Providence Health Plan

Providence Health Assurance

Healthcare Services Medical & Pharmacy Policy Alerts

Number 277

December 1, 2022

This is the December 1, 2022 issue of the Providence Health Plans, Providence Health Assurance and Providence Plan Partners, Medical and Pharmacy Policy Alert to our providers. The focus of this update is to communicate to providers' new or revised Medical or Pharmacy policy changes. The Health Plan has a standard process to review all Medical & Pharmacy Policies annually. Policies will be available for review on ProvLink and via the PHP website at: https://healthplans.providence.org/providers/provider-support/medical-policy-pharmacy-policy-and-provider-information/

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

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

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

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

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

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MEDICAL POLICY COMMITTEE

MEDICAL

All Lines of Business

Effective 12/1/2022

COVID-19 Testing **MP350**	**Policy Updates:** • Add Z11.59 (encounter for screening for other viral illness) to the list of not medically necessary screening diagnosis codes • COVID coverage document will be updated to align with this 12/1 change **Codes/PA:** Z11.59 will be added to the existing u21 configuration for covid testing codes **OHP:** Continue to follow the Prioritized List for coverage of COVID-19 Testing

COMPANY POLICIES

Effective 1/1/2023

Gender Affirming Surgical Interventions	**Policy Updates:** WPATH Standards Version 8 was released in September 2022. The medical necessity criteria for GASI is based on WPATH criteria; therefore, the following changes are recommended: • Complete reorganization of criteria from treatment-specific to just “adults” and “adolescent”

MP32	○ WPATH criteria are no longer treatment specific. They have been generalized to include just adult and adolescent surgical treatment. • Terminology update to include gender incongruence (in addition to gender dysphoria). GD is still recognized by DSM and APA, but gender incongruence is "no longer seen as pathological or a mental disorder in the world health community", so GI is recognized term by ICD. • Added "Documentation Requirements" section, which will require clinical notes from the operating surgeon and one referral letter for adults and adolescents. • "Policy Guidelines" updated with new language from WPATH guidelines where relevant: ○ Marked and Sustained Gender Diversity/Incongruence ○ Competency of Mental Health Professionals Working with Adults who Present with Gender Dysphoria ○ Referral Letters • Updated "Description" section with new definitions where relevant. <u>Adults</u> • General criteria which were defined further in the Policy Guidelines. • No longer requiring 12 months of hormone therapy. Now recommends 6 months but may "not be desired or contraindicated" • No longer requiring referral from independent health care professional but does say "if written documentation or a letter is required to recommend GAMST, only one letter of assessment from a health care professional who has competencies in the assessment of transgender and gender diverse people is needed." ○ The referral letter(s) may be an important mechanism for ensuring member meets the recommended WPATH criteria for GASI, especially now that they are more generalized. <u>Adolescents</u> • New recommendation from WPATH. The previous WPATH SOC, stated GASI "should not be carried out until patients reach the legal age of majority in a given country" (which is 18 in the US). • Same/similar criteria as adults, except recommends 12 months of hormone therapy, unless not desired or not medically indicated. **Codes/PA:** No Prior Authorization required for gender affirming surgeries as of 1/1/2023 **OHP:** OHP will follow the Company Policy above

Foot Care Guidelines (All Lines of Business Except Medicare) **MP368**	**Policy Updates:** New medical policy. To assist with Benefit Application for covered and non-covered routine foot care, this topic and its related code configuration are **currently** managed via a Coding Policy (56.0, *Foot Care Guidelines*), which is based on the Centers for Medicare and Medicaid Services (CMS) guidance. The recommendation is to transition the policy responsibility and configuration from Coding Policy to Medical Policy. **Codes/PA:** Code and configuration changes include the following: • Codes 11055-11057: Continue current diagnosis code configuration (which is based on LCA A57957, updating per 10/1/2022 ICD-10 code updates), and add additional payable diagnosis codes based on LCA A58567. Continue to deny as not a covered benefit if not billed with a payable dx code. • Codes 11719-11721 and G0127: Continue current diagnosis code configuration (which is also based on LCA A57957, again updating per 10/1/2022 ICD-10 code updates) and continue to deny as not covered benefits if not billed with payable dx code. Code S0390: No change to current configuration, which is addressed by Coding Policy 22.0 (*HCPCS S-Codes and H-Codes*, not valid for PHP use) **OHP:** These changes do not apply to OHP. The Prioritized List and the Oregon Administrative Rules will be followed.
Genetic Testing: Thyroid Nodules (All Lines of Business Except Medicare) **MP39**	**Policy Updates:** 1/1 code updates. No other changes. **Codes/PA:** Add 0362U as NMN, new code effective 1/1/2023. Removed 81545 (termed 12/31/2020). Revised HCPCS code 81445- effective 1/1. **OHP:** These changes do not apply to OHP. The Prioritized List and the Oregon Administrative Rules will be followed.
Liver Tumor Treatment (All Lines of Business Except Medicare) **MP151**	**Policy Updates:** Medical necessity criteria for radiofrequency ablation (RFA) for breast cancer liver metastasis (BCLM) **Codes/PA:** Add 0686T (Histotripsy) to policy and remove from IMT (E/I). **OHP:** These changes do not apply to OHP. The Prioritized List and the Oregon Administrative Rules will be followed.
Non-Small Cell Lung Cancer: Molecular Testing for Targeted Therapy (All LOB except CMS) **MP194**	**Policy Updates:** 1/1 code updates. Allow testing of KRAS & NTRK1/2/3 to align with NCCN guidelines. **Codes/PA:** • **Code updates- effective 1/1/2023: Add:** 0360U (NMN) **OHP:** These changes do not apply to OHP. The Prioritized List and the Oregon Administrative Rules will be followed.

Effective 2/1/2023

Back: Ablative Procedures to Treat Back and Neck Pain (All Lines of Business Except Medicare) **MP21**	**Policy Updates:** • Change in denial language in criterion IV. **Codes/PA:** • Change denials for non-pulsed RFA for the treatment of non-facet-related back and/or neck pain from "investigational" to "not medically necessary." (64625, 64628, 64629) • Updated dx code list for 64640 per updates to commercial policies "Knee: Genicular Nerve Ablation" and "RFA for Plantar Fasciitis." **OHP:** These changes do not apply to OHP. The Prioritized List and the Oregon Administrative Rules will be followed.
Transcranial Magnetic Stimulation (All Lines of Business Except Medicare) **MP269**	**Policy Updates:** • Criterion I.A.: change criteria by which Major Depressive Disorder (MDD) is established from rating scales, to DSM-5 definition. ○ Scales only determine severity of depression, not diagnosis of depression (e.g. patient could be bipolar and depressed, borderline and depressed, but not have MDD) • Retain requirement that depression be rated as "severe" per an evidence-based rating scale. • Criterion I.D.: Clarify that "supervision" of TMS entails that the ordering provider is "present in the area and immediately available during the treatment" following CMS and other payers' language. • Add "accelerated TMS" and "persistent depressive disorder" to list of not covered services/indications. **Codes/PA:** No changes to codes/PA **OHP:** These changes do not apply to OHP. The Prioritized List and the Oregon Administrative Rules will be followed.
Gender Affirming Surgical Interventions (All Lines of Business)	**Policy Updates:** See Codes/PA. **Codes/PA:** Add CPT 54410 as PA: Removal and Replacement of All Component(s) Of A Multi-Component, Inflatable Penile Prosthesis, Same Operative Session

MP32	**OHP:** OHP will follow the Company Policy above
Cosmetic and Reconstructive Procedures (All Lines of Business Except Medicare) **MP98**	**Policy Updates:** See Codes/PA. **Codes/PA:** Add CPT 54410 as PA: Removal and Replacement of All Component(s) Of A Multi-Component, Inflatable Penile Prosthesis, Same Operative Session **OHP:** OHP will follow the Company Policy above
Vestibular Function Testing **MP82**	**Recommendation:** Change denial for VEMP testing from "investigational" to "not medically necessary." **Codes/PA:** VEMP codes will be configured to deny as "not medically necessary" (92517-19). **OHP:** These changes do not apply to OHP. The Prioritized List and the Oregon Administrative Rules will be followed.
Wheelchair and Power Vehicles (All Lines of Business Except Medicare) **MP140**	**Policy Updates:** Minor revisions to criteria for clarification purposes, but no change to intent of coverage. **Codes/PA:** Update configuration for HCPCS code E2311 to match and align with related code E2310. Both codes are subject to the same criteria in the medical policy, which is based on the same Medicare rationale. **OHP:** These changes do not apply to OHP. The Prioritized List and the Oregon Administrative Rules will be followed.

