Healthcare Services Medical & Pharmacy Policy Alerts

Number 264

November 1, 2021

This is the November 1, 2021 issue of the Providence Health Plans, Providence Health Assurance and Providence Plan Partners, Medical and Pharmacy Policy Alert to our providers. The focus of this update is to communicate to providers' new or revised Medical or Pharmacy policy changes. The Health Plan has a standard process to review all Medical & Pharmacy Policies annually. Policies will be available for review on ProvLink and via the PHP website at: https://healthplans.providence.org/providers/provider-support/medical-policy-pharmacy-policy-and-provider-information/

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

Lab Management FAQ

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

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

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

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

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

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

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

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

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

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

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

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

MEDICAL POLICY COMMITTEE

MEDICAL

Effective 1/1/2022

Back: Fusion and Decompression Procedures **MP34**	**Policy Updates:** • Clarified requirement for detailed, physical examination (which includes a neurological examination) prior to laminectomy (criteria. I.C. and III.C.) • "Facet syndrome" added to list of non-covered indications for lumbar fusion. • Removed requirement for physical exam for abnormalities suggestive of nerve root or spinal cord compression (criteria I.D. and III.D.) ○ "Radicular pain" added to list of example abnormalities suggestive of nerve root or spinal cord compression. **Codes/PA:** Prior authorization will be required for codes 62287, 62380, S2348, C2614 for Medicare LOB due to lack of explicit CMS guidance documents.
Intraoperative Monitoring (All Lines of Business Except Medicare) **MP295**	**Policy Updates** • New policy created addressing intraoperative neurophysiological monitoring (IOM). • IOM may be covered when performed as part of monitoring of nerves during various surgeries (e.g. monitoring a cranial nerve during head and/or neck surgery, monitoring of recurrent laryngeal nerve function during high-risk thyroid surgery.) • IOM may be covered when performed during various spinal surgeries (e.g. surgery with instrumentation, high-risk cervical spine surgery.) • IOM will deny as not medically necessary when performed during radiofrequency a Intraoperative Monitoring (Medicare Only)

	• MP296blation, epidural steroid injections, facet joint injections, spinal cord stimulator placement or when performed during various spine surgeries (e.g. routine decompression, surgery performed below L1/L2. **Codes/PA:** • 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
Intraoperative Monitoring (Medicare Only) **MP296**	**Policy Updates** • New policy created addressing intraoperative neurophysiological monitoring (IOM), per the following Medicare guidance documents: ○ National Coverage Determination (NCD) for Electroencephalographic Monitoring During Surgical Procedures Involving the Cerebral Vasculature (160.8) ○ Local Coverage Determination (LCD): Nerve Conduction Studies and Electromyography (L36526) ○ Local Coverage Article: Billing and Coding: Nerve Conduction Studies and Electromyography (A54992) ○ Local Coverage Determination (LCD): Intraoperative Neurophysiological Testing (L34623) ○ Local Coverage Article: Billing and Coding: Intraoperative Neurophysiological Testing (A57604) **Codes/PA:** • IOM codes (95940 and G04539) will be considered medically necessary and covered only when billed with one of the diagnosis codes listed in the Billing Guidelines Appendix, as listed in the relevant LCA.
Hysterectomy for Benign Conditions (Commercial and Individual Lines of Business) **MP286**	**Policy Updates** • New policy created addressing hysterectomies for benign conditions, including: ○ Policy does not apply to ASO, OHP and Medicare lines of business ○ Abnormal uterine bleeding ○ Adenomyosis ○ Chronic Pelvic Pain ○ CIN 2, CIN 2,3, and CIN 3 ○ Endometrial hyperplasia ○ Endometriosis ○ Pelvic Inflammatory Disease ○ Uterine Prolapse **Codes/PA:** 24 CPT codes related to hysterectomies will be configured to require prior authorization when billed with diagnosis codes for conditions listed above. These codes will not require prior authorization when billed with other diagnosis codes.

Varicose Veins (All Lines of Business Except Medicare) **MP182**	**Policy Updates** • Added criterion XX. "Endovascular embolization with a cyanoacrylate adhesive (e.g., VenaSeal™) has similar efficacy to but is more costly than standard treatments; therefore, it does not meet the definition of medical necessity and is considered not medically necessary and not covered for any indication." • Removed Criterion XXIII, which states that cyanoacrylate adhesive is investigational. **Codes/PA:** Change configuration for codes 36482 and 36483 from "investigational" denial to "not medically necessary."

Genetic and Molecular Testing (Medicare Only)
 	
MP317
	New Policy
	Summary of new policy highlights:
	• New Medicare genetic and molecular testing policy to replace the prior Medicare non-covered genetic testing panel policy.
	• The rationale for coverage/non-coverage may be detailed in a more specific policy. Those other policies are indicated when applicable. Other tests will have either the Medicare reference or overall rationale for coverage/non-coverage provided.
	  ○ Whole exome and whole genome sequencing/testing: Once this Medicare Only policy "goes live" the All LOB version of the policy will be changed to Commercial use only.
	Codes/PA: Configuration includes the following:
	• 302 codes will be in the "Prior Authorization Required" section
	  ○ 189 codes will continue with existing PA requirements
	  ○ 45 codes will have existing E/I or NMN denials removed and replaced with PA edits instead
	  ○ 66 codes are currently allowed to process without review or PA, but will have PA added.
	  ○ 2 additional codes will have PA added – one uses a diagnosis code list and the other is currently found on the PA list and the non-covered list for Medicare, so will resolve by formalizing PA.
	  ○ Noted PA additions will result in an approximate 95 new PAs per year, based on past year claim volume. Note, this volume number also includes PA changes in the policies that follow.
	• 35 codes will deny "Not medically necessary" or NMN
	  ○ 23 codes will continue current NMN denials
	  ○ 7 will be removed from the PA list and added to non-covered list
	  ○ 3 codes will be removed from E/I list and changed to NMN denial
	  ○ 2 codes are currently allowed to process without review or PA, but will have an NMN denial edit added instead.
	• 19 codes are in the policy, but will be allowed to process without review or PA.
	  ○ 18 will continue with existing No PA processes
	  ○ 1 will have PA added and changed to No PA.

Genetic Testing: Hereditary Breast and Ovarian Cancer	**Policy Updates** • Several updates to Medicare criteria, as well as clarifications. • Local coverage articles (LCAs) that don't provide "criteria" moved to "Billing Guidelines" section of the policy. • Table of various tests added to the "Policy Guidelines" section.

Genetic Testing (Medicare Only) **MP144**	• Removed any references in the "References" section that were duplicates of citations elsewhere in the policy. **Codes/PA:** Moved 5 codes from the "No PA" section of the policy to the PA policy.
Genetic Testing: Inherited Susceptibility to Colorectal Cancer (Medicare Only) **MP117**	**Policy Updates** • Several updates to Medicare criteria, as well as clarifications. • Local coverage articles (LCAs) that do not provide "criteria" moved to "Billing Guidelines" section of the policy. • Table of various tests added to the "Policy Guidelines" section. • Removed any references in the "References" section that were duplicates of citations elsewhere in the policy. **Codes/PA:** • Added CPT 0130U and 0134U to this policy, will be configured to deny "not medically necessary" for Medicare per LCAs. • Added prior authorization to CPT 0101U and CPT 81210 for Medicare. • Remove PA for CPT codes 0157U-0162U and deny "not medically necessary" for Medicare per LCAs.
Genetic Testing: Pharmacogenetic Testing (Medicare Only) **MP217**	**Policy Updates** • Added "Documentation Requirements" section. • Several updates to Medicare criteria, as well as clarifications. • Local coverage articles (LCAs) that don't provide "criteria" moved to "Billing Guidelines" section of the policy. • Removed *PDGFRß* Genetic Testing row since it can be addressed using the FDA-approved companion diagnostics references in the policy instead. • Removed *TPP1* gene testing, as this is associate with a pediatric condition, not likely to be applicable to a Medicare member. • Clarified and re-wrote how Commercial criteria may be used. • Rather than try to maintain the FDA table and also refer users to the FDA site for current information, the table has been removed. Users will only be referred to the FDA website for the most current and up-to-date information. • Tables of various tests added to the "Policy Guidelines" section. • Removed any references in the "References" section that were duplicates of citations elsewhere in the policy. **Codes/PA:** Configuration changes include the following: • Moved 26 codes from the "No Prior Authorization" required or "Not Covered" sections of the policy to the "prior authorization required" section.
Genetic Testing: Thyroid Nodules (Medicare Only) **MP40**	**Policy Updates** • Several updates to Medicare criteria, as well as clarifications. • Deleted the "Policy Guidelines" section regarding NRAS for proliferative thyroid lesions. If the user is reading the LCD as directed in the criteria section, they are already seeing this information. Thus, the Policy Guidelines" section was redundant. • Local coverage articles (LCAs) that don't provide "criteria" were moved to "Billing Guidelines" section of the policy.

