Providence Health Plan

Providence Health Assurance

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

Number 122

September 1, 2026

This is the September 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

COMPANY POLICIES

ARCHIVE

Effective 9/1/2026

Apheresis (Therapeutic Pheresis) **MP305**	**Policy Updates:** Archived policy based on low utilization **Codes/PA:** Removed PA and NMN from codes on policy

MEDICARE POLICIES

Effective 10/1/2026

Blood Counts **MP209**	**Policy Updates:** Centers for Medicare and Medicaid Services (CMS) NCD Lab policy. No change to criteria, continue to apply CMS NCD 190.15 for blood counts. **Codes/PA:** Based on the 10/1/2026 ICD-10 updates from CMS Change Request (CR) 14536, CPT codes in this policy will require configuration updates to align with CMS changes. Effective 10/1/2026, CMS is removing & adding some ICD-10 codes to their pair-to-**deny** configuration. See policy for full details.

Partial Thromboplastin Time (PTT) **MP326**	**Policy Updates:** Centers for Medicare and Medicaid Services (CMS) NCD Lab policy. No change to criteria, continue to apply CMS NCD 190.16 for PTT testing. **Codes/PA:** Based on the 10/1/2026 ICD-10 updates from CMS Change Request (CR) 14536, CPT codes in this policy will require configuration updates to align with CMS changes. Effective 10/1/2026, CMS is removing & adding some ICD-10 codes to their pair-to-**pay** configuration. See policy for full details.
Prothrombin Time (PT) **MP413**	**Policy Updates:** Centers for Medicare and Medicaid Services (CMS) NCD Lab policy. No change to criteria, continue to apply CMS NCD 190.17 for PT testing. **Codes/PA:** Based on the 10/1/2026 ICD-10 updates from CMS Change Request (CR) 14536, CPT codes in this policy will require configuration updates to align with CMS changes. Effective 10/1/2026, CMS is removing & adding some ICD-10 codes to their pair-to-**pay** configuration. See policy for full details.
Serum Iron Studies **MP322**	**Policy Updates:** Centers for Medicare and Medicaid Services (CMS) NCD Lab policy. No change to criteria, continue to apply CMS NCD 190.18 for serum iron testing. **Codes/PA:** Based on the 10/1/2026 ICD-10 updates from CMS Change Request (CR) 14536, CPT codes in this policy will require configuration updates to align with CMS changes. Effective 10/1/2026, CMS is removing & adding some ICD-10 codes to their pair-to-**pay** configuration. See policy for full details.
Thyroid Testing **MP207**	**Policy Updates:** Centers for Medicare and Medicaid Services (CMS) NCD Lab policy. No change to criteria, continue to apply CMS NCD 190.22 for thyroid testing. **Codes/PA:** Based on the 10/1/2026 ICD-10 updates from CMS Change Request (CR) 14536, CPT codes in this policy will require configuration updates to align with CMS changes. Effective 10/1/2026, CMS is removing & adding some ICD-10 codes to their pair-to-**pay** configuration. See policy for full details.
Rhinoplasty and Other Nasal Surgeries **MP247**	**Policy Updates:** Created a separate row for rhinoplasty procedures performed for cleft lip/palette repair. Coverage is technically based on the same LCD as other rhinoplasty procedures, but since removing PA, a statement was added that they are considered reconstructive and medically necessary. **Codes/PA:** CPT codes 30460, 30462 – termed PA requirement. No change to other codes or their configuration.

Transcranial Magnetic Stimulation **MP268**	**Policy Updates:** Updated criteria for non-repetitive TMS (or non-rTMS) services to change from Medicare LCD to Company criteria. **Codes/PA:** Code changes include the following: • Code 0858T – Termed PA, no edits • Codes 0889T-0892T – Termed PA, added NMN denial • All other codes - No change.

ARCHIVE

Effective 9/1/2026

Apheresis (Therapeutic Pheresis) **MP310**	**Policy Updates:** Archiving policy based on low utilization **Codes/PA:** Removed PA and NMN from codes on policy

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

Pharmacy & Therapeutics (P&T) Committee

Oregon Region P&T Committee Consent Agenda Survey August 2026
Go-Live Date: Thursday, October 01, 2026, unless otherwise noted

Table of Contents:

- New Indications Monitoring
- Drug Safety Monitoring

Clinical Policy Changes

MAJOR CHANGES	
Policy Name	**Summary of Change**
Anti-Amyloid Monoclonal Antibodies - Medicaid	Anti-amyloid antibodies are no longer considered medically necessary due to lack of evidence of benefit and safety concerns
Antipsychotics	Update preferred therapies and trial and failure criteria based on cost and utilization.
• **Botulinum Toxin** • **Botulinum Toxin – Medicare Part B**	Botulinum therapies will be set up to process automatically through claims editing. Codes for botulinum therapy that are submitted with medically accepted indications (ICD-10 codes) will automatically adjudicate. Other code pairings will be considered not medically necessary.
Cardiac Myosin Inhibitors	Correction - this drug is NOT part of the high-cost drug carve-out program for Medicaid. Updated Myqorzo required left ventricular outflow track peak gradient for initial authorization and left ventricular ejection fraction minimum for reauthorization.
Formulary and Quantity Limit Exceptions - Medicare Part D	Updated to clarify requirements for formulary expceptions is an "all" statement, rather than "one of the following." Included language regarding bisoimilar reviews.
Infusion Therapy Site of Care	Benlysta, Cosentyx, Orencia, and tocilizumab products removed from drug list.
• **Lemtrada** • **Lemtrada Prior Authorization and Step Therapy Policy - Medicare Part B**	Remove requirement for highly active disease and change trial/failure requirement to trail of two high efficacy agents: ocrelizumab and fingolimod.
Long-Acting Stimulant Medications Quantity Limit	Align Medicaid criteria with Commercial
• **Medically Administered Multiple Sclerosis Agents** • **Medically Administered Multiple Sclerosis Agents Prior Authorization and Step Therapy Policy – Medicare Part B**	Age restriction added to policy criteria that age must be appropriate based on FDA-approved indication.
Multiple Sclerosis Agents - Medicaid	New policy - split out Medicaid and designated preferred products
Narcolepsy Agents	Updated prescriber restrictions for obstructive sleep apnea and Sunosi
Pituitary Disorder Therapies	For Isturisa, require trial of Signifor/Signifor LAR. Remove criteria regarding surgical resection and/or radiation for acromegaly

