Providence Health Plan

Providence Health Assurance

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

Number 124

November 1, 2026

This is the November 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

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# MEDICAL

## COMPANY POLICIES

*Effective 11/1/2026*

| | |
|---|---|
| **Allergen Subcutaneous Immunotherapy (SCIT)**<br><br>**MP448** | **Policy Updates:** Clarified language in criteria III and IV regarding rapid desensitization for home-based care.<br>**Codes/PA:** No changes to codes and PA |
| **Prostate Specific Antigen**<br><br>**MP319** | **Policy Updates:** Changed "treatment" to "evaluation" in criteria I.B and C.<br>**Codes/PA:** No changes to codes and PA |

## MEDICARE POLICIES

*Effective 11/1/2026*

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|---|---|
| **Autologous Chondrocyte Implantation (ACI) for Cartilaginous Defects of the Knee**<br><br>**MP355** | **Policy Updates:** No change to criteria.<br>**Codes/PA:** Termed PA for CPT 29870. No change to other codes or their configuration |
| **Knee Arthroscopy and Open Procedures**<br><br>**MP435** | **Policy Updates:** No change to criteria, but remove CPT 29870 from scope.<br>**Codes/PA:** Termed PA for CPT 29870. No change to other codes or their configuration |

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|---|---|
| **Ganglion Impar Blocks**<br><br>**MP362** | **Policy Updates:** Replaced LCD L35456 with LCD L40265, which will be finalized 11/1/2026. Services will be considered not medically necessary with this new LCD. No other changes to policy criteria.<br>**Codes/PA:** No change to codes or configuration. Services reported with unlisted code. |
| **Genetic and Molecular Testing**<br><br>**MP317** | **Policy Updates:** Minor wording changes. Added *SERPINA1* gene testing to policy (CPT code already in the policy). Added Tempus xR tests (Heme & Solid Tumor).<br>**Codes/PA:** Removed NMN denial from 0419U. No change to other codes or their configuration. |
| **Genicular Nerve Blocks and Nerve Ablation for Knee Pain**<br><br>**MP354** | **Policy Updates:** Noridian is retiring LCD L35456, and replacing it with a new LCD L40265 as of 11/1/2026. Due to the short time remaining for MA business and 60-day notification requirements, the policy document will be updated with this information, but no code configuration changes will be performed. This policy has already received its final annual review, and because the changes to this policy are significant, the policy was updated as an interim update, rather than a "revision/republication."<br>**Codes/PA:** No change to codes or configuration. See above notes regarding configuration changes. |

## VENDOR UPDATES

*Effective 1/1/27*

| | |
|---|---|
| **Carelon** | **Policy Updates:** Due to PHP sunsetting, vendor contract is ending with Carelon 1/1/27. As such, codes with PA configuration through Carelon are being removed. See PEMC ticket for more information.<br>**Effective:** 1/1/2027 |
| **EviCore** | **Policy Updates:** Due to PHP sunsetting, vendor contract is ending with EviCore 1/1/27. As such, codes with PA configuration through EviCore are being removed. See PEMC ticket for more information.<br>**Effective:** 1/1/2027 |

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

## Pharmacy & Therapeutics (P&T) Committee

Oregon Region P&T Committee Meeting October 2, 2026
Go-Live Date: Friday, January 01, 2027, unless otherwise noted

## Table of Contents:


- Clinical Policy Changes
- Other Formulary Changes
- New Drugs or Combinations
- New Indications Monitoring
- Drug Safety Monitoring


## Clinical Policy Changes:

| MAJOR CHANGES | |
|---|---|
| **Policy Name** | **Policy Change Summary** |
| **Acne Medications - Medicaid** | • Added coverage criteria for treatment of hidradenitis suppurativa (previously unfunded condition).<br>• For acne, updated preferred product options: 1) require failure of topical clindamycin prior to coverage of topical erythromycin and 2) require failure of adapalene prior to coverage of tretinoin.<br>• Removed the following drugs from the formulary: clindamycin/benzoyl peroxide 1-5%, tretinoin 0.025% gel, clindamycin 1% lotion, and sulfacetamide suspension. |
| **Anti-Cancer Medications - Self-Administered** | Update policy to require trial of nilotinib (generic Tasigna) in addition to imatinib for non-preferred products (such as Cavhanza, Danziten, nilotinib d-tartrate, bosutinib, Phyrago, and dasatinib) |

| MAJOR CHANGES | |
|---|---|
| **Policy Name** | **Policy Change Summary** |
| **Antifungal Medications - Medicaid** | Split out policy specific to Medicaid. Criteria will align with Oregon Health Authority criteria that defines medically necessary systemic fungal infections. Flucytosine was added to this policy to ensure appropriate use. In addition, the policy establishes preferred therapies, as indicated, as itraconazole tablet/solution, fluconazole tablet/suspension, and terbinafine tablet. |
| **Complement Inhibitors** | Added criteria for primary immunoglobulin A nephropathy (IgAN) that patients must have stable on a sodium-glucose cotransporter 2 (SGLT2) inhibitor for at least three months. |
| **Constipation Agents – Medicaid** | • Removed references to the Oregon Health Authority (OHA) prioritized list funding line, as the funding line will be retired for 2027. Constipation will be coverable with meeting medical necessity criteria.<br>• For less cost-effective therapies (Trulance, Relistor), added prerequisite therapy requirements. |
| **Continuous Glucose Monitors for Personal Use** | Updated criteria for post-bariatric hypoglycemia. Clarified preferred products are Dexcom and Freestyle Libre. |
| **FcRn Antagonists** | For chronic inflammatory demyelinating polyneuropathy (CIDP): removed “current active disease” wording from criterion for CIDP Disease Activity Status, as a score of 2 indicates remission. |
| **Formulary and Quantity Limit Exceptions - Medicaid** | Removed references to the Oregon Health Authority (OHA) prioritized list funding line, as the funding line will be retired for 2027. |
| **Gene Therapy for Hemophilia** | Removed Beqvez and Roctavian from policy as they have been removed from the market. No clinical changes to policy. |
| **Hyperhidrosis Agents** | Removed references to the Oregon Health Authority (OHA) prioritized list funding line, as the funding line will be retired for 2027. Primary axillary hyperhidrosis is no longer considered unfunded and medical necessity criteria will apply for Medicaid. Coverage criteria reviewed without significant changes. |
| **Infusion Therapy Site of Care** | Removed Radicava from list. |
| **Insomnia Agents - Medicaid** | • Removed references to the Oregon Health Authority (OHA) prioritized list funding line, as the funding line will be retired for 2027. Insomnia will be coverable with meeting medical necessity criteria.<br>• Updated criterion regarding cognitive behavioral therapy (CBT) to require current CBT or brief behavioral treatment or documented failure to multiple interventions. |

| MAJOR CHANGES | |
|---|---|
| **Policy Name** | **Policy Change Summary** |
| | • Added criteria outlining coverage requires either 1) exclusion evaluation for chronic insomnia disorder or 2) documented sleep-wake disorder and request is for melatonin agonist. |
| **Interleukin-1 Inhibitors** | Added prescriber restriction for Medicaid. |
| **Intranasal Allergy Medications – Medicaid** | • Removed references to the Oregon Health Authority (OHA)) prioritized list funding line, as the funding line will be retired for 2027.<br>• Consolidated criteria for all patients (removed separate criteria for EPSDT eligible patients). |
| **Lynkuet, Veozah** | Updated trial and failure criteria for Medicaid to align with Oregon Health Authority. |
| **Medical Nutrition Policy - Medicaid** | • Removed references to the Oregon Health Authority (OHA) prioritized list funding line, as the funding line will be retired for 2027.<br>• Updated criteria to align with OHA criteria and Oregon Administrative Rules (OAR) language. |
| **Medically Infused Therapeutic Immunomodulators - Commercial** | • Updated coverage duration for initial authorization to six months and one year for reauthorization (for all indications).<br>• For asthma: 1) updated criteria for defining uncontrolled asthma, 2) added trial of Cinqair (reslizumab) for Exdensur (depemokinab), 3) removed specific criteria defining positive response to therapy. |
| **Medications for Dry Eye Disease** | New prior authorization policy to align with Oregon Health Authority (OHA) utilization management criteria for dry eye disease medications. Products are newly covered as prioritized list and funding line eliminated for 2027. Medications include cyclosporine 0.005% eye emulsion droperette (preferred therapy), Cequa, Eysuvis, Miebo, Restasis Multidose, Tryptyr, Tyrvaya, Verkazia, Vevye, Xiidra |
| **New Medications and Formulations without Established Benefit** | • Removed obsolete medications.<br>• Removed chlorzoxazone 365 mg and 750 mg from policy and added to formulary without restriction.<br>• Removed Seysara (sarecycline) from policy but will remain non-formulary.<br>• Removed Absorica from policy and added to Commercial formulary without restriction. Abosrica will be managed through Acne medication policy for Medicaid. |
| **Primary Biliary Cholangitis Agents** | Removed reference to "documentation" to be compliant with cost-positioning contract requirements |
| **Saphnelo** | Added criteria requiring use of self-administered formulation instead of intravenous formulation. |

