Providence Health Plan

Providence Health Assurance

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

Number 117

April 1, 2026

This is the April 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.

MEDICAL

COMPANY POLICIES

Effective 5/1/2026

Spinal Epidural Steroid Injections **MP14**	**Policy Updates:** • Removed the word "documented" from criterion I.F., since impingement and/or contact point may be assumed per criterion I.C.1.a-b. • Liberalized conservative care duration period prior to initial injection to 4 weeks (currently 6 weeks). • Maintain 6-week required benefit duration prior to repeat injections **Codes/PA:** No changes to codes/PA.
Advanced Diabetes Management Technology (Company) **MP27**	**Policy Updates:** Added NMN counterpart to V. Added clarification to types of CGMs. Removing discontinued devices and adding new devices to the device table. **Codes/PA:** No changes to codes or criteria.

Effective 6/1/2026

Laboratory Testing Services **MP455**	**New Policy** **Policy Updates:** Created a new policy with both generic and generalized medical necessity criteria for laboratory services. Criteria based on clinical practice guideline recommendations. **Codes/PA:** N/A – no codes at this time, but codes with configuration may be added in the future.

ARCHIVE

Effective 4/1/2026

Genetic Testing for Inherited Thrombophilia (Company) **MP266**	**Policy Updates:** Archive policy due to low utilization **Codes/PA:** PA will be removed from the following codes: 81240, 81241. NMN will be removed from code 0529U

MEDICARE POLICIES

Effective 6/1/2026

Laboratory Testing Services **MP456**	**New Policy** **Policy Updates:** New Medicare Advantage medical policy. Created a new policy with both generic and generalized medical necessity criteria for laboratory services. Criteria based on clinical practice guideline recommendations. This overarching policy will address basic coverage requirements for laboratory services under Medicare. **Codes/PA:** N/A - no codes at this time, but codes with configuration are expected to be added in the future
Inpatient Surgical Site of Service **MP395**	**Policy Updates:** Updated Medicare policy to include procedures that used to be on the CMS Inpatient Only (IPO) list, and thus, were previously excluded. Adding codes to this Medicare policy that are currently found in the Company version of the policy so the code lists in each policy align. **Codes/PA:** Add **IP SOS** PA requirements (PA required for POS 21) to the following CPT codes: 22532, 22533, 22548, 22556, 22558, 22586, 22610, 22857, 22861 and 22862. (*NOTE: All of these codes require PA today for general medical necessity review, and of this list, only 22532, 22556, 22558, 22610 have MA utilization.)* Intent is to also add a note to the PA list to clarify when the new SOS PA requirement starts.

ARCHIVE

Effective 5/1/2026

Total Shoulder Arthroplasty **MP431**	**Policy Updates:** Archive medical policy for Medicare only. **Codes/PA:** Term general medical necessity PA review. Any CPT codes with IP SOS review requirements will continue to be reviewed for IP SOS.

REIMBURSEMENT POLICIES

Effective 6/1/26

Anesthesia Services: P Status Modifiers	**Updated Reimbursement Policy** Effective for dates of service on or after **June 1, 2026**, Providence Health Plan will no longer reimburse additional units associated with anesthesia physical status modifiers P3, P4, or P5 for **commercial lines of business**. Policy Background: Under Reimbursement Policy RP26 – Anesthesia Services, anesthesia reimbursement for commercial products is based on: • Applicable base units • Time units (reported as total anesthesia time) • Eligible payment modifiers, as outlined in the policy Beginning June 1, 2026, physical status modifiers P3, P4, and P5 will no longer result in additional reimbursable units for commercial plans, even when appropriately reported. These modifiers may continue to be reported for clinical documentation purposes; however, no additional payment will be made for these modifiers.
Hospital-Based Clinic Billing **RP29**	**New Reimbursement Policy** **Recommendation:** • New reimbursement policy to address a practice known as hospital-based clinic billing for **Commercial** members. For these plan members, the Company does **not** intend to follow Original Medicare reimbursement methodology. • This policy will not apply to **Medicaid** and **Medicare Advantage** plan members.

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VENDOR UPDATES

Effective 4/4/26

Carelon – Q2 HCPCS Coding Alert	Interim Update
	Carelon is removing a code and also offering a new code for high tech imaging and 4 new codes for cardiology. Carelon PA will be added to these codes.
	Changes to current criteria: N/A
	Codes/PA:
	• **Remove:**
	  ○ S8092 - Electron beam computed tomography (also known as ultrafast ct, cine ct)
	• **Add with PA requirements**:
	  ○ 70472- Computed tomographic (CT) cerebral perfusion analysis with contrast material(s), including image postprocessing performed with concurrent CT or CT angiography of the same anatomy (List separately in addition to code for primary procedure)
	  ○ C7568- Catheter placement in coronary artery(ies) for coronary angiography, including intraprocedural injection(s) for coronary angiography, imaging supervision and interpretation, with intravascular doppler velocity and/or pressure derived coronary flow reserve measurement (initial coronary vessel or graft) during coronary angiography including pharmacologically induced stress
	  ○ C7569- Percutaneous transluminal coronary angioplasty, single major coronary artery or branch with endoluminal imaging of initial coronary vessel or graft using intravascular ultrasound (ivus) or optical coherence tomography (oct) during diagnostic evaluation and/or therapeutic intervention including supervision, interpretation and report
	  ○ C7570- Catheter placement in coronary artery(s) for coronary angiography, including intraprocedural injection(s) for coronary angiography, imaging supervision and interpretation with intraprocedural coronary fractional flow reserve (ffr) with 3d functional mapping of color-coded ffr values for the coronary tree, derived from coronary angiogram data, for real-time review and interpretation of possible atherosclerotic stenosis(es) intervention (list separately in addition to code for primary procedure)
	  ○ C7571- Percutaneous transluminal coronary angioplasty, single major coronary artery or branch with percutaneous transluminal coronary lithotripsy

	If you have questions, comments, or concerns on the above please reach out to Carelon at MedicalBenefitsManagement.guidelines@Carelon.com

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

Pharmacy & Therapeutics (P&T) Committee

Oregon Region P&T Committee Meeting February 6, 2026
Go-Live Date: Wednesday, April 01, 2026, unless otherwise noted

Table of Contents:

New Drugs and Combinations:

1. **Elamipretide hcl (Forzinity) Vial**
   a. **Indication:** To improve muscle strength in adult and pediatric patients with BTHS weighing at least 30 kg.
   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	Four 280 mg/3.5 mL, single-patient use vials every 28 days	Four 280 mg/3.5 mL, single-patient use vials every 28 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: None			

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

PA PROGRAM NAME	Medications for Rare Indications
MEDICATION NAME	Elamipretide (Forzinity)
EXCLUSION CRITERIA	N/A
REQUIRED MEDICAL INFORMATION	For initial authorization: 1. Confirmed diagnosis of Barth syndrome by either genetic testing for TAZ gene deficiency or MLCL/CL ratio assay 2. Patient weight is greater than or equal to 30 kg 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 evidenced 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 with be approved for 6 months Reauthorization will be approved for 12 months

2. **Donidalorsen (Dawnzera) Injection**
   a. **Indication:** For prophylaxis to prevent attacks of hereditary angioedema (HAE) in adult and pediatric patients ≥12 years of age.
   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	N/A; Non-Formulary	N/A	N/A
Utilization Management Edits	Prior Authorization	Prior Authorization	N/A
Quantity Limit	0.8 mL per 28 days	0.8 mL per 28 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: Orladeyo			

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

PA PROGRAM NAME	Prophylactic Hereditary Angioedema Therapy
MEDICATION NAME	Dawnzera (donidalorsen)
PA INDICATION INDICATOR	1 - All FDA-Approved Indications
OFF-LABEL USES	N/A
EXCLUSION CRITERIA	Combination prophylactic therapy with Andembry, Cinryze, Dawnzera, Haegarda, Takhzyro, or Orladeyo
REQUIRED MEDICAL INFORMATION	For initiation of therapy for prophylaxis of hereditary angioedema (HAE) attacks, all the following criteria (1-4) must be met: 1. Diagnosis of HAE confirmed by a history of recurrent angioedema and one of the following (a or b): a. For HAE Type I and Type II, documentation of one of the following (per laboratory standard): i. Type 1 HAE: Decreased quantities of C4 level, C1-INH protein level, and C1-INH function level OR ii. Type 2 HAE: Decreased quantities of C4 level and C1-INH function level (C1-INH protein level may be normal or elevated) b. For HAE with normal C1-INH: i. Normal or near normal C4, C1-INH antigen, and C1-INH function, and at least one of the following: 1) Presence of a mutation in the C1-INH gene altering protein synthesis and/or function

