Providence Health Plan

Providence Health Assurance

Healthcare Services Medical & Pharmacy Policy Alerts

Number 100

November 1, 2024

This is the November 1, 2024 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.

NOTE: For Oregon Medicaid requests, services which do not require prior authorization will process against the Prioritized List. To determine which services require prior-authorization, please see the current PHP prior authorization list here.

****EXTERNAL PROVIDER REVIEW OPPORTUNITY****

PHP Medical Policy Committee is seeking feedback from providers to serve as clinical subject matter experts (SMEs) through the policy development and annual review processes. This review process allows providers to offer their expertise and discuss relevant research in their field that will be used to support how these policy decisions are made. This will allow providers an opportunity to offer valuable insight that will help shape policies that affect provider reimbursement and patient care.

If interested, please email us at PHPmedicalpolicyinquiry@providence.org with your name, specialty, and preferred email address.

Providence Health Plan

Providence Health Assurance

MEDICAL POLICY COMMITTEE

MEDICAL

COMPANY POLICIES

Effective 12/1/2024

COVID-19 Testing
 	
MP350
	Policy Updates:
	• No changes to criteria.
	• Updated CMS guidance regarding ICD-10 coding for various clinical scenarios, on which diagnosis code configuration is based.
	  ○ Company version will not include the dx code for "encounter for screening for COVID-19."
	Codes/PA:
	• Added the following dx codes to pair-to-pay list:
	  ○ J02.9 Acute Pharyngitis, unspecified
	  ○ J06.9 Acute upper respiratory infection
	  ○ J11.1 Influenza due to unidentified virus with other respiratory manifestations
	  ○ J20.9 Acute Bronchitis, unspecified
	  ○ R05.8 Other specified Cough
	
	OHP: These changes do not apply to OHP. The Prioritized List and the Oregon Administrative Rules will be followed.

Balloon Dilation of the Sinuses or Eustachian Tubes **MP33**	**Policy Updates:** Removal of age criteria for sinus procedures. Added a note in criteria stating eustachian tube dilation in pediatric (>8 y/o) patients with chronic eustachian tube dysfunction that has been refractory to at least one surgical procedure may be medically necessary upon an individual basis. **Codes/PA:** No changes. **OHP:** These changes do not apply to OHP. The Prioritized List and the Oregon Administrative Rules will be followed.

Prostate Specific Antigen **MP319**	**Policy Updates:** No recommended changes to criteria. **Codes/PA:** Added 5 dx codes to pair to pay with CPT 84153 **OHP:** These changes do not apply to OHP. The Prioritized List and the Oregon Administrative Rules will be followed
Osteochondral Allografts and Autografts for Cartilaginous Defects **Mp149**	**Policy Updates:** Added "not medically necessary" criterion addressing osteochondral autograft of the ankle. **Codes/PA:** No changes to coding or criteria **OHP:** These changes do not apply to OHP. The Prioritized List and the Oregon Administrative Rules will be followed.

Effective 1/1/2025

Spinal Fusion and Decompression Procedures **MP10**	**Policy Updates:** No recommended changes to criteria. Update "Documentation Requirements" for surgeon evaluation and physical therapy requirements. **Codes/PA:** No changes to codes or PA **OHP:** These changes do not apply to OHP. The Prioritized List and the Oregon Administrative Rules will be followed.
Outpatient Surgical Site of Service	**Policy Updates:** Additional PA for facility for select procedures (ASC vs hospital outpatient department): plastic procedures of the nose, spinal cord stimulator/dorsal root ganglion stimulator placement, or implantable cardiac loop recorder. These codes already process with PA for medical necessity. **Codes/PA:** Administrative code changes additional level of PA. **OHP:** These changes do not apply to OHP. The Prioritized List and the Oregon Administrative Rules will be followed.
Blood Glucose Monitor and Supplies **MP239**	**Policy Updates:** No change to criteria. **Codes/PA:** Updated configuration for multiple supply codes (A4233, A4234, A4235, A4236, A4255, A4256, A4258, A4259), as well as E2104/A4271, to align with LCD A52464. (Adding "not separately reimbursable" when billed with A4239) **OHP:** These changes do not apply to OHP. The Prioritized List and the Oregon Administrative Rules will be followed.

Hysterectomy for Benign Conditions **MP286**	**Policy Updates:** Criteria changes based on InterQual 2024 guideline updates, as well as review by medical directors for the following indications: ○ Abnormal uterine bleeding ○ Chronic pelvic pain ○ Endometriosis ○ Tubo-ovarian abscess ○ Uterine **Codes/PA:** Pair to PA with CPT codes with diagnosis codes that were previously missed, related to established criteria. N80.352, N81.89, N85.00, N85.01, N99.85 **OHP:** These changes do not apply to OHP. The Prioritized List and the Oregon Administrative Rules will be followed.

MEDICARE POLICIES

Effective 12/1/2024

Respiratory Viral Panels **MP255**	**Policy Updates:** No change to criteria. **Codes/PA:** Updated diagnosis code configuration for CPT codes 87632, 87633, 0115U, 0202U, 0223U, 0225U (codes subject to the "Group 6" diagnosis code list of LCA A58726.)

Effective 1/1/2025

COVID-19 Testing **MP401**	**Policy Updates:** No change to overall criteria or coverage intent, but there are updates to format and regulatory language. Continue to apply LCDs when available, and for services without a specific LCD, apply general Medicare coverage rules. Added language to reinforce when testing may be considered covered, vs. non-covered scenarios under Medicare national standards. Also clarified definition of "screening" for the purposes of Z11.52, when the code is appropriate for use, and why it is non-covered by Medicare.

	Codes/PA: Configuration update information is as follows:
	• Current configuration is based on CMS ICD-10 Coding Guidelines resource. Further review of these CMS guidelines for ICD-10 coding identified that these instructions are provided to assist with ICD-10 coding for various clinical scenarios; however, it does not state that the ICD-10 codes to be used for each scenario makes that testing medically necessary. Therefore, further evaluation of the diagnosis code configuration was done.
	• None of the 8XXXX codes are "proprietary test" specific, which means any lab across the country could potentially use them and the "criteria" used is determined by test location.
	• Sometimes an LCD is available for coverage, while other times, there is no LCD or LCA at all. According to communication from Noridian, some of the CPT codes in this policy that apply a Noridian LCD are also subject to dx codes in the companion LCA, even though this is not expressly stated within the LCA.
	• To complicate things further, the LCAs that ***are*** available for the various service areas and that provide medically necessary diagnosis codes do NOT match each other, nor do they align with diagnosis codes currently allowed as medically necessary.
	• Therefore, configuration changes were made. Essentially a "custom" Medicare medically necessary diagnosis code list was created to for the most part align with LCA A58726, A58577, and/or A58575, as well as general Medicare statutory coverage requirements. Key changes and/or observations include the following:
	  ○ Over 250 dx codes are being ***added*** to pay, while 16 dx codes are being *removed* from the medically necessary dx code list.
	  ○ R05.9 (Cough, unspecified) was not found on either LCA, so removing as a covered dx code. Providers need to use other, more specific cough dx code options.

Artificial Intervertebral Discs **MP263**	**Policy Updates:** • Added criteria for revision, replacement and removal. Policy includes codes for these procedures, but it didn't provide criteria. Due to perceived "restriction" by the addition of this criteria, will provide 60-day notice, but no true change to intent or current practice. • Continue to apply Medicare criteria where available, and apply Company policy criteria in the absence of fully established Medicare criteria. • Updated formatting and Medicare regulatory language. **Codes/PA:** No change to codes or configuration.
Genetic and Molecular Testing **MP317**	**Policy Updates:** Annual review. No change to general coverage or non-coverage positions. Added BDX-XL2 test to the policy, with the corresponding LCD and CPT. **Codes/PA:** • 0080U: For BDX-XL2 test; added to policy and added PA • 0323U: Removed PA and added NMN

	• No change to codes or configuration for other codes at this time.
New and Emerging Technologies and Other Non-covered Services **MP220**	**Policy Updates:** Updates to criteria include the following: • Updated format of Table 1 to match the "set" of Table 2, which allows like-services to be bundled together, as well as services with similar Medicare non-coverage rationale. This allows the Medicare coverage policy and rationale to be cited just one time, rather than repeatedly throughout the document. • Removed several services with zero utilization for MA members. If we see an increase in utilization for any of the following services, we can re-evaluate the need for a Medicare policy at that time. • Added 0730T to align with Company policy. **Codes/PA:** • 81506, 97545, 97546, 0333T, 0335T, 0444T, 0445T, 0510T, 0511T, 0623T, 0624T, 0625T, 0626T, 0631T, 0640T, 0660T, 0661T: Removed from the policy, ***term*** NMN denial • 0730T: Added to policy, ***add*** NMN denial • No change to other codes in the policy.

Providence Health Plan

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

Pharmacy & Therapeutics (P&T) Committee

Oregon Region P&T Committee Meeting October 4, 2024

Go-Live Date: Wednesday, January 01, 2025, unless otherwise noted

Table of Contents:

New Drugs or Combinations:

1. **Fidanacogene elaparvovec-dzkt (Beqvez) Kit and Vial**
   a. **Indication**: For adults with hemophilia B containing human factor IX transgene which encodes a functional copy of the Padua variant of the Factor IX gene.
   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	One administration per lifetime	One administration per lifetime	One administration per lifetime

* 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: etranacogene dezaparvovec-drlb (Hemgenix®), Factor IX replacement therapy (Alphanine SD®, Alprolix®, Benefix®, Idelvion®, Ixinity®, Mononine®, Profilnin®, Rebinyn®, Rixubis®)

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

PA PROGRAM NAME	Gene Therapy for Hemophilia
MEDICATION NAME	Fidanacogene elaparvovec-dzkt (Beqvez®) Kit and Vial
PA INDICATION INDICATOR	1 - All FDA-Approved Indications
EXCLUSION CRITERIA	• Current or prior presence of factor IX inhibitors (Beqvez® and Hemgenix®) or Factor VIII inhibitors (Roctavian®) • HIV not controlled with antiviral therapy (CD4+ counts equal to 200/µL or by a viral load of greater than 200 copies/mL) • Active hepatitis B or C infection unless evaluated by hepatology • Evidence of advanced liver fibrosis (Fibroscan score of 9 kPA or greater) • ALT, AST, total bilirubin, alkaline phosphatase, or creatinine greater than two times the upper limit of normal, unless evaluated by hepatology • Previous treatment with gene therapy for the same indication
REQUIRED MEDICAL INFORMATION	Gene therapy may be approved when all the following criteria are met: 1. One of the following: a. For Beqvez® or Hemgenix®: Diagnosis of severe or moderately severe hemophilia B, defined by one of the following: Factor IX level less than 2 IU/dL or less than or equal to 2% of normal, provider attestation, or prior records of moderate to severe hemophilia B. b. For Roctavian®: Diagnosis of severe hemophilia A, defined by Factor VIII level less than 1 IU/dL or less than or equal to 1% of normal ~~2. Patient is a biological male~~ 3. One of the following: a. Patient is currently on a stable dose of prophylaxis therapy (has been receiving prophylaxis for two months of more) with greater than 150 exposure days of prophylaxis b. Current or historical life-threatening hemorrhage c. Documentation of repeated, serious spontaneous bleeding episodes 4. Patient is negative for Factor inhibitors, defined by a Factor inhibitor level assay less than 0.6 Bethesda units (BU) per mL. If initial test is positive, documentation of a subsequent negative test within 1-4 weeks will be allowed.

