Providence Health Plan

Providence Health Assurance

Healthcare Services Medical & Pharmacy Policy Alerts

Number 103

February 1, 2025

This is the February 1, 2025 issue of the Providence Health Plans, Providence Health Assurance and Providence Plan Partners, Medical and Pharmacy Policy Alert to our providers. The focus of this update is to communicate to providers' new or revised Medical or Pharmacy policy changes. The Health Plan has a standard process to review all Medical & Pharmacy Policies annually. Policies will be available for review on ProvLink and via the PHP website at: https://healthplans.providence.org/providers/provider-support/medical-policy-pharmacy-policy-and-provider-information/

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

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

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

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

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

Providence Health Plan

Providence Health Assurance

MEDICAL POLICY COMMITTEE

MEDICAL

COMPANY POLICIES

Effective 3/1/2025

Sleep Disorder Testing **MP60**	**Policy Updates:** • Removed criteria regarding mental health indications (IV.C.) • Add hypoglossal nerve stimulation as an example of surgical procedure for which post-implantation testing criteria might apply (VI.B.) **Codes/PA:** No changes. **OHP:** These changes do not apply to OHP. The Prioritized List and the Oregon Administrative Rules will be followed.

Effective 4/1/2025

Lidocaine Injections for Chronic Pain **MP428**	**New Policy** **Policy Updates:** Created a new policy to deny "not medically necessary" use of lidocaine injections for the treatment of chronic pain indications. **Codes/PA:** Codes for injection and lidocaine will deny as "not medically necessary" when billed together on same claim, along with a dx code for a chronic pain indication (i.e. migraine, cluster headaches, headaches, neuralgia/neuropathy, diabetes (neurological). **OHP:** These changes do not apply to OHP. The Prioritized List and the Oregon Administrative Rules will be followed.

Complementary and Alternative Medicine **MP260**	**Policy Updates:** Added criterion addressing "not medically necessary" services for behavioral health indications. **Codes/PA:** No changes. **OHP:** These changes do not apply to OHP. The Prioritized List and the Oregon Administrative Rules will be followed.

New and Emerging Technologies and Other Non-covered Services
 	
MP23
	Policy Updates: No changes.
	Codes/PA:
	• Added 93592 to policy and NMN configuration.
	  • An add-on code for CPT codes 93590/93591, already listed on NET
	• Added C1839 to policy and NMN configuration
	  • Code should deny alongside other relevant codes already on NET (66683)
	• Changed 0559T- 0562T to NMN from investigational.
	  ○ Services are likely billed with surgery.
	
	OHP: These changes do not apply to OHP. The Prioritized List and the Oregon Administrative Rules will be followed.

Myoelectric Upper Limb Prosthesis **MP26**	**Policy Updates:** • Reformatting to include a not medically necessary section- addition of criteria to include expanded non-covered section- includes language on additional features that are for convenience or recreational activities are not covered (similar to language in other policies) • Added criterion to include replacement prothesis. • Updated criterion I. to clarify that there is one prosthetic limb per limb as well as added the limitation of 5 years per new product. • Updated Billing Guideline- included note for no codes should be billed with L6680 as the code is considered all inclusive. • Unchecked Medicaid box with additional language. **Codes/PA:** None **OHP:** These changes do not apply to OHP. The Prioritized List and the Oregon Administrative Rules will be followed.
Skin and Tissue Substitutes **MP16**	**Policy Updates:** Additional codes added that appeared relevant to policy. Similar to other codes already in place. No additional criteria needed. **Codes/PA:** • Added codes with PA (except for gender affirming dx codes): C5271, C5272, C5273, C5274, C5275, C5276, C5277, C5278 • Added codes with no PA: C9358, C9360 **OHP:** These changes do not apply to OHP. The Prioritized List and the Oregon Administrative Rules will be followed.

ARCHIVE

Effective 2/1/2025

Wireless Capsule for Gastrointestinal Motility Monitoring **MP80**	**Archive** **Recommendation:** Archived policy due to minimal utilization for Commercial LOB **Codes/PA:** Removed NMN denial for CPT 91112. CPT 91112 will process according to member benefits and eligibility. **OHP:** These changes do not apply to OHP. The Prioritized List and the Oregon Administrative Rules will be followed.

MEDICARE POLICIES

Effective 3/1/2025

Skin and Tissue Substitutes **MP371**	**Policy Updates:** Updated policy criteria. Noridian has a new LCD effective mid-February 2025 for the use of certain skin and tissue products for diabetic foot ulcers (DFUs) and venous leg ulcers (VLUs). Will use available Medicare coverage criteria for services with Medicare criteria available. For services or uses of products that do not have an applicable Medicare coverage policy, continue to use Company policy criteria. **Codes/PA:** • HCPCS A2019, Q4110, Q4158, Q4159, Q4160, Q4187, Q4203 - Update configuration based on the future Noridian LCA. Removed current NMN denial (which denies for all indications) and added pair-to-pay diagnosis code configuration (Noridian allows for select indications). Continue to deny if billed with diagnosis code not on the provided list. • HCPCS Q4101, Q4102, Q4105, Q4106, Q4107, Q4121, Q4122, Q4128, Q4133, Q4151, Q4186 – Currently require PA (except for F64.X diagnosis codes). Updated configuration to add more dx codes that can be allowed as medically necessary without PA. Codes will continue to require PA for all other dx codes.

	• No change to any other codes in the policy. Other codes in the policy may either be allowed by Noridian or considered non-covered by Noridian, but since the products may also be impacted by Company criteria, will leave the PA in place. For any product not addressed by Noridian, but deemed NMN by Company policy, the NMN denial will also remain in place.

Effective 4/1/2025

Lidocaine Injections for Chronic Pain **MP429**	**New Medicare Advantage medical policy** **Policy Updates:** New policy for Medicare Advantage. The policy will use internal Company medical policy criteria due to lack of fully established Medicare criteria. **Codes/PA:** Added diagnosis code configuration to deny CPT codes 96365 and J2003 when billed together **AND** when billed with one of the listed diagnosis codes. ***NOTE:*** *HCPCS code J2003 (and previously, J2001) deny per Coding Policy 13.0.*
Skin and Tissue Substitutes **MP371**	**Policy Updates:** No change to policy criteria from the version presented above; however, with the new Noridian LCD/LCA that is effective mid-February 2025, there are several HCPCS codes in the LCA that are not on the policy. Due to new configuration that is restrictive in nature, this requires 60-day provider notice. **Codes/PA:** • HCPCS C5271-C5278 - Added to policy, and added PA for all indications except F64.X dx codes (this is consistent with other "application" codes already in the policy) • HCPCS C9368 and C9360 – added to policy, but no medical policy configuration at this time. • No change to any other codes in the policy.
Myoelectric Upper Limb Prosthesis **MP374**	**Policy Updates:** Annual review. Updates include: • Formatting and Medicare regulatory language. • Continue to use either the Medicare coverage criteria provided, or internal Company coverage criteria in the absence of fully established Medicare criteria. • Added language that intent is to allow one prosthetic, per limb, at a time. This is not meant to be a restriction, as existing replacement criteria would be applied, but the note is added for clarification. **Codes/PA:** No change to codes or configuration.

New and Emerging Technologies and Other Non-Covered Services **MP220**	**Policy Updates:** New annual review month, to align with Company version. **Codes/PA:** Added C1839 to policy and NMN configuration (to align with other relevant codes already on NET [previously 0616T-0618T, now 66683]). No other changes to codes in policy.

ARCHIVE

Effective 2/1/25

Premature Rupture of Membranes (PROM) Testing **MP383**	**Policy Updates:** Archived policy due to low utilization for Medicare Advantage LOB. **Codes/PA:** Removed NMN denial for CPT 84112. CPT 84112 will process according to member benefits and eligibility.
Wireless Capsule for Gastrointestinal Motility Monitoring **MP378**	**Policy Updates:** Archived policy due to low utilization for Medicare Advantage LOB. **Codes/PA:** Removed NMN denial for CPT 91112. CPT 91112 will process according to member benefits and eligibility.

REIMBURSEMENT POLICIES

Effective 3/1/25

Associated Services and Related Claims **RP9**	**Policy Updates:** No change to policy document. **Reimbursement Methodology:** No change to current reimbursement methodology. **Codes/PA:** Updated list of codes which are configured to initiate the associated services denial (u80) due to changes in other medically policies, which are having either codes with existing NMN denial configuration added or removed. Changes for this update include the following:

	• *Changed "medical policy" for CPTs 0795T-0797T, 0801T-0804T, 0823T-0825T on the non-Medicare list only. These codes are moving to new policy. Effective Date: 3/1/2025.* • *Removed 0616T-0618T from both lists and add 66683. Codes 0616T-0618T were termed 12/31/2024 and replaced with 66683 effective 1/1/2025. Effective Date: 1/1/2025* • *Added to **non-Medicare** list codes 0915T-0931T and C9807 and add to **Medicare** list 0915T-0918T, 0923T-0931T. For **both lists**, add C8003, C9809, 0908T, and 0909T. These are all new codes 1/1/2025. Effective Date: 1/1/2025.*
Facility Routine Supplies and Services **RP43**	**Policy Updates:** Changes include the following: • Indicated *outpatient* claims, as well as *inpatient* claims are, subject to this policy. The same concept applies (the "room" or "accommodation" rate includes routine services/supplies typically rendered in that unit). • Updated CPT references, language, and concepts (prior reference was 2020, replaced with 2025). • Enhanced the "routine nursing" section, clarifying what the incremental nursing revenue codes are intended for. • Updated references. **Reimbursement Methodology:** No change to current reimbursement methodology.

