Providence Health Plan

Providence Health Assurance

Healthcare Services Medical & Pharmacy Policy Alerts

Number 276

November 1, 2022

This is the November 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.

Providence Health Plan

Providence Health Assurance

MEDICAL POLICY COMMITTEE

MEDICAL

ALL LINES OF BUSINESS

Effective 12/1/2022

COVID-19 Testing
 	
MP350
	Policy Updates:
	• No changes to policy criteria: **Link to Covid-19 Testing FAQ**
	• Coding Guidelines section has been added. Outlines coding recommendations, including:
	  ○ Added section outlining the COVID-19 Testing Guidelines from CMS' ICD-10-CM Official Guidelines for Coding and Reporting, which was updated in January 2021 in response to the COVID-19 PHE.
	  ▪ These guidelines also include recommendations from the CDC, which state that diagnosis code Z11.52 (encounter for screening for COVID-19) is not appropriate during the COVID-19 pandemic.
	• Billing & Reimbursement Guidelines section has been added. Outlines the following:
	  ○ Diagnosis codes that are not medically necessary, per criterion IV (i.e., the screening diagnosis codes).
	  ○ CPT 87913 which is not reimbursable because it is used to report research related testing.
	  ○ Pricing requirements, as required by the CARES Act.
	  ▪ Contracted rate or posted cash price.
	
	• **OHP:** Continue to follow the Prioritized List for coverage of COVID-19 Testing

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COMPANY POLICIES

Effective 12/1/2022

Balloon Dilation of the Sinuses or Eustachian Tubes (All Lines of Business Except Medicare) **MP33** *Formerly All Lines of Business*	**Policy Updates:** • Change policy title to reflect line of business • Cover balloon dilation of the eustachian tubes (BDET) when criteria are met. ○ Criteria based largely on plan survey and FDA indications of use. • Add policy guidelines clarifying tympanogram images **Codes/PA:** • Add PA to BDET codes (69705, 69706) **OHP:** OHP will follow the Company Policy above
Back: Artificial Intervertebral Disc (All Lines of Business Except Medicare) **MP34**	**Policy Updates:** • Remove requirement that pain be radicular for lumbar artificial disc replacements **Codes/PA:** • Remove one termed code from coding table **OHP:** These changes do not apply to OHP.
Knee: Autologous Chondrocyte Implantation (ACI) for Cartilaginous Defects (All Lines of Business Except Medicare) **MP137** *Formerly All Lines of Business*	**Policy Updates:** Change policy title to reflect line of business. **Codes/PA:** Move S2112 to “not covered” section; code currently denies per coding policy. **OHP:** These changes do not apply to OHP.

Stereotactic Body Radiation Therapy and Stereotactic Radiosurgery (All Lines of Business Except Medicare) **MP229**	**Policy Updates:** • Add uveal or ocular melanoma as covered indication for stereotactic radiosurgery (SRS), per ASTRO update. **Codes/PA:** • Add the following diagnosis codes for uveal or ocular melanoma to pay when billed with SRS (CPT 77371, 77372, 77432): ○ C69.31 ○ C69.32 ○ C69.41 ○ C69.42 ○ C69.91 ○ C69.92 **OHP:** These changes do not apply to OHP. The Prioritized List and the Oregon Administrative Rules will be followed.
Genetic Testing: Reproductive Planning and Prenatal Testing **MP78**	**Policy Updates:** No changes to criteria. **Codes/PA:** • Remove PA of 81265- maternal cell contamination. Standard of care. • Removal of 0168U- code was termed 10/1/2021. **OHP:** OHP will follow the Company Policy above
Varicose Veins (All Lines of Business Except Medicare) **MP182**	**Policy Updates:** Deny two different procedures done on same vein at same time as NMN. This is not best practice and further supported by an AllMed Review. **Codes/PA:** Add S2202 (Echosclerotherapy) to PA coding table as reflected in Billing Guideline and Medicare policy. **OHP:** These changes do not apply to OHP. The Prioritized List and the Oregon Administrative Rules will be followed.
Partial Thromboplastin Time (All Lines of Business Except Medicare)	**Policy Updates:** No changes to criteria. **Codes/PA:** No changes- addition of diagnosis codes related to Von Willebrand disease.