	• Removed any references in the "References" section that were duplicates of citations elsewhere in the policy. **Codes/PA:** Configuration changes include the following: • Removed CPT code 81545 (termed 12/31/2020)
Non-Small Cell Lung Cancer: Molecular Testing for Targeted Therapy (Medicare Only) **MP193**	**Policy Updates** • Several updates to Medicare criteria, as well as clarifications. • Rather than try to maintain the FDA table and also refer users to the FDA site for current information, the table has been removed. Users will only be referred to the FDA website for the most current and up-to-date information. • Local coverage articles (LCAs) that don't provide "criteria" moved to "Billing Guidelines" section of the policy. • Table of various tests added to the "Policy Guidelines" section and updated test/code table in this section. • Removed any references in the "References" section that were duplicates of citations elsewhere in the policy. **Codes/PA:** Configuration changes include the following: • Some codes were re-arranged within the policy list, but no changes to the codes themselves. • Add PA to CPT 0048U and CPT 81538 for Medicare lines of business (codes currently deny "investigational.") • Add PA to CPTs 81210, 81235, 81275, 81276 PA for Medicare lines of business.

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

<u>Updates by Guideline</u>
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 October 1, 2021
Go-Live Date: Saturday, January 01, 2022, unless otherwise noted

Special Announcement: Effective January 1st 2022, the biosimilars for infliximab, Inflectra® and Renflexis®, will be the preferred infliximab products for Commercial, Medicaid, and Medicare Part B.

Table of Contents:

New Drugs and Combinations:

1. **Asparaginase Erwinia Chrysanthemi (Recombinant)-RYWN (Rylaze) Vial**
   a. **Indication**: FDA Indication: As a component of a multi-agent chemotherapeutic regimen for the treatment of acute lymphoblastic leukemia (ALL) and lymphoblastic lymphoma (LBL) in adult and pediatric patients 1 month or older who have developed hypersensitivity to E. coli-derived asparaginase.
   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: None, Erwinaze has been on short supply since 2016 and is being phased out of the U.S. market.

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

2. **Belumosudil mesylate (Rezurock) Tablet**
   a. **Indication**: For treatment of adult and pediatric patients 12 years and older with chronic graft-versus-host disease (cGVHD).
   b. **Decision**:

	Commercial	Medicaid	Medicare
Formulary Status*	Formulary	Formulary	Part D: Formulary Part B: N/A
Tier**	Tier 6 - Non-Preferred Specialty	N/A	Specialty
Affordable Care Act Eligible	No	N/A	N/A
Utilization Management Edits	Prior Authorization	Prior Authorization	Prior Authorization
Quantity Limit	1 tablet per day	1 tablet per day	1 tablet per day
* Recommendations for placement may differ between lines of business due to regulatory requirements. ** Medications will be placed on recommended tier above for the base formulary; tier placement for custom formulary(ies) will be based on designation above. For example, Commercial Tier 6 designation above means that the medication will be placed on the highest cost-sharing tier on the respective formulary(ies).			
Formulary Alternatives: Imbruvica tablet			

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

PA PROGRAM NAME	Rezurock
MEDICATION NAME	Belumosudil (Rezurock)
PA INDICATION INDICATOR	1 - All FDA-Approved Indications
OFF-LABEL USES	N/A
EXCLUSION CRITERIA	N/A
REQUIRED MEDICAL INFORMATION	Initial authorization for chronic graft-versus-host disease: indication supported by National Comprehensive Cancer Network guidelines with recommendation 2A or higher For patients established on therapy: Documentation of adequate response to the medication must be provided

	For coverage of twice daily dosing, all of the following must be met: 1. Patient is on an interacting drug and dosing is recommended per labeling 2. The interacting drug cannot be substituted with an alternative agent treating the same condition 3. The interacting drug is medically necessary to continue
AGE RESTRICTIONS	May be covered for patients 12 years of age and older
PRESCRIBER RESTRICTIONS	Must be prescribed by, or in consultation with, an oncologist or transplant specialist
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	Rezurock
MEDICATION NAME	Belumosudil (Rezurock)
PA INDICATION INDICATOR	3 - All Medically-Accepted Indications
OFF-LABEL USES	N/A
EXCLUSION CRITERIA	N/A
REQUIRED MEDICAL INFORMATION	Initial authorization for chronic graft-versus-host disease: indication supported by National Comprehensive Cancer Network guidelines with recommendation 2A or higher For coverage of twice daily dosing, all of the following must be met: 1. Patient is on an interacting drug and dosing is recommended per labeling 2. The interacting drug cannot be substituted with an alternative agent treating the same condition 3. The interacting drug is medically necessary to continue
AGE RESTRICTIONS	May be covered for patients 12 years of age and older
PRESCRIBER RESTRICTIONS	Must be prescribed by, or in consultation with, an oncologist or transplant specialist
COVERAGE DURATION	Authorization will be approved until no longer eligible with the plan.

3. **Artesunate Vial**
   a. **Indication**: For the initial treatment of severe malaria in adult and pediatric patients.
   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	N/A	N/A	N/A
Quantity Limit			
* Recommendations for placement may differ between lines of business due to regulatory requirements. ** Medications will be placed on recommended tier above for the base formulary; tier placement for custom formulary(ies) will be based on designation above. For example, Commercial Tier 6 designation above means that the medication will be placed on the highest cost-sharing tier on the respective formulary(ies).			
Formulary Alternatives: None			

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

4. **Ferric maltol (Accrufer) Capsule**
   a. **Indication**: For iron replacement in adults
   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	N/A	N/A	N/A
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: OTC ferrous gluconate tablet and ferrous sulfate liquid/tablets or IV iron dextran, iron sucrose			

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

5. **Pegcetacoplan (Empaveli) Vial**
   a. **Indication**: For the treatment of adult patients with paroxysmal nocturnal hemoglobinuria (PNH).
   b. **Decision**:

	Commercial	Medicaid	Medicare
Formulary Status*	Medical	Medical	Part D: N/A Part B: Medical
Tier**	N/A	N/A	N/A

Affordable Care Act Eligible	No	N/A	N/A
Utilization Management Edits	Prior Authorization	Prior Authorization	Prior Authorization
Quantity Limit	160 mL/28 day supply	160 mL/ 28 day supply	160 mL/28 day supply
* 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: Soliris®, Ultomiris® (both medical benefit medications)			

c. **Prior Authorization Criteria**:

PA PROGRAM NAME	Empaveli
MEDICATION NAME	Pegetacoplan subcutaneous injection
PA INDICATION INDICATOR	1 - All FDA-Approved Indications
OFF-LABEL USES	N/A
EXCLUSION CRITERIA	Concurrent therapy with another FDA-approved product for PNH (i.e. Soliris®, Ultomiris®) unless the member is in a four-week period of cross-titration between Soliris and Empaveli
REQUIRED MEDICAL INFORMATION	Paroxysmal Nocturnal Hemoglobinuria (PNH): For initial authorization, all of the following must be met: 1. Documented, 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 glychophosphatidylinositol (GPI)-linked proteins (which may include CD59, CD55, CD14, CD15, CD16, CD24, CD45, and CD64) 2. Severe disease as defined by at least one of the following (a or b): a. Documented history of thrombosis, OR b. Documentation of at least 10% PNH type III red cells AND at least one of the following: 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 Reauthorization: 1. Documentation of reduced LDH levels, reduced transfusion requirements, or improvement in PNH related symptoms

AGE RESTRICTIONS	18 years of age and older
PRESCRIBER RESTRICTIONS	Must be prescribed by, or in consultation with, a hematologist/oncologist or nephrologist
COVERAGE DURATION	Initial approval for up to three months and reauthorization will be approved for up to one year.

