Providence Health Plan

Providence Health Assurance

Healthcare Services: Medical, Pharmacy, Reimbursement, and Coding Policy Alerts

Number 121

August 1, 2026

This is the August 1, 2026 issue of the Providence Health Plans, Providence Health Assurance and Providence Plan Partners, Policy Alert to our providers. The focus of this update is to communicate to providers' new or revised Medical, Pharmacy, Reimbursement, and Coding policy changes. The Health Plan has a standard process to review all 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 subsequent 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

Neuromuscular Drugs Claims Edit Implementation

Effective October 1, 2026, Providence Health Plan will implement a claims editing process for select neuromuscular drugs, including Botox® and other botulinum toxin products.

For Commercial members, claims will be evaluated based on the presence of a medically necessary diagnosis code and applicable FDA-approved minimum age requirements for the billed indication. For Medicare members, claim adjudication will align with the covered diagnosis codes and coverage criteria outlined in the applicable Noridian Local Coverage Article (LCA) for botulinum toxin injections.

Providers are encouraged to ensure that submitted claims include diagnosis coding that accurately reflects the member's condition and supports medical necessity consistent with applicable FDA labeling and Medicare coverage guidance.

COMPANY POLICIES

Effective 8/1/2026

Corneal Collagen Cross-Linking **MP158**	**Policy Updates:** • Broadened criterion I. to allow FDA-approved corneal cross-linking products (i.e. Photrexa and Epioxa). • Revised criterion III.A.1 to explicitly exclude non-FDA-approved products (i.e. products other than Photrexa and Epioxa). ○ Photrexa manufacturing ended in February 2026 and remaining supply has been exhausted while manufacturer introduces their new product "Epioxa," which was FDA-approved for epithelium-on CXL October 2025. **Codes/PA:** J2789 – remove NMN denial and add PA

Effective 9/1/2026

Lipid Testing **MP304**	**Policy Updates:** No changes to criteria. **Codes/PA:** Updated list of pair-to-pay codes based on Medicare criteria.

Effective 10/1/2026

Walkers **MP212**	**Policy Updates:** • No changes to criteria. • Updated "Billing Guidelines" - clarify that certain walker accessory codes are conditionally bundled (t07) and only denied when billed with specific base codes, aligned to CMS LCA A52503 with added table detail. **Codes/PA:** Added "not medically necessary" configuration to E0150 (Rollz Motion walker), following CMS guidance.
Colorectal Cancer Screening **MP106**	**Policy Updates:** Added medical necessity criteria for ColoSense test (Criterion VI). **Codes/PA:** Removed configuration from CPT 0421U
Urinary Dysfunction Treatments **MP180**	**Policy Updates:** Added criterion IV for repeat treatment with injectable bulking agents. **Codes/PA:** Removed termed codes.

MEDICARE POLICIES

Effective 9/1/2026

Circulating Tumor Cell and DNA Assays for Cancer Management **MP306**	**Policy Updates:** Changes include the following: • Update LCDs & LCAs for JF service areas when needed. • Updated LCA for Colvera test (A52986 to A59125). • Updated coverage or non-coverage of tests as necessary based on DEX Registry entries, as well as adding detailed description of why each test is not covered. **Codes/PA:** • Code 0487U: Termed NMN denial, added PA.
Urinary Dysfunction Treatments **MP231**	**Policy Updates:** Changes include the following: • Removed external male catheters or female urinary collection devices (*excluding* PureWick) from policy because the codes to report these items are not included in policy scope. • Added CPT and HCPCS codes to the criteria table for clarity. • Changed criteria for the Flyte System (E0715, E0716) and Vivally® system operated by smartphone (E0737) from using Company criteria to using Medicare-based instruction (no change to non-coverage position). **Codes/PA:** While no change to criteria for the InFlow system, termed NMN (u21) denial for 0596T & 0597T based on LCD statements. No change to other codes or configuration.
Electrical Stimulation and Electromagnetic Therapies **MP333**	**Policy Updates:** Changes include the following: Clarify requirements regarding the Reactiv8 System. The policy states the language seen is based on a Noridian billing & coding local coverage article (LCA) for peripheral nerve stimulation; however, this LCA was updated in June 2025, and the language currently found in the Plan's policy is no longer supported by the LCA as of 6/2025. **Codes/PA:** No change to codes or configuration with this update.

Effective 10/1/2026

Walkers **MP211**	**Policy Updates:** Changes to policy include the following: • Rearranged order of items in the "Criteria" table to address non-covered items first, then continue with general criteria. • Specified source of non-coverage for Rollz Motion device. • Added detailed information around why the Rollz Motion walker (E0150) is not covered under "Policy Guideline" section.

	• Several codes have “separate reimbursement” denials (t07) in place if reported with other HCPCS codes. Details on these denials was added to the “Billing/Coding” section of the policy. • Updated “References.” **Codes/PA:** Added NMN denial to E0150 consistent with Medicare coverage policy. No change to other codes or their configuration.

ARCHIVE

Effective 8/1/2026

Negative Pressure Wound Therapy **MP192**	**Policy Updates:** Archived negative pressure wound therapy (NPWT) medical policy due to limited utilization management measures in place **Codes/PA:** Termed all medical policy configuration on codes ***EXCEPT*** for code A9272. HCPCS A9272 will continue to deny u21 (not medically necessary, or NMN),but will transfer to the Medicare DMEPOS policy to reference instead.
Proton Beam Radiation Therapy **MP340**	**Policy Updates:** Archived policy due to low utilization **Codes/PA:** Termed PA on codes 77550-77525. HCPCS code S8030 will continue to deny as invalid per Coding Policy 22.0.

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

Pharmacy & Therapeutics (P&T) Committee

Oregon Region P&T Committee Meeting June 5, 2026
Go-Live Date: Saturday, August 01, 2026, unless otherwise noted

Providence Health Plan

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Clinical Policy Changes:

POLICY NAME	POLICY CHANGE SUMMARY
Benlysta	Subcutaneous age restriction changed to 5 years and older for lupus nephritis. Added criteria for coverage of intravenous product (self-administration is preferred). Simplified wording for quantity limit.
Brinsupri	Policy criteria reworded to provide more clarity for number of non-cystic fibrosis bronchiectasis exacerbations per year that are required.
Camzyos	Updated indication to restrict to hypertrophic obstructive cardiomyopathy, consistent with FDA label. Added exclusion to preclude use of concurrent use with another cardiac myosin inhibitor.
CFTR Modulators	Updated corresponding criteria requirements to require mutations responsive to these drugs (in vivo or in vitro) per table/package insert
Corlanor	Added criteria for patients established on therapy
Elidel, Protopic (Medicaid)	Add requirement for trial of tacrolimus for pimecrolimus coverage
Geographic Atrophy Agents	Criteria choroidal neovascularization (CNV) criteria to clarify the eye being treated. Updated quantity limit information for Izervay to specify how many eyes are being treated. Updates Syfovre criteria to include baseline visual acuity score, correlating with inclusion criteria in Syfovre clinical trials.
GLP-1 Receptor Agonists and Related Medications for Non-diabetes Indications – Medicaid	Updated criteria for obstructive sleep apnea to require current body mass index (within 30 days). Made Zepbound KwikPen preferred over other Zepbound formulations.

• **Homozygous Familial Hypercholesterolemia (HoFH) Agents** • **Homozygous Familial Hypercholesterolemia (HoFH) Agents Prior Authorization Policy - Medicare Part B**	Added medical quantity limit criteria for Evkeeza.
• **Immune Gamma Globulin (IgG)** • **Immune Gamma Globulin (IGG) Prior Authorization and Step Therapy Policy - Medicare Part B**	Removed criteria requiring plasma exchange for Guillain Barre syndrome as American Academy of Neurology notes both plasma exchange (PE) and immune globulins have strong evidence of support but PE may carry greater risk of side effects and is more difficult to administer.
Intranasal Allergy Medications - Medicaid	Updated preferred drug to include azelastine and removed restrictions on ipratropium and cromolyn nasal sprays to align with the Oregon Health Authority.
Lodoco	Added statin, blood pressure, aspirin, and prescriber requirements for the Oregon Health Authority to align with Commercial.
Medically Infused Therapeutic Immunomodulators (Tims) - Comm	Require medical necessity for intravenous administration of secukinumab, abatacept, and tocilizumab over self-administration.
Nexletol, Nexlizet	Criteria updated to align with new guideline recommendations. For primary prevention, coronary artery calcium (CAC) score was added as an indicator of high risk of cardiovascular disease. Pre-treatment LDL cholesterol levels were updated to require at least 70 mg/dL (or 55 for high risk of recurrent disease).
Oxervate	Remove optometrist from prescriber restriction and allow only ophthalmologist.
• **PCSK-9 Inhibitors – Commercial** • **PCSK-9 Inhibitors – Medicaid**	Criteria updated to align with new guideline recommendations (LDL goal updates) and updated package labeling (new indications).
PCSK9 Inhibitors Prior Authorization Policy – Medicare Part B	Added new hypercholesterolemia indication and removed atherosclerotic cardiovascular disease (ASCVD) secondary prevention indication based on package insert updates. Policy changed to Medicare Part B step therapy as statin step requirement is no longer part of the FDA approved indication.
Pulmonary Hypertension	Added Tyvaso to Tyvaso DPI criteria requiring use of Yutrepia. Removed Ventavis as medication is obsolete. Added quantity limit criteria that dosing must follow FDA labeling or compendia supported guidelines

Pulmonary Hypertension Prior Authorization and Step Therapy Policy - Medicare Part B	Updated policy to align with Medicare Local Coverage Determination with specific criteria for epoprostenol (Flolan and Veletri only) and treprostinil (Remodulin only): 1) diagnosis requires mean pulmonary artery pressure greater than 25 mm Hg at rest or 30 mm Hg with exertion, and 2) condition must have progressed despite maximal medical and/or surgical treatment of the identified condition, including calcium channel blockers if appropriate. Added quantity limit criteria that dosing must follow FDA labeling or compendia supported guidelines. Added step through Yutrepia for Tyvaso to align with other lines of business.
Redemplo, Tryngolza	Changed Tryngolza to be preferred medication; therefore, Redemplo will require failure of Tryngolza prior to coverage.
Therapies for Interstitial Lung Diseases Policy	Removed Jascayd from policy for Medicaid as this is a high-cost drug carve-out and directly management by OHA. Removed 8 week duration requirement for combo therapy with Jascayd and another product, added requirement for trial and failure of generic nintedanib prior to coverage of Jasccayd for chronic fibrosing interstitial lung diseases with a progressive phenotype.
Topical Agents for Skin Conditions - Medicaid	Removed specific requirements defining severity of disease for children due to Oregon Health Authority rules regarding Early and Periodic Screening, Diagnostic and Treatment (EPSDT).
Transthyretin (TTR) Stabilizing Agents	Updated criteria requiring signs/symptoms of heart failure to include OR hospitalization to align with other insurers and Amvuttra criteria.
Upneeq	Quantity limit updated to allow for treatment of two eyes.
Vascepa	Added criteria for patients established on therapy to have shown a reduction in triglyceride levels from pre-treatment. Updated coverage duration to one year on initial authorization.