Effective 4/1/25

Associated Services and Related Claims **RP9**	**Policy Updates:** No change to policy document. **Reimbursement Methodology:** No change to current reimbursement methodology. **Codes/PA:** Updated list of codes which are configured to initiate the associated services denial (u80) due to changes in other medical policies, which are having either codes with existing NMN denial configuration added or removed. Changes for this update include the following: • *Added CPT 93592 to Company list only (code is already on Medicare list). Effective Date: 4/1/2025.*

Vendor Updates

Effective 3/23/25

Carelon	**Annual Update** **Changes to current criteria:** • Effective for dates of service on and after [March 23, 2025] the following updates will apply to the Carelon Medical Benefits Management, Inc. Clinical Appropriateness Guidelines. As part of the Carelon guideline annual review process, these updates are focused on advancing efforts to drive clinically appropriate, safe, and affordable health care services. • For questions related to guidelines, please contact Carelon via email at MedicalBenefitsManagement.guidelines@Carelon.com. Additionally, you may access and download a copy of the current and upcoming guidelines here. **Oncologic Imaging** • NCCN alignments for Cancer Screening and tumor-specific indications (see Change Summary), largely addressing time intervals of screening or surveillance imaging. • Added FDG PET allowances for Colorectal Cancer and Lung Cancer (Small Cell) accounting for nondiagnostic standard imaging. **Imaging of the Abdomen and Pelvis** • Tumor or neoplasm – Added requirement for initial evaluation of testicular masses with US • Endometriosis – Removed US requirement for follow-up of patients with established diagnosis • Obstetric indications – Specified that fetal MRI is indicated in second or third trimester • Diffuse liver disease – Removed criteria for LiverMultiScan as an alternative to MR elastography • Abdominal and/or pelvic pain, undifferentiated – clarified language regarding initial imaging and lab evaluation **Imaging of the Chest** • Added indication for dyspnea **Codes/PA**: No codes

Providence Health Plan

Providence Health Assurance

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

Pharmacy & Therapeutics (P&T) Committee

Oregon Region P&T Committee Meeting December 6, 2024
Go-Live Date: Saturday, February 01, 2025, unless otherwise noted

Table of Contents:

- New Drugs and Combinations
- New Strengths and Formulations
- New Indications Monitoring
- Drug Safety Monitoring
- Other Formulary Changes
- Clinical Policy Changes

New Drugs and Combinations:

1. **Donanemab-azbt (Kisunla) Vial**
    a. **Indication**: For the treatment of Alzheimer's disease (AD).
    b. **Decision**:

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

* Recommendations for placement may differ between lines of business due to regulatory requirements.
** Medications will be placed on recommended tier above for the base formulary; tier placement for custom formulary(ies) will be based on designation above. For example, Commercial Tier 6 designation above means that the medication will be placed on the highest cost-sharing tier on the respective formulary(ies).

Formulary Alternatives: N/A

c. **Prior Authorization Criteria for Commercial/Medicaid/Medicare Part B**: Added to the Anti-Amyloid Monoclonal Antibodies Policies

2. **Xanomeline tart-trospium chlor (Cobenfy) Capsule**
   a. **Indication**: For the treatment of schizophrenia in adults.
   b. **Decision**:

	Commercial	Medicaid	Medicare
Formulary Status*	Formulary	Non-formulary	Part D: Formulary Part B: N/A
Tier**	Tier 4	N/A	Specialty
Affordable Care Act Eligible	No	N/A	N/A
Utilization Management Edits	Prior Authorization	N/A	Prior Authorization
Quantity Limit	2 capsules/day	N/A	2 capsules/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: Generics include quetiapine, olanzapine, ziprasidone, risperidone, aripiprazole. Brands include Caplyta®, Fanapt®, Lybalvi®, Rexulti®, Saphris®, Secuado®, and Vraylar®.			

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

PA PROGRAM NAME	Antipsychotics
MEDICATION NAME	Xanomeline/trospium chloride capsule, coated pellets (Cobenfy™)
PA INDICATION INDICATOR	3 - All Medically-Accepted Indications
EXCLUSION CRITERIA	For Cobenfy™ • Urinary retention • Moderate or severe hepatic impairment • Gastric retention • Untreated narrow-angle glaucoma
REQUIRED MEDICAL INFORMATION	1. For all requests, the patient must have a Food and Drug Administration (FDA) labeled indication for the requested agent or use to treat the indication is supported in drug compendia (such as the American Hospital Formulary Service Drug Information (AHFS-DI) or Truven Health Analytics' DRUGDEX® System.) 2. One of the following criteria must be met:

	b. All the following indication-specific criteria must be met: ii. For schizophrenia: Documented trial, failure, intolerance, or contraindication to two formulary, generic, atypical antipsychotics (such as quetiapine, olanzapine, ziprasidone, risperidone, aripiprazole)
AGE RESTRICTIONS	N/A
PRESCRIBER RESTRICTIONS	N/A
COVERAGE DURATION	Authorization will be approved until no longer eligible with the plan, subject to formulary and/or benefit changes.
QUANTITY LIMIT	For Cobenfy™: Two capsules per day

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

PA PROGRAM NAME	ANTIPSYCHOTICS
MEDICATION NAME	xanomeline and trospium chloride capsule, coated pellets (Cobenfy™)
PA INDICATION INDICATOR	3 - All Medically-Accepted Indications
EXCLUSION CRITERIA	For Cobenfy™: • Urinary retention • Moderate or severe hepatic impairment • Gastric retention • Untreated narrow-angle glaucoma
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 schizophrenia: Documented trial and failure, intolerance, or contraindication to two formulary, generic antipsychotics (e.g., quetiapine, olanzapine, ziprasidone, risperidone, aripiprazole, lurasidone)
AGE RESTRICTIONS	N/A
PRESCRIBER RESTRICTIONS	N/A
COVERAGE DURATION	Authorization will be approved until no longer eligible with the plan.
QUANTITY LIMIT	For Cobenfy™: Two capsules per day

3. **Afamitresgene autoleucel (Tecelra) Plast. Bag**
   a. **Indication**: For the treatment of adults with unresectable or metastatic synovial sarcoma.
   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	1 dose/patient's lifetime	1 dose/patient's lifetime	1 dose/patient's 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: Anthracycline-based chemotherapy, Pazopanib (Votrient)			

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

PA PROGRAM NAME	T-Cell Therapy
MEDICATION NAME	Afamitresgene autoleucel (Tecelra)
PA INDICATION INDICATOR	1 - All FDA-Approved Indications
EXCLUSION CRITERIA	For Tecelra: patients with HLA-A*02:05P in either allele T-cell therapy, Amtagvi, and Tecelra. Repeat administration is not considered medically necessary as the effectiveness of this approach has not been established
REQUIRED MEDICAL INFORMATION	For all requests, the following criteria must be met: 1. Use must be for an indication supported by National Comprehensive Cancer Network (NCCN) guidelines with recommendation 2A or higher 2. Documentation of adequate bone marrow, cardiac, pulmonary and organ function (such as kidney, liver) 3. One of the following regarding functional status must be met: a. For Kymriah® for B-cell precursor acute lymphoblastic leukemia (ALL) only: Karnofsky or Lansky Scale greater than or equal to 50% b. Provider attestation/documentation that the patient's functional status is sufficient to undergo treatment. This may include but is not limited to a documented Eastern Cooperative Oncology Group (ECOG) performance status of 0-1 or a written statement acknowledging that the patient is fit to tolerate therapy. 4. No evidence of active infection or inflammatory disorder (including hepatitis B or C, active graft vs. host disease) 5. For B-cell lymphomas, patient does not have primary central nervous system lymphoma
AGE RESTRICTIONS	Age must be appropriate based on FDA-approved indication
PRESCRIBER RESTRICTIONS	Must be prescribed by, or in consultation with, an oncologist
COVERAGE DURATION	For chimeric antigen receptor (CAR) T-cell therapy, Amtagvi, and Tecelra: Two months (limited to one treatment course per lifetime, with four doses of tocilizumab [Actemra®] at up to 800 mg per dose)

4. **Arimoclomol citrate (Miplyffa) Capsule**
   a. **Indication**: For the treatment of neurological manifestations of Niemann-Pick disease type C (NPC) in adult and pediatric patients 2 years of age and older.
   b. **Decision**:

	Commercial	Medicaid	Medicare
Formulary Status*	Non-formulary	Non-formulary	Part D: Non-formulary Part B: N/A
Tier**	N/A	N/A	N/A
Affordable Care Act Eligible	No	N/A	N/A
Utilization Management Edits	Prior Authorization	Prior Authorization	N/A
Quantity Limit	3 capsules/day	3 capsules/day	N/A
* Recommendations for placement may differ between lines of business due to regulatory requirements. ** Medications will be placed on recommended tier above for the base formulary; tier placement for custom formulary(ies) will be based on designation above. For example, Commercial Tier 6 designation above means that the medication will be placed on the highest cost-sharing tier on the respective formulary(ies).			
Formulary Alternatives: miglustat, although not FDA approved for NPC. Generic miglustat is NF for Medicare and brand is NF for Medicaid and Medicare. For Commercial and Medicaid, miglustat (Zavesca®) is on the Medications for Rare Indications prior authorization policy.			

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

PA PROGRAM NAME	Medications for Rare Indications
MEDICATION NAME	Arimoclomol citrate (Miplyffa®)
PA INDICATION INDICATOR	1 - All FDA-Approved Indications
OFF-LABEL USES	N/A
EXCLUSION CRITERIA	For Miplyffa only – concurrent therapy with levacetylleucine (Aqneursa®)
REQUIRED MEDICAL INFORMATION	1.Confirmation of FDA-labeled indication (appropriate lab values and/or genetic tests must be submitted – See Table 1 and Table 2) j. For Miplyffa®: Diagnosis of Niemann-Pick disease type C (NPC) confirmed by mutations in both alleles of NPC1 or NPC2, or mutation in only one allele of NPC1 or NPC2 plus either positive filipin staining or elevated cholestane triol/oxysterols (over two times the upper limit of normal) **AND** 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 **AND**

	8. For miglustat for Niemann-Pick disease type C (NPC): Documentation that miglustat will be used in combination with Miplyffa® for NPC Reauthorization Criteria: 8. For Miplyffa®: Documentation of benefit of therapy as evidence by improvement from baseline in the 5-domain NPC Clinical Severity Scale (NPCCSS) score
AGE RESTRICTIONS	Age must be appropriate based on FDA-approved indication
PRESCRIBER RESTRICTIONS	Must be prescribed by, or in consultation with a specialist in the respective disease state.
COVERAGE DURATION	For Miplyffa: Initial authorization will be approved for 12 months. Reauthorization will be approved for 12 months.