	2) Positive family history for HAE and attacks lack response to high dose antihistamines or corticosteroids 2. Documentation of at least two HAE attacks per month on average for the past three months despite removal of triggers (such as estrogen containing oral contraceptives, angiotensin converting enzyme inhibitors) unless medically necessary 3. Dose and frequency are in accordance with the Food and Drug Administration-approved labeling 4. For coverage of Cinryze: Documentation of trial and failure, intolerance, or contraindication to Haegarda
AGE RESTRICTIONS	Age appropriate per FDA label
PRESCRIBER RESTRICTIONS	Must be prescribed by, or in consultation with, an immunologist or allergist
COVERAGE DURATION	Initial prior authorization and reauthorization will be approved for one year

3. **Elinzanetant (Lynkuet) Capsule**
   a. **Indication:** For the treatment of moderate to severe vasomotor symptoms (VMS) due to menopause.
   b. **Decision:**

	Commercial	Medicaid	Medicare
Formulary Status*	Formulary	Non-formulary	Part D: Formulary Part B: N/A
Tier**	Tier 4	N/A	Non-preferred Drug
Affordable Care Act Eligible	N/A; Non-Formulary	N/A	N/A
Utilization Management Edits	Prior Authorization	Prior Authorization	N/A
Quantity Limit	2 capsules per day	2 capsules 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: Veozah, estradiol patch			

   c. **Prior Authorization Criteria for Commercial/Medicaid:** Added to Veozah Policy

4. **Nerandomilast (Jascayd) Tablet**
   a. **Indication:** For the treatment of idiopathic pulmonary fibrosis (IPF) and progressive pulmonary fibrosis (PPF) in adult patients.
   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	2 tablets per day	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: pirfenidone, Ofev			

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

PA PROGRAM NAME	Ofev®, pirfenidone Therapies for Interstitial Lung Diseases
MEDICATION NAME	Nerandomilast film coated tablet (Jascayd®)
PA INDICATION INDICATOR	1 - All FDA-Approved Indications
OFF-LABEL USES	None
EXCLUSION CRITERIA	Pirfenidone (Esbriet®) and Ofev® used in combination
REQUIRED MEDICAL INFORMATION	For Idiopathic Pulmonary Fibrosis (IPF), all the following criteria must be met: 1. Diagnosis of Idiopathic Pulmonary Fibrosis confirmed by the presence of a histological pattern associated with usual interstitial pneumonia (UIP) on high-resolution computed tomography (HRCT) or histological pattern of probable or indeterminate UIP and diagnosis is supported by lung biopsy 2. Exclusion of other known causes of interstitial lung disease (ILD) such as domestic and occupational environmental exposures, drug toxicity, or connective tissue disease 3. For Ofev® or Jascayd®: Documentation of medical rationale for use over Trial and failure, intolerance, or contraindication to generic pirfenidone 4. For Jascayd® in combination with pirfenidone (Esbriet®) or Ofev®: Patient is on a stable dose of pirfenidone (Esbriet®) or Ofev® for at least 8 weeks without clinical improvement or stabilization. For other chronic fibrosing interstitial lung diseases (ILD) with a progressive phenotype (Ofev® and Jascayd® only), all the following criteria must be met: 1. Presence of ILD confirmed by evidence of pulmonary fibrosis on HRCT 2. One of the following criteria: a. Relative decline in FVC of at least 10% of predicted value (as reported by spirometry performed on two different dates within the last two years)

	b. Relative decline in FVC of at least 5% of predicted value combined with worsening of respiratory symptoms c. Relative decline in FVC of at least 5% of predicted value combined with increased extent of fibrotic changes on chest imaging d. Increased extent of fibrotic changes on chest imaging combined with worsening of respiratory symptoms e. Increased fibrotic changes on HRCT
AGE RESTRICTIONS	Age must be appropriate based on FDA-approved indication
PRESCRIBER RESTRICTIONS	Must be prescribed by or in consultation with a pulmonologist
COVERAGE DURATION	Initial authorization and reauthorization will be approved for one year.

5. **Paltusotine hcl (Palsonify) Tablet**
   a. **Indication:** For the treatment of adults with acromegaly who had an inadequate response to surgery and/or for whom surgery is not an option.
   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	2 tablets per day	2 tablets 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: Octreotide vial, Mycapssa, Sandostatin LAR, Somatuline Depot			

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

PA PROGRAM NAME	Pituitary Disorder Therapies
MEDICATION NAME	Paltusotine tablet (Palsonify®)
REQUIRED MEDICAL INFORMATION	For initiation of therapy, must meet indication-specific criteria below: 1. For acromegaly, Signifor® LAR, Sandostatin® LAR, Somatuline® Depot, Somavert®, Palsonify®, or Mycapssa® may be covered if all the following are met: a. Confirmed diagnosis of acromegaly

	b. Documentation that the patient has persistent disease (such as biochemical or clinical) following surgical resection or is not a candidate for surgical resection c. For coverage of Somavert®, Palsonify®, or Signifor® LAR, documentation of trial and failure, intolerance or contraindication to both octreotide injection therapy and lanreotide subcutaneous depot d. For coverage of Mycapssa®, patient has been maintained (for at least six months) on octreotide injection or lanreotide therapy and responded to and tolerated therapy For quantity limit exception requests for paltusotine: 1. Dose does not exceed 120 mg per day 2. Documentation that patient is taking a moderate or strong CYP3A4 inducer 3. Medical rationale is provided for not discontinuing interacting medication 4. Medical rationale is provided for not using another therapy for acromegaly (such as Mycapssa, Signifor LAR, Sandostatin LAR, etc)

6. **Plozasiran sodium (Redemplo) Syringe**
   a. **Indication:** As an adjunct to diet to reduce triglycerides in adults with familial chylomicronemia syndrome (FCS).
   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	25 mg/90 days	25 mg/90 days	None
* 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. Tryngolza is a therapeutic alternative but is not on formulary.			

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

PA PROGRAM NAME	Redemplo, Tryngolza
MEDICATION NAME	Olezarsen (Tryngolza) injection Plozasiran sodium (Redemplo) syringe

PA INDICATION INDICATOR	1 - All FDA-Approved Indications
EXCLUSION CRITERIA	N/A
REQUIRED MEDICAL INFORMATION	For initial authorization for Redemplo or Tryngolza, all of the following must be met: 1. Diagnosis of familial chylomicronemia syndrome (FCS) confirmed by one of the following (1 or 2): 1. Genetic testing 2. Both of the following (a and b): a. History of at least three triglyceride measurements over 1000 mg/dL (over 11.3 mmol/L), and b. Previous episode in the past year of acute pancreatitis not caused by alcohol or cholelithiasis 2. For Tryngolza only: documented trial, failure, intolerance, or contraindication to plozasiran (Redemplo) For reauthorization for Redemplo or Tryngolza, must have documentation of benefit (such as a reduction in episodes of acute pancreatitis)
AGE RESTRICTIONS	Age must be appropriate based on FDA-approved indication
PRESCRIBER RESTRICTIONS	Must be prescribed by, or in consultation with, a specialist experienced in the treatment of familial chylomicronemia syndrome (FCS)
COVERAGE DURATION	Initial authorization will be approved for 6 months. Reauthorization will be approved for 12 months.
QUANTITY LIMIT	Tryngolza: 1 injector (0.8 mL) per 28 days Redemplo: 1 syringe (0.5 mL) every 90 days

7. **Remibrutinib (Rhapsido) Tablet**
   a. **Indication:** For the treatment of chronic spontaneous urticaria (CSU) in adult patients who remain symptomatic despite H1 antihistamine treatment.
   b. **Decision:**

	Commercial	Medicaid	Medicare
Formulary Status*	Non-formulary	Non-formulary	Part D: Non-formulary Part B: N/A
Tier**	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	Two tablets per day	Two tablets 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: dupilumab (Dupixent), omalizumab (Xolair)

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

PA PROGRAM NAME	Therapeutic Immunomodulators
MEDICATION NAME	Remibrutinib (Rhapsido) tablet
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. Symptoms of hives and itching, angioedema, or both for over six weeks 2. Inadequate response (after two weeks of therapy) or intolerance to a scheduled second-generation non-sedating H1 antihistamine (e.g., levocetirizine, loratadine, cetirizine, fexofenadine) at four times the standard dosing or FDA-labeled contraindication to all second-generation non-sedating H1 antihistamines 3. For Rhapsido: Inadequate response, intolerance, or contraindication to omalizumab 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, an allergist, immunologist, or dermatologist
COVERAGE DURATION	Initial authorization will be approved for six months. Reauthorization will be approved until no longer eligible with the plan, subject to formulary or benefit changes
Quantity Limit	Two tablets per day