Providence Health Plan

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MEDICARE

Effective 1/1/23

Foot Care Guidelines (Medicare Only) **MP369**	**Policy Updates:** New Medicare medical policy. To assist with Benefit Application for covered and non-covered routine foot care, this topic and its related code configuration are **currently** managed via a Coding Policy (56.0, *Foot Care Guidelines*), which is based on the Centers for Medicare and Medicaid Services (CMS) guidance. The recommendation is to transition the policy responsibility and configuration from Coding Policy to Medical Policy. **Codes/PA:** Code and configuration changes include the following: • Codes 11055-11057: Continue current diagnosis code configuration (which is based on LCA A57957, updating per 10/1/2022 ICD-10 code updates), and add additional payable diagnosis codes based on LCA A58567. Continue to deny as not a covered benefit if not billed with a payable dx code. • Codes 11719-11721 and G0127: Continue current diagnosis code configuration (which is also based on LCA A57957, again updating per 10/1/2022 ICD-10 code updates) and continue to deny as not covered benefits if not billed with payable dx code. • Code S0390: No change to current configuration, which is addressed by Coding Policy 22.0 (*HCPCS S-Codes and H-Codes*, not valid for PHP use)
Liver Tumor Treatment (Medicare Only) **MP265**	**Policy Updates:** No change to criteria, but updated policy to new format. **Codes/PA:** No changes to codes or configuration in the policy currently but moving 0686T from the IMT/NET policy to this policy (continue NMN denial, which is effective 11/1/2022).

New and Emerging Technologies and Other Non-Covered Services (Medicare Only)
 	
MP220
 	
(Previously: Investigational and Non-Covered Medicare Technologies (Medicare Only)
	Policy Updates: No change to criteria. See codes below:
	Codes/PA: No changes to configuration but removed code 0686T from this policy and relocated it to the *Liver Tumor Treatment (Medicare Only)* policy (will continue current NMN denial in the Liver Tumor policy).
	• **Also include Annual Code Updates in this draft version:**
	  ○ **Add:** 95919, 0738T, 0739T, 0743T, 0744T, 0748T, 0764T, 0765T, 0770T, 0771T, 0772T, 0773T, 0774T, 0776T, 0777T, 0778T, 0779T, 0781T, 0782T, 0357U, 0358U, 0361U (All are NMN for MA)
	  ○ **Revise:** 0733T, 0734T
	  ○ **Term:** 0470T, 0471T, 0487T, 0491T, 0492T, 0493T

Circulating Tumor Cell and DNA Assays for Cancer Management (Medicare Only) **MP306**	**Policy Updates:** Updating criteria for Colvera (PLA code 0229U) and also incorporated Q1 2023 Code Updates into this version. **Codes/PA:** No changes to codes or configuration (including no changes to configuration for PLA code 0229U). However, there are Q1 2023 code updates, which are below: • **Q1 2023 Code Updates:** Add 0356U (NMN for MA)

Effective 2/1/23

Eye: Automated Evacuation of the Meibomian Glands (Medicare Only) **MP366**	**Policy Updates:** New Medicare Only medical policy, separating Medicare from Commercial. Continue to use Company criteria. **Codes/PA:** Code and configuration changes include the following: • Codes 0207T and 0563T: Remove E/I denial and replace with NMN denial. • Codes 0330T: Continue current configuration to deny if reported with 0207T; however, will deny as NMN instead of E/I.
Back: Ablative Procedures to Treat Back and Neck Pain (Medicare Only) **MP13** *Formerly: Back: Facet Joint Interventions for Pain Management (Medicare Only)*	**Policy Updates:** • No change to criteria, continue to use Medicare guidance when available, or Company policy criteria in the absence of Medicare guidance. • Add intraosseous basivertebral nerve ablation (e.g., Intracept) to this policy (currently in Medicare NET policy); no change to non-coverage, just relocating to new policy to align with Company policy version. • Update policy title to reflect this expanded policy scope and align with the Company policy version. **Codes/PA:** Code and configuration changes are as follows: • No changes to configuration for codes *currently* in the policy. • Add CPT codes 64628 and 64629 to this policy (currently in the Medicare NET policy - continue NMN configuration for Medicare, just removing from NET policy and adding to this policy instead). • Adding CPT code 64640, which is having diagnosis code configuration changes to align with a Noridian LCA and is associated with other policies that will be effective 2/1/2023.
New and Emerging Technologies and Other	**Policy Updates:** No change to criteria. **Codes/PA:** No changes to configuration but remove codes 64628 and 64629 from this policy and relocate to the *Back: Ablative Procedures to Treat Back and Neck Pain (Medicare Only)* policy (will continue current NMN denial in the Back policy).

Non-Covered Services (Medicare Only) **MP220**	
Cosmetic and Reconstructive Surgery (Medicare Only) **MP232**	**Policy Updates:** No change to criteria. **Codes/PA:** Add CPT code 54410 to the policy and add PA (currently has no medical policy edits in place today). This is to align configuration for 54410 with the configuration for similar codes (e.g., 54405).
Wheelchair and Power Vehicles (Medicare Only) **MP300**	**Policy Updates:** No change to criteria. **Codes/PA:** Update configuration for HCPCS code E2311 to match and align with related code E2310. Both codes are subject to the same criteria and Medicare rationale.

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VENDOR UPDATES

AIM Clinical Appropriateness Guidelines for Advanced Imaging	• The following AIM Specialty Health Advanced Imaging Clinical Appropriateness Guidelines have been updated
	  ○ Cardiac Imaging
	  ○ Abdomen/Pelvis Imaging
	  ○ Brain Imaging
	  ○ Chest Imaging
	  ○ Head and Neck Imaging
	  ○ Oncologic Imaging
	• No code changes
	• Expansive changes: effective November 6, 2022
	• Restrictive changes: effective April 9, 2023
	• For more information about these updates please click here
	
	Please **submit your feedback to** AIM.guidelines@aimspecialtyhealth.com

InterQual	**Interim Updates** InterQual has made several interim updates to various criteria subsets (revision summaries linked below): • LOC Acute Adult • LOC Acute Pediatric • Home Care • Inpatient List • Outpatient Rehab and Chiropractic • Adult and Geriatric Psychiatry • Child and Adolescent Psychiatry • Substance Use Disorder • Behavioral Health Services • ASAM Criteria Navigator

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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 7, 2022

Go-Live Date: Sunday, January 01, 2023, unless otherwise noted

Infusion therapy Site of Care

- Drugs have been added to the Infusion therapy Site of Care policy
- Effective 1/1/2023, the following drugs will be required to be administered at an approved site of care unless and authorization has been granted for continued administration at an unapproved site of care:
  - Adakveo® (Crizanlizumab)
  - Glassia® (Alpha-1 proteinase inhibitor)
  - Vyepti® (Eptinezumab)
- The most up-to-date list of approved site-of-care facilities/providers can be found at: https://www.providencehealthplan.com/providers/medical-policy-rx-pharmacy-and-provider-information#8B73CB96FAB24891B9792ED270E5B1D8
  - Click on "Pharmacy Policies" then scroll down to "Infusion Therapy Site of Care"
    - Infusion Therapy SOC Policy
    - Sit of care Prior Authorization Request Form
    - Approved Site of Care Facility List

Providence Health Plan

Providence Health Assurance

Table of Contents:

Special Announcement – Medicare Calendar Year (CY) 2023 Updates

Annually, Medicare Part D plans are required to submit a formulary to the Centers for Medicare & Medicaid Services (CMS) for the upcoming calendar year. As part of this annual review, the formulary is reviewed in its entirety and changes are made based on the safety, comparative efficacy, and cost-effectiveness of therapies.