5. **Bexagliflozin (Brenzavvy) Tablet**
   a. **Indication**: For the treatment of adult patients with type 2 diabetes.
   b. **Decision**:

	Commercial	Medicaid	Medicare
Formulary Status*	Non-formulary	Non-formulary	Part D: Non-formulary Part B: N/A
Tier**	N/A	N/A	N/A
Affordable Care Act Eligible	N/A; Non-Formulary	N/A	N/A
Utilization Management Edits	N/A	N/A	N/A
Quantity Limit	None	None	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: Farxiga, Jardiance			

6. **Lazertinib mesylate (Lazcluze) Tablet**
   a. **Indication**: For first-line treatment in combination with intravenous amivantamab (Rybrevant®) of non–small cell lung cancer (NSCLC), locally advanced or metastatic, with EGFR exon 19 deletion or exon 21 L858R substitution mutation.
   b. **Decision**:

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

Tier**	N/A	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	2/day for 80 mg and 1/day for 240 mg	2/day for 80 mg and 1/day for 240 mg	2/day for 80 mg and 1/day for 240 mg
* 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: osimertinib, erlotinib, gefitinib, afatinib, dacomitinib			

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

PA PROGRAM NAME	Anti-Cancer Medications – Self-administered
MEDICATION NAME	Lazertinib mesylate (Lazcluze)
PA INDICATION INDICATOR	3 - All Medically-Accepted Indications
OFF-LABEL USES	For off-label use criteria, please see the Chemotherapy Treatment Utilization Criteria, Coverage for Non-FDA Approved Indications ORPTCOPS105.
EXCLUSION CRITERIA	N/A
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 2. For requests for Lazcluze, member must have a documented contraindication to Tagrisso® or clinical rationale must be provided for why Tagrisso® with or without chemotherapy is not appropriate
AGE RESTRICTIONS	N/A
PRESCRIBER RESTRICTIONS	Must be prescribed by, or in consultation with, an oncologist
COVERAGE DURATION	Authorization will be approved until no longer eligible with the plan, subject to formulary and/or benefit changes

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

PA PROGRAM NAME	Anti-Cancer Agents
MEDICATION NAME	Lazertinib mesylate (Lazcluze)
PA INDICATION INDICATOR	3 - All Medically-Accepted Indications
OFF-LABEL USES	N/A

EXCLUSION CRITERIA	N/A
REQUIRED MEDICAL INFORMATION	Indication is supported by CMS-approved compendia.
AGE RESTRICTIONS	N/A
PRESCRIBER RESTRICTIONS	Must be prescribed by, or in consultation with, an oncologist, transplant specialist, neurologist or, for abiraterone, a urologist
COVERAGE DURATION	Authorization will be approved until no longer eligible with the plan.

7. **Lebrikizumab-lbkz (Ebglyss Pen) Pen Injctr**
   a. **Indication**: For the treatment of adults and pediatric patients 12 years of age and older who weigh at least 40 kg with moderate-to-severe atopic dermatitis whose disease is not adequately controlled with topical prescription therapies or when those therapies are not advisable.
   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	
Quantity Limit	2 mL/28 days	2 mL/28 days	
* Recommendations for placement may differ between lines of business due to regulatory requirements. ** Medications will be placed on recommended tier above for the base formulary; tier placement for custom formulary(ies) will be based on designation above. For example, Commercial Tier 6 designation above means that the medication will be placed on the highest cost-sharing tier on the respective formulary(ies).			
Formulary Alternatives: Dupixent®			

   c. **Prior Authorization Criteria for Commercial/Medicaid**: Added to Interleukin-13 Inhibitors Policy

8. **Seladelpar lysine (Livdelzi) Capsule**
   a. **Indication**: For the treatment of primary biliary cholangitis (PBC) in combination with ursodeoxycholic acid (UDCA) in adults who have an inadequate response to UDCA, or as monotherapy in patients unable to tolerate UDCA. The drug received accelerated approval based on the surrogate endpoint of reduction in alkaline phosphatase.
   b. **Decision**:

	Commercial	Medicaid	Medicare
Formulary Status*	Non-formulary	Non-formulary	Part D: Non-formulary

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

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

PA PROGRAM NAME	Primary Biliary Cholangitis Agents
MEDICATION NAME	Livdelzi
PA INDICATION INDICATOR	1 - All FDA-Approved Indications
OFF-LABEL USES	N/A
EXCLUSION CRITERIA	• Non-alcoholic steatohepatitis (NASH) • Decompensated cirrhosis (such as Child-Pugh Class B or C) or a prior decompensated event • Use in combination with Ocaliva®, Iqirvo®, or Livdelzi® • Compensated cirrhosis with evidence of portal hypertension (e.g., ascites, gastroesophageal varices, persistent thrombocytopenia) – Additional condition that applies to Ocaliva® only.
COVERAGE DURATION	Initial authorization will be approved for six months. Reauthorization will be approved for one year
QUANTITY LIMIT	One tablet/capsule per day

9. **Tislelizumab-jsgr (Tevimbra) Vial**

a. **Indication**: For the treatment of adult patients with unresectable or metastatic esophageal squamous cell carcinoma (ESCC) after prior systemic chemotherapy that did not include a PD-(L)1 inhibitor.

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	-	-	-
* 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: Keytruda, Opdivo, docetaxel, paclitaxel, irinotecan			

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

10. **Vorasidenib citrate (Voranigo) Tablet**

a. **Indication**: For the treatment of patients 12 years of age and older with WHO grade 2 astrocytoma or oligodendroglioma with a susceptible IDH1 or IDH 2 mutation following surgical resection or biopsy.

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	10 mg tablets: 60 tablets per 30 day supply 40 mg tablets: 30 tablets per 30 day supply	10 mg tablets: 60 tablets per 30 day supply 40 mg tablets: 30 tablets per 30 day supply	10 mg tablets: 60 tablets per 30 day supply 40 mg tablets: 30 tablets per 30 day supply
* Recommendations for placement may differ between lines of business due to regulatory requirements. ** Medications will be placed on recommended tier above for the base formulary; tier placement for custom formulary(ies) will be based on designation above. For example, Commercial Tier 6 designation above means that the medication will be placed on the highest cost-sharing tier on the respective formulary(ies).			
Formulary Alternatives: ivosidenib (Tibsovo®), temozolomide, lomustine (Gleostine®)			

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

New Drug Strengths and Formulations:

1. **Palopegteriparatide (Yorvipath) Pen Injector**
   a. **Indication**: For the treatment of hypoparathyroidism in adults.
   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 pens / 28 days	2 pens / 28 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: calcitriol with over-the-counter calcium carbonate or calcium citrate			

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

PA PROGRAM NAME	Yorvipath
MEDICATION NAME	Yorvipath subcutaneous pen injector 168 mcg/0.56 mL Yorvipath subcutaneous pen injector 294 mcg/0.98 mL Yorvipath subcutaneous pen injector 420 mcg/1.4 mL
PA INDICATION INDICATOR	1 - All FDA-Approved Indications
OFF-LABEL USES	None
EXCLUSION CRITERIA	Use of osteoporosis therapies known to influence calcium and bone metabolism less than 2 years before screening (such as abaloparatide or teriparatide)
REQUIRED MEDICAL INFORMATION	For initiation of therapy all the following criteria must be met: 1. Confirmed diagnosis of chronic hypoparathyroidism of postsurgical, autoimmune, genetic, or idiopathic origins, for at least 26 weeks, based on hypocalcemia in the setting of inappropriately low serum parathyroid hormone levels. Note: Coverage will not be provided in the case of acute postsurgical hypoparathyroidism 2. Documentation that patient is currently receiving conventional therapy, including active vitamin D (calcitriol) and elemental calcium

	3. Provider attestation that patient's disease cannot be adequately controlled on conventional therapy alone or that conventional therapy causing significant side effects 4. Recent (within the last 3 months) serum 25 (OH) vitamin D in normal range (20-80 ng/mL) and albumin-adjusted serum calcium greater than or equal to 7.8 mg/dL For patients established on therapy all the following criteria must be met (Note: Medications obtained as samples, coupons, or any other method of obtaining medications outside of an established health plan benefit are NOT considered established on therapy): 1. Documentation of a recent (within the last 3 months) albumin-corrected serum calcium in the lower-half of the normal reference range or just below the normal reference range 2. One of the following: a. Patient no longer requires active vitamin D or therapeutic doses of calcium, OR b. Patient has had a significant reduction in required dosages or active vitamin D or therapeutic doses of calcium and is still actively titrating doses of palopegteriparatide (Yorvipath®)
AGE RESTRICTIONS	May be approved for patients 18 years of age and older
PRESCRIBER RESTRICTIONS	Must be prescribed by, or in consultation with, an endocrinologist
COVERAGE DURATION	Initial authorization and reauthorization will be approved for one year

New Indications:

The following information is gathered from the United States Food and Drug Administration (FDA) Approved Drug Products database from 8/1/2024– 9/30/2024

Therapies with Prior Authorization Policies (Non-oncology)

1. **BIMZELX** (BIMEKIZUMAB-BKZX)
   a. Previous Indication(s):
      i. The treatment of moderate to severe plaque psoriasis in adult patients who are candidates for systemic therapy or phototherapy
   b. New indication approved 09/20/2024:
      i. The treatment of adult patients with active psoriatic arthritis
      ii. The treatment of adult patients with active non-radiographic axial spondyloarthritis with objective signs of inflammation
      iii. The treatment of adult patients with active ankylosing spondylitis
   c. **RECOMMENDATION:** Inform prescribers via Medical Policy Alert. Update policy with new indication. Update criteria for Commercial. No criteria updates required for Medicaid.

