Providence Health Plan

Providence Health Assurance

Healthcare Services Medical & Pharmacy Policy Alerts

Number 95

June 1, 2024

This is the June 1, 2024 issue of the Providence Health Plans, Providence Health Assurance and Providence Plan Partners, Medical and Pharmacy Policy Alert to our providers. The focus of this update is to communicate to providers' new or revised Medical or Pharmacy policy changes. The Health Plan has a standard process to review all Medical & Pharmacy Policies annually. Policies will be available for review on ProvLink and via the PHP website at: https://healthplans.providence.org/providers/provider-support/medical-policy-pharmacy-policy-and-provider-information/

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

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

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

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

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

Providence Health Plan

Providence Health Assurance

MEDICAL POLICY COMMITTEE

MEDICAL

COMPANY POLICIES

Effective 6/1/2024

Alpha-Fetoprotein **MP406**	**New Policy** **Policy Updates: N**ew lab policy for Alpha-Fetoprotein primarily based on the NCD: Alpha-Fetoprotein (190.25). **Codes/PA:** • CPT code 82105 will pay when paired with certain diagnostic codes listed based on NCD Coding Policy Manual and Change Report. • This configuration does not apply to ASO and OHP groups. **OHP:** These changes do not apply to OHP. The Prioritized List and the Oregon Administrative Rules will be followed.
Bacterial Urine Cultures **MP408**	**New Policy** **Policy Updates: N**ew lab policy for Bacterial Urine Cultures primarily based on the NCD: Urine Culture, Bacterial (190.12). **Codes/PA:** • CPT codes 87086 and 87088 will deny when paired with certain d diagnostic codes listed based on NCD Coding Policy Manual and Change Report. • This configuration does not apply to ASO and OHP groups. **OHP:** These changes do not apply to OHP. The Prioritized List and the Oregon Administrative Rules will be followed.
Human Chorionic Gonadotropin **MP410**	**New Policy** **Policy Updates:** New lab policy for Human Chorionic Gonadotropin primarily based on the NCD: Human Chorionic Gonadotropin (190.27).

	Codes/PA: • CPT code 84702 will pay when paired with certain diagnostic codes based on NCD Coding Policy Manual and Change Report. • This configuration does not apply to ASO and OHP groups. **OHP:** These changes do not apply to OHP. The Prioritized List and the Oregon Administrative Rules will be followed
Prothrombin Time (PT) **MP412**	**New Policy** **Policy Updates:** New lab policy, based on CMS guidance. **Codes/PA:** • Added pair-to-pay diagnosis code configuration to CPT 85610. (CPT 85611 is **not** included in this policy scope.) • This configuration does not apply to ASO and OHP groups. **OHP:** These changes do not apply to OHP. The Prioritized List and the Oregon Administrative Rules will be followed.
Tumor Antigen Assays **MP 414**	**New Policy** **Policy Updates:** New lab policy, based on CMS guidance. Configurations will not apply to ASO and OHP groups. **Codes/PA:** Added a pair-to-pay diagnosis code configuration to CPT 86300, 86301, 86304 **OHP:** These changes do not apply to OHP. The Prioritized List and the Oregon Administrative Rules will be followed.

Effective 7/1/2024

Psychological and Neuropsychological Testing **MP274**	**Policy Updates:** Broke out non-covered criteria into indications and methodologies. **Codes/PA:** Added F88 to approved diagnosis list **OHP:** These changes do not apply to OHP. The Prioritized List and the Oregon Administrative Rules will be followed.

Effective 8/1/2024

Cochlear Implants and Auditory Brainstem Implants **MP127**	**Policy Updates:** Changed denials in criteria from investigational to not medically necessary. **Codes/PA:** No changes to codes or PA **OHP:** These changes do not apply to OHP. The Prioritized List and the Oregon Administrative Rules will be followed.
Compression Bandages, Stockings, and Wraps **MP146**	**Policy Updates:** Updated criteria to reflect recent Medicare changes to the new lymphedema compression benefit. This includes separating criteria for standard and custom garments, adding criteria for accessories, as well as criteria for replacements or quantities exceeding Medicare's set limits, Medicare's FDA registration requirements, and billing guidelines. **Codes/PA:** Medicare (Noridian) has published updated billing/coding guidance to include medically necessary diagnosis codes tied to the new lymphedema benefit. In addition, prior non-coverage for some codes has been changed to potential coverage. • For the 66 new 2024 HCPCS codes (A6520, A6521, A6522, A6523, A6524, A6525, A6526, A6527, A6528, A6529, A6552, A6553, A6554, A6555, A6556, A6557, A6558, A6559, A6560, A6561, A6562, A6563, A6564, A6565, A6566, A6567, A6568, A6569, A6570, A6571, A6572, A6573, A6574, A6575, A6576, A6577, A6578, A6579, A6580, A6581, A6582, A6583, A6584, A6585, A6586, A6587, A6588, A6589, A6593, A6594, A6595, A6596, A6597, A6598, A6599, A6600, A6601, A6602, A6603, A6604, A6605, A6606, A6607, A6608, A6609, A6610), add diagnosis code configuration (previously No PA). *This will be effective 8/1/2024, since this is more restrictive than their current configuration* **OHP:** These changes do not apply to OHP. The Prioritized List and the Oregon Administrative Rules will be followed.
Sleep Disorder Testing **MP60**	**Policy Updates:** • Updated cross reference policy section with other policy name updates. Minor formatting updates. • Updated criteria on excessive daytime sleepiness to better define and be in alignment with other payers (Epworth Sleepiness scale (ESS)). **Codes/PA:** No changes. **OHP:** These changes do not apply to OHP. The Prioritized List and the Oregon Administrative Rules will be followed.

MEDICARE POLICIES

Alpha-Fetoprotein **MP407**	**New Medicare Advantage medical policy** **Policy Updates:** New lab policy based on the CMS NCD 190.25 for serum alpha-fetoprotein testing for carcinoma. **Codes/PA:** Added pair-to-pay diagnosis code configuration to CPT 82105. (CPT 82106 is not included in this policy scope.)
Bacterial Urine Cultures **MP409**	**New Medicare Advantage medical policy** **Policy Updates:** New lab policy based on the CMS NCD 190.12 for urine culture testing. **Codes/PA:** Added pair-to-pay diagnosis code configuration to CPTs 87086 and 87088. (CPTs 87070, 87071, or 87073 are **not** included in this policy scope.)
Human Chorionic Gonadotropin **MP411**	**New Medicare Advantage medical policy** **Policy Updates:** New lab policy based on the CMS NCD 190.27 for quantitative human chorionic gonadotropin (hCG) testing. **Codes/PA:** Added pair-to-pay diagnosis code configuration to CPT 84702. (CPT 84703 is **not** included in this policy scope.)
Prothrombin Time (PT) **MP413**	**New Medicare Advantage medical policy** **Policy Updates:** New lab policy based on the CMS NCD 190.17 for prothrombin time (PT) testing. **Codes/PA:** Added pair-to-pay diagnosis code configuration to CPT 85610. (CPT 85611 is **not** included in this policy scope.)
Tumor Antigen Assays **MP415**	**New Medicare Advantage medical policy** **Policy Updates:** New lab policy based on the CMS NCDs 190.28, NCD 190.29, and NCD 190.30 for various tumor antigen assays. **Codes/PA:** Added pair-to-pay diagnosis code configuration to CPT 86300, 86301, 86304. (CPT 86300/86301 are **not** included in this policy scope.)

Effective 7/1/2024

Back: Percutaneous Vertebroplasty and Sacroplasty **MP342**	**Policy Updates:** No change to criteria. **Codes/PA:** Updated configuration to add diagnoses codes added to Noridian LCA. ***NOTE**: This configuration change will apply to **all** lines of business. The Company policy is not being presented separately because the Company policy already includes these diagnoses codes.*

Effective 8/1/2024

Compression Bandages, Stockings, and Wraps **MP139**	**Policy Updates:** Updated criteria to reflect recent additional Medicare changes. **Codes/PA:** Medicare (Noridian) has published updated billing/coding guidance to include medically necessary diagnosis codes tied to the new lymphedema benefit. In addition, prior non-coverage for some codes has been changed to potential coverage. • For the 66 new 2024 HCPCS codes (A6520, A6521, A6522, A6523, A6524, A6525, A6526, A6527, A6528, A6529, A6552, A6553, A6554, A6555, A6556, A6557, A6558, A6559, A6560, A6561, A6562, A6563, A6564, A6565, A6566, A6567, A6568, A6569, A6570, A6571, A6572, A6573, A6574, A6575, A6576, A6577, A6578, A6579, A6580, A6581, A6582, A6583, A6584, A6585, A6586, A6587, A6588, A6589, A6593, A6594, A6595, A6596, A6597, A6598, A6599, A6600, A6601, A6602, A6603, A6604, A6605, A6606, A6607, A6608, A6609, A6610), add diagnosis code configuration (previously No PA). *This will be effective 8/1/2024, since this is more restrictive than their current configuration.*
Sleep Disorder Treatment with Positive Airway Pressure ***Formerly:** Sleep Disorder Treatment: Positive Airway Pressure* **MP53**	**Policy Updates:** • Added Medicare reference for expiratory PAP devices (A7049), but no change to non-coverage position. • No change to other criteria in the policy, continue to apply Medicare NCD, LCD, LCA, and coverage manuals as directed. • Added definitions, acronyms, and background to Policy Guidelines. • Added list of accessories and their related HCPCS codes, but did not formally add them to the policy, and no configuration added to the codes. **Codes/PA:** • HCPCS E0471 & E0472: Added diagnostic code configuration to deny for diagnostic code for OSA when in the primary diagnostic code condition (based on LCD/LCA). • No change to codes or configuration.