	5. ~~Roctavian®: Patient is negative for pre-existing immunity to the AAV5 capsid as measured by AAV5 transduction inhibition or AAV5 total antibodies.~~ Provider attestation that patient has been tested for appropriate adeno-associated virus (AAV) antibodies and is deemed a suitable candidate for treatment. See Table 1 for specific adeno-associated (AAV) virus antibodies according to the therapy requested 6. Gene therapy will be administered by or in consultation with a Hemophilia Treatment Center (HTC) 7. For Commercial Beqvez® requests: The patient has a contraindication to Hemgenix® (etranacogene dezaparvovec)
AGE RESTRICTIONS	May be approved for patients aged 18 years and older.
PRESCRIBER RESTRICTIONS	Must be prescribed by, or in consultation with, a hematologist.
COVERAGE DURATION	Authorization will be limited to one treatment course per lifetime

2. **Aprocitentan (Tryvio) Tablets**
   a. **Indication**: For the treatment of hypertension in combination with other antihypertensive drugs, to lower blood pressure in adult patients who are not adequately controlled on other drugs.
   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	1 tablet per day	1 tablet 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: spironolactone, eplerenone, carvedilol, clonidine, doxazosin, hydralazine			

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

PA PROGRAM NAME	Therapies for Resistant Hypertension
MEDICATION NAME	Aprocitentan tablets (Tryvio®)
PA INDICATION INDICATOR	1 - All FDA-Approved Indications
OFF-LABEL USES	None
EXCLUSION CRITERIA	N/A

REQUIRED MEDICAL INFORMATION	For patients initiating therapy, the following criteria are required: 1. Documentation that patient has resistant hypertension, defined by blood pressure that remains above goal despite the concurrent use of maximum or maximally tolerated daily doses of three antihypertensive agents of different classes including: a. A calcium channel blocker (such as amlodipine, diltiazem, verapamil) b. An angiotensin-converting enzyme inhibitor (ACE-I) (such as lisinopril, enalapril) or angiotensin receptor blocker (ARB) (such as losartan, valsartan, candesartan) c. A diuretic (such as hydrochlorothiazide, chlorthalidone) 2. Documentation that patient will be using in combination with a calcium channel blocker, an angiotensin-converting enzyme inhibitor or angiotensin receptor blocker, and a diuretic 3. Documentation that patient has tried and had an inadequate response to, or has an intolerance or contraindication to both of the following: a. A mineralocorticoid receptor antagonist (such as spironolactone) b. One more medication indicated for hypertension from a different therapeutic class (such as a beta-blocker [such as carvedilol], a centrally acting BP-lowering medication [such as clonidine], an alpha-blocker ~~[such as doxazosin]~~, hydralazine, minoxidil) 4. Confirmation of uncontrolled high blood pressure as demonstrated by systolic blood pressure greater than or equal to 140 mm Hg or diastolic blood pressure greater than or equal to 90 mm Hg taken on at least two separate occasions 6. Provider attestation that pseudo- and secondary hypertension have been ruled out (see Table 1 for examples) For reauthorization: 1. Documentation that patient is responding to treatment as documented by sustained improvement in blood pressure, taken on at least two consecutive measurements 2. Documentation that patient will be using in combination with a calcium channel blocker, an angiotensin-converting enzyme inhibitor or angiotensin receptor blocker, and a diuretic
AGE RESTRICTIONS	Ages eighteen (18) years and older
PRESCRIBER RESTRICTIONS	Must be prescribed by, or in consultation with, a cardiologist or a nephrologist
COVERAGE DURATION	Initial authorization will be approved for three months, and reauthorization will be approved for one year

3. **Atidarsagene autotemcel (Lenmeldy) Plast. Bag** reviewed by Jessica Niculcea, PharmD.
   a. **Indication**: For the treatment of children with pre-symptomatic late infantile (PSLI), pre-symptomatic early juvenile (PSEJ) or early symptomatic early juvenile (ESEJ) metachromatic leukodystrophy (MLD).
   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: None			

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

PA PROGRAM NAME	Lenmeldy
MEDICATION NAME	Lenmeldy
PA INDICATION INDICATOR	1 - All FDA-Approved Indications
OFF-LABEL USES	N/A
EXCLUSION CRITERIA	• Previous use of atidarsagene autotemcel (Lenmeldy®) or any other gene therapy previously • Concurrent use in combination with other autologous genome edited hematopoietic stem cell-based gene therapies • Positive test result for HIV or for hepatitis C or B
REQUIRED MEDICAL INFORMATION	For authorization, all the following criteria must be met: 1. Diagnosis of metachromatic leukodystrophy (MLD) as evidence by all the following (a and b): a. Arylsulfatase A (ARSA) activity below the normal range in peripheral blood mononuclear cells or fibroblasts b. Identification of two disease-causing ARSA alleles, either known or novel mutations i. If a novel ARSA variant is identified, documentation of presence of elevated sulfatides in a 24-hour urine collection 2. Documentation of one of the following MLD subtypes (a, b, or c): a. Pre-symptomatic late-infantile (PSLI) MLD with absence of neurological signs/symptoms and one of the following: i. The recipient has an older sibling with a diagnosis of MLD whose age at symptoms onset was equal to or less than 6 years of age (had not celebrated their 7th birthday) ii. Age at expected disease onset less than or equal to 30 months b. Pre-symptomatic early juvenile MLD and both of the following (i and ii): i. Age at expected disease onset greater than 30 months and less than 7 years of age

	ii. Absence of neurological signs/symptoms or only abnormal reflexes and/or clonus on exam c. Early-symptomatic early juvenile MLD) and all the following (i, ii, and iii): i. Disease onset greater than 30 months and less than 7 years of age ii. Ability to walk independently, defined by a gross motor function classification for MLD (GMFC MLD) level 0 with ataxia, or GMFC MLD level 1 iii. IQ equal to or greater than 85 on age-appropriate neurocognitive testing
AGE RESTRICTIONS	Age must be 18 years of age or younger
PRESCRIBER RESTRICTIONS	Must be prescribed by, or in consultation with, a neurologist or hematologist/oncologist or physician experienced in the treatment of metachromatic leukodystrophy (MLD)
COVERAGE DURATION	Authorization will be approved for six months (limited to a one-time single-dose intravenous treatment per lifetime).

4. **Crovalimab-akkz (Piasky) Vial**
   a. **Indication**: For the treatment of adult and pediatric patients 13 years and older with paroxysmal nocturnal hemoglobinuria (PNH) and body weight of at least 40 kg.
   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: Medical benefit: eculizumab (Soliris®), ravulizumab (Ultomiris®)			

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

PA PROGRAM NAME	Complement Inhibitors
MEDICATION NAME	Crovalimab-akkz
PA INDICATION INDICATOR	1 - All FDA-Approved Indications

EXCLUSION CRITERIA	Must not be given concurrently with another Complement Inhibitor (for example Ultomiris® or Empaveli®), or neonatal Fc receptor blocker (for example, Rystiggo®, Vyvgart®, Vyvgart Hytrulo®)
REQUIRED MEDICAL INFORMATION	**For initial authorization for Paroxysmal Nocturnal Hemoglobinuria (PNH):** 1. Documented, confirmed diagnosis of PNH by Flow Cytometric Immunophenotyping (FCMI) using at least two independent flow cytometry reagents on at least two cell lineages (such as red blood cells [RBCs] and white blood cells [WBCs]) demonstrating that the patient's peripheral blood cells are deficient in glycosylphosphatidylinositol (GPI)-linked proteins (which may include CD59, CD55, CD14, CD15, CD16, CD24, CD45, and CD64) 2. Symptomatic hemolytic PNH defined as lactate dehydrogenase (LDH) levels greater than or equal to 1.5 times the upper limit of normal and at least one of the following prior to initiating therapy with a complement inhibitor: A. Documented history of thrombosis B. Transfusion dependence (for example, hemoglobin less than 7 g/dL or symptomatic anemia with hemoglobin less than 9 g/dL) C. Disabling fatigue D. End-organ complications E. Frequent pain paroxysms (for example, dysphagia or abdominal pain) 3. For Soliris, Piasky and Fabhalta: Trial and failure, intolerance, or contraindication to ravulizumab-cwvz (Ultomiris) and pegcetacoplan (Empaveli) For reauthorization for PNH: reduced LDH levels, reduced transfusion requirements, increase or stabilization of hemoglobin levels, or improvement in symptoms
AGE RESTRICTIONS	Age must be appropriate based on FDA-approved indication
PRESCRIBER RESTRICTIONS	Must be prescribed by, or in consultation with, a hematologist/oncologist or nephrologist
COVERAGE DURATION	Initial authorization for up to three months and reauthorization will be approved for up to one year.

5. **Elafibranor (Iqirvo) Tablet**
   a. **Indication**: For the treatment of primary biliary cholangitis (PBC) in combination with ursodeoxycholic acid (UDCA) in adults who have an inadequate response to UDCA, or as monotherapy in patients unable to tolerate UDCA.
   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	One tablet per day	One 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: ursodiol, Ocaliva®			

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

PA PROGRAM NAME	Primary Biliary Cholangitis Agents
MEDICATION NAME	Iqirvo
PA INDICATION INDICATOR	1 - All FDA-Approved Indications
OFF-LABEL USES	N/A
EXCLUSION CRITERIA	• Non-alcoholic steatohepatitis (NASH) • Decompensated cirrhosis (such as Child-Pugh Class B or C) or a prior decompensated event • Combination use of Ocaliva®, Iqirvo®, or Livdelzi® • Ocaliva® only: Compensated cirrhosis with evidence of portal hypertension (e.g., ascites, gastroesophageal varices, persistent thrombocytopenia)
REQUIRED MEDICAL INFORMATION	For initial authorization, all the following criteria must be met: 1. Confirmed diagnosis of primary biliary cholangitis (PBC) as evidenced by two of the following criteria: a. Elevated alkaline phosphatase (ALP) [above the upper limit of normal (ULN) as defined by laboratory reference values] b. Presence of antimitochondrial antibody (AMA) c. Histologic evidence of primary biliary cholangitis from liver biopsy AND 2. Both of the following: a. Use of ursodiol for a minimum of 12 months and has had an inadequate response according to prescribing physician, unless patient is unable to tolerate ursodiol b. Documentation that the medication will be used in combination with ursodiol, unless patient is unable to tolerate ursodiol 3. For non-formulary drugs: must have tried and failed all formulary drug(s) indicated for PBC, unless all are not tolerated or contraindicated. For reauthorization, all the following criteria must be met: 1. Maintenance of biochemical response, defined as all the following: a. Alkaline phosphatase (ALP) less than or equal to 1.67 times the upper limit of normal (ULN)

	b. Total bilirubin (tBili) less than or equal to ULN c. ALP decrease of at least 15% 2. Documentation that ursodiol will be continued, if tolerated 3. Hepatic function is assessed at least annually
AGE RESTRICTIONS	N/A
PRESCRIBER RESTRICTIONS	Must be prescribed by, or in consultation with, a gastroenterologist or hepatologist.
COVERAGE DURATION	Initial authorization will be approved for four months. Reauthorization will be approved for one year

6. **Givinostat hydrochloride (Duvyzat) Oral Susp**
   a. **Indication**: For the treatment of Duchenne muscular dystrophy (DMD) in patients 6 years of age and older.
   b. **Decision**:

	Commercial	Medicaid	Medicare
Formulary Status*	Non-formulary	Non-formulary	Part D: Non-formulary Part B: N/A
Tier**	N/A	N/A	N/A
Affordable Care Act Eligible	N/A; Non-Formulary	N/A	N/A
Utilization Management Edits	Prior Authorization	Prior Authorization	N/A
Quantity Limit	420 mL/30 days	420 mL/30 days	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: Prednisone; Non-formulary with PA - deflazacort (Emflaza) and vamorolone (Agamree)			

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

PA PROGRAM NAME	Duvystat
MEDICATION NAME	Givinostat hydrochloride (Duvyzat)
PA INDICATION INDICATOR	1 - All FDA-Approved Indications
OFF-LABEL USES	N/A

EXCLUSION CRITERIA	For Duvyzat: Use in combination with exon skipping therapies (such as Exondys 51®, Vyondys 53®, Amondys 45®, Viltepso®) and in those who have previously received gene therapy, such as Elevidys® (delandistrogene moxeparvovec)
REQUIRED MEDICAL INFORMATION	For initiation of therapy (new starts), all the following must be met for Duvyzat: 1. Confirmed diagnosis of Duchenne muscular dystrophy by genetic testing (prescriber must provide genetic test to confirm diagnosis) 2. The member is ambulatory, defined as walking without assistance 3. Documentation the member has been on a corticosteroid for at least six (6) months, and will continue to receive a corticosteroid while on givinostat, unless contraindicated or intolerant 4. Documentation of baseline motor function prior to starting therapy with at least one appropriate standardized tool such as 4-stair climb (4SC), six-minute walk test (6MWT), North Star Ambulatory Assessment (NSAA), time to rise from the floor Note: This is be utilized for reauthorization For members established on therapy, all the following must be met: 1. Confirmed diagnosis of Duchenne muscular dystrophy by genetic testing 2. Documentation that a corticosteroid is being used concurrently with givinostat unless intolerant or contraindicated 3. Documentation of benefit of therapy as evidence by stabilization or improvement in motor function test scores performed at baseline or lack of decline compared to the natural disease progression 4. Member is ambulatory, defined as walking without assistance Note: Medications obtained as samples, coupons, or any other method of obtaining medications outside of an established health plan benefit are NOT considered established on therapy.
AGE RESTRICTIONS	Six (6) years of age and older
PRESCRIBER RESTRICTIONS	Must be prescribed by, or in consultation with a provider that specializes in the treatment of Duchenne muscular dystrophy (DMD) and/or neuromuscular disorders
COVERAGE DURATION	Initial authorization and reauthorization will be approved for one year.