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

PA PROGRAM NAME	Therapeutic Immunomodulators
MEDICATION NAME	Remibrutinib (Rhapsido) tablet
PA INDICATION INDICATOR	1 - All FDA-Approved Indications

EXCLUSION CRITERIA	The requested agent will not be given concurrently with another therapeutic immunomodulator agent unless there is no agent which covers all indications.
REQUIRED MEDICAL INFORMATION	For Initial Authorization: 1. 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, perform activities of daily living, etc.) 2. Documentation of failure to have benefit with, or contraindication to, recommended conventional first-line treatments options, defined as a four-week trial of both of the following: a. Second-generation antihistamines (cetirizine, loratadine, fexofenadine) at four times the standard dosing b. Leukotriene receptor antagonist (montelukast, zafirlukast) added to second-generation antihistamine therapy 3. Documentation of disease severity prior to initiation of a targeted immune modulator, defined as both of the following: a. Recurrent pruritic hives with or without angioedema for more than 6 weeks b. One of the following scores: ▪ Weekly Urticaria Score (UAS7) ³ 28 ▪ Urticaria Activity Score (UAS) ³ 3 ▪ Dermatology Life Quality Index (DLQI) ³ 10 4. For Rhapsido: Inadequate response (after three months of therapy), intolerance, or contraindication to omalizumab 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) 2. Patient remains eligible for EPSDT review
AGE RESTRICTIONS	Age must be appropriate based on FDA-approved indication
PRESCRIBER RESTRICTIONS	Must be prescribed by, or in consultation with, an allergist, immunologist, or dermatologist
COVERAGE DURATION	Initial authorization will be approved for 6 months. Reauthorization will be approved until no longer eligible with the plan, subject to formulary or benefit changes.
Quantity Limit	Two tablets per day

8. **Sevabertinib (Hyrnuo) Tablet**
   a. **Indication:** For the treatment of adult patients with locally advanced or metastatic non-squamous non-small cell lung cancer (NSCLC) whose tumors have human epidermal growth factor receptor 2 (HER2/ERBB2) tyrosine kinase domain (TKD) activating mutations, as detected by an FDA-approved test, and who have received a prior systemic 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	No	N/A	N/A
Utilization Management Edits	Prior Authorization	Prior Authorization	Prior Authorization
Quantity Limit	Four (4) tablets per day	Four (4) tablets per day	Four (4) 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: Hernexeos, Enhertu			

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

PA PROGRAM NAME	Anti-Cancer Medications – Self-Administered
MEDICATION NAME	Sevabertinib film coated tablet (Hyrnuo)
REQUIRED MEDICAL INFORMATION	For initiation of therapy, all the following criteria must be met: 1. Use must be for an FDA approved indication or indication supported by National Comprehensive Cancer Network guidelines with recommendation 2A or higher AND 2. For Hernexeos for patients weighing 90 kilograms or greater: Documented contraindication to sevabertinib or prescriber has provided clinical rationale in support of zongertinib (Hernexeos) over sevabertinib (Hyrnuo).

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

PA PROGRAM NAME	Anti-Cancer Agents
MEDICATION NAME	Sevabertinib film coated tablet (Hyrnuo)
PA INDICATION INDICATOR	3 - All Medically-Accepted Indications

REQUIRED MEDICAL INFORMATION	One of the following for initiation of the requested agent: 1. For Hernexeos for patients weighing 90 kilograms or greater: Documentation of use of Hyrnuo for the requested indication, unless one of the following: a. The patient has an intolerance or hypersensitivity to Hyrnuo, b. The patient has an FDA labeled contraindication to Hyrnuo, c. CMS-approved compendia do not support the use of Hyrnuo for the requested indication, or d. The prescriber has provided information in support of use of Hernexeos over Hyrnuo for the requested indication. 2. For all other agents: Indication is supported by CMS-approved compendia.

9. **Ziftomenib (Komzifti) Capsule**
   a. **Indication:** For the treatment of adults with relapsed or refractory (R/R) acute myeloid leukemia (AML) with a susceptible nucleophosmin 1 (NPM1) mutation who have no satisfactory alternative treatment options.
   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	3 capsules per day	3 capsules per day	3 capsules 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: Revuforj			

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

PA PROGRAM NAME	Anti-Cancer Medications – Self-Administered
MEDICATION NAME	Komzifti
REQUIRED MEDICAL INFORMATION	For initiation of therapy, all the following criteria must be met: 1. Use must be for an FDA approved indication or indication supported by National Comprehensive Cancer Network guidelines with recommendation 2A or higher

	AND 2. For requests for revumernib (Revuforj) in adult patients with relapse or refractory acute myeloid leukemia (AML) with nucleophosmin 1 (NPM1) mutation: Documented contraindication to ziftomenib (Komzifti) or prescriber has provided clinical rationale in support of revumernib (Revuforj) over ziftomenib (Komzifti)

New Drug Strengths and Formulations:

1. **Denileukin diftitox-cxdl (Lymphir) Vial**
   a. **Indication**: For the treatment of adult patients with relapsed or refractory (R/F) Stage I-III cutaneous lymphoma (CTCL) after at least one prior systemic therapy.
   b. **Decision**:

	Commercial	Medicaid	Medicare
Formulary Status*	Medical	Medical	Part D: Non-formulary Part B: Medical
Tier**	N/A	N/A	N/A
Affordable Care Act Eligible	N/A; Non-Formulary	N/A	N/A
Utilization Management Edits	Prior Authorization	Prior Authorization	Prior Authorization
Quantity Limit	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: bexarotene capsules			

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

New Indications:

The following information is gathered from the United States Food and Drug Administration (FDA) Approved Drug Products database from 10/1/2025–11/30/2025

Therapies with Prior Authorization Policies (Non-oncology)

1. **SIMPONI** (GOLIMUMAB)
   a. New indication approved 10/07/2025:
      i. Adult and pediatric patients weighing at least 15 kg with moderate to severely active ulcerative colitis (UC)

b. **RECOMMENDATION:** Inform prescribers via Medical Policy Alert. Commercial and Medicaid 'Therapeutic Immunomodulator' policies were updated with revised indication at October 2025 P&T.

2. **PRALUENT** (ALIROCUMAB)
   a. New indication approved 10/09/2025:
      i. To reduce the risk of major adverse cardiovascular (CV) events (coronary heart disease death, myocardial infarction, stroke, or unstable angina requiring hospitalization) in adults at increased risk for these events
   b. **RECOMMENDATION:** Inform prescribers via Medical Policy Alert. Update Commercial and Medicaid 'PCSK-9 Inhibitors' policies with revised indication. No other policy criteria updates warranted.

3. **RINVOQ** (UPADACITINIB)
   a. New indication approved 10/10/2025:
      i. For the treatment of adult patients with moderately to severely active ulcerative colitis (UC) who have had an inadequate response or intolerance to one or more TNF blockers. If TNF blockers are clinically inadvisable, patients should have received at least one approved systemic therapy prior to use of Rinvoq
      ii. For the treatment of adult patients with moderately to severely active Crohn's disease (CD) who have had an inadequate response or intolerance to one or more TNF blockers. If TNF blockers are clinically inadvisable, patients should have received at least one approved systemic therapy prior to use of Rinvoq
   b. **RECOMMENDATION:** Inform prescribers via Medical Policy Alert. No policy updates warranted.

4. **CARVYKTI** (CILTACABTAGENE AUTOLEUCEL)
   a. New indication approved 10/10/25:
      i. For the treatment of adult patients with relapsed or refractory multiple myeloma, who have received at least 1 prior line of therapy, including a proteasome inhibitor and an immunomodulatory agent, and are refractory to lenalidomide
   b. **RECOMMENDATION:** Inform prescribers via Medical Policy Alert. Commercial/Medicaid/Medicare Part B 'T-Cell Therapy' policy updated during annual policy review for February 2026 P&T.

5. **OLPRUVA** (SODIUM PHENYLBUTYRATE)
   a. New indication approved 10/10/2025:
      i. Adjunctive therapy to standard of care, which includes dietary management, for the chronic management of adult and pediatric patients 1 year of age and older weighing 7 kg or greater, with urea cycle disorders involving deficiencies of carbamylphosphate synthetase, ornithine transcarbamylase, or argininosuccinic acid synthetase
   b. **RECOMMENDATION:** Inform prescribers via Medical Policy Alert. Update Commercial/Medicaid 'Medications for Rare Indications' policy with revised indication. No other policy criteria updates warranted.

6. **XELJANZ** (TOFACITINIB)
    a. New indication approved 10/16/2025:
        i. Treatment of pediatric patients 2 years of age and older with active psoriatic arthritis, who have had an inadequate response or intolerance to one or more TNF blocker
    b. **RECOMMENDATION:** Inform prescribers via Medical Policy Alert. Update Commercial and Medicaid 'Therapeutic Immunomodulator' policies with revised indication. No other policy criteria updates warranted.

