Providence Health Plan

Providence Health Assurance

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

Number 119

June 1, 2026

This is the June 1, 2026 issue of the Providence Health Plans, Providence Health Assurance and Providence Plan Partners, Policy Alert to our providers. The focus of this update is to communicate to providers' new or revised Medical, Pharmacy, Reimbursement, and Coding policy changes. The Health Plan has a standard process to review all policies annually. Policies will be available for review on ProvLink and via the PHP website at: https://healthplans.providence.org/providers/provider-support/medical-policy-pharmacy-policy-and-provider-information/

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

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

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

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

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

Providence Health Plan

Providence Health Assurance

# MEDICAL POLICY COMMITTEE

## MEDICAL

### COMPANY POLICIES

*Effective 7/1/2026*

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|---|---|
| **Whole Exome, Whole Genome, and Proteogenomic Sequencing and Genetic Testing for Mitochondrial Disorders**<br><br>**MP219** | **Policy Updates:**<br>• Permit reanalysis of WES when new gene-disease associations emerge or phenotype evolves.<br>• Extend coverage to young adults (18–21) with childhood-onset CA/DD/ID, when genetic evaluation was initiated but not completed prior to age 18.<br>• Cover WGS in pediatric patients when specific criteria are met.<br>**Codes/PA:** Added PA to WGS codes, currently configured to deny as "not medically necessary." |
| **Tumor Antigen Assays**<br><br>**MP414** | **Policy Updates:** No changes.<br>**Codes/PA:** Added several eligible dx codes per updates to relevant NCDs. |
| **Alpha-Fetoprotein**<br><br>**MP406** | **Policy Updates:** No changes. Added contraindication statement.<br>**Codes/PA:** Added two eligible dx codes per updates to relevant NCD. |
| **Human Chorionic Gonadotropin**<br><br>**MP410** | **Policy Updates:** No recommended changes<br>**Codes/PA:** Updated pay to pair configuration based on Medicare guidelines |

*Effective 8/1/2026*

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|---|---|
| **Bacterial Urine Cultures (Company)**<br><br>**MP408** | **Policy Updates:** No recommended changes to criteria.<br>**Codes/PA:** Added new ICD codes to deny on the pair-to-deny list associated with the CPT codes on the policy. |
| **Prothrombin Time (PT) (Company)**<br><br>**MP412** | **Policy Updates:** No recommended changes to criteria.<br>**Codes/PA:** Added new ICD codes to pay on the pair-to-pay list associated with the CPT codes on the policy. |
| **Knee Arthroscopy and Open Procedures**<br><br>**MP434** | **Policy Updates:**<br>• Added criterion II. - knee arthroscopy for acute and traumatic meniscal tears, per feedback from SME and comparable payer language.<br>• Updated criterion XIII.C – "instability" vs "symptoms."<br>• Removed criterion XVIII. (joint lavage).<br>**Codes/PA:** Removed PA from CPT 297811 (joint lavage) |
| **Spinal Fusion and Decompression**<br><br>**MP10** | **Policy Updates:** Criterion IV: added requirement of physical and neurological exam<br>**Codes/PA:** No changes to codes or PA |

## REIMBURSEMENT POLICIES

*Effective 8/1/26*

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|---|---|
| **Reimbursement Policy 10**<br><br>**High Dollar Drug Review** | Effective 8/1/2026 the High Dollar Drug Review Reimbursement Policy will include an addition of 3 pharmaceutical revenue codes for High Dollar Drug Reviews:<br>▪ 0343 - Diagnostic radiopharmaceuticals |

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|---|---|
| | ▪ 0891- Special Processed Drugs - Cell Therapy<br>▪ 0892 - Special Processed Drugs - Gene Therapy |

## VENDOR UPDATES

*Effective 5/4/26*

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|---|---|
| **EviCore – Physical Occupational Therapy** | Interim Update<br>• Overall changes are editorial and clarifying, with no substantive changes to coverage intent, medical necessity standards, or authorization outcomes.<br>• Language was refined to better distinguish that the policy governs visit authorization, not specific therapy techniques or treatment plans.<br>• Definitions were clarified and expanded (e.g., caregiver, skilled care, severity, complexities) to improve consistency and reduce ambiguity in review.<br>• Medical necessity and dosage guidance was clarified to better reflect consideration of severity, post-procedural status, and evidence-based practice without introducing new thresholds.<br>• Explicit acknowledgement of health equity and social determinants of health was added as contextual considerations in review.<br>• Minor updates were made to determination and appeals language to improve transparency and member/provider understanding.<br>• Condition-specific sections were updated with light editorial changes and evidence alignment, without changing indications for care.<br>• References were refreshed to replace superseded guidelines and add recent supporting literature. |

*Effective 9/19/26*

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|---|---|
| **Carelon Clinical Appropriateness Guidelines** | Interim Update<br>Clinical Review Criteria:<br>• Co **Radiology**<br>  ○ Imaging of the Brain<br>  ○ Imaging of the Extremities<br>  ○ Imaging of the Spine<br>  ○ Nuclear Medicine Imaging<br>  ○ SPECT imaging<br>  ○ Vascular ImagingE<br>  ○ Imaging of the Heart<br>• **Cardiology**<br>  ○ Diagnostic Coronary Angiography<br>  ○ Percutaneous Coronary Intervention<br>  ○ Wearable Cardioverter Defibrillators<br>  ○ Cardiac Implantable Electronic Devices<br>  ○ Transcatheter Ablation for Management of Atrial Fibrillation and Supraventricular and Ventricular Arrhythmias |

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

Providence Health Plan

Providence Health Assurance

# Pharmacy & Therapeutics (P&T) Committee

Oregon Region P&T Committee Meeting April 3, 2026

Go-Live Date: Monday, June 01, 2026, unless otherwise noted

## Table of Contents:



## Clinical Policy Changes

| MAJOR CHANGES | |
|---|---|
| **Policy Name** | **Summary of Change** |
| • **Anti-Cancer Medications - Medical Benefit**<br>• **Anti-Cancer Medications Prior Authorization and Step Therapy Policy - Medicare Part B** | Added Rybrevant Faspro and Keytruda Qlex to policy. Added step criteria for Keytruda Qlex to step through Keytruda. Added step criteria for Opdivo Qvantig to step through Opdivo. |
| **Anti-Cancer Medications – Self-Administered** | Added step therapy for Medicaid for the following agents when clinically appropriate: 1) Talzenna - step through Lynparza, 2) nilotinib (Tasigna), nilotinib (Danziten), nilotinib d-tartrate, bosutinib (Bosulif), or dasatinib (Sprycel) – step through imatinib, and 3) Xtandi – step through generic abiraterone 250 mg tab |
| **Calcitonin Gene-Related Peptide (CGRP) Receptor Antagonists - Medicaid** | Updated criteria to required failure of OnabotulinumtoxinA prior to CGRP approval for chronic migraine. Added Emgality as a preferred therapy. |
| • **Continuous Glucose Monitors for Personal Use**<br>• **Continuous Glucose Monitors for Personal Use - Medicare Part B** | Updated replacement criteria, expanded coverage for type 2 diabetes to all patients utilizing diabetes medications to align with new 2026 American Diabetes Association Standards of Care. |
| **Crysvita** | Added age restrictions. |
| **Crysvita Prior Authorization and Step Therapy Policy – Medicare Part B** | New policy; split out Medicare Part B due to Step Therapy requirements. |
| **Fertility and Related Medications** | Updated criteria to allow for menstrual suppression when other fertility preservation methods are not appropriate or patient requires emergent oncologic therapy. |