7. **Ensifentrine (Ohtuvayre) Ampul-Neb**
   a. **Indication**: For the treatment of chronic obstructive pulmonary disease (COPD) in adults.
   b. **Decision**:

	Commercial	Medicaid	Medicare
Formulary Status*	Non-formulary	Non-formulary	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	Step Therapy
Quantity Limit	2 ampules per day	2 ampules per day	2 ampules 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: dual LAMA-LABA (e.g. Anoro Ellipta); triple LAMA-LABA-ICS (e.g. Trelegy Ellipta)			

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

PA PROGRAM NAME	Ohtuvayre
MEDICATION NAME	Ohtuvayre™ inhalation suspension for nebulization 3 mg/2.5 mL
PA INDICATION INDICATOR	1 - All FDA-Approved Indications
OFF-LABEL USES	N/A
EXCLUSION CRITERIA	N/A
REQUIRED MEDICAL INFORMATION	1. Documented diagnostic spirometry confirming COPD. 2. One of the following: a. Documentation of inadequate response to a 60-day trial of dual therapy with a formulary combination of a long-acting muscarinic antagonist and long-acting beta agonist (LAMA and LABA), or triple therapy with Trelegy Ellipta ®. Inadequate response is defined as persistent exacerbations or uncontrolled symptoms (such as dyspnea, chronic cough, sputum production, wheezing, chest tightness) despite ongoing treatment. b. Documentation of contraindication or intolerance to all formulary LAMA/LABA combination inhalers and triple therapy inhalers (Trelegy®)
AGE RESTRICTIONS	Age must be appropriate based on FDA-approved indication.
PRESCRIBER RESTRICTIONS	N/A
COVERAGE DURATION	Initial authorization will be approved for six months, and reauthorization will be approved for one year. FDA-labeled dosing will be approved until no longer eligible with the plan, subject to formulary and/or benefit changes.
QUANTITY LIMITS	QL = 2 ampules per day

8. **Imetelstat sodium (Rytelo) Vial**

a. **Indication**: For the treatment of adult patients with low- to intermediate-1 risk myelodysplastic syndromes (MDS) with transfusion-dependent anemia who have not responded to or have lost response to or are ineligible for erythropoiesis-stimulating agents.
    a. Myelodysplastic syndromes also referred to as myelodysplastic neoplasms (MDS) in the 5th edition of the World Health Organization Classification of Haematolymphoid Tumours.

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: Reblozyl (luspatercept), erythropoiesis stimulating agents			

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

PA PROGRAM NAME	Reblozyl, Rytelo
MEDICATION NAME	Imetelstat (Rytelo)
PA INDICATION INDICATOR	1 - All FDA-Approved Indications
EXCLUSION CRITERIA	Deletion 5q [del(5q)] cytogenic abnormalities Concurrent use of imetelstat and luspatercept
REQUIRED MEDICAL INFORMATION	For all requests for myelodysplastic syndrome (MDS), all the following must be met (supporting documentation required): 1. A score of very low to intermediate risk based on the Revised International Prognostic Scoring System 2. Dose is within FDA-approved dosing For initiation of therapy (new starts), the following medication specific criteria must be met: For Reblozyl, ~~1. Symptomatic anemia defined as a pretreatment or pretransfusion Hgb level less than or equal to 11 grams per deciliter~~ 1. Member has transfusion-dependent anemia requiring RBC transfusions of at least two units over an eight week period

	2. Meets one of the following (a or b): a. MDS-SF3B1 with ring sideroblasts greater than or equal to 15% (or ring sideroblasts greater than or equal to 5% and less than 15% with a SF3B1 mutation) b. Both of the following: i. Ring sideroblasts <15% (or ring sideroblasts <5% with an SF3B1 mutation) ii. Endogenous erythropoietin level less than 500 mU/mL For Rytelo, 1. Member has transfusion-dependent anemia requiring RBC transfusions of at least four units over an eight week period 2. Member has not responded to, lost response to, or is ineligible for erythropoiesis-stimulating agents (ESAs) 3. For MDS-SF3B1 with ring sideroblasts greater than or equal to 15% (or ring sideroblasts greater than or equal to 5% and less than 15% with a SF3B1 mutation), documented trial and failure (after at least of 16 weeks), intolerance or contraindication to luspatercept For patients that are established on therapy for MDS, documentation of positive response to therapy as evidenced by a decrease in transfusion burden from baseline. ~~that patient was able to achieve transfusion independence for at least eight weeks during previous treatment period~~ For initiation of therapy (new starts) for all other indications, use must be for an FDA approved indication or indication supported by National Comprehensive Cancer Network guidelines with recommendation 2A or higher. For patients that are established on therapy for all other indications, documentation of adequate response to the medication must be provided.
AGE RESTRICTIONS	At least 18 years of age
PRESCRIBER RESTRICTIONS	Must be prescribed by or in consultation with a hematologist/oncologist
COVERAGE DURATION	For initiation of therapy authorization will be for six months. For continuation of therapy will be for one year

9. **Mavorixafor (Xolremdi) Capsule**
   a. **Indication**: For in patients 12 years of age and older with WHIM syndrome (warts, hypogammaglobulinemia, infections and myelokathexis) to increase the number of circulating mature neutrophils and lymphocytes.
   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	4 capsules/day	4 capsules/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: Granulocyte-colony stimulating factor (G-CSF) or granulocyte-macrophage colony-stimulating factor (GM-CSF) injections, Immunoglobulin (Ig), anti-infectives, plerixafor			

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

PA PROGRAM NAME	Medications for Rare Indications
MEDICATION NAME	Mavorixafor capsules (Xolremdi®)
PA INDICATION INDICATOR	1 - All FDA-Approved Indications
OFF-LABEL USES	None
EXCLUSION CRITERIA	N/A
REQUIRED MEDICAL INFORMATION	Both of the following must be met: 1. Confirmation of FDA-labeled indication (appropriate lab values and/or genetic tests must be submitted – See Table 1 and Table 2) (For Xolremdi®: Diagnosis of WHIM syndrome confirmed by genotype variant of CXCR4) 2. Dosing is within FDA-labeled guidelines OR documentation has been submitted in support of therapy with a higher dose for the intended diagnosis such as high-quality peer reviewed literature, guidelines, other clinical information 3. For Xolremdi®: Documentation of baseline absolute neutrophil count (ANC) and absolute neutrophil count (ALC) to assess clinical response to treatment Reauthorization Criteria: The following must be met: 1. Documentation of benefit of therapy as evidence by improvement in symptoms, disease stabilization or lack of decline compared to the natural disease progression 2. Dosing is within FDA-labeled guidelines OR documentation has been submitted in support of therapy with a higher dose for the intended diagnosis such as high-quality peer reviewed literature, guidelines, other clinical information

	3. For Xolremdi®: Documentation of sustained improvement in absolute neutrophil count (ANC) and absolute neutrophil count (ALC)
AGE RESTRICTIONS	Age must be appropriate based on FDA-approved indication
PRESCRIBER RESTRICTIONS	Must be prescribed by, or in consultation with a specialist in the respective disease state.
COVERAGE DURATION	For Daybue® and Xolremdi®: Initial authorization will be approved for six months. Reauthorization will be approved for 12 months. For all other medications: 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.

10. **Sofpironium bromide (Sofdra) Gel with Pump**
    a. **Indication**: For the treatment of primary axillary hyperhidrosis in adults and pediatric patients 9 years and older.
    b. **Decision**:

	Commercial	Medicaid	Medicare
Formulary Status*	Non-formulary	Non-formulary	Part D: Non-formulary Part B: N/A
Tier**	N/A	N/A	N/A
Affordable Care Act Eligible	N/A; Non-Formulary	N/A	N/A
Utilization Management Edits	Prior Authorization	Prior Authorization	N/A
Quantity Limit	One bottle per 30 days	One bottle per 30 days	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: N/A

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

PA PROGRAM NAME	Hyperhidrosis Agents
MEDICATION NAME	Sofpironium bromide 12.45% gel
PA INDICATION INDICATOR	1 - All FDA-Approved Indications
EXCLUSION CRITERIA	List ONLY if it's a clear contraindication in the labeling or if it's a safety concern
REQUIRED MEDICAL INFORMATION	Initial authorization must meet all of the following criteria: 1. Diagnosis of severe primary axillary hyperhidrosis 2. Documentation that the patient has had axillary hyperhidrosis for at least six months 3. Documentation that member's hyperhidrosis is causing social anxiety, depression, or other issues that are impacting quality of life 4. Documented trial and failure of Drysol for at least one month, unless contraindicated or clinically significant side effects were experienced 5. For Sofdra®: Documented trial and failure of topical glycopyrronium (Qbrexa) for at least one month, unless contraindicated or clinically significant side effects were experienced Reauthorization requires documentation of positive response to therapy
AGE RESTRICTIONS	Approved for nine years and older
PRESCRIBER RESTRICTIONS	Must be prescribed by, or in consultation with, a dermatologist
COVERAGE DURATION	Initial authorization will be approved for six months. Reauthorization will be approved for one year.
QUANTITY LIMIT	One bottle per 30 days

11. **Tarlatamab-dlle (Imdelltra) Vial**

a. **Indication**: For the treatment of adult patients with extensive stage small cell lung cancer (ES-SCLC) with disease progression.

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: Lurbinectedin, Topotecan, Irinotecan

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

12. **Vadadustat (Vafseo) Tablet**

a. **Indication**: For the treatment of anemia due to chronic kidney disease (CKD) in adults who have been receiving dialysis for at least 3 months.

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	Prior Authorization	Prior Authorization	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: Jesduvroq, Aranesp, Epogen, Procrit, Retacrit			

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

PA PROGRAM NAME	Jesduvroq, Vafseo
MEDICATION NAME	Vafseo (vadadustat) tablet
PA INDICATION INDICATOR	1 - All FDA-Approved Indications
OFF-LABEL USES	N/A
EXCLUSION CRITERIA	Uncontrolled hypertension

REQUIRED MEDICAL INFORMATION	**For initial authorization, all the following must be met:** 1. Documentation of anemia due to chronic kidney disease (CKD) 2. Documentation that the patient has received dialysis for at least three months 3. Adequate iron stores as indicated by current (within the last three months) serum ferritin level greater than or equal to 100 mcg/L or serum transferrin saturation greater than or equal to 20% 4. Documentation is patient is hyporesponsive to erythropoiesis-stimulating agent therapy after at least three months of therapy **For reauthorization, all the following must be met:** 1. Documentation of anemia due to CKD 2. Documentation the patient has experienced a therapeutic response, defined by an increase in hemoglobin from baseline
AGE RESTRICTIONS	May be approved for patients aged 18 years and older
PRESCRIBER RESTRICTIONS	Must be prescribed by, or in consultation with, a nephrologist
COVERAGE DURATION	Initial authorization and reauthorization will be approved for six (6) months. Reauthorization will be approved for one year.

New Indications Monitoring:

The following information is gathered from the United States Food and Drug Administration (FDA)

Approved Drug Products database from 4/1/2024– 4/30/2024

Therapies with Prior Authorization Policies (Non-oncology)

1. **FANAPT** (ILOPERIDONE)
    a. Previous Indication(s):
        i. Treatment of schizophrenia in adults.
    b. New indication approved 04/02/2024:
        i. Acute treatment of manic or mixed episodes associated with bipolar I disorder in adults.
    c. **RECOMMENDATION:** Inform prescribers via Medical Policy Alert. Update Antipsychotics policy with new indication.

2. **FASENRA (**BENRALIZUMAB)
    a. Previous Indication(s):
        i. Add-on maintenance treatment of patients with severe asthma aged 12 years and older, and with an eosinophilic phenotype.
    b. New indication approved 04/05/2024:
        i. Add-on maintenance treatment of patients with severe asthma aged 6 years and older, and with an eosinophilic phenotype.

c. **RECOMMENDATION:** Inform prescribers via Medical Policy Alert. IL-5 Inhibitors policy already updated with new indication April 2024; no further updates required.