MP325	**OHP:** These changes do not apply to OHP. The Prioritized List and the Oregon Administrative Rules will be followed.

Effective 1/1/2023

Osteochondral Allografts and Autografts for Cartilaginous Defects (All Lines of Business Except Medicare) **MP149** *Formerly All Lines of Business*	**Policy Updates:** • Change policy title to reflect line of business and expanded scope: policy will now also address osteochondral allografts of the ankle and elbow, which will continue to deny as not medically necessary. **Codes/PA:** • Add billing guidelines to clarifying proper coding. • Add unlisted codes for procedures of the ankle, foot and elbow. • Add "not medically necessary" denial to 28446 **OHP:** These changes do not apply to OHP. The Prioritized List and the Oregon Administrative Rules will be followed.
Eye: Blepharoplasty, Blepharoptosis Repair, and Brow Lift (All Lines of Business Except Medicare) **MP101**	**Policy Updates:** Updated criteria for medically necessary reconstructive procedures to better align with LCD that policy is based on. **Codes/PA:** No changes **OHP:** These changes do not apply to OHP. The Prioritized List and the Oregon Administrative Rules will be followed.
Back: Fusion and Decompression Procedures (All Lines of Business Except Medicare) **MP10**	**Policy Updates:** • Change policy title to reflect line of business. • Add OptiLIF to list of investigational considerations; already denying per "including but not limited to" language. **Codes/PA:** • Add 0274T, 0275T, 0719T to policy where these codes will continue to deny - IMT policy • Add note to billing guidelines discussing removal of PA from 22841 - code is currently listed per coding policy as a service that is "not separately payable."

Formerly All Lines of Business	**OHP:** These changes do not apply to OHP. The Prioritized List and the Oregon Administrative Rules will be followed.
Organic Acid Testing (All Lines of Business Except Medicare) **MP254** *Formerly All Lines of Business*	**Policy Updates:** • Change policy title to reflect line of business. • Liberalize criteria to allow for organic acid testing for patients with metabolic disorders. **Codes/PA:** Coding and configuration is as follows: • Continue current configuration (unlisted code review for CPT 81599). • Add three codes specific to organic acids to coding table (83918, 83919, 83921). ○ For non-newborns, codes will pay only when billed with one of the dx codes listed in the billing guidelines (relevant metabolic disorders); otherwise deny as "not medically necessary" ○ For newborns (<12 mo), codes will continue to allow for screening as a Preventive Benefit. No change to this Benefit configuration. **OHP:** These changes do not apply to OHP. The Prioritized List and the Oregon Administrative Rules will be followed.
Radiofrequency Ablation or Cryoablation for Plantar Fasciitis (All Lines of Business Except Medicare) **MP165** *Formerly All Lines of Business*	**Policy Updates:** • Change policy title to reflect line of business. **Codes/PA:** • Continue diagnosis code configuration for CPT codes 0441T and 64640. Since these codes are also shared with the *Knee: Genicular Nerve Blocks and Nerve Ablation for Knee Pain (All Lines of Business Except Medicare)*, the diagnosis code lists were updated to ensure they were the same for both policies. **OHP:** These changes do not apply to OHP. The Prioritized List and the Oregon Administrative Rules will be followed.
Investigational and Non-Covered Medical Technologies (All Lines of Business Except Medicare)	**Policy Updates:** No change to criteria. **Codes/PA:** Change denial for "Shockwave Coronary Intravascular Lithotripsy (IVL) System" from "investigational" (member responsibility) to "not medically necessary" (provider responsibility). This device received FDA approval on the basis of a predicate device. That device ("Shockwave Medical Lithoplasty System) received FDA approval over 5 years ago and should now be considered "not medically necessary."

