Operational Policy		
SUBJECT: **New Drug and or Indication Awaiting P&T Review – Prior Authorization Request**	DEPARTMENT: **Pharmacy**	
ORIGINAL EFFECTIVE DATE: **07/06**	DATE(S) REVIEWED/REVISED: **06/06, 12/06, 08/07, 12/07, 12/08, 12/09,12/10, 04/12, 04/13, 04/14, 04/15, 04/16, 03/17, 03/18, 08/18, 03/19, 03/20, 03/21, 03/22, 03/23 (SNM/JLS)**	
EFFECTIVE DATE: **5/1/2023**		
APPROVED BY: **Oregon Region Pharmacy and Therapeutics Committee**	NUMBER: **ORPCTOPS047.0423**	PAGE: **1 of 3**

SCOPE:
Providence Health Plan, Providence Health Assurance, Providence Plan Partners, and Ayin Health Solutions as applicable (referred to individually as "Company" and collectively as "Companies").

APPLIES TO:

Fully Insured						
Individual	Small Group	Large Group	Self-Insured	Medicare	Medicaid	Delegated Services to Ayin
Oregon On Exchange Oregon Off Exchange Washington Off Exchange	Oregon On Exchange (SHOP) Oregon Off Exchange (SHOP)	Oregon Washington	ASO PBM	Medicare	Medicaid	YCCO WHA
APPLIES TO ALL ABOVE LINES OF BUSINESS						

POLICY:
The Oregon Region Pharmacy & Therapeutics Committee (ORPTC) will make a reasonable effort to review a new chemical entity or new Food and Drug Administration (FDA) indication within 90 days, and will make a decision on each new chemical entity or new FDA indication within 180 days of its release onto the market, or a clinical justification will be provided if this timeframe is not met. In some instances, the ORTPC may require an extended amount of time to allow for the availability of sufficient clinical and safety data. New medications or newly approved indications within the six Protected Classes defined by the Centers for Medicare and Medicaid Services (CMS) for Medicare Part D will be subject to an expedited ORPTC review. The ORPTC will make a decision within 90 days of its release onto the market, rather than the normal 180-day requirement.

Medications delivered under the supervision of a covered/eligible health care provider are covered under the medical benefit and are also subject to review by the ORPTC. Coverage will be limited to terms and conditions of plan medical benefit. Vaccinations administered under the medical benefit

are subject to benefits and vaccine-specific policy if available. See operational policy "Vaccine Program" OPS068 and "Vaccines - Influenza and Pneumococcal" OPS014

DEFINITIONS: N/A

PROCEDURE:
This policy applies if ORPTC reviews a new medication or indication and the committee defers its decision for a future meeting, or if a request is received for a drug that has not yet been reviewed by ORPTC. If ORPTC reviews a new medication or indication and determines that prior authorization is required, then drug specific criteria will be used to evaluate subsequent reauthorization requests, if applicable.

For Medicare Part D, the coverage of a new drug or new indication will depend on the formulary status and utilization management associated with the drug in question

- Formulary drugs without utilization management will process for new indications without review
- Formulary drugs with PA will block at point-of-service and will be reviewed for medical necessity
    - If the PA program approved by CMS covers all FDA approved indications, the requested medication may be covered with confirmed diagnosis
    - If the PA program approved by CMS does not cover all FDA indications, coverage will be reviewed on case-by-case basis for medical appropriateness
- Drugs that are non-formulary will be reviewed according to the criteria outlined in the Standard Coverage Determinations, Exceptions, and Reopening Policy (ORPTCOPS 006)

For Commercial, Medicaid, and Medicare Part B, the following criteria will apply:

- **Required Medical Information:** A prior authorization form and relevant chart notes documenting medical rationale are required.
- **Clinical Criteria**: To obtain a new medication or an existing medication with a new FDA indication awaiting a decision by the ORPTC, urgency must be established by meeting the following criteria:
    1. The medication requested is consistent with the FDA approved indication(s) and evidence-based medicine.

    AND

2. One of the following:
    a. The medication is considered a new drug entity or an existing drug with a new indication with no effective formulary alternatives available
    OR
    b. Reasonable trial and failure of suitable formulary alternatives have been documented by the provider in the chart notes.
    OR
    c. No treatment alternatives are available due to the member being at high risk for or experiencing an adverse drug event. The adverse event risk and prior therapies must be documented. An adverse event is defined as a contraindication, allergy, or sensitivity to the medication.

    AND
3. The medication is being prescribed by, or in consultation with, a specialist in the treatment of the condition, or a provider with at least five years of experience treating the condition
    AND
4. The prescriber indicates that the patient will experience harm (i.e., worsening clinical outcome and inability to return to baseline, loss of life or limb), if the requested medication is not covered until review by ORPTC
    AND
5. For Medicaid (OHP): coverage 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

REFERENCES:

1. Medicare Prescription Drug Benefit Manual, Ch. 6, Part D Drugs and Formulary Requirements; Rev.18, 1-15-16 https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/Part-D-Benefits-Manual-Chapter-6.pdf (accessed 2023 March 6)
2. Oregon Revised Statutes. Chapter 743A — Health Insurance: Reimbursement of Claims. Available at https://www.oregonlegislature.gov/bills_laws/ors/ors743a.html (Accessed March 21, 2023)
3. WAC 182-50 Prescription Drug Programs https://apps.leg.wa.gov/wac/default.aspx?cite=182-50 (accessed 2023 March 6)