6. **Ibrexafungerp citrate (Brexafemme) Tablet**
   a. **Indication**: For the treatment of adult and post-menarchal pediatric females with vulvovaginal candidiasis (VVC)
   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	N/A	N/A	N/A
Quantity Limit			
* Recommendations for placement may differ between lines of business due to regulatory requirements. ** Medications will be placed on recommended tier above for the base formulary; tier placement for custom formulary(ies) will be based on designation above. For example, Commercial Tier 6 designation above means that the medication will be placed on the highest cost-sharing tier on the respective formulary(ies).			
Formulary Alternatives: Fluconazole, terconazole, miconazole			

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

7. **Serdexmethylphenidate chloride-dexmethylphenidate hcl (Azstarys) Capsule**
   a. **Indication**: For the treatment of Attention Deficit Hyperactivity Disorder (ADHD).
   b. **Decision**:

	Commercial	Medicaid	Medicare
Formulary Status*	Non-formulary	Non-formulary	Part D: Non-formulary Part B: N/A
Tier**	N/A	N/A	N/A
Affordable Care Act Eligible	N/A; Non-Formulary	N/A	N/A
Utilization Management Edits	N/A	Prior Authorization	N/A
Quantity Limit	1 capsule per day	1 capsule per day	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: methylphenidate immediate-release tablet/chewable tablet/solution, methylphenidate extended-release (Concerta, Metadate CD), dexmethylphenidate extended-release (Focalin XR)

c. **Prior Authorization Criteria for Medicaid**: Added to Long-Acting Stimulant Medications Policy

8. **Anifrolumab-FNIA (Saphnelo) vial**
   a. **Indication**: For the treatment of adult patients with moderate to severe systemic lupus erythematosus (SLE), who are receiving standard therapy.
   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: belimumab (Benylsta®), azatbioprine, methotrexate, mycophenolate mofetil, hydroxychloroquine, chloroquine, cyclophosphamide			

   c. **Prior Authorization Criteria**:

PA PROGRAM NAME	Saphnelo®
MEDICATION NAME	Saphnelo® 300mg/2ml vial
PA INDICATION INDICATOR	1 - All FDA-Approved Indications
OFF-LABEL USES	N/A
EXCLUSION CRITERIA	Anifrolumab-fnia will not be approved if any of the following are present: 1. Severe active lupus nephritis 2. Severe active central nervous system lupus 3. Current use of other biologic immunomodulators 4. Concurrent use of Lupkynis® and Benlysta®

New

REQUIRED MEDICAL INFORMATION	All of the following must be met: 1. Documented diagnosis of Systemic Lupus Erythematosus (SLE) by a rheumatologist AND 2. Documentation of laboratory test results indicating that patient has presence of auto-antibodies, defined as one of the following: a. Positive Antinuclear antibody (ANA) b. Positive anti-double-stranded DNA (anti-dsDNA) on two or more occasions, OR if tested by ELISA, an antibody level above laboratory reference range c. Positive anti-Smith (Anti-Sm) d. Positive anti-RO/SSA and anti-La.SSB antibodies AND 3. Documented failure of an adequate trial (such as inadequate control with ongoing disease activity and/or frequent flares), contraindication, or intolerance to at least one of the following: a. Oral corticosteroids b. Azathioprine c. Methotrexate d. Mycophenolate mofetil e. Hydroxychloroquine f. Chloroquine g. Cyclophosphamide 4. Documentation that patient will continue to receive standard therapy (e.g., corticosteroids, hydroxychloroquine, mycophenolate, azathioprine, methotrexate) Reauthorization: 1. Documentation of positive clinical response to anifrolumab- (e.g. improvement in functional impairment, decrease of corticosteroid dose, decrease in pain medication, decrease in number of exacerbations since prior to start of anifrolumab) 2. Patient is currently receiving standard therapy for SLE
AGE RESTRICTIONS	Age 18 years and older
PRESCRIBER RESTRICTIONS	Must be prescribed by or in consultation with rheumatologist
COVERAGE DURATION	Initial authorization will be approved for six months. Reauthorization will be approved for 12 months

Indications:

Therapies with Prior Authorization Policies (Non-oncology)

A. **TRIKAFTA® (**Elexacaftor, tezacaftor, ivacaftor)
   a. Previous Indication(s):
      i. Indicated for the treatment of cystic fibrosis (CF) in patients aged 12 years and older who have at least one F508del mutation in the CFTR gene or a mutation in the CFTR gene that is responsive based on in vitro data. If the patient's genotype is unknown,

an FDA-cleared CF mutation test should be used to confirm the presence of at least one F508del mutation or a mutation that is responsive based on in vitro data

b. New indication approved 06/08/2021:
   i. Indicated for the treatment of cystic fibrosis (CF) in patients aged six years and older who have at least one F508del mutation in the CFTR gene or a mutation in the CFTR gene that is responsive based on in vitro data. If the patient's genotype is unknown, an FDA-cleared CF mutation test should be used to confirm the presence of at least one F508del mutation or a mutation that is responsive based on in vitro data
c. **RECOMMENDATION:** Inform prescribers via Medical Policy Alert and update prior authorization criteria for Commercial and Medicaid as outlined below. No updates to criteria warranted for Medicare Part D.
   Prior Authorization for Commercial/Medicaid

PA PROGRAM NAME	CFTR Modulators
MEDICATION NAME	Trikafta
COVERED USES	1 - All FDA-Approved Indications
EXCLUSION CRITERIA	N/A
REQUIRED MEDICAL INFORMATION	For ivacaftor (Kalydeco®): Diagnosis of cystic fibrosis with documentation of at least one copy of a cystic fibrosis transmembrane regulator (CFTR) gene mutation that is responsive to ivacaftor (See Appendix 1 and/ or package insert) For lumacaftor-ivacaftor (Orkambi®): Diagnosis of cystic fibrosis with documentation of homozygous F508del mutation in the CFTR gene For tezacaftor-ivacaftor (Symdeko™): Diagnosis of cystic fibrosis with documentation of homozygous F508del mutation in the CFTR gene or a mutation in the CFTR gene that is responsive to tezacaftor-ivacaftor based on clinical evidence and/or in vitro data (See Appendix 2 and/ or package insert) For elexacaftor- tezacaftor-ivacaftor (Trikafta™): Diagnosis of cystic fibrosis with documentation of at least one F508del mutation in the CFTR gene or a mutation in the CFTR gene that is responsive to elexacaftor- tezacaftor-ivacaftor based on in vitro data (See Appendix 3 and/or package insert) **Reauthorization:** Documented response to therapy as defined as one of the following: a. A lack of decline in lung function as measured by the FEV1 when the patient is clinically stable

	b. A reduction in the incidence of pulmonary exacerbations c. Reduced respiratory symptoms (e.g., persistent productive cough, wheezing, shortness of breath) d. A significant improvement in BMI by 10% from baseline
AGE RESTRICTIONS	For elexacaftor- tezacaftor-ivacaftor (Trikafta™): six years or older
PRESCRIBER RESTRICTIONS	Must be prescribed by or in consultation with a pulmonologist or provider at a Cystic Fibrosis Center.
COVERAGE DURATION	Authorization will be approved until no longer eligible with the plan, subject to formulary or benefit changes