      Prior Authorization for **Commercial**:

PA PROGRAM NAME	Therapeutic Immunomodulators (TIMs)

MEDICATION NAME	Bimzelx (bimekizumab-bkzx)
COVERED USES	1 - All FDA-Approved Indications
REQUIRED MEDICAL INFORMATION	A. For **psoriatic arthritis**, all the following criteria (1 and 2) must be met: 1) Documentation of trial and failure (after at least three months of therapy), intolerance, or contraindication to at least one of the following conventional therapies: methotrexate, leflunomide, or sulfasalazine 2) Preferred adalimumab products (Humira® Simlandi®, Hadlima®, adalimumab-adaz¥ and adalimumab-aaty¥), etanercept (Enbrel®, guselkumab (Tremfya®), secukinumab (Cosentyx®), ustekinumab (Stelara®), risankizumab-rzaa (Skyrizi®), or apremilast (Otezla®) may be covered. Other therapies may be covered as outlined below: a. Bimekizumab-bkzx (Bimzelx®) may be covered with documentation of trial and failure (after at least three months of therapy), intolerance, or contraindication to **three** of the following preferred agents: i. Preferred adalimumab product (Humira® Simlandi®, Hadlima®, adalimumab-adaz and adalimumab-aaty) ii. apremilast (Otezla®) iii. etanercept (Enbrel®) iv. guselkumab (Tremfya®) v. secukinumab (Cosentyx®) vi. tofacitinib (Xeljanz/Xeljanz XR®) vii. ustekinumab (Stelara®) viii. risankizumab-rzaa (Skyrizi®) ix. upadacitinib (Rinvoq®) B. For **ankylosing spondylitis**, preferred adalimumab products (Humira® Simlandi®, Hadlima®, adalimumab-adaz and adalimumab-aaty), etanercept (Enbrel®), or secukinumab (Cosentyx®) may be covered. Other therapies may be covered as outlined below:

	1) Bimekizumab-bkzx (Bimzelx®) may be covered with documentation of trial and failure (after at least three months of therapy), intolerance, or contraindication to **three** of the following preferred agents: a) Preferred adalimumab product (Humira® Simlandi®, Hadlima®, adalimumab-adaz and adalimumab-aaty) b) etanercept (Enbrel®) c) secukinumab (Cosentyx®) d) tofacitinib (Xeljanz/Xeljanz XR®) e) upadacitinib (Rinvoq®) C. For **non-radiographic axial spondyloarthritis** with objective signs of inflammation (such as elevated C-reactive protein or sacroiliitis on MRI), certolizumab (Cimzia®) or secukinumab (Cosentyx®) may be covered. Other therapies may be covered as outlined below: 1) Bimekizumab-bkzx (Bimzelx®) may be covered with documentation of trial and failure (after at least three months of therapy), intolerance, or contraindication to **three** of the following preferred agents: a) certolizumab (Cimzia®) b) secukinumab (Cosentyx®) c) upadacitinib (Rinvoq®)

2. **CIMZIA** (CERTOLIZUMAB PEGOL)
    a. Previous Indication(s):
        i. Reducing signs and symptoms of Crohn's disease and maintaining clinical response in adult patients with moderately to severely active disease who have had an inadequate response to conventional therapy
        ii. Treatment of adults with moderately to severely active rheumatoid arthritis
        iii. Treatment of adult patients with active psoriatic arthritis
        iv. Treatment of adults with active ankylosing spondylitis
        v. Treatment of adults with active non-radiographic axial spondyloarthritis with objective signs of inflammation
        vi. Treatment of adults with moderate-to-severe plaque psoriasis who are candidates for systemic therapy or phototherapy
    b. New indication approved 09/13/2024:
        i. Treatment of active polyarticular juvenile idiopathic arthritis (pJIA) in patients 2 years of age and older

c. **RECOMMENDATION:** Inform prescribers via Medical Policy Alert. Update policy with new indication. Update criteria for Commercial. No criteria updates required for Medicaid.

Prior Authorization for **Commercial**:

PA PROGRAM NAME	Therapeutic Immunomodulators (TIMs)
MEDICATION NAME	Cimzia (certolizumab)
COVERED USES	1 - All FDA-Approved Indications
REQUIRED MEDICAL INFORMATION	A. For **polyarticular juvenile idiopathic arthritis (PJIA)**, all the following criteria (1 and 2) must be met: 1) Documentation of trial and failure (after at least three months of therapy), intolerance, or contraindication to at least one of the following conventional therapies: methotrexate, leflunomide, or sulfasalazine 2) Etanercept (Enbrel®) and preferred adalimumab products (Humira®, Simlandi®, Hadlima®, adalimumab-adaz and adalimumab-aaty) may be covered. Other therapies may be covered as outlined below: a) Certolizumab (Cimzia®) requires documentation of trial and failure (after at least three months of therapy), intolerance, or contraindication to **two** of the following: i. Preferred adalimumab product (Humira®, Simlandi®, Hadlima®, adalimumab-adaz and adalimumab-aaty) ii. etanercept (Enbrel®) iii. upadacitinib (Rinvoq®) iv. tofacitinib (Xeljanz/Xeljanz XR®)

3. **DUPIXENT** (DUPILUMAB)
   a. Previous Indication(s):
      i. Adult and pediatric patients aged 6 months and older with moderate-to-severe atopic dermatitis (AD) whose disease is not adequately controlled with topical prescription therapies or when those therapies are not advisable. DUPIXENT can be used with or without topical corticosteroids
      ii. Add-on maintenance treatment of adult and pediatric patients aged 6 years and older with moderate-to-severe asthma characterized by an eosinophilic phenotype or with oral corticosteroid dependent asthma
      iii. Add-on maintenance treatment in **adult patients** with inadequately controlled chronic rhinosinusitis with nasal polyposis (CRSwNP)

iv. Adult and pediatric patients aged 1 year and older, weighing at least 15 kg, with eosinophilic esophagitis (EoE)
v. Adult patients with prurigo nodularis (PN)

b. New indication approved 09/12/2024 & 09/27/2024:
   i. Add-on maintenance treatment in adult and **pediatric patients aged 12 years and older** with inadequately controlled chronic rhinosinusitis with nasal polyps (CRSwNP)
   ii. Add-on maintenance treatment of adult patients with inadequately controlled chronic obstructive pulmonary disease (COPD) and an eosinophilic phenotype

c. **RECOMMENDATION:** Inform prescribers via Medical Policy Alert. Update policy with new indication. Add indication specific criteria for COPD.
   Prior Authorization for **Commercial**:

PA PROGRAM NAME	DUPIXENT
MEDICATION NAME	Dupixent (dupilumab)
PA INDICATION INDICATOR	1 - All FDA-Approved Indications
EXCLUSION CRITERIA	Combination therapy with another therapeutic immunomodulator (TIM) agent
REQUIRED MEDICAL INFORMATION	For initial authorization for chronic obstructive pulmonary disease (COPD): 1. Diagnosis of COPD with an eosinophilic phenotype, 2. The patient is currently being treated with AND will continue COPD control therapy (e.g., ICS, LABA, LAMA) in combination with the requested agent Reauthorization for COPD requires: 1. Documentation of response to therapy, such as attainment and maintenance of remission or decrease in number of relapses and 2. The patient is currently being treated with, and will continue COPD control therapy in combination with the requested agent, or has an intolerance/ contraindication to standard COPD control therapy (e.g., ICS, LABA, LAMA)
PRESCRIBER RESTRICTIONS	COPD: Medication must be prescribed by, or in consultation with a respiratory specialist (such as an allergist, immunologist, or pulmonologist)
AGE RESTRICTIONS	The patient's age must be within FDA labeling for the requested indication
COVERAGE DURATION	COPD: Initial authorization will be approved for one year. Reauthorization will be approved until no longer eligible with the plan, subject to formulary or benefit changes

Prior Authorization for **Medicaid**:

PA PROGRAM NAME	DUPIXENT
MEDICATION NAME	Dupixent (dupilumab)
COVERED USES	1 - All FDA-Approved Indications
REQUIRED MEDICAL INFORMATION	**For chronic obstructive pulmonary disease (COPD):** 1. For initiation of therapy, the following criteria must be met: a. Confirmed diagnosis of eosinophilic COPD, defined as a blood eosinophil count of at least 300 cells/microliter b. Inadequate response to at least three months of treatment with triple inhaler therapy (inhaled corticosteroid (ICS) with long-acting beta agonist (LABA) and long-acting muscarinic antagonist (LAMA) inhalers) c. Patient has experienced at least 1 hospitalization or 2 emergency department (ED) visits in the previous 12 months while on triple inhaler therapy **For reauthorization:** 1. Response to therapy indicating improvement or stabilization of condition 2. For COPD, patient must be using the requested medication with triple inhaler therapy (ICS/LABA/LAMA)
PRESCRIBER RESTRICTIONS	For COPD: Must be prescribed by, or in consultation with a respiratory specialist (such as an allergist, immunologist, or pulmonologist)
AGE RESTRICTIONS	The patient's age must be within FDA labeling for the requested indication
COVERAGE DURATION	COPD: Initial authorization will be approved for one year. Reauthorization will be approved until no longer eligible with the plan, subject to formulary or benefit changes

Prior Authorization for **Medicare Part D**:

PA PROGRAM NAME	DUPIXENT
MEDICATION NAME	Dupixent (dupilumab)
PA INDICATION INDICATOR	1 - All FDA-Approved Indications
EXCLUSION CRITERIA	Concurrent use with another therapeutic immunomodulator agent utilized for the same indication.

