Medications

	<ul style="list-style-type: none"> Medicare Part D: Formulary, Tier 5, Prior Authorization 	
Fenofibrate, micronized (Fenofibrate) Capsule	<ul style="list-style-type: none"> First generic (Antara). Line extend; Non-Formulary for all lines of business 	<ul style="list-style-type: none"> N/A

Clinical Policy Changes:

Policy Name	Summary of Change
Acute Hereditary Angioedema Therapy	Updated diagnostic criteria to align with recommendations from the United States Hereditary Angioedema Association (US HAEA) Medical Advisory Board Medical Advisory Board 2020 Guidelines for the Management of Hereditary Angioedema.
Acute Hereditary Angioedema Therapy - Medicare Part B	Updated diagnostic criteria to align with recommendations from the US HAEA Medical Advisory Board Medical Advisory Board 2020 Guidelines for the Management of Hereditary Angioedema.
Antifungal Agents	Covered uses have been modified from all FDA approved indications to all FDA and some medically accepted indications, as policy covers some off-label indications.
Continuous Glucose Monitors (CGMs)	CGMs have become a standard of care for patients with insulin-dependent diabetes according to the American Diabetes Association. To provide better access to these devices, the policy criteria was updated to allow coverage for patients on rapid-acting or short-acting insulin therapy. Additionally, the health plan will have the Dexcom and Freestyle Libre products as co-preferred.
Erythropoiesis Stimulating Agents (ESAs) - Medicare Part B	Changed Medicare Part B policy to specifically allow coverage for Myelodysplastic Syndromes (MDS).
Fertility and Related Medications	Criteria were updated to clarify coverage requirements for non-preferred gonadotropins.
Formulary and Quantity Limit Exceptions	A new clinical policy was created to improve transparency for how these exception requests are reviewed.
Hemlibra	Updating reauthorization coverage duration to until no lonfer eligible with the plan.
Hepatitis C - Direct Acting Antivirals	Removed prescriber restriction to improve access.
Hepatitis C - Direct Acting Antivirals – Medicaid	Criteria updated to align with the Risk Corridor Medicaid’s Fee-For-Service criteria.
Lotronex	Criteria has been modified to align with the 2021 American College of Gastroenterology (ACG) Guideline for the management irritable bowel syndrome by removing requirement for anti-spasmodic agents.
Medically Infused Therapeutic	The health plan will be moving to preferring two infliximab biosimilar products (Inflectra® and Renflexis®) over the innovator product Remicade®.

Immunomodulators (Tims) – Comm	
Medically Infused Therapeutic Immunomodulators (TIMs) - Medicare Part B	The health plan will be moving to preferring two infliximab biosimilar products (Inflectra® and Renflexis®) over the innovator product Remicade®.
Prophylactic Hereditary Angioedema Therapy	Updated diagnostic criteria to align with recommendations from the US HAEA Medical Advisory Board 2020 Guidelines for the Management of Hereditary Angioedema, extended-initial duration of approval to six months, recommend preferred agent (Takhzyro) with reauthorization criteria requiring dose de-escalation for stable patients, per the package insert.
Prophylactic Hereditary Angioedema Therapy - Medicare Part B	Updated diagnostic criteria to align with recommendations from the US HAEA Medical Advisory Board 2020 Guidelines for the Management of Hereditary Angioedema.
Proton Pump Inhibitors	Changed to step therapy program and removed requirement for specific doses of prerequisite therapy.
Reblozyl	Added requirement of a hemoglobin less than 11 g/dL for both conditions since they are indicated for anemia. Updated the MDS criteria to align with current National Comprehensive Cancer Network (NCCN) guidelines.
Rukobia, Trogarzo	Clarified Trogarzo is the only therapy on this policy that applies to Medicare part B.
Spravato	To provide better access to this medication, the prescriber restrictions were updated to include mental health nurse practitioners. In addition, other aspects of the criteria were updated to clarify the definition of treatment-resistant depression. The requirements for patients with suicidal ideation (SI) were updated to allow coverage with documentation of current SI with intent.
Therapeutic Immunomodulators – Medicaid	The health plan will be moving to preferring two infliximab biosimilar products (Inflectra® and Renflexis®) over other infliximab products.
Ultomiris	Removed age restriction for paroxysmal nocturnal hemoglobinuria to align with new FDA labelling. Removed requirement for genetic testing and prior use of plasma therapy for complement mediated hemolytic uremic syndrome. Kidney Disease - improving global outcomes (KDIGO) recommend all patients with a clinical diagnosis of atypical HUS be eligible for treatment with a complement inhibitor and genetic testing should not delay treatment. 50-70% of participants in approval trials had confirmed genetic mutation. This aligns with Soliris policy.
Viberzi	Criteria has been modified to align with the 2021 ACG Guideline for the management irritable bowel syndrome.
Xifaxan	Criteria has been modified to align with the 2021 ACG Guideline for the management irritable bowel syndrome.

Retired Policies:

- Difucid Step Therapy
- Promacta
- Doptelet, Mulpleta
- Nplate
- Tavalisse