B. **EPCLUSA® (**Sofosbuvir and velpatasvir)
   a. Previous Indication(s):
      i. EPCLUSA is a fixed-dose combination of sofosbuvir, a hepatitis C virus (HCV) nucleotide analog NS5B polymerase inhibitor, and velpatasvir, an HCV NS5A inhibitor, and is indicated for the treatment of adult and pediatric patients six years of age and older or weighing at least 17 kg with chronic HCV genotype 1, 2, 3, 4, 5, or 6 infection (1):
         1. without cirrhosis or with compensated cirrhosis
         2. with decompensated cirrhosis for use in combination with ribavirin
   b. New indication approved 06/10/2021:
      i. EPCLUSA is a fixed-dose combination of sofosbuvir, a hepatitis C virus (HCV) nucleotide analog NS5B polymerase inhibitor, and velpatasvir, an HCV NS5A inhibitor, and is indicated for the treatment of adults and pediatric patients three years of age and older with chronic HCV genotype 1, 2, 3, 4, 5, or 6 infection (1):
         1. without cirrhosis or with compensated cirrhosis
         2. with decompensated cirrhosis for use in combination with ribavirin
   c. **RECOMMENDATION:** Inform prescribers via Medical Policy Alert. No updates to criteria warranted.

C. **MAVYRET® (**Glecaprevir and pibrentasvir)
   a. Previous Indication(s):
      i. MAVYRET is a fixed-dose combination of glecaprevir, a hepatitis C virus (HCV) NS3/4A protease inhibitor, and pibrentasvir, an HCV NS5A inhibitor, and is indicated for the treatment of adult and pediatric patients 12 years and older or weighing at least 45 kg with chronic HCV genotype (GT) 1, 2, 3, 4, 5 or 6 infection without cirrhosis or with compensated cirrhosis (Child-Pugh A).
      ii. MAVYRET is indicated for the treatment of adult and pediatric patients 12 years and older or weighing at least 45 kg with HCV genotype 1 infection, who previously have been treated with a regimen containing an HCV NS5A inhibitor or an NS3/4A protease inhibitor, but not both.
   b. New indication approved 06/10/2021:

i. MAVYRET is a fixed-dose combination of glecaprevir, a hepatitis C virus (HCV) NS3/4A protease inhibitor, and pibrentasvir, an HCV NS5A inhibitor, and is indicated for the treatment of adult and pediatric patients three years and older with chronic HCV genotype (GT) 1, 2, 3, 4, 5 or 6 infection without cirrhosis or with compensated cirrhosis (Child-Pugh A).
ii. MAVYRET is indicated for the treatment of adult and pediatric patients three years and older with HCV genotype 1 infection, who previously have been treated with a regimen containing an HCV NS5A inhibitor or an NS3/4A protease inhibitor, but not both

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

D. **TOVIAZ®** **(**Fesoterodine fumarate)
a. Previous Indication(s):
i. Indicated for the treatment of overactive bladder with symptoms of urge urinary incontinence, urgency, and frequency
b. New indication approved MM/DD/YYYY:
i. Indicated for the treatment of overactive bladder (OAB) in adults with symptoms of urge urinary incontinence, urgency, and frequency.
ii. Indicated for the treatment of neurogenic detrusor overactivity (NDO) in pediatric patients 6 years of age and older and weighing greater than 25 kg.
c. **RECOMMENDATION:** Inform prescribers via Medical Policy Alert and update prior authorization criteria for Commercial and Medicaid as outlined below.

Prior Authorization for Commercial/Medicaid:

PA PROGRAM NAME	Overactive Bladder Medications
MEDICATION NAME	Toviaz
COVERED USES	3 - All Medically-Accepted Indications
EXCLUSION CRITERIA	N/A
REQUIRED MEDICAL INFORMATION	Trial, intolerance, or contraindication to: 1. One of the following: oxybutynin or tolterodine, AND 2. Solifenacin OR For Myrbetriq: Treatment of neurogenic detrusor overactivity (NDO) in pediatric patients three years and older and weighing 35 kilograms or more For Toviaz: Treatment of neurogenic detrusor overactivity (NDO) in pediatric patients six years and older and weighing 25 kilograms or more Note: Contraindications to anticholinergic agents include delirium, dementia/cognitive impairment, preexisting issue with chronic constipation, urinary retention, gastric retention, or uncontrolled narrow-angle glaucoma.
AGE RESTRICTIONS	N/A

PRESCRIBER RESTRICTIONS	N/A
COVERAGE DURATION	Authorization will be approved until no longer eligible with the plan, subject to formulary or benefit changes

E. **NOXAFIL**® **(**Posaconazole)
   a. Previous Indication(s):
      i. Noxafil is indicated for the prophylaxis of invasive Aspergillus and Candida infections in patients who are at high risk of developing these infections due to being severely immunocompromised, such as hematopoietic stem cell transplant (HSCT) recipients with graftversus-host disease (GVHD) or those with hematologic malignancies with prolonged neutropenia from chemotherapy as follows:
         1. Noxafil injection: adults and pediatric patients 2 years of age and older
         2. Noxafil delayed-release tablets: adults and pediatric patients 2 years of age and older who weigh greater than 40 kg
         3. Noxafil oral suspension: adults and pediatric patients 13 years of age and older
         4. Noxafil PowderMix for delayed-release oral suspension: pediatric patients 2 years of age and older (who weigh 40 kg or less)
      ii. Oral suspension: treatment of oropharyngeal candidiasis (OPC), including OPC refractory (rOPC) to itraconazole and/or fluconazole in adult and pediatric patients ages 13 years and older
   b. New indication approved 06/17/2021:
      i. Noxafil injection and Noxafil delayed-release tablets are indicated for the treatment of invasive aspergillosis in adults and pediatric patients 13 years of age and older
   c. **RECOMMENDATION:** Inform prescribers via Medical Policy Alert. No updates to criteria warranted.

F. **BYDUREON**® **(**Exenatide extended-release)
   a. Previous Indication(s):
      i. Indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus
   b. New indication approved 07/22/2021:
      i. Indicated as an adjunct to diet and exercise to improve glycemic control in adults and pediatric patients aged 10 years and older with type 2 diabetes mellitus
   c. **RECOMMENDATION:** Inform prescribers via Medical Policy Alert. No updates to criteria warranted.

G. **DRIZALMA SPRINKLE**® **(**Duloxetine delayed-release capsule)
   a. Previous Indication(s):
      i. Major Depressive Disorder (MDD) in adults
      ii. Generalized Anxiety Disorder (GAD) in adults and pediatric patients ages 7 years to 17 years old
      iii. Diabetic Peripheral Neuropathic Pain (DPNP) in adults
      iv. Chronic Musculoskeletal Pain in adults
   b. New indication approved MM/DD/YYYY:
      i. Generalized Anxiety Disorder (GAD) in adults and pediatric patients ages 7 years of age and older

ii. Fibromyalgia (FM) in adults

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

H. **VYVANSE**® **(**Lisdexamfetamine dimesylate)
   a. Previous Indication(s):
      i. Attention Deficit Hyperactivity Disorder (ADHD)
      ii. Moderate to Severe Binge Eating Disorder (BED) in adults
   b. New indication approved 07/29/2021:
      i. Attention Deficit Hyperactivity Disorder (ADHD) in adults and pediatric patients 6 years and older
   c. **RECOMMENDATION:** Inform prescribers via Medical Policy Alert. No updates to criteria warranted.