Other Formulary Changes:

Drug Name	Action Taken	Policy Name
Estradiol/norethindrone acet 1 mg/0.5 mg Tablet (Abigale, Mimvey)	Commercial Dynamic: Down tier generic from Tier 3 to Tier 2	N/A
Estradiol/norethindrone acet 0.5 mg/0.1 mg Tablet (Abigale Lo)	Commercial Dynamic: Down tier generic from Tier 4 to Tier 3	N/A
Clonidine HCL ER Tablet	Commercial Dynamic: Down tier generic from Tier 4 to Tier 2	N/A

Desloratadine Solution	Medicaid: Add Prior Authorization	Second and Third Generation Antihistamines - Medicaid
Relugolix/estradiol/norethindrone (Myfembree) Tablet	Commercial: Add to Formulary, Tier 3	GnRH Antagonists
• **Elagolix/estradiol/norethindrone (Oriahnn) Tablet** • **Elagolix sodium (Orilissa) Tablet**	Commercial: Down tier from Tier 4 to Tier 3	GnRH Antagonists
Estrogen,con/m-progest acet (Prempro) Tablet	Commercial: Down tier from Tier 4 to Tier 3	N/A
Testosterone 1% Gel (Gram)	Commercial Dynamic: Down tier generic from Tier 4 to Tier 2	N/A
Testosterone enanthate (Xyosted) Auto Injct	Commercial: Add to Formulary, Tier 4	Medical Hormone Therapy Policy
• **Lisdexamfetamine dimesylate (Arynta) Solution** • **Methocarbamol (Atmeksi) Oral Susp** • **Desmopressin acetate (Desmoda) Solution**	New formulations; • Non-Formulary for all lines of business	N/A
Tocilizumab-anoh (Avtozma) Pen Injctr / Syringe	New biosimilar; non-preferred • Commercial/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
Bimatoprost 0.01% Drops	New generic; • Commercial: Formulary, Tier 3, Step Therapy, Quantity Limit (0.1 mL per day) • Medicaid: Formulary, Step Therapy, Quantity Limit (0.1 mL per day) • Medicare Part D: Formulary, Tier 3	• Commercial/Medicaid: Anti-Glaucoma Agents Step Therapy • Medicare Part D: N/A
Fosfomycin disodium (Contepo) Vial	New entity; • Medical Benefit for all lines of business	N/A
Immune globulin,gamma(igg)kthm (Qivigy) Vial	New entity;	Immune Gamma Globulin (IgG)

	• Medical Benefit, Prior Authorization for all lines of business	
Gabapentin (Relgaabi) Capsule	New entity; • Commercial/Medicaid: Non-Formulary • Medicare Part D: Formulary, Tier 4, Quantity Limit (3 capsules per day)	N/A
Leucovorin calcium (Vykoura) Vial	New formulation; • Medical Prior Authorization for all lines of business	Anti-Cancer Medications - Medical Benefit
Semaglutide (Wegovy HD) Pen Injctr	New strength (7.2 mg/0.75); • Commercial Standard: Formulary, Tier 3, Prior Authorization, Quantity Limit (3 mL per 28 days) • Commercial Dynamic: Non-Formulary, Prior Authorization, Quantity Limit (3 mL per 28 days) • Medicaid: Non-Formulary, Prior Authorization, Quantity Limit (3 mL per 28 days) • Medicare Part D: Non- Formulary	• Commercial/Medicaid: GLP-1 Receptor Agonists and Related Medications for Non-Diabetes Indications • Medicare Part D: N/A
Carbachol/brimonidine tartrate (Yuvezzi) Droperette	New combination; • Commercial/Medicaid: Non-Formulary, Prior Authorization • Medicare Part D: Non- Formulary	• Commercial/Medicaid: Eye Drops for Presbyopia • Medicare Part D: N/A
• **Aflibercept (Eylea)** • **aflibercept-ayyh (Pavblu)** • **Ranibizumab (Lucentis)** • **Ranibizumab-nuna (Byooviz)** • **Ranibizumab-eqrn(Cimerli)**	Add Medical Prior Authorization for all lines of business	• Ophthalmic Vascular Endothelial Growth Factor (VEGF) Inhibitors • Ophthalmic Vascular Endothelial Growth Factor (VEGF) Inhibitors Prior Authorization and Step Therapy Policy - Medicare Part B
Cenegermin-bkbj (Oxervate) Drops	Remove from Medicaid formulary	Oxervate
Treprostinil sodium (Yutrepia) Cap w/Dev	Add to Medicare Part D Formulary, Tier 5, Prior Authorization	Pulmonary Hypertension

Nerandomilast (Jascayd) Tablet	Remove from Medicaid formulary, as part of High-Cost drug Carve-Out program managed by Oregon Health Authority	Therapies for Interstitial Lung Diseases Policy
Fenofibrate,micronize (Fenofibrate) 43 mg Capsule	• Commercial/Medicare Part D: Add to Formulary, Tier 2 • Medicaid: Add to Formulary	N/A
Azelastine hcl Spray/Pump	Add generic to Medicaid formulary	N/A
Pilocarpine hcl (Vuity) Drops	• Commercial/Medicaid: Add quantity limit (2.5 mL per 25 days) • Medicare Part D: Add to Formulary, Tier 4	Commercial/Medicaid: Eye Drops for Presbyopia
Oxymetazoline HCl (Upneeq) Droperette	Remove from Commercial/Medicaid formularies, increase quantity limit from 2 droperettes per day to 4 droperettes per day	Upneeq
Estradiol/norethindrone (Combipatch) transdermal patch	Commercial: Down-tier from Tier 4 to Tier 3	N/A

The formulary status for the following drugs was line extended in accordance with Providence Health Plan Pharmacy Operational Policy ORPTCOPS062

Drugs released from 2/13/2026 - 4/24/2026

INFORMATIONAL ONLY

NEW DRUGS / COMBINATIONS / STRENGTHS / DOSAGE FORMS		
Drug Name	**Action Taken**	**Policy Name**
Leuprolide acetate (Vabrinty) Syringe	Correction from April 2026 P&T: • Medicare Part D: Drug is Non-Formulary, not Formulary, Tier 4	N/A
Pegfilgrastim (Neulasta) Vial	New strength (4 mg/0.4 mL). Line extend with existing Neulasta strengths on J2506; • Commercial: Formulary, Tier 5, Specialty; Medical • Medicaid: Formulary, Specialty; Medical • Medicare Part D: Non-Formulary • Medicare Part B: Medical Benefit	N/A
• **Denosumab-kyqq (Aukelso) Vial** • **Denosumab-kyqq (Bosaya) Syringe**	New biosimilar. Line extend with non-preferred denosumab;	• Commercial/Medicaid: Denosumab

NEW DRUGS / COMBINATIONS / STRENGTHS / DOSAGE FORMS		
Drug Name	**Action Taken**	**Policy Name**
	• Medical Prior Authorization for all lines of business	• Medicare Part B: Denosumab Prior Authorization and Step Therapy Policy
Leuprolide acetate (Vabrinty) Syringe	New strength (7.5 mg). Line extend with existing Vabrinty J9217; • Medical Prior Authorization for all lines of business	• Commercial/Medicaid: Gonadotropin Releasing Hormone Agonists • Medicare Part B: Gonadotropin Releasing Hormone Agonists Prior Authorization and Step Therapy Polic
Lomitapide mesylate (Juxtapid) Capsule	New strength (2 mg). Line extend with existing Juxtapid strengths; • Commercial: Formulary, Tier 6, Prior Authorization • Medicaid: Non-Formulary, Specialty • Medicare Part D: Non-Formulary	Homozygous Familial Hypercholesterolemia (HoFH) Agents
Berotralstat hydrochloride (Orladeyo) Pellet Pack	New strength (72 mg, 96 mg, 108 mg, and 132 mg) and dosage form (pellet pack). Line extend with Orladeyo capsules; • Commercial: Formulary, Tier 6, Prior Authorization, Quantity Limit (1 pack per day) • Medicaid: Formulary, Specialty, Prior Authorization, Quantity Limit (1 pack per day) • Medicare Part D: Formulary, Tier 5, Prior Authorization, Quantity Limit (1 pack per day)	Prophylactic Hereditary Angioedema Therapy
Ustekinumab-stba (Steqeyma) Vial	New route for vial (sub-q). Line extend with Steqeyma prefilled SQ syringes; • Commercial: Formulary, Tier 5, Prior Authorization, Quantity Limit (0.5 mL per 84 days) • Medicaid: Formulary, Specialty, Prior Authorization, Quantity Limit (0.5 mL per 84 days) • Medicare Part D: Formulary, Tier 4, Prior Authorization, Quantity Limit (1 mL per 56 days)	Therapeutic Immunomodulators (TIMS)

NEW DRUGS / COMBINATIONS / STRENGTHS / DOSAGE FORMS		
Drug Name	**Action Taken**	**Policy Name**
Nusinersen sodium/pf (Spinraza) Vial	New strengths (28 mg/5 ml, 50 mg/5 ml). Line extend with Existing Spinraza J2326; • Medical Prior Authorization for all lines of business	Therapies for Spinal Muscular Atrophy

NEW GENERICS		
Drug Name	**Action Taken**	**Policy Name**
Azilsartan medoxomil Tablet	New generic. Line extend with brand Edarbi; • Non-Formulary for all lines of business	N/A
Beclomethasone dipropionate AER w/ADAP	New generic. Line extend with brand Qvar; • Commercial Standard: Formulary, Tier 2 • Commercial Dynamic: Formulary, Tier 3 • Medicaid: Formulary • Medicare Part D: Non- Formulary	N/A
Brivaracetam Vial	New generic. Line extend with brand Briviact IV; • Commercial/Medicaid/Medicare Part B: Medical Benefit • Medicare Part D: Non- Formulary	• Commercial/Medicaid: Antiepileptic Medications Step Therapy Policy • Medicare Part D: N/A
Brivaracetam Solution	New generic. Line extend with brand Briviact IV; • Commercial Standard: Formulary, Tier 2, Step Therapy, Quantity Limit (20 mL per day) • Commercial Dynamic: Formulary, Tier 4, Step Therapy, Quantity Limit (20 mL per day) • Medicaid: Formulary, Step Therapy, Quantity Limit (20 mL per day) • Medicare Part D: Formulary, Tier 2, Quantity Limit (20 mL per day)	• Commercial/Medicaid: Antiepileptic Medications Step Therapy Policy • Medicare Part D: N/A
Citalopram HBR Capsule	New generic. Line extend with brand citalopram capsule; • Non-Formulary for all lines of business	N/A
Dapagliflozin Tablet	New generic. Line extend with brand Farxiga;	N/A