REQUIRED MEDICAL INFORMATION	For initial authorization for chronic obstructive pulmonary disease (COPD): 1. Diagnosis of COPD with an eosinophilic phenotype 2. The patient is currently being treated with AND will continue COPD control therapy (e.g., ICS, LABA, LAMA) in combination with the requested agent Reauthorization for COPD requires: 1. Documentation of response to therapy, such as attainment and maintenance of remission or decrease in number of relapses and 2. The patient is currently being treated with, and will continue COPD control therapy in combination with the requested agent, or has an intolerance/ contraindication to standard COPD control therapy (e.g., ICS, LABA, LAMA)
PRESCRIBER RESTRICTIONS	Medications must be prescribed by, or in consultation with the following specialists based on the diagnosis: 1. COPD: respiratory specialist (such as an allergist, immunologist, or pulmonologist)
COVERAGE DURATION	COPD: Initial 1 yr/reauth until no longer eligible with plan

4. **FASENRA** (BENRALIZUMAB)
   a. Previous Indication(s):
      i. Add-on maintenance treatment of patients aged 6 years and older with severe asthma, and with an eosinophilic phenotype
   b. New indication approved 09/17/2024:
      i. Add-on maintenance treatment of **adult and** pediatric patients aged 6 years and older with severe asthma, and with an eosinophilic phenotype
      ii. Treatment of adult patients with eosinophilic granulomatosis with polyangiitis (EGPA)
   c. **RECOMMENDATION:** Inform prescribers via Medical Policy Alert. Update policy with new indication. Add benralizumab (Fasenra) to EGPA criteria for Commercial/Medicaid/Medicare Part D. Add new criteria for indication for Medicare Part D

Prior Authorization for **Commercial/Medicaid**:

PA PROGRAM NAME	IL-5 Inhibitors
MEDICATION NAME	Fasenra (benralizumab)

COVERED USES	1 - All FDA-Approved Indications
REQUIRED MEDICAL INFORMATION	**Eosinophilic Granulomatosis with Polyangiitis (EGPA)** 1. For patients initiating therapy for EGPA, Fasenra (benralizumab) or Nucala (mepolizumab) may be covered if the following criteria (a and b) are met: a. Confirmed diagnosis of EGPA defined as one of the following: i. The patient meets four of the following: 1. Asthma (history of wheezing or diffuse high-pitched rales on expiration) 2. Eosinophilia (greater than 10% eosinophils on white blood cell differential count) 3. Mononeuropathy (including multiplex), multiple mononeuropathies, or polyneuropathy attributed to a systemic vasculitis 4. Migratory or transient pulmonary infiltrates detected radiographically 5. Paranasal sinus abnormality 6. Biopsy containing a blood vessel showing the accumulation of eosinophils in extravascular areas ii. The patient meets ALL of the following: 1. Medical history of asthma 2. Peak peripheral blood eosinophilia greater than 1000 cells/microliter 3. Systemic vasculitis involving two or more extra-pulmonary organs b. Relapsing or refractory diseased defined as one of the following: i. History of relapse requiring an increase in glucocorticoid dose, initiation or increase in other immunosuppressive therapy, or hospitalization in the previous two years while receiving at least 7.5 mg/day prednisone (or equivalent)

	ii. Failure to achieve remission following a standard induction regimen administered for at least three months OR recurrence of symptoms of EGPA while tapering off glucocorticoids. Standard treatment regimens include: prednisone [or equivalent] dosed at least 7.5 mg/day in combination with an immunosuppressant such as cyclophosphamide, azathioprine, methotrexate, or mycophenolate mofetil 2. For patients established on therapy for EGPA, Fasenra (benralizumab) or Nucala (mepolizumab) may be covered if the following criteria are met: response to therapy indicating improvement or stabilization of condition

Prior Authorization and Step Therapy for **Medicare Part B**:

PA PROGRAM NAME	IL-5 Inhibitors
MEDICATION NAME	Fasenra (benralizumab)
COVERED USES	1 - All FDA-Approved Indications
REQUIRED MEDICAL INFORMATION	**For Eosinophilic Granulomatosis with Polyangiitis (EGPA),** Fasenra (benralizumab) or mepolizumab (Nucala®) may be covered if all the following criteria are met**:** 1. Confirmed diagnosis of EGPA defined as one of the following: a. The patient meets four of the following: i. Asthma (history of wheezing or diffuse high-pitched rales on expiration) ii. Eosinophilia (greater than 10% eosinophils on white blood cell differential count) iii. Mononeuropathy (including multiplex), multiple mononeuropathies, or polyneuropathy attributed to a systemic vasculitis iv. Migratory or transient pulmonary infiltrates detected radiographically v. Paranasal sinus abnormality

	vi. Biopsy containing a blood vessel showing the accumulation of eosinophils in extravascular areas b. The patient meets ALL the following: i. Medical history of asthma ii. Peak peripheral blood eosinophilia greater than 1000 cells/microliter iii. Systemic vasculitis involving two or more extra-pulmonary organs 2. Relapsing or refractory disease defined as one of the following: a. History of relapse requiring an increase in glucocorticoid dose, initiation or increase in other immunosuppressive therapy, or hospitalization in the previous two years while receiving at least 7.5 mg/day prednisone (or equivalent) b. Failure to achieve remission following a standard induction regimen administered for at least three months OR recurrence of symptoms of EGPA while tapering glucocorticoids. Standard treatment regimens include: prednisone [or equivalent] dosed at least 7.5 mg/day in combination with an immunosuppressant such as cyclophosphamide, azathioprine, methotrexate, or mycophenolate mofetil For patients established on the requested therapy within the previous year: Response to therapy indicating improvement or stabilization of condition

Prior Authorization for **Medicare Part D**:

PA PROGRAM NAME	Respiratory agents - Fasenra
MEDICATION NAME	Fasenra (benralizumab)
PA INDICATION INDICATOR	1 - All FDA-Approved Indications
EXCLUSION CRITERIA	Concurrent use with another therapeutic immunomodulator agent utilized for the same indication
REQUIRED MEDICAL INFORMATION	For initial authorization for eosinophilic granulomatosis with polyangiitis (EGPA): 1. Diagnosis of EGPA defined as blood eosinophil level of at least 10% or an absolute eosinophil count of more than 1000 cells/microliter,

	2. The patient is currently being treated with maximally tolerated oral corticosteroid, unless intolerance/contraindication to oral corticosteroids. Reauthorization for EGPA: 1. Documentation of positive clinical response to therapy and 2. The patient is currently being treated with maximally tolerated oral corticosteroid, unless intolerance/contraindication to oral corticosteroids.
PRESCRIBER RESTRICTIONS	Medications must be prescribed by, or in consultation with the following specialists based on the diagnosis: 1. EGPA: pulmonologist, neurologist, or rheumatologist
COVERAGE DURATION	EGPA: Initial 6 mo/reauth 1 yr

5. **FILSPARI** (SPARSENTAN)
   a. Previous Indication(s):
      i. To reduce proteinuria in adults with primary immunoglobulin A nephropathy (IgAN) at risk of rapid disease progression, generally a urine protein-to-creatinine ratio (UPCR) ≥1.5 g/g
         1. This indication is approved under accelerated approval based on reduction of proteinuria. It has not been established whether FILSPARI slows kidney function decline in patients with IgAN. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory clinical trial
   b. New indication approved 09/05/2024:
      i. To slow kidney function decline in adults with primary immunoglobulin A nephropathy (IgAN) who are at risk for disease progression
   c. **RECOMMENDATION:** Inform prescribers via Medical Policy Alert. Update policy with new indication. Update policy with new indication and update criteria.

Prior Authorization for **Commercial/Medicaid**:

PA PROGRAM NAME	Filspari
MEDICATION NAME	Filspari (sparsentan)
COVERED USES	1 - All FDA-Approved Indications
REQUIRED MEDICAL INFORMATION	For initial authorization, all the following criteria must be met: 1. Diagnosis of primary immunoglobulin A nephropathy (IgAN), confirmed by biopsy 2. Patient has been receiving a stable dose of an angiotensin-converting enzyme (ACE) inhibitor or angiotensin receptor blockers (ARB), at a

	maximally tolerated dose, with statement that ACE or ARB will be discontinued before sparsentan therapy is initiated 3. Patient is at high risk of disease progression, defined as meeting one of the following criteria (a or b): a. Proteinuria of more than 1.0 g/day; OR b. Urine protein-to-creatinine ratio of 1.5 g/g or more 4. eGFR greater than or equal to 30 mL/min1.73m^2 Reauthorization: Documentation of positive response to therapy defined as improvement in proteinuria.

6. **FUROSCIX** (FUROSEMIDE)
    a. Previous Indication(s):
        i. Treatment of congestion due to fluid overload in adult patients with NYHA Class II/III chronic heart failure
    b. **Revised** indication approved 08/09/2024:
        i. Treatment of congestion due to fluid overload in adult patients with chronic heart failure
        ii. Ascites also removed as contraindication
    c. **RECOMMENDATION:** Inform prescribers via Medical Policy Alert. Self-Administered Drugs (SAD) Clinical Policy does not list indications; no further updates required.

7. **PREVYMIS** (LETERMOVIR)
    a. Previous Indication(s):
        i. Prophylaxis of cytomegalovirus (CMV) infection and disease in adult patients who are CMV-seropositive recipients [R+] of an allogeneic hematopoietic stem cell transplant (HSCT)
        ii. Prophylaxis of CMV disease in adult who are kidney transplant recipients at high risk (Donor CMV seropositive/Recipient CMV seronegative [D+/R-])
    b. New indication approved 08/30/2024:
        i. Prophylaxis of cytomegalovirus (CMV) infection and disease in pediatric patients 6 months of age and older and weighing at least 6 kg who are CMV-seropositive recipients [R+] of an allogeneic hematopoietic stem cell transplant (HSCT)
        ii. Prophylaxis of CMV disease in pediatric patients 12 years of age and older and weighing at least 40 kg who are kidney transplant recipients at high risk (Donor CMV seropositive/Recipient CMV seronegative [D+/R-])
    c. **RECOMMENDATION:** Indication and age restrictions reviewed at December 2024 P&T annual policy review. Inform prescribers via Medical Policy Alert.