MAJOR CHANGES	
Policy Name	**Summary of Change**
Redemplo, Tryngolza	Updated diagnostic criteria for Familial chylomicronemia syndrome (FCS) to require history of at least three triglyceride measurements over 880 mg/dL, instead of 1,000 mg/dL to align with clinical trials for Tryngolza. Additionally, added criteria for newly approved indication for Tryngolza: severe hypertriglyceridemia
Therapeutic Immunomodulators (TIMs) Policy - Commercial	Made Icotyde co-preferred for plaque psoriasis. For Chronic Spontaneous Urticaria, updated prerequisite therapy requirements to allow dupilumab (Dupxent). Made Actemra (tocilizumab) co-preferred with Tyenne (tocilzumab biosimilar) due to shortage of Tyenne.
Therapies for Interstitial Lung Diseases Policy	Correction - Jascayd is NOT part of the high-cost drug carve-out program for Medicaid.
Therapies for Spinal Muscular Atrophy – Medicaid	New policy - Created new Medicaid only policy due to high-cost drug carve-out workflow with the Oregon Health Authority and to apply step-therapy for Spinraza, requiring a trial of Evrysdi for Medicaid members.
• **Tyruko, Tysabri** • **Tyruko, Tysabri Prior Authorization and Step Therapy Policy - Medicare Part B**	Change trial/failure requirement for Crohn's Disease to ustekinumab, vedolizumab, and either adalimumab or infliximab
• **Vijoice** • **Yorvipath**	Correction - this drug is NOT part of the high-cost drug carve-out program for Medicaid.
• **Zeposia** • **Zeposia - Medicaid**	Zeposia criteria updated to not require EKG requirement in order to be consistent with other among other multiple sclerosis prior authorization policies that do not require monitoring.
Zurzuvae	Removed exclusions

RETIRED POLICIES	
Policy Name	**Summary of Change**
Acute Migraine Medications	Retire policy as Reyvow discontinued and current policy criteria is similar to non-formulary policy
Nuedexta	Due to low risk of inappropriate utilization
Savella	Due to generic availability and low risk of inappropriate utilization

Other Formulary Changes:

Drug Name	Recommendation	Policy Name
Orforglipron calcium (Foundayo) Tablet	Correction from June 2026 P&T:	• GLP-1 Receptor Agonists for Non-Diabetes Indications (Policy A) – Commercial

Drug Name	Recommendation	Policy Name
	• Commercial Standard: Formulary with Prior Authorization (for groups with weight loss benefit), Quantity Limit (1 tablet per day) • Commercial Dynamic: Non-Formulary, Prior Authorization, Quantity Limit (1 tablet per day)	• GLP-1 Receptor Agonists for Non-Diabetes Indications (Policy B) - Commercial
Buspirone HCL Tablet	New strengths (2.5 mg; 12.5 mg); • Non-formulary for all lines of business	N/A
Atomoxetine hcl (Atoncy) Solution	New dosage form (solution); • Non-formulary for all lines of business	N/A
Benzonatate Capsule	New MedID (560485); • Non-formulary for all lines of business	N/A
Clonidine HCL Tablet	New strength (0.05 mg); • Non-formulary for all lines of business	N/A
Dexamethasone (Dexlyt) Tablet	New strength; • Non-formulary for all lines of business	N/A
Fluorouracil (Favlyxa) Vial	New to market brand; • Medical benefit with prior authorization	Anti-cancer medications – medical benefit
Fibrinogen, human-chmt (Fesilty) Vial	New biologic; • Medical benefit for all lines of business	N/A
Filgrastim-laha (Filkri) Syringe	New biosimilar; • Non-formulary for all lines of business	N/A
Folic Acid (Quiofic) Solution	New generic; • Non-formulary for all lines of business	N/A
Glipizide Tablet	New strength (15 mg); • Non-formulary for all lines of business	N/A
Bimatoprost/pf (Zolymbus) Droper Gel	New dosage form (droper gel); • Commercial/Medicaid: Non-Formulary, Quantity Limit (1 dropperette per day)	N/A
Etoposide (Avopef) Vial	New MedID (626045); • Medical Benefit, Prior Authorization for all lines of business	Anti-Cancer Medications - Medical Benefit
Trabectedin (Evdi) Vial	New to market brand; • Medical Benefit, Prior Authorization for all lines of business	Anti-Cancer Medications - Medical Benefit

Drug Name	Recommendation	Policy Name
Anifrolumab-fni (Saphnelo) Syringe and Autoinjector	New dosage form (syringe); • Commercial/Medicare Part D: Formulary, Tier 5, Prior Authorization, Quantity Limit (3.2 mL per 28 days) • Medicaid: Formulary, Prior Authorization, Quantity Limit (3.2 mL per 28 days)	Saphnelo
Icotrokinra hcl (Icotyde) Tablet	Commercial: Add to Formulary, Tier 5 as co-preferred agent	Therapeutic Immunomodulators (TIMs) Policy
Tirzepatide (Zepbound) Kwikpen	Medicaid: Added as preferred product over Zepbound pen/vial	GLP-1 Receptor Agonists and Related Medications for Non-Diabetes Indications Policy
Diclofenac potassium (Cambia) Powd Pack	Remove from Commercial formulary	N/A
Rufinamide Suspension/Tablet	Commercial Dynamic: Down tier from Tier 4 to Tier 2	Antiepileptic Medications Step Therapy Policy
Brivaracetam Solution	Commercial Dynamic: Down tier from Tier 4 to Tier 2	N/A
Ustekinumab-hmny (Starjemza) Syringe and Vial	Add as preferred biosimilar; • Commercial: Formulary, Tier 5, Prior Authorization, Quantity Limit (45 mg/0.5 mL vial/syringe: 0.5 mL per 84 days; 90 mg/mL: 1 mL per 84 days) • Medicaid: Formulary, Prior Authorization, Quantity Limit (45 mg/0.5 mL vial/syringe: 0.5 mL per 84 days; 90 mg/mL: 1 mL per 84 days), Specialty	Therapeutic Immunomodulators (TIMs) Policy
Ustekinumab-aekn (Selarsdi) Syringe and Vial	Change to non-preferred biosimilar; • Commercial: Non-Formulary, Prior Authorization, Quantity Limit (45 mg/0.5 mL vial/syringe: 0.5 mL per 84 days; 90 mg/mL: 1 mL per 84 days), Specialty • Medicaid: Non-Formulary, Prior Authorization, Quantity Limit (45 mg/0.5 mL vial/syringe: 0.5 mL per 84 days; 90 mg/mL: 1 mL per 84 days), Specialty	Therapeutic Immunomodulators (TIMs) Policy
Stiripentol (Diacomit) 250 mg Powd Pack	Added to Medicaid formulary	Diacomit

Drug Name	Recommendation	Policy Name
Tociluzumab (Actemra) Pen and Syringe	Commercial: Add to Formulary, Tier 5 as co-preferred agent	Therapeutic Immunomodulators (TIMs) Policy
Insulin glargine-yfgn Pen and Vial	Medicare: Add to Formulary, Tier 3 as co-preferred with Lantus (due to shortage issues)	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 4/7/2026 - 7/26/2026