As of October 1st 2022 the CMS approved Providence Health Assurance CY2023 Medicare formularies are available for review on the Providence Health Assurance website: https://www.providencehealthplan.com/medicare/medicare-advantage-plans/formulary-list-of-approved-drugs

- Patients and providers are encouraged to review the formularies for changes to their medications prior to the new year

A high-level summary of changes for CY2023 include:

- Tier 1 Expansion – Several drugs have been moved to Tier 1 for CY2023, which has a very low cost-share ($0 for many patients)

Table 1. Medications being added to Tier 1 (not all inclusive)

Blood Pressure		Blood Pressure/Diabetes	Other
Hydrochlorothiazide (HCTZ)	enalapril, enalapril/HCTZ	valsartan	levothyroxine
chlorthalidone	fosinopril	irbesartan	latanoprost
metoprolol succinate	trandolapril	losartan/HCTZ	tamsulosin
	benazepril/amlodipine		

Blood Thinners	Proton Pump Inhibitors	NSAIDs	
warfarin	omeprazole	meloxicam	
Jantoven	pantoprazole	naproxen	

- Examples of other medications moved to lower tiers (lower cost-share)
  - Candesartan/HCTZ
  - Telmisartan/HCTZ
  - Etodolac
  - Diclofenac 1% gel
  - Prempro®
  - Farxiga®/Xigduo® (dapagliflozin products)
  - Emtricitabine/tenofovir (generic for Truvada®)
  - Dimethyl fumarate (generic for Tecfidera®)
- Examples of medications moved to higher tiers (higher cost-share)
  - Advair Diskus®
  - Humulin R/N/70-30® vials
  - Opioid therapies (e.g., morphine sulfate, methadone, oxycodone, oxycodone/acetaminophen, fentanyl patch)
  - More cost-effective alternatives or formulations available on lower tiers (e.g., olanzapine ODT, aripiprazole ODT, travoprost, captopril, Caplyta®)
- Drugs Removed from Formulary, based on several reasons, including:
  - Preferred product changes (Stelgatro®, Invokana®)
  - A generic/biosimilar version has become available and was added to formulary in place of the brand/similar brands (Procrit®, Epogen®, Aranesp®)
  - Drugs that are considered a medical benefit, typically covered by Part B, and had no utilization under Part D in 2021
  - Drug is obsolete
  - Drug has safety concern or has been recalled from the market
  - More cost-effective alternatives or formulations available on the formulary (e.g., captopril/HCTZ, oxycodone/aspirin)

CY2023 Part B Step Therapy:

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Providence Health Assurance will continue to participate in the Centers for Medicare & Medicaid Services (CMS) Part B Step Therapy Program (ST) for CY2023.

- The ST program applies to drugs covered under the Part B benefit (outpatient healthcare administered medications)
- If a drug is part of the ST program, it requires a trial of a preferred drug to treat a medical condition before covering a non-preferred drug
    - Both preferred and non-preferred drugs may still be subject to prior authorization medical necessity criteria or quantity limits
- ST program requirements for preferred therapies will only be for members being initiated on therapy; patients established on the requested medication within the previous 365 days will not be subject to ST requirements
    - Prior authorization medical necessity criteria or quantity limits may still apply

Details of the Part B ST program are available on the Providence Health Assurance website at:
https://www.providencehealthplan.com/medicare/medicare-advantage-plans/formulary-list-of-approved-drugs

New Drugs and Combinations:

1. **Tirzepatide (Mounjaro) Pen Injctr**
    a. **Indication**: For the treatment of type 2 diabetes mellitus (T2DM)
    b. **Decision**:

	Commercial	Medicaid	Medicare
Formulary Status*	Non-formulary	Non-formulary	Part D: Non-formulary Part B: N/A
Tier**	N/A	N/A	N/A
Affordable Care Act Eligible	N/A; Non-Formulary	N/A	N/A
Utilization Management Edits	Step Therapy	Step Therapy	N/A
Quantity Limit	2 mL/28 days	2 mL/28 days	FDA MAX: 2 mL/28 days
* Recommendations for placement may differ between lines of business due to regulatory requirements. ** Medications will be placed on recommended tier above for the base formulary; tier placement for custom formulary(ies) will be based on designation above. For example, Commercial Tier 6 designation above means that the medication will be placed on the highest cost-sharing tier on the respective formulary(ies).			
Formulary Alternatives: Ozempic® (semaglutide), Trulicity® (dulaglutide), Victoza® (liraglutide), DPP-4 inhibitors, insulin etc.			

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

PA PROGRAM NAME	GLP-1 Receptor Agonists Step Therapy
MEDICATION NAME	tirzepatide (Mounjaro®)

PA INDICATION INDICATOR	All Food and Drug Administration (FDA) approved indications not otherwise excluded from the benefit.
OFF-LABEL USES	N/A
EXCLUSION CRITERIA	N/A
REQUIRED MEDICAL INFORMATION	1. One of the following: a. History of use of a medication containing metformin within the previous 180 days (verified by pharmacy claims), or b. Documentation of trial, intolerance, or contraindication to metformin **AND** 2. For tirzepatide (Mounjaro®), exenatide (Byetta®), exenatide ER (Bydureon®), and lixisenatide (Adlyxin®): Documentation of trial, contraindication, or intolerance to at least TWO of the preferred glucagon-like peptide-1 (GLP-1) receptor agonists: liraglutide (Victoza®), semaglutide (Ozempic®/Rybelsus®), or dulaglutide (Trulicity®)
AGE RESTRICTIONS	N/A
PRESCRIBER RESTRICTIONS	N/A
COVERAGE DURATION	Authorization will be approved until no longer eligible with the plan, subject to formulary and/or benefit changes

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

PA PROGRAM NAME	GLP-1 Receptor Agonists Step Therapy - Medicaid
MEDICATION NAME	tirzepatide (Mounjaro®)
PA INDICATION INDICATOR	All medically accepted indications not otherwise excluded from the benefit.
OFF-LABEL USES	N/A
EXCLUSION CRITERIA	N/A
REQUIRED MEDICAL INFORMATION	1. Documentation of trial (at least three months of treatment), contraindication, or intolerance to metformin 2. For tirzepatide (Mounjaro®), exenatide (Byetta®), exenatide ER (Bydureon®), and lixisenatide (Adlyxin®): Documentation of trial, contraindication, or intolerance to at least TWO of the preferred glucagon-like peptide-1 (GLP-1) receptor agonists: liraglutide (Victoza®), semaglutide (Ozempic®/Rybelsus®), or dulaglutide (Trulicity®)
AGE RESTRICTIONS	N/A
PRESCRIBER RESTRICTIONS	N/A
COVERAGE DURATION	Authorization will be approved until no longer eligible with the plan, subject to formulary and/or benefit changes

2. **Ganaxolone (Ztalmy) Tablet**
   a. **Indication**: For the treatment of seizures associated with cyclin-dependent kinase-like 5 (CDKL5) deficiency disorder (CDD) in patients 2 years of age and older.
   b. **Decision**:

	Commercial	Medicaid	Medicare
Formulary Status*	Formulary	Formulary	Part D: Formulary Part B: N/A
Tier**	Tier 6 - Non-Preferred Specialty	N/A	Specialty
Affordable Care Act Eligible	No	N/A	N/A
Utilization Management Edits	Prior Authorization	Prior Authorization	Prior Authorization
Quantity Limit	36 mL/day	36 mL/day	FDA MAX: 36 mL/day
* Recommendations for placement may differ between lines of business due to regulatory requirements. ** Medications will be placed on recommended tier above for the base formulary; tier placement for custom formulary(ies) will be based on designation above. For example, Commercial Tier 6 designation above means that the medication will be placed on the highest cost-sharing tier on the respective formulary(ies).			
Formulary Alternatives: Other anticonvulsants including but not limited lamotrigine, topiramate, levetiracetam, topiramate, clobazam, phenobarbital, vigabatrin (requires PA), and valproate.			

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

PA PROGRAM NAME	Ztalmy
MEDICATION NAME	Ztalmy
PA INDICATION INDICATOR	1 - All FDA-Approved Indications
OFF-LABEL USES	N/A
EXCLUSION CRITERIA	N/A
REQUIRED MEDICAL INFORMATION	For initiation of therapy, all the following criteria must be met: 1. Diagnosis of CDKL5 deficiency disorder (CDD) confirmed with genetic testing 2. Documented trial and failure with three or more antiepileptic drugs 3. Documentation that it will be used as adjunctive therapy with other antiepileptic drugs 4. The dose requested is within FDA labeled dosing based on the patients weight (patient's weight must be provided) For patients established on therapy, the following criteria must be met:

	1. Documentation of positive response to therapy such as a decrease in seizure frequency or intensity since beginning therapy 2. The dose requested is within FDA labeled dosing based on the patients weight (updated weight must be provided)
AGE RESTRICTIONS	The patient's age must be within FDA labeling for the requested indication
PRESCRIBER RESTRICTIONS	Must be prescribed by, or in consultation with, a neurologist
COVERAGE DURATION	Initial authorization will be approved for six months and reauthorization will be approved for one year

d. **Prior Authorization Criteria for Medicare Part D (new starts only)**:

PA PROGRAM NAME	Ztalmy
MEDICATION NAME	Ztalmy
PA INDICATION INDICATOR	1 - All FDA-Approved Indications
OFF-LABEL USES	N/A
EXCLUSION CRITERIA	N/A
REQUIRED MEDICAL INFORMATION	For initiation of therapy, all the following criteria must be met: 1. Diagnosis of CDKL5 deficiency disorder (CDD) as confirmed with genetic testing 2. Documented trial and failure with two or more antiepileptic drugs 3. Documentation that it will be used as adjunctive therapy with other antiepileptic drugs
AGE RESTRICTIONS	N/A
PRESCRIBER RESTRICTIONS	Must be prescribed by, or in consultation with, an epilepsy specialist or neurologist
COVERAGE DURATION	Authorization will be approved until no longer eligible with the plan.