8. **QSYMIA** (PHENTERMINE AND TOPIRAMATE)
    a. Previous Indication(s):
        i. An adjunct to a reduced-calorie diet and increased physical activity for chronic weight management in:
            1) Adults with an initial body mass index (BMI) of:
                a) 30 kg/m2 or greater (obese) or
                b) 27 kg/m2 or greater (overweight) in the presence of at least one weight related comorbidity such as hypertension, type 2 diabetes mellitus, or dyslipidemia
            2) Pediatric patients aged 12 years and older with BMI in the 95th percentile or greater standardized for age and sex
        ii. Limitations of Use:
            1) The effect of QSYMIA on cardiovascular morbidity and mortality has not been established
            2) The safety and effectiveness of QSYMIA in combination with other products intended for weight loss, including prescription and over-the-counter drugs, and herbal preparations, have not been established
    b. New indication approved 09/13/2024:
        i. In combination with a reduced-calorie diet and increased physical activity to reduce excess body weight and maintain weight reduction long term in:
            1) Adults and pediatric patients aged 12 years and older with obesity
            2) Adults with overweight in the presence of at least one weight-related comorbid condition
        ii. Limitations of Use:
            1) The effect of QSYMIA on cardiovascular morbidity and mortality has not been established
            2) The safety and effectiveness of QSYMIA in combination with other products intended for weight loss, including prescription and over-the-counter drugs, and herbal preparations, have not been established
    c. **RECOMMENDATION:** Inform prescribers via Medical Policy Alert. Update policy with new indication. No updates to criteria required.

9. **TREMFYA** (GUSELKUMAB)
    a. Previous Indication(s):
        i. Moderate-to-severe plaque psoriasis who are candidates for systemic therapy or phototherapy
        ii. Active psoriatic arthritis
    b. New indication approved 09/11/2024:
        i. Moderately to severely active ulcerative colitis
    c. **RECOMMENDATION:** Inform prescribers via Medical Policy Alert. New indication reviewed at October 2024 P&T; no further updates required.

10. **YUFLYMA** (ADALIMUMAB-AATY)
    a. Previous Indication(s):

i. Reducing signs and symptoms, inducing major clinical response, inhibiting the progression of structural damage, and improving physical function in adult patients with moderately to severely active rheumatoid arthritis
ii. Reducing signs and symptoms of moderately to severely active polyarticular juvenile idiopathic arthritis in patients 2 years of age and older
iii. Reducing signs and symptoms, inhibiting the progression of structural damage, and improving physical function in adult patients with active psoriatic arthritis
iv. Reducing signs and symptoms in adult patients with active ankylosing spondylitis
v. Treatment of moderately to severely active Crohn's disease in adults and pediatric patients 6 years of age and older
vi. Treatment of moderately to severely active ulcerative colitis in adult patients.
    1. Limitations of Use: Effectiveness has not been established in patients who have lost response to or were intolerant to TNF blockers
vii. Treatment of adult patients with moderate to severe chronic plaque psoriasis who are candidates for systemic therapy or phototherapy, and when other systemic therapies are medically less appropriate
viii. Treatment of moderate to severe hidradenitis suppurativa in adult patients

b. New indication approved 08/16/2024:
    i. Treatment of non-infectious intermediate, posterior, and panuveitis in adult patients
c. **RECOMMENDATION:** Inform prescribers via Medical Policy Alert. TIMS Policies previously updated with new indication; no further updates required.

Therapies with Prior Authorization Policies (Oncology)

11. **IMFINZI** (DURVALUMAB)
    a. New indication(s) approved 08/15/2024:
        i. In combination with platinum-containing chemotherapy as neoadjuvant treatment, followed by Imfinzi continued as a single agent as adjuvant treatment after surgery, for the treatment of adult patients with resectable (tumors ≥ 4 cm and/or node positive) non small cell lung cancer (NSCLC) and no known epidermal growth factor receptor (EGFR) mutations or anaplastic lymphoma kinase (ALK) rearrangements
    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. **JEMPERLI** (DOSTARLIMAB-GXLY)
    a. New indication(s) approved 08/01/2024:
        i. In combination with carboplatin and paclitaxel, followed by JEMPERLI as a single agent, for the treatment of adult patients with primary advanced or recurrent endometrial cancer.

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.

13. **KEYTRUDA** (PEMBROLIZUMAB)
    a. New indication(s) approved 09/17/2024:
        i. In combination with pemetrexed and platinum chemotherapy, is indicated for the first-line treatment of adult patients with unresectable advanced or metastatic malignant pleural mesothelioma (MPM)
    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.

14. **KISQALI** (RIBOCICLIB)
    a. New indication(s) approved 09/17/2024:
        i. In combination with an aromatase inhibitor for the adjuvant treatment of adults with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative stage II and III early breast cancer at high risk of recurrence
    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.

15. **KISQALI® FEMARA® CO-PACK** (RIBOCICLIB AND LETROZOLE)
    a. New indication(s) approved 09/17/2024:
        i. Adjuvant treatment of adults with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative stage II and III early breast cancer at high risk of recurrence
    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.

16. **RETEVMO** (SELPERCATINIB)
    a. New indication(s) approved 09/27/2024:
        i. Treatment of adult and pediatric patients 2 years of age and older with advanced or metastatic medullary thyroid cancer (MTC) with a *RET* mutation, as detected by an FDA-approved test, who require systemic therapy
    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.

17. **RYBREVANT** (AMIVANTAMAB-VMJW)
    a. New indication(s) approved 08/19/2024:

   i. Amivantamab in combination with lazertinib for first-line treatment of adult patients with locally advanced or metastatic non-small cell lung cancer (NSCLC) with epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 L858R substitution mutations, as detected by an FDA-approved test
b. New indication(s) approved 09/19/2024:
   i. In combination with carboplatin and pemetrexed for the treatment of adult patients with locally advanced or metastatic NSCLC with EGFR exon 19 deletions or exon 21 L858R substitution mutations, whose disease has progressed on or after treatment with an EGFR tyrosine kinase inhibitor.
c. **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.

18. **SARCLISA** (ISATUXIMAB-IRFC)
    a. New indication(s) approved 09/20/2024:
       i. In combination with bortezomib, lenalidomide and dexamethasone, for the treatment of adult patients with newly diagnosed multiple myeloma who are not eligible for autologous stem cell transplant (ASCT)
    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.

19. **TAGRISSO** (OSIMERTINIB)
    a. New indication(s) approved 09/25/2024:
       i. Treatment of adult patients with locally advanced, unresectable (stage III) non-small cell lung cancer (NSCLC) whose disease has not progressed during or following concurrent or sequential platinum-based chemoradiation therapy and whose tumors have EGFR exon 19 deletions or exon 21 L858R mutations, as detected by an FDA-approved 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.

Therapies Without Prior Authorization Policies

20. **FABHALTA** (IPTACOPAN HYDROCHLORIDE)
    a. Previous Indication(s):
       i. Treatment of adults with paroxysmal nocturnal hemoglobinuria (PNH)
    b. New indication(s) approved 08/07/2024:
       i. Reduction of proteinuria in adults with primary immunoglobulin A nephropathy (IgAN) at risk of rapid disease progression, generally a urine protein-to-creatinine ratio (UPCR) ≥1.5 g/g
    c. **RECOMMENDATION:** Inform prescribers via Medical Policy Alert.

21. **NEXOBRID** (ANACAULASE-BCDB)
    a. Previous Indication(s):
        i. Eschar removal in adults with deep partial thickness and/or full thickness thermal burns
    b. New indication(s) approved 08/07/2024:
        i. Eschar removal in pediatric burn patients with deep partial thickness and /or full thickness thermal burns
    c. **RECOMMENDATION:** Inform prescribers via Medical Policy Alert.

22. **PROTONIX IV** (PANTOPRAZOLE SODIUM)
    a. Previous Indication(s):
        i. Short-term treatment (7 to 10 days) of gastroesophageal reflux disease (GERD) associated with a history of Erosive Esophagitis (EE) in adults
        ii. Pathological hypersecretion conditions including Zollinger-Ellison (ZE) Syndrome in adults
    b. New indication(s) approved 08/12/2024:
        i. Treatment of gastroesophageal reflux disease (GERD) and a history of erosive esophagitis (EE) for up to 7 days in pediatric patients 3 months and older
    c. **RECOMMENDATION:** Inform prescribers via Medical Policy Alert.

Vaccine New Indications

23. **ACAM2000** (SMALLPOX AND MPOX (VACCINIA) VACCINE, LIVE)
    a. Previous Indication(s):
        i. Prevention of smallpox disease in individuals determined to be at high risk for smallpox infection
    b. New indication(s) approved 08/07/2024:
        i. Prevention of mpox disease in individuals determined to be at high risk for mpox infection
    c. **RECOMMENDATION:** Inform prescribers via Medical Policy Alert.