NEW GENERICS		
Drug Name	**Action Taken**	**Policy Name**
	• Commercial/Medicare Part D: Formulary, Tier 2 • Medicaid: Formulary	

Dapagliflozin-metformin ER Tab BP 24h	New generic. Line extend with brand Xigduo XR;
	• Commercial: Formulary, Tier 2
	• Medicaid: Formulary
	• Medicare Part D: Formulary, Tier 2, Quantity Limit:
	  ○ 5 mg-500 mg; 10 mg-500 mg; 10-1000 mg: 1 tablet per day
	  ○ 5 mg-1000 mg: 2 tablets per day
		N/A

Ipratropium bromide HFA AER AD	New generic. Line extend with brand Atrovent HFA; • Commercial Standard: Formulary, Tier 2 • Commercial Dynamic: Formulary, Tier 3 • Medicaid: Formulary • Medicare Part D: Formulary, Tier 4, Quantity Limit (4 gm per day)	N/A
Umeclidinium bromide (Umeclidinium Ellipta) BLST w/Dev	New generic. Line extend with brand Incruse Ellipta; • Commercial Standard: Formulary, Tier 2 • Commercial Dynamic: Formulary, Tier 3 • Medicaid: Formulary • Medicare Part D: Formulary, Tier 3, Quantity Limit (1 per day)	N/A
Pomalidomide Capsule	New generic. Line extend with brand Pomalyst; • Commercial/Medicare Part D: Formulary, Tier 5, Prior Authorization, Quantity Limit (21 capsules per 28 days) • Medicaid: Formulary, Prior Authorization, Quantity Limit (21 capsules per 28 days), Specialty	Anti-Cancer Medications - Self-Administered
Tapentadol hcl (Tapentadol ER) Tab ER 12h	New generic. Line extend with Brand Nucynta ER;	• Commercial/Medicaid: Long-Acting Opioids • Medicare Part D: N/A

NEW GENERICS		
Drug Name	**Action Taken**	**Policy Name**
	• Commercial Standard: Formulary, Tier 2, Prior Authorization, Quantity Limit (2 tablets per day) • Commercial Dynamic: Formulary, Tier 4, Prior Authorization, Quantity Limit (2 tablets per day) • Medicaid: Non-Formulary, Prior Authorization, Quantity Limit (2 tablets per day) • Medicare Part D: Non-Formulary	
Halobetasol propionate Lotion	New generic. Line extend with brand Ultravate lotion; • 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
Milnacipran hcl Tablet	New generic. Line extend with Brand Savella; • Commercial Standard: Formulary, Tier 2, Prior Authorization, Quantity Limit (12.5 mg, 25 mg, 50 mg, 100 mg: 2 tablets per day; 12.5-25-50: 1 tablet per 365 days) • Commercial Dynamic: Formulary, Tier 4, Prior Authorization, Quantity Limit (12.5 mg, 25 mg, 50 mg, 100 mg: 2 tablets per day; 12.5-25-50: 1 tablet per 365 days) • Medicaid: Non-Formulary, Quantity Limit (12.5 mg, 25 mg, 50 mg, 100 mg: 2 tablets per day; 12.5-25-50: 1 tablet per 365 days) • Medicare Part D: Formulary, Tier 4, Quantity Limit (12.5 mg, 25 mg, 50 mg, 100 mg: 2 tablets per day; 12.5-25-50: 55 tablets per 28 days)	Commercial: Savella
Nintedanib esylate Capsule	New generic. Line extend with Brand Ofev; • Commercial: Formulary, Tier 6, Prior Authorization • Medicaid: Formulary, Specialty, Prior Authorization	• Commercial/Medicaid: Therapies for Interstitial Lung Diseases • Medicare Part D: Pulmonary Fibrosis Agents

NEW GENERICS		
Drug Name	**Action Taken**	**Policy Name**
	• Medicare Part D: Formulary, Tier 5, Prior Authorization, Quantity Limit (2 capsules per day)	

New Drugs and Combinations:

1. **Lerodalcibep-liga (Lerochol) Syringe**
   a. **Indication**: For the treatment of adults with hypercholesterolemia, including heterozygous familial hypercholesterolemia (HeFH) as an adjunct to diet and exercise.
   b. **Decision**:

	Commercial	Medicaid	Medicare
Formulary Status*	Formulary	Formulary	Part D: Non-formulary Part B: N/A
Tier**	Tier 6 - Non-Preferred Specialty	N/A	N/A
Affordable Care Act Eligible	No	N/A	N/A
Utilization Management Edits	Prior Authorization	Prior Authorization	N/A
Quantity Limit	1.2 mL per 30 days	1.2 mL 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: evolocumab (Repatha), alirocumab (Praluent), inclisiran (Leqvio), ezetimibe, bempedoic acid (Nexletol), atorvastatin, rosuvastatin			

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

PA PROGRAM NAME	PCSK9 Inhibitors
MEDICATION NAME	Lerochol Subcutaneous Syringe 300 mg/1.2 ml
PA INDICATION INDICATOR	1 - All FDA-Approved Indications
OFF-LABEL USES	N/A
REQUIRED MEDICAL INFORMATION	1. Requests must meet listed criteria below for each specific diagnosis. **i.** For **primary hyperlipidemia,** Repatha, **Lerochol**, Leqvio, and Praluent may be covered when the patient has a confirmed diagnosis of heterozygous familial hypercholesterolemia (HeFH), homozygous familial hypercholesterolemia (HoFH), or non-familial polygenic hypercholesterolemia indicated by one of the following:

	1) A "possible" or "definite" diagnosis of FH via Simon Broome criteria or a "probable" or "certain" diagnosis of FH via Dutch Lipid Clinic Network Criteria score of greater than or equal to 6 (see appendix) **OR** 2) Genetic mutation in one of the following genes: low-density lipoprotein receptors (LDLR), apolipoprotein B gene (APOB), or proprotein convertase subtilisin kexin type 9 (PCSK9), or ARH adaptor protein 1 (LDLRAP1) **OR** **3)** Clinical manifestations of disease (e.g. cutaneous xanthomas, tendon xanthomas, corneal arcus) **OR** **4)** The patient has a pre-treatment LDL-C level greater than or equal to 190 mg/dL (greater than or equal to 4.9 mmol/L) **ii.** For **clinical atherosclerotic cardiovascular disease (ASCVD)**, Repatha, Leqvio, and Praluent may be covered when the patient has a diagnosis of clinical ASCVD, defined as **one** of the following: **1)** Acute coronary syndromes **2)** History of myocardial infarction **3)** Stable/unstable angina **4)** Coronary or other arterial revascularization **5)** Stroke or transient ischemic attack **6)** Peripheral artery disease, including aortic aneurysm presumed to be of atherosclerotic origin 7) Clinically significant coronary heart disease of atherosclerotic origin identified by diagnostic catheterization, imaging (CT angiogram or cardiac MRI), or stress testing (nuclear stress test or stress echocardiogram) iii. To **reduce the risk of major adverse cardiovascular (CV) events** (e.g., CV death, myocardial infarction, stroke, unstable angina requiring hospitalization, or coronary revascularization), Repatha and Praluent may be covered iv. For **Hypercholesterolemia**, Repatha, Praluent, **Lerochol**, or Leqvio may be covered 2. For Praluent, Leqvio, or **Lerochol**: i. All of the previous criteria must be met AND there must be a documented trial and failure, intolerance, or contraindication to evolocumab (Repatha)

d. **Prior Authorization Criteria for Medicaid**:

PA PROGRAM NAME	PCSK9 Inhibitors
MEDICATION NAME	Lerochol Subcutaneous Syringe 300 mg/1.2 ml
PA INDICATION INDICATOR	1 - All FDA-Approved Indications

OFF-LABEL USES	N/A
EXCLUSION CRITERIA	Concomitant use with another PCSK9 inhibitor
REQUIRED MEDICAL INFORMATION	Must meet listed criteria below for each specific diagnosis: a. For **familial hypercholesterolemia (FH)** (heterozygous or homozygous familial hypercholesterolemia), **Lerochol**, Leqvio, Praluent, and Repatha may be covered when both of the following are met: i. Confirmed diagnosis by one of the following: 1) Genetic mutation in one of the following genes: low-density lipoprotein receptors (LDLR), apolipoprotein B gene (APOB), or proprotein convertase subtilisin kexin type 9 (PCSK9) OR 2) LDL-C greater than 190 mg/dL (pretreatment or highest level while on treatment) and secondary causes have been ruled out. Secondary causes may include hypothyroidism, nephrosis, or extreme dietary patterns 3) A "possible" or "definite" diagnosis of FH via Simon Broome criteria or a "probable" or "certain" diagnosis of FH via Dutch Lipid Clinic Network Criteria score of greater than or equal to 6 (see appendix) ii. Documentation of current (within previous three months) LDL-C greater than 100 mg/dL, taken after at least three months of continuous therapy with statin and ezetimibe outlined in criteria 1 and 2 above 3. For **Lerochol** and Leqvio, in addition to the above criteria the following must be met: a. Documented trial and failure, intolerance, or contraindication to evolocumab (Repatha) or alirocumab (Praluent). Failure of these PCSK9 inhibitors includes adherence to the PCSK9 inhibitor for at least 12 weeks with an LDL-C that remains >70 mg/dL in patients with evidence of clinical ASCVD. **Initial Reauthorization**: Documentation of response to therapy, defined as a decrease in LDL-C levels compared to pre-treatment levels.
AGE RESTRICTIONS	The patient's age must be within FDA labeling for the requested indication
PRESCRIBER RESTRICTIONS	N/A
COVERAGE DURATION	Initial authorization for one year. Reauthorization will be approved until no longer eligible with the plan

2. **Orforglipron calcium (Foundayo) Tablet**
   a. **Indication**: To reduce excess body weight and maintain weight reduction long term in adults with obesity or adults with overweight in the presence of at least one weight-related comorbid condition
   b. **Decision**:

	Commercial	Medicaid	Medicare
Formulary Status*	Non-formulary	Formulary	Part D: Non-formulary
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 tablet per day	One 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: Wegovy injection and tablets, Zepbound injection, Saxenda injection			

c. **Prior Authorization Criteria for Commercia**: Added to the following policies as non-preferred agent:
   a. GLP-1 Receptor Agonists for Non-Diabetes Indications (Policy A) – Commercial
   b. GLP-1 Receptor Agonists for Non-Diabetes Indications (Policy B) - Commercial