3. **Daridorexant hcl (Quviviq) Tablet**
   a. **Indication**: For the treatment of adult patients with insomnia characterized by difficulties with sleep onset and/or maintenance.
   b. **Decision**:

	Commercial	Medicaid	Medicare
Formulary Status*	Non-formulary	Non-formulary	Part D: Non-formulary Part B: N/A
Tier**	N/A	N/A	N/A
Affordable Care Act Eligible	No	N/A	N/A
Utilization Management Edits	N/A	Prior Authorization	N/A
Quantity Limit	1 tablet per day	1 tablet per day	N/A

* Recommendations for placement may differ between lines of business due to regulatory requirements. ** Medications will be placed on recommended tier above for the base formulary; tier placement for custom formulary(ies) will be based on designation above. For example, Commercial Tier 6 designation above means that the medication will be placed on the highest cost-sharing tier on the respective formulary(ies).
Formulary Alternatives: zolpidem, zaleplon, temazepam, ramelteon, eszopiclone, trazodone, doxepin concentrate and capsules

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

4. **Vonoprazan Fumarate-Amoxicillin Trihydrate (Voquezna Dual Pak) Combo. Pkg**
   a. **Indication**: For the treatment of Helicobacter pylori (*H.pylori*) infection in adults.
   b. **Decision**:

	Commercial	Medicaid	Medicare
Formulary Status*	Non-formulary	Non-formulary	Part D: Non-formulary Part B: N/A
Tier**	N/A	N/A	
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. ** 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: lansoprazole and other PPIs, clarithromycin, amoxicillin, bismuth, metronidazole, tetracycline			

5. **Tapinarof (Vtama) Cream (G)**
   a. **Indication**: For the topical treatment of plaque psoriasis in adults.
   b. **Decision**:

	Commercial	Medicaid	Medicare
Formulary Status*	Non-formulary	Non-formulary	Part D: Non-formulary Part B: N/A
Tier**	N/A	N/A	N/A
Affordable Care Act Eligible	No	N/A	N/A

Utilization Management Edits	Prior Authorization	Prior Authorization	N/A
Quantity Limit	60 grams (1 tube) every 30 days	60 grams (1 tube) every 30 days	N/A
* Recommendations for placement may differ between lines of business due to regulatory requirements. ** Medications will be placed on recommended tier above for the base formulary; tier placement for custom formulary(ies) will be based on designation above. For example, Commercial Tier 6 designation above means that the medication will be placed on the highest cost-sharing tier on the respective formulary(ies).			
Formulary Alternatives: calcipotriene cream/solution (Dovonex®), calcipotriene ointment (Calcitrene®), tazarotene cream (Tazorac®), calcipotriene/betamethasone ointment/suspension (Taclonex®)			

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

PA PROGRAM NAME	Tapinarof 1% Cream (Vtama®)
MEDICATION NAME	Vtama 1% Cream
PA INDICATION INDICATOR	1 - All FDA-Approved Indications
OFF-LABEL USES	N/A
EXCLUSION CRITERIA	N/A
REQUIRED MEDICAL INFORMATION	1. **For all requests**, the patient must have an FDA labeled indication for the requested agent. 2. For **initial authorization** of the requested product, all the following must be met: a. Inadequate response to an adequate trial (defined as at least two weeks of consistent use) of at least one of the following combinations: i. A high to ultra-high potency topical corticosteroid (such as betamethasone dipropionate 0.05% cream or ointment, triamcinolone 0.5%, clobetasol 0.05%) used concurrently with a generic topical calcipotriene product, OR ii. A generic calcipotriene/betamethasone combination product, OR iii. A high to ultra-high potency topical corticosteroid (such as betamethasone dipropionate 0.05% cream or ointment, triamcinolone 0.5%, clobetasol 0.05%) used concurrently with a generic tazarotene 0.1% cream b. For Medicaid, must have documented severe psoriasis (despite use of therapies outlined above) as defined as having functional impairment as indicated by Dermatology Life Quality Index (DLQI) ≥11 or Children's Dermatology Life Quality Index (CDLQI) ≥13 (or severe score on other validated tool) AND one or more of the following: i. At least 10% of body surface area involved ii. Hand, foot, face, or mucous membrane involvement.

	3. For **reauthorization** of the requested product (starting on samples will not be considered as established on therapy): Documentation of clinical improvement in signs and symptoms of plaque psoriasis
AGE RESTRICTIONS	May be approved for patients aged 18 years and older
PRESCRIBER RESTRICTIONS	Must be prescribed by, or in consultation with, a dermatologist or rheumatologist
COVERAGE DURATION	Initial authorization for six months. Reauthorization for one year

6. **Alpelisib (Vijoice) Tablet**
   a. **Indication**: For the treatment of adult and pediatric patients 2 years of age and older with severe manifestations of PIK3CA-Related Overgrowth Spectrum (PROS) who require systemic therapy. This indication is approved under accelerated approval based on response rate and duration of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial(s).
   b. **Decision**:

	Commercial	Medicaid	Medicare
Formulary Status*	Formulary	Formulary	Part D: Formulary Part B: N/A
Tier**	Tier 6 - Non-Preferred Specialty	N/A	Specialty
Affordable Care Act Eligible	No	N/A	N/A
Utilization Management Edits	Prior Authorization	Prior Authorization	Prior Authorization
Quantity Limit	50 mg/125 mg daily dose: one per day 250 mg daily dose: two per day	50 mg/125 mg daily dose: one per day 250 mg daily dose: two per day	50 mg/125 mg daily dose: one per day 250 mg daily dose: two per day
* Recommendations for placement may differ between lines of business due to regulatory requirements. ** Medications will be placed on recommended tier above for the base formulary; tier placement for custom formulary(ies) will be based on designation above. For example, Commercial Tier 6 designation above means that the medication will be placed on the highest cost-sharing tier on the respective formulary(ies).			
Formulary Alternatives: N/A			

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

PA PROGRAM NAME	Vijoice
MEDICATION NAME	Vijoice

PA INDICATION INDICATOR	1 - All FDA-Approved Indications
OFF-LABEL USES	N/A
EXCLUSION CRITERIA	N/A
REQUIRED MEDICAL INFORMATION	Initial authorization requires criteria 1-3 to be met: 1. Confirmed diagnosis of PIK3CA-related overgrowth spectrum (PROS) as defined by meeting all the following criteria (a-d): a. Presence of somatic PIK3CA mutation b. Congenital or early childhood onset c. Overgrowth sporadic or mosaic (other terms: patchy, irregular) d. Clinical features as described by one of the following: i. Spectrum (require two or more of the following): 1. Overgrowth (adipose, muscle, nerve, skeletal) 2. Vascular malformations (capillary, venous, arteriovenous malformations, lymphatic) 3. Epidermal nevus ii. Isolated features (one of the following): 1. Large isolated lymphatic malformation 2. Isolated macrodactyly OR overgrown splayed feet/hands, overgrown limbs 3. Truncal adipose overgrowth 4. Hemimegalencephaly (bilateral)/dysplastic megalencephaly/focal cortical dysplasia 5. Epidermal nevus 6. Seborrheic keratoses 7. Benign lichenoid keratoses large, AND 2. Patient has at least one target lesion identified on imaging, AND 3. Patient's condition is severe or life-threatening and treatment is deemed necessary as determined by the treating physician. Reauthorization requires documentation of positive response defined all of the following: 1. At least a 20% reduction from baseline in the sum of measurable target lesion volume (1 to 3 lesions) confirmed by at least one subsequent imaging assessment, AND 2. Absence of a at least a 20% increase from baseline in any target lesion, progression of non-target lesions, or appearance of a new lesion.
AGE RESTRICTIONS	Approved for patients 2 years of age and older
PRESCRIBER RESTRICTIONS	Must be prescribed by, or in consultation with, a specialist in treating PROS

COVERAGE DURATION	Initial authorization and reauthorization will be approved for six months

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

PA PROGRAM NAME	Vijoice
MEDICATION NAME	Vijoice
PA INDICATION INDICATOR	1 - All FDA-Approved Indications
OFF-LABEL USES	N/A
EXCLUSION CRITERIA	N/A
REQUIRED MEDICAL INFORMATION	Initial authorization requires criteria 1-3 to be met: 1. Confirmed diagnosis of PIK3CA-related overgrowth spectrum (PROS) as defined by meeting criteria A-D: A. Presence of somatic PIK3CA mutation B. Congenital or early childhood onset C. Overgrowth sporadic or mosaic (other terms: patchy, irregular) D. Clinical features as described in either a or b: a. Spectrum (require two ore more of the following): i. Overgrowth (adipose, muscle, nerve, skeletal) ii. Vascular malformations (capillary, venous, arteriovenous malformations, lymphatic) iii. Epidermal nevus b. Isolated features (one of the following): i. Large isolated lymphatic malformation ii. Isolated macrodactyly OR overgrown splayed feet/hands, overgrown limbs iii. Truncal adipose overgrowth iv. Hemimegalencephaly (bilateral)/dysplastic megalencephaly/focal cortical dysplasia v. Epidermal nevus vi. Seborrheic keratoses vii. Benign lichenoid keratoses large, AND 2. Patient has at least one target lesion identified on imaging, AND 3. Patient's condition is severe or life-threatening and treatment is deemed necessary as determined by the treating physician. Reauthorization requires documentation of positive response to therapy such as reduction in the sum of measurable target lesion volume.
AGE RESTRICTIONS	Approved for patients 2 years of age and older
PRESCRIBER RESTRICTIONS	Must be prescribed by, or in consultation with, a specialist in treating PROS
COVERAGE DURATION	Initial authorization and reauthorization will be approved for six months