| MAJOR CHANGES | |
|---|---|
| **Policy Name** | **Summary of Change** |
| **Formulary and Quantity Limit Exceptions** | Updated language to clarify that requests for brand-name drugs applies to all drugs with generic availability. Updated quantity exception language to allow for compendia or guideline supported dosing. |
| **GLP-1 Receptor Agonists and Related Medications for Diabetes - Commercial** | Reduced quantity limit for exenatide 5 mcg to 1.2 mL per 30 days |
| **GLP-1 Receptor Agonists and Related Medications for Diabetes - Medicaid** | The preferred GLP-1 agent was updated to liraglutide. Updated criteria to require failure of maximally tolerated oral therapies prior to use of GLP-1 therapy (specifically metformin and sodium-glucose cotransporter-2 inhibitors), unless clinically inappropriate.<br><br>Effective 5/1/2026 |
| **Hepatitis C - Direct Acting Antivirals** | Updated criteria to allow coverage in both acute and chronic Hepatitis C infection (HCV). Mavyret is approved in both acute and chronic HCV and treatment is recommended by American Association for the Study of Liver Diseases (AASLD). |
| **Human Growth Hormones - Medicaid** | Changed preferred products from Norditropin/Genotropin to Omnitrope. |
| • **Immune Gamma Globulin (IgG)**<br>• **Immune Gamma Globulin (IGG) Prior Authorization and Step Therapy Policy - Medicare Part B** | Added IVIG preferred product strategy criteria to reflect new preferred IVIG and SCIG products. The preferred products are: Gammagard Liquid, Gammaked, Gamunex-C, Hizentra, Octagam, and Privigen |
| **Kerendia** | Updated policy criteria to require a trial of a sodium-glucose cotransporter 2 (SGLT2) inhibitor for heart failure to align with clinical guidelines, including American College of Cardiology/American Heart Association. |
| **Korlym** | Added criteria to require generic mifepristone for Brand Korlym requests. |
| **Lantidra** | Updated duration of diagnosis from over five years to at least five years. |
| **Medical Hormone Therapy Policy** | Updated Medicaid information, added testosterone 30 mg pump as a trial and failure option for topical products and for 'all other requests', added testosterone cypionate as a trial and failure option for delayed puberty. Added quantity limits for most drugs on policy. |

| MAJOR CHANGES | |
|---|---|
| **Policy Name** | **Summary of Change** |
| **Medical Hormone Therapy Prior Authorization and Step Therapy Policy – Medicare Part B** | Added testosterone 30mg pump as a trial and failure option for topical products and for 'all other requests', added testosterone cypionate as a trial and failure option for delayed puberty. Added quantity limits for most drugs on policy. Updated CMS LCD (combined with another LCD, no substantive changes). |
| • **Osteoanabolic Agents**<br>• **Osteoanabolic Agents Prior Authorization and Step Therapy Policy - Medicare Part B** | Extend coverage duration of Evenity to allow for 12 fills. Added language that all product dosing must follow FDA approved or compendia-supported guidelines. |
| **Pituitary Disorder Therapies** | Policy criteria updated for acromegaly to include trial and failure of surgical resection and/or radiation; reauthorization criteria updated for oncological diagnoses. |
| **Rezdiffra** | Updated criteria for diagnosis, specified maximum quantity of alcohol consumption allowed, removed requirement for pharmacotherapy for other conditions (such as diabetes, cardiovascular disease), and added requirement of trial of Wegovy (excluding combination therapy). |
| **Self-Administered Drugs (SAD) Policy** | • Several drugs were added to this policy as "pharmacy benefit only" including, calcitonin salmon (J0630), cortotrophin gel (J0802), Lasix ONYU (J3490/C9399), Imcivree (J3490), Sogroya (J3590), and Egrifta (J3590).<br>• Several drugs were added with "medical transition allowed" including apomorphine (J0364), Rivfloza (J3490), Palynziq (J3590), Arcalyst (J2793).<br>• Additionally, all formulations of Orencia, Benlysta, and tocilizumab will be required to transition to self-administration. |
| **Somatostatin Analogs Prior Authorization and Step Therapy Policy – Medicare Part B** | Updated acromegaly criteria to include trial and failure of surgical resection and/or radiation to align with FDA approved indication and made minor formatting changes. |
| **Strensiq** | Added clarification that this medication is now part of the Oregon Health Authority (OHA) high-cost drug carve-out (HCDC) list and will be managed by OHA. |
| **Tarpeyo** | Updated policy criteria to align with 2025 KDIGO guidelines: add required trial and failure of a sodium-glucose cotransporter-2 inhibitor (SGLT2i) and update high risk of disease progression to include fifty percent (50%) or more decline in eGFR. |

| MAJOR CHANGES | |
|---|---|
| **Policy Name** | **Summary of Change** |
| **Therapeutic Immunomodulators – Medicaid** | Added specific criteria for the coverage of the following indications with criteria: Behcet's disease, bullous pemphigoid, enthesitis related arthritis, giant cell arteritis, polymyalgia rheumatica, systematic juvenile idiopathic arthritis, systemic-sclerosis associated interstitial lung disease, uveitis, and other FDA approved/compendia supported.<br>Added prescriber restrictions; updated coverage duration to six months for initial authorization and one year for reauthorization; updated preferred and non-preferred agents; added conventional therapy requirements; specified/clarified diagnostic requirements<br><br>Effective 5/1/2026 |
| **Total Parenteral Nutrition (TPN) Policy** | Updated TPN criteria to require evidence of failure of oral nutrition or non-functioning GI tract. Added criteria for initiation of intradialytic parenteral nutrition (IDPN) based on ASPEN/KDOQI guidelines. Added policy exclusion for intraperitoneal nutrition (IPN) or intraperitoneal amino acid (IPAA) administration due to lack of evidence of medical necessity. |
| **Total Parenteral Nutrition Policy -Medicare Part B** | Added clarification of Part B vs Part D coverage of intradialytic parenteral nutrition (IDPN) and intraperitoneal nutrition (IPN) or intraperitoneal amino acid (IPAA) treatment. |
| **Tzield** | Updated policy criteria to expand the definition of abnormal glucose. |
| **Vaginal Progesterone Formulations** | Clarified that crinone 8% is only strength covered for Assisted Reproductive Technology. |
| **Vijoice** | Added clarification that this medication is now part of the Oregon Health Authority (OHA) high-cost drug carve-out (HCDC) list and will be managed by OHA. |
| • **Weight Management Medications Policy (Policy A)**<br>• **Weight Management Medications Policy - Medicaid**<br>• **Weight Management Medications Policy (Policy B)** | Changed names to "GLP-1 receptor agonists and related medications for non-diabetes Indications" and updated policy to include only GLP-1 related medications (removed Qsymia and phentermine references). Removed BMI requirement and updated diagnostic requirements for metabolic dysfunction-associated steatohepatitis (MASH). Added exclusion for combination with Rezdiffra. |
| **Yorvipath Policy** | Added clarification that this medication is now part of the Oregon Health Authority (OHA) high-cost drug carve-out (HCDC) list and will be managed by OHA.<br>Updated reauthorization criteria to require monitoring of parathyroid hormone levels and shortened initial authorization from one year to six months. |

| RETIRED POLICIES | |
|---|---|
| **Policy Name** | **Summary of Change** |
| **DPP-4 Inhibitors Step Therapy Policy** | Due to low-cost generic availability. |
| **Tolvaptan** | Due to low risk of inappropriate utilization and generic availability. |

## Other Formulary Changes:

| Drug Name | Recommendation | Policy Name |
|---|---|---|
| **Amivantamab-hyaluronidase-lpuj (Rybrevant Faspro) Vial** | New biologic product for Rybrevant; Line extend with Rybrevant<br>• Medical Benefit, Prior Authorization for all lines of business | Anti-Cancer Medications - Medical Benefit |
| **Amlodipine besylate (Sdamlo) Powder Con** | New formulation;<br>• Non-formulary for all lines of business | N/A |
| **Besifloxacin hcl Drops Susp** | New generic;<br>• Commercial: Formulary, Tier 4<br>• Medicaid/Medicare Part D: Non-Formulary | N/A |
| **Brivaracetam 10 mg Tablet** | New generic for existing brand (Briviact)<br>• Commercial: Formulary, Tier 2, Quantity Limit (4 tablets per day)<br>• Medicaid: Formulary, Quantity Limit (4 per day)<br>• Medicare Part D: Formulary, Tier 2, Quantity Limit (2 tablets per day) | N/A |
| **Brivaracetam 25, 50, 75, 100 mg Tablet** | New generic for existing brand (Briviact)<br>• Commercial/Medicare Part D: Formulary, Tier 2, Quantity Limit (2 tablets per day)<br>• Medicaid: Formulary, Quantity Limit (2 per day) | N/A |
| **Cefixime Tablet** | New generic;<br>• Non-formulary for all lines of business | N/A |
| **Dasatinib anhydrous (Phyrago) Tablet** | New MedID; Previously reviewed as same product as Sprycel, but is different brand name/.<br>• Commercial: Formulary, Tier 6, Prior Authorization, Quantity Limit (1 tablet per day)<br>• Medicaid: Non-Formulary, Specialty, Prior Authorization, Quantity Limit (1 tablet per day)<br>• Medicare Part D: Formulary, Tier 5, Prior Authorization, Quantity Limit (1 tablet per day) | • Commercial/Medicaid: Anti-Cancer Medications - Self-Administered<br>• Medicare Part D: Phyrago |
| | **Commercial: Add to imatinib step therapy criteria in policy** | |