INFORMATIONAL ONLY

NEW DRUGS / COMBINATIONS / STRENGTHS / DOSAGE FORMS		
Drug Name	**Action Taken**	**Policy Name**
Dextromethorphan hbr/bupropion (Auvelity) TB IRER PK	New strength (30-45-105) and dosage form (TB IRER PK). Line extend with Auvelity 45 mg-105 mg tablet, extended release; • Commercial: Non-Formulary, Quantity Limit (51 tablets per 365 days) • Medicaid: Non-Formulary • Medicare Part D: Formulary, Tier 5, Step Therapy, Quantity Limit (102 tablets per 365 days)	• Commercial/Medicaid: N/A • Medicare Part D: Antidepressants Step Therapy Policy
Budesonide/glycopyr/formoterol (Breztri Aerosphere) HFA AER AD	New strength (160-18-4.8). Line extend with Existing Breztri inhaler; • Non-formulary for all lines of business	N/A
Granisetron hcl (Granisol) Solution	New formulation. Line extend with Kytril/granisetron; • Non-formulary for all lines of business	N/A
Eplontersen sodium (Wainua) Syringe	New dosage form (syringe). Line extend with Wainua 45mg/0.8ml autoinjector; • Commercial: Formulary, Tier 6, Prior Authorization, Quantity Limit (0.8 mL per 30 days)	• Commercial/Medicaid: Transthyretin (TTR) Lowering Agents • Medicare Part D: N/A

NEW DRUGS / COMBINATIONS / STRENGTHS / DOSAGE FORMS		
Drug Name	**Action Taken**	**Policy Name**
	• Medicaid: Formulary, Prior Authorization, Quantity Limit (0.8 mL per 30 days), Specialty • Medicare Part D: Non- Formulary	
Ruxolitinib phosphate (Jakafi XR) Tab ER 24h	New strengths (11 mg; 22 mg; 33 mg; 44 mg; 55 mg) and formulation (extended release). Line extend with immediate release Jakafi; • Commercial: Formulary, Tier 6, Prior Authorization, Quantity Limit (1 per day) • Medicaid: Formulary, Prior Authorization, Quantity Limit (1 per day), Specialty • Medicare Part D: Formulary, Tier 5, Prior Authorization, Quantity Limit (1 per day)	Anti-Cancer Medications - Self-Administered
Denosumab-desu (Jubereq) Vial	New biosimilar (Xgeva biosimilar). Line extend with non-preferred denosumab; • Medical Prior Authorization for all lines of business	• Commercial/Medicaid: Denosumab • Medicare Part B: Denosumab Prior Authorization and Step Therapy Policy
Denosumab-desu (Osvyrti) Syringe	New biosimilar (Prolia biosimilar). Line extend with non-preferred denosumab; • Medical Prior Authorization for all lines of business	• Commercial/Medicaid: Denosumab • Medicare Part B: Denosumab Prior Authorization and Step Therapy Policy
Marstacimab-hncq (Hympavzi Pen) Pen Injctr	New strength (75mg/0.5ml). Line extend with Hympavzi 150mg/ml; • Medical Prior Authorization for all lines of business	• Commercial/Medicaid: Hemophilia Prophylactic Agents • Medicare Part B: Hemophilia Prophylactic Agents Prior Authorization and Step Therapy Policy
Insulin infusion set/cartridge (Pivot Supply Kit) Combo. Pkg	New tubeless insulin pump. Line extend with non-preferred personal insulin pump (Twiist); • Commercial/Medicaid: Non-Formulary, Prior Authorization, Quantity Limit (10 per 3 days) • Medicare Part D: Non-Formulary	• Commercial/Medicaid: Insulin Delivery Systems • Medicare Part D: N/A
Insulin pump/cart/set/syr/need (Pivot Insulin Pump Starter Kit) Kit	New tubeless insulin pump. Line extend with non-preferred personal insulin pump (Twiist);	• Commercial/Medicaid: Insulin Delivery Systems • Medicare Part D: N/A

NEW DRUGS / COMBINATIONS / STRENGTHS / DOSAGE FORMS		
Drug Name	**Action Taken**	**Policy Name**
	• Commercial/Medicaid: Non-Formulary, Prior Authorization, Quantity Limit (1 per 365 days) • Medicare Part D: Non-Formulary	
Treprostinil (Tyvaso DPI) Cart Inhal	New Strength (48-80 MCG). Line extend with existing Tyvaso DPI; • Commercial/Medicaid: Non-Formulary, Prior Authorization, Specialty • Medicare Part D: Non-Formulary	• Commercial/Medicaid: Pulmonary Hypertension • Medicare Part D: N/A
Risankizumab-rzaa (Skyrizi) Syringe	New strength (55 mg/0.37). Line extend with Skyrizi; • Commercial: Formulary, Tier 5, Prior Authorization, Quantity Limit (0.37 mL per 84 days) • Medicaid: Non-Formulary, Prior Authorization, Quantity Limit (0.37 mL per 84 days), Specialty • Medicare Part D: Formulary, Tier 5, Prior Authorization, Quantity Limit (0.37 mL per 28 days)	Therapeutic Immunomodulators (TIMs) Policy

NEW GENERICS		
Drug Name	**Action Taken**	**Policy Name**
Methylphenidate (Methylphenidate ER ODT) Tab Rap BP	New generic. Line extend with brand Cotempla XR-ODT; • Commercial/Medicaid: Non-Formulary, Quantity Limit (1 tablet per day) • Medicare Part D: Non-Formulary	N/A
Dronabinol Solution	New generic. Line extend with brand Syndros; • Commercial/Medicaid: Non-Formulary, Quantity Limit (4 mL per day) • Medicare Part D: Non-Formulary	N/A
Gabapentin Capsule	New generic. Line extend with brand Relgaabi 200mg; • Commercial/Medicaid: Non-Formulary	N/A