7. **AMJEVITA** (ADALIMUMAB-ATTO)
    a. New indication approved 10/16/2025:
        i. For the treatment of moderate to severe hidradenitis suppurativa in patients 12 years of age and older
        ii. For the treatment of non-infectious intermediate, posterior, and panuveitis in adults and pediatric patients 2 years of age and older
    b. **RECOMMENDATION:** Inform prescribers via Medical Policy Alert. Update Commercial and Medicaid 'Therapeutic Immunomodulator' policies with revised indication. No other policy criteria updates warranted.

8. **CYLTEZO** (ADALIMUMAB-ADBM)
    a. New indication approved 10/16/2025:
        i. For the treatment of moderate to severe hidradenitis suppurativa in patients 12 years of age and older
        ii. For the treatment of non-infectious intermediate, posterior, and panuveitis in adults and pediatric patients 2 years of age and older
    b. **RECOMMENDATION:** Inform prescribers via Medical Policy Alert. Update Commercial and Medicaid 'Therapeutic Immunomodulator' policies with revised indication. No other policy criteria updates warranted.

9. **HYRIMOZ** (ADALIMUMAB-ADAZ)
    a. New indication approved 10/16/2025:
        i. For the treatment of moderate to severe hidradenitis suppurativa in patients 12 years of age and older
        ii. For the treatment of non-infectious intermediate, posterior, and panuveitis in adults and pediatric patients 2 years of age and older
    b. **RECOMMENDATION:** Inform prescribers via Medical Policy Alert. Update Commercial and Medicaid 'Therapeutic Immunomodulator' policies with revised indication. No other policy criteria updates warranted.

10. **YUFLYMA** (ADALIMUMAB-AATY)
    a. New indication approved 10/16/2025:
        i. For the treatment of moderate to severe hidradenitis suppurativa in patients 12 years of age and older
        ii. For the treatment of non-infectious intermediate, posterior, and panuveitis in adults and pediatric patients 2 years of age and older

b. **RECOMMENDATION:** Inform prescribers via Medical Policy Alert. Update Commercial and Medicaid 'Therapeutic Immunomodulator' policies with revised indication. No other policy criteria updates warranted.

11. **SIMLANDI** (ADALIMUMAB-RYVK)
    a. New indication approved 10/16/2025:
        i. For the treatment of moderate to severe hidradenitis suppurativa in patients 12 years of age and older
        ii. For the treatment of non-infectious intermediate, posterior, and panuveitis in adults and pediatric patients 2 years of age and older
    b. **RECOMMENDATION:** Inform prescribers via Medical Policy Alert. Update Commercial and Medicaid 'Therapeutic Immunomodulator' policies with revised indication. No other policy criteria updates warranted.

12. **RYBELSUS** (SEMAGLUTIDE)
    a. New indication approved 10/17/2025:
        i. To reduce the risk of major adverse cardiovascular (CV) events (CV death, non-fatal myocardial infarction or non-fatal stroke) in adults with type 2 diabetes mellitus who are at high risk for these events
    b. **RECOMMENDATION:** Inform prescribers via Medical Policy Alert. Update Commercial/Medicaid 'GIP and GLP-1 Receptor Agonists' policy with new indication. No other policy criteria updates warranted.

13. **TEZSPIRE** (TEZEPELUMAB-EKKO)
    b. New indication approved 10/17/25:
        i. Add-on maintenance treatment of adult and pediatric patients aged 12 years and older with inadequately controlled chronic rhinosinusitis with nasal polyps (CRSwNP)
    c. **RECOMMENDATION:** Inform prescribers via Medical Policy Alert. Update Commercial and Medicaid 'Therapeutic Immunomodulator' policies with new indication. No other policy criteria updates warranted.

14. **LINZESS** (LINACLOTIDE)
    a. New indication approved 11/04/2025:
        i. Irritable bowel syndrome with constipation (IBS-C) in adults and pediatric patients 7 years of age and older
    b. **RECOMMENDATION:** Inform prescribers via Medical Policy Alert. Update Medicaid 'Constipation Agents' policy with revised indication. No other policy criteria updates warranted.

15. **CAPLYTA** (LUMATEPERONE)
    a. New indication approved 11/05/2025:
        i. Adjunctive therapy with antidepressants for the treatment of major depressive disorder (MDD) in adults

b. **RECOMMENDATION:** Inform prescribers via Medical Policy Alert. Update Commercial 'Antipsychotics' policy with new indication. No other policy criteria updates warranted.

16. **EPKINLY** (EPCORITAMAB-BYSP)
    a. New indication approved 11/18/25:
        i. In combination with lenalidomide and rituximab for the treatment of adult patients with relapsed or refractory follicular lymphoma (FL)
        ii. As monotherapy for the treatment of adult patients with relapsed or refractory FL after two or more lines of systemic therapy
    b. **RECOMMENDATION:** Inform prescribers via Medical Policy Alert. Commercial/Medicaid/Medicare Part B 'T-Cell Therapy' policy updated during annual policy review for February 2026 P&T.

17. **EYLEA HD** (AFLIBERCEPT)
    a. New indication approved 11/19/2025:
        i. Macular edema following retinal vein occlusion
    b. **RECOMMENDATION:** Inform prescribers via Medical Policy Alert. Update Commercial/Medicaid and Medicare Part B 'Ophthalmic Vascular Endothelial Growth Factor (VEGF) Inhibitors' policy with new indication. No other policy criteria updates warranted.

18. **NEXLETOL** (BEMPEDOIC ACID)
    a. New indication approved 11/21/2025:
        i. To reduce the risk of major adverse cardiovascular events (cardiovascular death, myocardial infarction, stroke, or coronary revascularization) in adults at increased risk for these events who are unable to take recommended statin therapy (including those not taking a statin).
    b. **RECOMMENDATION:** Inform prescribers via Medical Policy Alert. Update Commercial/Medicaid 'Nexletol/Nexlizet' policy with revised indication. No other policy criteria updates warranted.

19. **NEXLIZET** (BEMPEDOIC ACID AND EZETIMIBE)
    a. New indication approved 11/21/2025:
        i. Bempedoic acid, a component of Nexlizet, is indicated to reduce the risk of major adverse cardiovascular events (cardiovascular death, myocardial infarction, stroke, or coronary revascularization) in adults at increased risk for these events who are unable to take recommended statin therapy (including those not taking a statin)
    b. **RECOMMENDATION:** Inform prescribers via Medical Policy Alert. Update Commercial/Medicaid 'Nexletol/Nexlizet' policy with revised indication. No other policy criteria updates warranted.

Therapies with Prior Authorization Policies (Oncology)

1. **ZEPZELCA** (LURBINECTEDIN)
    a. New indication(s) approved 10/02/2025:
        i. In combination with atezolizumab or atezolizumab and hyaluronidase-tqjs, for the maintenance treatment of adult patients with extensive-stage small cell lung cancer whose disease has not progressed after first-line induction therapy with atezolizumab or atezolizumab and hyaluronidase-tqjs, carboplatin and etoposide
    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 10/02/2025:
        i. In combination with lurbinectedin, for the maintenance treatment of adult patients with ES-SCLC whose disease has not progressed after first-line induction therapy with TECENTRIQ or atezolizumab and hyaluronidase-tqjs, carboplatin and etoposide
    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. **AXTLE** (PEMETREXED)
    a. New indication(s) approved 10/03/2025:
        i. In combination with pembrolizumab and platinum chemotherapy, for the initial treatment of patients with metastatic non-squamous non-small cell lung cancer (NSCLC), with no EGFR or ALK genomic tumor aberrations
    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. **LIBTAYO** (CEMIPLIMAB-RWLC)
    a. New indication(s) approved 10/08/2025:
        i. Adjuvant treatment of patients with cutaneous squamous cell carcinoma (CSCC) at high risk of recurrence after surgery and radiation
    b. **RECOMMENDATION:** Inform prescribers via Medical Policy Alert. Prior authorization policy coverage criteria are based on recommendations from the National Comprehensive Cancer Network (NCCN); no updates to the policy are warranted.
5. **REVUFORJ** (REVUMENIB)
    a. New indication(s) approved 10/24/2025:
        i. Treatment of relapsed or refractory acute myeloid leukemia with a susceptible nucleophosmin 1 (NPM1) mutation in adult and pediatric patients 1 year and older who have no satisfactory alternative treatment options
    b. **RECOMMENDATION:** Inform prescribers via Medical Policy Alert. Prior authorization policy coverage criteria are based on recommendations from the National Comprehensive Cancer Network (NCCN); no updates to the policy are warranted.

