

Tina Kotek, Governor

OFFICIAL WEBSITE NOTICE

Posting Date: December 11, 2024

**OREGON HEALTH AUTHORITY DIRECTOR'S DECISION ON PHARMACY
AND THERAPEUTICS COMMITTEE RECOMMENDATIONS
DATED DECEMBER 9, 2024**

I have reviewed the recommendations of the Pharmacy and Therapeutics Committee set out below and have reviewed a staff memo dated December 9, 2024. Based on my review:

The recommendations of the Pharmacy and Therapeutics Committee are approved.

Recommendations with respect to the inclusion of a drug on the Oregon Practitioner-Managed Prescription Drug Plan will be put into place no earlier than 7 days from the date this notice is posted on the website.



Sejal Hathi, MD MBA
Director

Dec. 11, 2024

Approval date

A request for reconsideration of this decision to adopt the recommendations of the Drug Use Review / Pharmacy and Therapeutics Committee must be filed with and received by the Director no later than 7 calendar days from the date of this notice. ORS 414.361(6)(b).

RECOMMENDATIONS OF DRUG USE REVIEW / PHARMACY AND THERAPEUTICS COMMITTEE

The Oregon Drug Use Review / Pharmacy and Therapeutics Committee met virtually on Thursday, Dec. 5, 2024. The Committee considered in order of priority: the safety and efficacy of the drugs being considered; the ability of Oregonians to access effective prescription drugs that are appropriate for their clinical conditions; and substantial differences in costs of drugs within the same therapeutic class. Based upon the clinical information presented by staff ⁱ and all public comment offered,ⁱⁱ while considering the impact on people, populations and communities who have been most impacted by historic and contemporary injustices and health inequities including but not limited to Oregon Tribal Nations, American Indian or Alaska Native persons, Hispanic, Latino, Latina, or Latinx persons, Black or African American persons, Asian or Asian American persons, Pacific Islander or Native Hawaiian persons, people with disabilities, people with limited English proficiency, and immigrants and refugees, the Committee makes the following recommendations for Drug Use Review, the Oregon Practitioner-Managed Prescription Drug Plan (PMPDP), or for any other preferred drug list established by the Oregon Health Authority:

Attention Deficit Hyperactivity Disorder (ADHD) Drugs Literature Scan

The Committee recommended making no changes based on the clinical review of the evidence, and to maintain Onyda™ XR (clonidine ER oral suspension) as voluntary non-preferred on the PMPDP. After comparative cost consideration in the executive session, the Committee recommended making dextroamphetamine ER capsules, amphetamine tablets and methylphenidate ER tablets preferred on the PMPDP.

DRUG	CHANGE
dextroamphetamine ER capsules	Make preferred on the PMPDP
amphetamine tablets	Make preferred on the PMPDP
methylphenidate ER tablets	Make preferred on the PMPDP

Oncology Policy Updates

The Committee recommended adding the following antineoplastic agents recently approved by the U.S. Food and Drug Administration (FDA) to Table 1 in the Oncology Agents Prior Authorization (PA) criteria: Tecentriq Hybreza™ (atezolizumab and hyaluronidase-tqjs); Itovebi™ (inavolisib); and Vyloy® (zolbetuximab-clzb).

Orphan Drugs and Biologics for Rare Diseases PA Update

The Committee recommended moving Uplinza® (inebilizumab-cdon), Ultomiris® (ravulizumab-cwvz), Enspryng® (satralizumab-mwge), Soliris® (eculizumab), Bkemv™ (eculizumab-aeeb), Ephysqli® (eculizumab-aagh), Empaveli® (pegcetacoplan), and PiaSky® (crovalimab-akkz) to the Orphan Drug class, remove their PDL coding, retire their dedicated PA criteria and apply the Orphan Drug policy. The Committee also recommended updating Table 1 in the Orphan Drugs PA criteria to support medically appropriate use of these newly approved orphan drugs: Aqneursa™ (levacetylleucine); and Miplyffa™ (arimoclomol citrate).

Targeted Therapy for Alzheimer's Disease Class Update and New Drug Evaluation (NDE)

The Committee recommended designating donanemab non-preferred on the PMPDP, to require PA for donanemab and update the Alzheimer's Disease (Monoclonal Antibodies) PA criteria as proposed.

Pulmonary Arterial Hypertension (PAH) Drugs Class Update, NDE, and Drug Use Evaluation (DUE)

The Committee recommended making no changes to the PMPDP based on the clinical review of the evidence and implement the proposed PA criteria for sotatercept to support use as add-on treatment in PAH. The Committee also supported implementing PA for preferred PDE-5 inhibitors to prevent coverage for treatment of erectile dysfunction in men and to auto-approve prescriptions for any of the following criteria:

- Diagnosis of PAH;
- Prior claims for other PAH drug classes;
- Identified female gender; OR
- Prescriptions written by a pulmonologist

After comparative cost consideration in the executive session, the Committee recommended making tadalafil tablets preferred on the PMPDP.

DRUG	CHANGE
tadalafil tablets	Make preferred on the PMPDP

Chronic Obstructive Pulmonary Disease (COPD) Class Update and NDE

The Committee recommended making no changes to the PMPDP based on the clinical review of the evidence, to update the Oral Roflumilast PA criteria as proposed, and update the Targeted Immune Modulators for Severe Asthma and Atopic Dermatitis PA criteria to include dupilumab use in adults with inadequately controlled COPD on triple inhaler therapy. The Committee also supported maintaining ensifentribe as non-preferred on the PMPDP and implement the proposed Ensifentribe PA criteria to ensure guideline-directed therapy prior to adding ensifentribe to a therapeutic regimen.

Urea Cycle Disorders Class Review

The Committee recommended adding the Urea Cycle Disorders drug class to the PMPDP and to implement an auto-PA to allow continuation of therapy for the non-preferred agents after initial approval. After comparative cost consideration in the executive session, the Committee recommended making Pheburane® (sodium phenylbutyrate granules), Buphenyl® (sodium phenylbutyrate tablets and powder) and generics preferred, and to make Ravicti® (glycerol phenylbutyrate liquid) and Olpruva® (sodium phenylbutyrate pellet pack) nonpreferred on the PMPDP.

DRUG	CHANGE
Pheburane® granules	Make preferred on the PMPDP
Buphenyl® tablets and powder	Make preferred on the PMPDP
Olpruva® pellet pack	Make non-preferred on the PMPDP
Ravicti® oral liquid	Make non-preferred on the PMPDP

Bone Metabolism Drugs Class Update

The Committee recommended making no changes to the PMPDP based on the clinical review of the evidence, and to revise the Bone Metabolism Agents PA criteria to align with recently published guidelines and FDA safety alerts. After comparative cost consideration in the executive session, the Committee recommended making no changes to the PMPDP.

Platelet Inhibitors Class Update

The Committee recommended making ticagrelor preferred on the PMPDP due to evidence of superior efficacy compared to other antiplatelets for some indications and to retire the Platelet Inhibitors PA criteria and default to general Preferred Drug List (PDL) – Non-Preferred Drugs in Select PDL Classes PA criteria.

DRUG	CHANGE
Brilinta® (ticagrelor)	Make preferred on the PMPDP

The Committee has made these recommendations to the Oregon Health Authority for approval by the Director of the Oregon Health Authority.

ⁱ https://www.orpdl.org/durm/meetings/meetingdocs/2024_12_05/finals/2024_12_05_PnT_Complete.pdf
ⁱⁱ https://www.orpdl.org/durm/meetings/meetingdocs/2024_12_05/finals/2024_12_05_WrittenTestimony.pdf