NEW GENERICS		
Drug Name	**Action Taken**	**Policy Name**
	• Medicare Part D: Formulary, Tier 4, Quantity Limit (3 tablets per day)	
Mirabegron (Mirabegron ER) Sus ER Rec	New generic. Line extend with generic mirabegron tablets; • Non-Formulary for all lines of business, Quantity Limit (10 mL per day)	N/A
Sitagliptin Phosphate Tablet	New generic. Line extend with brand Januvia; • Commercial Standard: Formulary, Tier 2, Quantity Limit (1 tablet per day) • Commercial Dynamic: Formulary, Tier 4, Quantity Limit (1 tablet per day) • Medicaid: Formulary, Quantity Limit (1 tablet per day) • Medicare Part D: Formulary, Tier 3, Quantity Limit (1 tablet per day)	N/A
Sitagliptin phos/metformin hcl (Sitagliptin-Metformin) Tablet	New generic. Line extend with brand Janumet; • Commercial Standard: Formulary, Tier 2, Quantity Limit (2 tablets per day) • Commercial Dynamic: Formulary, Tier 4, Quantity Limit (2 tablets per day) • Medicaid: Formulary, Quantity Limit (2 tablets per day) • Medicare Part D: Formulary, Tier 3, Quantity Limit (2 tablets per day)	N/A
Tacrolimus (Tacrolimus XL) Cap ER 24H	New generic. Line extend with brand Astragraf XL; • Commercial Standard: Formulary, Tier 2 • Commercial Dynamic: Formulary, Tier 4 • Medicaid: Formulary • Medicare Part D: Non-Formulary,	N/A
Romidepsin Vial	New generic. Line extend with Brand Romidepsin; • Medical Benefit, Prior Authorization for all lines of business	Anti-Cancer Medications - Medical Benefit
Bosutinib Tablet	New generic. Line extend as with brand Bosulif;	Anti-Cancer Medications - Self-Administered

NEW GENERICS		
Drug Name	**Action Taken**	**Policy Name**
	• Commercial: Formulary, Tier 6, Prior Authorization, Quantity Limit (100mg: 4 per day; 400 & 500 mg: 1 per day) • Medicaid: Formulary, Prior Authorization, Quantity Limit (100mg: 4 per day; 400 & 500 mg: 1 per day), Specialty • Medicare Part D: Formulary, Tier 5, Prior Authorization, Quantity Limit (100mg: 4 per day; 400 & 500 mg: 1 per day)	
Deflazacort (Kymbee) Oral Susp	New generic. Line extend with deflazacort 22.75mg/ml suspension; • Commercial/Medicaid: Non- Formulary, Prior Authorization, Specialty • Medicare Part D: Non-Formulary	• Commercial/Medicaid: Corticosteroids for Duchenne Muscular Dystrophy • Medicare Part D: N/A
Macitentan Tablet	New generic. Line extend with brand Opsumit; • Commercial: Formulary, Tier 5, Prior Authorization • Medicaid: Formulary, Prior Authorization, Specialty • Medicare Part D: Non-Formulary	• Commercial/Medicaid: Pulmonary Hypertension • Medicare Part D: N/A
Loratadine Tab Chew	New generic. Line extend with Claritin 10mg chews; • Commercial/Medicare Part D: Non-Formulary • Medicaid: Non-Formulary, Prior Authorization	• Commercial/Medicare Part D: N/A • Medicaid: Second and Third Generation Antihistamines
Tofacitinib Citrate Tablet	New generic. Line extend with brand Xeljanz; • Commercial: Formulary, Tier 5, Prior Authorization, Quantity Limit (5 & 10 mg: 2 tablets per day; 1 mg/mL: 10 mL per day; 11 mg & 22 mg: 1 tablet per day) • Medicaid: Formulary, Prior Authorization, Quantity Limit (5 & 10 mg: 2 tablets per day; 1 mg/mL: 10 mL per day; 11 mg & 22 mg: 1 tablet per day), Specialty • Medicaid Part D: Non-Formulary	• Commercial/Medicaid: Therapeutic Immunomodulators (TIMs) Policy • Medicare Part D: N/A

New Drugs and Combinations:

1. **Milsaperidone (Bysanti) Tablet & Tab DS PK**
   a. **Indication**: For the treatment of adults with schizophrenia or manic or mixed episodes associated with bipolar I disorder.
   b. **Decision**:

	Commercial	Medicaid	Medicare
Formulary Status*	Non-formulary	State Carve-Out	Part D: Formulary Part B: N/A
Tier**	N/A	N/A	Non-preferred Drug
Affordable Care Act Eligible	No	N/A	N/A
Utilization Management Edits	Prior Authorization	N/A	Prior Authorization
Quantity Limit	Two (2) tablets per day. Titration dose packs: One (1) pack per year	N/A	Two (2) tablets per day. Titration dose packs: Two (2) packs per year
* 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: Fanapt (iloperidone), second-generation antipsychotics, first-generation antipsychotics			

   c. **Prior Authorization Criteria for Commercial/Medicaid**: Added to New Medications and Formulations Without Established Benefit Policy
   d. **Prior Authorization Criteria for Medicare Part D**:

PA PROGRAM NAME	Antipsychotics
MEDICATION NAME	Asenapine maleate, Bysanti, Bysanti Titration Pack A, Bysanti Titration Pack B, Bysanti Titration Pack C, Caplyta, Cobenfy, Cobenfy Starter Pack, Fanapt, Fanapt Titration Pack A, Fanapt Titration Pack B, Fanapt Titration Pack C, Lybalvi, Rexulti oral tablet, Secuado, Vraylar oral capsule
PA INDICATION INDICATOR	3 - All Medically-Accepted Indications
OFF-LABEL USES	N/A
EXCLUSION CRITERIA	N/A
REQUIRED MEDICAL INFORMATION	1. For all requests, documentation of medically accepted diagnosis, defined as Food and Drug Administration (FDA) approved indication or compendia-supported use, AND 2. One of the following indication-specific criteria must be met: a. For adjunctive treatment of major depressive disorder, both of the following must be met:

	i. Documentation of current use of an antidepressant (e.g., citalopram, sertraline, paroxetine, duloxetine, mirtazapine, venlafaxine) AND ii. Documented trial and failure, intolerance, or contraindication to quetiapine and aripiprazole, b. For schizophrenia: Documented trial and failure, intolerance, or contraindication to two formulary, generic antipsychotics (e.g., quetiapine, olanzapine, ziprasidone, risperidone, aripiprazole, lurasidone), c. For bipolar disorder: Documented trial and failure, intolerance, or contraindication to two formulary, generic medications for bipolar disorder (e.g., lithium, quetiapine, lamotrigine, divalproex, aripiprazole, risperidone, olanzapine, lurasidone), d. For agitation with Alzheimer's dementia (brexpiprazole), all the following criteria must be met: i. Diagnosis of Alzheimer's dementia with signs and symptoms of agitation (such as excessive motor activity, verbal and/or physical aggression) and ii. Documentation of medical rationale for antipsychotic therapy given risk of significant adverse effects. Rationale may include significant safety concern for patient or caregiver, or significant distress for patient. 3. For Bysanti: Documented medical rationale for use of this agent over Fanapt (iloperidone)
AGE RESTRICTIONS	N/A
PRESCRIBER RESTRICTIONS	N/A
COVERAGE DURATION	Authorization will be approved until no longer eligible with the plan.

