OFFICIAL WEBSITE NOTICE

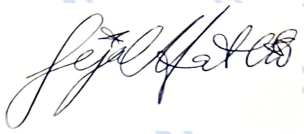
Posting Date: August 8, 2024

OREGON HEALTH AUTHORITY DIRECTOR'S DECISION ON PHARMACY AND THERAPEUTICS COMMITTEE RECOMMENDATIONS DATED AUGUST 5, 2024

I have reviewed the recommendations of the Pharmacy and Therapeutics Committee set out below and have reviewed a staff memo dated August 5, 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

August 8, 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, August 1, 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:

Drug Use Review Recommendations:

Zelsuvmi (berdazimer) Abbreviated Drug Review

The Committee recommended applying the Drugs for Non-funded Conditions' prior authorization (PA) criteria to limit use to funded conditions.

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 PA criteria: Anktiva® (nogapendekin alfa inbakicept-pmln); Imdelltra™ (tarlatamab-dlle); and Ojemda™ (tovorafenib).

Orphan Drug Policy Updates

The Committee recommended updating Table 1 in the Orphan Drugs PA criteria to support medically appropriate use of: Voydeya™ (danicopan);

Fabhalta® (iptacopan); Xolremdi™ (mavorixafor); Rystiggo® (rozanolixizumab-noli); Qalsody® (tofersen); and Zilbrysq® (zilucoplan).

Xolair® (omalizumab) Prior Authorization Update

The Committee recommended updating the PA criteria for Targeted Immune Modulators (TIMs) for Severe Asthma and Atopic Dermatitis to include Xolair® (omalizumab) for food allergies in patients at high risk of frequent and/or severe allergic reactions due to accidental exposure to foods, after amending the proposed criteria to permit use of *in vitro* reactivity to a perennial allergen as an option for diagnostic allergy testing. The Committee also recommended removing the diagnostic requirement for a food challenge from the Xolair® and Palforzia® PA criteria.

Non-alcoholic Steatohepatitis (NASH) and Weight Management Drugs for NASH and Cardiovascular Disease

The Committee recommended implementing PA for Rezdiffra™ (resmetirom) to ensure appropriate use, after amending the proposed criteria to remove the requirement of a liver biopsy for all patients. In the absence of a liver biopsy, the Committee recommended including criteria to confirm other causes of liver disease such as alcoholic liver disease have been ruled out, and to confirm that the patient has at least three of five risk factors/comorbidities for NASH.

The Committee also recommended updating the Weight Management and Glucagon-like Peptide-1 Receptor Agonists (GLP-1 RA) PA criteria to cover specific GLP-1 RAs with compendia-support for treatment of NASH in adult patients with overweight or obesity. For people with NASH, the Committee recommended amending the proposed criteria to limit coverage to people with a diagnosis of NASH based on either biopsy OR the presence of at least three of five risk factors/comorbidities for NASH, with other causes of liver disease ruled out for people who have F2 or F3 fibrosis stages, and when prescribed by or in consultation with a hepatologist or gastroenterologist.

After review of the evidence for recurrent cardiovascular events in people less than 45 years of age, the Committee recommended removing the age restrictions for semaglutide in people with established cardiovascular (CV) disease with overweight or obesity because this population is at increased risk of recurrent major adverse cardiovascular events (MACE), independent of age.

Practitioner-Managed Prescription Drug Plan (PMPDP) Recommendations:

Targeted Immune Modulators (TIMs) Drug Effectiveness Review Project (DERP) Report Summaries

The Committee recommended updating the TIMs PA criteria as proposed to include coverage for new drugs and indications and to create tiered step therapy for common diagnoses. The Committee also supported maintaining etrasimod, mirikizumab, bimekizumab, deucravacitinib, and spesolimab as non-preferred on the PMPDP.

After comparative cost consideration in the executive session, the Committee recommended designating: Avsola®; Simlandi® (brand name only); Amjevita™ 100 mg/mL (high concentration); and generic adalimumab-fkjp 50 mg/mL (low concentration) as preferred Tier 1 agents; and to designate Taltz®, Otezla® and Xeljanz® as preferred Tier 2 agents on the PMPDP. Currently preferred products Humira® and Enbrel® were recommended to be included in Tier 1. Cosentyx® was recommended to be made non-preferred on the PMPDP.

DRUG	CHANGE
Avsola® (infliximab-axxq)	Make preferred on the PMPDP- Tier 1
Simlandi® (adalimumab-ryvk) BRAND	Make preferred on the PMPDP- Tier 1
Amjevita™ (adalimumab-atto) 100 mg/mL	Make preferred on the PMPDP- Tier 1
adalimumab-fkjp 50 mg/mL	Make preferred on the PMPDP- Tier 1
Taltz® (ixekizumab)	Make preferred on the PMPDP- Tier 2
Otezla® (apremilast)	Make preferred on the PMPDP- Tier 2
Xeljanz® (tofacitinib)	Make preferred on the PMPDP- Tier 2
Cosentyx® (secukinumab)	Make non-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.

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[i] https://www.orpdl.org/durm/meetings/meetingdocs/2024_08_01/finals/2024_08_01_PnT_Complete.pdf
[ii] https://www.orpdl.org/durm/meetings/meetingdocs/2024_08_01/finals/2024_08_01_WrittenTestimony.pdf