| MAJOR CHANGES | |
|---|---|
| **Policy Name** | **Policy Change Summary** |
| **Second and Third Generation Antihistamines - Medicaid** | • Removed references to the Oregon Health Authority (OHA) prioritized list funding line, as the funding line will be retired for 2027.<br>• Consolidated criteria for all patients (removed separate criteria for EPSDT eligible patients).<br>• Added levocetirizine tablet as a preferred drug. |
| **Therapeutic Immunomodulators - Commercial** | • Added tocilizumab products as co-preferred with adalimumab products.<br>• Defined "established on therapy" as within 90 days.<br>• Updated coverage duration for initial authorization to six months and one year for reauthorization (for all indications).<br>• Added criteria for coverage of ustekinumab every four-week dosing.<br>• Updated prescriber restrictions for several indications.<br>• For asthma/COPD: updated criteria defining uncontrolled disease.<br>• Added/updated diagnostic and/or trial criteria for allergic fungal rhinosinusitis, Behcet's disease, bullous pemphigoid, hidradenitis suppurativa, non-radiographic axial spondyloarthritis, polyarticular juvenile arthritis, psoriatic arthritis, rheumatoid arthritis, and uveitis.<br>• Added specific criteria for other diagnoses not already listed in the policy. |
| **Therapeutic Immunomodulators - Medicaid** | • Removed references to the Oregon Health Authority (OHA) prioritized list funding line, as the funding line will be retired for 2027.<br>• Added Avtozma (tocilizumab-anoh) as co-preferred biosimilar (with Tyenne).<br>• Added criteria for coverage of ustekinumab every four week dosing.<br>• Defined "established on therapy" as within 90 days.<br>• For asthma: updated criteria defining uncontrolled disease.<br>• Updated prescriber restrictions for several indications. Added/updated diagnostic and/or trial criteria for allergic fungal rhinosinusitis, bullous pemphigoid, eosinophilic esophagitis, hidradenitis suppurativa, polyarticular juvenile idiopathic arthritis, and rheumatoid arthritis. |
| **Therapies for Duchenne Muscular Dystrophy** | Updated policy to note that medication is managed directly by the Oregon Health Authority for Medicaid due to being on the High Cost Drug Carve Out List |
| **Topical Agents for Skin Conditions – Medicaid** | • Removed references to the Oregon Health Authority (OHA) prioritized list funding line, as the funding line will be retired for 2027.<br>• Removed criteria specific to the Early and Periodic Screening, Diagnostic and Treatment (EPSDT) benefit. |

| MAJOR CHANGES | |
|---|---|
| **Policy Name** | **Policy Change Summary** |
| | • For atopic dermatitis: require failure to both steroid (2 weeks) and calcineurin inhibitor (4 weeks) and added additional trial of Eucrisa (crisaborole) and Zoryve (roflumilast) for less cost-effective agents, Vtama (tapinarof) and Opzelura (ruxolitinib).<br>• For chronic hand eczema, added requirement of confirmation of moderate to severe condition.<br>• For vitiligo, added requirement that condition affects 10% or less of body surface area and requirment for trial of phototherapy.<br>• For plaque psoriasis: updated required prerequisite therapies to include topical vitamins D analogues, tazarotenem and topcial calcineurin inhibitors (in addition to steroids); added requirement for coverage of less cost-effective therapies (Enstilar, Wynzora, or Vtama) to fail Zoryve.<br>• Added coverage criteria for seborrheic dermatitis (require trial of topical antifungal with either steroid or calcineurin inhibitor). |
| **Transthyretin Lowering Agents** | • Updated exclusions to reflect contraindications per package insert.<br>• Added criteria for Polyneuropathy of Hereditary Transthyretin-mediated Amyloidosis to confirm that peripheral neuropathy is not caused by scondary condition. |
| **Xiaflex** | • Removed references to the Oregon Health Authority (OHA) prioritized list funding line, as the funding line will be retired for 2027. Peyronie's disease is no longer considered unfunded and medical necessity criteria will apply for Medicaid.<br>• Coverage criteria reviewed without significant changes |

## Other Formulary Changes:

| Drug Name | Recommendation | Policy Name |
|---|---|---|
| **Budesonide/glycopyr/formoterol (Breztri Aerosphere) HFA AER AD** | Commercial: Add to Formulary, Tier 3<br>Effective 11/1/2026 | N/A |
| **Insulin aspart/b3/pump cart (Fiasp Pumpcart) Cartridge** | Commercial: add in parity with other Fiasp products, Formulary, Tier 3<br>Effective 11/1/2026 | N/A |
| **Ranibizumab-leyk (Nufymco) Vial** | New biosimilar; non-preferred<br>• Commercial/Medicaid/Medicare Part B: Medical Prior Authorization<br>• Medicare Part D: Non-Formulary | Ophthalmic Vascular Endothelial Growth Factor (VEGF) Inhibitors |

| Drug Name | Recommendation | Policy Name |
|---|---|---|
| **Nilotinib (Cavhanza) Tab Rapdis** | New dosage form (tab rapdis); non-preferred<br>• Commercial/Medicaid: Non-Formulary, Prior Authorization, Quantity Limit (4 tablets per day)<br>• Medicare Part D: Formulary, Tier 5, Prior Authorization, Quantity Limit (4 tablets per day) | Self-Administered Anti-Cancer Medication Policy |
| **Fulvestrant (Cligavyx) Syringe** | New branded fulvestrant product;<br>• Commercial/Medicaid/Medicare Part B: Medical, Prior Authorization<br>• Medicare Part D: Non-Formulary | Anti-Cancer Medications - Medical Benefit<br>• Added as non-preferred product behind fulvestrant (J9393, J9394, J9395) |
| **Fosaprepitant dimeglumine (Navitrux) Vial** | New brand fosaprepitant;<br>• Commercial/Medicaid/Medicare Part B: Medical Prior Authorization<br>• Medicare Part D: Non-Formulary | Anti-Cancer Medications - Medical Benefit<br>• Added as non-preferred product behind fosaprepitant (J1453) |
| **Revtorpyk Vial** | New entity;<br>• Commercial/Medicaid/Medicare Part B: Medical Prior Authorization<br>• Medicare Part D: Non-Formulary | Anti-Cancer Medications - Medical Benefit |
| **Clotrimazole (Clotic) Droperette** | New formulation;<br>• Commercial/Medicaid/Medicare Part D: Non-Formulary | N/A |
| **Duloxetine HCl Capsule DR** | New strengths (80 mg; 90 mg; 120 mg);<br>• Commercial/Medicaid/Medicare Part D: Non-Formulary | N/A |
| **Omalizumab-igec (Omlyclo) Syringe** | New biosimilar for Xolair;<br>• Commercial: Non-Formulary, Prior Authorization, Quantity Limit (one injection per 28 days)<br>• Medicaid: Formulary, Prior Authorization, Quantity Limit (one injection per 28 days)<br>• Medicare Part D: Non-Formulary | Therapeutic Immunomodulators |
| **Isatuximab-irfc (Sarclisa Escena) Vial** | New subQ version;<br>• Commercial/Medicaid/Medicare Part B: Medical, Prior Authorization<br>• Medicare Part D: Non-Formulary | Anti-Cancer Medications - Medical Benefit |