| Drug Name | Recommendation | Policy Name |
|---|---|---|
| | **Medicare Part D PA Criteria**:<br>For initial authorization, all the following:<br>1. Indication is supported by CMS-approved compendia AND<br>2. Documentation of use of both imatinib AND generic dasatinib unless one of the following:<br>a. The patient has an intolerance or hypersensitivity to both imatinib AND generic dasatinib,<br>b. The patient has an FDA labeled contraindication to both imatinib AND generic dasatinib,<br>c. CMS-approved compendia do not support the use of both imatinib AND generic dasatinib for the requested indication,<br>d. The prescriber has provided information in support of use of Phyrago over both imatinib AND generic dasatinib for the requested indication, and<br>3. If Phyrago is preferred over generic dasatinib due to concerns of drug interactions with acid reducers (such as proton pump inhibitors or h2 blockers), please provide medical rationale why the patient is unable to space the drugs apart by two hours per product label recommendation.<br>Coverage Duration: Authorization will be approved until no longer eligible with the plan.<br>Prescriber Restrictions: Must be prescribed by, or in consultation with an oncologist or hematologist | |
| **Finerenone (Kerendia) Tablet** | Commercial Dynamic: Down tier to Tier 3 | Kerendia |
| **Lunsumio Velo (mosunetuzumab-axgb) vial** | New formulation. Line extend with Lunsumio<br>• Medical Benefit, Prior Authorization for all lines of business | T-cell therapy |
| **Meloxicam (Zybic) Oral Susp** | New to market brand;<br>• Commercial Standard: Formulary, Tier 1<br>• Commercial Dynamic: Formulary, Tier 4<br>• Medicaid/Medicare Part D: Non-Formulary | N/A |
| **Metoprolol tartrate (Lopressor) Tablet** | New strength (12.5 mg);<br>• Non-formulary for all lines of business | N/A |
| **Nebivolol hcl Tablet** | Add to Medicaid formulary | N/A |
| **Nilotinib d-tartrate Capsule** | Add to Medicare Part D formulary due to protected class status and new salt form: Formulary, Tier 5, Prior Authorization, Quantity Limit (4 capsules per day) | Medicare Part D: Nilotinib D-Tartrate |
| | **PA Criteria for Nilotinib d-tartrate:**<br>For initial authorization, both of the following:<br>1. Indication is supported by CMS-approved compendia AND<br>2. Documentation of use of generic nilotinib (generic Tasigna) unless one of the following:<br>a. The patient has an intolerance or hypersensitivity to generic nilotinib (generic Tasigna),<br>b. The patient has an FDA labeled contraindication to generic nilotinib (generic Tasigna),<br>c. CMS-approved compendia do not support the use of generic nilotinib (generic Tasigna) for the requested indication, | |

| Drug Name | Recommendation | Policy Name |
|---|---|---|
| | d. The prescriber has provided information in support of use of nilotinib d-tartrate over generic nilotinib (generic Tasigna) for the requested indication.<br>Coverage Duration: Authorization will be approved until no longer eligible with the plan.<br>Prescriber Restrictions: Must be prescribed by, or in consultation with an oncologist or hematologist | |
| **Nivolumab-hyaluronidase-nvhy (Opdivo Qvantig) Vial** | Make non-preferred product for all lines of business<br>• Commercial/Medicaid/Medicare Part B: Medical Benefit, Prior Authorization<br>• Medicare Part D: Non-Formulary<br>• Medicare Part B: Medical Benefit, Prior Authorization/Step Therapy | • Commercial/Medicaid: Anti-Cancer Medications - Medical Benefit<br>• Medicare Part B: Anti-Cancer Medications Prior Authorization and Step Therapy Policy<br><br>**Criteria for Opdivo Qvantig:** failure of therapy with Opdivo IV |
| **Onasemnogene abeparvovec-brve (Itvisma) Vial** | New formulation; Line extend with Zolgensma<br>• Commercial/Medicare Part B: Medical Benefit, Prior Authorization<br>• Medicaid: Medical Benefit (HCRU Carve-Out)<br>• Medicare Part D: Non-Formulary | • Commercial/Medicare Part B: Therapies For Spinal Muscular Atrophy<br>• Medicaid: N/A |
| **Palopegteriparatide (Yorvipath) Pen Injctr** | Remove from Medicaid formulary. Drug managed by Oregon Health Authority | N/A |
| **Pembrolizum-berahyaluron-pmph (Keytruda Qlex) Vial** | New formulation; Non-preferred product for all lines of business<br>• Commercial/Medicaid: Medical Benefit, Prior Authorization<br>• Medicare Part D: Non-formulary<br>• Medicare Part B: Medical, Prior Authorization/Step Therapy | • Commercial/Medicaid: Anti-Cancer Medications - Medical Benefit<br>• Medicare Part B: Anti-Cancer Medications Prior Authorization and Step Therapy Policy<br><br>**Criteria for Keytruda Qlex:** failure of therapy with Keytruda IV |
| • **Somatropin (Genotropin) Cartridge; Disp Syrin**<br>• **Somatropin (Norditropin Nordiflex) Pen Injctr** | Remove from Medicaid formulary<br>Effective: 07/01/2026 | Human Growth Hormones |
| **Somatropin (Omnitrope) Cartridge; Vial** | Add to Medicaid formulary | Human Growth Hormones |
| **Tizanidine hcl (Ontralfy) Solution** | New formulation;<br>• Non-formulary for all lines of business | N/A |
| **Tobramycin-Loteprednol Drops Susp** | New generic;<br>• Commercial/Medicare Part D: Formulary, Tier 4<br>• Medicaid: Formulary | N/A |
| **Tolvaptan (Jynarque/Samsca)** | Add Quantity Limit for Commercial and Medicaid: | N/A |

| Drug Name | Recommendation | Policy Name |
|---|---|---|
| | • 15 and 30 mg tablets: Four (4) tablets per day<br>• Titration/weekly sleeve packs: Two (2) tablets per day | |
| **Tyvaso (treprostinil) nebulizer** | Remove from Commercial and Medicaid formularies<br>Effective: 07/01/2026 | Pulmonary Hypertension |
| **SGLT-2 and DPP-4 Changes** | | |
| • **Ertugliflozin/sitagliptin (Steglujan) Tablet**<br>• **Dapagliflozin/sitagliptin (Qtern) tablet** | Remove from Commercial formulary | N/A |
| • **Linagliptin/metformin (Jentadueto) Tablet Linagliptin/empagliflozin (Glyxambi) Tablet**<br>• **Linagliptin/empagliflozin/metformin (Trijardy XR) Tab BP 24h** | Remove from Commercial formulary | N/A |
| • **Sitagliptin/metformin (Janumet XR) Tablet 24hr**<br>• **Linagliptin (Tradjenta) tablet**<br>• **Linagliptin/metformin (Jentadueto XR) Tablet** | Remove from Commercial and Medicaid formularies | N/A |
| • **Saxagliptin/metformin TBMP 24hr**<br>• **Saxagliptin Tablet** | Commercial Dynamic: Down tier to Tier 2 | N/A |
| • **Invokana (canagliflozin)**<br>• **Invokamet/Invokamet XR (canagliflozin/metformin)** | Remove from Medicaid formulary<br>Effective 7/1/2026 | N/A |
| **Synjardy/Synjardy XR (empagliflozin/metformin)** | Remove from Commercial and Medicaid formularies<br>Effective 7/1/2026 | N/A |