Providence Health Plan

Providence Health Assurance

REIMBURSEMENT POLICIES

Effective 6/1/24

Ambulatory Surgery Center (ASC) Payment Structure **RP3**	**Annual Review** **Reimbursement Methodology:** Added inverse statement regarding Medicare/Medicaid LOBs when a procedure is not found on the CMS ASC list, but no changes to reimbursement methodology and no change to intent. **Relevant References/CMS Guidance:** • Noridian Healthcare Solutions web page for Ambulatory Surgical Center (ASC) • Medicare Claims Processing Manual, Chapter 14 - Ambulatory Surgical Centers, §10.2 - Ambulatory Surgical Center Services on ASC List • Medicare Claims Processing Manual, Chapter 14 - Ambulatory Surgical Centers, §20.2 – Types of Services Included on the ASC Covered Procedures List • Medicare Benefit Policy Manual, Chapter 15 - Covered Medical and Other Health Services
Birthing Center Services **RP2**	**Annual Review** **Reimbursement Methodology:** Add billing information for the delivery of twins in a birthing center, but no intended change to current reimbursement methodology. This is a clarification only. **Relevant References/CMS Guidance:** For Medicare, birthing centers are a provider type which are not eligible to enroll in the Medicare program. Therefore, other non-Medicare sources are used, and they are as follows: • Oregon Health Authority. "Ambulatory Surgical Center and Birthing Center Services." Medical-Surgical Services Administrative Rulebook, Chapter 410, Division 130. Effective January 1, 2016. 410-130-0365, pp 40-41. • Oregon Health Authority, Health Systems Division: Medical Assistance Programs - Chapter 410, Division 130, MEDICAL-SURGICAL SERVICES • DHS Oregon Department of Human Services: Medical Surgical Services Rulebook • Medicare Program Integrity Manual, Chapter 10 - Medicare Enrollment, §10.2.8 - Providers/Suppliers Not Eligible to Enroll

Effective 8/1/24

Inpatient Hospital Admission and Length of Stay Reviews **RP7**	**New Reimbursement policy** **Recommendation:** New reimbursement policy for all lines of business. This new policy addresses: • Inpatient admission reviews. • Length of stay reviews. • Short stay considerations. • Two-midnight rule and application to MA plans. *NOTE: This policy does not represent a change to current workflow. It is a formal policy to support our current processes, as well as provide education and transparency to the provider community about our review practices.* **Reimbursement Methodology:** No changes to reimbursement methodology. **Relevant References/CMS Guidance:** • National Archives. Code of Federal Regulations 42 CFR § 412.3 • Centers for Medicare and Medicaid Services (CMS). *Reviewing Short Stay Hospital Claims for Patient Status: Admissions On or After January 1, 2016* • CMS. *Medicare Benefit Policy Manual. Chapter 1 - Inpatient Hospital Services Covered Under Part A* • CMS. *Medicare Benefit Policy Manual, Chapter 6 - Hospital Services Covered Under Part B* • CMS. *Medicare Managed Care Manual, Chapter 17, Subchapter B, Payment Principles for Cost-Based HMO/CMPs, §70 - Provider Receiving Payment Under the Prospective Payment System PPS* • CMS. *Medicare Program Integrity Manual, Chapter 6 - Medicare Contractor Medical Review Guidelines for Specific Services* • CMS. *Quality Improvement Organization Manual, Chapter 4 - Case Review* • CMS. *Medicare General Information, Eligibility, and Entitlement, Chapter 4 – Physician Certification and Recertification of Services* • CMS. *Medicare Benefit Policy Manual, Chapter 16 - General Exclusions From Coverage* • CMS. *Medicare Benefit Policy Manual, Chapter 15 – Covered Medical and Other Health Services* • CMS. *Medicare Program Integrity Manual, Chapter 3 - Verifying Potential Errors and Taking Corrective Actions* • CMS. *Inpatient Only List 2023* • CMS. *CY 2023 Medicare Hospital Outpatient Prospective Payment System and Ambulatory Surgical Center Payment System Final Rule (CMS-1772-FC)* • CMS. *Contract Year 2024 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicare Cost Plan Program, and Programs of All-Inclusive Care for the Elderly Final Rule (CMS-4201-F)* • CMS. *Acute Hospital Care at Home Data Release Fact Sheet* • CMS. *CMS Announces Comprehensive Strategy to Enhance Hospital Capacity Amid COVID-19 Surge* • CMS. *CMS Frequently Asked Questions (FAQ) for 2 Midnight Inpatient Admission Guidance & Patient Status Reviews for Admissions on or after October 1, 2013*

	• CMS. *CMS Manual System Pub 100-20 One-Time Notification. New Occurrence Span Code and Revenue Code for Acute Hospital Care at Home* • CMS. *Acute Inpatient PPS*
Scope of License, Scope of Practice, and Provider Qualifications **RP8**	**New Reimbursement Policy** **Recommendation:** New reimbursement policy for all lines of business. The purpose of this policy is to describe situations where a healthcare professional's qualifications, experience, training, and/or expertise may not be sufficient for that individual to render a specific service or procedure. The implementation of this policy is intended to target the following objectives: • Quality of care; • Patient safety; and, • Accurate and appropriate procedural coding. This policy will address the following scenarios: • Services provided must be rendered by qualified health care professionals. Non-physician practitioners may not be qualified to render certain procedures or services. • Services provided must be rendered by individuals with the proper education, training, and experience for the given procedure. Physicians may not be sufficiently trained or have the appropriate expertise to perform certain procedures. • Diagnostic tests must be ordered by qualified individuals, who plan to use the test results to make decisions regarding a condition for which they are treating the member. **Reimbursement Methodology:** Most member plan benefit language define a "provider" and most all require "providers" to be qualified. Some medical policies already call out specific scenarios where a specific provider specialty or qualification "physicians" (e.g., see Company Medical Policy for *Liposuction for Lipedema*). **Relevant References/CMS Guidance:** • CMS. Medicare Claims Processing Manual, Chapter 12 - Physicians/Nonphysician Practitioners, 190.6 - Payment Methodology for Physician/Practitioner at the Distant Site, 2. Payment Amount (professional fee) • CMS. Medicare Benefit Policy Manual, Chapter 15 - Covered Medical and Other Health Services • CMS. Medicare Program Integrity Manual, Chapter 3 - Verifying Potential Errors and Taking Corrective Actions, 3.6.2.2 - Reasonable and Necessary Criteria • 42 CFR §410.32(a) • CMS. Medicare Benefit Policy Manual, Ch. 15 - Covered Medical and Other Health Services, §80.1 -Clinical Laboratory Services • American Medical Association (AMA) Current Procedural Terminology (CPT®) guidelines. • AMA. What is scope of practice?

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VENDOR UPDATES

Effective 10/20/24

Carelon	Effective for dates of service on and after October 20, 2024 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. <u>Radiology</u> **Brain Imaging** Added indications for MRI and amyloid beta PET imaging in Alzheimer disease to address patients considering or receiving lecanemab **Spine Imaging** Changed "Perioperative and Periprocedural Imaging" to "Postoperative and Postprocedural Imaging;" pre-procedure requests should be reviewed based on more specific indication **Extremity Imaging** Separated criteria for osteomyelitis and septic arthritis into separate indications; US or arthrocentesis as preliminary tests were placed only in the "septic arthritis" indication **Vascular Imaging** CTA/MRA Head addition for chronic posterior circulation Stroke/TIA presentations (CTA/MRA neck already allowed, intracranial eval needed for full extent of anatomy) Lower Extremity PAD: Updated physiologic testing parameters and added allowance for ischemic signs/symptoms at presentation, in alignment with ACR Appropriateness Criteria Suboptimal imaging option downgrades/removals in Brain, Head and Neck and Abdomen/Pelvis <u>Cardiovascular</u> **Imaging of the Heart** Resting Transthoracic Echocardiography (TTE) Expanded frequency of echocardiographic evaluation in patients on mavacamten for treatment of hypertrophic obstructive cardiomyopathy (HOCM) Expanded criteria for echocardiographic evaluation to allow a single screening for cardiac disease in patients undergoing evaluation for solid organ or hematopoietic cell transplant

	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.