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

PA PROGRAM NAME	GLP-1 Receptor Agonists for Non-Diabetes Indications – Medicaid
MEDICATION NAME	Zepbound
PA INDICATION INDICATOR	1 - All FDA-Approved Indications
OFF-LABEL USES	N/A
EXCLUSION CRITERIA	Concomitant use with another PCSK9 inhibitor
REQUIRED MEDICAL INFORMATION	**For obstructive sleep apnea (Zepbound only), must meet all the following criteria:** a. Diagnosis of moderate to severe obstructive sleep apnea(OSA) as ~~defined by both of the following~~ confirmed by a ~~recent (within the last year)~~ polysomnography (PSG) or home sleep apnea test. Central or mixed apnea is excluded. b. Apnea-hypopnea index (AHI; the number of apneas and hypopneas during an hour of sleep) greater than or equal to15 events per hour prior to initiation of pharmacotherapy c. ~~Diagnosis of obesity as defined by a~~ Current BMI (within the last 30 days) of at least 30 ~~d. Current symptoms of OSA (such as excessive daytime sleepiness, loud snoring, choking, gasping, pauses inbreathing, sleep arousals, and difficulty maintaining sleep throughout the night) despite adherence to positive airway pressure (PAP) therapy, unless patient is unable to use PAP therapy. Adherence is defined as at least four (4) hours of use per night for at least 70% of nights over previous 90days~~ ~~e. Requested medication will be used in combination with PAP therapy, unless patient is unable to use PAP therapy~~ **For continuation of therapy for obstructive sleep apnea (Zepbound only), must meet all the following criteria:** a. Patient has had clinical benefit from the requested agent, as evidenced by one of the following: 1. ~~(e.g.,~~ Reduction in AHI, 2. Improvement in validated sleep apnea score (such as sleep apnea-specific hypoxia burden [SASHB], Epworth Sleepiness Scale(ESS], Calgary)

	3. Improvement in OSA symptoms ~~b. Requested medication will be used in combination with PAP therapy, unless patient is unable to use PAP therapy.~~

3. **Relacorilant (Lifyorli) Capsule**
   a. **Indication**: For the treatment of adults with platinum-resistant epithelial ovarian, fallopian tube, or primary peritoneal cancer who have received one to three prior systemic treatment regimens, at least one of which included bevacizumab.
   b. **Decision**:

	Commercial	Medicaid	Medicare
Formulary Status*	Formulary	Formulary	Part D: Formulary Part B: N/A
Tier**	Tier 6 - Non-Preferred Specialty	N/A	Specialty
Affordable Care Act Eligible	No	N/A	N/A
Utilization Management Edits	Prior Authorization	Prior Authorization	Prior Authorization
Quantity Limit	150mg: 27 caps/ 28 days 125mg: 18 caps/ 28 days	150mg: 27 caps/ 28 days 125mg: 18 caps/ 28 days	150mg: 27 caps/ 28 days 125mg: 18 caps/ 28 days
* Recommendations for placement may differ between lines of business due to regulatory requirements. ** Medications will be placed on recommended tier above for the base formulary; tier placement for custom formulary(ies) will be based on designation above. For example, Commercial Tier 6 designation above means that the medication will be placed on the highest cost-sharing tier on the respective formulary(ies).			
Formulary Alternatives: N/A			

   c. **Prior Authorization Criteria for Commercial/Medicaid**: Added to Anti-Cancer Medications – Self Administered Policy
   d. **Prior Authorization Criteria for Medicare Part D:** Added to Anti-Cancer Agents Policy

4. **Riboflavin 5-phosphate sodium (B2) (Epioxa) Kit**
   a. **Indication**: For the treatment of keratoconus in adults and pediatric patients aged 13 years and older, in conjunction with the O_2n System and the Boost Goggles.
   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	Excluded per Medical Policy 158	Excluded per Medical Policy 158	
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: Photrexa Cross-linking Kit			

c. **Prior Authorization Criteria for Commercial/Medicaid**: Added Epioxa to Providence Health Plan Commercial and Medicaid Medical Policy 158, Corneal Collagen Cross-linking

5. **Etripamil (Cardamyst) Spray** reviewed by Madeline Williams, PharmD.
   a. **Indication**: For the conversion of acute symptomatic episodes of paroxysmal supraventricular tachycardia (PSVT) to sinus rhythm in adults.
   b. **Decision**:

	Commercial	Medicaid	Medicare
Formulary Status*	Non-formulary	Non-formulary	Part D: Non-Formulary Part B: N/A
Tier**	N/A	N/A	N/A
Affordable Care Act Eligible	No	N/A	N/A
Utilization Management Edits	Prior Authorization	Prior Authorization	N/A
Quantity Limit	4 units per 30 days	4 units per 30 days	
* 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: verapamil, diltiazem, metoprolol, propranolol, nadolol, diltiazem, flecainide, propafenone			

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

PA PROGRAM NAME	Cardamyst
MEDICATION NAME	Etripamil nasal spray (Cardamyst)
PA INDICATION INDICATOR	1 - All FDA-Approved Indications
OFF-LABEL USES	None
EXCLUSION CRITERIA	• New York Heart Association (NYHA) Class II to IV heart failure • Wolff-Parkinson-White (WPW) • Lown-Ganong-Levine (LGL) syndromes

	• Manifest pre-excitation (delta wave) on a 12-lead ECG • Sick sinus syndrome (except in patients with a permanent pacemaker) • Second degree atrioventricular (AV) Mobitz 2 block or higher degree of AV block
REQUIRED MEDICAL INFORMATION	Initial authorization requires all the following criteria: 1. Diagnosis of paroxysmal supraventricular tachycardia (PSVT) confirmed by electrocardiogram (ECG) 2. Patient has recurrent, symptomatic episodes (≥ 20 minutes) of PSVT despite the following: a. Currently receiving, and will continue to receive, oral pharmacologic therapy for prevention of PSVT episodes (such as diltiazem, verapamil, metoprolol, atenolol, propranolol, nadolol, flecainide, propafenone) unless all are not tolerated or are contraindicated Reauthorization requires documentation of clinical benefit (such as successful conversion to sinus rhythm or a decrease in paroxysmal supraventricular tachycardia [PSVT]-related emergency department or provider visits)
AGE RESTRICTIONS	May be approved for patients 18 years and older
PRESCRIBER RESTRICTIONS	Must be prescribed by, or in consultation with, a specialist in the management of paroxysmal supraventricular tachycardia (PSVT) (such as a cardiologist or electrophysiologist)
COVERAGE DURATION	Initial and reauthorization will be approved for one year.

6. **Depemokimab-ulaa (Exdensur) Syringe**
   a. **Indication: For the treatment of severe eosinophilic asthma.**
   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	No	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: mepolizumab, benralizumab			

   c. **Prior Authorization Criteria for Commercial/Medicare Part B**: Added to Medically Infused Therapeutic Immunomodulators (Tims) Policy
   d. **Prior Authorization Criteria for Medicaid**: Added to Therapeutic Immunomodulators (TIMS) Policy

7. **Aficamten (Myqorzo) Tablet**
   a. **Indication: For the treatment of adults with symptomatic obstructive hypertrophic cardiomyopathy (oHCM) to improve functional capacity and symptoms.**
   b. **Decision:**

	Commercial	Medicaid	Medicare
Formulary Status*	Formulary	Non-formulary	Part D: Non-formulary Part B: N/A
Tier**	Tier 5 - Preferred Specialty	N/A	N/A
Affordable Care Act Eligible	No	N/A	N/A
Utilization Management Edits	Prior Authorization	N/A – HIGH-COST DRUG CARVE OUT	N/A
Quantity Limit	1 tablet per day	N/A	FDA MAX 20 mg/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: Camzyos, propranolol, metoprolol, atenolol, bisoprolol, verapamil, diltiazem			

   c. **Prior Authorization Criteria for Commercial**: Added to Camzyos Policy

8. **Narsoplimab-wuug (Yartemlea) Vial**
   a. **Indication**: For the treatment of adult and pediatric patients 2 years of age and older with hematopoietic stem cell transplant-associated thrombotic microangiopathy (TA-TMA).
   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	2 mL/ week	2 mL/ week	2 mL/ week
* 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**:

PA PROGRAM NAME	Medications for Rare Indications
MEDICATION NAME	Narsoplimag-wuug
PA INDICATION INDICATOR	1 - All FDA-Approved Indications
OFF-LABEL USES	N/A
EXCLUSION CRITERIA	N/A
REQUIRED MEDICAL INFORMATION	For initial authorization, the following must be met: 1. Diagnosis of TA-TMA confirmed by all the following: a. Platelet count less than 150,000 prior to initiation of therapy b. Evidence of microangiopathic hemolysis (such as, presence of schistocytes, serum lactate dehydrogenase [LDH] greater than the upper limit of normal and/or haptoglobin less than the lower limit of normal) c. Renal dysfunction (such as doubling of serum creatinine from pretransplant) For reauthorization, the following must be met: 1. Documentation that patient has medical need for ongoing therapy, such as continued signs and symptoms of active TA-TMA 2. Documentation of successful response to therapy, confirmed by all the following (a, b, and c): a. An improvement in LDH, defined as LDH levels less than 1.5 times the upper limit of normal b. An improvement in platelet count, defined as the following: i. For baseline platelet count equal to or less than 20,000 microL: 1) Equal to or greater than 3-fold increase in platelet count, AND 2) Post-baseline platelet count greater than 30,000 microL AND 3) No platelet transfusions within 2 days prior to the platelet count assessment ii. For baseline platelet count less than 20,000 microL: 1) Equal to or greater than 50 percent increase in platelet count, AND 2) Platelet count greater than 75,000 microL, AND 3) No platelet transfusions within 2 days prior to the platelet count assessment c. One of the following: i. Improvement in organ dysfunction ii. Reduction or independence from red blood cell and/or platelet transfusions For dose escalation to twice weekly: Documentation of inadequate improvement in TA-TMA signs and symptoms with at least eight weeks of once weekly dosing is required
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	Initial authorization will be approved for three months. Reauthorization will be approved for three months.

d. **Prior Authorization Criteria for Medicare Part B**:

PA PROGRAM NAME	Medications for Rare Indications
MEDICATION NAME	Narsoplimag-wuug
PA INDICATION INDICATOR	1 - All FDA-Approved Indications
OFF-LABEL USES	N/A
EXCLUSION CRITERIA	N/A
REQUIRED MEDICAL INFORMATION	For initial authorization, the following must be met: 1. Diagnosis of TA-TMA confirmed by all the following: a. Platelet count less than 150,000 prior to initiation of therapy b. Evidence of microangiopathic hemolysis (such as, presence of schistocytes, serum lactate dehydrogenase [LDH] greater than the upper limit of normal and/or haptoglobin less than the lower limit of normal) c. Renal dysfunction (such as doubling of serum creatinine from pretransplant) For reauthorization, all the following must be met: 1. Documentation that patient has medical need for ongoing therapy, such as continued signs and symptoms of active TA-TMA 2. Documentation of successful response to therapy, confirmed by all the following (a, b, and c): a. An improvement in LDH, defined as LDH levels less than 1.5 times the upper limit of normal b. An improvement in platelet count, defined as the following: i. For baseline platelet count equal to or less than 20,000 microL: 1) Equal to or greater than 3-fold increase in platelet count, AND 2) Post-baseline platelet count greater than 30,000 microL AND 3) No platelet transfusions within 2 days prior to the platelet count assessment ii. For baseline platelet count less than 20,000 microL: 1) Equal to or greater than 50 percent increase in platelet count, AND 2) Platelet count greater than 75,000 microL, AND 3) No platelet transfusions within 2 days prior to the platelet count assessment c. One of the following: i. Improvement in organ dysfunction ii. Reduction or independence from red blood cell and/or platelet transfusions For dose escalation to twice weekly: Documentation of inadequate improvement in TA-TMA signs and symptoms with at least eight weeks of once weekly dosing is required
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	Initial authorization will be approved for three months. Reauthorization will be approved for three months.