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

**Drugs released from 9/12/2025 – 2/13/2026**

| NEW DRUGS / COMBINATIONS / STRENGTHS / DOSAGE FORMS | | |
|---|---|---|
| **Drug Name** | **Action Taken** | **Policy Name** |
| **Trofinetide (Daybue Stix) Powd Pack** | New dosage form (powder packet). Line extend with Daybue oral solution; | • Commercial/Medicaid: Medications For Rare Indications<br>• Medicare Part D: N/A |

| NEW DRUGS / COMBINATIONS / STRENGTHS / DOSAGE FORMS | | |
|---|---|---|
| **Drug Name** | **Action Taken** | **Policy Name** |
| | • Commercial: Non-Formulary, Prior Authorization, Specialty<br>• Medicaid: Non-Formulary (HCRU Carve-out)<br>• Medicare Part D: Non-Formulary | |
| **Denosumab-qbde (Enoby) Syringe** | New biosimilar (Prolia biosimilar). Line extend with non-preferred denosumab biosimilars;<br>• Medical Prior Authorization for all lines of business | • Commercial/Medicaid: Denosumab<br>• Medicare Part B: Denosumab Prior Authorization and Step Therapy Policy |
| **Immun Glob G(IGG)/GLY/IGA 0-50 (Gammagard Liquid ERC) Vial** | New formulation. Line extend with Gammagard J1569;<br>• Commercial/Medicaid: Non-Formulary, Medical Prior Authorization<br>• Medicare Part D: Formulary, Tier 5, Prior Authorization<br>• Medicare Part B: Prior Authorization | • Immune Gamma Globulin (IgG)<br>• Immune Gamma Globulin (IGG) Prior Authorization and Step Therapy Policy |
| **Letibotulinumtoxina-wlbg (Letybo) Vial** | New entity. Line extend with other botulinum toxin products;<br>• Medical Benefit, Prior Authorization (treatment of wrinkles is excluded per policy) | Botulinum Toxin |
| **Nivolumab-hyaluronidase-nvhy (Opdivo Qvantig) Vial** | New strength (300MG-5000). Line extend with Opdivo Qvantig 600mg-10,000mg;<br>• Commercial/Medicaid/Medicare Part B: Medical Benefit, Prior Authorization/Step Therapy<br>• Medicare Part D: Non-Formulary | • Commercial/Medicaid: Anti-Cancer Medications - Medical Benefit<br>• Medicare Part B: Anti-Cancer Medications Prior Authorization and Step Therapy Policy |
| **Pivmecillinam hcl (Pivya) Tablet** | Re-launch of product. Line extend with previously reviewed Pivya;<br>• Commercial/Medicare Part D: Formulary, Tier 4, Step Therapy, Quantity Limit (3 tablets per day)<br>• Medicaid: Formulary, Step Therapy, Quantity Limit (3 tablets per day) | Pivya Step Therapy Policy |
| **Potassium chloride (Pokonza) Liquid** | New dosage form (liquid). Line extend with Pokonza packet;<br>• Non-formulary for all lines of business | N/A |
| **Varicella-zoster ge/as01b/pf (Shingrix) Syringe** | New formulation (prefilled syringe). Line extend with Shingrix vial; | N/A |

| NEW DRUGS / COMBINATIONS / STRENGTHS / DOSAGE FORMS | | |
|---|---|---|
| **Drug Name** | **Action Taken** | **Policy Name** |
| | • Commercial: Preventive, Quantity Limit (2 doses per lifetime)<br>• Medicaid: Formulary, Quantity Limit (2 doses per lifetime)<br>• Medicare Part D: Formulary, Tier 3, Quantity Limit (2 mL per 365 days) | |
| **Leuprolide acetate (Vabrinty) Syringe** | New product. Line extend with Eligard;<br>• Commercial/Medicaid/Medicare Part B: Medical Benefit, Prior Authorization<br>• Medicare Part D: Formulary, Tier 4 | • Commercial/Medicaid: Gonadotropin Releasing Hormone Agonists<br>• Medicare Part B: Gonadotropin Releasing Hormone Agonists Prior Authorization and Step Therapy Policy |
| **Cariprazine hcl (Vraylar) Capsule** | New strengths (0.5 mg & 0.75 mg). Line extend with existing strengths of Vraylar;<br>• Commercial: Formulary, Tier 3, Prior Authorization, Quantity Limit (1 capsule per day)<br>• Medicaid: Non-Formulary<br>• Medicare Part D: Formulary, Tier 5, Prior Authorization, Quantity Limit (1 capsule per day) | • Commercial/Medicare Part D: Antipsychotics<br>• Medicaid: N/A |
| **Semaglutide (Wegovy) Tablet** | New dosage form (tablet). Line extend with Wegovy injection;<br>• Commercial Standard: Formulary, Tier 3, Prior Authorization, Quantity Limit (1 tablet per day)<br>• Commercial Dynamic: Non-Formulary, Prior Authorization, Quantity Limit (1 tablet per day)<br>• Medicaid: Non-Formulary, Prior Authorization, Quantity Limit (1 tablet per day)<br>• Medicare Part D: Non-Formulary<br>Effective: 02/01/2026 | • Commercial/Medicaid: Weight Management Medications<br>• Medicare Part D: N/A |
| **Selinexor (Xpovio) Tablet** | New product/strength. Line extend with existing Xpovio strengths; | Anti-Cancer Medications - Self-Administered |

| NEW DRUGS / COMBINATIONS / STRENGTHS / DOSAGE FORMS | | |
|---|---|---|
| **Drug Name** | **Action Taken** | **Policy Name** |
| | • Commercial: Formulary, Tier 6, Prior Authorization, Quantity Limit (4 tablets per 28 days)<br>• Medicaid: Formulary, Specialty, Prior Authorization, Quantity Limit (4 tablets per 28 days)<br>• Medicare Part D: Formulary, Tier 5, Prior Authorization, Quantity Limit (4 tablets per 28 days) | |
| **Denosumab-qbde (Xtrenbo) Vial** | New biosimilar (Xgeva biosimilar). Line extend with non-preferred denosumab biosimilars;<br>• Medical, Prior Authorization for all lines of business | • Commercial/Medicaid: Denosumab<br>• Medicare Part B: Denosumab Prior Authorization and Step Therapy Policy |
| **Tirzepatide (Zepbound Kwikpen) Pen Injctr** | New dosage form (pen injector); Line extend with Zepbound vial and SQ injector;<br>• Commercial Standard: Formulary, Tier 3, Prior Authorization, Quantity Limit (2.4 mL per 28 days)<br>• Commercial Dynamic: Non-Formulary, Prior Authorization, Quantity Limit (2.4 mL per 28 days)<br>• Medicaid: Non-Formulary, Prior Authorization, Quantity Limit (2.4 mL per 28 days)<br>• Medicare Part D: Non-Formulary | • Commercial/Medicaid: Weight Management Medications<br>• Medicare Part D: N/A |
| **Ustekinumab-ttwe Vial** | New biosimilar. Line extend with non-preferred ustekinumab;<br>• Commercial/Medicaid: Non-Formulary, Prior Authorization, Quantity Limit (0.5 mL per 84 days)<br>• Medicare Part D: Non-Formulary | • Commercial/Medicaid: Therapeutic Immunomodulators (TIMS)<br>• Medicare Part D: N/A |

| NEW GENERICS | | |
|---|---|---|
| **Drug Name** | **Action Taken** | **Policy Name** |
| **Ceftaroline fosamil Vial** | First generic for Teflaro. Line extend with Teflaro; | N/A |

| NEW GENERICS | | |
|---|---|---|
| **Drug Name** | **Action Taken** | **Policy Name** |
| | • Commercial/Medicaid/Medicare Part B: Medical Benefit<br>• Medicare Part D: Formulary, Tier 5 | |
| • **Thyroid,pork (Evexithroid) Tablet**<br>• **Thyroid,pork (Renthyroid) Tablet** | New pork thyroid product. Line extend with Existing generic pork thyroid products such as NP Thyroid;<br>• Commercial: Formulary, Tier 2<br>• Medicaid: Formulary<br>• Medicare Part D: Formulary, Tier 4 | N/A |
| **Levetiracetam Tab Susp** | New generic. Line extend with brand Spritam, generic levetiracetam 250mg tab for oral suspension;<br>• Commercial/Medicaid: Non-Formulary, Prior Authorization<br>• Medicare Part D: Formulary, Tier 4, Step Therapy | • Commercial/Medicaid: New Medications and Formulations without Established Benefit<br>• Medicare Part D: Antiepileptic Agents |
| **Rilpivirine hcl (Rilpivirine) Tablet** | First generic for Edurant. Line extend with brand Edurant;<br>• Commercial Standard: Formulary, Tier 2<br>• Commercial Dynamic: Formulary, Tier 4<br>• Medicaid: Formulary<br>• Medicare Part D: Formulary, Tier 5, Quantity Limit (1 tablet per day) | N/A |
| **Tapentadol hcl Tablet** | First generic for immediate release Nucynta. Line extend with brand Nucynta;<br>• Commercial/Medicaid: Non-Formulary, Quantity Limit (6 tablets per day)<br>• Medicare Part D: Non-Formulary | N/A |
| **Tizanidine hcl 8 mg Capsule** | New generic. Line extend with brand Zanaflex 8mg capsule;<br>• Non-formulary for all lines of business | N/A |
| **Sapropterin dihydrochloride (Zelvysia) Powd Pack** | New product. Line extend with existing sapropterin powder packs;<br>• Commercial/Medicare Part D: Formulary, Tier 5<br>• Medicaid: Non-formulary, Specialty | N/A |

