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Kate Brown, Governor

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OFFICIAL WEBSITE NOTICE
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RECOMMENDATIONS OF DRUG USE REVIEW / PHARMACY AND THERAPEUTICS COMMITTEE

The Oregon Drug Use Review / Pharmacy and Therapeutics Committee met virtually on Thursday, December 2, 2021. 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 Tribal Nations, Tribal communities, Latino, Latina/Latinx, Black/African American, Asian, Pacific Islander and American Indian/Alaska Native populations, communities of color, 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 (DUR) Recommendations:

Oncology Policy Updates

The Committee recommended adding the following new FDA-approved antineoplastic agents to Table 1 in the Oncology Agents prior authorization (PA) criteria: Scemblix® (asciminib); Exkivity™ (mobecertinib); and Tivdak™ (tisotumab vedotin-tftv).

Orphan Drug Policy Updates

The Committee recommended updating Table 1 in the Orphan Drugs PA criteria to support medically appropriate use of Tavneos™ (avacopan); Livmarli™ (maralixibat) and Bylvay™ (odevixibat) based on FDA-approved labeling.

Evkeeza™ (evinacumab-dgnb) Prior Authorization Update

The Committee recommended better assessing clinical need by updating question #3 of the initial approval PA criteria to require 12 weeks of maximally tolerated therapy. The Committee also recommended adding the proposed renewal PA criteria, but with an added question to evaluate pregnancy risk.

Spravato® (esketamine) Safety Edit Update

The Committee recommended updating the safety edit for esketamine to clarify appropriate maintenance dose and use in patients with a history of substance use disorder.

HIV Pre-exposure Prophylaxis (PrEP) Drug Use Evaluation

The Committee recommended development of an educational retrospective DUR program to improve provider knowledge of PrEP for patients with a recent sexually transmitted infection, diagnosis of high-risk sexual behavior, or potential viral exposure.

Practitioner-Managed Prescription Drug Plan (PMPDP) Recommendations:

Inhaled Cystic Fibrosis Drugs Literature Scan

The Committee recommended making no changes to the PMPDP based on clinical evidence and to maintain inhaled mannitol as non-preferred. After comparative cost consideration in executive session, the Committee recommended making tobramycin in sodium chloride (NaCl) nebulized solution preferred, and Kitabis® Pak and its generic version tobramycin nebulizer solution non-preferred on the PMPDP.

DRUG	CHANGE
tobramycin in 0.225% NaCl neb solution	Make preferred on the PMPDP
Kitabis® Pak	Make non-preferred on the PMPDP
tobramycin nebulizer solution	Make non-preferred on the PMPDP

Glucagon Class Update and New Drug Evaluation (NDE)

The Committee recommended maintaining Zegalogue® (dasiglucagon) as non-preferred and to make no changes to the PMPDP based on the clinical evidence. After comparative cost consideration in executive session, the Committee recommended making no changes to the PMPDP.

Paroxysmal Nocturnal Hemoglobinuria (PNH) Class Update and NDE

The Committee recommended revising the Ultomiris® (ravulizumab) PA criteria to reflect an expanded indication for use in pediatric patients aged one month and older with PNH or atypical hemolytic uremic syndrome (aHUS) and to revise the accompanying dosing table. The Committee also recommended adding Empaveli™ (pegcetacoplan) to the "Biologics for Rare Diseases" drug class and to implement the proposed PA criteria for pegcetacoplan to limit use to FDA-approved indications funded by the OHP. After comparative cost consideration in executive session, the Committee recommended maintaining pegcetacoplan as non-preferred on the PMPDP.

Gonadotropin-Releasing Hormone (GnRH) Modifiers Class Update and NDE

The Committee recommended implementing new PA criterion for GnRH modifiers to evaluate GnRH antagonists separately from GnRH agonists. After comparative cost consideration in executive session, the Committee recommended maintaining Myfembree® (relugolix/estradiol/norethindrone) as non-preferred on the PMPDP.

Growth Hormone Class Update and NDE

The Committee recommended maintaining Skytrofa® (lonapegsomatropin) as non-preferred and to update the Growth Hormone PA criteria to include lonapegsomatropin. After comparative cost consideration in executive session, the Committee recommended making no changes to the PMPDP.

Bile Therapy Literature Scan and Prior Authorization Update

The Committee recommended making no changes to the PMPDP based on clinical evidence and to modify the Ocaliva® (obeticholic acid) PA criteria to include recommended dosing parameters and safety precautions. After comparative cost consideration in executive session, the Committee recommended making no changes to the PMPDP.

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

APPROVAL BY THE DIRECTOR OF THE OREGON HEALTH AUTHORITY

The recommendations of the Drug Use Review / Pharmacy and Therapeutics Committee are approved. Recommendations with respect to the inclusion of a drug on the Practitioner-Managed Prescription Drug Plan will be put into place no earlier than 7 days from the date this notice is posted on the web site.

Patrick M. Allen
Director, Oregon Health Authority

12/6/2021
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).

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[i] https://www.orpdl.org/durm/meetings/meetingdocs/2021_12_02/finals/2021_12_02_PnT_Complete.pdf
[ii] https://www.orpdl.org/durm/meetings/meetingdocs/2021_12_02/finals/2021_12_02_WrittenTestimony.pdf