9. **Copper histidinate (Zycubo) Vial**
    a. **Indication**: For the treatment of Menkes disease in pediatric patients.

b. **Decision**:

	Commercial	Medicaid	Medicare
Formulary Status*	Non-formulary	State Carve-Out	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	N/A	N/A
Quantity Limit	2 vials per day	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: N/A			

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

PA PROGRAM NAME	Medications for Rare Indications
MEDICATION NAME	Zycubo (copper histidinate)
PA INDICATION INDICATOR	1 - All FDA-Approved Indications
OFF-LABEL USES	N/A
EXCLUSION CRITERIA	N/A
REQUIRED MEDICAL INFORMATION	**For Initial Authorization, both of the following must be met:** 1. Confirmation of FDA-labeled indication and drug-specific criteria a. Diagnosis established by one of the following: i. Biochemical (plasma catecholamine analysis - elevated dihydroxyphenylacetic acid/dihydroxyphenylglycol ratios or dopamine/norepinephrine ratios) or genetic confirmation of ATP7A mutation consistent with a severe Menkes disease phenotype ii. Documentation of clinical signs and symptoms (including but not limited to characteristic Menkes kinky hair, skin abnormalities, progressive neurologic impairment, growth and developmental delays, and multisystem complications affecting the brain, bones, and connective tissues) that are strongly consistent with Menkes disease when biochemical or genetic results are pending, and delay would result in harm b. 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 **For Reauthorization, all 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. Confirmation of drug-specific criteria, if applicable a. For initial approvals that were based on clinical signs and symptoms: biochemical or genetic confirmation of diagnosis must be provided b. For requests beyond three years of use: documentation of medical necessity to continue therapy
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	Initial authorization approved for 6 months when diagnosis is confirmed. Initial authorization will be approved for 3 months if approval is based on clinical documentation only and biochemical/genetic testing results are pending. Reauthorization approved for 12 months.

10. **Pegzilarginase-nbln (Loargys) Vial**

a. **Indication**: For the treatment of hyperargininemia in adult and pediatric patients 2 years of age and older with Arginase1 Deficiency (ARG1-D).

b. **Decision**:

	Commercial	Medicaid	Medicare
Formulary Status*	Medical	State Carve-Out	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	N/A	Prior Authorization
Quantity Limit	N/A	N/A	N/A
* Recommendations for placement may differ between lines of business due to regulatory requirements. ** Medications will be placed on recommended tier above for the base formulary; tier placement for custom formulary(ies) will be based on designation above. For example, Commercial Tier 6 designation above means that the medication will be placed on the highest cost-sharing tier on the respective formulary(ies).			
Formulary Alternatives: Glycerol phenylbutyrate, sodium phenylbutyrate			

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

PA PROGRAM NAME	Medications for Rare Indications
MEDICATION NAME	Zycubo (copper histidinate)
PA INDICATION INDICATOR	1 - All FDA-Approved Indications
OFF-LABEL USES	N/A
EXCLUSION CRITERIA	N/A
REQUIRED MEDICAL INFORMATION	**For Initial Authorization, both of the following must be met:** 2. Confirmation of FDA-labeled indication and drug-specific criteria

	a. Diagnosis established by one of the following: i. Biochemical (plasma catecholamine analysis - elevated dihydroxyphenylacetic acid/dihydroxyphenylglycol ratios or dopamine/norepinephrine ratios) or genetic confirmation of ATP7A mutation consistent with a severe Menkes disease phenotype ii. Documentation of clinical signs and symptoms (including but not limited to characteristic Menkes kinky hair, skin abnormalities, progressive neurologic impairment, growth and developmental delays, and multisystem complications affecting the brain, bones, and connective tissues) that are strongly consistent with Menkes disease when biochemical or genetic results are pending, and delay would result in harm b. 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 **For Reauthorization, all the following must be met:** 4. Documentation of benefit of therapy as evidence by improvement in symptoms, disease stabilization or lack of decline compared to the natural disease progression 5. 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 6. Confirmation of drug-specific criteria, if applicable a. For initial approvals that were based on clinical signs and symptoms: biochemical or genetic confirmation of diagnosis must be provided b. For requests beyond three years of use: documentation of medical necessity to continue therapy
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	Initial authorization approved for 6 months when diagnosis is confirmed. Initial authorization will be approved for 3 months if approval is based on clinical documentation only and biochemical/genetic testing results are pending. Reauthorization approved for 12 months.

11. **Sildenafil citrate (Vybrique) Film**
    a. **Indication**: For the treatment of erectile dysfunction (ED).
    b. **Decision**:

	Commercial	Medicaid	Medicare
Formulary Status*	Non-formulary	Non-formulary	Part D: Non-formulary Part B: N/A
Tier**	N/A	N/A	N/A
Affordable Care Act Eligible	N/A; Non-Formulary	N/A	N/A
Utilization Management Edits	N/A	N/A	N/A

Quantity Limit	1 film per day	1 film 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: for groups with sexual dysfunction benefit, generic tadalafil and sildenafil are covered			

12. **Tividenofusp alfa-eknm (Avlayah) Vial**
    a. **Indication**: For the treatment of neurologic manifestations of Hunter syndrome (Mucopolysaccharidosis type II [MPS II]) when initiated in presymptomatic or symptomatic pediatric patients weighing at least 5 kg prior to advanced neurologic impairment.
    b. **Decision**:

	Commercial	Medicaid	Medicare
Formulary Status*	Medical	State Carve-Out	Part B: Medical
Tier**	N/A	N/A	N/A
Affordable Care Act Eligible	No	N/A	N/A
Utilization Management Edits	Prior Authorization	N/A	Prior Authorization
Quantity Limit	N/A	N/A	N/A
* 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: idursulfase (Elaprase)			

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

PA PROGRAM NAME	Enzyme Replacement Therapy
MEDICATION NAME	Tividenofusp alfa-eknm vial (Avlayah)
PA INDICATION INDICATOR	1 - All FDA-Approved Indications
EXCLUSION CRITERIA	N/A
REQUIRED MEDICAL INFORMATION	For initiation of therapy (new starts to therapy) all the following criteria must be met: 1. Dosing is within FDA-labeling guidelines 2. Documentation of Mucopolysaccharidosis type II (MPS II), also known as Hunter's Disease, as confirmed by one of the following: a. Iduronate-2-sulfatase (IDS) enzymatic deficiency b. Genetic confirmation of deletion or mutations in the IDS gene 3. Patient weighs at least 5 kg 4. Documentation of neurologic manifestations associated with MPS II or that patient is at risk for neurologic manifestations

	5. Patient does not have advanced neurologic impairment (symptoms such as severe cognitive decline, minimal ability to communicate or interact, or significant functional dependence), which would significantly reduce treatment benefit 6. Patient will not be using in combinations with another enzyme replacement therapy For patients currently established on the requested therapy, all the following criteria must be met. 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. 1. Documentation of successful response to therapy (e.g., disease stability, improvement in symptoms or lack of decline compared to natural disease progression). Note: If request is for a non-FDA approved dose, medical rational must be submitted in support of therapy with a higher dose for the intended diagnosis such as high-quality peer reviewed literature, accepted compendia or evidence-based practice guidelines and exceptions will be considered on a case-by-case basis.

13. **Icotrokinra hcl (Icotyde) Tablet** reviewed
    a. **Indication**: For the treatment of adults and pediatric patients 12 years of age and older with moderate to severe plaque psoriasis (PsO) who weigh at least 40 kg.
    b. **Decision**:

	Commercial	Medicaid	Medicare
Formulary Status*	Non-formulary	Non-formulary	Part D: Non-formulary
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	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: adalimumab, Skyrizi, Tremfya, ustekinumab, Bimzelx, Cosentyx, Sotyktu, Taltz, Enbrel, Cimzia, Otezla, infliximab			

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

PA PROGRAM NAME	Therapeutic Immunomodulators
MEDICATION NAME	Icotrokinra tablet (Icotyde)
PA INDICATION INDICATOR	1 - All FDA-Approved Indications
EXCLUSION CRITERIA	The requested product will not be given concurrently with another therapeutic immunomodulator product unless there is no product which covers all indications

REQUIRED MEDICAL INFORMATION	For initial authorization: 1. Diagnosis of moderate to severe plaque psoriasis 2. One of the following: a. Inadequate response (after three months of therapy) or intolerance to one of the following conventional therapies: acitretin, anthralin, calcipotriene, calcitriol, coal tar products, cyclosporine, methotrexate, pimecrolimus, PUVA (phototherapy), tazarotene, topical corticosteroids or FDA-labeled contraindication to all conventional products b. Severe active plaque psoriasis (e.g., greater than 10% body surface area involvement, occurring on select locations [i.e., hands, feet, scalp, face, genitals], intractable pruritis, serious emotional complications) c. Concomitant severe psoriatic arthritis (e.g., erosive disease, elevated markers of inflammation [e.g., ESR, CRP] attributable to psoriatic arthritis, long-term damage that interferes with function [i.e., joint deformities, vision loss, rapidly progressive]) 3. Preferred and non-preferred TIMs products may be covered as outlined below when criteria 1 and 2 are met: a. Preferred products may be covered: Preferred adalimumab products (Simlandi, Hadlima, adalimumab-adaz and adalimumab-aaty), preferred ustekinumab products (Selarsdi, Steqeyma, and Yesintek), risankizumab-rzaa (Skyrizi), apremilast (Otezla), etanercept (Enbrel), guselkumab (Tremfya), secukinumab (Cosentyx), and deucravacitinib (Sotyktu) b. Certolizumab (Cimzia) and bimekizumab (Bimzelx) require inadequate response (after three months of therapy), intolerance, or FDA-labeled contraindication to two products listed in criterion 3a c. All other therapies (including icotrokinra [Icotyde]) require inadequate response (after three months of therapy), intolerance, or FDA-labeled contraindication to three products listed in criterion 3a For patients established on therapy: 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 1. Response to therapy (e.g., slowing of disease progression or decrease in symptom severity and/or frequency)

d. **Prior Authorization Criteria for Medicaid**:

PA PROGRAM NAME	Therapeutic Immunomodulators
MEDICATION NAME	Icotrokinra tablet (Icotyde)
PA INDICATION INDICATOR	1 - All FDA-Approved Indications
EXCLUSION CRITERIA	The requested product will not be given concurrently with another therapeutic immunomodulator product unless there is no product which covers all indications
REQUIRED MEDICAL INFORMATION	For initial authorization: 1. Diagnosis of moderate to severe plaque psoriasis 2. One of the following: a. Patient must have severe disease, as defined by both of the following:

	i. Documentation of functional impairment as indicated by Dermatology Life Quality Index (DLQI) score of at least 11, Children's Dermatology Life Quality Index (CDLQI) score of at least 13, or severe score on another validated tool ii. At least one of the following: 1. At least 10% of body surface area involvement 2. Hand, foot, face, or mucous membrane involvement b. Patient is eligible for EPSDT review with documentation that the condition is of sufficient severity that it impacts the patient's health (e.g., quality of life, function, growth, development, ability to participate in school, or perform activities of daily living) 3. Inadequate response, intolerance or FDA-labeled contraindication to each of the following first line products: a. Topical high-potency corticosteroids[28] for four weeks b. Another topical product (i.e., calcipotriene, tazarotene, anthralin) for eight weeks c. Phototherapy for eight weeks d. Systemic therapy (i.e., acitretin, methotrexate, or cyclosporine) for 16 weeks 4. Preferred and non-preferred TIMs products may be covered as outlined below when criteria 1-3 are met: a. Preferred products may be covered: preferred adalimumab products (Hadlima, Simlandi, and adalimumab-ryvk), preferred infliximab products (Inflectra and Renflexis), and preferred ustekinumab products (Selarsdi, Steqeyma, and Yesintek) b. Apremilast (Otezla)*, tildrakizumab-asmn (Ilumya), brodalumab (Siliq), and deucravacitinib (Sotyktu) require inadequate response (after three months of therapy), intolerance, or FDA-labeled contraindication to adalimumab, infliximab, and ustekinumab c. Icotrokinra (Icotyde)*, Ixekizumab (Taltz)*, guselkumab (Tremfya)*, risankizumab-rzaa (Skyrizi), etanercept (Enbrel)*°, bimekizumab (Bimzelx), and secukinumab (Cosentyx)* require inadequate response (after three months of therapy), intolerance, or FDA-labeled contraindication to adalimumab, infliximab, ustekinumab, and one product listed in criterion 4b d. Certolizumab (Cimzia) requires inadequate response (after three months of therapy), intolerance, or FDA-labeled contraindication to adalimumab, infliximab, ustekinumab, one product listed in criterion 4b, and one product listed in criterion 4c *Adalimumab and infliximab may be waived for patients less than 18 years of age For patients established on therapy: 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 5. Response to therapy (e.g., slowing of disease progression or decrease in symptom severity and/or frequency)

14. **Doxecitine-doxribtimine (Kygevvi) Powd Pack**
    a. **Indication**: For the treatment of thymidine kinase 2 deficiency (TK2d) in adult and pediatric patients with symptom onset at or before 12 years of age.
    b. **Decision**:

	Commercial	Medicaid	Medicare

Formulary Status*	Non-formulary	State Carve-Out	Part D: Non-formulary
Tier**	N/A	N/A	N/A
Affordable Care Act Eligible	N/A; Non-Formulary	N/A	N/A
Utilization Management Edits	Prior Authorization	N/A	N/A
Quantity Limit	N/A	N/A	N/A
* Recommendations for placement may differ between lines of business due to regulatory requirements. ** Medications will be placed on recommended tier above for the base formulary; tier placement for custom formulary(ies) will be based on designation above. For example, Commercial Tier 6 designation above means that the medication will be placed on the highest cost-sharing tier on the respective formulary(ies).			
Formulary Alternatives: None			

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

PA PROGRAM NAME	Medications for Rare Indications
MEDICATION NAME	Doxecitine-doxribtimine powder (Kygevvi)
PA INDICATION INDICATOR	1 - All FDA-Approved Indications
EXCLUSION CRITERIA	N/A
REQUIRED MEDICAL INFORMATION	For initial authorization: 1. Diagnosis of thymidine kinase 2 deficiency (TK2d) confirmed by genetic testing 2. Documentation of symptom onset at or before 12 years of age 3. 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 For reauthorization: 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
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	Initial authorization will be approved for six months. Reauthorization will be approved for one year.

15. **Navepegritide (Yuviwel) Vial**

a. **Indication**: To increase linear growth in pediatric patients 2 years of age and older with achondroplasia with open epiphyses.

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	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: Voxzogo			

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

PA PROGRAM NAME	Voxzogo, Yuviwel
MEDICATION NAME	Vosoritide for subcutaneous injection Navepegritide for subcutaneous injection
PA INDICATION INDICATOR	1 - All FDA-Approved Indications
OFF-LABEL USES	N/A
EXCLUSION CRITERIA	• History of bone-related surgery or fracture of long bone or spine within the previous six months • Planned bone surgery • Use in combination with vosoritide (Voxzogo) or navepegritide (Yuviwel)
REQUIRED MEDICAL INFORMATION	For Medicaid: Coverage is limited to a condition that has been designated a covered line item number by the Oregon Health Services Commission listed on the Prioritized List of Health Care Services For initial authorization, ALL the following criteria must be met: 1. Documentation of confirmed diagnosis of achondroplasia (Q77.4) through genetic testing AND 2. Documentation of a baseline annual growth velocity (AGV) AND ~~3. Current annual growth velocity greater than or equal to 1.5 cm/year (0.6 in/year)~~ ~~AND~~ 4. Evidence of open epiphyses, defined as follows: a. Tanner stage less than 4 OR b. Bone age less than 16 years in male or less than 14 years in female. Bone age must be obtained annually when chronologic age reaches 15 years in male or 13 years in female AND 5. Person is ambulatory and able to stand without assistance

	For reauthorization, ALL of the following criteria must be met: 1. Documentation of an improvement in annual growth velocity of greater than or equal to 1.0 cm/year from baseline (for example, if baseline AGV is 2.0 cm/year, 3.0 cm/year is required for reauthorization) AND ~~2. Current growth velocity greater than or equal to 1.5 cm/year (0.6 in/year)~~ AND 3. One of the following: a. Tanner stage less than 4 OR b. Bone age less than 16 years in male or less than 14 years in female. Bone age must be obtained annually when chronologic age reaches 15 years in male or 13 years in female AND 4. Person is ambulatory and able to stand without assistance
AGE RESTRICTIONS	Age must be appropriate based on FDA-approved indication
PRESCRIBER RESTRICTIONS	Must be prescribed by, or in consultation with, a pediatric endocrinologist or other prescriber specialized in the care of patients with achondroplasia or skeletal dysplasia.
COVERAGE DURATION	Initial authorization and reauthorization will be approved for one year. Shorter reauthorization period may be approved based on slowing of growth velocity or bone age approaching epiphyseal closure.

16. **Tradipitant (Nereus) Capsule**
    a. **Indication**: For the prevention of vomiting induced by motion in adults.
    b. **Decision**:

	Commercial	Medicaid	Medicare
Formulary Status*	Non-formulary	Non-formulary	Part D: Non-formulary Part B: N/A
Tier**	N/A	N/A	N/A
Affordable Care Act Eligible	N/A; Non-Formulary	N/A	N/A
Utilization Management Edits	N/A	N/A	N/A
Quantity Limit	8 capsules per 30 days	8 capsules per 30 days	FDA MAX 2/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: scopolamine patch, promethazine			

New Drug Strengths and Formulations:

1. **Mitapivat sulfate (Aqvesme) Tablet**
   a. **Indication**: For the treatment of anemia in adults with alpha- or beta-thalassemia.
   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	N/A	N/A
Quantity Limit	2 tablets per day	2 tablets 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: For beta-thalassaemia - luspatercept-aamt (Reblozyl), betibeglogene autotemcel (Zynteglo) and exagamglogene autotemcel (Casgevy)			

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

PA PROGRAM NAME	Reblozyl, Rytelo, Aqvesme
MEDICATION NAME	Aqvesme
PA INDICATION INDICATOR	1 - All FDA-Approved Indications
OFF-LABEL USES	N/A
EXCLUSION CRITERIA	Concurrent use of mitapivat, imetelstat and luspatercept
REQUIRED MEDICAL INFORMATION	**Thalassemia:** A. For initiation of therapy (new starts) all the following criteria must be met (supporting documentation required): 1. Diagnosis of alpha- or beta-thalassemia confirmed by hemoglobin analysis such as high-performance liquid chromatography (HPLC) or genetic testing 2. For Aqvesme in alpha- or beta-thalassemia, one of the following: a. Hemoglobin level less than or equal to 10 g/dL, or b. Patient is transfusion-dependent defined as having had at least six units transfused and no longer than a 6-week transfusion-free period during the prior 24 weeks B. For patients established on therapy, continued authorization requires documentation of patient response to therapy, such as improvements in anemia and/or transfusion burden.
AGE RESTRICTIONS	Age must be appropriate based on FDA-approved indication

PRESCRIBER RESTRICTIONS	Must be prescribed by or in consultation with a hematologist/oncologist
COVERAGE DURATION	Aqvesme: For initiation and reauthorization, authorization will be approved for one year.

New Indications:

The following information is gathered from the United States Food and Drug Administration (FDA) Approved Drug Products database from **2/1/2026–3/31/2026**

Therapies with Prior Authorization Policies (Non-oncology)

1. **LEQVIO** (INCLISIRAN)
    a. New indication approved 02/12/2026:
        i. Indicated as an adjunct to diet and exercise to reduce low-density lipoprotein cholesterol (LDL-C) in:
            - Adults with hypercholesterolemia
            - Adults and pediatric patients aged 12 years and older with heterozygous familial hypercholesterolemia (HeFH)
            - Pediatric patients aged 12 years and older with homozygous familial hypercholesterolemia (HoFH)
    b. **RECOMMENDATION:** Inform prescribers via Medical Policy Alert. Expanded indication reviewed at June 2026 P&T as part of the annual policy review. Commercial, Medicaid, Medicare Part B 'PCSK-9 Inhibitors' policies updated.