| Drug Name | Recommendation | Policy Name |
|---|---|---|
| **Isotretinoin (Absorica) 10 mg; 20 mg; 40 mg Capsules** | • Commercial: Add to Formulary, Tier 2<br>• Medicaid: Add generic to Formulary, Prior Authorization (age ≥21 years) | • Commercial: N/A<br>• Medicaid: Acne Medications |
| **Isotretinoin (Absorica) 30 mg Capsule** | • Commercial Dynamic: Move from Tier 4 to Tier 2 | N/A |
| **Chlorzoxazone Tablet** | • Commercial: Add to Formulary, Tier 2<br>• Medicaid: Add to Formulary | N/A |
| • **Ustekinumab-hmny (Starjemza) 45mg/0.5mL Vial**<br>• **Ustekinumab-hmny (Starjemza) 90mg/mL Syringe** | Add as preferred ustekinumab biosimilar<br>• Commercial: Add to Formulary, Tier 5, Prior Authorization, Quantity Limit (one injection per 84 days)<br>• Medicaid: Add to Formulary, Prior Authorization, Quantity Limit (one injection per 84 days) | Therapeutic Immunomodulators (TIMS) |
| **Ustekinumab-stba (Steqeyma) 45mg/0.5mL Syringe** | Medicare Part D: Down-tier to Tier 4 from Tier 5 | Therapeutic Immunomodulators (TIMS) |
| **Eplontersen sodium (Wainua) 45mg/0.8mL Auto Injct** | Commercial: Add to Formulary, Tier 6 | Transthyretin (TTR) Lowering Agents |
| **Omalizumab (Xolair) 75mg/0.5ml; 150 mg/mL Auto Injct/Syringe** | Add to Medicaid formulary | Therapeutic Immunomodulators (TIMS) |
| • **Elafibranor (Iqirvo) Tablet**<br>• **Seladelpar lysine (Livdelzi) Capsule** | Commercial: Add to Formulary, Tier 5<br>Effective: 9/1/2026 - Approved by chair vote | Primary Biliary Cholangitis Agents |
| **Tepmetko (tepotinib) tablet** | Commercial: Move to Tier 5 from Tier 6 | Anti-Cancer Agents – Self-Administered |
| • **Clindamycin phosphate 1 % Lotion**<br>• **Clindamycin/benzoyl peroxide 1%-5% Gel/Gel w/Pump**<br>• **Clindamycin/benzoyl peroxide 1.2%-2.5% Gel w/Pump**<br>• **Crofelemer (Mytesi) Tablet DR**<br>• **Diphenoxylate/atropine Liquid**<br>• **Fluorometholone (FML Forte) Drops Susp**<br>• **Griseofulvin Oral Susp and Tablet**<br>• **Guaifenesin/dextromethorphan/phenylephrine Liquid**<br>• **Hydrocodone/homatropine Tablet**<br>• **Ketorolac tromethamine Drops** | Remove from Medicaid formulary | N/A |

| Drug Name | Recommendation | Policy Name |
|---|---|---|
| • **Loperamide Capsule**<br>• **Opium Tincture**<br>• **Prednisolone acetate (Pred Mild) Drops Susp**<br>• **Promethazine/codeine Syrup**<br>• **Promethazine/dextromethorphan Solution**<br>• **Promethazine-phenylephrine Syrup**<br>• **Tretinoin 0.025% Gel (Gram)** | | |
| • **Aluminum chloride 20% Solution**<br>• **Azelaic Acid 15% Gel (Gram)**<br>• **Ciclopirox 0.77% Cream**<br>• **Ciclopirox 8% Topical Solution**<br>• **Cromolyn Sodium 4% Eye Drops**<br>• **Levocetirizine dihydrochloride Tablet**<br>• **Metronidazole 0.75% Gel w/Appl; Gel; and Cream** | Add to Medicaid formulary | N/A |
| **Cyclosporine 0.05 % Droperette** | Add to Medicaid formulary | Medications for Dry Eye Disease |
| **Nitisinone (Nityr) Tablet** | Remove from Commercial and Medicaid formularies<br>Approved by chair vote | 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 7/10/2026 – 8/14/2026**

**INFORMATIONAL ONLY**

| NEW DRUGS / COMBINATIONS / STRENGTHS / DOSAGE FORMS | | |
|---|---|---|
| **Drug Name** | **Action Taken** | **Policy Name** |
| **Aflibercept-jbvf (Yesafili) Syringe** | New biosimilar. Line extend as non-preferred VEGF;<br>• Commercial/Medicaid/Medicare Part B: Medical Prior Authorization<br>• Medicare Part D: Non-Formulary | • Commercial/Medicaid: Ophthalmic Vascular Endothelial Growth Factor (VEGF) Inhibitors<br>• Medicare Part B: Ophthalmic Vascular Endothelial Growth Factor (VEGF) Inhibitors Prior Authorization and Step Therapy Policy |
| **Doxycycline hyclate Capsule** | New strength (75 mg). Line extend with doxycycline hyclate 75mg tablet;<br>• Non-Formulary for all lines of business | N/A |

| NEW DRUGS / COMBINATIONS / STRENGTHS / DOSAGE FORMS | | |
|---|---|---|
| **Drug Name** | **Action Taken** | **Policy Name** |
| **Furosemide (Furoscix Readyflow) Auto Injct** | New dosage form (auto injc). Line extend with Furoscix On-Body;<br>• Commercial/Medicaid: Non-Formulary, Specialty<br>• Medicare Part D: Non-Formulary | N/A |
| **Norelgestromin/ethin.estradiol (Gwyn Lo) Patch TDWK** | New formulation. Line extend with brand Ortho Evra Patch;<br>• Commercial: Preventive<br>• Medicaid: Formulary<br>• Medicare Part D: Non-Formulary | N/A |
| **Tapentadol hcl Solution** | New strength (20 mg/mL) and dosage form (solution). Line extend with tapentadol tablets;<br>• Commercial/Medicaid: Non-Formulary, Quantity Limit (30 mL per day)<br>• Medicare Part D: Non-Formulary | N/A |
| **Thiotepa (Tepadina) Plast. Bag** | New strength (400 mg). Line extend with Tepadina;<br>• Medical benefit for all lines of business | N/A |
| **Ursodiol (Ursolign) Capsule** | New strength (150 mg). Line extend with ursodiol 200mg and 400mg capsules;<br>• Non-Formulary for all lines of business | N/A |
| **Lecanemab-irmb (Leqembi Iqlik) Auto Injct** | New strength (500 MG/2.5). Line extend with Leqembi Iqlik 360mg/1.8ml;<br>• Commercial/Medicaid: Non-Formulary, Prior Authorization, Specialty<br>• Medicare Part D: Non-Formulary | • Commercial/Medicaid: Anti-Amyloid Monoclonal Antibodies<br>• Medicare Part D: N/A |
| **Fluorouracil (Favlyxa) Vial** | New strength (2.5g/100mL). Line extend with Favlyxa;<br>• Medical benefit for all lines of business | • Commercial/Medicaid: Anti-Cancer Medications - Medical Benefit<br>• Medicare Part B: Anti-Cancer Medications Prior Authorization and Step Therapy Policy |
| **Tislelizumab-jsgr (Tevimbra) Vial** | New strength (150mg/15mL). Line extend with Tevimbra;<br>• Medical benefit for all lines of business | • Commercial/Medicaid: Anti-Cancer Medications - Medical Benefit<br>• Medicare Part B: Anti-Cancer Medications Prior Authorization and Step Therapy Policy |