New Drug Strengths and Formulations:

1. **Donepezil hcl (Adlarity) Patch TDWK**
   a. **Indication**: Indicated for the treatment of mild, moderate, and severe dementia of the Alzheimer's type.
   b. **Decision**:

	Commercial	Medicaid	Medicare
Formulary Status*	Non-formulary	Non-formulary	Part D: Non-formulary Part B: N/A
Tier**	N/A	N/A	N/A
Specialty Medication	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	4 patches per 28 days	4 patches per 28 days	N/A
* Recommendations for placement may differ between lines of business due to regulatory requirements. ** Medications will be placed on recommended tier above for the base formulary; tier placement for custom formulary(ies) will be based on designation above. For example, Commercial Tier 6 designation above means that the medication will be placed on the highest cost-sharing tier on the respective formulary(ies).			
Formulary Alternatives: donepezil tablet, donepezil ODT, rivastigmine patch, Exelon® patch			

New Indications:

Therapies with Prior Authorization Policies (Non-oncology)

1. **DIACOMIT® (**STIRIPENTOL)
   a. Previous Indication(s):
      a. For the treatment of seizures associated with Dravet syndrome in **patients 2 years of age and older** taking clobazam. There are no clinical data to support the use of DIACOMIT as monotherapy in Dravet syndrome.
   b. New indication approved 07/14/2022:
      a. For the treatment of seizures associated with Dravet syndrome (DS) in patients taking clobazam who are **6 months of age and older and weighing 7 kg or more**. There are no clinical data to support the use of DIACOMIT as monotherapy in Dravet syndrome.
   c. **RECOMMENDATION:** Inform prescribers via Medical Policy Alert. Remove age restrictions from prior authorization policy as outlined below.

Prior Authorization for Commercial/Medicaid:

PA PROGRAM NAME	Diacomit

MEDICATION NAME	Diacomit
COVERED USES	1 - All FDA-Approved Indications
AGE RESTRICTIONS	~~Approved for two years of age and older~~ N/A

Prior Authorization for Medicare Part D:

PA PROGRAM NAME	Diacomit
MEDICATION NAME	Diacomit
PA INDICATION INDICATOR	1 - All FDA-Approved Indications
AGE RESTRICTIONS	~~Approved for two years of age and older~~ N/A

2. **OPZELURA® (**RUXOLITINIB)
   a. Previous Indication(s):
      a. The topical short-term and non-continuous chronic treatment of mild to moderate atopic dermatitis in non-immunocompromised adult and pediatric patients 12 years of age and older whose disease is not adequately controlled with topical prescription therapies or when those therapies are not advisable
   b. New indication approved 07/18/2022:
      a. The topical treatment of nonsegmental vitiligo in adult and pediatric patients 12 years of age and older

- **RECOMMENDATION:** Inform prescribers via Medical Policy Alert. Update Commercial and Medicaid policy with new indication and add new criteria excluding use for nonsegmental vitiligo. Add to Medicare Part D formulary (Tier 4) with prior authorization

Prior Authorization for Commercial/Medicaid:

PA PROGRAM NAME	Opzelura
MEDICATION NAME	Opzelura
COVERED USES	1 - All FDA-Approved Indications
EXCLUSION CRITERIA	• Concurrent use with biologics, other Janus kinase (JAK) inhibitors, or potent immunosuppressants • Use for vitiligo other than nonsegmental vitiligo
REQUIRED MEDICAL INFORMATION	**Nonsegmental vitiligo** **1. For Commercial and Medicaid:** a. Diagnosis of nonsegmental vitiligo with depigmented areas affecting less than or equal to 10% total BSA, which has both facial and non-facial involvement b. Inadequate response to all of the following: 1. Phototherapy for at least six months 2. A topical calcineurin inhibitor (such as tacrolimus)

	3. A moderate to high topical corticosteroid (such as clobetasol 0.05% or fluocinolone 0.05%) **AND** **2. For Medicaid only: Patient must have severe disease, as defined by both of the following:** a. Documentation of functional impairment as indicated by Dermatology Life Quality Index (DLQI) score of at least 11, Children's Dermatology Life Quality Index (CDLQI) score of at least 13, or severe score on another validated tool b. Hand, foot, face, or mucous membrane involvement
AGE RESTRICTIONS	May be approved for patients aged 12 years and older
PRESCRIBER RESTRICTIONS	Atopic Dermatitis: Must be prescribed by, or in consultation with, a dermatologist, allergist, or immunologist Nonsegmental Vitiligo: Must be prescribed by, or in consultation with, a dermatologist
COVERAGE DURATION	Initial authorization will be approved for six months. Reauthorization will be approved until no longer eligible with the plan, subject to formulary or benefit changes.

Prior Authorization for Medicare Part D:

PA PROGRAM NAME	Opzelura
MEDICATION NAME	Opzelura
PA INDICATION INDICATOR	2 - Some FDA-Approved Indications
EXCLUSION CRITERIA	Concurrent use with biologics, other Janus kinase (JAK) inhibitors, or potent immunosuppressants
REQUIRED MEDICAL INFORMATION	For initial authorization for atopic dermatitis, all the following criteria must be met: 1. Diagnosis of mild to moderate atopic dermatitis despite therapies outlined in criterion number 2. Mild to moderate atopic dermatitis may be defined by all of the following: a. Patient has a body surface area (BSA) involvement of 3% to 20% b. Chronic condition, affecting patient for at least two years 2. Documented trial and failure, contraindication, or hypersensitivity to both of the following treatment modalities: a. A moderate to high potency topical corticosteroids (such as clobetasol 0.05%, betamethasone dipropionate 0.05%, triamcinolone 0.5%) applied once daily for at least two weeks b. A topical calcineurin inhibitor (such as tacrolimus ointment) applied twice daily for at least one month For reauthorization for atopic dermatitis: Documentation of reduction or stabilization from baseline of flares, pruritis, erythema, edema, xerosis, erosions/excoriation, oozing/crusting, lichenification or affected BSA.

	For initial authorization for nonsegmental vitiligo, all the following criteria must be met: 1. Diagnosis of nonsegmental vitiligo with depigmented areas affecting less than or equal to 10% total BSA, which has both facial and non-facial involvement 2. Inadequate response to two of the following: a. Phototherapy for at least six months b. A topical calcineurin inhibitor (such as tacrolimus) c. A moderate to high topical corticosteroid (such as clobetasol or fluocinolone) For reauthorization for nonsegmental vitiligo: Documentation of positive clinical response to therapy
AGE RESTRICTIONS	N/A
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. Reauthorization will be approved for one year

3. **QSYMIA® (**PHENTERMINE AND TOPIRAMATE EXTENDED-RELEASE CAPSULES)
   a. Previous Indication(s):
      a. For use as an adjunct to a reduced-calorie diet and increased physical activity for chronic weight management in:
         1. Adults with an initial body mass index (BMI) of:
            a. 30 kg/m^2 or greater (obese) or
            b. 27 kg/m^2 or greater (overweight) in the presence of at least one weight-related comorbidity such as hypertension, type 2 diabetes mellitus, or dyslipidemia
   b. New indication approved 06/24/2022
      a. Pediatric patients aged 12 years and older with BMI in the 95th percentile or greater standardized for age and sex
   c. **RECOMMENDATION:** Inform prescribers via Medical Policy Alert. No changes to the policy, which already accounts for FDA-labeled age restrictions

4. **OLUMIANT® (**BARICITINIB)
   a. Previous Indication(s):
      a. For the treatment of adult patients with moderately to severely active rheumatoid arthritis who have had an inadequate response to one or more TNF blockers
      b. For the treatment of COVID-19 in hospitalized adults requiring supplemental oxygen, non-invasive or invasive mechanical ventilation, or ECMO
   b. New indication approved 06/13/2022:
      a. For the treatment of adult patients with severe alopecia areata
   c. **RECOMMENDATION:** Inform prescribers via Medical Policy Alert. This indication is considered a benefit exclusion and will not be covered for all lines of business. This indication is not covered as the condition is considered cosmetic in nature and treatments have not been shown to improve function or reduce morbidity/mortality.