2. **WAKIX** (PITOLISANT)
    a. New indication approved 02/13/2026:
        i. Treatment of excessive daytime sleepiness (EDS) or cataplexy in patients 6 years of age and older with narcolepsy
    b. **RECOMMENDATION:** Inform prescribers via Medical Policy Alert. Update Commercial/Medicaid 'Narcolepsy Agents' policy with expanded indication. No policy criteria updates warranted.

3. **DUPIXENT** (DUPILUMAB)
    a. New indication approved 02/23/2026:
        i. Treatment of adult and pediatric patients aged 6 years and older with allergic fungal rhinosinusitis (AFRS) who have a history of sino-nasal surgery
    b. **RECOMMENDATION:** Inform prescribers via Medical Policy Alert. Update Commercial, Medicaid 'Therapeutic Immunomodulators' and Medicare Part D 'Dupixent' policies with new indication and criteria.

Prior Authorization for **Comm/Medicaid:**

PA PROGRAM NAME	Therapeutic Immunomodulators
MEDICATION NAME	Dupixent (dupilumab)
COVERED USES	1 - All FDA-Approved Indications
EXCLUSION CRITERIA	N/A
REQUIRED MEDICAL INFORMATION	Initial authorization: 1. Diagnosis of allergic fungal rhinosinusitis as evidenced by all the following: a. Immunoglobulin E (IgE)-mediated inflammatory response to fungal hyphae as evidenced by specific IgE serology or skin test b. Presence of nasal polyps as evidenced by direct examination, endoscopy, or sinus computed tomography (CT) scan c. Presence of signs characteristic of allergic fungal rhinosinusitis on CT scan 2. History of sino-nasal surgery for the treatment of AFRS
AGE RESTRICTIONS	Age must be appropriate based on FDA-approved indication
PRESCRIBER RESTRICTIONS	Medication is prescribed by or in consultation with an allergist, immunologist, otolaryngologist (ear, nose, and throat [ENT] physician specialist), rhinologist, pulmonologist, or infectious disease specialist
COVERAGE DURATION	Initial authorization will be approved for six months. Reauthorization will be approved for one year.

Prior Authorization for **Medicare Part D**:

PA PROGRAM NAME	Dupixent
MEDICATION NAME	Dupixent (dupilumab)
COVERED USES	1 - All FDA-Approved Indications
EXCLUSION CRITERIA	Concurrent use with another therapeutic immunomodulator agent utilized for the same indication.
REQUIRED MEDICAL INFORMATION	For initial authorization for allergic fungal rhinosinusitis (AFRS): 1. Patient has a history of sino-nasal surgery (e.g., endoscopic sinus surgery) for the treatment of AFRS

AGE RESTRICTIONS	N/A
PRESCRIBER RESTRICTIONS	Medication is prescribed by or in consultation with an allergist, immunologist, otolaryngologist (ear, nose, and throat [ENT] physician specialist), rhinologist, pulmonologist, or infectious disease specialist
COVERAGE DURATION	Initial authorization will be approved for six months. Reauthorization will be approved for one year.

4. **PALYNZIQ** (PEGVALIASE-PQPZ)
    a. New indication approved 02/27/2026:
        i. Indicated to reduce blood phenylalanine concentrations in adult and pediatric patients 12 years of age and older with phenylketonuria (PKU) who have uncontrolled blood phenylalanine concentrations greater than 600 micromol/L on existing management.
    b. **RECOMMENDATION:** Inform prescribers via Medical Policy Alert. Expanded indication reviewed at April 2026 P&T as part of the annual policy review. Commercial/Medicaid 'Palynziq' policy was updated.

5. **SOGROYA** (SOMAPACITAN-BECO)
    a. New indication approved 02/27/2026:
        i. Treatment of pediatric patients aged 2.5 years and older with short stature born small for gestational age (SGA) and with no catch-up growth by 2 years of age
        ii. Treatment of pediatric patients aged 2.5 years and older with growth failure associated with Noonan syndrome (NS)
        iii. Treatment of pediatric patients aged 2.5 years and older with idiopathic Short Stature (ISS)
    b. **RECOMMENDATION:** Inform prescribers via Medical Policy Alert. Update Commercial and Medicaid 'Human Growth Hormones' policy with new indication. No policy criteria updates warranted.

6. **SOTYKTU** (DEURAVACITINIB)
    a. New indication approved 03/06/2026:
        i. Treatment of active psoriatic arthritis in adults
    b. **RECOMMENDATION:** Inform prescribers via Medical Policy Alert. Update Commercial and Medicaid 'Therapeutic Immunomodulators' policies with new indication and criteria.

Prior Authorization for **Commercial:**

PA PROGRAM NAME	Therapeutic Immunomodulators
MEDICATION NAME	Sotyktu (deuravacitinib)
COVERED USES	1 - All FDA-Approved Indications
EXCLUSION CRITERIA	N/A
REQUIRED MEDICAL INFORMATION	**For initial authorization:** 1. One of the following: a. Inadequate response (after three months of therapy) or intolerance to one conventional therapy (e.g., non-steroidal anti-inflammatory drug (NSAID), cyclosporine, methotrexate, leflunomide, or sulfasalazine) or FDA-labeled contraindication to all conventional products b. Severe active psoriatic arthritis (e.g., erosive disease, elevated markers of inflammation [e.g., ESR, CRP] attributable to psoriatic arthritis, long-term damage that interferes with function [i.e., joint deformities, vision loss, rapidly progressive]) c. Concomitant severe psoriasis (e.g., greater than 10% body surface area involvement, occurring on select locations [i.e., hands, feet, scalp, face, genitals], intractable pruritis, serious emotional complications) 2. Preferred and non-preferred TIMs products may be covered as outlined below when criterion 1 is met: a. Preferred products may be covered: preferred adalimumab products (Simlandi, Hadlima, adalimumab-adaz and adalimumab-aaty), deucravacitinib (Sotyktu), etanercept (Enbrel), guselkumab (Tremfya), secukinumab (Cosentyx), preferred ustekinumab product (Selarsdi, Steqeyma, and Yesintek), risankizumab-rzaa (Skyrizi), and apremilast (Otezla) b. Upadacitinib (Rinvoq/Rinvoq LQ) and tofacitinib (Xeljanz/Xeljanz XR) require inadequate response (after three months of therapy), intolerance, or FDA-labeled contraindication to one TNF inhibitor c. Certolizumab (Cimzia), abatacept (Orencia), golimumab (Simponi), ixekizumab (Taltz), and bimekizumab (Bimzelx) may be covered with inadequate response (after three months of therapy), intolerance, or FDA-labeled contraindication to two products listed in criteria 2a and/or 2b

	d. All other therapies require inadequate response (after three months of therapy), intolerance, or FDA-labeled contraindication to three products listed in criteria 2a and/or 2b
AGE RESTRICTIONS	Age must be appropriate based on FDA-approved indication
PRESCRIBER RESTRICTIONS	N/A
COVERAGE DURATION	Initial authorization will be approved for one year. Reauthorization will be approved until no longer eligible with the plan, subject to formulary or benefit changes

Prior Authorization for **Medicaid:**

PA PROGRAM NAME	Therapeutic Immunomodulators
MEDICATION NAME	Sotyktu (deuravacitinib)
COVERED USES	1 - All FDA-Approved Indications
EXCLUSION CRITERIA	Below the line diagnoses
REQUIRED MEDICAL INFORMATION	**For initial authorization:** 1. Inadequate response or intolerance to one of the following conventional therapies or FDA-labeled contraindication to all conventional therapies: a. Four-week trial of a non-steroidal anti-inflammatory drug (NSAID) such as naproxen b. Three-month trial of a conventional synthetic disease-modifying antirheumatic drug (csDMARD) such as cyclosporine, methotrexate, leflunomide, or sulfasalazine 2. Preferred and non-preferred TIMs products may be covered as outlined below when criterion 1 is met: a. Preferred products may be covered: preferred adalimumab products (Hadlima, Simlandi, and adalimumab-ryvk), preferred infliximab products (Inflectra and Renflexis), and preferred ustekinumab products (Selarsdi, Steqeyma, and Yesintek) b. Apremilast (Otezla/Otezla XR)* and tofacitinib (Xeljanz/Xeljanz XR)° require inadequate response (after three months of therapy), intolerance, or FDA-labeled contraindication to adalimumab, infliximab, and ustekinumab c. Abatacept (Orencia)°, certolizumab (Cimzia), golimumab (Simponi), deucravacitinib (Sotyktu) and upadacitinib (Rinvoq)° require inadequate

	response (after three months of therapy), intolerance, or FDA-labeled contraindication to adalimumab, infliximab, ustekinumab, and one product listed in criterion 2b d. Bimekizumab (Bimzelx), etanercept (Enbrel), guselkumab (Tremfya)*, ixekizumab (Taltz), risankizumab-rzaa (Skyrizi), and secukinumab (Cosentyx)° require inadequate response (after three months of therapy), intolerance, or FDA-labeled contraindication to adalimumab, infliximab, ustekinumab, one product listed in criterion 2b, and one product listed in criterion 2c *For Otezla, Otezla XR, and Tremfya: infliximab may be waived for patients < 18 years of age °For Cosentyx, Orencia, Rinvoq, Xeljanz, and Xeljanz X: infliximab may be waived for patients < 18 years of age and adalimumab and ustekinumab may be waived for patients < 6 years of age **For patients established on therapy:** *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* 1. Response to therapy (e.g., slowing of disease progression or decrease in symptom severity and/or frequency)
AGE RESTRICTIONS	Age must be appropriate based on FDA-approved indication
PRESCRIBER RESTRICTIONS	Must be prescribed by, or in consultation with, a dermatologist or rheumatologist
COVERAGE DURATION	Initial authorization will be approved for six months. Reauthorization will be approved for one year

7. **COSENTYX** (SECUKINUMAB)
    a. New indication approved 03/12/2026:
        i. Treatment of moderate to severe hidradenitis suppurativa (HS) in adults and pediatric patients 12 years of age and older
    b. **RECOMMENDATION:** Inform prescribers via Medical Policy Alert. Update Commercial and Medicaid 'Therapeutic Immunomodulators' policies with expanded indication. No policy criteria updates warranted.

8. **IMCIVREE** (SETMELANOTIDE)

a. New indication approved 03/19/2026:
    i. Reduce excess body weight and maintain weight reduction long term in adults and pediatric patients aged 4 years and older with acquired hypothalamic obesity (HO)
b. **RECOMMENDATION:** Inform prescribers via Medical Policy Alert. Update Commercial/Medicaid 'Medications for Rare Indications' policy with new indication and criteria.