Discontinued Therapies

24. **TRANSMUCOSAL IMMEDIATE-RELEASE FENTANYL (TIRF) PRODUCTS** (SUCH AS ACTIQ, FENTORA [FENTANYL CITRATE])
    a. **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 8/1/2024–9/30/2024

FDA Drug Safety Communications

1. **Drug Name:** fezolinetant/Veozah
    - **Date Posted:** 09/12/2024
    - **Safety Alert Title:** FDA adds warning about rare occurrence of serious liver injury with use of Veozah (fezolinetant) for hot flashes due to menopause: Stop medicine if signs and symptoms of liver injury occur
    - **Link to more information:** https://www.fda.gov/drugs/drug-safety-and-availability/fda-adds-warning-about-rare-occurrence-serious-liver-injury-use-veozah-fezolinetant-hot-flashes-due
    - **What safety concern is FDA announcing?**
        - The U.S. Food and Drug Administration (FDA) is warning that Veozah (fezolinetant), a medicine used to treat hot flashes due to menopause, can cause rare but serious liver injury. If there are signs and symptoms suggesting liver injury, stopping the medicine could prevent worsening liver injury and potentially return liver function to normal.
    - **What is FDA doing?**
        - The FDA added a warning about the risk of liver injury to the existing warning about elevated liver blood test values and required liver blood testing in the prescribing information for Veozah. This update was made after reviewing a post marketing report of a patient with elevated liver blood test values and signs and symptoms of liver injury after taking the medicine for about 40 days. New recommendations for patients and health care professionals were provided regarding increasing the frequency of liver blood testing, adding monthly testing for the next 2 months after starting Veozah, and then at months 3, 6, and 9 of treatment as already recommended. The updated prescribing information also instructs patients to stop the medicine immediately and contact the health care professional who prescribed the medicine if signs and symptoms of liver injury occur.
    - **What should health care professionals do?**
        - Health care professionals should conduct hepatic laboratory testing before prescribing Veozah, then every month for the first three months after patients start treatment, and then at months 6 and 9 of treatment. When prescribing Veozah, inform patients about the risk of elevated liver blood test values that may occur during treatment and the rare but serious risk of liver injury, and advise them of the need for regular liver blood testing. Discuss the signs and symptoms of liver injury and instruct patients to stop Veozah immediately and contact the health care professional who prescribed the medicine if they develop these any time during treatment.
    - **Health Plan Recommendation:** Notify providers via Medical Policy Alert.

Drug Recalls/Market Withdrawals

1. **Drug Name:** heparin sodium 0.9% sodium chloride
    - **Date of Recall:** 08/05/2024
    - **Reason for recall:** Elevated endotoxin levels
    - **Link to more information:** https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/baxter-issues-voluntary-nationwide-recall-one-lot-heparin-sodium-09-sodium-chloride-injection-due
    - **Health Plan Recommendation:** Notify providers via Medical Policy Alert

2. **Drug Name:** 0.9% sodium chloride for injection USP 1000mL in E3 containers
    - **Date of Recall:** 08/08/2024
    - **Reason for recall:** Potential for particulate matter and fluid leakage of the containers

- **Link to more information:** https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/b-braun-issues-voluntary-nationwide-recall-09-sodium-chloride-injection-usp-1000-ml-e3-containers
- **Health Plan Recommendation:** Notify providers via Medical Policy Alert

3. **Drug Name:** Endurance Pro Energy Boost Capsules
   - **Date of Recall:** 08/20/2024
   - **Reason for recall:** Product is tainted with sildenafil
   - **Link to more information:** https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/veata-llc-issues-voluntary-nationwide-recall-endurance-pro-capsules-due-potential-presence
   - **Health Plan Recommendation:** Notify providers via Medical Policy Alert

4. **Drug Name:** Atovaquone Oral Suspension, 750 mg/mL
   - **Date of Recall:** 09/17/2024
   - **Reason for recall:** Product found to be contaminated with Cohnella bacteria
   - **Link to more information:** https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/bionpharma-inc-issues-voluntary-nationwide-recall-atovaquone-oral-suspension-due-bacterial
   - **Health Plan Recommendation:** Notify providers via Medical Policy Alert

5. **Drug Name:** Vail-Bon Jie Yang Wan
   - **Date of Recall:** 09/18/2024
   - **Reason for recall:** Product is tainted with dexamethasone and chlorpheniramine
   - **Link to more information:** https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/123herbals-llc-123herbalscom-issues-voluntary-nationwide-recall-vail-bon-jie-yang-wan-capsules-due
   - **Health Plan Recommendation:** Notify providers via Medical Policy Alert

6. **Drug Name:** Veklury (remdesivir) for Injection
   - **Date of Recall:** 09/20/2024
   - **Reason for recall:** Due to presence of glass particle
   - **Link to more information:** https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/gilead-issues-voluntary-nationwide-recall-one-lot-veklury-remdesivir-injection-100-mgvial-due
   - **Health Plan Recommendation:** Notify providers via Medical Policy Alert

7. **Drug Name:** Oxbryta (voxelotor)
   - **Date of Recall:** 09/26/2024
   - **Reason for recall:** Safety concerns

- **Link to more information:** https://www.fda.gov/drugs/drug-safety-and-availability/fda-alerting-patients-and-health-care-professionals-about-voluntary-withdrawal-oxbryta-market-due
- **Health Plan Recommendation:** Notify providers via Medical Policy Alert; PHP action was taken: Letter sent to 2 commercial members and 4 providers

Safety-related Labelling Updates

8. **Drug Name:** Cosentyx (secukinumab)
   - **Date of Update:** 08/16/2024
   - **Reason for update:** Risk of hepatitis B reactivation (HBV-R) and opportunistic infections associated with the use of Cosentyx
   - **Link to label:** https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=77c4b13e-7df3-42d4-81db-3d0cddb7f67a#s5p1
   - **Health Plan Recommendation:** Notify providers via Medical Policy Alert

9. **Drug Name:** Taltz (ixekizumab**)**
   - **Date of Update:** 08/20/2024
   - **Reason for update:** Risk of opportunistic infections and eczematous eruptions
   - **Link to label:** https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=ac96658a-d7dc-4c7c-8928-2adcdf4318b2
   - **Health Plan Recommendation:** Notify providers via Medical Policy Alert

10. **Drug Name:** Zeposia (ozanimod hydrochloride)
    - **Date of Update:** 08/30/2024
    - **Reason for update:** Risk of severe liver injury
    - **Link to label:** https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=93ce2fab-edfb-4804-8074-963071de51e4
    - **Health Plan Recommendation:** Notify providers via Medical Policy Alert

Other Formulary Changes:

OTHER FORMULARY CHANGES		
Drug Name	**Action Taken**	**Policy Name**
Calcium Acetate Tablet	Add to Commercial Formulary, Tier 2 Effective: 01/01/2025	N/A
Guanfacine HCl 1 and 2 mg Tablets	Add to Medicare Part D formulary, Tier 2	N/A
Hydroxychloroquine sulfate Tablet	Add to Medicare Part D formulary, Tier 2	N/A
Ramelteon Tablet	Add to Medicare Part D formulary, tier 4, Quantity Limit (1 tablet per day)	N/A
Febuxostat (Uloric) Tablet	• Commercial Dynamic: Down tier generic to Tier 3 • Medicaid: Add generic to formulary	N/A

Naltrexone microspheres (Vivitrol) Sus ER Rec	Add to Medicare Part D formulary, Tier 5	N/A
Clobetasol propionate Drops Susp	New route; • Non-formulary for all lines of business	N/A
Carbidopa/Levodopa (Crexont) Cap IR ER	New formulation; • Commercial/Medicaid: Non-Formulary, Quantity Limit (6 capsules per day) • Medicare Part D: Non-Formulary	N/A
Glimepiride Tablet	New strength (3 mg); • Non-formulary for all lines of business	N/A
Phenylephrine HCl/tropicamide (Mydcombi) Cartridge	New entity; • Medical benefit for all lines of business	N/A
Epinephrine (Neffy) Spray	New dosage form; • Commercial/Medicaid: Non-Formulary, Quantity Limit (2 sprays per 30 days) • Medicare Part D: Non-Formulary	N/A
Clonidine HCl (Onyda XR) Sus ER 24h	New formulation; • Commercial/Medicaid: Non-Formulary, Quantity Limit (4 mL day) • Medicare Part D: Non-Formulary	N/A
Atezolizumab-hyaluronidas-tqjs (Tecentriq Hybreza) Vial	New entity; • Commercial/Medicaid: Medical Benefit, Prior Authorization • Medicare Part D: Non-Formulary • Medicare Part B: Prior Authorization, Step Therapy	• Commercial/Medicaid: Anti-Cancer Medications - Medical Benefit • Medicare Part B: Anti-Cancer Medications Prior Authorization and Step Therapy Policy - Medicare Part B
Guselkumab (Tremfya) Vial	New dosage form; • Commercial/Medicaid: Medical Benefit, Prior Authorization • Medicare Part D: Non-Formulary • Medicare Part B: Prior Authorization, Step Therapy	Medically Infused Therapeutic Immunomodulators
Chenodiol (Chenodal) Tablet	Remove from Medicaid formulary Effective: 03/01/2025	Chenodal
Cholic acid (Cholbam) Capsule	Remove from Medicaid formulary Effective: 03/01/2025	Medications For Rare Indications
Teduglutide (Gattex) Kit	Remove from Commercial and Medicaid formularies	Gattex

Daprodustat (Jesduvroq) Tablet	Remove from Commercial and Medicaid formularies	Jesduvroq, Vafseo
Linaclotide (Linzess) Capsule	Add to Commercial Formulary, Tier 3, Retire prior authorization Effective: 01/01/2025	N/A
Obeticholic acid (Ocaliva) Tablet	Remove from Commercial and Medicaid formularies	Primary Biliary Cholangitis Agents
Granisetron (Sancuso) Patch TDWK	Remove from Commercial and Medicaid formularies	N/A
Avacopan (Tavneos) Capsule	Add to Commercial Formulary, Tier 6, Prior Authorization, Quantity Limit (6 capsules per day)	Tavneos
Budesonide (Uceris) 9 mg Tab DR/ER	• Commercial: Add Quantity Limit (one tablet per day) • Medicaid: Remove from formulary and add Quantity Limit (one tablet per day) Effective: 03/01/2025	Uceris
Erlotinib **Lapatinib** **dasatinib**	Down-tier generics to Tier 5 (with Prior Authorization) for Commercial	Anti-Cancer Medications - Self-Administered