| NEW DRUGS / COMBINATIONS / STRENGTHS / DOSAGE FORMS | | |
|---|---|---|
| **Drug Name** | **Action Taken** | **Policy Name** |
| **Ropeginterferon alfa-2b-njft (Besremi Pen) Pen Injctr** | New dosage form (pen inctr). Line extend with Besremi injection;<br>• Commercial: Formulary, Tier 6, Prior Authorization, Quantity Limit (1 ml per 28 days)<br>• Medicaid: Non-Formulary, Prior Authorization, Quantity Limit (1 ml per 28 days), Specialty<br>• Medicare Part D: Formulary, Tier 5, Prior Authorization, Quantity Limit (1 ml per 28 days) | Anti-Cancer Medications - Self-Administered |
| **Axatilimab-csfr (Niktimvo) Vial** | New strength (22 mg/2.2mL). Line extend with Niktimvo;<br>• Medical Prior Authorization for all lines of business | • Commercial/Medicaid: Medications For Graft-versus-Host-Disease<br>• Medicare Part B: Medications for Graft-versus-Host-Disease Prior Authorization and Step Therapy Policy |
| **Buspirone hcl (Bucapsol) Capsule** | New strength (5 mg). Line extend with existing strengths of Bucapsol;<br>• Commercial: Non-Formulary, Prior Authorization<br>• Medicaid/Medicare Part D: Non-Formulary | • Commercial: New Medications and Formulations without Established Benefit<br>• Medicaid/Medicare Part D: N/A |
| **Selexipag (Uptravi) Tablet** | New strengths (100 mcg and 150 mcg). Line extend with existing strengths of Uptravi;<br>• Commercial: Formulary, Tier 5, Prior Authorization, Quantity Limit (2 tablets per day)<br>• Medicaid: Formulary, Prior Authorization, Quantity Limit (2 tablets per day), Specialty<br>• Medicare Part D: Non-Formulary | • Commercial/Medicaid: Pulmonary Hypertension<br>• Medicare Part D: N/A |
| **Olezarsen sodium (Tryngolza) Auto Injct** | New strength (50 mg/0.8 ml). Line extend with Tryngolza 80mg/0.8ml;<br>• Commercial/Medicaid: Non-Formulary, Prior Authorization, Quantity Limit (0.8 mL per 28 days), Specialty<br>• Medicare Part D: Non-Formulary | • Commercial/Medicaid: Redemplo, Tryngolza<br>• Medicare Part D: N/A |
| **Ustekinumab-aauz (Otulfi) Vial** | New formulation (single dose vial). Line extend with Otulfi 45mg/0.5ml syringe; | • Commercial/Medicaid: Therapeutic Immunomodulators (TIMS)<br>• Medicare Part D: N/A |

| NEW DRUGS / COMBINATIONS / STRENGTHS / DOSAGE FORMS | | |
|---|---|---|
| **Drug Name** | **Action Taken** | **Policy Name** |
| | • Commercial/Medicaid: Non-Formulary, Prior Authorization, Quantity Limit (0.5 mL per 84 days)<br>• Medicare Part D: Non-Formulary | |

| NEW GENERICS | | |
|---|---|---|
| **Drug Name** | **Action Taken** | **Policy Name** |
| **Ferric carboxymaltose Vial** | New generic (injectafer). Line extend as generic;<br>• Medical benefit for all lines of business | N/A |
| **Mesalamine (Mesalamine ER) Capsule ER** | New generic (Pentasa). Line extend as generic;<br>• Commercial: Non-Formulary, Quantity Limit (16 capsules per day)<br>• Medicaid/Medicare Part D: Non-Formulary | N/A |
| **Thyroid, pork (Amerithroid) Tablet** | New generic (Armour Thyroid). Line extend as generic;<br>• Commercial: Formulary, Tier 2<br>• Medicaid: Formulary<br>• Medicare Part D: Formulary, Tier 4 | N/A |
| **Atomoxetine hcl Solution** | New generic (Atoncy). Line extend with brand Atoncy;<br>• Non-Formulary for all lines of business | N/A |
| **Dextromethorphan hbr-quinidine** | New generic. Line extend with brand Nuedexta;<br>• Commercial Standard: Formulary, Tier 2, Quantity Limit (2 capsules per day)<br>• Commercial Dynamic: Formulary, Tier 4, Quantity Limit (2 capsules per day)<br>• Medicaid: Non-Formulary<br>• Medicare Part D: Formulary, Tier 5, Quantity Limit (2 capsules per day) | N/A |
| **Rifapentine Tablet** | New generic (Priftin). Line extend as generic;<br>• Commercial Standard: Formulary, Tier 2,<br>• Commercial Dynamic: Formulary, Tier 4,<br>• Medicaid: Non-Formulary | N/A |

| NEW GENERICS | | |
|---|---|---|
| **Drug Name** | **Action Taken** | **Policy Name** |
| | • Medicare Part D: Formulary, Tier 4 | |
| **Dimethyl sulfoxide 50% Solution** | New generic (RIMSO-50). Line extend as generic;<br>• Medical benefit for all lines of business | N/A |
| **Sitagliptin phos-metformin ER TBMP 24hr** | New generic (Janumet XR). Line extend as generic;<br>• Commercial/Medicaid: Non-Formulary, Quantity Limit (1 tablet per day)<br>• Medicare Part D: Formulary, Tier 3, Quantity Limit (1 tablet per day) | N/A |
| **Prednisone Tablet DR** | New generic (Rayos). Line extend as generic;<br>• Commercial/Medicaid: Non-Formulary, Prior Authorization<br>• Medicare Part D: Non-Formulary | • Commercial/ Medicaid: New Medications and Formulations without Established Benefit<br>• Medicare Part D: N/A |

## New Drugs or Combinations:

1. **Atacicept-vymj (Trutakna) Auto Injct**
   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** | 4 mL per 28 days | 4 mL per 28 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:** N/A | | | |

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

| | |
|---|---|
| PA PROGRAM NAME | Filspari, Vanrafia, Voyxact, Trutakna |

| | |
|---|---|
| MEDICATION NAME | Trutakna (atacicept) |
| COVERED USES | All Food and Drug Administration (FDA). |
| EXCLUSION CRITERIA | Atacicept and sibeprenlimab should not be administered concurrently due to lack of clinical trial data supporting additive efficacy |
| REQUIRED MEDICAL INFORMATION | For initial authorization, sparsentan (Filsapri), atrasentan (Vanrafia), sibeprenlimab-szsi (Voyxact), atacicept-vymj (Trutakna) may be covered when all the following criteria are met:<br>1. Diagnosis of primary immunoglobulin A nephropathy (IgAN), confirmed by biopsy<br>2. Failure of a renin-angiotensin-aldosterone system (RAAS) inhibitor (e.g., irbesartan, losartan, lisinopril, benazepril) for at least 12 weeks<br>3. Failure of a 12-week trial of a sodium-glucose cotransporter-2 (SGLT2) inhibitor (e.g., empagliflozin, dapagliflozin) at up to maximally indicated doses, unless clinically significant adverse effects are experienced or all are contraindicated<br>4. Patient is at high risk of disease progression, defined as one of the following:<br>a. Urine protein-to-creatinine ratio greater than or equal to 0.5 g/g<br>b. Proteinuria greater than or equal to 0.5 g/day<br>5. eGFR greater than or equal to 30 mL/min/1.73m^2<br>6. For sparsentan (Filspari): provider attestation that ACEi or ARB will be discontinued before sparsentan therapy is initiated<br>7. For sibeprenlimab (Voyxact): documented trial and failure, intolerance, or contraindication to sparsentan (Filspari) or atrasentan (Vanrafia)<br>Reauthorization for all indications: Documentation of positive response to therapy |
| AGE RESTRICTIONS | Age must be appropriate per FDA label |
| PRESCRIBER RESTRICTIONS | Must be prescribed by, or in consultation with, a nephrologist |
| COVERAGE DURATION | Initial authorization and reauthorization will be approved for one year |

2. **Insulin icodec-abae (Awiqli FlexTouch) Insulin Pen**
   a. **Indication:** An adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus.
   b. **Decision:**

| | Commercial | Medicaid | Medicare |
|---|---|---|---|
| **Formulary Status*** | | 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** | N/A | N/A | N/A |
| **Quantity Limit** | N/A | 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**: insulin glargine, insulin degludec | | | |