Prior Authorization for Commercial/Medicaid**:**

PA PROGRAM NAME	Medications for Rare Indications
MEDICATION NAME	Imcivree (setmelanotide)
COVERED USES	1 - All FDA-Approved Indications
EXCLUSION CRITERIA	N/A
REQUIRED MEDICAL INFORMATION	**For initial authorization:** 1. Confirmation of FDA-labeled indication and drug-specific criteria a. Acquired HO due to hypothalamic injury or dysfunction b. Diagnosis of obesity, defined as: i. Adult patients: BMI of ≥30 kg/m2 ii. Pediatric patients: BMI ≥95th percentile for age and sex 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
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	Initial authorization will be approved for one year. Reauthorization will be approved until no longer eligible with the plan, subject to formulary or benefit changes

9. **LICART** (DICLOFENAC EPOLAMINE)
    a. New indication approved 03/27/2026:
        i. For the topical treatment of acute pain due to minor strains, sprains, and contusions in adults and pediatric patients 6 years of age and older
    b. **RECOMMENDATION:** Inform prescribers via Medical Policy Alert. No policy updates warranted.

10. **TRIKAFTA** (ELEXACAFTOR/TEZACAFTOR/IVACATOR)
    a. New indication approved 03/27/2026:
        i. Treatment of cystic fibrosis (CF) in adult and pediatric patients aged 2 years and older who have a clinical diagnosis of CF and who have at least one variant in the cystic fibrosis transmembrane conductance regulator (*CFTR*) gene that is either responsive based on clinical and/or in vitro data or results in production of CFTR protein
    b. **RECOMMENDATION:** Inform prescribers via Medical Policy Alert. Expanded indication reviewed at June 2026 P&T as part of the annual policy review. Commercial/Medicaid 'CFTR Modulators' policy updated.

11. **ALYFTREK** (VANZACAFTOR/TEZACAFTOR/DEUTIVACAFTOR)
    a. New indication approved 03/27/2026:
        i. Treatment of cystic fibrosis (CF) in adult and pediatric patients 6 years of age and older who have a clinical diagnosis of CF and who have at least one variant in the cystic fibrosis transmembrane conductance regulator (*CFTR*) gene that is either responsive based on clinical and/or in vitro data or results in production of CFTR protein
    b. **RECOMMENDATION:** Inform prescribers via Medical Policy Alert. Expanded indication reviewed at June 2026 P&T as part of the annual policy review. Commercial/Medicaid 'CFTR Modulators' policy updated.

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

1. **YESCARTA** (AXICABTAGENE CILOLEUCEL)
    a. New indication approved 02/05/2026:
        i. Limitations of Use for Primary Central Nervous System Lymphoma was removed from the indication
    b. **RECOMMENDATION:** Inform prescribers via Medical Policy Alert. Update Commercial/Medicaid/Medicare Part B 'T-Cell Therapy' policy with updated indication. Update policy criteria stating that patients must not have primary central nervous system lymphoma for B-cell lymphoma does not apply to Yescarta.

2. **KEYTRUDA/KEYTRUDA QLEX** (PEMBROLIZUMAB)
    a. New indication(s) approved 02/10/2026:
        i. In combination with paclitaxel, with or without bevacizumab, for the treatment of adult patients with platinum-resistant epithelial ovarian, fallopian tube, or primary peritoneal carcinoma whose tumors express PD-L1 (CPS≥1) as determined by an FDA-authorized test, and who have received one or two prior systemic treatment regimens

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.

3. **VENCLEXTA** (VENETOCLAX)
    a. New indication(s) approved 02/19/2026:
        i. In combination with acalabrutinib as a new combination regimen for patients with previously untreated chronic lymphocytic leukemia/small lymphocytic lymphoma
    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.

4. **CALQUENCE** (ACALABRUTINIB)
    a. New indication(s) approved 02/19/2026:
        i. In combination with venetoclax as a new combination regimen for the treatment of adult patients with chronic lymphocytic leukemia or small lymphocytic lymphoma
    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.

5. **BRAFTOVI** (ENCORAFENIB)
    a. New indication(s) approved 02/24/2026:
        i. In combination with cetuximab and fluorouracil- based chemotherapy, for the treatment of adult patients with metastatic colorectal cancer (mCRC) with a BRAF V600E mutation, as detected by an FDA-authorized test
    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.

6. **HERNEXEOS** (ZONGERTINIB)
    a. New indication(s) approved 02/26/2026:
        i. Treatment of adult patients with unresectable or metastatic non-squamous non-small cell lung cancer (NSCLC) whose tumors have HER2 (ERBB2) tyrosine kinase domain activating mutations as detected by an FDA-authorized test
    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.

7. **TECVAYLI** (TECLISTAMAB-CQYV)
    a. New indication approved 03/05/2026:
        i. In combination with daratumumab hyaluronidase-fihj for the treatment of adult patients with relapsed or refractory multiple myeloma who have received at least one prior line of therapy, including a proteasome inhibitor and an immunomodulatory agent
    b. **RECOMMENDATION:** Inform prescribers via Medical Policy Alert. Update Commercial/Medicaid/Medicare Part B 'T-Cell Therapy' policy with new indication. No policy criteria updates warranted.

8. **OPDIVO** (NIVOLUMAB)
    a. New indication(s) approved 03/20/2026:
        i. In combination with doxorubicin, vinblastine, and dacarbazine (AVD), for the treatment of adult and pediatric patients 12 years and older with previously untreated, Stage III or IV classical Hodgkin lymphoma (cHL)
    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>

1. **PREZCOBIX/PREZCOBIX PED** (DARUNAVIR/COBICISTAT)
    a. Previous Indication(s):
        i. Treatment of HIV-1 in treatment-naïve and treatment-experienced adults and pediatric patients weighing at least 25 kg with no darunavir resistance-associated substitutions
    b. New indication(s) approved 02/27/2026:
        i. In combination with other antiretroviral agents for the treatment of human immunodeficiency virus (HIV-1) in treatment-naïve and treatment-experienced adults and pediatric patients 3 years of age and older weighing at least 15 kg with no darunavir resistance-associated substitutions
    c. **RECOMMENDATION:** Inform prescribers via Medical Policy Alert.

2. **NEFFY** (EPINEPHRINE)
    a. Previous Indication(s):
        i. For emergency treatment of type I allergic reactions, including anaphylaxis, in adult and pediatric patients 4 years of age and older who weigh 15 kg or greater

b. New indication(s) approved 03/26/2026:
    i. For emergency treatment of type I allergic reactions, including anaphylaxis, in adult and pediatric patients who weigh 15 kg or greater
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

2/1/2026– 3/31/2026

FDA Drug Safety Communications

1. **Drug Name:** Carbidopa/Levodopa
    - **Date Posted:** 03/30/2026
    - **Safety Alert Title:** FDA Is Requiring Warning about Vitamin B6 Deficiency and Associated Seizures for Drug Products Containing Carbidopa/Levodopa
    - **Link to more information:** https://www.fda.gov/drugs/drug-safety-communications/fda-requiring-warning-about-vitamin-b6-deficiency-and-associated-seizures-drug-products-containing
    - **What safety concern is FDA announcing?**
        - FDA conducted a safety review and identified 14 cases of seizures linked to vitamin B6 deficiency in patients using drug products containing carbidopa/levodopa.
        - Drug products containing carbidopa/levodopa can deplete vitamin B6 levels during the process by which levodopa is converted to dopamine. Additionally, carbidopa binds to the active form of vitamin B6, which creates additional functional loss of vitamin B6.
    - **What is FDA doing?**
        - The Agency is requiring the addition of a warning, and corresponding revisions, to the prescribing information to state that these medications, approved to treat symptoms of Parkinson's disease, can cause vitamin B6 deficiency and vitamin B6 deficiency-associated seizures.
    - **What should health care professionals do?**
        - Evaluate baseline vitamin B6 levels prior to starting patients on treatment with carbidopa/levodopa therapies and periodically while on treatment and to supplement with vitamin B6 as necessary.
    - **Health Plan Recommendation:** Notify providers via Medical Policy Alert.

2. **Drug Name:** Tavneos (avacopan)
    - **Date Posted:** 03/31/2026

- **Safety Alert Title:** FDA Identifies Cases of Serious Liver Injury in Patients Taking Tavneos (avacopan) for Severe Active Anti-neutrophil Cytoplasmic Autoantibody (ANCA)-associated Vasculitis

- **Link to more information:** https://www.fda.gov/drugs/drug-safety-communications/fda-identifies-cases-serious-liver-injury-patients-taking-tavneos-avacopan-severe-active-anti
- **What safety concern is FDA announcing?**
    - After reviewing postmarketing data from the applicant's submission (cases from their global safety database), the literature, and the FDA Adverse Event Reporting System (FAERS) database, FDA identified 76 cases of drug-induced liver injury (DILI) with reasonable evidence of a causal association with avacopan use.
- **What is FDA doing?**
    - FDA is alerting patients and health care professionals about serious postmarketing cases, including fatal cases, of DILI associated with Tavneos. Some cases involved vanishing bile duct syndrome (VBDS), which is characterized by progressive destruction and disappearance of the bile ducts in the liver. This condition can slow or stop the flow of bile and may lead to permanent liver damage. VBDS is often accompanied by the yellowing of skin or eyes (jaundice), itchiness, and tiredness.
    - Although hepatotoxicity is a serious adverse reaction for Tavneos identified in premarket clinical trials and described in product labeling, VBDS and DILI cases with fatal outcomes represent new safety concerns. FDA is continuing to monitor postmarketing cases of DILI, including VBDS, involving Tavneos and will provide updates as appropriate.
- **What should health care professionals do?**
    - Conduct liver panel testing every 2 weeks in the first month of treatment, monthly for the next 5 months, and then as clinically indicated.
    - Promptly discontinue Tavneos treatment, evaluate patients, and consider alternative treatments for patients with severe active ANCA-associated vasculitis if:
        1. Alanine aminotransferase (ALT) or aspartate aminotransferase (AST) is >3 times the upper limit of normal (ULN) or alkaline phosphatase (ALP) is >2 times the ULN;
        2. A patient presents with evidence of symptomatic cholestasis such as jaundice or pruritus.
    - If liver test abnormalities or symptoms of liver injury do not improve, patients should be referred to a hepatologist for further evaluation.
- **Health Plan Recommendation:** Notify providers via Medical Policy Alert.

Drug Recalls/Market Withdrawals

1. **Drug Name:** Magnesium Sulfate in Water for Injection
    - **Date of Recall:** 03/24/2026
    - **Reason for recall:** A Magnesium Sulfate in Water for Injection pouch was found to contain an IV bag of Tranexamic Acid in 0.7% Sodium Chloride Injection, 10 mg/mL

- **Link to more information:** https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/amneal-pharmaceuticals-llc-issues-voluntary-nationwide-recall-magnesium-sulfate-water-injection-usp
- **Health Plan Recommendation:** Notify providers via Medical Policy Alert.