## New Drugs and Combinations:

1. **Delgocitinib (Anzupgo) Cream (G)**
   a. **Indication: For the treatment of moderate to severe chronic hand eczema in adults.**
   b. **Decision:**

| | Commercial | Medicaid | Medicare |
|---|---|---|---|
| **Formulary Status*** | Non-formulary | Non-formulary | Part D: Non-formulary<br>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** | 30 grams per month | 30 grams per month | N/A |
| * Recommendations for placement may differ between lines of business due to regulatory requirements.<br>** 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: Topical corticosteroids: betamethasone dipropionate, clobetasol propionate, triamcinolone acetate; Topical calcineurin inhibitor: tacrolimus ointment** | | | |

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

| | |
|---|---|
| **PA PROGRAM NAME** | Topical Agents for Skin Conditions |
| **MEDICATION NAME** | Delgocitinib (Anzupgo) Cream |
| **PA INDICATION INDICATOR** | 1 - All FDA-Approved Indications |
| **EXCLUSION CRITERIA** | Concurrent use with biologics, other Janus kinase (JAK) inhibitors, or potent immunosuppressants |
| **REQUIRED MEDICAL INFORMATION** | For Chronic Hand Eczema (CHE):<br>For Anzupgo, patient must meet the following:<br>1. A diagnosis of moderate to severe CHE defined as an Investigator's Global Assessment for CHE (IGA-CHE) score of 3-4<br>2. Documentation of hand eczema persisting for at least three months or recurring at least two times within 12-month time frame<br>3. A trial, failure, or contraindication to both a high potency topical corticosteroid and topical calcineurin inhibitor |

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| | For reauthorization, documentation of response to therapy is required by either:<br>1. Reduction in severity, duration, or recurrence of CHE<br>2. At least a two-step improvement of IGA-CHE or a score of 0 to 1 |
| **AGE RESTRICTIONS** | Age must be appropriate based on FDA-approved indication |
| **PRESCRIBER RESTRICTIONS** | Must be prescribed by, or in consultation, with a dermatologist, allergist, or immunologist |
| **COVERAGE DURATION** | Initial authorization will be approved for six months<br>Reauthorization will be approved for 1 year |

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

| | |
|---|---|
| **PA PROGRAM NAME** | Topical Agents for Skin Conditions |
| **MEDICATION NAME** | Delgocitinib (Anzupgo) Cream |
| **PA INDICATION INDICATOR** | 1 - All FDA-Approved Indications |
| **EXCLUSION CRITERIA** | Concurrent use with biologics, other Janus kinase (JAK) inhibitors, or potent immunosuppressants |
| **REQUIRED MEDICAL INFORMATION** | For patients less than 21 years of age or are under age 26 and have Young Adults with Special Health Care Needs (YSHCN) benefits:<br>1. Documentation of covered disease severity defined as one of the following:<br>a. Documentation of severe disease as defined by both of the following:<br>i. Documentation that the patient is having functional impairment as indicated by one of the following:<br>1) Having functional impairment as indicated by Dermatology Life Quality Index (DLQI) ≥ 11<br>2) Children's Dermatology Life Quality Index (CDLQI) ≥ 13<br>3) Severe score on other validated tool<br>ii. Documentation of one of the following:<br>1) At least 10% of body surface area involved<br>2) Hand, Food, face, or mucous membrane involvement<br>b. 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, or perform activities of daily living)<br><br>2. Documentation that they meet the following indication-specific criteria: |

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|---|---|
| | a. For Chronic Hand Eczema: Anzupgo may be covered when the following criteria are met:<br>i. Documentation of hand eczema persisting for at least three months or recurring at least two times within 12-month time frame<br>ii. Documentation of contraindication, intolerance or failed two-week trials from both of the following drug categories:<br>1) Topical corticosteroid (e.g., mometasone, betamethasone, clobetasol)<br>2) Topical calcineurin inhibitors (e.g., tacrolimus)<br><br>For adult patients greater than or equal to 21 years of age:<br>1. Documentation of severe disease defined as both of the following:<br>a. Documentation that patient is having functional impairment as indicated by one of the following:<br>i. Having functional impairment as indicated by Dermatology Life Quality Index (DLQI) ≥ 11<br>ii. Children's Dermatology Life Quality Index (CDLQI) ≥ 13<br>iii. Severe score on other validated tool<br>b. Documentation of one of the following:<br>i. At least 10% of body surface area involved<br>ii. Hand, Food, face, or mucous membrane involvement<br>2. Documentation that they meet the following indication-specific criteria:<br>a. For Severe Chronic Hand Eczema: Anzupgo may be covered when the following criteria are met:<br>i. Documentation of hand eczema persisting for at least three months or recurring at least two times within 12-month time frame<br>ii. Documentation of contraindication, intolerance or failed two-week trials from both of the following drug categories:<br>1) Topical corticosteroid (e.g., mometasone, betamethasone, clobetasol)<br>2) Topical calcineurin inhibitors (e.g., tacrolimus)<br><br>For reauthorization: Must have documentation of response to therapy indicating improvement or stabilization of condition (e.g., reduced symptoms and/or affected BSA) |

| | |
|---|---|
| **AGE RESTRICTIONS** | Age must be appropriate based on FDA-approved indication |
| **PRESCRIBER RESTRICTIONS** | N/A |
| **COVERAGE DURATION** | Initial authorization will be approved for six months<br>Reauthorization will be approved for 1 year |

2. **Omidenepag isopropy (Omlonti) Drops**
   a. **Indication:** For the reduction of elevated intraocular pressure (IOP) in patients with open-angle glaucoma or ocular hypertension.
   b. **Decision:**

| | Commercial | Medicaid | Medicare |
|---|---|---|---|
| **Formulary Status*** | Formulary | Formulary | Part D: Non-Formulary<br>Part B: N/A |
| **Tier**** | Tier 3 | N/A | N/A |
| **Affordable Care Act Eligible** | No | N/A | N/A |
| **Utilization Management Edits** | Step Therapy | Step Therapy | N/A |
| **Quantity Limit** | 2.5 mL per 25 days | 2.5 mL per 25 days | N/A |
| * Recommendations for placement may differ between lines of business due to regulatory requirements.<br>** 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: Lumigan, Durysta implant, bimatoprost, Xalatan, Xelpros, latanoprost, Ziptan, Travatan Z, travoprost, Betimol, timolol, Alphagan, brimonidine, Rhopressa, Azopt, brinzolamide, Combigan, brimonidine/timolol, Rocklatan, Cosopt, dorzolamide/timolol, Simbrinza** | | | |

   c. **Prior Authorization Criteria for Commercial/Medicaid:** Added to Anti-Glaucoma Agents Step Therapy Policy

3. **Sepiapterin (Sephience) Powd Pack**
   a. **Indication:** For the treatment of hyperphenylalaninemia (HPA) in adult and pediatric patients 1 month of age and older with sepiapterin-responsive phenylketonuria (PKU). Sepiapterin is to be used in conjunction with a phenylalanine (Phe)- restricted diet.
   b. **Decision:**

| | Commercial | Medicaid | Medicare |
|---|---|---|---|
| **Formulary Status*** | Non-formulary | Non-formulary | Part D: Non-formulary<br>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** | 250 mg packets: 3 packets/day<br>1000 mg packets: N/A | 250 mg packets: 3 packets/day<br>1000 mg packets: N/A | N/A |
| * Recommendations for placement may differ between lines of business due to regulatory requirements.<br>** 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: Palynziq, saptropterin tablets and powder pack** | | | |