<u>Therapies with Prior Authorization Policies (Oncology)</u>

I. **AYVAKIT**® **(**Avapritinib)
   a. New indication(s) approved 06/16/2021:
      i. Gastrointestinal stromal tumor (GIST)
         1. the treatment of adults with unresectable or metastatic GIST harboring a platelet-derived growth factor receptor alpha (PDGFRA) exon 18 mutation, including PDGFRA D842V mutations.
      ii. Advanced Systemic Mastocytosis (AdvSM)
         1. the treatment of adult patients with AdvSM. AdvSM includes patients with aggressive systemic mastocytosis (ASM), systemic mastocytosis with an associated hematological neoplasm (SMAHN), and mast cell leukemia (MCL).
         2. Limitations of Use: AYVAKIT is not recommended for the treatment of patients with AdvSM with platelet counts of less than 50 X 109 /L (1.2)
   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.

J. **LENVIMA**® **(**Lenvatinib)
   a. New indication(s) approved 07/21/2021:
      i. For the treatment of patients with locally recurrent or metastatic, progressive, radioactive iodine-refractory differentiated thyroid cancer (DTC)
      ii. In combination with everolimus, for the treatment of patients with advanced renal cell carcinoma (RCC) following one prior antiangiogenic therapy
      iii. For the first-line treatment of patients with unresectable hepatocellular carcinoma (HCC)
      iv. 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. **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

K. **Morphine Sulfate**
   a. Previous Indication(s):
      i. Indicated for the management of acute and chronic pain severe enough to require an opioid analgesic and for which alternative treatments are inadequate
   b. New indication(s) approved 06/02/21:
      i. Morphine sulfate 2mg/mL and 4mg/mL:
         1. Indicated for adults with acute and chronic pain severe enough to require and opioid analgesic and for which alternative treatments are inadequate
         2. Pediatric patients 2 years of age and older with acute pain severe enough to require an opioid analgesic and for which alternative treatments are inadequate
      ii. Morphine sulfate 20mg/ml:
         1. Indicated for the relief of acute and chronic pain in opioid-tolerant adult patients
   c. **RECOMMENDATION:** Inform prescribers via Medical Policy Alert. We will continue to monitor utilization of medication and add to pediatric analgesic policy as needed.

L. **PRADAXA**® **(**Dabigatran etexilate)
   a. Previous Indication(s):
      i. To reduce the risk of stroke and systemic embolism in patients with non-valvular atrial fibrillation
      ii. For the treatment of deep venous thrombosis (DVT) and pulmonary embolism (PE) in patients who have been treated with a parenteral anticoagulant for 5-10 days
      iii. To reduce the risk of recurrence of DVT and PE in patients who have been previously treated
      iv. For the prophylaxis of DVT and PE in patients who have undergone hip replacement surgery
   b. New indication(s) approved 06/21/2021:
      i. For the treatment of venous thromboembolic events (VTE) in pediatric patients 8 to less than 18 years of age who have been treated with a parenteral anticoagulant for at least 5 days
      ii. To reduce the risk of recurrence of VTE in pediatric patients 8 to less than 18 years of age who have been previously treated
   c. **RECOMMENDATION:** Inform prescribers via Medical Policy Alert.

M. **BRIDION**® **(**Sugammadex)
   a. Previous Indication(s):
      i. Indicated for the reversal of neuromuscular blockade induced by rocuronium bromide and vecuronium bromide in adults undergoing surgery.

b. New indication(s) approved 06/25/2021:
    i. Indicated for the reversal of neuromuscular blockade induced by rocuronium bromide and vecuronium bromide in adults and pediatric patients aged 2 years and older undergoing surgery.
c. **RECOMMENDATION:** Inform prescribers via Medical Policy Alert.

N. **SOLOSEC® (**Secbudazole)
a. Previous Indication(s):
    i. Indicated for the treatment of bacterial vaginosis in adult women.
b. New indication(s) approved 06/30/2021:
    i. indicated for treatment of trichomoniasis in adults.
c. **RECOMMENDATION:** Inform prescribers via Medical Policy Alert.

O. **ARMONAIR RESPICLICK/DIGIHALER® (**Fluticasone propionate)
a. Previous Indication(s):
    i. Indicated for the maintenance treatment of asthma as prophylactic therapy in patients 12 years of age and older
b. New indication(s) approved 07/09/2021:
    i. Indicated for the maintenance treatment of asthma as prophylactic therapy in adult and pediatric patients 4 years of age and older
c. **RECOMMENDATION:** Inform prescribers via Medical Policy Alert.

P. **AIRDUO RESPICLICK/DIGIHALER® (**Fluticasone propionate)
a. Previous Indication(s):
    i. Indicated for treatment of asthma in patients aged 12 years and older
b. New indication(s) approved 07/09/2021:
    i. Indicated for treatment of asthma in adult and pediatric patients aged 12 years and older
c. **RECOMMENDATION:** Inform prescribers via Medical Policy Alert.

Q. **PROGRAF® (**Tacrolimus)
a. Previous Indication(s):
    i. Indicated for the prophylaxis of organ rejection in adult and pediatric patients receiving allogeneic liver, kidney or heart transplants, in combination with other immunosuppressants
b. New indication(s) approved 07/16/2021:
    i. Indicated for the prophylaxis of organ rejection in adult and pediatric patients receiving allogeneic liver, kidney, heart, or lung transplants, in combination with other immunosuppressants
c. **RECOMMENDATION:** Inform prescribers via Medical Policy Alert.

R. **Oxycodone hydrochloride**

a. Previous Indication(s):
    i. Indicated for the management of pain severe enough to require an opioid analgesic and for which alternative treatments are inadequate
b. New indication(s) approved 07/21/2021:
    i. Immediate-release 5mg capsule/oral solution 5mg/5ml: Indicated in adults for the management of pain severe enough to require an opioid analgesic and for which alternative treatments are inadequate
    ii. Oral solution100mg/5ml: indicated for the relief of pain in opioid-tolerant adults
c. **RECOMMENDATION:** Inform prescribers via Medical Policy Alert. Providers should assess risk vs benefit when prescribing these medications outside of FDA indicated age range. See Appendix for SBAR related to this change in indication

S. **DALVANCE®** (Dalbavancin)
a. Previous Indication(s):
    i. Indicated for acute bacterial skin and skin structure infections (ABSSSI) caused by designated susceptible strains of Gram-positive microorganisms
b. New indication(s) approved 07/22/2021:
    i. Indicated for the treatment of adult and pediatric patients with acute bacterial skin and skin structure infections (ABSSSI) caused by designated susceptible strains of Grampositive microorganisms
c. **RECOMMENDATION:** Inform prescribers via Medical Policy Alert.

T. **ARCALYST®** (Rilonacept)
a. Previous Indication:
    i. Treatment of Cryopyrin-Associated Periodic Syndromes (CAPS), including Familial Cold Auto-inflammatory Syndrome (FCAS) and Muckle-Wells Syndrome (MWS) in adults and children 12 and older
    ii. Maintenance of remission of Deficiency of Interleukin-1 Receptor Antagonist (DIRA) in adults and pediatric patients weighing at least 10 kg
b. New indication approved 03/18/2021:
    i. Treatment of recurrent pericarditis (RP) and reduction in risk of recurrence in adults and children 12 years and older
c. **RECOMMENDATION:** Criteria for Commercial, Medicare Part B, and Medicaid were reviewed at June 2021 ORPTC. Criteria for Medicare Part D prior authorization policy will be updated as followed:

PA PROGRAM NAME	Arcalyst
MEDICATION NAME	Arcalyst
PA INDICATION INDICATOR	1 - All FDA-Approved Indications
EXCLUSION CRITERIA	N/A
REQUIRED MEDICAL INFORMATION	For Cryopyrin-Associated Periodic Syndrome (CAPS) including Familial Cold Autoinflammatory Syndrome (FCAS) and Muckle-Wells Syndrome (MWS): Diagnosis confirmed by: 1. Laboratory evidence of genetic mutation NLRP-3 (Nucleotide-binding domain, leucine rich family pyrin domain containing 3) or CIAS1 (Cold-induced auto-

	inflammatory syndrome-1), AND 2. Classic symptoms associated with FCAS or MWS (e.g., recurrent intermittent fever and rash typically associated with natural or artificial cold). For Deficiency of Interleukin-1 Receptor Antagonist (DIRA): 1. Confirmed by laboratory evidence of genetic mutation in IL1RN (encodes for interleukin-1 receptor antagonist) 2. Current inflammatory remission of DIRA 3. Weight of at least 10 kg. For recurrent pericarditis: 1. Diagnosis of recurrent pericarditis (RP) confirmed by an acute episode of pericarditis followed by a 4-6 week symptom free period prior to the next episode without an identified cause 2. Documentation trial and failure, contraindication or intolerance to NSAIDs or glucocorticoids. Reauthorization: Documentation submitted of improvement of symptoms (such as fever, urticaria-like rash, arthralgia, myalgia, fatigue, and conjunctivitis for CAPS)
AGE RESTRICTIONS	For CAPS (which includes FCAS, MWS) and RP: Approved for patients 12 years of age and older
PRESCRIBER RESTRICTIONS	N/A
COVERAGE DURATION	Initial authorization will be approved for six months. Reauthorization will be approved for one year.