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

Pharmacy & Therapeutics (P&T) Committee

Oregon Region P&T Committee Meeting April 5, 2024
Go-Live Date: Saturday, June 01, 2024, unless otherwise noted

Special Announcement for GLP-1 receptor agonists:
For Commercial and Medicaid, the Prior Authorization policy has taken effect as of 5/1/24 for patients initiating therapy with a GLP-1 agent FDA approved for type 2 diabetes. For coverage, patient must have a confirmed diagnosis of type 2 diabetes and have one of the following:

1. Inadequate response to a medication containing metformin or insulin,
2. Intolerance or FDA labeled contraindication to metformin or insulin,
3. Patient has comorbid atherosclerotic cardiovascular disease (or is at high risk of atherosclerotic cardiovascular disease), heart failure, or chronic kidney disease

Note: This does not apply to those approved for weight management. Agents approved for weight management have different criteria and are only covered for groups that have the benefit for coverage of weight loss therapies,

Table of Contents:

New Drugs and Combinations:

1. **Tirzepatide (Zepbound) Pen Inctr**:
   a. **Indication**: For the treatment of adults with:
      - obesity (BMI ≥30) or
      - overweight (BMI ≥27) with presence of at least one weight-related comorbidity

b. **Decision**:

	Commercial	Medicaid	Medicare
Formulary Status*	Formulary for groups with weight loss benefit only	Non-formulary	Part D: Non-formulary Part B: N/A
Tier**	Tier 3 for groups with weight loss benefit only	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 mL per 28 days	2 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: Anti-obesity GLP-1's semaglutide (Wegovy®), liraglutide (Saxenda®)			

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

PA PROGRAM NAME	Weight Management Medications
MEDICATION NAME	Zepbound®
PA INDICATION INDICATOR	1 - All FDA-Approved Indications
OFF-LABEL USES	None
EXCLUSION CRITERIA	• For tirzepatide (Zepbound), liraglutide (Saxenda), and semaglutide (Wegovy): Concurrent use with another GLP-1 receptor agonist for any indication
REQUIRED MEDICAL INFORMATION	For initiation of therapy, Zepbound®, Wegovy®, Saxenda®, or Qsymia® may be covered if all the following criteria must be met: a. Member's benefit provides coverage for weight management medications (Note that some benefits may have additional requirements, such as specific prescribing provider or program enrollment) b. For adults: i. Documentation of current height and weight (measured within the previous month) indicating one of the following: 1. Body mass index (BMI) of at least 30 2. BMI of at least 27 with the presence of at least one weight-related comorbidity (such as hypertension, type 2 diabetes mellitus/pre-diabetes, dyslipidemia, sleep apnea) c. For children: i. Documentation of current height and weight (measured within the previous month) indicating BMI is in the 95th percentile or greater, standardized for age and sex Notes: If race is known, lower BMI thresholds (usually reduced by 2.5) are used for people from South Asian, Chinese, other Asian, Middle Eastern, Black African, African-Caribbean, Native Hawaiian,

	Pacific Islanders, or American Indians/Alaska Natives family backgrounds. If race is not known, standard BMI parameters will be applied. For continuation of therapy, all the following criteria must be met: a. Patient's benefit provides coverage for weight management medications b. Patient has previous authorization for coverage with the plan or attestation from provider that coverage was provided through another health plan (new start to this plan). 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. c. Patient achieved and maintained at least a 5% weight loss from baseline body weight while on the requested medication (documentation of baseline and most recent weight while on the medication are required)

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

PA PROGRAM NAME	Weight Management Medications
MEDICATION NAME	Zepbound®,
PA INDICATION INDICATOR	1 - All FDA-Approved Indications
OFF-LABEL USES	None
EXCLUSION CRITERIA	• For tirzepatide (Zepbound), liraglutide (Saxenda), and semaglutide (Wegovy): Concurrent use with another GLP-1 receptor agonist for any indication
REQUIRED MEDICAL INFORMATION	For initiation of therapy, Zepbound®, Wegovy®, Saxenda®, or Qsymia® may be covered if all the following criteria are met: a. Patient is less than 21 years of age b. Documentation of current height and weight (measured within the previous month) indicating BMI is in the 95th percentile or greater, standardized for age and sex Notes: If race is known, lower BMI thresholds (usually reduced by 2.5) are used for people from South Asian, Chinese, other Asian, Middle Eastern, Black African, African-Caribbean, Native Hawaiian, Pacific Islanders, or American Indians/Alaska Natives family backgrounds. If race is not known, standard BMI parameters will be applied. c. Documentation that the condition is of sufficient severity that it impacts the patient's health (such as quality of life, function, growth, development, ability to participate in school, perform activities of daily living, etc) For continuation of 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): a. Patient is less than 21 years of age, b. Patient achieved and maintained at least a 5% weight loss from baseline body weight while on the requested medication

2. **Ritlecitinib tosylate (Litfulo) Capsule**:

a. **Indication**: For treatment of severe alopecia areata in patients 12 years of age and older.

b. **Decision**:

	Commercial	Medicaid	Medicare
Formulary Status*	Non-formulary	Non-formulary	Part D: Non-formulary Part B: N/A
Tier**	N/A	N/A	N/A
Affordable Care Act Eligible	N/A; Non-Formulary	N/A	N/A
Utilization Management Edits	Prior Authorization	Prior Authorization	
Quantity Limit	1 capsule/day	1 capsule/day	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: N/A			

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

PA PROGRAM NAME	Therapeutic Immunomodulators
MEDICATION NAME	Litfulo
EXCLUSION CRITERIA	N/A
REQUIRED MEDICAL INFORMATION	1. For all requests, the patient must have an 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. The requested agent will not be given concurrently with another therapeutic immunomodulator agent 3. One of the following: a. For patients already *established* on the requested therapeutic immunomodulator: i. Documentation of response to therapy (such as slowing of disease progression or decrease in symptom severity and/or frequency). 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. b. Patients not established on the requested therapeutic immunomodulator must meet ALL the following indication-specific criteria i. For severe alopecia areata (AA), baricitinib (Olumiant®) or ritlecitinib (Litfulo®) may be covered **if the member's benefit covers treatment for hair loss or alopecia areata** and all the following criteria are met: 1. Confirmation of severe disease, defined as current episode of AA lasting more than six months with at least 50% scalp hair loss at baseline

	2. Other causes of hair loss have been ruled out (such as androgenetic alopecia) 3. For Medicaid, coverage for adults is unfunded. Coverage for children less than 21 years of age requires 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.)
AGE RESTRICTIONS	Age must be appropriate based on FDA-approved indication
PRESCRIBER RESTRICTIONS	Must be prescribed by, or in consultation with, a dermatologist
COVERAGE DURATION	Authorization and reauthorization will be approved for one year

3. **Tenapanor hcl (Xphozah) Tablet**:
   a. **Indication**: For treatment of high serum phosphorus in adults with chronic kidney disease (CKD) on dialysis as add-on therapy in patients who have an inadequate response to phosphate binders or who are intolerant of any dose of phosphate binder therapy.
   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	60 tablets/30 days	60 tablets/30 days	60 tablets/30 days
* Recommendations for placement may differ between lines of business due to regulatory requirements. ** Medications will be placed on recommended tier above for the base formulary; tier placement for custom formulary(ies) will be based on designation above. For example, Commercial Tier 6 designation above means that the medication will be placed on the highest cost-sharing tier on the respective formulary(ies).			
Formulary Alternatives: calcium acetate oral capsule, lanthanum oral tablet, sevelamer carbonate oral tablet, sevelamer carbonate oral powder, sevelamer HCL oral tablet, Renvela® oral tablet, Renvela® oral powder, Fosrenol® oral tablet, Fosrenol® oral powder, Auryxia® oral tablet, Velphoro® oral tablet			

   c. **Prior Authorization Criteria for Commercial/Medicaid/Medicare Part D:** N/A

4. **Eflornithine hcl (Iwilfin) Tablet**
   a. **Indication**: To reduce the risk of relapse in adult and pediatric patients with high-risk neuroblastoma (HRNB).
   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	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: N/A			

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

5. **Nirogacestat hydrobromide (Ogsiveo) Tablet**
a. **Indication**: For the treatment of adult patients with progressing desmoid tumors (DTs) who require systemic treatment.
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	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: N/A			

a. **Prior Authorization Criteria for Commercial/Medicaid**: Added to Oral Anti-Cancer Medications Policy
b. **Prior Authorization Criteria for Medicare Part D**: Added to the Anti-Cancer Agents Policy

6. **Cipaglucosidase alfa-atga (Pombiliti) Vial**

a. **Indication**: For the treatment of adult patients with late-onset Pompe disease (lysosomal acid alpha-glucosidase [GAA] deficiency) weighing ≥40 kg and who are not improving on their current enzyme replacement therapy (ERT).