5. **IMCIVREE®** (SETMELANOTIDE ACETATE)
   a. Previous Indication(s):
      a. For chronic weight management in adult and pediatric patients 6 years of age and older with monogenic or syndromic obesity due to pro-opiomelanocortin (POMC), proprotein convertase subtilisin/kexin type 1 (PCSK1), or leptin receptor (LEPR) deficiency as determined by an FDA-approved test demonstrating variants in POMC, PCSK1, or LEPR genes that are interpreted as pathogenic, likely pathogenic, or of uncertain significance (VUS)
   b. New indication(s) approved 06/16/2022:
      a. For chronic weight management in adult and pediatric patients 6 years of age and older with monogenic or syndromic obesity due to Bardet-Biedl syndrome (BBS).
   c. **RECOMMENDATION:** Inform prescribers via Medical Policy Alert. Update Commercial and Medicaid policy with new indication and criteria for BBS. No changes to Medicare non-formulary designation.

Prior Authorization for Commercial/Medicaid:

PA PROGRAM NAME	Imcivree
MEDICATION NAME	Imcivree
COVERED USES	1 - All FDA-Approved Indications Coverage for Medicaid is limited to a condition that has been designated a covered line item number by the Oregon Health Services Commission listed on the Prioritized List of Health Care Services. • Obesity due to proopiomelanocortin (POMC), proprotein convertase subtilisin/kexin type 1 (PCSK1), or leptin receptor (LEPR) deficiency is considered below the line • Obesity due to Bardet-Biedl syndrome (BBS) is considered below the line
EXCLUSION CRITERIA	Prior gastric bypass surgery resulting in greater than 10% weight loss that was maintained
AGE RESTRICTIONS	May be approved for patients aged six years and older
REQUIRED MEDICAL INFORMATION	For initial authorization~~, all the following must be met~~: 1. For Bardet-Biedl syndrome (BBS): a. Documented presence of four primary features OR three major features and two minor features b. Major features include: i. Retinal cone-rod dystrophy ii. Postaxial polydactyly iii. Cognitive impairment or learning difficulties iv. Kidney disease v. Central obesity c. Minor features include:

	i. Neurologic abnormalities ii. Olfactory dysfunction iii. Oral/dental abnormalities iv. Cardiovascular & other thoraco-abdominal abnormalities v. Gastrointestinal abnormalities vi. Endocrine/metabolic abnormalities 2. For deficiencies in proopiomelanocortin (POMC), proprotein convertase subtilisin/kexin type 1 (PCSK1), or leptin receptor (LEPR): a. Confirmation that obesity is due to a homozygous, or presumed compound heterozygous variant in at least one of the listed genes (POMC, PCSK1, or LEPR), confirmed by genetic testing b. Documentation of genetic testing demonstrating that the variants in POMC, PCSK1, or LEPR genes are interpreted as pathogenic, likely pathogenic, or of uncertain significance (VUS) 3. For all indications: diagnosis of obesity, defined as either of the following: a. For adults: Body mass index (BMI) of greater than or equal to 30 b. For pediatrics, using growth chart assessments: i. For POMC, PCSK1, and LEPR deficiencies: Greater than or equal to the 95th percentile ~~using growth chart assessments~~ ii. For BBS: Greater than or equal to the 97th percentile ~~4. Confirmation that obesity is due to a homozygous, or presumed compound heterozygous variant in at least one of the following genes, confirmed by genetic testing: proopiomelanocortin (POMC), proprotein convertase subtilisin/kexin type 1 (PCSK1), or leptin receptor (LEPR), **AND**~~ ~~5. Documentation of genetic testing demonstrating that the variants in POMC, PCSK1, or LEPR genes are interpreted as pathogenic, likely pathogenic, or of uncertain significance (VUS)~~ For reauthorization, the following must be met: Documentation of response to therapy, as evidenced by: at least a 5% reduction in baseline body weight OR at least 5% reduction in baseline BMI for patients with continued growth potential

Therapies with Prior Authorization Policies (Oncology)

6. **XALKORI®** (CRIZOTINIB)
   a. New indication(s) approved 07/14/2022:

   a. Adult and pediatric patients 1 year of age and older with unresectable, recurrent, or refractory inflammatory myofibroblastic tumor (IMT) that is ALK-positive
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. **ZYDELIG®** (IDELALISIB)
   a. Indication change published 07/06/2022:
      a. Withdrawn indications (accelerated approval):
         1. Relapsed follicular B-cell non-Hodgkin lymphoma (FL) in patients who have received at least two prior systemic therapies.
         2. Relapsed small lymphocytic lymphoma (SLL) in patients who have received at least two prior systemic therapies.
      b. The manufacturer voluntarily withdrew its accelerated approval for these indications due to difficulty with enrollment for the confirmatory study.
      c. Though the NCCN reviewing panel has acknowledged the withdrawn indication for SLL, they have made the decision to continue listing this drug for this use in the relevant guideline.
   b. **RECOMMENDATION:** Inform prescribers via Medical Policy Alert. Prior authorization policy coverage criteria are based on recommendations from the National Comprehensive Cancer Network (NCCN); no updates to the policy are warranted.
8. **RUBRACA®** (RUCAPARIB)
   a. Indication change published 06/10/2022:
      a. Withdrawn indication: for the treatment of adult patients with a deleterious BRCA mutation (germline and/or somatic)-associated epithelial ovarian, fallopian tube, or primary peritoneal cancer who have been treated with two or more chemotherapies. Select patients for therapy based on an FDA-approved companion diagnostic for RUBRACA.
   b. The manufacturer voluntarily withdrew its accelerated approval for this indication. This was due to data from the Ariel4 post marketing trial linking this drug to an increased risk of death over chemo in patients with third or later-line ovarian cancer, despite showing benefit in stalling disease progression. As of 9/9/2022, the NCCN has not acknowledged the withdrawn indication in its guideline for ovarian cancer, including fallopian tube cancer and primary peritoneal cancer.
   c. **RECOMMENDATION**: Inform prescribers via Medical Policy Alert. Prior authorization policy coverage criteria are based on recommendations from the National Comprehensive Cancer Network (NCCN); no updates to the policy are warranted.
9. **TAFINLAR®** (DABRAFENIB MESYLATE)
   a. New indication(s) approved 06/22/2022:
      a. The treatment of adult and pediatric patients 6 years of age and older with unresectable or metastatic solid tumors with BRAF V600E mutation who have progressed following prior treatment and have no satisfactory alternative treatment options. This indication is approved under accelerated approval based on overall response rate and duration of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial(s)
   b. **RECOMMENDATION**: Inform prescribers via Medical Policy Alert. Prior authorization policy coverage criteria are based on recommendations from the National Comprehensive Cancer Network (NCCN); no updates to the policy are warranted.

10. **MEKINIST®** (TRAMETINIB DIMETHYL SULFOXIDE)
    a. New indication(s) approved 06/22/2022:
        a. The treatment of adult and pediatric patients 6 years of age and older with unresectable or metastatic solid tumors with BRAF V600E mutation who have progressed following prior treatment and have no satisfactory alternative treatment options. This indication is approved under accelerated approval based on overall response rate and duration of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial(s).
    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

11. **CELLCEPT® (MYCOPHENOLATE MOFETIL**)
    a. Previous Indication(s):
        a. for the prophylaxis of organ rejection in recipients of allogeneic kidney, heart or liver transplants, and should be used in combination with other immunosuppressants
    b. New indication(s) approved 06/06/2022:
        a. For the prophylaxis of organ rejection in **adult and pediatric recipients 3 months of age and older** of allogeneic kidney, heart, or liver transplants, in combination with other immunosuppressants
    c. **RECOMMENDATION:** Inform prescribers via Medical Policy Alert.
12. **ZULRESSO® (BREXANOLONE**)
    a. Previous Indication(s):
        a. For the treatment of postpartum depression (PPD) in adults.
    b. New indication(s) approved 06/16/2022:
        a. For the treatment of postpartum depression (PPD) in patients 15 years and older.
    c. **RECOMMENDATION:** Inform prescribers via Medical Policy Alert.

Drug Safety Monitoring:

FDA Drug Safety Communications

1. **Drug Name:** Copiktra® (duvelisib)
    - **Date Posted:** 06/30/2022
    - **Safety Alert Title:** FDA warns about possible increased risk of death and serious side effects with cancer drug Copiktra (duvelisib)
    - **Link to more information:** https://www.fda.gov/drugs/drug-safety-and-availability/fda-warns-about-possible-increased-risk-death-and-serious-side-effects-cancer-drug-copiktra
    - **What safety concern is FDA announcing?**

1. The U.S. Food and Drug Administration (FDA) is warning that results from a clinical trial show a possible increased risk of death with Copiktra (duvelisib) compared to another medicine to treat a chronic blood cancer called leukemia and a lymphoma, a cancer found in the lymph nodes. The trial also found Copiktra was associated with a higher risk of serious side effects, including infections, diarrhea, inflammation of the intestines and lungs, skin reactions, and high liver enzyme levels in the blood.