3. **MIRCERA** (METHOXY POLYETHYLENE GLYCOL-EPOETIN BETA)
   a. Previous Indication(s):
      i. Treatment of anemia associated with chronic kidney disease (CKD) in
         1. Adult patients on dialysis and adult patients not on dialysis
         2. Pediatric patients 5 to 17 years of age on hemodialysis who are converting from another erythropoiesis-stimulating agent (ESA) after their hemoglobin level was stabilized with an ESA.
   b. New indication approved 04/30/2024:
      i. Treatment of anemia associated with chronic kidney disease (CKD) in pediatric patients 3 months to 17 years of age on dialysis and not on dialysis who are converting from another ESA after their hemoglobin level was stabilized with an ESA.
   c. **RECOMMENDATION:** Inform prescribers via Medical Policy Alert. Update Erythropoiesis Stimulating Agents policy with new indication and add new criteria.
   Prior Authorization for Commercial/Medicaid/Medicare Part B:

PA PROGRAM NAME	Erythropoiesis Stimulating Agents
MEDICATION NAME	**Mircera** (Methoxy Polyethylene Glycol-Epoetin Beta)
COVERED USES	1 - All FDA-Approved Indications
REQUIRED MEDICAL INFORMATION	g. Mircera only: For the treatment of pediatric patients 3 months to 17 years of age (with or without dialysis) who are converting from another ESA after their hemoglobin level was stablized with an ESA: i. Documented stable maintenance treatment with epoetin alfa, epoetin beta, or darbepoetin alfa for at least eight weeks prior to initiation of therapy ii. Documented stable hemoglobin (HGB) levels for at least eight weeks prior to initiation of therapy.

4. **OTEZLA** (APREMILAST)
   a. Previous Indication(s):
      i. Adult patients with active psoriatic arthritis.
      ii. Adult patients with plaque psoriasis who are candidates for phototherapy or systemic therapy
      iii. Adult patients with oral ulcers associated with Behçet's Disease.
   b. New indication approved 04/25/2024:
      i. Pediatric patients 6 years of age and older and weighing at least 20 kg with moderate to severe plaque psoriasis who are candidates for phototherapy or systemic therapy.
   c. **RECOMMENDATION:** Inform prescribers via Medical Policy Alert. Update policy with new indication.

5. **RINVOQ** (UPADACITINIB)

a. Previous Indication(s):
    i. Adults with moderately to severely active rheumatoid arthritis who have had an inadequate response or intolerance to one or more TNF blockers. Limitations of Use: RINVOQ is not recommended for use in combination with other JAK inhibitors, biologic DMARDs, or with potent immunosuppressants such as azathioprine and cyclosporine.
    ii. Adults with active psoriatic arthritis who have had an inadequate response or intolerance to one or more TNF blockers. Limitations of Use: RINVOQ is not recommended for use in combination with other JAK inhibitors, biologic DMARDs, or with potent immunosuppressants such as azathioprine and cyclosporine.
    iii. Adults and pediatric patients 12 years of age and older with refractory, moderate to severe atopic dermatitis whose disease is not adequately controlled with other systemic drug products, including biologics, or when use of those therapies are inadvisable. Limitations of Use: RINVOQ is not recommended for use in combination with other JAK inhibitors, biologic immunomodulators, or with other immunosuppressants.
    iv. Adults with moderately to severely active ulcerative colitis who have had an inadequate response or intolerance to one or more TNF blockers. Limitations of Use: RINVOQ is not recommended for use in combination with other JAK inhibitors, biological therapies for ulcerative colitis, or with potent immunosuppressants such as azathioprine and cyclosporine.
    v. Adults with moderately to severely active Crohn's disease who have had an inadequate response or intolerance to one or more TNF blockers. Limitations of Use: RINVOQ is not recommended for use in combination with other JAK inhibitors, biological therapies for Crohn's disease, or with potent immunosuppressants such as azathioprine and cyclosporine.
    vi. Adults with active ankylosing spondylitis who have had an inadequate response or intolerance to one or more TNF blockers. Limitations of Use: RINVOQ is not recommended for use in combination with other JAK inhibitors, biologic DMARDs, or with potent immunosuppressants such as azathioprine and cyclosporine.
    vii. Adults with active non-radiographic axial spondyloarthritis with objective signs of inflammation who have had an inadequate response or intolerance to TNF blocker therapy. Limitations of Use: RINVOQ is not recommended for use in combination with other JAK inhibitors, biologic DMARDs, or with potent immunosuppressants such as azathioprine and cyclosporine.
b. New indication approved 04/26/2024:
    i. Adults and pediatric patients 2 years of age and older with active psoriatic arthritis who have had an inadequate response or intolerance to one or more TNF blockers. Limitations of Use: RINVOQ/RINVOQ LQ is not recommended for use in combination with other JAK inhibitors, biologic DMARDs, or with potent immunosuppressants such as azathioprine and cyclosporine.
    ii. Patients 2 years of age and older with active polyarticular juvenile idiopathic arthritis who have had an inadequate response or intolerance to one or more TNF blockers. Limitations of Use: RINVOQ/RINVOQ LQ is not recommended for use in combination with other JAK inhibitors, biologic DMARDs, or with potent immunosuppressants such as azathioprine and cyclosporine.
c. **RECOMMENDATION:** Inform prescribers via Medical Policy Alert. Policy was updated with the new indications prior to this audit; no additional policy updates warranted.

Therapies with Prior Authorization Policies (Oncology)

6. **ABECMA** (IDECABTAGENE VICLEUCEL)
    a. New indication(s) approved 04/04/2024:
        i. Treatment of adult patients with relapsed or refractory multiple myeloma after two or more prior lines of therapy including an immunomodulatory agent, a proteasome inhibitor, and an anti-CD38 monoclonal antibody.

   b. **RECOMMENDATION:** Inform prescribers via Medical Policy Alert. Update policy with new indication. Prior authorization policy coverage criteria are based on recommendations from the National Comprehensive Cancer Network (NCCN).

7. **ALECENSA** (ALECTINIB HYDROCHLORIDE)
   a. New indication(s) approved 04/18/2024:
      i. Adjuvant treatment in adult patients following tumor resection of anaplastic lymphoma kinase (ALK)-positive non-small cell lung cancer (NSCLC) (tumors ≥ 4 cm or node positive), as detected by an FDA-approved test.
   b. **RECOMMENDATION:** Inform prescribers via Medical Policy Alert. Update policy with new indication. Prior authorization policy coverage criteria are based on recommendations from the National Comprehensive Cancer Network (NCCN).
8. **CARVYKTI** (CILTACABTAGENE AUTOLEUCEL)
   a. New indication(s) approved 04/05/2024:
      i. Treatment in lenalidomide-refractory participants, following 1 to 3 prior lines of therapy for multiple myeloma.
   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.
9. **ENHERTU** (FAM-TRASTUZUMAB DERUXTECAN-NXKI)
   a. New indication(s) approved 04/05/2024:
      i. Treatment of adult patients with unresectable or metastatic HER2-positive (IHC 3+) solid tumors who have received prior systematic treatment and have no satisfactory alternative treatment options.
   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.
10. **LUTATHERA** (LUTETIUM LU 177 DOTATATE)
    a. New indication(s) approved 04/23/2024:
       i. Treatment of pediatric patients 12 years and older with somatostatin receptor-positive gastroenteropancreatic neuroendocrine tumors (GEP-NETs), including foregut, midgut, and hindgut neuroendocrine tumors.
    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.
11. **TIVDAK** (TISOTUMAB VEDOTIN-TFTV)
    a. New indication(s) approved 04/29/2024:
       i. Treatment of adult patients with recurrent or metastatic cervical cancer with disease progression on or after chemotherapy.
    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.

<u>Therapies Without Prior Authorization Policies</u>

12. **CLINOLIPID 20%** (OLIVE OIL, SOYBEAN OIL)
    a. Previous Indication(s):
       i. Adults for parenteral nutrition providing a source of calories and essential fatty acids when oral or enteral nutrition is not possible, insufficient, or contraindicated.
    b. New indication approved 04/24/2024:

i. Pediatric patients, including term and preterm neonates, for use as a source of calories and essential fatty acids for parenteral nutrition (PN) when oral or enteral nutrition is not possible, insufficient, or contraindicated.

c. **RECOMMENDATION:** Inform prescribers via Medical Policy Alert.

13. **DOVATO** (DOLUTEGRAVIR SODIUM, LAMIVUDINE)
    a. Previous Indication(s):
        i. A complete regimen for the treatment of HIV-1 infection in adults with no antiretroviral treatment history or to replace the current antiretroviral regimen in those who are virologically suppressed (HIV-1 RNA less than 50 copies per mL) on a stable antiretroviral regimen with no history of treatment failure and no known substitutions associated with resistance to the individual components of DOVATO.
    b. New indication(s) approved 04/05/2024:
        i. A complete regimen for the treatment of HIV-1 infection in adolescents aged 12 to less than 18 years and weighing at least 25 kg with no antiretroviral treatment history or to replace the current antiretroviral regimen in those who are virologically suppressed (HIV-1 RNA less than 50 copies/mL) on a stable antiretroviral regimen with no history of treatment failure and no known substitutions associated with resistance to the individual components of DOVATO.
    c. **RECOMMENDATION:** Inform prescribers via Medical Policy Alert.
14. **ENTRESTO** (SACUBITRIL, VALSARTAN)
    a. Previous Indication(s):
        i. To reduce the risk of cardiovascular death and hospitalization for heart failure in adult patients with chronic heart failure.
    b. New indication(s) approved 04/12/2024:
        i. Treatment of symptomatic heart failure with systemic left ventricular systolic dysfunction in pediatric patients aged one year and older.
    c. **RECOMMENDATION:** Inform prescribers via Medical Policy Alert.

The following information is gathered from the United States Food and Drug Administration (FDA)

Approved Drug Products database from 5/1/2024– 5/31/2024

Therapies with Prior Authorization Policies (Oncology)

1. **RETEVMO** (selpercatinib)
    a. New indication(s) approved 05/29/2024:
        i. Adult and pediatric patients **2 years of age and older** with advanced or metastatic medullary thyroid cancer (MTC) with a RET mutation, as detected by an FDA-approved test, who require systemic therapy
        ii. Adult and pediatric patients **2 years of age and older** with advanced or metastatic thyroid cancer with a RET gene fusion, as detected by an FDA-approved test, who require systemic therapy and who are radioactive iodine-refractory (if radioactive iodine is appropriate)
        iii. Adult and **pediatric patients 2 years of age and older** with locally advanced or metastatic solid tumors with a RET gene fusion, **as detected by an FDA-approved test**, that have progressed on or following prior systemic treatment or who have no satisfactory alternative treatment options
    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.

2. **BREYANZI** (lisocabtagene maraleucel)
    a. New indication(s) approved 05/15/2024:
        i. treatment of adult patients with relapsed or refractory follicular lymphoma (FL) who have received two or more prior lines of systemic therapy
        ii. treatment of adult patients with relapsed or refractory mantle cell lymphoma (MCL) who have received at least two prior lines of systemic therapy, including a Bruton tyrosine kinase (BTK) 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); Update policy with new indications

The following information is gathered from the United States Food and Drug Administration (FDA)

Approved Drug Products database from 6/1/2024– 6/30/2024

Therapies with Prior Authorization Policies (Non-oncology)

1. **AREXVY** (RESPIRATORY SYNCYTIAL VIRUS VACCINE, ADJUVANTED)
    a. Previous Indication(s):
        i. Active immunization for the prevention of Lower Respiratory Tract Disease (LRTD) caused by Respiratory Syncytial Virus (RSV) in individuals 60 years of age and older.
    b. New indication approved 06/07/2024:
        i. Active immunization for the prevention of Lower Respiratory Tract Disease (LRTD) caused by Respiratory Syncytial Virus (RSV) in individuals 50 through 59 years of age who are at increased risk for LRTD caused by RSV.
    c. **RECOMMENDATION:** Inform prescribers via Medical Policy Alert. No policy criteria update needed.