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	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: Lumizyme, Nexviazyme			

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

PA PROGRAM NAME	Enzyme Replacement Therapy
MEDICATION NAME	cipaglucosidase alfa-atga vial (Pombiliti®)
PA INDICATION INDICATOR	1 - All FDA-Approved Indications
OFF-LABEL USES	None
EXCLUSION CRITERIA	N/A
REQUIRED MEDICAL INFORMATION	For initiation of therapy (new starts to therapy) all the following criteria must be met: 1. Documentation of FDA-labeled indication (See Appendix 1) for the requested product 2. Dosing is within FDA-labeled guidelines (See Appendix 1). 3. For cipaglucosidase alfa-atga vial (Pombiliti®) only, the following additional criteria must be met: a. Documentation of baseline percent-predicted forced vital capacity (FVC) of 30% or higher than the predicted value for healthy adults b. Documentation of baseline 6-minute walk test (6MWT) of 75 meters or greater Note: If request is for a non-FDA approved dose, medical rational must be submitted in support of therapy with a higher dose for the intended diagnosis such as high-quality peer reviewed literature, accepted compendia or evidence-based practice guidelines and exceptions will be considered on a case-by-case basis.

	For patients currently established on the requested therapy, all the following criteria must be met. Note: Medications obtained as samples, coupons, or any other method of obtaining medications outside of an established health plan benefit are NOT considered established on therapy. 1. Documentation of successful response to therapy (e.g., disease stability or improvement in symptoms). 2. Dosing is within FDA-labeled guidelines Note: If request is for a non-FDA approved dose, medical rational must be submitted in support of therapy with a higher dose for the intended diagnosis (such as high-quality peer reviewed literature, accepted compendia or evidence-based practice guidelines) and exceptions will be considered on a case-by-case basis. QUANTITY LIMIT: Initial dose approval will be based on patient's current weight (See Appendix 1). Increases in dose will require new authorization with patient's weight and relevant chart notes *Other drug's drug-specific criteria not included*

7. **Motixafortide acetate (Aphexda) Vial**
   a. **Indication**: Used in combination with filgrastim (G-CSF) to mobilize hematopoietic stem cells to the peripheral blood for collection and subsequent autologous transplantation in patients with multiple myeloma.
   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	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: plerixafor (Mozobil®)			

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

PA PROGRAM NAME	INJECTABLE ANTI-CANCER MEDICATIONS

MEDICATION NAME	APHEXDA SUBCUTANEOUS RECON SOLN 62 MG
PA INDICATION INDICATOR	1 - All FDA-Approved Indications
OFF-LABEL USES	None
EXCLUSION CRITERIA	None
REQUIRED MEDICAL INFORMATION	For initial authorization: 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 Aphexda: Dosing is within FDA-labeled guidelines
AGE RESTRICTIONS	N/A
PRESCRIBER RESTRICTIONS	Must be prescribed by, or in consultation with, an oncologist
COVERAGE DURATION	For Aphexda: Initial authorization will be approved for three months. No reauthorization; must meet initial authorization criteria.

8. **Bimekizumab-bkzx (Bimzelx) Auto Injct - Syringe**

a. **Indication**: For the treatment of adults with moderate to severe plaque psoriasis (PsO).

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	2 syringes (320mg) /56 days	2 syringes (320mg) /56 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: Adalimumab, Enbrel®, Cosentyx®, Stelara®, Tremfya®, Skyrizi®			

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

PA PROGRAM NAME	Therapeutic Immunomodulators
MEDICATION NAME	Bimekizumab (Bimzelx)
PA INDICATION INDICATOR	1 - All FDA-Approved Indications
OFF-LABEL USES	N/A

EXCLUSION CRITERIA	N/A
REQUIRED MEDICAL INFORMATION	1. For all requests, the patient must have an 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.) Exception: biosimilar products may be covered for all FDA-approved indications that the innovator product has been granted 2. The requested agent will not be given concurrently with another therapeutic immunomodulator agent 3. For patients already established on the requested therapeutic immunomodulator: a. Documentation of response to therapy (such as slowing of disease progression or decrease in symptom severity and/or frequency). 4. Patients not established on the requested therapeutic immunomodulator must meet ALL the following indication-specific criteria (note: if indication is not listed below, the requested drug may be cove red if it is an FDA approved indication for the requested drug): a. For moderate to severe plaque psoriasis, all the following criteria (i and ii) must be met: i. 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, tazarotene, topical corticosteroids, calcitriol, coal tar products, anthralin, calcipotriene, acitretin, cyclosporine, methoxsalen, tacrolimus, pimecrolimus, or phototherapy ii. Ixekizumab (Taltz®), brodalumab (Siliq®), and deucravacitinib (Sotyktu®) and bimekizumab (Bimzelx®) require documentation of trial and failure (after at least three months of therapy), intolerance, or contraindication to **three** of the following preferred agents: 1) preferred adalimumab product 2) apremilast (Otezla®) 3) etanercept (Enbrel®) 4) secukinumab (Cosentyx®) 5) ustekinumab (Stelara®) 6) gulselkumab (Tremfya®) 7) risankizumab-rzaa (Skyrizi®)

d. **Prior Authorization Criteria for Medicare Part D**: Added to Therapeutic Immunomodulators (TIMs) Policy - Medicaid

9. **Daprodustat (Jesduvroq) Tablet**

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

b. **Decision**:

	Commercial	Medicaid	Medicare

Formulary Status*	Formulary	Formulary	Part D: Non-formulary Part B: Medical
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	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: Aranesp, Epogen/Procrit/Retacrit/Mircera			

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

PA PROGRAM NAME	Jesduvroq®
MEDICATION NAME	Jesduvroq®
PA INDICATION INDICATOR	1 - All FDA-Approved Indications
OFF-LABEL USES	N/A
EXCLUSION CRITERIA	• Concomitant use of strong CYP2C8 inhibitors (such as gemfibrozil) • Patients with uncontrolled hypertension
REQUIRED MEDICAL INFORMATION	For initial authorization, all the following must be met: 1. Documentation of anemia due to chronic kidney disease (CKD) 2. Documentation that the patient has received dialysis for at least four months. 3. Adequate iron stores as indicated by current (within the last three months) serum ferritin level greater than or equal to 100 mcg/L or serum transferrin saturation greater than or equal to 20% 4. Documentation is patient is hyporesponsive to erythropoiesis-stimulating agent therapy after at least four (4) months of therapy For reauthorization, all the following must be met: 1. Documentation of anemia due to CKD 2. Documentation the patient has experienced a therapeutic response, defined by an increase in hemoglobin from baseline
AGE RESTRICTIONS	May be approved for patients aged 18 and older.
PRESCRIBER RESTRICTIONS	Must be prescribed by, or in consultation with, a nephrologist.
COVERAGE DURATION	Authorization will be approved for six months. Reauthorization will be approved for 12 months.

10. **Colchicine (Lodoco) Tablet**

a. **Indication**: To reduce the risk of myocardial infarction (MI), stroke, coronary revascularization, and cardiovascular death in adult patients with established atherosclerotic disease or with multiple risk factors for cardiovascular disease.

b. **Decision**:

	Commercial	Medicaid	Medicare
Formulary Status*	Formulary	Formulary	Part D: Formulary Part B: N/A
Tier**	Tier 4	N/A	Non-preferred Drug
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:			

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

PA PROGRAM NAME	Lodoco
MEDICATION NAME	Colchicine tablet
PA INDICATION INDICATOR	1 - All FDA-Approved Indications
EXCLUSION CRITERIA	• Concurrent use of strong CYP3A4 or P-glycoprotein inhibitors • Renal failure (CrCl less than 15 mL/min) • Severe hepatic impairment • Pre-existing blood dyscrasias
REQUIRED MEDICAL INFORMATION	For initial authorization, patient must meet all of the following criteria: 1. Diagnosis of clinical Atherosclerotic Cardiovascular Disease (ASCVD) or previous cardiovascular (CV) event 2. Documentation that patient is receiving maximally tolerated statin therapy or, if statin intolerant, other lipid-lowering therapy unless contraindicated or not tolerated 3. Documentation of blood pressure less than 130/80 or that patient is optimized on standard of care medications for high blood pressure unless contraindicated or not tolerated

	4. Documentation that patient is on aspirin therapy for secondary ASCVD prevention unless contraindicated or not tolerated
AGE RESTRICTIONS	N/A
PRESCRIBER RESTRICTIONS	Must be prescribed by, or in consultation with, a cardiologist
COVERAGE DURATION	Authorization will be approved until no longer eligible with the plan, subject to formulary and/or benefit changes

11. **Somatrogon-ghla (Ngenla) Pen Injctr**
    a. **Indication**: For treatment of pediatric patients aged 3 years and older who have growth failure due to inadequate secretion of endogenous growth hormone.
    b. **Decision**:

	Commercial	Medicaid	Medicare
Formulary Status*	Non-formulary	Non-formulary	Part D: Non-formulary Part B: N/A
Tier**	N/A	N/A	N/A
Affordable Care Act Eligible	N/A; Non-Formulary	N/A	N/A
Utilization Management Edits	Prior Authorization	Prior Authorization	N/A
Quantity Limit	N/A	N/A	N/A
* Recommendations for placement may differ between lines of business due to regulatory requirements. ** Medications will be placed on recommended tier above for the base formulary; tier placement for custom formulary(ies) will be based on designation above. For example, Commercial Tier 6 designation above means that the medication will be placed on the highest cost-sharing tier on the respective formulary(ies).			
Formulary Alternatives: Genotropin®, Norditropin®, Omnitrope®			

    c. **Prior Authorization Criteria for Commercial/Medicaid**: Added to Human Growth Hormones Policy

12. **Palovarotene (Sohonos) Capsule**
    a. **Indication**: To reduce the volume of new heterotopic ossification (HO) in adults and children aged 8 years and older for females and 10 years and older for males with fibrodysplasia ossificans progressiva (FOP).
    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	N/A	N/A	N/A
* Recommendations for placement may differ between lines of business due to regulatory requirements. ** Medications will be placed on recommended tier above for the base formulary; tier placement for custom formulary(ies) will be based on designation above. For example, Commercial Tier 6 designation above means that the medication will be placed on the highest cost-sharing tier on the respective formulary(ies).			
Formulary Alternatives: None			

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

PA PROGRAM NAME	Medications for rare indications
MEDICATION NAME	Palovarotene capsule (Sohonos®)
EXCLUSION CRITERIA	N/A
REQUIRED MEDICAL INFORMATION	For initial authorization, all the following must be met: 1. Confirmation of FDA-labeled indication (appropriate lab values and/or genetic tests must be submitted – (See Table 1 and Table 2) a. For Sohonos®: Diagnosis of fibrodysplasia ossificans progressiva with presence of a R206H *ACVR1* (activin A type 1 receptor) mutation confirmed by genetic testing 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 For reauthorization, all the following must be met: 1. Documentation of benefit of therapy as evidence by improvement in symptoms, disease stabilization or lack of decline compared to the natural disease progression a. For palovarotene (Sohonos®) only, documentation of one of the following must be met: i. Reduction in the volume of new heterotopic ossification as confirmed by radiographic assessment such as X-ray, computed tomography (CT), magnetic resonance imaging (MRI) ii. Reduction in the rate of flare-ups iii. Stabilization or improvement in one of the following: Cumulative Analogue Joint Involvement Scale (CAJIS), fibrodysplasia ossificans progressiva (FOP) – Physical Function Questionnaire (FOP-PFQ) 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

COVERAGE DURATION	For palovarotene (Sohonos®), initial authorization and reauthorization will be approved for one year. For all other medications, initial authorization will be approved for one year and reauthorization will be approved until no longer eligible with the plan, subject to formulary or benefit changes.

d. **Prior Authorization Criteria for Medicare Part D**: N/A

13. **Vonoprazan fumarate (Voquezna) Tablet**

a. **Indication**: For the treatment of Helicobacter pylori(HP) infection in adults.

b. **Decision**:

	Commercial	Medicaid	Medicare
Formulary Status*	Non-formulary	Non-formulary	Part D: Non-formulary Part B: N/A
Tier**	N/A	N/A	N/A
Affordable Care Act Eligible	N/A; Non-Formulary	N/A	N/A
Utilization Management Edits	N/A	N/A	N/A
Quantity Limit	For *H.pylori*: 1 pack/14 days	For *H.pylori*: 1 pack/14 days	For *H.pylori*: 1 pack/14 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: Erosive esophagitis: esomeprazole, lansoprazole, omeprazole, pantoprazole, rabeprazole H. Pylori: amoxicillin-clarithromycin-lansoprazole oral combo pack 500-500-30mg; Omeclamox-Pak oral combo pack 20-500-500mg; Talicia oral capsule 10-250-12.5mg; bismuth subcitrate-metronidazole-tetracycline oral capsule 140-125-125mg; Pylera oral capsule 140-125-125mg			

14. **Adamts13, recombinant-krhn (Adzynma) Kit**

a. **Indication**: For prophylactic or on demand treatment of adult and pediatric patients with congenital thrombotic thrombocytopenic purpura (cTTP).

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: N/A for pharmacy benefit; plasma based therapies for medial benefit			

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

PA PROGRAM NAME	Enzyme Replacement Therapy
MEDICATION NAME	ADAMTS13, recombinant-krhn (Adzynma®)
PRESCRIBER RESTRICTIONS	Must be prescribed by or in consultation with a Hepatologist, Endocrinologist, Medical Geneticist, Cardiologist, Pulmonologist, Hematologist, Oncologist or Bone and Mineral specialist

15. **Efgartigimod alfa-hyaluronidase-qvfc (Vyvgart Hytrulo) Vial**

a. **Indication**: For the treatment of generalized myasthenia gravis (gMG) in adult patients who are anti-acetylcholine receptor (AChR) antibody positive.

b. **Decision**:

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

c. **Prior Authorization Criteria for Commercial/Medicaid/Medicare Part B**: Added to the FcRn Antagonists Policies

New Indications:

Therapies with Prior Authorization Policies (Non-oncology)

1. **Cresemba** (isavuconazonium)
    a. Previous Indication(s):
        a. Treatment of
            1. Invasive aspergillosis
            2. Mucormycosis
    b. New indication approved 12/08/2023:
        a. Treatment of invasive aspergillosis and mucormycosis:
            1. Injection: adults and pediatric patients 1 year of age and older
            2. Capsule: adults and pediatric patients 6 years of age and older who weigh 16 kilograms and greater
    c. **RECOMMENDATION:** Inform prescribers via Medical Policy Alert. Update policy with new indication.

2. **Adbry** (tralokinumab)
    a. Previous Indication(s):
        a. For the treatment of moderate-to-severe atopic dermatitis in adult patients whose disease is not adequately controlled with topical prescription therapies or when those therapies are not advisable
    b. New indication approved 12/14/2023:
        a. For the treatment of moderate-to-severe atopic dermatitis in patients aged **12 years and older** whose disease is not adequately controlled with topical prescription therapies or when those therapies are not advisable
    c. **RECOMMENDATION:** Inform prescribers via Medical Policy Alert. Update policy with new indication and age restriction.

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

PA PROGRAM NAME	Adbry
MEDICATION NAME	Adbry
PA INDICATION INDICATOR	1 - All FDA-Approved Indications
AGE RESTRICTIONS	The patient's age must be within FDA labeling for the requested indication

3. **Zoryve Foam** (roflumilast)
    a. Previous Indication(s):
        a. N/A
    b. New indication approved 12/15/2023:
        a. Treatment of seborrheic dermatitis in adult and pediatric patients 9 years of age and older
    c. **RECOMMENDATION:** Inform prescribers via Medical Policy Alert. Update policy with new indication and age restriction.

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

PA PROGRAM NAME	Vtama, Zoryve
PA INDICATION INDICATOR	1 - All FDA-Approved Indications
AGE RESTRICTIONS	Zoryve® Foam - Approved for patients 9 years and older
REQUIRED MEDICAL INFORMATION	For Commercial initial authorization: A. Plaque psoriasis: Vtama cream or Zoryve cream may be covered when the following criteria are met: 1. Inadequate response to a sufficient trial (defined as two weeks or more of consistent use) of at least one of the following combinations: a) A high to ultra-high potency topical corticosteroid (such as betamethasone dipropionate 0.05% cream or ointment, triamcinolone 0.5%, clobetasol 0.05%) used concurrently with a generic topical calcipotriene product, OR b) A generic calcipotriene/betamethasone combination product, OR c) A high to ultra-high potency topical corticosteroid (such as betamethasone dipropionate 0.05% cream or ointment, triamcinolone 0.5%, clobetasol 0.05%) used concurrently with a generic tazarotene 0.1% cream B. Seborrheic dermatitis: Zoryve foam may be covered when the following criteria are met: 1. Inadequate response to a sufficient trial (defined as two weeks or more of consistent use) of at least one of the following combinations: a) Topical antifungal (such as ketoconazole 2%, econazole 1%, oxiconazole 1%, or ciclopirox 0.77%) used concurrently with a high-potency topical corticosteroid (moderate to severe scalp condition) or low-potency topical corticosteroid (non-scalp/face condition), OR b) Topical antifungal (such as ketoconazole 2%, econazole 1%, oxiconazole 1%, or ciclopirox 0.77%) used concurrently with a topical calcineurin inhibitor (such as tacrolimus 0.1%)

4. **Tarpeyo** (budesonide)
    a. Previous Indication(s):
        a. Reduce proteinuria in adults with primary immunoglobulin A nephropathy (IgAN) at risk of rapid disease progression, generally a urine protein-to-creatinine ratio (UPCR) greater than or equal to 1.5 g/g
    b. New indication approved 12/20/2023:
        a. Reduce the loss of kidney function 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. Policy under review for April P&T.