2. **Doravirine-islatravir (Idvynso) Tablet**
   a. **Indication**: A complete regimen for the treatment of HIV-1 infection in adults to replace the current antiretroviral regimen in those who are virologically-suppressed (HIV-1 RNA less than 50 copies per mL) on a stable antiretroviral regimen with no history of virologic treatment failure and no known substitutions associated with resistance to doravirine.
   b. **Decision**:

	Commercial	Medicaid	Medicare
Formulary Status*	Formulary	Formulary	Part D: Formulary Part B: N/A
Tier**	Tier 3	N/A	Specialty
Affordable Care Act Eligible	No	N/A	N/A
Utilization Management Edits	N/A	N/A	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: Cabenuva, Biktarvy, Dovato, Genvoya, Stribild

3. **Pivekimab sunirine-pvzy (Decnupaz) Vial**
   a. **Indication**: For the treatment of adult patients with blastic plasmacytoid dendritic cell neoplasm (BPDCN).
   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: tagraxofusp-erzs (Elzonris)			

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

4. **Vepdegestrant (Veppanu) Tablet**
   a. **Indication**: For the treatment of adults with estrogen receptor (ER)-positive, human epidermal growth factor receptor 2 (HER2)-negative, estrogen receptor-1 (ESR1)-mutated advanced or metastatic breast cancer, as detected by an FDA-authorized test, with disease progression following at least one line of endocrine therapy.
   b. **Decision**:

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

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

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

5. **Lunsotogene parvec-cwha (Otarmeni) Vial**
   a. **Indication**: For the treatment severe-to-profound sensorineural hearing loss associated with molecularly confirmed biallelic variants in the *OTOF* gene in adult and pediatric patients.
   b. **Decision**:

	Commercial	**Medicaid**	**Medicare**
Formulary Status*	Medical	Medical	Part D: Non-formulary Part B: Medical
Tier**	N/A	N/A	N/A
Affordable Care Act Eligible	No	N/A	N/A
Utilization Management Edits	Prior Authorization	Prior Authorization	Prior Authorization
Quantity Limit	One administration, per ear, per lifetime	One administration, per ear, per lifetime	One administration, per ear, per lifetime
* Recommendations for placement may differ between lines of business due to regulatory requirements. ** Medications will be placed on recommended tier above for the base formulary; tier placement for custom formulary(ies) will be based on designation above. For example, Commercial Tier 6 designation above means that the medication will be placed on the highest cost-sharing tier on the respective formulary(ies).			
Formulary Alternatives: None			

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

PA PROGRAM NAME	Otarmeni
MEDICATION NAME	Otarmeni
PA INDICATION INDICATOR	1 - All FDA-Approved Indications
EXCLUSION CRITERIA	Health plan coverage of the medication will not be granted when the medication is being supplied by the manufacturer at no-cost to the member. Note: This does not include administration costs associated with the surgical infusion of Otarmeni, which may require prior authorization.
REQUIRED MEDICAL INFORMATION	For all authorization requests, the following criteria must be met: 1. Confirmed biallelic pathogenic or likely pathogenic mutations in the *OTOF* gene 2. Profound hearing loss defined as an average pure tone audiometric threshold of greater than 90 decibel hearing level over frequencies between 500 and 4,000 Hertz in the ear to be treated with Otarmeni 3. Evidence of preserved outer hair cell (OHC) function as confirmed by otoacoustic emission (OAE) testing, including transient evoked otoacoustic emissions (TEOAEs) and/or distortion product otoacoustic emissions (DPOAEs). If DPOAEs are used, a minimum of 6 frequencies should be tested. 4. Preoperative imaging confirms there are no significant anatomic variations in the middle ear or inner ear and there is no evidence of abnormal mastoid pneumatization 5. Otarmeni will be administered at an authorized treatment center by a provider skilled in cochlear surgery 6. Member has not previously received prior gene therapy or had a cochlear implant in the ear to be treated with Otarmeni 7. Otarmeni is not being used in an investigational way or as part of a clinical-trial
AGE RESTRICTIONS	May be approved for patients aged 17 years and less
PRESCRIBER RESTRICTIONS	Must be prescribed by, or in consultation with, an otolaryngologist
COVERAGE DURATION	Authorization will be approved for a one-time (per ear) infusion per lifetime

6. **Baxdrostat (Baxfendy) Tablet**

a. **Indication**: For the treatment of hypertension in combination with other antihypertensive drugs, to lower blood pressure in adults who are not adequately controlled on other agents.

b. **Decision**:

	Commercial	Medicaid	Medicare
Formulary Status*	Non-formulary	Non-formulary	Part D: Non-formulary Part B: N/A

Tier**	N/A	N/A	N/A
Affordable Care Act Eligible	N/A; Non-Formulary	N/A	N/A
Utilization Management Edits	Prior Authorization	Prior Authorization	N/A
Quantity Limit	One 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: spironolactone, eplerenone			

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

PA PROGRAM NAME	Therapies for Resistant Hypertension
MEDICATION NAME	Baxfendy (baxdrostat)
PA INDICATION INDICATOR	1 - All FDA-Approved Indications
OFF-LABEL USES	N/A
EXCLUSION CRITERIA	N/A
REQUIRED MEDICAL INFORMATION	For patients initiating therapy, the following criteria are required: 1. Documentation that patient has resistant hypertension, defined by blood pressure that remains above goal despite the concurrent use of maximum or maximally tolerated daily doses of three antihypertensive agents of different classes including: a. A calcium channel blocker (such as amlodipine, diltiazem, verapamil) b. An angiotensin-converting enzyme inhibitor (ACE-I) (such as lisinopril, enalapril) or angiotensin receptor blocker (ARB) (such as losartan, valsartan, candesartan) c. A diuretic (such as hydrochlorothiazide, chlorthalidone) 2. Documentation that the medication will be used in combination with at least three antihypertensive medications from different classes at maximally tolerated doses 3. Documentation that patient has tried and had an inadequate response to, or has an intolerance or contraindication to both of the following: a. A mineralocorticoid receptor antagonist (such as spironolactone) b. One more medication indicated for hypertension from a different therapeutic class (such as a beta-blocker [such as carvedilol], a centrally acting BP-lowering medication [such as clonidine], an alpha-blocker, hydralazine, minoxidil) 4. Confirmation of uncontrolled high blood pressure as demonstrated by systolic blood pressure greater than or equal to 140 mm Hg or diastolic blood pressure greater than or equal to 90 mm Hg taken on at least two separate occasions

	5. Provider attestation that pseudo- and secondary hypertension have been ruled out (see Table 2 for examples) For reauthorization: 1. Documentation that patient is responding to treatment as documented by sustained improvement in blood pressure, taken on at least two consecutive measurements 2. Documentation that patient will be using the medication in combination with other antihypertensive drugs
AGE RESTRICTIONS	May be approved for patients aged eighteen (18) years and older
PRESCRIBER RESTRICTIONS	Must be prescribed by, or in consultation with, a cardiologist, nephrologist, endocrinologist
COVERAGE DURATION	Initial authorization will be approved for three months. Reauthorization will be approved for one year.