Therapies with Indication(s) Removed

U. **ISTODAX**® **(**Romidepsin)
   a. Previous Indication(s):
      i. Treatment of cutaneous T-cell lymphoma (CTCL) in adult patients who have received at least one prior systemic therapy
      ii. Treatment of peripheral T-cell lymphoma (PTCL) in adult patients who have received at least one prior therapy
   b. Indication(s) removed 07/30/2021:
      i. 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.

Appendix

SBAR – Oxycodone and Morphine New Indication

S	**Situation:** The FDA has updated the indications for morphine sulfate and oxycodone on 6/2/21 and 7/21/21. Morphine oral solution 2mg/ml and 4mg/ml now includes patients 2 years and older while 20mg/ml i now only indicated for adult patients. Oxycodone immediate release 5mg capsule and 5mg/5ml oral solution is now indicated for adults and 100mg/5ml is indicated for opioid-tolerant adults. These products are on formulary and do not require a PA. Providence Health Plan has quantity limit edits in place for all opioids (MME dose and 7-day first fill limit), however, these do not currently address age limits. Therefore, further exploration is needed to determine if additional edits or restrictions should be put in place.

B	**Background:** Currently PHP policy, has several opioid safety edits in place: • 7-day supply initial fill for acute pain in opioid naïve patients – hard reject for all lines of business • Cumulative opioid dose ≥ 90MME per day – soft care coordination reject for Medicare • Cumulative opioid dose ≥ 90MME per day – hard reject for commercial, and OHP • Cumulative opioid dose ≥ 200 MME per day (without prescriber/pharmacy counts) – hard reject for Medicare • Concurrent use of opioids and buprenorphine – soft reject for all lines of business • Concurrent use of opioids and benzodiazepines – soft reject for all lines of business • Duplicative long-acting opioid therapy – soft reject for all lines of business - soft care coordination reject = dispensing pharmacist must coordinate with prescriber to ensure therapy is medically appropriate - hard reject = requires prior authorization - soft reject = point of sale edit, requires intervention from dispensing pharmacist to determine if therapy is medically appropriate and to educate patient on risk of taking these medications together Quantity limits in place (applicable line of business) • Morphine 2mg/ml – 60ml/1 day (Commercial) • Morphine 4mg/ml – 30ml/1 day (Commercial) • Morphine 20mg/ml – none • Oxycodone 5mg capsule – 10 capsule/1 day (Commercial) • Oxycodone 5mg/5ml oral solution – none • Oxycodone 20mg/ml – none In addition, there is also a pediatric analgesic policy in place for codeine and tramadol due to the risk of respiratory depression and death. Required medical information includes trial, failure, or contraindication to over-the-counter alternatives such as acetaminophen and ibuprofen as well as a statement that the risk of use of codeine or tramadol for pediatric patients has been reviewed. The FDA drug safety communication is as follows: "The FDA is restricting the use of codeine and tramadol medicines in children. These medicine carry serious risks, including slowed or difficult breathing and death, which appear to be a greater risk in children younger than 12 years, and should not be used in these children" VistaPharm Inc. completed a phase IV study to evaluate the safety and pharmacokinetics of single-dose of oxycodone oral solution in patients 2 years to less than 17 years of age with postoperative pain. The results are unpublished, however, according to the package insert, conclusions were not possible because of insufficient evidence. According to an expert panel opinion released on November 11, 2020, there is no single opioid that is recommended for pediatric pain management. Rather, the article emphasized optimizing perioperative non-opioid regimens such as utilizing enteral and intravenous non-opioid analgesics. Another point of emphasis was patient and family education regarding expectations and methods of pain management, as well as how to safely store and properly dispose of unused opioid medications. In addition, this article also provided a table where opioid-free

	recovery is recommended and when it is possible. For example, otolaryngology procedures such as tonsillectomy/adenoidectomy and cochlear implant are procedures where opioid-free recovery is possible. According to the FDA's presentation on Development of Opioids in Pediatric Patients, most analgesic use in pediatric patients is off-label. Although pediatric studies have been required by law since 2003, few analgesic studies have been completed. In an article published by the World Health Organization for pharmacological treatment of persisting pain in children with medical illness, morphine is recommended as the first-line strong opioid for the treatment of moderate to severe pain.
A	**Assessment:** In evaluating utilization of morphine from 2020 to 2021, the number of pediatric members under the age of 2 utilizing the medication is as follows: • 2mg/ml: 1 member (~2% of all utilization) • 4mg/ml: 2 members (~15% of all utilization) No utilization of morphine sulfate solution 20mg/ml were found for members under 18 years of age. In evaluating utilization of oxycodone from 2020 to 2021, the number of members under the age of 18 utilizing the medication is as follows: • 5mg IR capsule: 1 member (< 1% of all utilization) • 5mg/5ml oral solution: 595 members (~54% of all utilization) It is important to note that the safety and effectiveness of oxycodone have not been established in pediatric patients despite being commonly used. Considering the utilization of the liquid formulation by pediatric and adolescents, implementing utilization edits will create unnecessary burden and delays to care. A quick review of provider breakdown showed that the highest type of specialty that prescribes oxycodone 5mg/5ml solution is otolaryngology (~42% of total prescriptions) followed by urology (~21% of total prescriptions). In addition, most prescriptions were authorized for short-term use. Optimal pain management may compromise the use of non-opioid analgesics, opioid analgesics, adjuvants, and non-pharmacological strategies. Pharmacological pain management should optimize non-opioid analgesics first, such as using around-the-clock acetaminophen and ibuprofen. Caregivers and children should receive adequate education regarding expectations of pain management and include instructions regarding storage and proper disposal of opioids. An emphasis will be placed to monitor any safety and efficacy data and consider edits in the future as necessary. In addition, there is a potential to see if certain prescriber groups can benefit from provider education compared to implementing another opioid safety edit.