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

| | |
|---|---|
| **PA PROGRAM NAME** | PALYNZIQ Phenylalanine-Lowering Therapies for Phenylketonuria |
| **MEDICATION NAME** | Sepiapterin (Sephience) 1000 mg powder pack<br>Sepiapterin (Sephience) 250 mg powder pack |
| **PA INDICATION INDICATOR** | 1 - All FDA-Approved Indications |
| **OFF-LABEL USES** | None |
| **EXCLUSION CRITERIA** | Used in combination with sapropterin (Kuvan) Use in combination with another drug for phenylketonuria, such as sapropterin (Kuvan), Palynziq, or Sephience |
| **REQUIRED MEDICAL INFORMATION** | For initial authorization, both of the following criteria must be met:<br>1. Diagnosis of phenylketonuria (PKU)<br>2. One of the following:<br>a. For Palynziq: Documentation of blood phenylalanine concentration more than 600 micromol/L (10 mg/dL) despite management with dietary phenylalanine restriction and sapropterin<br>b. For Sephience: Both of the following:<br>i. Documentation of failure with sapropterin in combination with dietary phenylalanine restriction. Failure is defined as blood phenylalanine concentration more than 360 micromol/L (10 mg/dL).<br>ii. Medication will be used in conjunction with a phenylalanine (Phe)-restricted diet<br><br>For reauthorization for Sephience: both of the following must be met:<br>1. Documentation that blood phenylalanine concentration levels have decreased by at least 15% from baseline (prior to initiating therapy for phenylketonuria) and remain at least 15% below pretreatment baseline OR member has maintained blood phenylalanine concentrations less than 360 micromol/L (10 mg/dL) |

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|---|---|
| | 2. Medication will be used in conjunction with a phenylalanine (Phe)-restricted diet<br><br>For reauthorization for Palynziq, one of the following criteria must be met:<br>1. Documentation that blood phenylalanine concentration levels have decreased by at least 20% from baseline and remain at least 20% below pretreatment baseline, OR<br>2. Documentation of a blood phenylalanine concentration less than or equal to 600 micromol/L (10 mg/dL), OR<br>3. For those not on maximum allowed dose of 60 mg once daily: Authorization for six months may be approved for those who have not met blood phenylalanine control when there is a documented plan for further dose increase up to a maximum dose of 60 mg once daily<br>*Note: Prescribing information recommends considering dose increase in those you have been on pegvaliase 20 mg daily for at least 24 weeks or 40 mg daily for at least 16 weeks and have not met blood phenylalanine control, up to a maximum dose of 60 mg once daily.* |
| **AGE RESTRICTIONS** | Palynziq: Approved for 18 years and older. |
| **PRESCRIBER RESTRICTIONS** | Initial authorization and reauthorization: Must be prescribed by, or in consultation with, a metabolic disease specialist or a provider who specializes in the treatment of phenylketonuria (PKU). |
| **COVERAGE DURATION** | Palynziq: Initial authorization will be approved for six months.<br>Sephience: Initial authorization will be approved for one month.<br><br>Reauthorization will be approved for one year. |

4. **Sibeprenlimab-szsi (Voyxact) Syringe**
   a. **Indication:** To reduce proteinuria in adults with primary immunoglobulin A nephropathy (IgAN) at risk for disease progression.
   b. **Decision:**

| | Commercial | Medicaid | Medicare |
|---|---|---|---|
| **Formulary Status*** | Non-formulary | Non-formulary | Part D: Non-formulary<br>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** | 2mL/28 days | 2mL/28 days | None |

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| * Recommendations for placement may differ between lines of business due to regulatory requirements.<br>** 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: Filspari, Vanrafia, Tarpeyo, Fabhalta** |

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

| | |
|---|---|
| **PA PROGRAM NAME** | Filspari, Vanrafia, Voyxact |
| **MEDICATION NAME** | Filspari (sparsentan tablet)<br>Vanrafia (atrasentan tablet)<br>Voyxact (sibeprenlimab-szsi syringe) |
| **PA INDICATION INDICATOR** | 1 - All FDA-Approved Indications |
| **OFF-LABEL USES** | N/A |
| **EXCLUSION CRITERIA** | For sparsentan only: Concurrent therapy with angiotensin receptor blockers, endothelin receptor antagonists, or aliskiren |
| **REQUIRED MEDICAL INFORMATION** | For initial authorization, all the following criteria must be met:<br>1. Diagnosis of primary immunoglobulin A nephropathy (IgAN), confirmed by biopsy<br>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<br>3. Patient is at high risk of disease progression, defined as meeting one of the following criteria (a or b):<br>a. Proteinuria of more than 1.0 g/day; OR<br>b. For Filspari or Vanrafia: Urine protein-to-creatinine ratio of 1.5 g/g or more<br>c. For Voyxact: Urine protein-to creatinine ratio of 0.75 g/g or more<br>4. eGFR greater than or equal to 30 mL/min1.73m^2<br>5. For sparsentan (Filspari): provider attestation that ACE inhibitor or ARB will be discontinued before sparsentan therapy is initiated<br>6. For Voyxact: documented trial and failure, intolerance, or contraindication to sparsentan (Filspari) and atrasentan (Vanrafia)<br><br>Reauthorization: Documentation of positive response to therapy defined as improvement in proteinuria. |
| **AGE RESTRICTIONS** | May be approved for patients aged 18 years and older. |

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| **PRESCRIBER RESTRICTIONS** | Must be prescribed by, or in consultation with, a nephrologist. |
| **COVERAGE DURATION** | May be approved for patients aged 18 years and older. |

## New Indications:

Therapies with Prior Authorization Policies (Non-oncology)

1. **BREYANZI** (LISOCABTAGENE MARALEUCEL)
   a. New indication approved 12/04/2025:
      i. Treatment of adult patients with relapsed or refractory marginal zone lymphoma (MZL) who have received at least 2 prior lines of systemic therapy
   b. **RECOMMENDATION:** Inform prescribers via Medical Policy Alert. New indication was reviewed and 'T-Cell Therapy' policy was updated for February 2026 P&T annual policy review.

2. **OMISIRGE** (OMIDUBICEL-ONLV)
   a. New indication approved 12/04/2025:
      i. Treatment of adults and pediatric patients 6 years and older with severe aplastic anemia (SAA) following reduced intensity conditioning
   b. **RECOMMENDATION:** Inform prescribers via Medical Policy Alert. New indication was reviewed and 'Omisirge' policy was updated for February 2026 P&T annual policy review.

3. **BLUJEPA** (GEPOTIDACIN)
   a. New indication approved 12/11/2025:
      i. For the treatment of uncomplicated urogenital gonorrhea caused by susceptible strains of Neisseria gonorrhoeae in adult and pediatric patients 12 years of age and older weighing at least 45 kilograms who have limited or no alternative treatment options. Approval of this indication is based on limited clinical safety data for this indication
   b. **RECOMMENDATION:** Inform prescribers via Medical Policy Alert. Update Commercial/Medicaid 'Antibiotics for Urinary Tract Infections' policy with new indication and criteria.

Prior Authorization for **Commercial/Medicaid:**

| | |
|---|---|
| PA PROGRAM NAME | Antibiotics for Urinary Tract Infections |
| MEDICATION NAME | Blujepa (gepotidacin mesylate) |
| COVERED USES | 1 - All FDA-Approved Indications |
| EXCLUSION CRITERIA | N/A |
| REQUIRED MEDICAL INFORMATION | Coverage requires medical rationale for use over the following ~~formulary~~ alternative antibiotics. Acceptable rationale includes, but is not limited to: member has failed or has an intolerance to all other available therapies or susceptibility testing results show a strain of bacteria only susceptible to the requested antibiotic therapy:<br>A. For uncomplicated urinary tract infection: |

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|---|---|
| | 1. Nitrofurantoin monohydrate/macrocrystals<br>2. Trimethoprim-sulfamethoxazole, trimethoprim<br>3. Fosfomycin trometamol<br>4. Fluoroquinolones (such as ofloxacin, ciprofloxacin, and levofloxacin)<br>5. Beta-Lactam agents (such as amoxicillin-clavulanate, cefdinir, cefaclor, cefpodoxime-proxetil, cefadroxil, cephalexin, amoxicillin, ampicillin)<br><br>B. For uncomplicated urogenital gonorrhea:<br>1. Ceftriaxone<br>2. Other cephalosporins (such as cefixime)<br>3. Azithromycin-based regimens |
| AGE RESTRICTIONS | May be approved for patients aged 12 years and older |
| PRESCRIBER RESTRICTIONS | N/A |
| COVERAGE DURATION | Authorization will be approved for one month. No reauthorization. |

4. **UPLIZNA** (INEBILIZUMAB-CDON)
   a. New indication approved 12/11/2025:
      i. Generalized myasthenia gravis (gMG) in adult patients who are antiacetylcholine receptor (AChR) or anti-muscle specific tyrosine kinase (MuSK) antibody positive
   b. **RECOMMENDATION:** Inform prescribers via Medical Policy Alert. Update Commercial/Medicaid and Medicare Part B 'Uplizna' policies with new indication and criteria.