- **What is FDA doing?**
  - We are notifying the public of these risks and are continuing to evaluate the safety of Copiktra. We plan to hold a future public meeting to discuss the findings from the clinical trial and whether Copiktra should continue to be prescribed for patients. We will update the public when we have more information.
- **What should health care professionals do?**
  - Health care professionals should consider the risks and benefits of continuing Copiktra in the context of other available treatments. Advise patients receiving Copiktra of the possible increased risk of death and higher risk of serious adverse events.
- **Health Plan Recommendation:** Notify providers via Medical Policy Alert.

2. **Drug Name:** Ukoniq (umbralisib)
   - **Date Posted:** 06/01/2022
   - **Safety Alert Title:** FDA approval of lymphoma medicine Ukoniq (umbralisib) is withdrawn due to safety concerns
   - **Link to more information:** https://www.fda.gov/drugs/drug-safety-and-availability/fda-approval-lymphoma-medicine-ukoniq-umbralisib-withdrawn-due-safety-concerns
   - **What safety concern is FDA announcing?**
     - Due to safety concerns, the U.S. Food and Drug Administration (FDA) has withdrawn its approval for the cancer medicine Ukoniq (umbralisib). Ukoniq was approved to treat two specific types of lymphoma: marginal zone lymphoma (MZL) and follicular lymphoma (FL).
     - Updated findings from the UNITY-CLL clinical trial continued to show a possible increased risk of death in patients receiving Ukoniq.
   - **What is FDA doing?**
     - We determined the risks of treatment with Ukoniq outweigh its benefits. Based upon this determination, the drug's manufacturer, TG Therapeutics, it was voluntarily withdrawing Ukoniq from the market for the approved uses in MZL and FL.
   - **What should health care professionals do?**
     - Health care professionals should stop prescribing Ukoniq and switch patients to alternative treatments. Inform patients currently taking Ukoniq of the increased risk of death seen in the clinical trial and advise them to stop taking the medicine. In limited circumstances in which a patient may be receiving benefit from Ukoniq, TG Therapeutics plans to make it available under expanded access.

- **Health Plan Recommendation:** Notify providers via Medical Policy Alert. Providence Health Plan did not have any patients using this medication; therefore, no recall notification letters were sent.

Drug Recalls/Market Withdrawals

1. **Drug Name:** Major (Milk of Magnesia Suspension and Magnesium Hydroxide /Aluminum Hydroxide /Simethicone Oral Suspension)
   - **Date of Recall:** 06/08/2022
   - **Reason for recall:** Due to microbial contamination, multiple lots recalled
   - **Link to more information:** https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/plastikon-healthcare-issues-voluntary-nationwide-recall-milk-magnesia-oral-suspension-and-magnesium
   - **Health Plan Recommendation:** Notify providers via Medical Policy Alert.

2. **Drug Name:** Magnesium Citrate Saline Laxative Oral Solution, Lemon Flavor by Vi-Jon LLC, all lots recalled
   - **Date of Recall:** 07/15/2022
   - **Reason for recall:** Microbial contamination with *Gluconacetobacter liquefaciens*
   - **Link to more information:** https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/vi-jon-llc-expands-voluntary-nationwide-recall-magnesium-citrate-saline-laxative-oral-solution-lemon
   - **Health Plan Recommendation:** Notify providers via Medical Policy Alert.

3. **Drug Name:** Dose Vital Honey
   - **Date of Recall:** 07/19/2022
   - **Reason for recall:** Undeclared active pharmaceutical ingredient tadalafil, full product recall
   - **Link to more information:** https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/mks-enterprise-llc-voluntary-recalls-dose-vital-vip-vital-honey-due-presence-undeclared-tadalafil
   - **Health Plan Recommendation:** Notify providers via Medical Policy Alert.

4. **Drug Name:** Sustango Dietary Supplement for Male Enhancement
   - **Date of Recall:** 07/25/2022
   - **Reason for recall:** Undeclared Tadalafil, nationwide recall
   - **Link to more information:** https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/ultra-supplement-llc-issues-voluntary-nationwide-recall-sustango-due-presence-undeclared-tadalafil
   - **Health Plan Recommendation:** Notify providers via Medical Policy Alert.

5. **Drug Name:** Magnesium Citrate Saline Laxative Oral Solution – multiple brands from Vi-Jon LLC
   - **Date of Recall:** 07/26/2022
   - **Reason for recall:** Potential Gluconacetobacter liquefaciens contamination, recall all lots of all flavors within expiry

- **Link to more information:** https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/vi-jon-llc-expands-voluntary-nationwide-recall-all-flavors-and-lots-within-expiry-magnesium-citrate
- **Health Plan Recommendation:** Notify providers via Medical Policy Alert.

Other Formulary Changes:

Drug Name	Recommendation	Policy Name
Methylphenidate hcl (Adhansia XR) CPBP 20-80 **Amphetamine (Adzenys XR-ODT) Tab Rap BP** **Amphetamine (Adzenys ER) Susp** **Amphetamine sulfate (Evekeo ODT) Tab Rapdis**	• Commercial: Retire Prior Authorization (medications will remain non-formulary) • Medicaid: Added to Long-Acting Stimulant Medications - Medicaid	• Commercia: N/A • Medicaid: Long-Acting Stimulant Medications - Medicaid
Ranolazine (Aspruzyo Sprinkle) Pack ER GR	New dosage form (Pack ER GM); Non-formulary for all lines of business	N/A
Sirolimus (Hyftor) Gel (Gram)	New route (Topical), dosage form (Gel) and strength (0.2%); • Non-formulary for all lines of business	N/A
Echothiophate iodide (Phospholine Iodide) Drops	Non-formulary for all lines of business	N/A
Ranolazine (Ranolazine ER) Tab ER 12h	Add to Medicaid formulary	N/A
Treprostinil (Tyvaso DPI) Cart Inhal	New dosage form (Cart Inhal) and strengths; • Commercial: Formulary, Tier 6, Prior Authorization • Medicaid: Formulary, Specialty, Prior Authorization • Medicare Part D: Formulary, Tier 5, Prior Authorization	Pulmonary Arterial Hypertension
Sodium phenylbutyrate Tablet **Carglumic acid Tab Disper**	Commercial: Down-tier generic from Tier 6 to Tier 5	Medications For Rare Indications

Arnuity Ellipta (fluticasone furoate)	Remove From Medicaid formulary	N/A
Asmanex (mometasone furoate)	Remove From Medicaid formulary	N/A
Flovent Diskus (fluticasone propionate)	Remove From Medicaid formulary	N/A
Pulmicort Flexhaler (budesonide)	Remove From Medicaid formulary	N/A
Frovatriptan tablet	Add to Commercial formulary with Prior Authorization	Non-Preferred Triptans
Harvoni® brand name (90-400 mg) tablet	Remove from Commercial formulary	Hepatitis C - Direct Acting Antivirals
Epclusa® brand name (400-100 mg) tablet	Remove from Commercial formulary	Hepatitis C - Direct Acting Antivirals
Reyvow (Lasmiditan)	Add to Commercial formulary: Tier 4, Prior Authorization, Quantity Limit: • 50 mg: 4 tablets per 30 days • 100 mg: 8 tablets per 30 days	Reyvow
Rhopressa (netarsudil)	Add to Commercial formulary: Tier 4, Step therapy	Anti-Glaucoma Agents
Mylotarg (gemtuzumab ozogamicin)	Add Prior Authorization for all lines of business	Injectable Anti-Cancer Medications
Quetiapine fumarate 150 mg tablet	New strength • Commercial/Medicaid: Non-Formulary • Medicare Part D: Formulary, Tier 4	N/A

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

NEW DRUGS / COMBINATIONS / STRENGTHS / DOSAGE FORMS		
Drug Name	**Action Taken**	**Policy Name**
Ferric carboxymaltose (Injectafer) Vial	New package size. Line extend with Injectafer 750mg/15ml; • Medical benefit for all lines of business	N/A
Risankizumab-rzaa (Skyrizi On-Body) Wear Injct	New dosage form (Wear injectable) and strength (360,g/2.4ml); • Commercial: Formulary, Tier 5, Prior Authorization, Quantity Limit (2.4 ml per 56 days)	• Commercial: Therapeutic Immunomodulators (TIMS) – Comm