6. **OPDIVO QVANTIG** (NIVOLUMAB AND HYALURONIDASE-NVHY)
    a. New indication(s) approved 10/27/2025, 11/24/2025:
        i. As monotherapy, for the first-line treatment of adult patients with unresectable or metastatic hepatocellular carcinoma (HCC) following treatment with intravenous nivolumab and ipilimumab combination therapy
        ii. For the treatment of adult and pediatric patients 12 years and older who weigh 30 kg or greater with unresectable or metastatic microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) colorectal cancer (CRC) following treatment with intravenous nivolumab and ipilimumab combination therapy
        iii. As monotherapy, for the treatment of adult and pediatric patients 12 years and older who weigh 30 kg or greater, with MSI-H or dMMR metastatic CRC that has progressed following treatment with a fluoropyrimidine, oxaliplatin, and irinotecan
        iv. As monotherapy, for the adjuvant treatment of adult and pediatric patients 12 years and older who weigh 30 kg or greater with completely resected Stage IIB, Stage IIC, Stage III, or Stage IV melanoma
    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. **DARZALEX FASPRO** (DARATUMUMAB AND HYALURONIDASE-FIHJ)
    a. New indication(s) approved 11/06/2025:
        i. For the treatment of adult patients with high-risk smoldering multiple myeloma as monotherapy
    b. **RECOMMENDATION:** Inform prescribers via Medical Policy Alert. Prior authorization policy coverage criteria are based on recommendations from the National Comprehensive Cancer Network (NCCN); no updates to the policy are warranted.

8. **KEYTRUDA** (PEMBROLIZUMAB)
    a. New indication(s) approved 11/21/2025:
        i. In combination with enfortumab vedotin, as neoadjuvant treatment, and then continued after cystectomy as adjuvant treatment for the treatment of adult patients with muscle invasive bladder cancer who are ineligible for cisplatin containing 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.

9. **KEYTRUDA QLEX** (PEMBROLIZUMAB AND BERAHYALURONIDASE ALFA-PMPH)
    a. New indication(s) approved 11/21/2025:
        i. In combination with enfortumab vedotin, as neoadjuvant treatment, and then continued after cystectomy as adjuvant treatment for the treatment of adult patients with muscle invasive bladder cancer who are ineligible for cisplatin containing 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.

10. **PADCEV** (ENFORTUMAB VEDOTIN-EJFV)
    a. New indication(s) approved 11/21/2025:
        i. In combination with pembrolizumab, as neoadjuvant treatment, and then continued after cystectomy as adjuvant treatment for the treatment of adult patients with muscle invasive bladder cancer who are ineligible for cisplatin-containing 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.

11. **TECENTRIQ HYBREZA** (ATEZOLIZUMAB AND HYALURONIDASE-TQJS)
    a. New indication(s) approved 11/24/2025:
        i. As monotherapy, for the treatment of adult patients and pediatric patients (12 years of age and older who weigh 40 kg or greater) with unresectable or metastatic alveolar soft part sarcoma
    b. **RECOMMENDATION:** Inform prescribers via Medical Policy Alert. Prior authorization policy coverage criteria are based on recommendations from the National Comprehensive Cancer Network (NCCN); no updates to the policy are warranted.

12. **IMFINZI** (DURVALUMAB)
    a. New indication(s) approved 11/25/2025:
        i. In combination with fluorouracil, leucovorin, oxaliplatin and docetaxel (FLOT) as neoadjuvant and adjuvant treatment, followed by single-agent Imfinzi, is indicated for the treatment of adult patients with resectable gastric or gastroesophageal junction adenocarcinoma
    b. **RECOMMENDATION:** Inform prescribers via Medical Policy Alert. Prior authorization policy coverage criteria are based on recommendations from the National Comprehensive Cancer Network (NCCN); no updates to the policy are warranted.

Therapies Without Prior Authorization Policies

1. **UZEDY** (RISPERIDONE EXTENDED-RELEASE)
    a. Previous Indication(s):
        i. For the treatment of schizophrenia in adults
    b. New indication(s) approved 10/10/2025:
        i. Monotherapy or adjunctive therapy to lithium or valproate for the maintenance treatment of bipolar I disorder in adults
    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 10/1/2025 - 11/30/2025

FDA Drug Safety Communications

1. **Drug Name: Ciltacabtagene Autoleucel (Carvykti®)**
    a. **Date Posted:** October 10, 2025
    b. **Safety Alert Title:** FDA approves labeling changes that include a Boxed Warning for Immune Effector Cell-associated Enterocolitis following treatment with Ciltacabtagene Autoleucel (CARVYKTI, Janssen Biotech, Inc.)
    c. **Link to more information:** https://www.fda.gov/vaccines-blood-biologics/safety-availability-biologics/fda-approves-labeling-changes-include-boxed-warning-immune-effector-cell-associated-enterocolitis
    d. **What safety concern is FDA announcing?**
        i. Reports were received from clinical trials and postmarketing adverse event data of immune effector cell-associated enterocolitis (IEC-EC) in patients who received treatment with Carvykti.
    e. **What is FDA doing?**
        i. FDA has completed the review of data from the clinical trial and the postmarketing adverse event reports, and has approved updates to the Boxed Warning (also known as Black Box Warning), Warnings and Precautions, and Adverse Reactions – Postmarketing Experience sections of the prescribing information and Medication Guide to include the risk of IEC-EC.
    f. **What should health care professionals do?**
        i. Patients and clinical trial participants with IEC-EC should be managed according to the institutional guidelines including referral to gastroenterology and infectious disease specialists. In patients with treatment refractory IEC-EC, additional work up should be considered to rule out T cell lymphoma of the gastrointestinal tract which has been reported in patients with treatment refractory IEC-EC in the postmarketing setting.
    g. **Health Plan Recommendation:** Notify providers via Medical Policy Alert.

2. **Drug Name: Immune Globulin (Asceniv®, Bivigam®)**
    a. **Date Posted:** October 28, 2025
    b. **Safety Alert Title:** Immune Globulin Intravenous (IGIV) and/or Immune Globulin Subcutaneous (IGSC) Lots with Increased Reports of Allergic/Hypersensitivity Reactions
    c. **Link to more information:** https://www.fda.gov/vaccines-blood-biologics/immune-globulin-intravenous-igiv-andor-immune-globulin-subcutaneous-igsc-lots-increased-reports
    d. **What safety concern is FDA announcing?**
        i. The FDA Adverse Event Reporting System (FAERS) has received increased reporting of allergic/hypersensitivity type reactions following infusion of specific lots of Immune Globulin Intravenous (IGIV) and/or and Immune Globulin Subcutaneous (IGSC) listed below.

Product Lot	Expiration Date	Manufacturer
Asceniv lot # 239825	31-Aug-2027	ADMA Biologics
Bivigam lot # 237452	31-Oct-2027	ADMA Biologics

ii. Though hypersensitivity and anaphylactic/anaphylactoid reactions are a known risk with immune globulin products, the increased reporting of hypersensitivity reactions to these lots presents heightened safety risks for patients.

e. **What is FDA doing?**
   i. While FDA investigates this safety issue, the Agency recommends examining stock immediately and cease use of affected lots.
f. **What should health care professionals do?**
   i. Cease use of affected lots.
   ii. Continue to report suspected adverse events to the FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.
g. **Health Plan Recommendation:** Notify providers via Medical Policy Alert.