3. **Allogeneic regulatory T cell immunotherapy with HSPC and T cells-vldq (Tregzi) Plast. Bag**
   a. **Indication:** For use in matched donor hematopoietic stem cell transplantation with myeloablative preparative regimen, for hematopoietic and immunologic reconstitution and to improve chronic graft-versus-host disease-free survival, in the treatment of adults with hematological malignancies.
   b. **Decision:**

| | **Commercial** | **Medicaid** | **Medicare** |
|---|---|---|---|
| **Formulary Status*** | Medical | Medical | Part D: Non-formulary<br>Part B: Medical |
| **Tier**** | N/A | N/A | N/A |
| **Affordable Care Act Eligible** | No | N/A | N/A |
| **Utilization Management Edits** | Prior Authorization | Prior Authorization | Prior Authorization |
| **Quantity Limit** | One Treatment per Lifetime | One Treatment per Lifetime | One Treatment per Lifetime |
| * 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**: None | | | |

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

| | |
|---|---|
| PA PROGRAM NAME | T-Cell Therapy |
| MEDICATION NAME | Allogeneic regulatory T cell immunotherapy with HSPC and T cells-vldq (Tregzi) |
| PA INDICATION INDICATOR | 1 - All FDA-Approved Indications |
| EXCLUSION CRITERIA | For Tregzi: Patient has not previously received an allogeneic hematopoietic stem cell transplant (allo-HSCT). Repeat administration of Tregzi is not considered medically necessary as the effectiveness of this approach has not been established. |
| REQUIRED MEDICAL INFORMATION | For all requests, the following criteria must be met: |

| | |
|---|---|
| | • Use must be for an indication supported by National Comprehensive Cancer Network (NCCN) guidelines with recommendation 2A or higher<br>  ○ For Tregzi: must be used to treat acute lymphocytic leukemia (ALL), acute myeloid leukemia (AML), mixed-phenotype acute leukemia (MPAL), or myelodysplastic syndrome (MDS)<br>• Documentation of adequate bone marrow, cardiac, pulmonary and organ function (such as kidney, liver)<br>• One of the following regarding functional status must be met:<br>  ○ For Kymriah for B-cell precursor acute lymphoblastic leukemia (ALL) only: Karnofsky or Lansky Scale greater than or equal to 50%<br>  ○ Provider attestation/documentation that the patient's functional status is sufficient to undergo treatment. This may include but is not limited to a documented Eastern Cooperative Oncology Group (ECOG) performance status of 0-1, Karnofsky or Lansky Scale greater than or equal to 50%, or a written statement acknowledging that the patient is fit to tolerate therapy.<br>• No evidence of active infection or inflammatory disorder (including hepatitis B or C, active graft vs. host disease) |
| AGE RESTRICTIONS | Age must be appropriate based on FDA-approved indication |
| PRESCRIBER RESTRICTIONS | Must be prescribed by, or in consultation with, an oncologist |
| COVERAGE DURATION | Two months (limited to one treatment course per lifetime) |

4. **Enlicitide decanoate (Lipfendra) Tablet**
   a. **Indication:** As an adjunct to diet and exercise to reduce low-density lipoprotein cholesterol (LDL-C) in adults with hypercholesterolemia (HC), including heterozygous familial.
   b. **Decision:**

| | Commercial | Medicaid | Medicare |
|---|---|---|---|
| **Formulary Status*** | Non-formulary | Formulary | Part D: Non-formulary |
| **Tier**** | N/A | N/A | N/A |
| **Affordable Care Act Eligible** | N/A; Non-Formulary | N/A | N/A |
| **Utilization Management Edits** | Prior Authorization | Prior Authorization | N/A |
| **Quantity Limit** | One tablet per day | One tablet per day | 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**: evolocumab (Repatha) | | | |

c. **Prior Authorization Criteria for Commercial:** Added to PCSK-9 Inhibitor policy as non-preferred therapy
d. **Prior Authorization Criteria for Medicaid:** Added to PCSK-9 Inhibitor policy as preferred therapy

5. **Etuvetidigene autotemcel (Waskyra) Plast. Bag**
   a. **Indication:** For the treatment of pediatric patients aged 6 months and older and adults with Wiskott-Aldrich Syndrome (WAS) who have a mutation in the WAS gene for whom hematopoietic stem cell transplantation (HSCT) is appropriate and no suitable human leukocyte antigen (HLA)-matched hematopoietic related stem cell donor is available.
   b. **Decision:**

| | Commercial | Medicaid | Medicare |
|---|---|---|---|
| **Formulary Status*** | Medical | State Carve-Out | Part D: Non-formulary<br>Part B: Medical |
| **Tier**** | N/A | N/A | N/A |
| **Affordable Care Act Eligible** | No | N/A | N/A |
| **Utilization Management Edits** | Prior Authorization | N/A | Prior Authorization |
| **Quantity Limit** | N/A | 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**: None | | | |

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

| | |
|---|---|
| PA PROGRAM NAME | Medications for Rare Indications |
| MEDICATION NAME | Etuvetidigene autotemcel injection (Waskyra) |
| PA INDICATION INDICATOR | 1 - All FDA-Approved Indications |
| OFF-LABEL USES | N/A |
| EXCLUSION CRITERIA | For Waskyra:<br>• Cytogenetic alterations characteristic of myelodysplastic syndrome and acute myeloid leukemia<br>• Prior hematopoietic stem cell transplantation within 6 months or evidence of residual cells of donor origin<br>• Prior treatment with gene therapy |
| REQUIRED MEDICAL INFORMATION | INITIAL AUTHORIZATION CRITERIA: both of the following must be met:<br>1. Confirmation of FDA-labeled indication and drug-specific criteria |

| | |
|---|---|
| | 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<br>3. Drug-specific criteria:<br>• Classic Wiskott-Aldrich Syndrome (WAS), confirmed by one of the following:<br>○ Severe WAS mutation<br>○ Absent of WAS protein (WASP) expression (defined as <5% of lymphocytes expressing WASP)<br>○ Severe clinical score (Zhu clinical score ≥3)<br><br>REAUTHORIZATION CRITERIA: all the following must be met:<br>1. Documentation of successful response to therapy<br>2. Dosing is within FDA-labeled guidelines OR documentation has been submitted in support of therapy with a higher dose for the intended diagnosis such as high-quality peer reviewed literature, guidelines, other clinical information |
| AGE RESTRICTIONS | Age must be appropriate based on FDA-approved indication |
| PRESCRIBER RESTRICTIONS | Must be prescribed by, or in consultation with a specialist in the respective disease state |
| COVERAGE DURATION | Authorization is limited to one treatment course per lifetime. Approval duration will be for 12 weeks. |

6. **Finafloxacin (Xtoro) Drops Susp**
   a. **Indication:** For the treatment of acute otitis externa (AOE) caused by susceptible strains of *Pseudomonas aeruginosa* and *Staphylococcus aureus*.
   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** | N/A | N/A | N/A |
| **Quantity Limit** | N/A | 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**: ofloxacin, ciprofloxacin/hydrocortisone, neomycin/polymyxin/hydrocortisone, ciprofloxacin/dexamethasone | | | |

7. **Influenza vaccine, mRNA injection, suspension (mFLUSIVA 2026-2027) Syringe (Informational)**
    a. **Indication:** Active immunization for the prevention of influenza disease caused by influenza virus subtypes A and type B represented in the vaccine. Approved for use in persons 50 years of age and older. For persons 65 years of age and older is approved under accelerated approval based on immune responses. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial.
        - Vaccine is covered in full for patients age ≥50 years per Federal rules and requirements

8. **Gedatolisib (Revtorpyk) Vial**
    a. **Indication:** For the treatment of adult patients with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative locally advanced or metastatic breast cancer without a PIK3CA mutation detected following progression on or after treatment with at least one line of endocrine therapy in the metastatic setting.
    b. **Decision:**

| | Commercial | Medicaid | Medicare |
|---|---|---|---|
| **Formulary Status*** | Medical | Medical | **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.<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**: N/A | | | |