5. **Yuflyma** (adalimumab-AATY)
    a. Previous Indication(s):
        a. Rheumatoid Arthritis
        b. Juvenile Idiopathic Arthritis
        c. Psoriatic Arthritis
        d. Ankylosing Spondylitis

e. Crohn's Disease
f. Ulcerative Colitis
g. Plaque Psoriasis
h. Hidradenitis Suppurativa

b. New indication approved 12/22/2023:
    a. Uveitis
c. **RECOMMENDATION:** Inform prescribers via Medical Policy Alert. Update policy with new indication.

6. **Dupixent** (dupilumab)
    a. Previous Indication(s):
        a. Eosinophilic Esophagitis
            1. For the treatment of adult and pediatric patients aged 12 years and older, weighing at least 40 kg, with eosinophilic esophagitis (EoE)
    b. New indication approved 1/25/2024:
        a. Eosinophilic Esophagitis
            1. For the treatment of adult and pediatric patients aged **1 year and older**, weighing at least **15 kg**, with eosinophilic esophagitis (EoE)
    c. **RECOMMENDATION:** Inform prescribers via Medical Policy Alert. Update policy with new indication.

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

PA PROGRAM NAME	Dupixent
MEDICATION NAME	Dupixent
PA INDICATION INDICATOR	1 - All FDA-Approved Indications
REQUIRED MEDICAL INFORMATION	For Eosinophilic Esophagitis (EoE), all the following must be met for initial authorization: 1. Diagnosis of eosinophilic esophagitis, defined as all of the following: a) Eosinophil-predominant inflammation on esophageal biopsy with greater than or equal to 15 eosinophils per high power field (HPF) b) Symptoms of esophageal dysfunction such as dysphagia, chest pain, stomach pain, heartburn, regurgitation, and vomiting 2. Patient weighs at least 15 kg 3. Patient had an inadequate response to one of the following therapies, or has an intolerance/contraindication to all of the following therapies: a) Eight weeks of a proton pump inhibitor b) Eight weeks of a topical glucocorticoid (e.g., fluticasone inhaler, swallowed budesonide)

7. **Vabysmo** (faricimab-svoa)
    a. Previous Indication(s):
        a. Neovascular (Wet) Age-Related Macular Degeneration (nAMD)
        b. Diabetic Macular Edema (DME)

b. New indication approved 10/26/2023:
    a. Macular Edema Following Retinal Vein Occlusion (RVO)
c. **RECOMMENDATION:** Inform prescribers via Medical Policy Alert. Update policy with new indication.

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

PA PROGRAM NAME	Ophthalmic Vascular Endothelial Growth Factor (VEGF) Inhibitors
MEDICATION NAME	Vabysmo
PA INDICATION INDICATOR	1 - All FDA-Approved Indications
REQUIRED MEDICAL INFORMATION	**Macular edema following retinal vein occlusion:** a. For ranibizumab (Lucentis®) and faricimab (Vabysmo®): Documentation that ALL of the following agents have been ineffective, not tolerated, or contraindicated or rationale is provided why therapy is not appropriate for the patient: i. bevacizumab ii. aflibercept (Eylea®) iii. ranibizumab-nuna (Byooviz®) or ranibizumab-eqrn (Cimerli®)

Therapies with Prior Authorization Policies (Oncology)

1. **Welireg** (belzutifan)
    a. New indication(s) approved 12/14/2023:
        i. Von Hippel-Lindau (VHL) disease:
            - Treatment of adult patients with von Hippel-Lindau (VHL) disease who require therapy for associated renal cell carcinoma (RCC), central nervous system (CNS) hemangioblastomas, or pancreatic neuroendocrine tumors (pNET), not requiring immediate surgery
        ii. Advanced Renal Cell Carcinoma:
            - Treatment of adult patients with advanced renal cell carcinoma (RCC) following a programmed death receptor-1 (PD-1) or programmed death-ligand 1 (PD-L1) inhibitor and a vascular endothelial growth factor tyrosine kinase inhibitor (VEGF-TKI)
    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. **Keytruda** (dabrafenib)
    a. New indication(s) approved 12/15/2023, 1/12/2024, 1/25/2023:
        i. Urothelial Cancer:
            - In combination with enfortumab vedotin, for the treatment of adult patients with locally advanced or metastatic urothelial cancer
        ii. Cervical Cancer:
            - In combination with chemoradiotherapy, for the treatment of patients with FIGO 2014 Stage III-IVA cervical cancer

iii. Adult Classical Hodgkin Lymphoma and Adult Primary Mediastinal Large B-Cell Lymphoma: Additional Dosing Regimen of 400 mg Every 6 Weeks:
- MSI-H or dMMR Endometrial Carcinoma: 200 mg every 3 weeks or 400 mg every 6 weeks

iv. Hepatocellular Carcinoma:
- For the treatment of patients with HCC secondary to hepatitis B who have received prior systemic therapy other than a PD1/PD-L1-containing regimen

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. **Padcev** (enfortumab)
   a. New indication(s) approved 12/15/2023:
      i. In combination with pembrolizumab for the treatment of adult patients with locally advanced or metastatic urothelial 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.

4. **Piquay** (alpelisib)
   a. New indication(s) approved 1/18/2024:
      i. In combination with fulvestrant for the treatment of adults with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative, PIK3CA-mutated, advanced or metastatic breast cancer as detected by an FDA-approved test following progression on or after an endocrine-based regimen
   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. **Balversa** (erdafitinib)
   a. New indication(s) approved 1/19/2024:
      i. Treatment of adult patients with locally advanced or metastatic urothelial carcinoma (mUC) with susceptible FGFR3 genetic alterations whose disease has progressed on or after at least one line of prior systemic therapy
   b. **RECOMMENDATION:** Inform prescribers via Medical Policy Alert. Prior authorization policy coverage criteria are based on recommendations from the National Comprehensive Cancer Network (NCCN); no updates to the policy are warranted.

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

1. **Zynrelef** (bupivacaine/meloxicam)
   a. Previous Indication(s):
      i. Indicated in adults for soft tissue or periarticular instillation to produce postsurgical analgesia for up to 72 hours after foot and ankle, small-to-medium open abdominal, and lower extremity total joint arthroplasty surgical procedures
   b. New indication approved 1/23/2024:
      i. Indicated in adults for postsurgical analgesia for up to 72 hours after:

1. Soft tissue surgical procedures
2. Orthopedic surgical procedures
    a. Foot and ankle procedures
    b. Other orthopedical surgical procedures (e.g., total joint arthroplasty) in which direct exposure to articular cartilage is avoided

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

2. **Avycaz** (avibactam sodium; ceftazidime)
    a. Previous Indication(s):
        i. Indicated for the treatment of the following infections caused by designated susceptible Gram-negative microorganisms in adult and pediatric patients aged 3 months and older:
            1. Complicated Intra-abdominal Infections (cIAI), used in combination with metronidazole
            2. Complicated Urinary Tract Infections (cUTI), including Pyelonephritis
            3. Hospital-acquired Bacterial Pneumonia and Ventilator-associated Bacterial Pneumonia (HABP/VABP)
    b. New indication approved 1/26/2024:
        i. Indicated for the treatment of the following infections caused by designated susceptible Gram-negative microorganisms in adult and pediatric patients (at least **31 weeks gestational age**):
            1. Complicated Intra-abdominal Infections (cIAI), used in combination with metronidazole
            2. Complicated Urinary Tract Infections (cUTI), including Pyelonephritis
            3. Hospital-acquired Bacterial Pneumonia and Ventilator-associated Bacterial Pneumonia (HABP/VABP)
    c. **RECOMMENDATION:** Inform prescribers via Medical Policy Alert.

Drug Safety Monitoring:

FDA Drug Safety Communications

1. Drug Name: All FDA-Approved GLP-1 RAs

- **Date Posted: 1/11/2024**
- **Safety Alert Title: Update on FDA's ongoing evaluation of reports of suicidal thoughts or actions in patients taking a certain type of medicines approved for type 2 diabetes and obesity**
- **Link to more information:** https://www.fda.gov/drugs/drug-safety-and-availability/update-fdas-ongoing-evaluation-reports-suicidal-thoughts-or-actions-patients-taking-certain-type
- **What safety concern is FDA announcing?**
    - The U.S. Food and Drug Administration (FDA) has been evaluating reports of suicidal thoughts or actions in patients treated with a class of medicines called glucagon-like peptide-1 receptor agonists (GLP-1 RAs; see the list in Table 1 below). These medicines are used to treat people with type 2 diabetes or to help those with obesity or overweight to lose weight. FDA's preliminary evaluation has not found evidence that use of these medicines causes suicidal thoughts or actions.
- **What is FDA doing?**

- FDA has conducted detailed reviews of reports of suicidal thoughts or actions received in the FDA Adverse Event Reporting System (FAERS). Because the information provided was often limited and because these events can be influenced by other potential factors, FDA determined that the information in these reports did not demonstrate a clear relationship with the use of GLP-1 RAs. Similarly, FDA's review of the clinical trials, including large outcome studies and observational studies, did not find an association between use of GLP-1 RAs and the occurrence of suicidal thoughts or actions. However, because of the small number of suicidal thoughts or actions observed in both people using GLP-1 RAs and in the comparative control groups, FDA cannot definitively rule out that a small risk may exist; therefore, the FDA is continuing to look into this issue. Additional evaluations include a meta-analysis of clinical trials across all GLP-1 RA products and an analysis of post marketing data in the Sentinel System External Link Disclaimer. A meta-analysis is a large, combined analysis of findings from clinical trials. Sentinel is a very large data network that contains health insurance claims and patient health records that can be used to investigate safety questions about FDA-regulated products. FDA will communicate the final conclusions and recommendations after a complete review or have more information to share.