7. **Bulevirtide acetate-gmod (Hepcludex) Vial**
   a. **Indication**: For the treatment of chronic hepatitis delta virus (HDV) infection in adults without cirrhosis or with compensated cirrhosis.
   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	N/A; Non-Formulary	N/A	N/A
Utilization Management Edits	Prior Authorization	Prior Authorization	N/A
Quantity Limit	One vial (8.5 mg) per day	One vial (8.5 mg) 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: None			

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

PA PROGRAM NAME	Medications for Rare Indications
MEDICATION NAME	Bulevirtide acetate-gmod
PA INDICATION INDICATOR	1 - All FDA-Approved Indications
EXCLUSION CRITERIA	1. Uncontrolled HIV

	2. Active HCV
REQUIRED MEDICAL INFORMATION	For initial authorization: 1. Positive HDV antibody test or HDV RNA PCR 6 months prior to start of treatment 2. Current positive HDV RNA PCR result 3. ALT greater than 1 but less than 10 times upper limit of normal 4. No history of decompensated liver disease For reauthorization: 1. Response to therapy (such as evidence of a virologic response [undetectable HDV RNA or at least 2 log10 IU/mL decline in HDV RNA over baseline], ALT decline, decrease in liver stiffness, or HbsAg response [HbsAg loss or HbsAg decrease by at least 1 log10 IU/mL] compared to baseline)
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 and reauthorization will be approved for one year.
QUANTITY LIMIT	One vial (8.5 mg) per day

8. **Ensitrelvir fumarate (Xocova) Tablet**
   a. **Indication**: For post-exposure prophylaxis of coronavirus disease 2019 (COVID-19) in adults and adolescents 12 years of age and older following contact with an individual who has COVID-19.
   b. **Decision**:

	Commercial	Medicaid	Medicare
Formulary Status*	Formulary	Formulary	Part D: Formulary
Tier**	Tier 3	N/A	Preferred Brand
Affordable Care Act Eligible	No	N/A	N/A
Utilization Management Edits	N/A	N/A	N/A
Quantity Limit	N/A	N/A	14 tablets per 180 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: None			

New Indications:

The following information is gathered from the United States Food and Drug Administration (FDA) Approved Drug Products database from 4/1/2026– 5/31/2026

Therapies with Prior Authorization Policies (Non-oncology)

1. **FILSPARI** (SPARSENTAN)
   a. New indication approved 04/13/2026:
      i. Indicated to reduce proteinuria in adult and pediatric patients aged 8 years and older with focal segmental glomerulosclerosis (FSGS) without nephrotic syndrome
   b. **RECOMMENDATION:** Inform prescribers via Medical Policy Alert. Update Commercial/Medicaid 'Filspari, Vanrafia, Voyxact' policy with new indication and criteria.

Prior Authorization for **Commercial/Medicaid:**

PA PROGRAM NAME	Filspari, Vanrafia, Voyxact
MEDICATION NAME	Filspari (sparsentan)
COVERED USES	All FDA-Approved Indications
EXCLUSION CRITERIA	• For sparsentan only: Concurrent therapy with renin-angiotensin aldosterone system inhibitors (such as angiotensin converting enzyme inhibitors or angiotensin receptor blockers), endothelin receptor antagonists [ERAs] (such as bosentan, ambrisentan), or aliskiren. • Use in combination with sparsentan (Filspari), atrasentan (Vanrafia) or iptacopan (Fabhalta)
REQUIRED MEDICAL INFORMATION	For initial authorization, all the following criteria must be met: 1. Biopsy-proven focal segmental glomerulosclerosis (FSGS) or a genetic mutation known to cause FSGS 2. Patient does not have nephrotic syndrome 3. Urine protein-to-creatinine ratio (UPCR) greater than or equal to 1.5 g/g 4. Estimated glomerular filtration rate (eGFR) greater than or equal to 30 mL/min/1.73 m^2 Reauthorization: Documentation of positive response to therapy defined as improvement in proteinuria.
AGE RESTRICTIONS	Age appropriate per FDA label
PRESCRIBER RESTRICTIONS	Must be prescribed by, or in consultation with, a nephrologist.

COVERAGE DURATION	Initial authorization and reauthorization will be approved for one year.

2. **STELARA** (USTEKINUMAB)
    a. Updated indication approved 04/15/2026:
        i. Moderately to severely active Crohn's disease (CD) in adult and pediatric patients 2 years and older
    b. **RECOMMENDATION:** Inform prescribers via Medical Policy Alert. Update Commercial, Medicaid, Medicare Part B 'Therapeutic Immunomodulators' policies with expanded indication. No policy criteria updates warranted.

3. **DUPIXENT** (DUPILUMAB)
    a. Updated indication approved 04/16/2026:
        i. Treatment of adult and pediatric patients aged 2 years and older with chronic spontaneous urticaria (CSU) who remain symptomatic despite H1 antihistamine treatment
    b. **RECOMMENDATION:** Inform prescribers via Medical Policy Alert. Update Commercial, Medicaid 'Therapeutic Immunomodulators' policies with expanded indication. No policy criteria updates warranted.

4. **COSENTYX** (SECUKINUMAB)
    a. Updated indication approved 04/17/2026:
        i. Treatment of active ankylosing spondylitis (AS) in adults and pediatric patients 12 years of age and older
    b. **RECOMMENDATION:** Inform prescribers via Medical Policy Alert. Update Commercial, Medicaid, Medicare Part B 'Therapeutic Immunomodulators' policies with expanded indication. No policy criteria updates warranted.

5. **TZIELD** (TEPLIZUMAB-MZWV)
    a. Updated indication approved 04/20/2026:
        i. Indicated to delay the onset of Stage 3 type 1 diabetes (T1D) in adult and pediatric patients 1 year of age and older with Stage 2 T1D
    b. **RECOMMENDATION:** Inform prescribers via Medical Policy Alert. Update Commercial/Medicaid/Medicare Part B 'Tzield' policy with expanded indication. Update age restrictions.