2. **ELEVIDYS** (DELANDISTROGENE MOXEPARVOVEC-ROKL)
    a. Previous Indication(s):
        i. Ambulatory pediatric patients aged four through five years with Duchenne muscular dystrophy (DMD) with a confirmed mutation in the dystrophin (DMD) gene. This indication is approved under accelerated approval. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial(s).
    b. New indication approved 06/20/2024:
        i. Treatment of ambulatory individuals at least 4 years of age with Duchenne muscular dystrophy (DMD) with a confirmed mutation in the dystrophin (DMD) gene.
        ii. Treatment of non-ambulatory individuals at least 4 years of age with Duchenne muscular dystrophy (DMD) with a confirmed mutation in the DMD gene, according to the regulations for accelerated approval, 21 CFR 601.41, approved under accelerated approval based on expression of ELEVIDYS micro-dystrophin.
    c. **RECOMMENDATION:** Inform prescribers via Medical Policy Alert. Elevidys® policy was updated with new indication at August 2024 P&T meeting. No policy criteria update needed.

3. **KEVZARA** (SARILUMAB)
    a. Previous Indication(s):
        i. Adult patients with moderately to severely active rheumatoid arthritis (RA) who have had an inadequate response or intolerance to one or more disease-modifying antirheumatic drugs (DMARDs).
        ii. Adult patients with polymyalgia rheumatica (PMR) who have had an inadequate response to corticosteroids or who cannot tolerate corticosteroid taper.
    b. New indication approved 06/10/2024:
        i. Patients who weight 63 kg or greater with active polyarticular juvenile idiopathic arthritis (pJIA).
    c. **RECOMMENDATION:** Inform prescribers via Medical Policy Alert. Therapeutic Immunomodulators (TIMs) policy is being updated with new indication at October 2024 P&T. No policy criteria update needed.

4. **SKYRIZI** (RISANKIZUMAB-RZAA)
    a. Previous Indication(s):
        i. Treatment of moderate to severe plaque psoriasis in adults who are candidates for systemic therapy or phototherapy.
        ii. Treatment of active psoriatic arthritis in adults.
        iii. Treatment of moderately to severely active Crohn's disease in adults.
    b. New indication approved 06/18/2024:
        i. Treatment of moderately to severely active ulcerative colitis in adults.
    c. **RECOMMENDATION:** Inform prescribers via Medical Policy Alert. Therapeutic Immunomodulators (TIMs) policy is under review for October 2024 P&T.

5. **VYVGART HYTRULO** (EFGARTIGIMOD ALFA AND HYALURONIDASE-QVFC)
    a. Previous Indication(s):
        i. Treatment of generalized myasthenia gravis (gMG) in adult patients who are anti-acetylcholine receptor (AChR) antibody positive.
    b. New indication approved 06/21/2024:
        i. Treatment of chronic inflammatory demyelinating polyneuropathy (CIDP) in adult patients.
    c. **RECOMMENDATION:** Inform prescribers via Medical Policy Alert. Update policy with new indication and add new criteria.

Prior Authorization for Commercial/Medicaid/Medicare Part B:

PA PROGRAM NAME	FcRn Antagonists
MEDICATION NAME	**VYVGART HYTRULO** (EFGARTIGIMOD ALFA AND HYALURONIDASE-QVFC)
COVERED USES	1 - All FDA-Approved Indications
REQUIRED MEDICAL INFORMATION	For chronic inflammatory demyelinating polyneuropathy (CIDP), all the following criteria must be met: 1. Documentation of current active disease, defined by a CIDP Disease Activity Status (CDAS) of at least 2 2. Documentation of Inflammatory Neuropathy Cause and Treatment (INCAT) Disability Score of at least 3, or a score of 2 of the legs

	3. Documentation of inadequate response to treatment with one of the following, unless both are not tolerated or contraindicated a. Systemic corticosteroids b. Immune gamma globulin therapy

6. **WAKIX** (PITOLISANT HYDROCHLORIDE)
    a. Previous Indication(s):
        i. Treatment of excessive daytime sleepiness (EDS) or cataplexy in adult patients with narcolepsy.
    b. New indication approved 06/21/2024:
        i. Treatment of excessive daytime sleepiness (EDS) in patients 6 years of age and older with narcolepsy.
    c. **RECOMMENDATION:** Inform prescribers via Medical Policy Alert. Update Narcolepsy Agents policy with new indication. No policy criteria update needed.

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

7. **AUGRYEO** (REPOTRECTINIB)
    a. New indication approved 06/13/2024:
        i. Treatment of adult and pediatric patients 12 years of age and older with solid tumors that: have a neurotrophic tyrosine receptor kinase (NTRK) gene fusion, are locally advanced or metastatic or where surgical resection is likely to result in severe morbidity and have progressed following treatment or have no satisfactory alternative 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.

8. **BLINCYTO** (BLINATUMOMAB)
    a. New indication approved 06/14/2024:
        i. Treatment of CD19-positive Philadelphia chromosome-negative B-cell precursor acute lymphoblastic leukemia (ALL) in the consolidation phase of multiphase chemotherapy in adult and pediatric patients one month 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.

9. **EPKINLY** (EPCORITAMAB-BYSP)
    a. New indication(s) approved 06/26/2024:
        i. Treatment of adult patients with relapsed or refractory follicular lymphoma (FL) after two or more lines of systemic 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.

10. **IMFINZI** (DURVALUMAB)
    a. New indication(s) approved 06/14/2024:

i. In combination with carboplatin and paclitaxel followed by Imfinzi as a single agent, for the treatment of adult patients with primary advanced or recurrent endometrial cancer that is mismatch repair deficient (dMMR).

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.

11. **KEYTRUDA** (PEMBROLIZUMAB)
    a. New indication approved 06/17/2024:
        i. In combination with carboplatin and paclitaxel, followed by KEYTRUDA as a single agent, for the treatment of adult patients with primary advanced or recurrent endometrial carcinoma.
    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. **KRAZATI** (ADAGRASIB)
    a. New indication(s) approved 06/21/2024:
        i. In combination with cetuximab for the treatment of adult patients with KRAS G12C mutated locally advanced or metastatic colorectal cancer who have been previously treated with fluoropyrimidine-, oxaliplatin-, and irinotecan-based chemotherapy.
    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.

<u>Therapies Without Prior Authorization Policies</u>

13. **FARXIGA** (DAPAGLIFLOZIN)
    a. Previous Indications:
        i. To reduce the risk of sustained eGFR decline, end stage kidney disease, cardiovascular death, and hospitalization for heart failure in adults with chronic kidney disease at risk of progression.
        ii. To reduce the risk of cardiovascular death, hospitalization for heart failure, and urgent heart failure visit in adults with heart failure.
        iii. To reduce the risk of hospitalization for heart failure in adults with type 2 diabetes mellitus and either established cardiovascular disease or multiple cardiovascular risk factors.
        iv. An adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus.
    b. New indication approved 06/12/2024:
        i. An adjunct to diet and exercise to improve glycemic control in pediatric patients aged 10 years and older with type 2 diabetes mellitus.
    c. **RECOMMENDATION:** Inform prescribers via Medical Policy Alert.

14. **MOTPOLY XR** (LACOSAMIDE)
    a. Previous Indication(s):
        i. Treatment of partial-onset seizures in adults and pediatric patients weighing at least 50 kg.
    b. New indication(s) approved 06/07/2024:
        i. Adjunctive therapy in the treatment of primary generalized tonic-clonic seizures in adults and in pediatric patients weighing at least 50 kg.
    c. **RECOMMENDATION:** Inform prescribers via Medical Policy Alert.

15. **XIGDUO XR** (DAPAGLIFLOZIN, METFORMIN HYDROCHLORIDE)
    a. Previous Indication:
        i. An adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus.
    b. New indication approved 06/12/2024:
        i. An adjunct to diet and exercise to improve glycemic control in pediatric patients aged 10 years and older with type 2 diabetes mellitus.
    c. **RECOMMENDATION:** Inform prescribers via Medical Policy Alert.

The following information is gathered from the United States Food and Drug Administration (FDA)

Approved Drug Products database from 7/1/2024– 7/31/2024

Therapies with Prior Authorization Policies (Non-oncology)

1. **XEOMIN** (incobotulinumtoxinA)
    a. Previous Indication(s):
        i. Chronic sialorrhea in patients two years and older
        ii. Upper limb spasticity in patients at least two years of age
            1. Upper limb spasticity in pediatric patients 2 to 17 years of age, excluding spasticity caused by cerebral palsy
        iii. Cervical dystonia in adults
        iv. Blepharospasm in adults
    b. New indication approved 07/05/2024:
        i. the appearance of upper facial lines in adults:
            1. moderate to severe glabellar lines associated with corrugator and/or procerus muscle activity
            2. moderate to severe horizontal forehead lines associated with frontalis muscle activity
            3. moderate to severe lateral canthal lines associated with orbicularis oculi muscle activity
    c. **RECOMMENDATION:** Inform prescribers via Medical Policy Alert. No updates to policy required, as this therapy is a benefit exclusion for wrinkles.

2. **PALFORZIA** ([Peanut (Arachis hypogaea) Allergen Powder-dnfp])
    a. Previous Indication(s):
        i. PALFORZIA is an oral immunotherapy indicated for the mitigation of allergic reactions, including anaphylaxis, that may occur with accidental exposure to peanut.
        ii. PALFORZIA is approved for use in patients with a confirmed diagnosis of peanut allergy. Initial Dose Escalation may be administered to patients aged 1 through 17 years. Up-Dosing and Maintenance may be continued in patients 1 year of age and older.
        iii. PALFORZIA is to be used in conjunction with a peanut-avoidant diet. Limitation of Use: Not indicated for the emergency treatment of allergic reactions, including anaphylaxis.
    b. New indication approved 07/26/2024:

i. To expand the age indication to include **patients 1 through 3 years of age** with a confirmed diagnosis of peanut allergy

c. **RECOMMENDATION**: Inform prescribers via Medical Policy Alert. Update policy with new indication and add new criteria.

Prior Authorization for Commercial/Medicaid:

PA PROGRAM NAME	PALFORZIA
MEDICATION NAME	PALFORZIA
COVERED USES	1 - All FDA-Approved Indications
AGE RESTRICTIONS	For Initiation of therapy: Aged 1 to 17 years For Continuation (up-dosing or maintenance): Aged 1 year of age or older

3. **BRINEURA** (cerliponase alfa)
   a. Previous Indication(s):
      i. Brineura is a hydrolytic lysosomal N-terminal tripeptidyl peptidase indicated to slow the loss of ambulation in symptomatic **pediatric patients 3 years of age and older** with late infantile neuronal ceroid lipofuscinosis type 2 (CLN2), also known as tripeptidyl peptidase 1 (TPP1) deficiency
   b. New indication approved 07/24/2024:
      i. BRINEURA is a hydrolytic lysosomal N-terminal tripeptidyl peptidase indicated to slow the loss of ambulation **in pediatric patients** with neuronal ceroid lipofuscinosis type 2 (CLN2 disease), also known as tripeptidyl peptidase 1 (TPP1) deficiency
   c. **RECOMMENDATION:** Inform prescribers via Medical Policy Alert. Update policy with new indication.

4. **ZORYVE** (roflumilast)
   a. Previous Indication(s):
      i. ZORYVE cream, 0.3%, is indicated for the topical treatment of plaque psoriasis, including intertriginous areas, in adult and pediatric patients 6 years of age and older
   b. New indication approved 07/09/2024:
      i. ZORYVE cream, 0.15%, is indicated for the topical treatment of mild to moderate atopic dermatitis in adult and pediatric patients 6 years of age and older
   c. **RECOMMENDATION:** Inform prescribers via Medical Policy Alert. Update policies with new indication and update criteria.

Prior Authorization for Commercial:

PA PROGRAM NAME	Topical Agents for Skin Conditions
MEDICATION NAME	Zoryve
COVERED USES	1 - All FDA-Approved Indications
REQUIRED MEDICAL INFORMATION	For mild to moderate Atopic Dermatitis (Eucrisa®, Zoryve® 0.15% cream, and Opzelura® only): Patient must meet both of the following criteria: 1. Documentation of inadequate efficacy, intolerable side effects, or contraindication to both of the following: a. Two-week trial of moderate potency topical corticosteroids

	b. One-month trial of topical calcineurin inhibitor (such as tacrolimus ointment)

Prior Authorization for Medicaid:

PA PROGRAM NAME	Topical Agents for Skin Conditions - Medicaid
MEDICATION NAME	Zoryve
COVERED USES	1 - All FDA-Approved Indications
REQUIRED MEDICAL INFORMATION	For mild to moderate Atopic Dermatitis: Eucrisa, Zoryve® 0.15% cream, or Opzelura may be covered if there is documentation of contraindication, intolerance, or failed two-week trials of at least two different topical agents from one or both of the following categories i. Topical corticosteroids (e.g., mometasone, betamethasone, clobetasol) ii. Topical calcineurin inhibitors (e.g., tacrolimus)

5. **LIVMARLI** (maralixibat)
    a. Previous Indication(s):
        i. the treatment of cholestatic pruritus in patients 3 months of age and older with Alagille syndrome (ALGS)
        ii. the treatment of cholestatic pruritus in patients **5 years of age and older** with progressive familial intrahepatic cholestasis (PFIC).
    b. New indication approved 07/24/2024:
        i. the treatment of cholestatic pruritus in patients **12 months of age and older** with progressive familial intrahepatic cholestasis (PFIC)
    c. **RECOMMENDATION:** Inform prescribers via Medical Policy Alert. Update policy with new indication.