	• Medicaid: Non-Formulary, Specialty, Prior Authorization, Quantity Limit (2.4 ml per 56 days) • Medicare Part D: Formulary, Tier 5, Prior Authorization, Quantity Limit (2.4 ml per 56 days)	• Medicaid: Therapeutic Immunomodulators (TIMS) – Medicaid • Medicare Part D: Therapeutic Immunomodulators
Sodium, potassium, mag sulfates (Sod Sulf-Potass Sulf-Mag Sulf) Soln Recon	Marketed under NDA (Suprep). Line extend as generic; • Commercial/Medicare Part D: Non-Formulary • Medicaid: Formulary	N/A
Clindamycin phosphate (Xaciato) Gel w/Appl	New dosage form (Gel w/app); Line extend with Clindesse/Cleocin; • Non-Formulary for all lines of business	N/A
Lumateperone tosylate (Caplyta) Capsule	New dosage strengths (10.5 mg & 21 mg). Line extend with Caplyta 42 mg; • Commercial: Formulary, Tier 4, Step Therapy • Medicaid: Non-Formulary (covered by DMAP) • Medicare Part D: Formulary, Tier 4, Prior Authorization	• Commercial: Antipsychotics Step Therapy Policy • Medicaid: N/A • Medicare Part D: Antipsychotics Program
Acalabrutinib maleate (Calquence) Tablet	New dosage form (tablet). Line extend with Calquence tablet; • Commercial: Formulary, Tier 6, Prior Authorization • Medicaid: Formulary, Specialty, Prior Authorization • Medicare Part D: Formulary, Tier 5, Prior Authorization	• Commercial/Medicaid: Oral Anti-Cancer Medications • Medicare Part D: Anti-Cancer Agents Program
Amphetamine (Dyanavel XR) Tab BP 24H	New dosage form (Tab BP 24h). Line extend with Dyanavel susp; • Commercial: Non-Formulary, Quantity Limit (one tablet per day) • Medicaid: Non-Formulary, Prior Authorization, Quantity Limit (one tablet per day) • Medicare Part D: Non-Formulary	• Commercial: Long-Acting Stimulant Medications Quantity Limit • Medicaid: Long-Acting Stimulant Medications – Medicaid • Medicare Part D: N/A
Amphetamine (Dyanavel XR) Tab BP 24h	New dosage form (Tab BP 24h). Line extend with Dyanavel susp; • Commercial: Non-Formulary, Quantity Limit (1 tablet per day) • Medicaid: Non-Formulary, Prior Authorization, Quantity Limit (1 tablet per day)	• Commercial: Long-Acting Stimulant Medications Quantity Limit • Medicaid: Long-Acting Stimulant Medications Quantity Limit

	• Medicare Part D: Non-Formulary	• Medicare Part D: N/A

New Generics:

Drug Name	Action Taken	Policy Name
Norethindrone acetate-ethinyl estradiol/ferrous fumarate (Finzala) Tab Chew	Line extend with other Minastrin 24 FE generic; • Commercial: Preventive • Medicaid: Non-Formulary • Medicare Part D: Formulary, Tier 4	N/A
Methylphenidate Patch TD24	First generic (Daytrana). Line extend as generic; • Commercial Standard: Formulary, Tier 2, Quantity Limit (one patch per day) • Commercial Cost-Based: Formulary, Tier 4, Quantity Limit (one patch per day) • Medicare Part D: Non-Formulary	N/A
Dabigatran etexilate mesylate (Dabigatran Etexilate) Capsule	First generic (Pradaxa). Line extend as generic; • Commercial Standard: Formulary, Tier 2 • Commercial Cost-Based: Formulary, Tier 3 • Medicaid: Formulary • Medicare Part D: Formulary, Tier 4	
Fesoterodine fumarate (Fesoterodine Fumarate ER) Tab ER 24H	First generic (Toviaz). Line extend as generic; • Non-formulary for all lines of business	N/A
Pirfenidone Tablet	New strength (534mg); Line extend with other Esbriet generics; • Commercial: Formulary, Tier 6, Prior Authorization • Medicaid: Formulary, Specialty, Prior Authorization • Medicare Part D: Formulary, Tier 5, Prior Authorization	Esbriet, Ofev

Clinical Policy Changes:

MAJOR CHANGES	
Policy Name	**Summary of Change**

Calcitonin Gene-Related Peptide (CGRP) Receptor Antagonists – Medicaid	Preferred products were updated to align with oregon health Authority. Quantity limits were added to the injectable medications to align with FDA labeling.
Compounded Drugs	Added FDA Bulk List items in appendix to aid clinical reviewers
Formulary and Quantity Limit Exceptions	Updated language to require a minimum of four drug therapies tried, to include all drugs in the same therapeutic class if available.
Immune Gamma Globulin (IGG)	Criteria were added for pediatric autoimmune neuropsychiatric disorders associated with streptococcal infections/pediatric acute-onset neuropsychiatric syndrome (PANDA/PANS).
Insomnia Agents – Medicaid	Increased coverage duration to 12 months
Interleukin-1 Inhibitors **Interleukin-1 Inhibitors – Medicare Part B**	Added exclusion for combination therapy with biologics. Still's Disease: Replaced conventional Disease-Modifying Antirheumatic Drugs and Tumor Necrosis Factor Drug requirement from Still's Diseases requirement with Non-Steroidal Anti-Inflammatory Drugs based on updates from the 2021 guidelines. Periodic Fever Syndromes (PFS): Updated age restriction to and symptoms required per 2021 taskforce recommendations. Deficiency of Interleukin-1 Receptor Antagonist (DIRA): Added requirement for the presence of symptoms. Familial Mediterranean Fever: Added requirement for genetic confirmation
Lucemyra Step Therapy Policy	Quantity limit changed to align with maximum dose found in package labeling.
Medically Infused Therapeutic Immunomodulators **Medically Infused Therapeutic Immunomodulators - Medicare Part B**	New FDA indications for products were added. Preferred infliximab biosimilar products will be based on contracting. Certolizumab (Cimzia®) was added to this policy due to one formulation required to be administered by a healthcare professional.
Medications For Rare Indications	Gamifant and Keveyis added to the policy (the respective policies for each will be retired)
New Medications and Formulations without Established Benefit	The following drugs will be removed from this policy (will remain non-formulary for Commercial) and added Medicaid Long-Acting Stimulant Policy • Adhansia: • Adzenys ODT • Evekeo ODT Added the following quantity limits • Conzip: One per day • Tramadol 100 mg: Four per day • Tosymra: 6 sprays per 30 days

Non-Preferred Triptan Therapy	Frovatriptan was required to be added to the formulary due to state regulations for drug counts. This was added with prior authorization with requirement to try more cost-effective triptan therapies.
Oral Rinses	Updated to no longer require a failure of other agents, as this would typically be used as adjunctive therapy.
Sylvant	Requiring additional documentation that therapy will be used as a single agent to better align with National Comprehensive Cancer Network recommendations.
Therapeutic Immunomodulators (TIMs) - Comm	Criteria related to trial of preferred products for Crohn's disease were updated. Non-preferred therapies will be required to try adalimumab (Humira®) and one of the following: ustekinumab (Stelara®) or Risankizumab-rzaa (Skyrizi®). Additionally, baracitinib (Olumiant®) was recently approved for alopecia areata. This indication is considered a benefit exclusion and the policy was updated to reflect this.
Therapeutic Immunomodulators (TIMs) - Medicaid	Criteria were added for the diagnosis of atopic dermatitis to align with the Oregon Health Authority. Additionally, baracitinib (Olumiant®) was recently approved for alopecia areata. This indication is not covered by the Oregon health Authority (considered “unfunded”).
Trientine	Removed requirement of penicillamine trial. Policy is in place to ensure appropriate prescriber and indication for use
Uplizna **Uplizna – Medicare Part B**	Aligned prescriber restrictions and coverage duration between these policies.
Vyleesi	Removed prescriber restriction as this indication is most often evaluated by primary care providers. Added requirement for six months of symptoms and clarified approved diagnosis to include Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition new classification.
Xiaflex	Dupuytren's Contracture (DC): Removed limit of 80 degrees for Proximal Interphalangeal Joint (flexion contracture will be allowed if at least 20 degrees). Updated reauthorization criteria to limit to three total injections per cord. Peyronie’s disease: Removed Isolated Hourglass Deformity from list of excluded conditions as it is not necessary if patient meets other criteria. Updated reauthorization criteria to limit to eight total injections. Added exclusion for Peyronie’s disease involving the urethra.

RETIRED POLICIES	
Gamifant	Combined with Medications for Rare Indications (Orphan Drugs) Policy
Keveyis	Combined with Medications for Rare Indications (Orphan Drugs) Policy
Insomnia Agents (Commercial)	Drugs will remain non-formulary