MP23	• C1761 • C9764 • C9765 • C9766 • C9767 • C9772 • C9773 • C9774 • C9775 • 0715T **OHP:** OHP will follow the Company Policy above

MEDICARE

Effective 12/1/22

Balloon Dilation of the Sinuses or Eustachian Tubes (Medicare Only) **MP359**	**New Medicare Advantage medical policy** **Policy Updates:** New Medicare Only medical policy, separating Medicare from Commercial. Continue to use Company criteria, which is being liberalized to now include medically necessary criteria. **Codes/PA:** • Codes 69705 and 69706: Remove E/I denial, add PA. • No configuration changes to other codes in this policy (continue either PA or unlisted code review).
Knee: Autologous Chondrocyte Implantation (ACI) for Cartilaginous Defects (Medicare Only) **MP355**	**New Medicare Advantage medical policy** **Policy Updates:** New Medicare Advantage policy, separating Commercial from Medicare lines of business. Use Medicare guidance if available and Company policy criteria in the absence of a Medicare policy or guideline. **Codes/PA:** Use same codes found on current All Lines of Business policy. Continue current configuration except for HCPCS code S2112. For this code, remove PA and allow Coding Policy 22.0 to take precedent (this policy will instruct the provider to submit with a different code).

Cochlear Implants and Auditory Brainstem Implants (Medicare Only)
 	
MP189
	Policy Updates:
	• Continue to use Medicare references when available and Company criteria in the absence of Medicare coverage guidance. Changes include the following:
	  ○ Effective September 26, 2022, CMS determined to expand cochlear implant coverage by broadening the patient criteria and removing the clinical trial/ investigational device exemption (IDE) requirement for individuals with hearing test scores of > 40 % and ≤ 60 %.
	  ○ CMS has also elected to potentially provide coverage of cochlear implants for individuals who do not meet the coverage criteria of the NCD 50.3 if the service is performed in the context of a Category B IDE study or a Medicare-approved clinical trial (this was previously left to MAC discretion). While the NCD is not yet updated, according to CMS regulation, these coverage changes are in effect as of the date of the Final Decision Memorandum
	  ○ Update criteria for hybrid implant devices (like any other cochlear implant device, use according to FDA indications, per the NCD) and unilateral hearing loss (NCD requires bilateral hearing loss for coverage, which is emphasized in the released Decision Memo).
	Codes/PA: Changes to codes and/or configuration are as follows:
	• HCPCS code S2235: Remove NMN denial and allow Coding Policy 22.0 to take precedent (this policy will instruct the provider to submit with a different code).
	• No changes to any other code in this policy.

Salivary Hormone Testing (Medicare Only) **MP54**	**Policy Updates:** Updates and clarifications made to criteria, but no change to coverage intent. **Codes/PA:** Configuration changes required for CPT 83520. For this code, continue current configuration, but deny as NMN instead of E/I if billed with select other CPT codes. No changes to the configuration to any other code in this policy.
Varicose Veins (Medicare Only) **MP187**	**Policy Updates:** No change to criteria. **Codes/PA:** Continue current configuration for all codes except for HCPCS code S2202. For this code, since the NMN denial is not supported by the relevant LCD, recommendation is to remove the NMN denial and allow Coding Policy 22.0 to take precedent (this policy will instruct the provider to submit with a different code).

Effective 1/1/23

Back: Fusion and Decompression Procedures (Medicare Only) **MP358**	**New Medicare Advantage Medical Policy** **Policy Update:** New Medicare Advantage policy, separating Commercial from Medicare lines of business. Use Medicare guidance when available and Company policy criteria in the absence of a Medicare policy or guideline. **Codes/PA:** • 0274T, 62287: Remove E/I denial edit and add NMN denial. • 0275T, G0276: Continue dx code configuration, but instead of denying E/I if not reported with an approved diagnosis code, deny as NMN. • 62380, C1831, C2614, S2348: Remove PA and add NMN denial. • CPT 22841: Remove PA and allow Coding Policy 13.0 to take precedent (bundled code). • No changes to any other code in the policy (continue PA or unlisted code review for all remaining codes).

Organic Acid Testing (Medicare Only)
 	
MP363
	New Medicare Advantage medical policy
	Policy Update: New Medicare Only medical policy, separating Medicare from Commercial. Continue to use Company criteria.
	Codes/PA:
	• Use same code found in the current All Lines of Business policy. Continue current configuration (unlisted code review for CPT 81599).
	• Add three organic acid testing codes (83918, 83919, 83921) to the policy, with new diagnosis code configuration.
	  • For newborns (<12 mo), continue to allow for screening as a Preventive Benefit. No change to this Benefit configuration.
	  • For all ages, for all other indications, codes will pair-to-**pay** with select diagnoses codes (relevant metabolic disorders) and deny NMN otherwise.