R	**Recommendation:** Providers should assess risk vs benefit when prescribing these medications outside of FDA indicated age range. Morphine sulfate oral solution 2mg/ml, 4mg/ml, 20mg/ml: • No changes due to low utilization Oxycodone IR 5mg capsule/oral solution: • No changes to avoid creating unnecessary burden and delays for acute pain • Continue to closely monitor safety/efficacy data • Future consideration: include oxycodone in pediatric analgesic policy • Plan for targeted provider education for those with high prescribing rates
References	1. Morphine sulfate [package insert]. Berkeley Heights, NJ: Hikma Pharmaceuticals USA Inc.; 2021 2. Oxycodone hydrochloride oral solution [package insert]. Largo, FL: VistaPharm Inc.; 2021 3. Oxycodone hydrochloride oral solution [package insert]. Allentown, PA: Genus Lifescienes Inc.; 2021 4. Oxycodone hydrochloride capsule [package insert]. Allentown, PA: Genus Lifescienes Inc.; 2021 5. ClinicalTrials.gov [Internet]. Bethesda (MD): National Library of Medicine (US). 2000 Feb 29 -. Identifier NCT01959204, Evaluate the Pharmacokinetics and Safety of Oxycodone Oral Solution in Pediatric and Adolescent Subjects 6. Kelley-Quon LI, Kirkpatrick MG, Ricca RL, et al. Guidelines for opioid prescribing in children and adolescents after surgery: an expert panel opinion. *JAMA Surg*. 2021;156(1):76-90. doi:10.1001/jamasurg.2020.5045 7. Food and Drug Administration. Development of Opioids in Pediatric Patients: Conclusions from FDA's September 15-16, 2016 Joint Meeting of the Anesthetic Analgesic and Drug Products Advisory Committee (AADPAC), Drug Safety and Risk Management Advisory Committee (DSaRM), and Pediatric Advisory Committee (PAC), and the Latest Agency Thinking on Studying Opioids in Children. Available from: https://www.fda.gov/media/107946/download 8. WHO Guidelines on the Pharmacological Treatment of Persisting Pain in Children with Medical Illnesses. Geneva: World Health Organization; 2012.

Drug Safety Monitoring:

1. **Drug Name: HMG-CoA Reductase Inhibitors (Statins)**
   - **Date Posted: 07-20-2021**
   - **Safety Alert Title:** FDA requests removal of strongest warning against using cholesterol-lowering statins during pregnancy; still advises most pregnant patients should stop taking statins
   - **Link to more information:** https://www.fda.gov/drugs/drug-safety-and-availability/fda-requests-removal-strongest-warning-against-using-cholesterol-lowering-statins-during-pregnancy
   - **What safety concern is FDA announcing?**
     - The U.S. Food and Drug Administration (FDA) is requesting removal of its strongest warning against using cholesterol-lowering statin medicines in pregnant patients. Despite the change, most patients should stop statins once they learn they are pregnant. We have conducted a comprehensive review of all available data and are requesting that statin manufacturers make this

change to the prescribing information as part of FDA's ongoing effort to update the pregnancy and breastfeeding information for all prescription medicines.
    - Patients should not breastfeed when taking a statin because the medicine may pass into breast milk and pose a risk to the baby. Many can stop statins temporarily until breastfeeding ends. However, patients requiring ongoing statin treatment should not breastfeed and instead use infant formula or other alternatives.
- **What is FDA doing?**
    - We are requesting revisions to the information about use in pregnancy in the prescribing information of the entire class of statin medicines. These changes include removing the contraindication against using these medicines in all pregnant patients. A contraindication is FDA's strongest warning and is only added when a medicine should not be used because the risk clearly outweighs any possible benefit. Because the benefits of statins may include prevention of serious or potentially fatal events in a small group of very high-risk pregnant patients, contraindicating these drugs in all pregnant women is not appropriate.
    - FDA expects removing the contraindication will enable health care professionals and patients to make individual decisions about benefit and risk, especially for those at very high risk of heart attack or stroke. This includes patients with homozygous familial hypercholesterolemia and those who have previously had a heart attack or stroke. Statins are safe to use in patients who are not pregnant but may become pregnant.
- **What should health care professionals do?**
    - Health care professionals should discontinue statin therapy in most pregnant patients, or they can consider the ongoing therapeutic needs of the individual patient, particularly those at very high risk for cardiovascular events during pregnancy. Because of the chronic nature of cardiovascular disease, treatment of hyperlipidemia is not generally necessary during pregnancy. Discuss with patients whether they may discontinue statins temporarily while breastfeeding. Advise those who require a statin because of their cardiovascular risk that breastfeeding is not recommended because the medicine may pass into breast milk.
    - We hope the revised language in the prescribing information will help reassure health care professionals that statins are safe to prescribe in patients who can become pregnant, and help them reassure patients with unintended statin exposure in early pregnancy or before pregnancy is recognized that the medicine is unlikely to harm the unborn baby.
- **Health Plan Recommendation:** Notify providers via Medical Policy Alert

2. **Drug Name: Clozapine**
    - **Date Posted: 07-29-2021**
    - **Safety Alert Title:** Clozapine Risk Evaluation and Mitigation (REMS) requirements will change on November 15, 2021
    - **Link to more information:** https://www.fda.gov/drugs/drug-safety-and-availability/clozapine-risk-evaluation-and-mitigation-strategy-rems-requirements-will-change-november-15-2021
    - **Health Plan Recommendation:** Notify providers via Medical Policy Alert

Other Formulary Changes:

Drug Name	Recommendation	Policy Name

Duloxetine HCl 40 mg Capsule DR	• 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
Riluzole (Exservan) Film	New Dosage Form (Film); • Commercial: Formulary, Tier 6, Specialty • Medicaid: Formulary, Specialty • Medicare Part D: Non-Formulary	N/A
Estradiol valerate 40 mg/mLVial	Add to Commercial and Medicaid formulary; • Commercial Standard: Formulary, Tier 2 • Commercial Cost-Based: Formulary, Tier 4 • Medicaid: Formulary	N/A
Ketorolac tromethamine 0.5% Drops	Add to Medicaid formulary	N/A
Mesalamine w/cleansing wipes Enema Kit	Remove from Commercial formulary (kits are a benefit exclusion)	N/A
Relugolix/estradiol/ norethindrone acetate (Myfembree) Tablet	New combination; • Commercial/Medicaid: Non-Formulary, Prior Authorization • Medicare Part D: Non-Formulary	• Commercial/Medicaid: GNRH Antagonists • Medicare Part D: N/A
Trazodone 300 mg hcl tablet	Remove from Commercial formulary	N/A
Clobetasol propionate Spray	Add to Commercial/Medicaid formularies; • Commercial Standard: Formulary, Tier 2 • Commercial Cost-Based: Formulary, Tier 3 • Medicaid: Formulary	N/A
Butalbital/acetaminophen/ caffeine 50/300/40 mg Capsule	Add to Medicaid/Medicare Part D formularies; • Medicaid: Formulary • Medicare Part D: Formulary, Tier 4	N/A
Trientine hcl Capsule	• Commercial: Formulary, Tier 5, Prior Authorization	Trientine
COVID-19 vaccine, mrna, bnt162b2, lnp-s (Pfizer)/pf (Comirnaty) Vial	First FDA Approved COVID-19 vaccine • Covered medical benefit for all lines of business, Quantity Limit (0.5 mL per day)	N/A

The formulary status for the following drugs was line extended in accordance with Providence Health Plan Pharmacy Operational Policy ORPTCOPS06

NEW DRUGS / COMBINATIONS / STRENGTHS / DOSAGE FORMS		
Drug Name	**Action Taken**	**Policy Name**
Naloxone HCL (Kloxxado) Spray	New strength (8mg). Line Extend with Narcan; • Commercial: Formulary, Tier 2 • Medicaid: Formulary • Medicare Part D: Formulary, Tier 3	N/A
Nimodipine (Nymalize) Solution	New dosage Form (solution). Line extend with existing dose form (solution/syringe); • Non-formulary for all lines of business	N/A
Sucralfate malate, polymerized (Silatrix) Gel	New dosage form (gel). Line extend with ProThelial Paste, Orafate Paste; • Non-Formulary for all lines of business	N/A
Baloxavir Marboxil (Xofluza) Tablet	New strength (80 mg). Line extend with 40mg (80mg dose); • Commercial/Medicaid: Non-Formulary, Quantity Limit (1 tablet per 30 days) • Medicare Part D: Formulary, Tier 4	N/A
Afluria quad 2021-22 (influenza virus vaccine quadrival 2021-22 (6 mos-35 mos)/PF) Syringe	New entity and combination; • Commercial: Preventive; Quantity Limit (0.5 per day) • Medicaid/Medicare Part B: Medical Benefit	N/A
Hexatrione (Triamcinolone Hexacetonide) Ampul	New dosage form. Line extend with existing form (Aristospan vial) • Medical Benefit for all lines of business	N/A
Uptravi (Selexipag) Vial	New route, dosage form, and strength (vial; previous dosage form tablets). Line extend as medical; • Commercial/Medicaid: Medical Benefit, Prior Authorization • Medicare Part D: Non-Formulary • Medicare Part B: Medical Benefit, Prior Authorization	• Commercial/Medicaid: Pulmonary Arterial Hypertension • Medicare Part B: Pulmonary Arterial Hypertension - Part B
Myrbetriq (Mirabegron) Sus ER Rec	New dosage form and strength. Line Extend with existing dosage forms; • Commercial: Formulary, Tier 4, Step Therapy	• Commercial/Medicaid: Overactive Bladder Medications Step Therapy • Medicare Part D: N/A