6. **AUVELITY** (BUPROPION/DEXTROMETHORPHAN)
    a. New indication approved 04/30/2026:
        i. For the treatment of agitation associated with dementia due to Alzheimer's disease
    b. **RECOMMENDATION:** Inform prescribers via Medical Policy Alert. Update Medicare Part D 'Antidepressants' policy with new indication and criteria.
    Prior Authorization for **Medicare Part D:**

PA PROGRAM NAME	Antidepressants Step Therapy
MEDICATION NAME	Auvelity (bupropion/dextromethorphan)
COVERED USES	All Medically Necessary Indications
EXCLUSION CRITERIA	N/A

REQUIRED MEDICAL INFORMATION	One of the following: 1) History of paid claims or documented trial (totaling at least two months of therapy) of two different generic selective serotonin reuptake inhibitors (SSRIs), or serotonin-norepinephrine reuptake inhibitors (SNRIs) or 2) Documented intolerance/contraindication to all formulary generic SSRIs/SNRIs (such as citalopram, sertraline, paroxetine, venlafaxine, duloxetine, escitalopram, fluoxetine, desvenlafaxine and fluvoxamine) or 3) Diagnosis of Alzheimer's dementia with signs and symptoms of agitation (such as excessive motor activity, verbal and/or physical aggression)

7. **ASCENIV** (HUMAN IMMUNOGLOBULIN G)
    a. Updated indication approved 04/30/2026:
        i. For the treatment of primary humoral immunodeficiency (PI) in adults and pediatric patients 2 years of age and older
    b. **RECOMMENDATION:** Inform prescribers via Medical Policy Alert. Expanded indication reviewed, no policy updates warranted.

8. **OCREVUS** (OCRELIZUMAB)
    a. New indication approved 05/08/2026:
        i. For the treatment of relapsing-remitting MS, in pediatric patients 10 years of age and older who weigh 25 kg or more
    b. **RECOMMENDATION:** Inform prescribers via Medical Policy Alert. Expanded indication reviewed, no policy updates warranted.

9. **VYVGART/VYVGART HYTRULO** (EFGARTIGIMOD ALFA)
    a. Updated indication approved 05/08/2026:
        i. For the treatment of adult patients with generalized myasthenia gravis (gMG)
    b. **RECOMMENDATION:** Inform prescribers via Medical Policy Alert. Update Commercial/Medicaid, Medicare Part B 'FcRn Antagonists' policy with updated indication. Update criteria to no longer require patients to be anti-acetylcholine receptor antibody positive.

10. **FASENRA** (BENRALIZUMAB)
    a. New indication approved 05/13/2026:
        i. Treatment of adult and pediatric patients aged 12 years and older with hypereosinophilic syndrome (HES) without an identifiable non hematologic secondary cause
    b. **RECOMMENDATION:** Inform prescribers via Medical Policy Alert. Update Commercial, Medicaid, Medicare Part B 'Therapeutic Immunomodulators' policy with new indication, no additional policy criteria updates warranted. Update Medicare Part D 'Respiratory Agents-Fasenra' policy with new indication and criteria.

    Prior Authorization for **Medicare Part D**:

PA PROGRAM NAME	Respiratory Agents - Fasenra
MEDICATION NAME	Fasenra (benralizumab)

COVERED USES	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 hypereosinophilic syndrome (HES): 1. Diagnosis of HES for at least six months confirmed by both of the following: a. One of the following: i. Peripheral blood eosinophil count of at least 1,000 cells/microliter, ii. Percentage of eosinophils in bone marrow section exceeding 20% of all nucleated cells, iii. Marked deposition of eosinophil granule proteins found, iv. Tissue infiltration by eosinophils that is extensive in the opinion of a pathologist, b. There has been evaluation of hypereosinophilia-related organ involvement, 2. No identifiable non-hematologic secondary (reactive) cause of HES, 3. Inadequate response or intolerance to one conventional therapy (such as oral corticosteroid therapy, hydroxyurea, methotrexate). Reauthorization for HES: 1. Documentation of positive clinical response to therapy
AGE RESTRICTIONS	N/A
PRESCRIBER RESTRICTIONS	Medications must be prescribed by, or in consultation with the following specialists based on the diagnosis: Asthma: asthma specialist (such as a pulmonologist, immunologist, or allergist). EGPA: pulmonologist, neurologist, or rheumatologist. HES: allergist, immunologist, otolaryngologist, pulmonologist, or rheumatologist
COVERAGE DURATION	Asthma: Initial 1 yr/reauth until no longer elig with plan. EGPA/HES: Initial 6 mo/reauth 1yr.

11. **TYENNE** (TOCILIZUMAB-AAZG)
    a. Updated indication approved 05/21/2026:
        i. Hospitalized adult and pediatric patients aged 2 years and older with coronavirus disease 2019 (COVID-19) who are receiving systemic corticosteroids and require supplemental oxygen, non-invasive or invasive mechanical ventilation, or extracorporeal membrane oxygenation (ECMO).
    b. **RECOMMENDATION:** Inform prescribers via Medical Policy Alert. Update Commercial, Medicaid, Medicare Part B 'Therapeutic Immunomodulators' policies with expanded indication. No policy criteria updates warranted.

12. **LINZESS** (LINACLOTIDE)
    a. Updated indication approved 05/21/2026:
        i. Functional constipation (FC) in pediatric patients 2 years of age and older
    b. **RECOMMENDATION:** Inform prescribers via Medical Policy Alert. Update Medicaid 'Constipation Agents' policy with expanded indication. No policy criteria updates warranted.

13. **TOFIDENCE** (TOCILIZUMAB-BAVI)

a. New and updated indications approved 05/21/2026:
    i. Treatment of chimeric antigen receptor (CAR) T cell-induced severe or life-threatening cytokine release syndrome in adults and pediatric patients 2 years of age and older
    ii. Hospitalized adult and pediatric patients aged 2 years and older with coronavirus disease 2019 (COVID-19) who are receiving systemic corticosteroids and require supplemental oxygen, non-invasive or invasive mechanical ventilation, or extracorporeal membrane oxygenation (ECMO)
b. **RECOMMENDATION:** Inform prescribers via Medical Policy Alert. Update Commercial, Medicaid, Medicare Part B 'Therapeutic Immunomodulators' policies with expanded indication. No policy criteria updates warranted.

14. **UPTRAVI** (SELEXIPAG)
    a. Updated indication approved 05/23/2026:
        i. Treatment of pulmonary arterial hypertension (PAH, WHO Group I) in adults to delay disease progression and reduce the risk of hospitalization for PAH
        ii. Treatment of pulmonary arterial hypertension (PAH, WHO Group I) in pediatric patients aged 2 years and older. Uptravi reduces NT-proBNP and is expected to delay disease progression and reduce the risk of hospitalization for PAH
    b. **RECOMMENDATION:** Inform prescribers via Medical Policy Alert. Update Commercial/Medicaid and Medicare Part B 'Pulmonary Hypertension' policies with expanded indication. No policy criteria updates warranted.