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

9. **Iberdomide hcl (Zenbexus) Capsule**
    a. **Indication:** For the treatment of adult patients with multiple myeloma who have received at least one prior line of therapy including a proteasome inhibitor and an immunomodulatory agent
    b. **Decision:**

| | Commercial | Medicaid | Medicare |
|---|---|---|---|
| **Formulary Status*** | Formulary | Formulary | Part D: Formulary<br>Part B: N/A |
| **Tier**** | Tier 6 - Non-Preferred Specialty | N/A | Specialty |
| **Affordable Care Act Eligible** | N/A; Non-Formulary | N/A | N/A |

| | | | |
|---|---|---|---|
| **Utilization Management Edits** | Prior Authorization | Prior Authorization | Prior Authorization |
| **Quantity Limit** | 21 capsules per 28 days | 21 capsules per 28 days | 21 capsules per 28 days |
| * 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**: N/A | | | |

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

10. **Linerixibat (Lynavoy) Tablet**
    a. **Indication: For the treatment of cholestatic pruritus associated with primary biliary cholangitis (PBC) in adult patients.**
    b. **Decision:**

| | **Commercial** | **Medicaid** | **Medicare** |
|---|---|---|---|
| **Formulary Status*** | Non-formulary | Non-formulary | Part D: Non-formulary |
| **Tier**** | N/A | N/A | N/A |
| **Affordable Care Act Eligible** | N/A; Non-Formulary | N/A | N/A |
| **Utilization Management Edits** | Prior Authorization | Prior Authorization | N/A |
| **Quantity Limit** | Two tablets per day | Two tablets per day | 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**: Livdelzi, cholestyramine, colestipol, naltrexone, rifampin, sertraline | | | |

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

| | |
|---|---|
| PA PROGRAM NAME | Primary Biliary Cholangitis Agents |
| MEDICATION NAME | Linerixibat (Lynavoy) tablet |
| PA INDICATION INDICATOR | 1 - All FDA-Approved Indications |
| EXCLUSION CRITERIA | 1. Decompensated cirrhosis (such as Child-Pugh Class B or C) or a prior decompensated event<br>2. Combination of Livdelzi, Iqirvo, and/or Lynavoy<br>3. For Livdelzi and Iqirvo: non-alcoholic steatohepatitis (NASH); |

| | |
|---|---|
| REQUIRED MEDICAL INFORMATION | For initial authorization, all the following criteria must be met:<br>1. Confirmed diagnosis of primary biliary cholangitis as evidenced by two (2) of the following criteria:<br>a. Elevated alkaline phosphatase (ALP) [above the upper limit of normal (ULN) as defined by laboratory reference values]<br>b. Presence of antimitochondrial antibody (AMA)<br>c. Histologic evidence of primary biliary cholangitis from liver biopsy<br>2. For Iqirvo and Livdelzi, both of the following must be met:<br>a. Inadequate response to 12 months of ursodiol according to prescribing physician, unless patient is unable to tolerate ursodiol<br>b. Documentation that the medication will be used in combination with ursodiol, unless patient is unable to tolerate ursodiol<br>3. For Lynavoy:<br>a. Moderate to severe cholestatic pruritus as defined by a Worst Itch Numerical Rating Scale (WI-NRS) score of at least 4<br>b. Inadequate response (after at least 14 days each) to at least two of the following or an intolerance or contraindication to all the following: bile acid sequestrants (cholestyramine or colestipol), naltrexone, rifampin, or sertraline<br>c. Inadequate response (after at least one month) to seladelpar (Livdelzi)<br><br>For reauthorization:<br>1. For Iqirvo and Livdelzi, all the following criteria must be met:<br>a. Maintenance of biochemical response, defined as all the following:<br>i. Alkaline phosphatase (ALP) less than or equal to 1.67 times the upper limit of normal (ULN)<br>ii. Total bilirubin (tBili) less than or equal to ULN<br>iii. ALP decrease of at least 15%<br>b. Documentation that ursodiol will be continued, if tolerated<br>c. Hepatic function is assessed at least annually<br>2. For Lynavoy:<br>a. Response to therapy as indicated by a reduction in the Worst Itch Numerical Rating Scale (WI-NRS) score of at least 3 points |
| AGE RESTRICTIONS | Age must be appropriate based on FDA-approved indication |
| PRESCRIBER RESTRICTIONS | Must be prescribed by, or in consultation with, a gastroenterologist or hepatologist. |
| COVERAGE DURATION | Initial authorization will be approved for six months. Reauthorization will be approved for one year. |

11. **Veligrotug-vvze (Lumvoa) Vial**
    a. **Indication:** For treatment of thyroid eye disease (TED) regardless of thyroid eye disease activity or duration.
    b. **Decision:**

| | Commercial | Medicaid | Medicare |
|---|---|---|---|
| **Formulary Status*** | Medical | Medical | Part D: Non-formulary<br>Part B: Medical |
| **Tier**** | N/A | N/A | Specialty |
| **Affordable Care Act Eligible** | No | N/A | N/A |
| **Utilization Management Edits** | Prior Authorization | Prior Authorization | Prior Authorization |
| **Quantity Limit** | 5 total infusions per lifetime | 5 total infusions per lifetime | 5 total infusions per lifetime |
| * 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:** Tepezza (medical benefit) | | | |

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

| | |
|---|---|
| PA PROGRAM NAME | Tepezza, Lumvoa |
| MEDICATION NAME | Veligrotug (Lumvoa) |
| PA INDICATION INDICATOR | 1 - All FDA-Approved Indications |
| EXCLUSION CRITERIA | Concomitant use of teprotumumab and veligrotug |
| REQUIRED MEDICAL INFORMATION | For initiation of therapy (new starts), must meet all the following criteria:<br>1. Confirmed diagnosis of moderate-to-severe thyroid eye disease/Grave's Orbitopathy, as defined as eye disease that significantly impacts quality of life and at least one of the following:<br>a. Lid retraction of at least 2 mm<br>b. Moderate or severe soft-tissue involvement (such as swelling or redness of the eyes)<br>c. Proptosis of at least 3 mm above normal for race or sex<br>d. Inconstant diplopia (diplopia at extremes of gaze) or constant diplopia (continuous diplopia in primary or reading position)<br>2. Laboratory evidence of euthyroid state or T4 (thyroxine) and free T3 (triiodothyronine) levels less than 50% above or below normal limits<br>3. For patients without diplopia or significant proptosis: Inadequate response to at least two weeks of therapy with high-dose intravenous (IV) glucocorticoid therapy (equivalent to methylprednisolone 0.5 g once weekly) unless there is a contraindication or intolerance |

| | |
|---|---|
| | 4. No previous treatment with veligrotug or teprotumumab<br>For patients established on the requested therapy (within the previous year): Documentation that the member has not received 8 doses of Tepezza or 5 doses of Lumvoa |
| AGE RESTRICTIONS | Age must be appropriate based on FDA-approved indication |
| PRESCRIBER RESTRICTIONS | Must be prescribed by, or in consultation with, an ophthalmologist |
| COVERAGE DURATION | Authorization will be approved for six months for a total of up to eight infusions for teprotumumab or five infusions for veligrotug |

12. **Zidesamtinib (Jideytro) Tablet**
    a. **Indication:** For the treatment of adults with locally advanced or metastatic ROS1-positive (ROS1+) non–small cell lung cancer (NSCLC) who have received a prior ROS1 TKI.
    b. **Decision:**

| | Commercial | Medicaid | Medicare |
|---|---|---|---|
| **Formulary Status*** | Formulary | Formulary | Part D: Formulary<br>Part B: N/A |
| **Tier**** | Tier 6 - Non-Preferred Specialty | N/A | Specialty |
| **Affordable Care Act Eligible** | N/A; Non-Formulary | N/A | N/A |
| **Utilization Management Edits** | Prior Authorization | Prior Authorization | Prior Authorization |
| **Quantity Limit** | 100 mg: 1 tablet per day<br>25 mg: 3 tablets per day | 100 mg: 1 tablet per day<br>25 mg: 3 tablets per day | 100 mg: 1 tablet per day<br>25 mg: 3 tablets per day |
| * 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**: Ibtrozi, Augtyro | | | |

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

## New Indications:

The following information is gathered from the United States Food and Drug Administration (FDA) Approved Drug Products database from **6/1/2026– 7/31/2026**

Therapies with Prior Authorization Policies (Non-oncology)

1. **HYMPAVZI** (MARSTACIMAB-HNCQ)

a. New indication approved 06/05/2026:
    i. For routine prophylaxis to prevent or reduce the frequency of bleeding episodes in adults and pediatric patients 6 years of age and older with: hemophilia A (congenital factor VIII deficiency) with or without factor VIII inhibitors, or hemophilia B (congenital factor IX deficiency) with or without factor IX inhibitors
b. **RECOMMENDATION:** Inform prescribers via Medical Policy Alert. Update Commercial/Medicaid and Medicare Part B 'Hemophilia Prophylactic Agents' policies with expanded indication. No policy criteria updates warranted.