6. **VELPHORO** (sucroferric oxyhydroxide)
    a. Previous Indication(s):
        i. Velphoro is a phosphate binder indicated for the control of serum phosphorus levels in patients with chronic kidney disease on dialysis.
    b. New indication(s) approved 07/01/2024:
        i. Velphoro is a phosphate binder indicated for the control of serum phosphorus levels in **adult and pediatric patients 9 years of age and older** with chronic kidney disease on dialysis.
    c. **RECOMMENDATION:** Inform prescribers via Medical Policy Alert. No policy updates are required.

Therapies with Prior Authorization Policies (Oncology)

7. **DARZALEX FASPRO** (daratumumab and hyaluronidase-fihj)
    a. New indication(s) approved 07/30/2024:
        i. multiple myeloma in combination with bortezomib, lenalidomide, and dexamethasone for induction and consolidation in newly diagnosed patients who are eligible for autologous stem cell transplant
    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.

8. **KISQALI** (ribociclib)
    a. New indication(s) approved 07/22/2024:
        i. KISQALI is a kinase inhibitor indicated for the treatment of adults with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative advanced or metastatic breast cancer in combination with:
            1. an aromatase inhibitor as initial endocrine-based therapy; or
            2. fulvestrant as initial endocrine-based therapy or with disease progression following endocrine 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

9. **FIBRYGA** (Fibrinogen [Human])
    a. Previous Indication(s):
        i. fibrinogen supplementation in bleeding **patients** with acquired fibrinogen deficiency
        ii. treatment of acute bleeding episodes in patients with congenital fibrinogen deficiency, including afibrinogenemia and hypofibrinogenemia
        iii. FIBRYGA is not indicated for dysfibrinogenemia
    b. New indication(s) approved 07/31/2024:
        i. fibrinogen supplementation in bleeding **adult and pediatric patients** with acquired fibrinogen deficiency indication
    c. **RECOMMENDATION:** Inform prescribers via Medical Policy Alert.

Drug Safety Monitoring:

The following information is gathered from the United States Food and Drug Administration (FDA)

database from 4/1/2024– 4/30/2024

Safety Labeling Changes (NOT FDA Drug Safety Communications)

1. **Drug Class: Immune checkpoint inhibitors**
    - **Drug Names:** IMFINZI (DURVALUMAB); LOQTORZI (TORIPALIMAB-TPZI); TECENTRIQ (ATEZOLIZUMAB); ZYNYZ (RETIFANLIMAB-DLWR)
    - **Date Posted:** 04/22/2024
    - **Safety Labeling Change:** FDA has determined that risk of transplant (including corneal graft) rejection should be included in the labeling for the class of immune checkpoint inhibitors, including those listed above.
    - **Link to labels:** IMFINZI; LOQTORZI; TECENTRIQ; ZYNYZ
    - **Health Plan Recommendation:** Notify providers via Medical Policy Alert.

2. **Drug Name:** KESIMPTA (OFATUMUMAB)
    - **Date Posted:** 04/12/2024
    - **Safety Labeling Changes:**

  - "KESIMPTA can result in systemic injection-related reactions and hypersensitivity reactions, which may be serious or life-threatening."
  - "There is a pregnancy exposure registry that monitors pregnancy outcomes in women exposed to KESIMPTA during pregnancy."
- **Link to label:** KESIMPTA
- **What should health care professionals do:** "Healthcare providers are encouraged to enroll pregnant patients, or pregnant women may register themselves in the MotherToBaby Pregnancy Study in Multiple Sclerosis by calling 1-877-311-8972, by sending an email to MotherToBaby@health.ucsd.edu, or by going to www.mothertobaby.org/join-study."
- **Health Plan Recommendation:** Notify providers via Medical Policy Alert.

3. **Drug Name: SUBLOCADE** (BUPRENORPHINE)
   - **Date Posted:** 04/19/2024
   - **Safety Labeling Changes:** Sublocade (buprenorphine extended-release) injection can now be stored at room temperature for up to 12 weeks (previously 7 days).
   - **Link to letter:** **Approval Letter_209819Orig1s029ltr.pdf (fda.gov)**
   - **Health Plan Recommendation:** Notify providers via Medical Policy Alert.

Drug Recalls/Market Withdrawals

1. **Drug Name:** Sapropterin Dihydrochloride Powder for Oral Solution 100 mg/Javygtor™
   - **Date of Recall:** 04/23/2024
   - **Reason for recall:** Decreased Potency
   - **Link to more information:** Dr. Reddy's Issues Voluntary Nationwide Recall of Sapropterin Dihydrochloride Powder for Oral Solution 100 mg Due to Sub-Potency | FDA
   - **Health Plan Recommendation:** Notify providers via Medical Policy Alert.

2. **Drug Name:** Atovaquone Oral Suspension, USP 750mg/5mL
   - **Date of Recall:** 04/01/2024
   - **Reason for recall:** Potential Bacillus cereus contamination
   - **Link to more information:** AvKARE, LLC. Issues Voluntary Nationwide Recall of Atovaquone Oral Suspension, USP 750 mg/5 mL Due to Potential Bacillus Cereus Contamination | FDA
   - **Health Plan Recommendation:** Notify providers via Medical Policy Alert.

The following information is gathered from the United States Food and Drug Administration (FDA) database from

5/1/2024– 5/31/2024

Safety Labeling Changes (NOT FDA Drug Safety Communications)

1. **Drug Class:** Vascular endothelial growth factor (VEGF) inhibitor

- **Drug Names:** CIMERLITM (ranibizumab-eqrn)
- **Date Posted:** 05/21/2024
- **Safety Labeling Change:** FDA has determined that the addition of a new warning for retinal vasculitis with or without occlusion in the WARNINGS AND PRECAUTIONS and PATIENT COUNSELING INFORMATION sections of the Prescribing Information. Retinal vasculitis with or without occlusion, typically in the presence of preexisting intraocular inflammation or post-treatment with other intravitreal agents, have been reported with the use of ranibizumab products. Discontinue treatment with CIMERLI in patients who develop these events. Patients should be instructed to report any change in vision without delay.
- **Link to labels:** CIMERLITM
- **Health Plan Recommendation:** Notify providers via Medical Policy Alert.

Drug Recalls/Market Withdrawals

1. **Drug Name:** Buprenorphine Hydrochloride Injection Carpuject Units and Labetalol Hydrochloride Injection, USP Carpuject Units
   - **Date of Recall:** 05/22/2024
   - **Reason for recall:** Device & Drug Safety – Potential Packaging Defect
   - **Link to more information:** https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/hospira-inc-issues-voluntary-nationwide-recall-buprenorphine-hydrochloride-injection-carpujecttm
   - **Health Plan Recommendation:** Notify providers via Medical Policy Alert.

2. **Drug Name:** Docetaxel Injection, USP
   - **Date of Recall:** 05/29/2024
   - **Reason for recall:** Potential presence of particulate matter
   - **Link to more information:** https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/sagent-pharmaceuticals-issues-voluntary-nationwide-recall-docetaxel-injection-usp-due-potential
   - **Health Plan Recommendation:** Notify providers via Medical Policy Alert.

The following information is gathered from the United States Food and Drug Administration (FDA) database from

6/1/2024– 6/30/2024

Drug Recalls/Market Withdrawals

1. **Drug Name:** Potassium Chloride Extended Release 750mg Capsules, 100 count and 500 count
   - **Date of Recall:** 06/26/2024
   - **Reason for recall:** Failed dissolution
   - **Link to more information:** American Health Packaging on Behalf of BluePoint Laboratories Issues Voluntary Nationwide Recall for Potassium Chloride Extended-Release Capsules, USP (750 mg) 10 mEq K Due to Failed Dissolution | FDA
   - **Health Plan Recommendation:** Notify providers via Medical Policy Alert.

2. **Drug Name:** Potassium Chloride Extended Release 750mg Capsules, 100 count and 500 count
    - **Date of Recall:** 06/25/2024
    - **Reason for recall:** Failed dissolution
    - **Link to more information:** Glenmark Pharmaceuticals Inc., USA Issues Voluntary Nationwide Recall for Potassium Chloride Extended-Release Capsules, USP (750 mg) 10 mEq K Due to Failed Dissolution | FDA
    - **Health Plan Recommendation:** Notify providers via Medical Policy Alert.
        - The health plan took action by sending letters to all members with claims for this medication on 07/02/2024.

The following information is gathered from the United States Food and Drug Administration (FDA) database from

7/1/2024– 7/31/2024

Safety Labeling Changes (NOT FDA Drug Safety Communications)

1. **Drug Class:** ENZYME REPLACEMENT THERAPY
    - **Drug Names:** CEREZYME (imiglucerase); ELELYSO (taliglucerase alfa); VPRIV (velaglucerase alfa); FABRAZYME (agalsidase beta); NAGLAZYME (galsulfase); STRENSIQ (asfotase alfa); KANUMA (sebelipase alfa); BRINEURA (cerliponase alfa)
    - **Date Posted:** 07/10/2024
    - **Safety Labeling Change:** FDA has determined that enzyme replacement therapy represent a class of products that have a serious risk of hypersensitivity reactions, including anaphylaxis, and this boxed warning was recently added to the labeling for the class of enzyme replacement therapy, including those listed above
    - **Link to labels:** CEREZYME; ELELYSO; VPRIV; FABRAZYME; NAGLAZYME; STRENSIQ; KANUMA; BRINEURA
    - **Health Plan Recommendation:** Notify providers via Medical Policy Alert

Drug Recalls/Market Withdrawals

1. **Drug Name:** Dietary Supplements for Male Sexual Enhancement
    - **Date of Recall:** July 12, 2024
    - **Reason for recall:** Tainted with Sildenafil and Acetaminophen
    - **Link to more information:** https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/supercore-products-group-inc-issues-voluntary-worldwide-recall-hard-steel-capsules-gold-hard-steel
    - **Health Plan Recommendation:** Notify providers via Medical Policy Alert.

2. **Drug Name:** Umary
    - **Date of Recall:** 07/15/2024
    - **Reason for recall:** Tainted with the drug ingredients, diclofenac and omeprazole
    - **Link to more information:** https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/solovitalcom-issues-voluntary-nationwide-recall-umary-acido-hialuronica-suplemento-alimenticio-850

- **Health Plan Recommendation:** Notify providers via Medical Policy Alert.

3. **Drug Name:** Infla-650 Herbal Dietary Supplement Capsules
   - **Date of Recall:** 07/16/2024
   - **Reason for recall:** Tainted with the drug ingredients: acetaminophen, diclofenac and phenylbutazone
   - **Link to more information:** https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/guru-inc-issues-voluntary-nationwide-recall-infla-650-herbal-dietary-supplement-capsules-due-hidden
   - **Health Plan Recommendation:** Notify providers via Medical Policy Alert.

4. **Drug Name:** Clonazepam Orally Disintegrating Tablets, USP (C-IV) 0.25 mg tablets
   - **Date of Recall:** July 17, 2024
   - **Reason for recall:** Mislabeled with the incorrect strength on the carton
   - **Link to more information:** https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/endo-usa-inc-issues-voluntary-nationwide-recall-one-lot-clonazepam-orally-disintegrating-tablets-usp
   - **Health Plan Recommendation:** Notify providers via Medical Policy Alert.

5. **Drug Name:** Umary
   - **Date of Recall:** July 22, 2024
   - **Reason for recall:** Undeclared Drug Ingredients: Diclofenac and Omeprazole
   - **Link to more information:** https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/main-products-inc-issues-voluntary-nationwide-recall-umary-acido-hialuronico-suplemento-alimenticio
   - **Health Plan Recommendation:** Notify providers via Medical Policy Alert.