3. **Drug Name: Delandistrogene moxeparvovec-rokl (Elevidys®)**
   a. **Date Posted:** November 14, 2025
   b. **Safety Alert Title:** FDA Takes Action on New Boxed Warning for Acute Serious Liver Injury and Acute Liver Failure Following Treatment with Elevidys and Revised Indication that is Limited to Ambulatory Duchenne Muscular Dystrophy Patients
   c. **Link to more information:** **https://www.fda.gov/vaccines-blood-biologics/safety-availability-biologics/fda-takes-action-new-boxed-warning-acute-serious-liver-injury-and-acute-liver-failure-following**
   d. **What safety concern is FDA announcing?**
      i. Fatal reports of acute liver failure were received from clinical trial and postmarketing data.
      ii. Life-threatening mesenteric vein thrombosis, complicated by bowel ischemia and necrosis, and portal hypertension has also been reported following serious non-fatal acute liver injury associated with Elevidys in a non-ambulatory DMD patient.
   e. **What is FDA doing?**
      i. FDA has completed a review of the safety data and, following FDA's issuance of a safety labeling change notification letter, has approved the following safety labeling changes to include new safety information on the risk of serious liver injury and acute liver failure including fatal outcomes: addition of *Boxed Warning*; updates to the *Indications and Usage* including addition of *Limitations of Use; Warnings and Precautions*; *Dosage and Administration*; *Adverse Reactions – Postmarketing Experience*; *Use in Specific Populations*; *Clinical Studies*; *Patient Counseling Information* sections of the prescribing information, and addition of a Medication Guide.

ii. The revised *Indications and Usage* limits the indication to ambulatory *DMD* patients who are 4 years of age or older and have a confirmed mutation in the DMD gene. The indication for use in the non-ambulatory population is no longer included in the *Indications and Usage* section of the labeling, and use in the non-ambulatory population is no longer licensed under the BLA. Therefore, Elevidys is only approved for use in ambulatory DMD patients 4 years of age and older.

f. **What should health care professionals do?**
   i. There is now a *Limitations of Use* section to emphasize careful consideration of appropriateness and timing of treatment. FDA concluded that addition of a *Boxed Warning* was warranted to highlight the risk of serious liver injury and acute liver failure and alert healthcare providers to obtain prompt consultation with a specialist if acute serious liver injury or impending acute liver failure is suspected, and instruct patients to maintain proximity to an appropriate healthcare facility, as determined by the healthcare provider, for at least 2 months following Elevidys infusion.

g. **Health Plan Recommendation:** Update PHP policy with revised indication. Notify providers via Medical Policy Alert.

4. **Drug Name: Apadamtase alfa (Adzynma®)**
   a. **Date Posted:** November 21, 2025
   b. **Safety Alert Title:** FDA Investigating Death Due to Neutralizing Antibodies to ADAMTS13 following Adzynma Treatment of Congenital Thrombotic Thrombocytopenic Purpura
   c. **Link to more information:** https://www.fda.gov/vaccines-blood-biologics/safety-availability-biologics/fda-investigating-death-due-neutralizing-antibodies-adamts13-following-adzynma-treatment-congenital
   d. **What safety concern is FDA announcing?**
      i. Postmarketing reports of neutralizing antibodies to ADAMTS13, including one death, in congenital thrombotic thrombocytopenic purpura patients treated with Adzynma (ADAMTS13, recombinant-krhn).
   e. **What is FDA doing?**
      i. FDA is investigating the risk of development of neutralizing antibodies with serious, including life-threatening or fatal, outcomes following treatment with Adzynma and is evaluating the need for further regulatory action.
   f. **What should health care professionals do?**
      i. The *Patient Package Insert* for this product instructs patients to consult with their healthcare provider for monitoring with blood tests for the development of inhibitors to ADAMTS13.
   g. **Health Plan Recommendation:** Notify providers via Medical Policy Alert.

Drug Recalls/Market Withdrawals

1. **Drug Name:** 20 mEq Potassium Chloride Injection
   a. **Date of Recall:** November 3, 2025
   b. **Reason for recall:** Potential for potassium chloride overdose: 20 mEq potassium chloride injection is mislabeled as 10 mEq potassium chloride injection

c. **Link to more information:** https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/otsuka-icu-medical-llc-issues-voluntary-nationwide-recall-20-meq-potassium-chloride-injection-due
d. **Health Plan Recommendation:** Notify providers via Medical Policy Alert.

2. **Drug Name:** Famotidine Injection
   a. **Date of Recall:** November 7, 2025
   b. **Reason for recall:** Voluntary recall of three lots of famotidine injection due to out-of-specification (OOS) endotoxin results of certain reserve samples.

Product Name/Product Size	Unit of Use NDC Number	Unit of Sale NDC Number	Product Code	Batch Number	Expiration Date	First Ship Date	Last Ship Date
Famotidine Injection, USP, 20 mg per 2 mL (10 mg per mL), 2mL fill in a 2 mL vial	63323-739-11	63323-739-12	730912	6133156	08/2026	01/02/2025	02/11/2025
				6133194	08/2026	02/04/2025	04/11/2025
				6133388	10/2026	04/15/2025	05/23/2025

   c. **Link to more information:** https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/fresenius-kabi-issues-voluntary-nationwide-recall-three-lots-famotidine-injection-usp-20-mg-2-ml-10
   d. **Health Plan Recommendation:** Notify providers via Medical Policy Alert.

Other Formulary Changes:

Drug Name	Recommendation	Policy Name
Methoxy polyethylene glycol-epoeting beta (Mircera) Syringe	Correction from December 2025 P&T: • Add Prior authorization to all lines of business	Erythropoiesis Stimulating Agents
Nitazoxanide (Alinia) Tablet	Correction from December 2025 P&T: • Medicare Part D: Drug should be Tier 5, not Tier 4	N/A
• **Humira (adalimumab)** • **Amjevita (adalimumab-atto)**	Remove from Medicaid formulary as non-preferred adalimumab Effective 3/1/26	Therapeutic Immunomodulators

Drug Name	Recommendation	Policy Name
• **Hulio (adalimumab-fkjp)**		
• **Hadlima (adalimumab-bwwd)** • **Simlandi (adalimumab-ryvk)**	Add to Medicaid formulary as preferred biosimilar Effective 3/1/26	Therapeutic Immunomodulators
Allopurinol 200 mg tablet	New strength • Commercial/Medicaid: Non-formulary, Prior Authorization • Medicare part D: Non-Formulary Effective 5/1/26	• Commercial/Medicaid: New Medications and Formulations Without Established Benefit • Medicare Part D: N/A
Nuvigil (armodafinil)	Remove brand from Commercial formulary	N/A
Olumiant (baricitinib)	Add to Commercial Standard formulary for groups that cover alopecia areata: • Commercial Standard: Formulary, Tier 6, Prior Authorization, Quantity Limit (one tablet per day)	Therapeutic Immunomodulators
Leqselvi (deuruxolitinib)	Add to Commercial Standard formulary for groups that cover alopecia areata: • Commercial Standard: Formulary, Tier 6, Prior Authorization, Quantity Limit (two tablets per day)	Therapeutic Immunomodulators
Litfulo (ritlecitinib)	Add to Commercial Standard formulary for groups that cover alopecia areata: • Commercial Standard: Formulary, Tier 6, Prior Authorization, Quantity Limit (one capsule per day)	Therapeutic Immunomodulators
• **Truqap (capivasertib)** • **Fruzaqla (fruquintinib)** • **Tagrisso (osimertinib)**	Commercial: Down-tier to Tier 5 from Tier 6	Anti-Cancer Medications - Self-Administered
Vyscoxa (celecoxib) 10 mg/mL oral suspension	New formulation • 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
Cladribine tablet (generic for Mavenclad)	Add to Commercial formulary (preferred over brand): Tier 5, Prior Authorization	Multiple Sclerosis Agents
Colchicine 0.6 mg capsule	Remove from Commercial and Medicaid formularies, add Prior Authorization	New Medications and Formulations Without Established Benefit

Drug Name	Recommendation	Policy Name
	Effective 5/1/26	
Tonmya (cyclobenzaprine) sublingual tablet	New formulation: Non-formulary for all lines of business	N/A
Desloratadine 0.5 mg/mL solution	New formulation: Non-formulary for all lines of business	N/A
Dicyclomine 40 mg tablet	New strength. Non-formulary with FDA Max Quantity limit (four tablets per day) for all lines of business	N/A
Entecavir tablet	Medicare Part D: Down-tier to Tier 2 from Tier 4	N/A
Xtandi (enzalutamide)	Add quantity limits for Commercial and Medicaid: • 40 mg tablet/capsule: four tablets/capsules per day • 80 mg tablet: two tablets per day	
Escitalopram oxalate capsule	New formulation • Commercial: Non-formulary, Quantity Limit (one per day) • Medicaid: Non-formulary (covered by DMAP) • Medicare part D: Formulary, Tier 4, Quantity Limit (one capsule per day)	N/A
Conjugated estrogens	First generic drug (Premarin) • Commercial/Medicare Part D: Non-formulary (brand preferred) • Medicaid: Formulary	N/A
Lasix Onyu (furosemide) injectable kit	New dosage form: Non-formulary for all lines of business	N/A
Gabarone (gabapentin) 100 and 400 mg tablets	New strength • Commercial/Medicaid: Non-formulary, Prior Authorization • Medicare part D: Non-Formulary	• Commercial/Medicaid: New Medications and Formulations Without Established Benefit • Medicare Part D: N/A
Avgemsi (gemcitabine) vial	New strength: Medical benefit with prior authorization for all lines of business	Anti-Cancer Medications – Medical Administration

Fanapt (iloperidone) dose packs	New dosage packs:
	• Commercial: Non-formulary, Quantity Limit
	  ○ 1-2-6-mg pack: eight tablets per year
	  ○ 1-2-6-8 mg pack: 12 tablets per year
		Antipsychotics