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

| | |
|---|---|
| PA PROGRAM NAME | Uplizna |
| MEDICATION NAME | Uplizna (inebilizumab) |
| COVERED USES | 1 - All FDA-Approved Indications |
| EXCLUSION CRITERIA | N/A |
| REQUIRED MEDICAL INFORMATION | **For ALL REQUESTS:**<br>1. Dose and frequency must be in accordance with FDA-approved labeling<br>2. The requested agent must not be given concurrently with another Complement Inhibitor (for example Ultomiris® or Empaveli®), or neonatal Fc receptor blocker (for example, Rystiggo®, Vyvgart®, Vyvgart Hytrulo®)<br><br>**For initiation of therapy (new starts) for generalized myasthenia gravis (gMG), all of the following must be met:** |

| | |
|---|---|
| | 1. Anti-acetylcholine receptor (anti-AChR) antibody positive or anti-muscle specific tyrosine kinase (MuSK) antibody positive<br>2. Myasthenia Gravis Foundation of America (MGFA) Clinical Classification Class II to IV<br>3. Myasthenia Gravis - Activities of Daily Living (MG-ADL) total score greater than five<br>4. Failure with treatment of one drug in two of the following categories over the course of at least 12 months, unless intolerance or contraindication to all therapies:<br>a. Acetylcholinesterase inhibitors (such as pyridostigmine)<br>b. Non-steroidal immunosuppressive agents (such as azathioprine, methotrexate, cyclosporine, mycophenolate, tacrolimus, cyclophosphamide, or rituximab)<br>c. Corticosteroids (such as prednisone)<br><br>**For patients established on therapy (within the previous year) the following indication-specific criteria must be met:**<br>1. For neuromyelitis optica spectrum disorder (NMOSD): Documentation of positive clinical response to therapy as defined by a reduction in relapses<br>2. For immunoglobulin G4-related disease (IgG4-RD): Documentation of positive clinical response to therapy as defined by a reduction in the frequency of disease flares or reduction in need for glucocorticoid treatment<br>3. For generalized myasthenia gravis (gMG): Improvement in Myasthenia Gravis - Activities of Daily (MG-ADL) by at least two points from baseline (for initial reauthorization) or sustained improvement in Myasthenia Gravis - Activities of Daily (MG-ADL) (subsequent reauthorizations) |
| AGE RESTRICTIONS | May be approved for patients aged 18 years and older |
| PRESCRIBER RESTRICTIONS | For NMOSD, gMG: Must be prescribed by, or in consultation with, a neurologist |
| COVERAGE DURATION | Initial authorization will be approved for three months. Reauthorization will be approved for one year |

5. **ADDYI** (FLIBANSERIN)
   a. New indication approved 12/13/2025:
      i. For the treatment of women less than 65 years of age with acquired, generalized hypoactive sexual desire disorder (HSDD) as characterized by low sexual desire that causes marked distress or interpersonal difficulty and is not due to:
         - A co-existing medical or psychiatric condition
         - Problems within the relationship
         - The effects of a medication or other drug substance

b. **RECOMMENDATION:** Inform prescribers via Medical Policy Alert. Update Commercial/Medicaid 'Medications for Female Sexual Interest and Arousal Disorder' policy with revised indication and criteria.

Prior Authorization for Commercial/Medicaid:

| | |
|---|---|
| PA PROGRAM NAME | Medications for Female Sexual Interest and Arousal Disorder |
| MEDICATION NAME | Addyi |
| COVERED USES | 1 - All FDA-Approved Indications |
| EXCLUSION CRITERIA | For Vyleesi: Uncontrolled hypertension, known cardiovascular disease |
| REQUIRED MEDICAL INFORMATION | For initial authorization, all the following must be met:<br>1. Patient is female ~~and pre-menopausal~~<br>2. Diagnosis of acquired, generalized hypoactive sexual desire disorder (HSDD) or Female Sexual Interest/Arousal Disorder (FSIAD), as characterized by low sexual desire that causes marked distress or interpersonal difficulty for at least six months and is NOT due to:<br>a. A co-existing medical condition (such as sexual pain, bladder dysfunction, endocrine disorders, and central nervous system disease)<br>b. A co-existing psychiatric condition (such as depression, anxiety, history of physical or sexual abuse, and alcohol use)<br>c. A co-existing psychological condition (such as loss of income and bereavement)<br>d. Problems within the relationship<br>e. The effects of a medication or drug substance<br><br>Reauthorization requires documentation of all the following:<br>~~1. Patient continues to be pre-menopausal~~<br>2. Documentation of positive response to the medication |
| AGE RESTRICTIONS | Age must be appropriate based on FDA indication |
| PRESCRIBER RESTRICTIONS | N/A |
| COVERAGE DURATION | Initial authorization will be approved for eight weeks and reauthorization will be approved for one year |

6. **VRAYLAR** (CARIPRAZINE)
   a. New indication approved 12/18/2025:
      i. Treatment of schizophrenia in adults and pediatric patients 13 years of age and older
      ii. Acute treatment of manic or mixed episodes associated with bipolar I disorder in adults and pediatric patients 10 years of age and older

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

7. **MOUNJARO** (TIRZEPATIDE)
   a. New indication approved 12/19/2025:
      i. Indicated as an adjunct to diet and exercise to improve glycemic control in adults and pediatric patients 10 years of age and older with type 2 diabetes mellitus
   b. **RECOMMENDATION:** Inform prescribers via Medical Policy Alert. Update Commercial and Medicaid 'GLP-1 Receptor Agonists and Related Medications for Diabetes' policies with expanded indication. No policy criteria updates warranted.

8. **CABLIVI** (CAPLACIZUMAB-YHDP)
   a. New indication approved 12/23/2025:
      i. For the treatment of adult and pediatric patients 12 years of age and older with acquired thrombotic thrombocytopenic purpura (aTTP), in combination with plasma exchange and immunosuppressive therapy
   b. **RECOMMENDATION:** Inform prescribers via Medical Policy Alert. Update Commercial/Medicaid 'Thrombocytopenia Medications' policy with expanded indication. No policy criteria updates warranted.

9. **IDACIO** (ADALIMUMAB-AACF)
   a. New indication approved 12/23/2025:
      i. Treatment of moderate to severe hidradenitis suppurativa in patients 12 years of age and older
      ii. Treatment of non-infectious intermediate, posterior, and panuveitis in adults and pediatric patients 2 years of age and older
   b. **RECOMMENDATION:** Inform prescribers via Medical Policy Alert. Update Commercial and Medicaid 'Therapeutic Immunomodulators' policy with expanded indication. No policy criteria updates warranted.

10. **CEREZYME** (IMIGLUCERASE)
    a. New indication approved 01/12/2026:
       i. For the treatment of non-central nervous system (CNS) manifestations of Type 1 or Type 3 Gaucher disease in adults and pediatric patients
    b. **RECOMMENDATION:** Inform prescribers via Medical Policy Alert. Expanded indication was reviewed and Commercial/Medicaid/Medicare Part B 'Enzyme Replacement Therapy' policies were updated for April 2026 P&T annual policy review.

11. **NOXAFIL** (POSACONAZOLE)
    a. New indication approved 01/12/2026:
       i. Noxafil is indicated for the treatment of invasive aspergillosis as follows:
          - Noxafil injection: adults and pediatric patients 2 years of age and older who weigh 10 kg or greater
          - Noxafil delayed-release tablets: adults and pediatric patients 2 years of age and older who weigh greater than 40 kg
          - Noxafil PowderMix for delayed-release oral suspension: pediatric patients 2 years of age and older who weigh 10 kg to 40 kg

ii. Noxafil is indicated for the prophylaxis of invasive Aspergillus and Candida infections in patients who are at high risk of developing these infections due to being severely immunocompromised, such as hematopoietic stem cell transplant (HSCT) recipients with graft versus-host disease (GVHD) or those with hematologic malignancies with prolonged neutropenia from chemotherapy as follows:
- Noxafil injection: adults and pediatric patients 2 years of age and older who weigh 10 kg or greater
- Noxafil delayed-release tablets: adults and pediatric patients 2 years of age and older who weigh greater than 40 kg
- Noxafil oral suspension: adults and pediatric patients 13 years of age and older
- Noxafil PowderMix for delayed-release oral suspension: pediatric patients 2 years of age and older who weigh 10 kg to 40 kg

b. **RECOMMENDATION:** Inform prescribers via Medical Policy Alert. Update Commercial/Medicaid 'Antifungal Agents' policy with expanded indication. No policy criteria updates warranted.