6. **Drug Name:** Acetaminophen Injection 1,000 mg per 100 mL (10 mg/mL) 100 mL
   - **Date of Recall:** July 22, 2024
   - **Reason for recall:** Potential presence of Dexmedetomidine HCL Injection (400mcg/100mL) inside the overwrap that is labelled Acetaminophen Injection, 1000mg/100mL, (10mg/mL)
   - **Link to more information:** https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/hikma-pharmaceuticals-usa-inc-extends-voluntary-nationwide-recall-one-lot-acetaminophen-injection
   - **Health Plan Recommendation:** Notify providers via Medical Policy Alert.
7. **Drug Name:** Migraine Relief Acetaminophen 250mg, Aspirin (NSAID) 250mg & Caffeine 65mg tablets
   - **Date of Recall:** July 24, 2024
   - **Reason for recall:** Device & Drug Safety – Mislabeling

- **Link to more information:** https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/aurobindo-pharma-usa-inc-behalf-aurohealth-issues-voluntary-nationwide-recall-one-1-lot-healthy
- **Health Plan Recommendation:** Notify providers via Medical Policy Alert.

Other Formulary Changes:

Drug Name	Recommendation	Policy Name
Diroximel fumarate (Vumerity) Capsule DR	Correction from August 2024 P&T: • Commercial: Remain on Formulary; not removed	Non-Preferred Fumarate Products
• **Sitagliptin (Januvia) Tablet** • **Sitagliptin/metformin (Janumet/Janumet XR) Tablet**	Correction from June 2024 P&T: • Commercial: Drugs were not moved to Tier 3, but remain on Tier 4	DPP-4 Inhibitors
Chlorzoxazone Tablet	Remove from Commercial and Medicaid formularies	N/A
Efavirenz/emtricit/tenofovr df (efavirenz-emtric-tenofov disop) 600-200 mg tablet	• Commercial Dynamic: Down tier from Tier 3 to Tier 2	N/A
Hydroxychloroquine Tablet	Add to Medicare Part D Formulary, Tier 2	N/A
Pomalidomide (Pomalyst) Capsule	• Commercial: Down tier from Tier 6 to Tier 5	Anti-Cancer Medications - Self-Administered
Tretinoin 0.05% Gel (Gram)	Remove from Commercial and Medicaid formularies	N/A
Docetaxel (Docivyx) Vial	New product; non-preferred docetaxel product • Commercial/Medicaid: Medical Benefit, Prior Authorization • Medicare Part D: Non-Formulary • Medicare Part B: Prior Authorization, Step Therapy	• Commercial/Medicaid: Anti-Cancer Medications - Medical Benefit • Medicare Part B: Anti-Cancer Medications - Medical Benefit Step Therapy
Halcinonide 0.1% solution	New product. Non-formulary for all lines of business	N/A
Ondansetron (Ondansetron OD) 16 mg Tab Rapdis	New strength; • 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
Sitagliptin-Metformin Tablet	New authorized generic; Non-formulary for all lines of business	N/A

Drug Name	Recommendation	Policy Name
Tocilizumab-bavi (Tofidence) Vial	New BLA; Non-preferred biosimilar • Commercial/Medicaid: Medical Benefit, Prior Authorization • Medicare Part D: Non-Formulary • Medicare Part B: Prior Authorization	Medically Infused Therapeutic Immunomodulators (Tims)
Tocilizumab-aazg (Tyenne Autoinjector) Pen Injctr / Syringe	New formulation/New entity; Preferred biosimilar • Commercial (preferred biosimilar to Actemra®): Formulary, Tier 6, Prior Authorization, Quantity Limit (3.6 mL per 28 days) • Medicaid: Non-Formulary, Prior Authorization, Quantity Limit (3.6 mL per 28 days) • Medicare Part D: Non- Formulary	• Commercial/Medicaid: Therapeutic Immunomodulators (TIMS) • Medicare Part D: N/A
Tociluzumab (Actemra) 162 mg/0.9 ml Disp Syring / Pen Inj	Removed from Commercial Formulary	Therapeutic Immunomodulators (TIMS) – Comm
Doxycycline hyclate 150 mg Tablet	• Add to Commercial Formulary, Tier 2 • Add to Medicaid Formulary	N/A
Hydrocortisone butyrate/emollient (Locoid Lipocream) Cream	• Add to Commercial Formulary, Tier 3 • Medicaid: Add to Formulary	N/A
Voclosporin (Lupkynis) Capsule	Remove from Medicaid formulary	Lupkynis
• **Abatacept (Orencia) Syringe / Auto Injct** • **Upadacitinib (Rinvoq/Rinvoq ER) tablet/solution** • **Golimumab (Simponi) Pen Injctr / Syringe** • **Ustekinumab (Stelara) Syringe / Vial** • **Tofacitinib citrate (Xeljanz/ Xeljanz XR) Solution / Tablet**	Remove from Medicaid formulary	Therapeutic Immunomodulators (TIMS) – Medicaid
Prednisone (Rayos) Tablet DR	Add to Medicaid formulary	New Medications and Formulations without Established Benefit
Desoximetasone Topical Spray	• Add to Commercial Formulary, Tier 2 • Add to Medicaid Formulary	New Medications and Formulations without Established Benefit
Inebilizumab-cdon (Uplizna) Vial	Add to Medicaid formulary with Prior Authorization	Uplizna

Drug Name	Recommendation	Policy Name
Bepotastine besilate (Bepreve) Drops	• Commercial Standard: Formulary, Tier 2, Prior Authorization • Commercial Dynamic: Formulary, Tier 4, Prior Authorization	Bepreve, Zerviate
Cetirizine hcl (Zerviate) Droperette	• Formulary, Tier 4, Prior Authorization	Bepreve, Zerviate
Testosterone undecanoate (Jatenzo) Capsule	Add to Commercial Formulary, Tier 4	Hormone Replacement Therapy
Epinephrine Auto Injectors	• Commercial/Medicaid: Change Quantity Limit to one 2-pack (2 pens) per 30 days	N/A
Vedolizumab (Entyvio) pen injector	Add to Commercial formulary as preferred product: Formulary, Tier 5, Prior Authorization, Quantity Limit (1.36 mL per 28 days)	Therapeutic Immunomodulators (TIMS) – Comm
Adalimumab-adaz (Hymrioz®)	Add low list price products to Commercial formulary as preferred biosimilar: Formulary, Tier 5, Prior Authorization, Quantity Limit (two injections per 28 days)	Therapeutic Immunomodulators (TIMS) – Comm
Adalimumab-aaty (Yuflyma) Autoinjkit / Syringekit	Add low list price products to Commercial formulary as preferred biosimilar: Formulary, Tier 5, Prior Authorization, Quantity Limit (two injections per 28 days)	Therapeutic Immunomodulators (TIMS) – Comm
Mirikizumab-mrkz (Omvoh) Pen Injctr / Syringe	Add to Commercial formulary as preferred product: Formulary, Tier 5, Prior Authorization, Quantity Limit (2 mL per 28 days)	Therapeutic Immunomodulators (TIMS) – Comm
Deucravacitinib (Sotyktu) Tablet	Down-tier for Commercial as preferred product: Formulary, Tier 5, Prior Authorization, Quantity Limit (one tablet per day)	Therapeutic Immunomodulators (TIMS) – Comm
Sacubitril/valsartan (Entresto Sprinkle®) pellet capsule	Non-formulary for all Lines of business: • Commercial/Medicaid: Quantity Limit (eight capsules per day)	N/A
Mycophenolate mofetil (Myhibbin) oral suspension	New Entity; Non-formulary for all lines of business	N/A
Balsalazide 750 mg (Colazal)	Commercial Dynamic: Up tier generic to Tier 4	N/A
• **Mesalamine (Canasa) 1000 mg Suppositories** • **Mesalamine (Lialda DR) 1.2-gram Tablets**	• Commercial Dynamic: Down tier generic from Tier 4 to Tier 3 • Medicare Part D: Down tier generic from Tier 4 to Tier 3	N/A
Mesalamine (Apriso ER) 0.375 g	Commercial Dynamic: Up tier brand to Tier 4	N/A

Drug Name	Recommendation	Policy Name
• **Mesalamine (Pentasa) 500 mg ER Capsules** • **Mesalamine (Asacol HD) 800 mg DR Tablets**	Remove from Commercial formulary	N/A
Mesalamine (Pentasa) 250 mg ER capsules	Remove from Commercial formulary; Update quantity limit to 16 capsules per day	N/A
Sulfasalazine (Azulfidine Entab) 500 mg EC	• Commercial Dynamic: Down tier generic from tier 3 to tier 2 • Medicare Part D: Down tier generic from Tier 3 to Tier 2	N/A

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

Pharmacy Operational Policy ORPTCOPS062

INFORMATIONAL ONLY

NEW DRUGS / COMBINATIONS / STRENGTHS / DOSAGE FORMS		
Drug Name	**Action Taken**	**Policy Name**

Selpercatinib (Retevmo) Tablet	New formulation (tablets). Line extend with Retevmo capsules;
	• Commercial: Formulary, Tier 6, Prior Authorization, Quantity Limit:
	  ○ 40 mg tab: 6 tablets per day
	  ○ 80 mg tab: 4 tablets per day
	  ○ 120 mg tab: 2 tablets per day
	• Medicaid: Formulary, Prior Authorization, Quantity Limit:
	  ○ 40 mg tab: 6 tablets per day
	  ○ 80 mg tab: 4 tablets per day
	  ○ 120 mg tab: 2 tablets per day
	• Medicare Part D: Formulary, Tier 5, Prior Authorization, Quantity Limit:
	  ○ 40 mg tab: 6 tablets per day
	  ○ 80 mg tab: 4 tablets per day
	  ○ 120 mg tab: 2 tablets per day
		Anti-Cancer Medications - Self-Administered

NEW DRUGS / COMBINATIONS / STRENGTHS / DOSAGE FORMS		
Drug Name	**Action Taken**	**Policy Name**
Maralixibat chloride (Livmarli) Solution	New strength. Line extend with Livmarli 9.5mg/ml; • Commercial/Medicaid: Non-Formulary, Prior Authorization, Quantity Limit (2 mL per day), Specialty • Medicare Part D: Non-Formulary	• Commercial/Medicaid: Cholestatic Pruritus Agents • Medicare Part D: N/A
Pegunigalsidase alfa-iwxj (Elfabrio) Vial	New strength. Line extend with Elfabrio 2 mg/mL intravenous solution; • Commercial/Medicaid: Medical Benefit, Prior Authorization • Medicare Part D: Non-Formulary • Medicare Part B: Prior Authorization	Enzyme Replacement Therapy
Rozanolixizumab-noli (Rystiggo) Vial	New strength. Line extend with other Rystiggo strengths; • Commercial/Medicaid: Medical Benefit, Prior Authorization, Specialty • Medicare Part D: Non-Formulary • Medicare Part B: Prior Authorization	FcRn Antagonists
Corticotropin (Acthar Selfject) Pen Injctr	New strength. Line extend with Acthar Gel; • Commercial: Formulary, Tier 6, Prior Authorization, Specialty • Medicaid: Formulary, Prior Authorization, Specialty • Medicare Part D: Non-Formulary	• Commercial/Medicaid: HP Acthar Gel • Medicare Part D: N/A
Methocarbamol (Tanlor) Tablet	New MedID. Line extend with methocarbamol 1000 mg; • Commercial/Medicaid: Non-Formulary, Prior Authorization • Medicare Part D: Non-Formulary	• Commercial/Medicaid: New Medications and Formulations without Established Benefit • Medicare Part D: N/A
Adalimumab-ryvk (Adalimumab-RYVK [CF]) Syringekit	New formulation (syringekit). Line extend as non-preferred biosimilar; • Commercial/Medicaid: Non-Formulary, Prior Authorization, Quantity Limit (2 syringes per 28 days) Specialty • Medicare Part D: Non-Formulary	• Commercial/Medicaid: Therapeutic Immunomodulators (TIMS) • Medicare Part D: N/A