2. **SKYRIZI** (RISANKIZUMAB-RZAA)
    a. New indication approved 06/26/2026:
        i. For the treatment of active psoriatic arthritis in adults and pediatric patients 6 years of age and older
    b. New indication approved 06/12/2026:
        i. For the treatment of moderate-to-severe plaque psoriasis in adults and pediatric patients 6 years of age and older who are candidates for systemic therapy or phototherapy
    c. **RECOMMENDATION:** Inform prescribers via Medical Policy Alert. Update Commercial and Medicaid 'Therapeutic Immunomodulator' policies with expanded indication. No policy criteria updates warranted.

3. **TZIELD** (TEPLIZUMAB-MZWV)
    a. New indication approved 06/12/2026:
        i. Delay the decline in endogenous insulin production in pediatric patients aged 8 to 17 years recently diagnosed with Stage 3 T1D
    b. **RECOMMENDATION:** Inform prescribers via Medical Policy Alert. Update Commercial/Medicaid/Medicare Part B 'Tzield' policy with new indication and criteria.

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

| | |
|---|---|
| PA PROGRAM NAME | Tzield |
| MEDICATION NAME | Teplizumab-mzwv (Tzield) |
| COVERED USES | All FDA-Approved Indications |
| EXCLUSION CRITERIA | • ~~Stage 3 (symptomatic) type 1 diabetes~~<br>• Previous treatment with teplizumab (Tzield) |
| REQUIRED MEDICAL INFORMATION | Initial authorization requires all the following be met:<br>1. Recent diagnosis (within the last 8 weeks) of Stage 3 T1D<br>2. At least one positive pancreatic islet cell autoantibody<br>3. Peak C-peptide ≥0.2 pmol/mL on a mixed-meal tolerance test (if a mixed meal tolerance test is not available, an alternative method for measuring peak C-peptide ≥0.2 pmol/mL may be appropriate) |

| | |
|---|---|
| | Quantity limit: Two treatment courses (12 days per course) per lifetime |
| AGE RESTRICTIONS | ~~May be approved for patients aged 1 year and older~~<br>Age must be appropriate per FDA label |
| PRESCRIBER RESTRICTIONS | Must be prescribed by, or in consultation with, an endocrinologist |
| COVERAGE DURATION | For Stage 3 T1D: Authorization will be approved for 6 months, two treatment courses (12 days per course) per lifetime |

4. **TRYNGOLZA** (OLEZARSEN)
    a. New indication approved 06/24/2026:
        i. Indicated as an adjunct to diet to reduce TG and the risk of acute pancreatitis in adults with severe hypertriglyceridemia (sHTG: TG greater than or equal to 500 mg/dL)
    b. **RECOMMENDATION:** Inform prescribers via Medical Policy Alert. New indication reviewed and Commercial/Medicaid 'Redemplo/Tryngolza' policy updated at August 2026 P&T. No further updates warranted.

5. **XEOMIN** (INCOBOTULINUMTOXINA)
    a. New indication(s) approved 06/25/26:
        i. For the treatment of upper limb spasticity in patients 2 years of age and older – removed the exclusion criterion of spasticity caused by cerebral palsy from the indication for pediatric upper limb spasticity
    b. **RECOMMENDATION:** Inform prescribers via Medical Policy Alert. Update Commercial/Medicaid and Medicare Part B 'Botulinum Toxin' policies with updated indication. No policy criteria updates warranted.

6. **ZORYVE 0.3% CREAM** (ROFLUMILAST)
    a. New indication(s) approved 06/29/26:
        i. Indicated for the topical treatment of plaque psoriasis, including intertriginous areas, in adult and pediatric patients 2 years of age and older
    b. **RECOMMENDATION:** Inform prescribers via Medical Policy Alert. Update Commercial and Medicaid 'Topical Agents for Skin Conditions' policies with updated indication. No policy criteria updates warranted.

7. **BKEMV** (ECULIZUMAB-AEEB)
    a. New indication(s) approved 06/29/26:
        i. Indicated for the treatment of neuromyelitis optica spectrum disorder (NMOSD) in adult patients who are anti-aquaporin-4 (AQP4) antibody positive
    b. **RECOMMENDATION:** Inform prescribers via Medical Policy Alert. Update Commercial/Medicaid and Medicare Part B 'Complement Inhibitors' policies with updated indication. No policy criteria updates warranted.

8. **EPYSQLI** (ECULIZUMAB-AAGH)
    a. New indication(s) approved 06/29/26:
        i. Indicated for the treatment of neuromyelitis optica spectrum disorder (NMOSD) in adult patients who are anti-aquaporin-4 (AQP4) antibody positive
    b. **RECOMMENDATION:** Inform prescribers via Medical Policy Alert. Update Commercial/Medicaid and Medicare Part B 'Complement Inhibitors' policies with updated indication. No policy criteria updates warranted.

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

1. **KEYTRUDA** (PEMBROLIZUMAB) & **KEYTRUDA QLEX** (PEMBROLIZUMAB/BERAHYALURONIDASE ALFA-PMPH)
    a. New indication approved 07/10/2026:
        i. In combination with enfortumab vedotin-ejfv, as neoadjuvant treatment and then continued after cystectomy as adjuvant treatment, for the treatment of adult patients with muscle invasive bladder cancer (MIBC)
    b. New indication approved 06/24/2026:
        i. In combination with sacituzumab govitecan-hziy, for the first-line treatment of adult patients with unresectable locally advanced or metastatic TNBC whose tumors express PD-L1 (CPS ≥10) as determined by an FDA-authorized test
    c. New indication approved 06/12/26:
        i. In combination with belzutifan, is indicated for the adjuvant treatment of adult patients with ccRCC at intermediate-high or high risk of recurrence following nephrectomy or following nephrectomy and resection of metastatic lesions
    d. **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. **WELIREG** (BELZUTIFAN)
    a. New indication(s) approved 06/12/26:
        i. In combination with pembrolizumab or pembrolizumab and berahyaluronidase alfa, is indicated for the adjuvant treatment of adult patients with ccRCC at intermediate-high or high risk of recurrence following nephrectomy, or following nephrectomy and resection of metastatic lesions
    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. **TRUQAP** (CAPIVASERTIB)
    a. New indication(s) approved 06/12/26:
        i. In combination with abiraterone and prednisone, is indicated for treatment of adult patients with metastatic androgen pathway modulation-naïve or -sensitive (mAPMN/S) prostate cancer that is PTEN-deficient as detected by an FDA-authorized test

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

4. **IBRANCE** (PALBOCICLIB)
   a. New indication(s) approved 06/24/26:
      i. In combination with trastuzumab, with or without pertuzumab, and endocrine therapy for the maintenance treatment of adult patients with HR-positive, HER2-positive locally advanced or metastatic breast cancer following induction treatment
   b. **RECOMMENDATION:** Inform prescribers via Medical Policy Alert. Prior authorization policy coverage criteria are based on recommendations from the National Comprehensive Cancer Network (NCCN); no updates to the policy are warranted.