- **What should health care professionals do?**
  - Health care professionals should monitor for and advise patients using GLP-1 RAs to report new or worsening depression, suicidal thoughts, or any unusual changes in mood or behavior.
  - Health care professionals should consult the prescribing information when treating patients with these medications.
- **Health Plan Recommendation:** Notify providers via Medical Policy Alert

2. **Drug Name: Denosumab (Prolia)**
   - **Date Posted: 1/19/2024**
   - **Safety Alert Title: FDA adds Boxed Warning for increased risk of severe hypocalcemia in patients with advanced chronic kidney disease taking osteoporosis medicine Prolia (denosumab)**
   - **Link to more information:** https://www.fda.gov/drugs/drug-safety-and-availability/fda-adds-boxed-warning-increased-risk-severe-hypocalcemia-patients-advanced-chronic-kidney-disease
   - **What safety concern is FDA announcing?**
     - Based on a completed U.S. Food and Drug Administration (FDA) review of available information, FDA has concluded that the osteoporosis medicine Prolia (denosumab) increases the risk of severe hypocalcemia, very low blood calcium levels, in patients with advanced chronic kidney disease (CKD), particularly patients on dialysis. Severe hypocalcemia appears to be more common in patients with CKD who also have a condition known as mineral and bone disorder (CKD-MBD). In patients with advanced CKD taking Prolia, severe hypocalcemia resulted in serious harm, including hospitalization, life-threatening events, and death. As a result, the FDA is revising the Prolia prescribing information to include a new Boxed Warning, FDA's most prominent warning, communicating this increased risk. Severe hypocalcemia can be asymptomatic or may present with symptoms that include confusion; seizures; irregular heart rhythm; fainting; face twitching; uncontrolled muscle spasms; or weakness, tingling, or numbness in parts of the body.
   - **What is FDA doing?**
     - FDA is adding a Boxed Warning to the Prolia prescribing information about the significant risk of developing severe hypocalcemia in patients with advanced CKD. This warning abend new labeling contains information to help reduce this risk, including appropriate patient selection for Prolia treatment, increased monitoring of blood calcium levels, and other strategies. This updated information is also being added to the patient Medication Guide and the Prolia Risk Evaluation and Mitigation Strategy (REMS), a drug safety program required by FDA to help ensure that Prolia's benefits outweigh its risks.

- **What should health care professionals do?**
  - It is important that the appropriateness of Prolia treatment in patients with advanced CKD be determined by a health care professional with expertise in the diagnosis and management of CKD-MBD including renal osteodystrophy, a complication that weakens bone. Treating bone disease in patients with advanced and dialysis-dependent CKD is challenging because of the difficulty in diagnosing and confirming the underlying altered bone metabolism responsible for the low bone mass and increased fracture risk, and the complex benefit-risk considerations of approved osteoporosis treatments in this population.
  - Before prescribing Prolia, health care professionals should assess their patients' kidney function. For patients with advanced CKD, particularly those on dialysis, health care professionals should consider the risk of severe hypocalcemia with Prolia in the context of other available treatments for osteoporosis. If Prolia is still being considered for these patients, for initial or continued use, check their calcium blood levels and assess them for evidence of CKD-MBD. Treatment with Prolia in patients with advanced CKD, including those on dialysis, and particularly patients with diagnosed CKD-MBD should involve a health care provider with expertise in the diagnosis and management of CKD-MBD. Proper management of CKD-MBD, correction of hypocalcemia, and supplementation with calcium and activated vitamin D prior to Prolia treatment is expected to decrease the risk of developing severe hypocalcemia and any associated complications. Following Prolia administration, close monitoring of blood calcium levels and prompt management of hypocalcemia is essential to prevent complications such as seizures or arrhythmias. Advise patients to promptly report symptoms that could be consistent with hypocalcemia.
- **Health Plan Recommendation:** Notify providers via Medical Policy Alert

Drug Recalls/Market Withdrawals

1. **Drug Name:** Vigabatrin for Oral Solution, USP 500 mg
   - **Date of Recall:** 12/18/2023
   - **Reason for recall:** Due to seal integrity issues allowing for powder leakage from the pouch.
   - **Link to more information:** https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/invagen-pharmaceuticals-issues-voluntary-nationwide-recall-vigabatrin-oral-solution-usp-500mg-due
   - **Health Plan Recommendation:** Notify providers via Medical Policy Alert

2. **Drug Name:** Bleomycin for Injection, USP 15 Units Single Dose ONCO-TAIN™ Glass Fliptop Vial
   - **Date of Recall:** 12/22/2023
   - **Reason for recall:** Presence of Glass Particulate Matter
   - **Link to more information:** https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/hospira-inc-issues-voluntary-nationwide-recall-one-lot-bleomycin-injection-usp-15-units-single-dose
   - **Health Plan Recommendation:** Notify providers via Medical Policy Alert

3. **Drug Name:** Americaine® 20% Benzocaine Topical Anesthetic Spray
   - **Date of Recall:** 12/22/2023
   - **Reason for recall:** Presence of benzene

- **Link to more information:** https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/insight-pharmaceuticals-issues-voluntary-nationwide-recall-americainer-20-benzocaine-topical
- **Health Plan Recommendation:** Notify providers via Medical Policy Alert

4. **Drug Name:** 4.2% Sodium bicarbonate injection, 8.4% Sodium bicarbonate injection, Atropine sulfate injection
   - **Date of Recall:** 12/26/2023
   - **Reason for recall:** Presence of Glass Particulate Matter
   - **Link to more information:** https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/hospira-inc-issues-voluntary-nationwide-recall-42-sodium-bicarbonate-injection-84-sodium-bicarbonate
   - **Health Plan Recommendation:** Notify providers via Medical Policy Alert

5. **Drug Name:** Vancomycin IV Bags, Phenylephrine IV Bags, and Fentanyl IV Bags
   - **Date of Recall:** 1/08/2024
   - **Reason for recall:** Potential for super potent drug
   - **Link to more information:** https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/leiters-health-issues-voluntary-nationwide-recall-vancomycin-iv-bags-phenylephrine-iv-bags-and
   - **Health Plan Recommendation:** Notify providers via Medical Policy Alert

6. **Drug Name:** Lubricant Gel Drops 15mL, Lubricant Eye Drops 15mL (Twin Pack)
   - **Date of Recall:** 1/22/2024
   - **Reason for recall:** Device & Drug Safety Potential Safety Concerns
   - **Link to more information:** https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/kilitch-healthcare-india-limited-issues-amendments-last-voluntary-nationwide-recall-press-release
   - **Health Plan Recommendation:** Notify providers via Medical Policy Alert

7. **Drug Name:** Robitussin Honey CF Max Day Adult 4oz, Robitussin Honey CF Max Day Adult 8oz, Robitussin Honey CF Max NT Adult 8oz
   - **Date of Recall:** 1/24/2024
   - **Reason for recall:** Microbial Contamination
   - **Link to more information:** https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/haleon-issues-voluntary-nationwide-recall-robitussin-honey-cf-max-day-adult-and-robitussin-honey-cf
   - **Health Plan Recommendation:** Notify providers via Medical Policy Alert

8. **Drug Name:** Zenzedi® (dextroamphetamine sulfate tablets, USP) 30 mg
   - **Date of Recall:** 1/25/2024
   - **Reason for recall:** Mislabeled package

- **Link to more information:** https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/azurity-pharmaceuticals-inc-issues-voluntary-nationwide-recall-zenzedir-dextroamphetamine-sulfate
- **Health Plan Recommendation:** Notify providers via Medical Policy Alert

9. **Drug Name:** Neptune's Fix Elixir, Neptune's Fix Extra Strength Elixir, and Neptune's Fix Tablets
    - **Date of Recall:** 11/15/2023
    - **Reason for recall:** Undeclared Tianeptine
    - **Link to more information:** https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/neptune-resources-llc-issues-voluntary-nationwide-recall-neptunes-fix
    - **Health Plan Recommendation:** Notify providers via Medical Policy Alert

Other Formulary Changes:

OTHER FORMULARY CHANGES		
Drug Name	**Action Taken**	**Policy Name**
Ropeginterferon alfa-2b-njft (Besremi) Syringe	Add to Commercial Formulary, Tier 6, Prior Authorization	Anti-Cancer Medications - Self-Administered
Leuprolide acetate (Eligard) Disp Syringe	Remove from Commercial, Medicaid, and Medicare Part D formularies, as requires healthcare professional administration (changed to medical benefit coverage) Effective date: 07/01/2024	Gonadotropin Releasing Hormone Agonists
Metoprolol Tartrate 37.5 mg and 75 mg Tablet	• Commercial Standard: Change from Tier 2 to Tier 1 • Medicare Part D: Add to Formulary, Tier 1 Effective date: 05/01/2024	N/A
Adapalene/benzoyl peroxide/clindamycin phosphate (Cabtreo) Gel	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
Oxaprozin (Coxanto) Capsule	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
Dapagliflozin Propanediol (Farxiga) Tablet	Add generic to Medicaid formulary; Remove brand	N/A
Sotagliflozin (Inpefa)	Remove from Medicaid formulary	N/A
• **Canagliflozin (Invokana) Tablet**	• Commercial: Remove from formulary	N/A

• **Canagliflozin/metformin hcl (Invokamet) Tablet** • **Canagliflozin/metformin hcl (Invokamet XR) Tablet PB 24h**	• Medicaid: Add to formulary (preferred on Preferred Drug List from Oregon Health Authority)	
Cyclosporine (Veyve) 0.1% drops	New Strength Non-formulary for all lines of business	N/A

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

INFORMATIONAL ONLY

NEW DRUGS / COMBINATIONS / STRENGTHS / DOSAGE FORMS		
Drug Name	**Action Taken**	**Policy Name**
Bosutinib (Bosulif) Capsule	New dosage form (capsule) and strength. Line extend with Bosulif tablets; • Commercial: Formulary, Tier 6, Prior Authorization • Medicaid: Formulary, Prior Authorization • Medicare Part D: Formulary, Tier 5, Prior Authorization	Anti-Cancer Medications - Self-Administered
Emicizumab-kxwh (Hemlibra) Vial	New strength (300mg/2ml). Line extend with existing Hemlibra; • Commercial/Medicaid: Medical Benefit, Prior Authorization, Specialty • Medicare Part D: Non-Formulary • Medicare Part B: Medical Benefit, Prior Authorization	Hemlibra
Omalizumab (Xolair) Auto Injct / Syringe	New formulation. Line extend with existing Xolair; • Commercial: Formulary, Tier 5, Prior Authorization • Medicaid: Formulary, Prior Authorization • Medicare Part D: Formulary, Tier 5, Prior Authorization	Xolair / Self-Administered Drugs (SADs)

NEW GENERICS		
Drug Name	**Action Taken**	**Policy Name**
Bromfenac sodium Drops	First generic (Prolensa). Line extend as generic; • Commercial Standard: Formulary, Tier 2 • Commercial Dynamic: Formulary, Tier 4 • Medicaid: Non-Formulary • Medicare Part D: Formulary, Tier 3	N/A
Valsartan Solution	First generic. Line extend as generic; • Non-Formulary for all line of business	N/A
Cefazolin sodium Vial	First generic drug. Line extend as generic; • Medical benefit for all lines of business	N/A
Dabigatran etexilate 110 mg Capsule	First generic drug. Line extend as generic; • Commercial Standard: Formulary, Tier 2 • Commercial Dynamic: Formulary, Tier 3 • Medicaid: Formulary • Medicare Part D: Formulary, Tier 4	N/A
Loteprednol etabonate Drops Susp	First generic drug (Alrex). Line extend as generic; • Commercial Standard: Formulary, Tier 2 • Commercial Dynamic: Formulary, Tier 4 • Medicaid: Non-Formulary • Medicare Part D: Formulary, Tier 3	N/A
Deflazacort Tablet	First generic drug (Emflaza). Line extend as generic; • Commercial/Medicaid: Non-Formulary, Prior Authorization, Quantity Limit (2 tablets per day) • Medicare Part D: Non-Formulary, Prior Authorization, Quantity Limit (2 tablets per day)	Emflaza
Mifepristone Tablet	First generic drug (Korlym). Line extend as generic; • Commercial/Medicaid: Non-Formulary, Prior Authorization • Medicare Part D: Formulary, Tier 5	Korlym
Gabapentin (Gabapentin ER) Tab ER 24h	First generic drug (Gralise). Line extend with generic; • Commercial/Medicaid: Non-Formulary, Prior Authorization • Medicaid Part D: Non-Formulary	• Commercial/Medicaid: New Medications and Formulations without Established Benefit • Medicare Part D: N/A

Clinical Policy Changes:

MAJOR CHANGES	
Policy Name	**Summary of Change**
Disposable Insulin Pumps	Increased quantity limit on insulin pods
Egrifta	Policy criteria has been updated to allow auto-processing at point of sale (PO) if diagnoses listed on the policy are submitted on the claim.
• **Enzyme Replacement Therapy** • **Enzyme Replacement Therapy Prior Authorization and Step Therapy Policy – Medicare Part B**	New drug Adzynma for congenital thrombotic thrombocytopenic purpura added to policy. Updated prescriber restrictions to include hematologist and oncologist.
GLP-1/GIP Receptor Agonists	Adlyxin® was removed from the policy as this medication is no longer available on the market.
• **Hepatitis C - Direct Acting Antivirals** • **Hepatitis C - Direct Acting Antivirals - Medicaid**	Updated to allow coverage for patients receiving a donor solid organ from a donor infected with the hepatitis C virus.
Hormone Replacement Therapy Prior Authorization and Step Therapy Policy – Medicare Part B	Clarified that elevated luteinizing hormone (LH)/follicle-stimulating hormone (FSH) is indicative of primary hypogonadism, but low LH/FSH requires further assessment of chronic conditions.
• **Human Growth Hormones** • **Human Growth Hormones - Medicaid**	Updated quantity limit language to be based on FDA labeling for all uses. Removed obsolete drugs Saizen® and Zorbtive® and all references to Short Bowel Syndrome.
• **Medical Nutrition – Commercial** • **Medical Nutrition – Medicaid**	Clarified medical food coverage and definition of inborn errors of metabolism.
Non-Preferred Insulins	Policy was updated to only include Apidra®, as this is the only non-preferred insulin on the formulary. All other non-preferred insulins are non-formulary and will be reviewed according to the formulary exception policy.
Osteoanabolic Agents	Simplified medical necessity criteria. Removed prescriber restrictions and the exclusion for history of myocardial infarction/stroke.
Osteoanabolic Agents Prior Authorization and Step Therapy Policy - Medicare Part B	Simplified medical necessity criteria. Removed prescriber restrictions and the exclusion for history of myocardial infarction/stroke.
• **Oxlumo** • **Oxlumo Prior Authorization and Step Therapy Policy – Medicare Part B**	Removed exclusion of estimated glomerular filtration rate less than 30 due to FDA labeling updates.
Palynziq	Increased reauthorization coverage duration to until no longer eligible with the plan.
Pituitary Disorder Therapies	Endocrine specialist consulted regarding Cushing's Syndrome criteria: 1. Removed criteria requiring baseline liver tests as no further evaluation of enzyme labs are required in prior authorization review. The safety warnings regarding monitoring of hepatic function are outlined in the package insert, will leave to providers to assess.

	2. Removed criteria regarding documentation of baseline urinary free cortisol as policy already requires documentation of a diagnosis of Cushing's syndrome.
Revcovi	Increased initial and reauthorization coverage duration to one year.
Tarpeyo	FDA label changed and this therapy is now approved for all adults with primary immunoglobulin A nephropathy (IgAN) who are at risk for disease progression [not just those at risk of rapid progression (urine protein creatinine ratio > 1.5 g/g)]. Updated criteria to allow for urine protein creatinine ratio ≥0.8 g/g or proteinuria ≥1 g/day to align with study inclusion criteria. Clarified timeframe of three months that individual must be on ACE-i/ARB therapy.
• **Tepezza** • **Tepezza Prior Authorization and Step Therapy Policy - Medicare Part B**	Removed exclusion for sight-threatening disease and updated thyroid requirement to include free thyroid levels.
Tolvaptan	Simplified criteria for autosomal dominant polycystic kidney disease (ADPKD) to allow for provider attestation of diagnosis and whether the patient is experiencing rapidly progressive disease.
Vijoice	Simplified reauthorization criteria and increased coverage duration from six months to one year, clarified where supporting documentation is required, clarified that prescriber restrictions apply to initial and reauthorization.

RETIRED	
Imcivree	Added to Medications for Rare Indications' policy
Kuvan	Due to generic availability and low risk of overutilization
• **SGLT-2 Inhibitors - Commercial** • **SGLT-2 Inhibitors - Medicaid**	1. Preferred products are covered without prior authorization. 2. Non-preferred products will be non-formulary and formulary exception criteria will apply.