Drug Name	Recommendation	Policy Name

	• Medicaid: Non-formulary (covered by DMAP)
	• Medicare part D: Formulary, Tier 4, Quantity Limit (24 tablets per year)
	  ○ 1-2-6-mg pack: 16 tablets per year
	  ○ 1-2-6-8 mg pack: 24 tablets per year	

Twiist Disposable insulin pumps	New product. Non-preferred for all lines of business (same criteria as non-preferred V-go product)
	• Commercial/Medicaid: Medical benefit (DME/diabetic supplies), Prior Authorization, Quantity Limit
	  ○ Starter kit: 1 kit per year
	  ○ Refill kit: 10 per 30 days
	• Medicare part D: Non-Formulary
		Disposable Insulin Pumps

Subvenite (lamotrigine) oral suspension	New formulation: • Commercial/Medicaid: Non-formulary • Medicare part D: Formulary, Tier 4	N/A
Midazolam auto-injector	New formulation: • Commercial/Medicaid: Non-formulary • Medicare part D: Formulary, Tier 4	N/A
Pazopanib 400 mg tablet	New strength: • Commercial/Medicaid: Non-formulary, Prior Authorization, Quantity Limit (two tablets per day) • Medicare Part D: Non-Formulary	• Commercial/Medicaid: Anti-Cancer Medications - Self-Administered • Medicare: N/A
Wakix (pitolisant)	Commercial: Up-tier to Tier 6 from Tier 5	
Zoryve (roflumilast) 0.15% cream	Commercial: Add to Formulary, Tier 4, Prior Authorization, Quantity Limit (60 g/30 days)	Topical Agents for Skin Conditions
Vtama (tapinarof) cream	Commercial: Add to Formulary, Tier 4, Prior Authorization, Quantity Limit (60 g/30 days)	Topical Agents for Skin Conditions
Trintellix (vortioxetine) tablet	Commercial: Add to Formulary, Tier 4, Step Therapy, Quantity Limit (one tablet per day) **Step therapy criteria:** prior use of one formulary, generic antidepressant	Trintellix Step Therapy

Drug Name	Recommendation	Policy Name
Javadin (clonidine) oral solution	New Formulation • 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
Beizray (docetaxel) vial	New formulation: Medical benefit with prior authorization for all lines of business	Anti-Cancer Medications – Medical Administration
Nilotinib D-tartrate capsule	New generic formulation. • Commercial: Add to formulary, Tier 6, Prior Authorization, Quantity Limit (four capsules per day) • Medicaid: Non-formulary, Prior Authorization, Quantity Limit (four capsules per day) • Medicare part D: Non-Formulary	Anti-Cancer Medications - Self-Administered
Bimzelx (bimekizumab-bkzx) syringe, autoinjector	Commercial: Add to formulary, Tier 6, Prior Authorization, Quantity Limit (one injection every 28 days)	Therapeutic Immunomodulators
Takhzyro (lanadelumab-flyo)	Commercial: Down-tier to Tier 5 from Tier 6	Prophylactic Hereditary Angioedema Therapy
Haegarda (C1 esterase inhibitor)	• Commercial: Down-tier to Tier 5 from Tier 6 • Medicare Part D: Add to formulary, Tier 5, Prior Authorization	• Commercial: Prophylactic Hereditary Angioedema Therapy • Medicare Part D: HAE Therapy

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

Drugs released from 8/1/2025 – 12/19/2025

INFORMATIONAL ONLY

NEW DRUGS / COMBINATIONS / STRENGTHS / DOSAGE FORMS		
Drug Name	**Action Taken**	**Policy Name**
Lactic acid/citric/potassium (Phexx) Gel/PF App	New MedID. Line extend with previously named product Phexxi; • Commercial: Preventive • Medicaid/Medicare Part D: Non-Formulary	N/A
Potassium chloride (Pokonza) Packet	New strength (15 mEq). Line extend with Pokonza 10mEq oral packet; • Non-formulary for all lines of business	N/A

NEW DRUGS / COMBINATIONS / STRENGTHS / DOSAGE FORMS		
Drug Name	**Action Taken**	**Policy Name**
Potassium chloride Packet	New strength (40 mEq). Line extend with Klor-Con 20 mEq powder packets; • Non-formulary for all lines of business	N/A
Hydrocortisone/pramoxine (Pramosone) Lotion	New route for existing brand (topical). Line extend with Pramosone 1 %-1 % cream and ointment;	
Thiotepa (Tepadina) Plast. Bag	New formulation (plast. Bag): Line extend with Tepadina 15mg and 100mg vials; • Commercial/Medicaid/Medicare Part B: Medical Benefit • Medicare Part D: Non-Formulary	N/A
Ustekinumab-aauz SYRINGE	New MedID. Line extend with Non-preferred ustekinumab; • Commercial/Medicaid: Non-Formulary, Prior Authorization, Quantity Limit (1 injection per 84 days) • Medicare Part D: Non-Formulary	• Commercial/Medicaid: Therapeutic Immunomodulators (TIMS) • Medicare Part D: N/A
Deflazacort (Jaythari) Oral Susp	New formulation. Line extend with deflazacort; • Commercial/Medicaid: Non-Formulary, Specialty, Prior Authorization • Medicare Part D: Non-Formulary	• Commercial/Medicaid: Corticosteroids for Duchenne Muscular Dystrophy • Medicare Part D: N/A
Nipocalimab-aahu (Imaavy) Vial	New strength (300MG/1.62). Line extend with Imaavy 185mg/ml; • Commercial/Medicaid/Medicare Part B: Medical Benefit • Medicare Part D: Non-Formulary	• Commercial/Medicaid: FcRn Antagonists • Medicare Part B: FcRn Antagonists Prior Authorization and Step Therapy Policy
Ustekinumab-hmny (Starjemza) Vial for intravenous	New BLA. Line extend with non-preferred ustenikumab biosimilar; • Commercial/Medicaid/Medicare Part B: Medical Benefit, Prior Authorization • Medicare Part D: Non-Formulary	• Commercial: Medically Infused Therapeutic Immunomodulators • Medicaid: Therapeutic Immunomodulators (TIMS) • Medicare Part B: Medically Infused Therapeutic Immunomodulators (TIMs) Prior Authorization and Step Therapy Policy

NEW DRUGS / COMBINATIONS / STRENGTHS / DOSAGE FORMS		
Drug Name	**Action Taken**	**Policy Name**
Spesolimab-sbzo (Spevigo) Syringe	New strength (300 mg/2 mL): Line extend with Spevigo 150mg/ml syringe; • Commercial/Medicaid/: Non-Formulary, Prior Authorization, Quantity Limit (two mL per 28 days) • Medicare Part D: Non-Formulary	• Commercial/Medicaid: Medications For Rare Indications • Medicare Part D: N/A
Treprostinil (Tyvaso DPI) Cart Inhal	New formulation. Line extend with existing Tyvaso strengths; • Commercial/Medicaid: Non-Formulary, Prior Authorization, Specialty • Medicare Part D: Non-Formulary	• Commercial/Medicaid: Pulmonary Hypertension • Medicare Part D: N/A
Ustekinumab-hmny (Starjemza) Syringe; Vial for SQ injection	New BLA. Line extend with non-preferred ustenikumab; • Commercial/Medicaid: Non-Formulary, Prior Authorization, Quantity Limit (one injection per 84 days), Specialty • Medicare Part D: Non-Formulary	• Commercial/Medicaid: Therapeutic Immunomodulators (TIMS) • Medicare Part D: N/A
Adalimumab-bwwd ("unbranded" Hadlima) syringe, autoinjector	New BLA. Line extend with non-preferred adalimumab; • Commercial/Medicaid: Non-Formulary, Prior Authorization, Quantity Limit (two injections per 28 days), Specialty • Medicare Part D: Non-Formulary	• Commercial/Medicaid: Therapeutic Immunomodulators (TIMS) • Medicare Part D: N/A
Blenrep (belantamab mafodotin-blmf) vial	New BLA. Line extend with Blenrep: Medical benefit, Prior Authorization for all lines of business	• Commercial/Medicaid: Anti-Cancer Medications – Medical Administration • Medicare Part D: N/A • Medicare Part B: Anti-Cancer Medications – Medical Administration

NEW GENERICS		
Drug Name	**Action Taken**	**Policy Name**
Ciprofloxacin-hydrocortisone Drops Susp	First generic drug. Line extend with brand Cipro HC;	N/A

NEW GENERICS		
Drug Name	**Action Taken**	**Policy Name**
	• Commercial Standard: Formulary, Tier 2 • Commercial Dynamic: Formulary, Tier 4 • Medicaid/Medicare Part D: Non-Formulary	
Dalbavancin hcl Vial	First generic. Line extend with brand Dalvance; • Commercial/Medicaid/Medicare Part B: Medical Benefit • Medicare Part D: Non-Formulary	N/A