5. **TRODELVY** (SACITUZUMAB GOVITECAN-HZIY)
   a. New indication(s) approved 06/24/26:
      i. Indicated as a single agent for the first-line treatment of adult patients with unresectable locally advanced or metastatic triple negative breast cancer (TNBC) who are not candidates for PD-1 or PD-L1 inhibitor based therapy
      ii. In combination with pembrolizumab or pembrolizumab and berahyaluronidase alfa-pmph, for the first-line treatment of adult patients with unresectable locally advanced or metastatic triple negative breast cancer (TNBC) whose tumors express PD-L1 [Combined Positive Score (CPS ≥10)] as determined by an FDA-authorized test
   b. **RECOMMENDATION:** Inform prescribers via Medical Policy Alert. Prior authorization policy coverage criteria are based on recommendations from the National Comprehensive Cancer Network (NCCN); no updates to the policy are warranted.

6. **PADCEV** (ENFORUMAB VEDOTIN-EJFV)
   a. New indication(s) approved 07/10/26:
      i. In combination with pembrolizumab or pembrolizumab and berahyaluronidase alfa pmph, as neoadjuvant treatment and then continued after cystectomy as adjuvant treatment, for the treatment of adult patients with muscle invasive bladder cancer (MIBC)
   b. **RECOMMENDATION:** Inform prescribers via Medical Policy Alert. Prior authorization policy coverage criteria are based on recommendations from the National Comprehensive Cancer Network (NCCN); no updates to the policy are warranted.

7. **PLUVICTO** (LUTETIUM LU 177 VIPIVOTIDE TETRAXETAN)
   a. New indication(s) approved 07/31/26:
      i. In combination with androgen receptor pathway inhibitor (ARPI) therapy for the treatment of adult patients with prostate-specific membrane antigen (PSMA)-positive metastatic androgen pathway modulation-naïve or -sensitive (mAPMN/S) prostate 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.

Therapies Without Prior Authorization Policies

1. **ZEGALOGUE** (DASIGLUCAGON)
    a. Previous Indication(s):
        i. For the treatment of severe hypoglycemia in pediatric and adult patients with diabetes aged 6 years and above
    b. New indication approved 06/18/2026:
        i. For the treatment of severe hypoglycemia in adults and pediatric patients with diabetes who weigh at least 20 kg
    c. **RECOMMENDATION:** Inform prescribers via Medical Policy Alert.

2. **RYALTRIS** (OLOPATADINE/MOMETASONE)
    a. Previous Indication(s):
        i. For the treatment of symptoms of seasonal allergic rhinitis in adult and pediatric patients 12 years of age and older
    b. New indication approved 07/07/2026:
        i. For the treatment of symptoms of seasonal allergic rhinitis in adult and pediatric patients 6 years of age and older
    c. **RECOMMENDATION:** Inform prescribers via Medical Policy Alert.

3. **REZZAYO** (REZAFUNGIN)
    a. Previous Indication(s):
        i. Indicated in patients 18 years of age or older who have limited or no alternative options for the treatment of candidemia and invasive candidiasis
    b. New indication approved 07/16/2026:
        i. Indicated in adults and pediatric patients 12 years of age or older who have limited or no alternative options for the treatment of candidemia and invasive candidiasis
    c. **RECOMMENDATION:** Inform prescribers via Medical Policy Alert.

## Drug Safety Monitoring:

The following information is gathered from the United States Food and Drug Administration (FDA) Approved Drug Products database from 6/1/2026– 7/31/2026

**FDA Drug Safety Communications**

1. **Drug Name:** Alli (orlistat)
    - **Date Posted:** 06/10/26
    - **Safety Alert Title:** FDA Approves Labeling Changes for Over-the-Counter (OTC) Weight Loss Drug alli (Orlistat) to Warn of Risk of Kidney Stones and Kidney Injury

- **Link to more information:** https://www.fda.gov/drugs/drug-safety-communications/fda-approves-labeling-changes-over-counter-otc-weight-loss-drug-alli-orlistat-warn-risk-kidney
- **What safety concern is FDA announcing?**
  - FDA received periodic safety reports of acute kidney injury associated with alli, which prompted a revaluation of this safety signal in the nonprescription product.
- **What is FDA doing?**
  - The Food and Drug Administration (FDA) approved changes to the drug label of the over-the-counter (OTC) weight loss drug, alli (orlistat) 60 mg capsules, to warn of risks of acute kidney injury, which is a rare side effect of the medication. The labeling now advises consumers to ask a health care provider before using alli if they have ever had kidney disease or kidney stones. The labeling changes also tell consumers to stop using alli and ask a doctor if they develop symptoms of kidney injury or kidney stones, such as back or groin pain, painful urination, blood in the urine, feet and leg swelling, or less frequent urination.
- **What should health care professionals do?**
  - Health care providers who counsel patients about weight loss should inform them about the rare reports of acute kidney injury, hyperoxaluria, calcium oxalate nephrolithiasis, or oxalate nephropathy associated with orlistat products. If a patient taking alli presents with signs of acute kidney injury or nephrolithiasis, providers should advise them to stop the drug and proceed with appropriate evaluation and management.
- **Health Plan Recommendation:** Notify providers via Medical Policy Alert.

**Drug Recalls/Market Withdrawals**

1. **Drug Name:** Gas-X
   - **Date of Recall:** 06/04/26
   - **Reason for recall:** Voluntary recall due to potential contamination with a diluted propylene glycol-based coolant from a machine leakage during the packaging process.
   - **Link to more information:** https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/haleon-issues-voluntary-nationwide-recall-gas-x-extra-strength-softgels-125mg-120-ct-and-72-ct
   - **Health Plan Recommendation:** Notify providers via Medical Policy Alert.

2. **Drug Name:** ChloraPrep Clear and ChloraPrep FREPP Clear
   - **Date of Recall:** 06/06/26
   - **Reason for recall:** Voluntary recall due to fungal contamination under certain environmental conditions allowing the growth of *Aspergillus penicillioides*.
   - **Link to more information:** https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/bd-issues-nationwide-recall-specific-lots-chlorapreptm-clear-single-sterile-1-ml-and-frepptm-clear
   - **Health Plan Recommendation:** Notify providers via Medical Policy Alert.

3. **Drug Name:** Beekeeper's Naturals Saline Nasal Spray
    - **Date of Recall:** 06/11/26
    - **Reason for recall:** Voluntary recall due to lot testing above acceptable microbiological limits for yeast and may contain *Aspergillus spp*.
    - **Link to more information:** https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/beekeepers-naturals-issues-voluntary-nationwide-recall-beekeepers-naturals-saline-nasal-spray-sold
    - **Health Plan Recommendation:** Notify providers via Medical Policy Alert.

4. **Drug Name:** Cetirizine 5 mg tablet
    - **Date of Recall:** 07/18/26
    - **Reason for recall:** Voluntary recall due to cross contamination with ranitidine.
    - **Link to more information:** https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/unique-pharmaceutical-laboratories-div-j-b-chemicals-pharmaceuticals-ltd-issues-voluntary-nationwide
    - **Health Plan Recommendation:** Notify providers via Medical Policy Alert.

5. **Drug Name:** Cyclophosphamide injection
    - **Date of Recall:** 07/24/26
    - **Reason for recall:** Voluntary recall due to the presence of particulate matter identified as steel.
    - **Link to more information:** https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/sunny-pharmtech-inc-issues-voluntary-nationwide-recall-cyclophosphamide-injection-usp-user-level-due
    - **Health Plan Recommendation:** Notify providers via Medical Policy Alert.

6. **Drug Name:** Cefazolin in dextrose injection
    - **Date of Recall:** 07/24/26
    - **Reason for recall:** Voluntary recall due to a report of particulate matter found in the solution identified as cardboard.
    - **Link to more information:** https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/baxter-issues-voluntary-nationwide-recall-cefazolin-dextrose-injection-usp-2g-100ml20mg-ml-single
    - **Health Plan Recommendation:** Notify providers via Medical Policy Alert.

7. **Drug Name:** Papaverine hydrochloride injection
    - **Date of Recall:** 07/24/26
    - **Reason for recall:** Voluntary recall due to the presence of particulate matter identified as glass and/or paraformaldehyde.

- **Link to more information:** https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/american-regent-inc-issues-voluntary-nationwide-recall-one-lot-papaverine-hydrochloride-injection
- **Health Plan Recommendation:** Notify providers via Medical Policy Alert.