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

INFORMATIONAL ONLY

NEW DRUGS / COMBINATIONS / STRENGTHS / DOSAGE FORMS		
Drug Name	**Action Taken**	**Policy Name**
Norethindrone ac/eth estradiol (Femlyv) Tab Rapdis	New formulation. Line extend with other norethindrone generics; • Commercial: Preventive • Medicaid: Non-Formulary • Medicare Part D: Formulary, Tier 4	N/A
Formoterol fumarate-nebulizer Vial-Neb	New dosage form (Vial-Neb). Line extend with formoterol; • Commercial Standard: Formulary, Tier 2 • Commercial Dynamic: Formulary, Tier 3 • Medicaid: Non-Formulary • Medicare Part D: Formulary, Tier 4	N/A
Oxycodone HCl (Roxybond) Tablet Orl	New strength. Line extend with generic; • Non-formulary for all lines of business	N/A

NEW DRUGS / COMBINATIONS / STRENGTHS / DOSAGE FORMS		
Drug Name	**Action Taken**	**Policy Name**
Sitagliptin/Metformin HCl (Zituvimet XR) TBMP 24hr	New Generic (NDA Authorized generic for Janumet XR). Different GCNs. Line extend as non-formulary; • Non-formulary for all lines of business	N/A
Bimatoprost/pf (Bimatoprost) Drops	New formulation. Line extend with bimatoprost; • Commercial Standard: Formulary, Tier 2, Step Therapy, Quantity Limit (5 mL per 28 days) • Commercial Dynamic: Formulary, Tier 3, Step Therapy, Quantity Limit (5 mL per 28 days) • Medicaid: Formulary, Step Therapy, Quantity Limit (5 mL per 28 days) • Medicare Part D: Formulary, Tier 3, Step Therapy	Anti-Glaucoma Agents Step Therapy Policy
Sodium oxybate (Lumryz Starter Pack)	New strength (starter pack). Line extend with Lumryz; • Commercial: Formulary, Tier 6, Prior Authorization, Quantity Limit (28 per 365 days) • Medicaid: Non-Formulary, Prior Authorization, Quantity Limit (28 per 365 days), Specialty • Medicare Part D: Non-Formulary	• Commercial/Medicaid: Narcolepsy Agents • Medicare Part D: N/A
Faricimab-svoa (Vabysmo) Syringe	New formulation. Line extend with Vabysmo solution; • Commercial/Medicaid: Medical Benefit, Prior Authorization • Medicare Part D: Non-Formulary • Medicare Part B: Medical Benefit, Prior Authorization	Ophthalmic Vascular Endothelial Growth Factor (VEGF) Inhibitors
Guselkumab (Tremfya) Syringe / Pen Injctr	New strength (200mg/ml). Line extend with Tremfya; • Commercial: Formulary, Tier 5, Prior Authorization, Quantity Limit (2 mL per 28 days)	Therapeutic Immunomodulators (TIMS)

NEW DRUGS / COMBINATIONS / STRENGTHS / DOSAGE FORMS		
Drug Name	**Action Taken**	**Policy Name**
	• Medicaid: Non-Formulary, Prior Authorization, Quantity Limit (2 mL per 28 days), Specialty • Medicare Part D: Formulary, Tier 5, Prior Authorization, Quantity Limit (2 mL per 28 days)	
Certolizumab pegol (Cimzia) Syringe kit	New strength. Line extend with Cimzia; • Commercial: Formulary, Tier 5, Prior Authorization, Quantity Limit (1 kit per 28 days) • Medicaid: Non-Formulary, Prior Authorization, Quantity Limit (1 kit per 28 days), Specialty • Medicare Part D: -/NF	Therapeutic Immunomodulators (TIMS)

New Generics:

NEW GENERICS		
Drug Name	**Action Taken**	**Policy Name**
Dasatinib Tablet	NDA authorized generic (Sprycel). Line extend as generic; • Commercial: Formulary, Tier 5, Prior Authorization • Medicaid: Formulary, Prior Authorization, Specialty • Medicare Part D: Tier 5, Prior Authorization, Quantity Limit (1 tablet per day)	Anti-Cancer Medications - Self-Administered
Fentanyl Citrate Tablet EFF	First generic drug (Fentora). Line extend as generic; • Commercial/Medicaid: Non-Formulary, Prior Authorization, Quantity Limit (4 tablets per day) • Medicare Part D: Non-Formulary	• Commercial/Medicaid: Fentanyl Citrate • Medicare Part D: N/A
Octreotide acetate,mi-spheres (Octreotide Acetate ER) Vial	First generic drug (Sandostatin LAR Depot). Line extend with generic;	• Commercial/Medicaid: Pituitary Disorder Therapies • Medicare Part D: N/A

	• Commercial/Medicaid: Medical Benefit, Prior Authorization • Medicare Part D: Non-Formulary • Medicare Part B: Medical Benefit, Prior Authorization	• Medicare Part B: Somatostatin Analogs Prior Authorization and Step Therapy Policy
Potassium chloride Tablet ER	New generic (Klor-con m15) with new GCN; • Commercial: Formulary, Tier 2 • Medicaid: Formulary • Medicare Part D: Formulary, Tier 2	N/A

Clinical Policy Changes:

MAJOR CHANGES	
Policy Name	**Summary of Change**
Anti-Cancer Medications – Self-Administered	Will require trial of imatinib before coverage of nilotinib (Tasigna®) and dasatinib (Sprycel®) will be authorized. This will apply to new starts only.
Acute Hereditary Angioedema Prior Authorization and Step Therapy Policy - Medicare Part B	Updated age restrictions language to require age be appropriate based on FDA approved indication.
Acute Hereditary Angioedema Therapy	Updated age restrictions language to require age be appropriate based on FDA approved indication. Updated quantity limit for icatibant to allow treatment for two exacerbations per month. Per package insert, may administer up to three doses per 24 hours.
• **Adakveo** • **Adakveo Prior Authorization and Step Therapy Policy - Medicare Part B**	Removed Oxbryta® under exclusion since the drug has been withdrawn from the market. Added Endari® under exclusion criteria to prevent combination use.
Alinia	Updated oral suspension quantity limit to allow for three days of treatment per package insert.
Chenodal	Remove from Medicaid formulary, added requirement for radiolucent stones in well-opacifying gallbladders, and clarified when patients are considered not a candidate for surgery.
Constipation Agents	Updated age restrictions language to require age be appropriate based on FDA approved indication. Retired prior authorization on Linzess® and added it as preferred therapy on formulary (non-preferred drugs on the policy will require trial of Linzess®). Step through Amitiza (lubiprostone) for IBS-C only applies for patients 18 years and older assigned female at birth due to FDA labeling.
Constipation Agents – Medicaid	Added criteria for reauthorization criteria, updated ICD-10 code list of non covered diagnosis codes to include functional constipation as they are also considered unfunded diagnoses.
Gene Therapies for Hemoglobin Disorders	Added note that additional genotypes will be considered on a case-by-case basis based on disease severity for sickle cell disease.

Givlaari	Updated active disease definition to include four or more porphyria attacks within a year (in addition to two or more within the past six months). This aligns with expert opinion statement from American Gastroenterological Association. Added for reauthorization that dosing must align with FDA-labeling.
Hemlibra	Added criteria requiring the dose and frequency align with FDA labeling.
• **Hepatitis C - Direct Acting Antivirals** • **Hepatitis C - Direct Acting Antivirals - Medicaid**	Allow coverage of generic Epclusa in solid organ transplant setting per AASLD guideline.
Jesduvroq, Vafseo	Updated prescriber restrictions to allow hematologist. Updated duration of approval to align with Erythropoietin Stimulating Agents clinical policy.
Livtencity	Updated criteria to require failure of one antiviral or intolerance/contraindication to all other listed antivirals.
Lotronex	Removed information on REMS program in prescriber restrictions and position statement as this is no longer required, increased initial authorization duration to 12 months, removed requirement that patient is female due to low risk of inappropriate utilization and low likelihood of males continuing on therapy if they are approved due to decreased efficacy in this population.
Medications For Rare Indications	For Cerdelga, add requirement for metabolic status of poor, intermediate, or extensive 2D6 metabolizer. For Galafold, updated diagnosis requirement to an amenable galactosidase alpha (GLA) gene variant. For Sohonos, required initial clinical scores. For Xolremdi, required initial labs.
• **Prevymis** • **Prevymis Prior Authorization and Step Therapy Policy - Medicare Part B**	Updated age restriction as medication is now approved down to those 6 months of age for hematopoietic stem cell transplantation (HSCT) and 12 years of age for kidney transplant recipients. Clarified that coverage requests for HSCT greater than 100 days post transplantation requires documentation the member is at high risk for late cytomegalovirus infection.
Primary Biliary Cholangitis Agents	Updated initial auth from four to six months to allow more time to assess response.
Prophylactic Hereditary Angioedema Prior Authorization and Step Therapy Policy - Medicare Part B	Updated duration of approval to align with Commercial policy.
Reblozyl, Rytelo	Clarified definition of transfusion-dependent anemia for beta-thalassemia.
Tavneos	Coverage duration clarified.
Thrombocytopenia Medications	For Immune Thrombocytopenia (ITP), removed rituximab as trial/failure option; For Severe aplastic anemia (AA), added requirement for combination or previous use of standard immunosuppressive therapy; For Chronic Liver Disease, removed requirement for when to start therapy; For continuation of ITP and AA, remove requirement for attestation of medical necessity; Add quantity limits to Doptelet and Promacta.
Thrombocytopenia Medications Prior Authorization and Step Therapy Policy - Medicare Part B	Updated ITP criteria to require corticosteroids first and allow IVIG or IV anti-D therapy if necessary.
Uceris	Removed tablet from Medicaid formulary and added quantity limit for tablet.

Retired Policies:

Policy Name	Summary of Change
Altuviiio	Due to low risk of inappropriate utilization and alignment with other factor products for hemophilia that do not require prior authorization.
Cablivi	Moved to Thrombocytopenia Medications policy.
Cholbam	Move to non-formulary for Medicaid, move to rare indications policy.
Enjaymo	Retire policy and move drug with diagnosis criteria to the Medications for Rare Indications policy.
Oxbryta	Drug is no longer available on the market.
Serotonin Antagonists Step Therapy Policy	Policy retired due to low utilization.