Deflazacort (Kymbee 6 mg; 18 mg) Tablet	New generic for existing brand; New branded generic. Line extend with generic deflazacort;
	• Commercial/Medicaid: Non-formulary, Prior Authorization, Quantity Limit:
	  ○ 6 mg: 2 per day
	  ○ 18 mg: 1 per day
	• Medicare Part D: Non-formulary
		• Commercial/Medicaid: Corticosteroids for Duchenne Muscular Dystrophy
		• Medicare Part D: N/A

Deflazacort (Kymbee 30 mg; 36 mg) Tablet	New generic for existing brand; New branded generic. Line extend with generic deflazacort; • Commercial/Medicaid: Non-formulary, Prior Authorization • Medicare Part D: Non-formulary	• Commercial/Medicaid: Corticosteroids for Duchenne Muscular Dystrophy • Medicare Part D: N/A
Prednisolone sodium phos odt Tab Rapdis	New generic. Line extend with brand Orapred; • Commercial Standard: Formulary, Tier 2 • Commercial Dynamic: Formulary, Tier 4 • Medicaid: Formulary • Medicare Part D: Non-Formulary	N/A
Tacrolimus Vial	New generic for existing brand. Line extend with brand Prograf injection; • Commercial/Medicaid/Medicare Part B: Medical Benefit • Medicare Part D: Non-Formulary	N/A
Lomustine Capsule	First generic drug (Gleostine). Line extend with brand Gleostine; • Commercial Standard: Formulary, Tier 2, Specialty	• Commercial/Medicaid: N/A • Medicare Part D: Anti-Cancer Agents

NEW GENERICS		
Drug Name	**Action Taken**	**Policy Name**
	• Commercial Dynamic: Formulary, Tier 4, Specialty • Medicaid: Formulary, Specialty • Medicare Part D: Formulary, Tier 4, Prior Authorization	
Perampanel Oral Susp	New generic. Line extend with perampanel generic tablets; • Commercial Standard: Formulary, Tier 2, Step Therapy, Quantity Limit (24 mL per day) • Commercial Dynamic: Formulary, Tier 4, Step Therapy, Quantity Limit (24 mL per day) • Medicaid: Formulary, Step Therapy, Quantity Limit (24 mL per day) • Medicare Part D: Formulary, Tier 5, Step Therapy, Quantity Limit (24 mL per day)	Antiepileptic Medications Step Therapy Policy
• **Linagliptin-metformin 2.5-500 mg Tablet** • **Linagliptin-metformin 2.5-1000 mg Tablet**	New generic. Line extend with brand Jentadueto; • Commercial Standard: Formulary, Tier 2, Step Therapy, Quantity Limit (2 tablets per day) • Commercial Dynamic: Formulary, Tier 4, Step Therapy, Quantity Limit (2 tablets per day) • Medicaid: Non-Formulary, Step Therapy, Quantity Limit (2 tablets per day) • Medicare Part D: Formulary, Tier 3, Quantity Limit (2 tablets per day)	• Commercial/Medicaid: DPP-4 Inhibitors Step Therapy Policy • Medicare Part D: N/A
Linagliptin-metformin 2.5-850 mg Tablet	New generic. Line extend with brand Jentadueto; • Commercial Standard: Formulary, Tier 2, Step Therapy, Quantity Limit (2 tablets per day) • Commercial Dynamic: Formulary, Tier 4, Step Therapy, Quantity Limit (2 tablets per day) • Medicaid: Non-Formulary, Step Therapy, Quantity Limit (2 tablets per day) • Medicare Part D: Non-Formulary	• Commercial/Medicaid: DPP-4 Inhibitors Step Therapy Policy • Medicare Part D: N/A
Prednisone Tablet DR	New generic. Line extend with brand Rayos;	• Commercial/Medicaid: New Medications and Formulations without Established Benefit

NEW GENERICS		
Drug Name	**Action Taken**	**Policy Name**
	• Commercial/Medicaid: Non-Formulary, Prior Authorization • Medicare Part D: Non-Formulary	• Medicare Part D: N/A

Clinical Policy Changes:

PHARMACY CLINICAL POLICIES – MAJOR CHANGES	
Policy Name	**Summary of Change**
• **Anti-Cancer Medications - Medical Benefit** • **Anti-Cancer Medications Prior Authorization and Step Therapy Policy - Medicare Part B**	Shorten coverage duration from long term authorization to one year. Added additional criteria for patients established on therapy to ensure use is supported in clinical guidelines/medical literature. Add Blenrep (belantamab mafodotin-blmf) to policy. Add step through generic medication for Kyxata (carboplatin) and Avgemsi (gemcitabine).
Anti-Cancer Medications - Self-Administered	Shorten coverage duration from long term authorization to one year. Added additional criteria for patients established on therapy to ensure use is supported in clinical guidelines/medical literature. Adding step criteria for pazopanib 400 mg tablets to step through generic pazopanib 200 mg tablets. Adding nilotinib d-tartrate to imatinib step criteria.
Filspari, Vanrafia	Filspari will have a quantity of one tablet per day for both 200mg and 400mg tablets. Use in combination with sparsentan (Filspari®), atrasentan (Vanrafia®) or iptacopan (Fabhalta®) is excluded. Added requirement of trial of SGLT-2 inhibitor prior to coverage.
• **Acute Hereditary angioedema (HAE) Therapy** • **Acute HAE Therapy Prior Authorization and Step Therapy Policy – Medicare Part B**	Duration of approval expanded to one year authorization for both initial and reauthorization.
• **Prophylactic HAE Therapy** • **Prophylactic HAE Therapy Prior Authorization and Step Therapy Policy – Medicare Part B**	Duration of approval expanded to one year authorization for both initial and reauthorization. Added dosing and age restrictions to require requests be aligned with Food and Drug Administration label.

Leucovorin Policy	Require documentation of suspected cerebral folate deficiency (CFD) for autism with suspected CFD.
Long-Acting Opioids	Updated morphine equivalent requirements to align with CDC recommendation for use of opioids prior to initiating long-acting therapy. Updated pain contract requirements to require documentation that contract has been reviewed within the last year and that patient is adherent to the requirements of the contract. Updated naloxone requirement to include education being provided.
Maximum Allowable Opioid Dose	Updated pain contract requirements to require documentation that contract has been reviewed within the last year and that patient is adherent to the requirements of the contract. Updated naloxone requirement to include education being provided.
Multiple Sclerosis Agents	Updating policy criteria to require trial and failure of generic cladribine for brand Mavenclad requests.
Omisirge	Updated criteria related to updated FDA approved indication for aplastic anemia.
Primary Biliary Cholangitis Agents	Removed Ocaliva and criteria pertaining to Ocaliva from policy as the drug was withdrawn from the market.
• **Reblozyl, Rytelo** • **Reblozyl, Rytelo Prior Authorization and Step Therapy Policy - Medicare Part B**	Simplified criteria for Myelodysplastic Syndrome (MDS) to require use be supported by National Comprehensive Cancer Network guidelines with recommendation 2A or higher.
• **Rituximab** • **Rituximab Prior Authorization and Step Therapy Policy - Medicare Part B**	For Rheumatoid Arthritis: updated trial and failure criteria to allow trial of any TNF antagonist (instead of specific agents), removed requirement to try an additional DMARD if patient is unable to take methotrexate. For Antineutrophil Cytoplasmic Antibody (ANCA)- Associated Vasculitis, removed requirement that patient must also have severe disease with critical organ involvement.
Tavneos	Removed requirement that patient must have organ- or life-threatening disease.
T-Cell Therapy	Updated FDA approved indications for Breyanzi, Carvykti, and Epkinly. Incorporated new NCCN recommendations on therapy sequencing.
Therapeutic Immunomodulators (TIMs) - Commercial	Updated criteria for Bimzelx to require a step through two agents, as opposed to three agents, for psoriasis, psoriatic arthritis, non-radiographic axial spondyloarthritis, and ankylosing spondylitis
Therapeutic Immunomodulators (TIMS) - Medicaid	Updated preferred adalimumab products to be Hadlima and SImlandi. For chronic spontaneous urticaria, require documentation of disease severity, trial of antihistamine and leukotriene antagonist, and trial of Xolair prior to a new agents, Rhapsido.
Topical Agents for Skin Conditions	For Atopic Dermatitis, updated to require trial of corticosteroid only for Eucrisa, Vtama, and Zoryve 0.15% and 0.05%. For Plaque Psoriasis, require trial of corticosteroid only for Vtama.