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OFFICIAL WEBSITE NOTICE
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OREGON HEALTH AUTHORITY DIRECTOR'S DECISION ON PHARMACY AND THERAPEUTICS (P&T) COMMITTEE RECOMMENDATIONS DATED OCTOBER 5, 2023

I have reviewed the recommendations of the P&T Committee set out below and have reviewed a staff memo dated October 19, 2023. Based on my review:

1. The recommendation to designate Sublocade® (buprenorphine ER) voluntary non-preferred on the PMPDP is ***disapproved***. Agency staff have clarified terms of the supplemental rebate with the manufacturer of Sublocade® (buprenorphine ER). As a result of the clarified terms, Sublocade® (buprenorphine ER) will remain preferred on the PMPDP.

2. All other recommendations of the P&T Committee are ***approved***.

Recommendations with respect to the inclusion of a drug on the PMPDP will be put into place no earlier than 7 days from the date this notice is posted on the website.

David Baden
Interim Director

10/19/2023
Approval date

A request for reconsideration of this decision must be filed with and received by the Director no later than 7 calendar days from the date this notice is posted on the website. 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, October 5, 2023. 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 (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: Elrexfio™ (elranatamab-bcmm); Akeega™ (niraparib and abiraterone acetate); Vanflyta® (quizartinib); and Talvey™ (talquetamab-tgvs).

Orphan Drug Policy Updates

The Committee recommended updating Table 1 in the Orphan Drugs PA criteria to support medically appropriate use of Sohonos™ (palovarotene) and Veopoz™ (pozelimab-bbfg).

Respiratory Syncytial Virus (RSV) PA Update

The Committee recommended updating the clinical PA criteria to align with the Advisory Committee on Immunization Practices (ACIP) recommendations for combination use of prophylactic therapies.

Gene Therapies for Hemophilia A and B, & Beta Thalassemia Drug Effectiveness Review Project (DERP) Summary & New Drug Evaluation (NDE)

The Committee recommended designating Zynteglo® (betibeglogene autotemcel), Hemgenix® (etranacogene dezaparvovec), and Roctavian™ (valoctocogene roxaparvovec-rvox) non-preferred on the PMPDP and to implement clinical PA criteria to ensure appropriate utilization. The Committee modified the proposed

betibeglogene autotemcel clinical PA criteria to allow for approval in people over 35 years of age with beta thalassemia.

DRUG	CHANGE
betibeglogene autotemcel	Make non-preferred on the PMPDP
etranacogene dezaparvovec	Make non-preferred on the PMPDP
valoctocogene roxaparvovec-rvox	Make non-preferred on the PMPDP

Asthma Rescue Inhalers Drug Use Evaluation

The Committee recommended implementing the proposed one-time targeted provider fax notifications to request short-acting beta agonist (SABA) therapy reassessment for select patients. The Committee also supported implementing a targeted RetroDUR to fax provider notification when three SABA inhalers are filled within six months - excluding patients with a COPD diagnosis.

Practitioner-Managed Prescription Drug Plan (PMPDP) Recommendations:

Colony Stimulating Factor Class Update and New Drug Evaluation (NDE)

The Committee recommended making no changes to the PMPDP based on review of recently published clinical evidence. After comparative cost consideration in the executive session, the Committee recommended making Nyvepria™ (pegfilgrastim-apgf) non-preferred on the PMPDP.

DRUG	CHANGE
pegfilgrastim-apgf	Make non-preferred on the PMPDP

Opioid Reversal Agents Class Update

The Committee recommended making no changes to the PMPDP based on review of recently published clinical evidence. After comparative cost consideration in the executive session, the Committee recommended adding over-the-counter (OTC) reversal agents as covered products and making Opvee® (nalmefene) nasal spray and naloxone cartridges preferred on the PMPDP.

DRUG	CHANGE
nalmefene nasal spray	Make preferred on the PMPDP
naloxone cartridge	Make preferred on the PMPDP

Substance Use Disorder Literature Scan

The Committee recommended making no changes to the PMPDP based on review of recently published clinical evidence. After comparative cost consideration in the executive session, the Committee recommended making Brixadi® (buprenorphine extended-release (ER)) injection preferred and Sublocade® (buprenorphine ER) injection voluntary non-preferred on the PMPDP.

DRUG	CHANGE
Brixadi® (buprenorphine ER) injection	Make preferred on the PMPDP
Sublocade® (buprenorphine ER) injection	Make voluntary non-preferred

Parenteral Antipsychotic Literature Scan

The P&T Committee recommended making no changes to the PMPDP based on review of recently published clinical evidence and advisement from the Mental Health Clinical Advisory Group. After comparative cost consideration in the executive session, the Committee recommended making Uzedy™ (risperidone ER) injection preferred on the PMPDP.

DRUG	CHANGE
Uzedy™ (risperidone ER)	Make preferred on the PMPDP

Sodium-Glucose Co-Transporter 2 (SGLT-2) Inhibitors Class Update & NDE

The Committee recommended making no changes to the PMPDP based on review of recently published clinical evidence and to maintain Brenzavvy™ (bexagliflozin) and Inpefa™ (sotagliflozin) as non-preferred. The Committee also recommended updating the PA criteria to allow for preferred SGLT-2 therapies to be used first-line in the treatment of type 2 diabetes mellitus.
After comparative cost consideration in the executive session, the Committee recommended making no changes to the PMPDP.

Alzheimer's Disease Drugs Class Update and NDE

The Committee recommended adding a Monoclonal Antibodies for Alzheimer's Disease drug class to the PMPDP and to maintain Leqembi® (lecanemab) as non-preferred. The Committee also recommended implementing the proposed Monoclonal Antibodies for Alzheimer's Disease clinical PA criteria for lecanemab and aducanumab, after removing the requirement for amyloid imaging in the renewal criteria, and retire the dedicated Aducanumab PA criteria. After comparative cost

consideration in executive session, the Committee recommended making no changes to the PMPDP.

Vesicular Monoamine Transporter 2 (VMAT-2) Inhibitors Class Update

The Committee recommended making no changes to the PMPDP based on review of recently published clinical evidence. After considering input from the Mental Health Clinical Advisory Group, the Committee recommended revising the proposed clinical PA criteria to remove the requirement of a specialist for initial approval and to update the renewal criteria to require a clinically significant reduction in symptoms of tardive dyskinesia from baseline. After comparative cost consideration in the 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.

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[i] https://www.orpdl.org/durm/meetings/meetingdocs/2023_10_05/finals/2023_10_05_PnT_Complete.pdf
[ii] https://www.orpdl.org/durm/meetings/meetingdocs/2023_10_05/finals/2023_10_05_WrittenTestimony.pdf