NEW DRUGS / COMBINATIONS / STRENGTHS / DOSAGE FORMS		
Drug Name	**Action Taken**	**Policy Name**
Apremilast (Otezla) Tablet	New strength. Line extend with other Otezla; • Commercial: Formulary, Tier 5, Prior Authorization, Quantity Limit (2 tablets per day) • Medicaid: Non-Formulary, Prior Authorization, Quantity Limit (2 tablets per day), Specialty • Medicare Part D: Formulary, Tier 5, Prior Authorization	Therapeutic Immunomodulators (TIMS)
Apremilast (Otezla) Tab DS PK	New strength. Line extend with other Otezla; • Commercial: Formulary, Tier 5, Prior Authorization, Quantity Limit (1 claim per 365 days) • Medicaid: Non-Formulary, Prior Authorization, Quantity Limit (1 claim per 365 days), Specialty • Medicare Part D: Formulary, Tier 5, Prior Authorization	Therapeutic Immunomodulators (TIMS)
Ixekizumab (Taltz 20 mg/0.25 & 40 mg/0.5 mL) Syringe	New strength. Line extend with Taltz; • Commercial: Formulary, Tier 6, Prior Authorization, Quantity Limit (one syringe per 28 days) • Medicaid: Non-Formulary, Prior Authorization, Quantity Limit (one syringe per 28 days), Specialty • Medicare Part D: Non-Formulary	• Commercial/Medicaid: Therapeutic Immunomodulators (TIMS) • Medicare Part D: N/A
Roflumilast (Zoryve) 0.15% Cream	New strength. Line extend with Zoryve 0.3%; • Commercial/Medicaid: Non-Formulary, Prior Authorization, Quantity Limit (60 gm per 30 days) • Medicare Part D: Non-Formulary	• Commercial/Medicaid: Topical Agents for Skin Conditions • Medicare Part D: N/A
Deutetrabenazine (Austedo XR) Tab ER 24H	New strength. Line extend with Austedo XR; • Commercial: Formulary, Tier 6, Prior Authorization, Quantity Limit (1 tablet per day) • Medicaid: Formulary, Prior Authorization, Quantity Limit (1 tablet per day), Specialty • Medicare Part D: Non-Formulary	• Commercial/Medicaid: VMAT2 Inhibitors • Medicare Part D: N/A

NEW DRUGS / COMBINATIONS / STRENGTHS / DOSAGE FORMS		
Drug Name	**Action Taken**	**Policy Name**
Deutetrabenazine (Austedo XR titration kt(wk1-4)) Tab 24H DSPK	New strength (titration pack). Line extend with Austedo XR; • Commercial: Formulary, Tier 6, Prior Authorization, Quantity Limit (1 claim per 365 days) • Medicaid: Formulary, Prior Authorization, Quantity Limit (1 claim per 365 days), Specialty • Medicare Part D: Non-Formulary	• Commercial/Medicaid: VMAT2 Inhibitors • Medicare Part D: N/A
Tirzepatide (Zepbound) Vial	New strength. Line extend with Zepbound pen injector; • Commercial/Medicaid: Non-Formulary, Prior Authorization, Quantity Limit (2 mL per 28 days) • Medicare Part D: Non-Formulary	• Commercial/Medicaid: Weight Management Medications • Medicare Part D: N/A
Vigabatrin (Vigafyde) Solution	New formulation; Line extend with vigabatrin for Medicare Part D: Formulary, Tier 5, Step Therapy, Quantity Limit (30 mL per day)	Antiepileptics Step Therapy

NEW GENERICS		
Drug Name	**Action Taken**	**Policy Name**
Tacrolimus (Astagraf XL) Cap ER 24h	First Generic (Astagraf XL). Line extend as generic; • Commercial Standard: Formulary, Tier 2 • Commercial Dynamic: Formulary, Tier 4 • Medicaid: Formulary • Medicare Part D: Non-Formulary	N/A
Hydrocodone bit/homatrop me-br (Hycodan) Syrup	First generic drug (Hycodan). Line extend as generic; • Commercial: Formulary, Tier 2 • Medicaid: Formulary • Medicare Part D: Non-Formulary	N/A
Lofexidine hcl Tablet	First generic drug (Lucemyra). Line extend as generic;	N/A

NEW GENERICS		
Drug Name	**Action Taken**	**Policy Name**
	• Commercial Standard: Formulary, Tier 2, Quantity Limit (224 tablets per 30 days) • Commercial Dynamic: Formulary, Tier 4, Quantity Limit (224 tablets per 30 days) • Medicaid: Formulary, Quantity Limit (224 tablets per 30 days) • Medicare Part D: Non-Formulary	
Oxycodone hcl Tablet	First generic drug (Roxybond). Line extend as generic; • Non-Formulary for all Lines of Business	N/A
Ivabradine hcl Tablet	First generic drug (Corlanor). Line extend as generic; • Commercial Standard: Formulary, Tier 2, Prior Authorization • Commercial Dynamic: Formulary, Tier 4, Prior Authorization • Medicaid: Formulary, Prior Authorization • Medicare Part D: Formulary, Tier 4, Quantity Limit (2 tablets per day)	Corlanor
Glutamine (L-Glutamine) Powd Pack	First generic drug (Endari). Line extend as generic; • Commercial/Medicaid: Non-Formulary, Specialty • Medicare Part D: Formulary, Tier 5, Step Therapy, Quantity Limit (6 packets per day)	• Commercial/Medicaid: N/A Medicare Part D: Endari
Edaravone Piggyback	First generic drug (Radicava). Line extend as generic; • Commercial/Medicaid: Medical Benefit, Prior Authorization, Specialty • Medicare Part D: Non-Formulary Medicare Part B: Prior Authorization	• Radicava, Radicava ORS

Clinical Policy Changes:

1. Major Changes:

Policy Name	Summary of Change
Bepreve, Zerviate	Reactivated retired policy to meet required drug class counts for Commercial formularies. Effective: 11/01/2024
Camzyos	Updated trial and failure criteria to align with updated guidelines. Policy now requires trial and failure of ONE of the following (instead of two): beta blockers or calcium channel blockers. Disopyramide removed from trial and failure options.
• **Complement Inhibitors** • **Complement Inhibitors Prior Authorization and Step Therapy Policy - Medicare Part B**	Added required trial of Empaveli® (in addition to Ultomiris®) for Soliris and fabhalta for paroxysmal nocturnal hemoglobinuria (PHN). Defined reauthorization criteria for neuromyelitis optica spectrum disorder (NMOSD) as reduction in relapses.
Compounded Drugs	Coverage criteria was clarified to ensure compounded medications are not being made to mimic FDA approved drugs, unless medical rationale is provided. This was added to combat issues with compounding providers using semaglutide to compound similar formulations of therapy (injections and oral use) to circumvent use of FDA approved products.
Continuous Glucose Monitors for Personal Use	Criterion was added for coverage in patients with gestational diabetes (with or without inuslin use).
Enspryng	Added requirement to rule out other diagnoses, reduced coverage duration for initial authorization to three months to align with similar medications, and clarified reauthorization requirement. For Medicaid, added prescriber restriction (neurologist) and trial/failure of rituximab.
• **FcRn Antagonists** • **FcRn Antagonists Prior Authorization and Step Therapy Policy - Medicare Part B**	Added exclusions of combination treatment with other immunomodulatory biologic therapies (such as rituximab, Soliris, Ultomiris, Vyvgart, Rystiggo), Updated reauthorization criteria to require improvement for initial authorization and sustained improvement for subsequent reauthorizations.
Formulary and Quantity Limit Exceptions	Criteria updated to clarify prior authorization criteria and formulary exception criteria must both be met for non-formulary reviews. Removed Medicaid from policy, as these requirements are outlined in separate Medical Necessity policy for Medicaid.
Hormone Replacement Therapy	Kyzatrex® was removed from the prerequisite therapy requirements, as this product is only available as "cash pay" directly from the manufacturer and not eligible for insurance billing. Also clarified that compounded testosterone pellets are not covered as they are not FDA approved. Testopel® is the FDA approved pellet formulation. Effective: 11/01/2024
Hormone Replacement Therapy Prior Authorization and Step Therapy Policy - Medicare Part B	Clarified that compounded testosterone pellets are not covered as they are not FDA approved or eligible for coverage through Medicare. Testopel® is the FDA approved pellet formulation.
• **IL-5 Inhibitors** • **Il-5 Inhibitors Prior Authorization and Step Therapy – Medicare Part B**	Fasenra® and Nucala® will be preferred agents (over Cinqair®). For eosinophilic asthma, added criteria to allow coverage for corticosteroid-dependent patients. Updated prescriber restrictions to make more generalized. Minor updates to criteria for the indication of hypereosinophilic syndrome.

Interleukin-1 Inhibitors	Added prescriber restrictions for Commercial to align with other insurers. For gout flares, added criteria that provider attests that repeat courses of corticosteroids are not appropriate per FDA indication and decreased coverage duration. For recurrent pericarditis, updated criteria to align with EULAR guideline that recommends NSAIDs or glucocorticoids PLUS colchicine.
Interleukin-1 Inhibitors Prior Authorization and Step Therapy – Medicare Part B	Added prescriber restrictions for Commercial to align with other insurers. For gout flares, added criteria that provider attests that repeat courses of corticosteroids are not appropriate per FDA indication and decreased coverage duration.
• **Medically Infused Therapeutic Immunomodulators (Tims) – Comm** • **Medically Infused Therapeutic Immunomodulators (TIMs) Prior Authorization and Step Therapy Policy - Medicare Part B**	Updated criteria for immune checkpoint inhibitor toxicity to align with NCCN guidelines, added criteria for non-radiographic axial spondyloarthritis and juvenile arthritis, removed criteria for systemic interstitial lung disease as only subcutaneous tocilizumab formulation is approved for this indication.
New Medications and Formulations without Established Benefit	Removed obsolete medications. Removed several medications that will remain non-formulary. Coverage may be authorized for these medications if formulary alternatives are tried or deemed not appropriate.
Saphnelo	Added nephrologist to prescriber restrictions.
Self-Administered Drugs (SAD) Policy	Several drugs were added to this policy, requiring use of self-administered products. These include Bimzelx®, Wainua®, Omvoh®, Spevigo®, and ustekinumab biosimilars (Selarsdi®, Wezlana®, Pyzchiva®)
Sylvant	Updated coverage duration to call out off-label uses will require case-by-case review since use in some indications may be used for short duration (such as one-time use for CAR-T related toxicities).
Therapeutic Immunomodulators (TIMS) - Comm	Updated prescriber restrictions and preferred drugs to align with cost-positioning contracts.
Therapeutic Immunomodulators (TIMS) – Medicaid	Updated criteria to align with Oregon Health Authority (OHA). Specifically, reauthorization criteria for atopic dermatitis and hidradenitis suppurativa were updated. Removed criteria for polymyalgia rheumatica as OHA does not have disease specific criteria. Updated immune checkpoint inhibitor criteria to encompass all related toxicities as outlined by NCCN guidelines.
Transthyretin (TTR) Lowering Agents	Added criteria for requiring baseline platelet count to be >100 x 109/L for Tegsedi®
Trientine	Clarified that if approved, only the generic 250 mg capsule will be covered and that brand-name Syprine® will require additional criteria for approval if requested over the generic formulation.
Uplizna	Added requirement to rule out other diagnoses and for trial/failure of Enspryng (in addition to rituximab). Added prescriber requirement and trial/failure of rituximab to Medicaid criteria. Reduced coverage duration for initial to 3 months, clarify reauthorization requirement.
Uplizna Prior Authorization and Step Therapy Policy - Medicare Part B	Add requirement to rule out other diagnoses, add trial/failure of Enspryng, reduce coverage duration for initial to 3 months, clarify reauthorization requirement.
Weight Management Medications	Updated criteria to align with new indication for Wegovy® for reducing cardiovascular risk in obesity. This medication/indication continues to only be covered for groups with weight loss benefit only.

Weight Management Medications – Medicaid	Updated criteria to align with the Oregon Health Authority coverage criteria.
Xiaflex	For Dupuytren's Contracture: removed tabletop test requirement. For Peyronie's disease: removed documentation of functional impairment, counseling requirements, and some exclusions that posed operational challenges for review (such as calcified plaque/significant pain/proximal plaque).
• **Xolair** • **Xolair Prior Authorization and Step Therapy Policy – Medicare Part B**	Updates were made to prescriber restrictions. Effective: 11/01/2024

2. **Deferred Policies: -** The following policies reviews are being deferred, to Click or tap to enter a date. ORPTC, for further evaluation:

Policy Name	
Calcitonin Gene-Related Peptide (CGRP) Receptor Antagonists – Comm	Medications For Rare Indications
Enzyme Replacement Therapy	Tysabri
Enzyme Replacement Therapy Prior Authorization and Step Therapy Policy - Medicare Part	

3. **Retired Policies:**

Policy Name	Summary of Change
• **Korsuva** • **Korsuva Prior Authorization and Step Therapy Policy - Medicare Part B**	Due to low risk of inappropriate utilization.