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

1. **BIZENGRI** (ZENOCUTUZUMAB-ZBCO)
    a. New indication(s) approved 05/08/2026:
        i. For the treatment of adults with advanced unresectable or metastatic cholangiocarcinoma harboring a neuregulin 1 (NRG1) gene fusion with disease progression on or after prior systemic therapy
    b. **RECOMMENDATION:** Inform prescribers via Medical Policy Alert. Prior authorization policy coverage criteria are based on recommendations from the National Comprehensive Cancer Network (NCCN); no updates to the policy are warranted.

2. **TECENTRIQ** (ATEZOLIZUMAB)
    a. New indication(s) approved 05/12/2026:
        i. Adjuvant treatment of adult patients with muscle invasive bladder cancer (MIBC) after cystectomy who have circulating tumor DNA molecular residual disease (ctDNA MRD) as determined 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.

3. **INQOVI** (CEDAZURIDINE/DECITABINE)
    a. New indication(s) approved 05/13/2026:
        i. In combination with venetoclax for the treatment of newly diagnosed acute myeloid leukemia (AML) in adults 75 years or older, or who have comorbidities that preclude use of intensive induction chemotherapy

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

4. **ENHERTU** (FAM-TRASTUZUMAB DERUXTECAN-NXKI)
   a. New indication(s) approved 05/15/2026:
      i. For the neoadjuvant treatment of adult patients with HER2-positive (IHC 3+ or ISH+) Stage II or III breast cancer as determined by an FDA-authorized test
      ii. For the adjuvant treatment of adult patients with HER2-positive (IHC 3+ or ISH+) breast cancer who have residual invasive disease following neoadjuvant trastuzumab (with or without pertuzumab) and taxane-based treatment
   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. **DATROWAY** (DATOPOTAMAB DERUXTECAN-DLNK)
   a. New indication(s) approved 05/22/2026:
      i. For the treatment of adult patients with unresectable or metastatic triple-negative breast cancer (TNBC) who are not candidates for PD-1/PD-L1 inhibitor therapy
   b. **RECOMMENDATION:** Inform prescribers via Medical Policy Alert. Prior authorization policy coverage criteria are based on recommendations from the National Comprehensive Cancer Network (NCCN); no updates to the policy are warranted.

6. **IMFINZI** (DURVALUMAB)
   a. New indication(s) approved 05/28/2026:
      i. In combination with Bacillus Calmette Guérin (BCG), for the treatment of adult patients with BCG-naïve, high-risk non-muscle-invasive bladder cancer (NMIBC)
   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. **BREZTRI AEROSPHERE** (BUDESONIDE/FORMOTEROL/GLYCOPYRROLATE)
   a. New indication(s) approved 04/27/2026:
      i. For the maintenance treatment of asthma in adult and pediatric patients 12 years of age and older
   b. **RECOMMENDATION:** Inform prescribers via Medical Policy Alert.

2. **SYMBICORT AEROSPHERE** (BUDESONIDE/FORMOTEROL)
   a. New indication(s) approved 04/27/2026:
      i. For the treatment of asthma in adult and pediatric patients aged 12 years and older
   b. **RECOMMENDATION:** Inform prescribers via Medical Policy Alert.

3. **ZERBAXA** (CEFTOLOZANE/TAZOBACTAM)

a. Updated indication(s) approved 05/12/2026:
    i. For the treatment of the following infections caused by designated susceptible microorganisms in adult and pediatric patients (at least 32 weeks gestational age):
        - Complicated Intra-abdominal Infections (cIAI), used in combination with metronidazole
        - Complicated Urinary Tract Infections (cUTI), Including Pyelonephritis
        - Hospital-acquired Bacterial Pneumonia and Ventilator-associated Bacterial Pneumonia (HABP/VABP)
b. **RECOMMENDATION:** Inform prescribers via Medical Policy Alert.

4. **AFREZZA** (INSULIN HUMAN)
    a. New indication(s) approved 05/29/2026:
        i. Indicated to improve glycemic control in adult and pediatric patients 6 years of age and older with diabetes mellitus
    b. **RECOMMENDATION:** Inform prescribers via Medical Policy Alert.

Drug Safety Monitoring:

The following information is gathered from the United States Food and Drug Administration (FDA) database from 4/1/2026– 5/31/2026

FDA Drug Safety Communications

- **None**

Drug Recalls/Market Withdrawals

1. **Drug Name:** Kian Pee Wan
    - **Date of Recall:** 04/01/2026
    - **Reason for recall:** Voluntary nationwide recall due to presence of undeclared dexamethasone and cyproheptadine
    - **Link to more information:** https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/aphreseller-buy-herbalcom-issues-voluntary-nationwide-recall-kian-pee-wan-capsules-due-presence
    - **Health Plan Recommendation:** Notify providers via Medical Policy Alert.

2. **Drug Name:** Revitaderm, Tridergel
    - **Date of Recall:** 04/08/2026
    - **Reason for recall:** Products were found to contain Lysinibacillus fusiformis, an environmental organism
    - **Link to more information:** https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/blaine-labs-inc-issues-voluntary-nationwide-recall-wound-care-gel-products-due-microbial
    - **Health Plan Recommendation:** Notify providers via Medical Policy Alert.

3. **Drug Name:** Lactated Ringer's injection (B. Braun Medical Inc.)

- **Date of Recall:** 04/28/2026
- **Reason for recall:** Voluntary nationwide recall due to presence of particulate matter in solution
- **Link to more information:** https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/b-braun-medical-inc-issues-voluntary-nationwide-recall-lactated-ringers-injection-1l-e7500-due
- **Health Plan Recommendation:** Notify providers via Medical Policy Alert.

4. **Drug Name:** MG217 Multi-symptom Treatment Cream & Skin Protectant Eczema Cream
   - **Date of Recall:** 05/12/2026
   - **Reason for recall:** Contaminated with Staphylococcus aureus
   - **Link to more information:** https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/pharmacal-issues-nationwide-recall-mg217-multi-symptom-treatment-cream-skin-protectant-eczema-cream
   - **Health Plan Recommendation:** Notify providers via Medical Policy Alert.

5. **Drug Name:** Doxorubicin HCL Liposome Injection (Sun Pharmaceutical Industries, Inc.)
   - **Date of Recall:** 05/13/2026
   - **Reason for recall:** Detection of glass particles in some vials
   - **Link to more information:** https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/sun-pharmaceutical-industries-inc-sun-pharma-initiates-voluntary-us-nationwide-recall-doxorubicin
   - **Health Plan Recommendation:** Notify providers via Medical Policy Alert.

6. **Drug Name:** WAP Sensual Enhancement Capsules
   - **Date of Recall:** 05/18/2026
   - **Reason for recall:** Product contains undeclared sildenafil, tadalafil, flibanserin
   - **Link to more information:** https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/best-supplements-best-prices-issues-voluntary-nationwide-recall-wap-sensual-enhancement-capsules-due
   - **Health Plan Recommendation:** Notify providers via Medical Policy Alert.