Therapies with Prior Authorization Policies (Oncology)

1. **JAYPIRCA** (PIRTOBRUTINIB)
   a. New indication(s) approved 12/02/2025:
      i. Adult patients with relapsed or refractory chronic lymphocytic leukemia or small lymphocytic lymphoma (CLL/SLL) who have previously been treated with a covalent BTK inhibitor.
   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. **AKEEGA** (ABIRATERONE/NIRAPARIB)
   a. New indication(s) approved 12/12/2025:
      i. Indicated with prednisone for the treatment of adult patients with deleterious or suspected deleterious BRCA2-mutated (BRCA2m) metastatic castration-sensitive prostate cancer (mCSPC)
   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. **ENHERTU** (FAM-TRASTUZUMAB DERUXTECAN-NXKI)
   a. New indication(s) approved 12/15/2025:
      i. Indicated in combination with pertuzumab for the first-line treatment of adult patients with unresectable or metastatic HER2-positive (IHC 3+ or ISH+) breast cancer as determined 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.

4. **DARZALEX FASPRO** (DARATUMUMAB/HYALURONIDASE-FIHJ)
   a. New indication(s) approved 01/27/2026:
      i. Indicated in combination with bortezomib, lenalidomide, and dexamethasone (VRd) for the treatment of adult patients with newly diagnosed multiple myeloma who are ineligible for autologous stem cell transplantation

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

Therapies Without Prior Authorization Policies

1. **RECARBRIO** (IMIPENEM/CILASTATIN/RELEBACTAM)
   a. New indication(s) approved 12/09/2025:
      i. Indicated in adult and pediatric patients weighing at least 2 kg for the treatment of the following infections caused by susceptible gram-negative microorganisms:
         - Hospital-acquired bacterial pneumonia and ventilator-associated bacterial pneumonia (HABP/VABP)
         - Complicated urinary tract infections, including pyelonephritis (cUTI) in patients who have limited or no alternative treatment options
         - Complicated intra-abdominal infections (cIAI) in patients who have limited or no alternative treatment options
   b. **RECOMMENDATION:** Inform prescribers via Medical Policy Alert.

2. **ACCRUFER** (FERRIC MALTOL)
   a. New indication(s) approved 12/19/2025:
      i. For the treatment of iron deficiency in adult and pediatric patients 10 years of age and older
   b. **RECOMMENDATION:** Inform prescribers via Medical Policy Alert.

3. **FUROSCIX** (FUROSEMIDE)
   a. New indication(s) approved 12/22/2025:
      i. For the treatment of edema in pediatric patients weighing 43 kg and above and in adult patients with chronic heart failure or chronic kidney disease, including the nephrotic syndrome
   b. **RECOMMENDATION:** Inform prescribers via Medical Policy Alert.

4. **IMPLANON/NEXPLANON** (ETONOGESTREL)
   a. New indication(s) approved 01/16/2026:
      i. For prevention of pregnancy in women of reproductive potential for up to 5 years
   b. **RECOMMENDATION:** Inform prescribers via Medical Policy Alert.

5. **CALDOLOR** (IBUPROFEN)
   a. New indication(s) approved 01/23/2026:
      i. For adults and pediatric patients aged 3 months and older for the:
         - Management of mild to moderate pain, including postoperative pain
         - Management of moderate to severe pain, including postoperative pain, as an adjunct to opioid analgesics
         - Reduction of fever
   b. **RECOMMENDATION:** Inform prescribers via Medical Policy Alert.

## Drug Safety Monitoring:

**FDA Drug Safety Communications**

1. **Drug Name:** Glucagon-Like Peptide-1 Receptor Agonist (GLP-1 RA) Medications
    - **Date Posted:** 01/13/2026
    - **Safety Alert Title:** FDA Requests Removal of Suicidal Behavior and Ideation Warning from Glucagon-Like Peptide-1 Receptor Agonist (GLP-1 RA) Medications
    - **Link to more information:** https://www.fda.gov/drugs/drug-safety-and-availability/fda-requests-removal-suicidal-behavior-and-ideation-warning-glucagon-peptide-1-receptor-agonist-glp
    - **What safety concern is FDA announcing?**
        - FDA is requesting that drug application holders remove information regarding the risk of suicidal ideation and behavior (SI/B) from the labeling of glucagon-like peptide-1 receptor agonist (GLP-1 RA) medications that currently include such language.
        - The affected products are Saxenda (liraglutide), Wegovy (semaglutide), and Zepbound (tirzepatide).
    - **What is FDA doing?**
        - Labeling of GLP-1 RA medications approved for weight reduction in persons with obesity or overweight contains information in the *Warnings and Precautions* section regarding a potential risk of SI/B.
        - In July 2023, after receiving postmarketing reports of SI/B in patients taking GLP-1 RA medications, FDA initiated further investigation of the potential risk of SI/B for GLP-1 RA medications.
        - The initial review of GLP-1 RA clinical trial data did not find an association between the use of GLP-1 RAs and the occurrence of SI/B. However, because of the small number of cases of SI/B observed in individual trials, there was considerable uncertainty in the risk estimate. To address this concern, FDA performed a comprehensive meta-analysis of clinical trials across GLP-1 RA drug development programs to improve the precision of the risk estimate. The meta-analysis assessed the risk of SI/B comparing GLP-1 RA medications to placebo. The results did not show an increased risk for SI/B or for other relevant psychiatric adverse events such as anxiety, depression, irritability, or psychosis.
        - In addition, FDA conducted a retrospective cohort study using administrative healthcare claims data from the FDA Sentinel System to compare the risk of intentional self-harm between new users of GLP-1 RAs and sodium-glucose cotransporter 2 inhibitors (SGLT2i) in patients with type 2 diabetes mellitus. After controlling for baseline confounders in the study, FDA did not find an increased risk of intentional self-harm in GLP-1 RA users compared to SGLT2i users. Similarly, FDA did not find an increased risk in the subgroup of patients with both type 2 diabetes mellitus and obesity.
    - **What should health care professionals do?**
        - Health care professionals should be aware that FDA found no increased risk of SI/B with the use of GLP-1 RA medications and is requesting the removal of this Warning and Precaution from the prescribing information for the GLP-1 RA medications (Saxenda, Wegovy, and Zepbound) that include such language.
        - Health care professionals should be prepared to discuss with patients that FDA has found no increased risk after conducting a comprehensive review of the available data.
        - If individuals disclose that they are experiencing SI/B, refer them to mental health professionals for evaluation.
    - **Health Plan Recommendation:** Notify providers via Medical Policy Alert.

**Drug Recalls/Market Withdrawals**

1. **Drug Name:** ReBoost nasal spray
   - **Date of Recall:** 12/10/2025
   - **Reason for recall:** Product has been found to contain yeast/mold and microbial contamination with one species identified as Achromobacter, at levels above specifications
   - **Link to more information:** https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/medinatura-new-mexico-inc-issues-voluntary-nationwide-recall-reboost-nasal-spray-due-microbial
   - **Health Plan Recommendation:** Notify providers via Medical Policy Alert.

2. **Drug Name:** MR7 Super 700000
   - **Date of Recall:** 12/15/2025
   - **Reason for recall:** Presence of undeclared sildenafil and tadalafil
   - **Link to more information:** https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/stuffbynainax-llc-issues-voluntary-nationwide-recall-mr7-super-700000-dietary-supplement-due
   - **Health Plan Recommendation:** Notify providers via Medical Policy Alert.

3. **Drug Name:** Rheumacare capsules
   - **Date of Recall:** 12/22/2025
   - **Reason for recall:** Elevated levels of lead
   - **Link to more information:** https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/handelnine-global-limited-dba-navafresh-issues-nationwide-recall-rheumacare-capsules-virgo-uap
   - **Health Plan Recommendation:** Notify providers via Medical Policy Alert.

4. **Drug Name:** Silintan capsules
   - **Date of Recall:** 01/07/2026
   - **Reason for recall:** Unapproved new drug found to contain undeclared meloxicam
   - **Link to more information:** https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/anthony-trinh-123herbals-llc-123herbalscom-issues-nationwide-recall-silintan-capsules-due-presence
   - **Health Plan Recommendation:** Notify providers via Medical Policy Alert.

5. **Drug Name:** Modern Warrior Ready dietary supplement
   - **Date of Recall:** 01/09/2026
   - **Reason for recall:** Unapproved new drug found to contain undeclared 1,4-DMAA and aniracetam, and tianeptine
   - **Link to more information:** https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/modern-warrior-recalls-modern-warrior-ready-dietary-supplement-due-undeclared-14-dmaa-and-aniracetam
   - **Health Plan Recommendation:** Notify providers via Medical Policy Alert.