	• Medicaid: Formulary, Step Therapy • Medicare Part D: Formulary, Tier 3	
Secukinumab (Cosentyx) Syringe	New strength; Line extent with Cosentyx • Commercial: Formulary, Tier 5, Prior Authorization, Quantity Limit (2 mL per 28 days) • Medicaid: Formulary, Specialty, Quantity Limit (2 mL per 28 days) • Medicare Part D: Formulary, Tier 5, Prior Authorization	Therapeutic Immunomodulators

New Generics:

NEW GENERICS		
Drug Name	**Action Taken**	**Policy Name**
Ferumoxytol Vial	First generic (Feraheme). Line extend with brand; • Medical Benefit for all lines of business	N/A
Sodium sulfacetamide-sulfur Med. Pad	First generic (Plexion). Line extend; • Non-Formulary for all lines of business	N/A
Varenicline tartrate Tablet	First generic (Chantix); Line extend with Brand; • Commercial: Formulary, Preventive • Medicaid: Formulary • Medicare Part D: Formulary, Tier 3	N/A
Baclofen Syringe	First generic (Gablofen). Line extend; • Medical benefit for all lines of business	N/A
Buprenorphine hcl Film	First generic (Belbuca). Line extend with brand; • Commercial/Medicaid: Non-Formulary, Prior Authorization, Quantity Limit (2 films per day) • Medicare Part D: Formulary, Tier 4, Prior Authorization	Long Acting Opioids
Enalapril maleate Solution	First generic (Epaned). Line extend with brand; • Commercial Standard: Formulary, Tier 4 • Commercial Cost-Based: Formulary, Tier 2 • Medicaid: Formulary • Medicare Part D 2021: Formulary, Tier 4 • Medicare Part D 2022: Non-Formulary	N/A

Dextroamphetamine sulfate (Sunitinib Malate) Tablet	First generic (Zenzedi). Line extend with brand; • Commercial/Medicare Part D: Non-Formulary • Medicaid: Non-Formulary, Prior Authorization	• Commercial/Medicare Part D: N/A • Medicaid: Long Acting Stimulant Medications
Ibuprofen-famotidine Tablet	First generic (Duexis). Line extend with brand; • 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
Sunitinib malate Capsule	First generic (Sutent); Line extend with brand; • Commercial: Formulary, Tier 5, Prior Authorization • Medicaid: Formulary, Specialty, Prior Authorization • Medicare Part D: Formulary, Tier 5, Prior Authorization	Oral Anti-Cancer Medications

Clinical Policy Changes:

Policy Name	Summary of Change
Benlysta	Add combination therapy with Saphnelo® (a new medication approved for lupus) to exclusion criteria.
Calcitonin Gene-Related Peptide Receptor (CGRP) Antagonists for Migraine Prophylaxis	Policy was combined with the Calcitonin Gene-Related Peptide (CGRP) Receptor Antagonists for Acute Migraine treatment policy so that all CGRP agents are on one policy. Clarified quantity exception request criteria.
Calcitonin Gene-Related Peptide Receptor (CGRP) Antagonists for Migraine Prophylaxis - Medicaid	Policy was combined with the Calcitonin Gene-Related Peptide (CGRP) Receptor Antagonists for Acute Migraine treatment policy so that all CGRP agents are on one policy. Clarified quantity exception request criteria and aligned criteria with Oregon Health Authority (Emgality® preferred)
Clovique/Syprine	Removing Clovique from policy and policy name as Clovique is now obsolete. FDA market ending date is 9/30/2021.
Enspryng	Updated prescriber restrictions for Commercial members to include opthalmologist. For Medicaid, removed prescriber restrictions and trial of rituximab to align with the Oregon Health Authority.
Gamifant	Policy update to clarify specific genetic tests for diagnosis of primary Hemophagocytic Lymphohistiocytosis (HLH) to help guide reviews rather than non-specific wording of molecular diagnosis.
Hepatitis C - Direct Acting Antivirals – Commercial and Medicaid	Medical rationale will be required for use of the pellet formulation of Harvoni® over the generic tablet formulation.

Lupkynis	Update criteria to exclude use with cyclophosphamide as the safety and efficacy of voclosporin have not been established in combination with cyclophosphamide. Use of voclosporin is not recommended in this situation.
Medically Infused Therapeutic Immunomodulators (TIMs) – Commercial and Medicare Part B policies	The preferred infliximab products will now be Inflectra® and Renflexis®, instead of Remicade®. The policy was updated to clarify the definition of patients that are established on therapy. In addition, criteria was added for coverage of infliximab for immune checkpoint inhibitor related diarrhea/colitis.
New Medications and Formulations without Established Benefit	Changed preferred Absorica agent to generic isotretinoin capsules and added duloxetine 40 mg delayed-release capsules to this policy.
Potassium Lowering Agents	Removed requirement for trial and failure of sodium polystyrene sulfonate (Kayexalate®), as this is no longer recommended as a first-line agent.
Soliris - Commercial and Medicare Part B policies	Exclusion criteria updated to exclude concurrent therapy with another FDA-approved product for paroxysmal nocturnal hemoglobinuria (i.e., Ultomiris®, Empaveli®) unless in a four-week period of cross titration between Soliris® and Empaveli®.
Therapeutic Immunomodulators - Commercial	The policy was updated to clarify the definition of patients that are established on therapy and prescriber restrictions. In addition, criteria for coverage of dose escalation was updated to limit dose escalations to inflammatory bowel disease when there is evidence of active inflammation after six months of therapy. This is the only disease state that has strong evidence supporting dose escalation in some patients.
Therapeutic Immunomodulators - Medicaid	The preferred infliximab products will now be Inflectra® and Renflexis®, removing Avsola® as one of the preferred products. The policy was updated to align with the criteria outlined by the Oregon Health Authority. Specifically, prescriber restrictions were removed, reauthorization criteria were added for rheumatic conditions, and added clinical scales to be used for evaluation of psoriasis. In addition, criteria for coverage of dose escalation was updated to limit dose escalations to inflammatory bowel disease when there is evidence of active inflammation after six months of therapy. This is the only disease state that has strong evidence supporting dose escalation in some patients.
Transthyretin (TTR) Lowering Agents	Criteria that use with other Transthyretin (TTR) Lowering Agents is not allowed was moved to the exclusion section as this is a more appropriate section. Exclusion section was cleaned up to align with other Health Plan policies and to make review easier. Updated baseline scores to require the more commonly used testing.
Ultomiris	Exclusion criteria updated to exclude concurrent therapy with another FDA-approved product for paroxysmal nocturnal hemoglobinuria (i.e., Soliris®, Empaveli®)
Uplizna	Updated prescriber restrictions to include ophthalmologist and removed trial of rituximab and extended initial authorization from six months to 12 months to align with the Oregon Health Authority.
Zeposia	This drug is a preferred agent for MS due to rebates, and we cannot require trial and failure of other agents, as our other preferred agents are available without prior authorization.

Retired Policies:

- Vistogard
- Evzio, Naloxone HCL
- Calcitonin Gene-Related Peptide Receptor (CGRP) Antagonists For Acute Migraine Treatment – combined with CGRPs for prophylaxis