Osteochondral Allografts and Autografts for Cartilaginous Defects (Medicare Only) **MP357**	**New Medicare Advantage medical policy** **Policy Update:** New Medicare Advantage policy. Prior version of this policy was an All Line of Business policy **and** it was specific to only conditions of the *knee*. This new policy separates by line of business, but in alignment with the Company policy, will also expand scope to include similar services for the *elbow and ankle*. Continue to use Company policy criteria in the absence of a Medicare policy or guideline. **Codes/PA:** Code changes are due to the expansion of policy scope to other body regions beyond the knee. No change to configuration for the unlisted codes added to the policy, but there is a change for CPT code 28446 which is also being added to this policy (add NMN denial) and CPT 29892 (add PA). Continue PA on other codes in the policy which already have PA edits in place.

Radiofrequency Ablation or Cryoablation for Plantar Fasciitis (Medicare Only) **MP364**	**New Medicare Advantage medical policy** **Policy Update:** New Medicare Only medical policy, separating Medicare from Commercial. Continue to use Company criteria or Medicare guidance, depending on the procedure performed. **Codes/PA:** Continue diagnosis code configuration for CPT codes 0441T and 64640. NOTE: Since these CPT codes are also shared with the *Knee: Genicular Nerve Blocks and Nerve Ablation for Knee Pain (Medicare Only)* policy, the diagnosis code lists were updated to ensure they were the same for both policies (this will prevent SA from receiving two different lists for the same code).

Genetic and Molecular Testing (Medicare Only)
 	
MP317
	Policy Update: Updates and clarifications made to criteria. Several tests were already in the policy, but with no "criteria" provided, so criteria for these tests were added.
	Codes/PA: Changes to codes and/or configuration are as follows:
	• 68 codes will either:
	  ○ Be added to the policy with new configuration ***OR***
	  ○ Codes already in the policy will have configuration changed ***OR***
	  ○ Codes will be moved from this policy to a different policy for Medicare.

New and Emerging Technologies and Other Non-Covered Services (Medicare Only) **MP220**	**Policy Update:** No change to overall criteria. See "Codes/PA" below for more information. **Codes/PA:** Changes to codes and/or configuration are as follows: • Add 0152U to policy and add NMN denial • Move CPT 0228U from the Medicare GMT policy to this policy and add NMN denial

REIMBURSEMENT POLICIES

Effective 11/1/2022

Observation Status	**Updated Reimbursement Policy** **Recommendation:** • Transitioning the existing UM policy on observation status to our new Reimbursement Policy template and format.

	• No recommended changes to existing criteria or processes around observation status.

VENDOR UPDATES

Level of Care Utilization System (LOCUS), Child and Adolescent Level of Care Utilization System (CALOCUS) and Child and Adolescent Service Intensity Instrument (CASII)	Starting January 1st, 2023 Providence Health Plan will be switching from using InterQual criteria to Level of Care Utilization System (LOCUS), Child and Adolescent Level of Care Utilization System (CALOCUS) and Child and Adolescent Service Intensity Instrument (CASII) for the following mental health services/levels of care in accordance with OR HB 3046: Inpatient, Residential Treatment, Partial Hospitalization, Intensive Outpatient. This change will apply to all lines of business with the exception of Medicare and Medicaid, which will continue using InterQual. To learn more about LOCUS/CALOCUS criteria, you may visit the American Association for Community Psychiatry page here. To learn more about CASII you may visit the American Association of Child & Adolescent Psychiatry page here.

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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

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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:

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.

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

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

Providence Health Plan

Providence Health Assurance

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) • 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)	• Commercial: Therapeutic Immunomodulators (TIMS) – Comm • 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)	• Commercial: Long-Acting Stimulant Medications Quantity Limit

	• Medicaid: Non-Formulary, Prior Authorization, Quantity Limit (one tablet per day) • Medicare Part D: Non-Formulary	• 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) • Medicare Part D: Non-Formulary	• Commercial: Long-Acting Stimulant Medications Quantity Limit • Medicaid: Long-Acting Stimulant Medications Quantity Limit • 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	New FDA indications for products were added. Preferred infliximab biosimilar products will be based on contracting.

Medically Infused Therapeutic Immunomodulators - Medicare Part B	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