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OFFICIAL WEBSITE NOTICE **Posting Date: April 21, 2022**

RECOMMENDATIONS OF DRUG USE REVIEW / PHARMACY AND THERAPEUTICS COMMITTEE

The Oregon Drug Use Review / Pharmacy and Therapeutics Committee met virtually on Thursday, April 7, 2022. 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 agent to Table 1 in the Oncology Agents prior authorization (PA) criteria: Kimmtrak® (tebentafusp).

Orphan Drug Policy Updates

The Committee recommended updating Table 1 in the Orphan Drugs PA criteria to support medically appropriate use of EnjaymoTM (sutimlimab-jome) based on FDA-approved labeling.

Emergency Drug Coverage for Citizenship Waived Medical (CWM)

The Committee recommended implementing the proposed PA criteria for emergency drug coverage of drugs prescribed for patients with the CWM benefit and supported updating the PA criteria with relevant diagnoses if emergency drug coverage is expanded to other conditions in the future.

Botulinum Toxins PA Update

The Committee recommended updating the PA criteria as proposed.

Non-Preferred Drugs in Select PDL classes PA Update

The Committee recommended updating the PA criteria as proposed to align with the final version of Statement of Intent 4 (SOI4) from the Health Evidence Review Commission's Prioritized List of Health Services.

Drugs for Non-Funded Conditions PA Update

The Committee recommended updating the PA criteria as proposed to align with the final version of Statement of Intent 4 (SOI4) from the Health Evidence Review Commission's Prioritized List of Health Services.

Hepatitis C Virus (HCV) Direct-Acting antivirals (DAAs) Policy Discussion

The Committee recommended removing PA criteria and required case management for preferred DAA regimens for treatment-naïve patients with hepatitis C virus, but to continue to require PA for: re-treatment of HCV; non-preferred DAAs; and for uses not FDA-approved. The Committee encouraged optional case management for patients that may benefit from additional support. The Committee also recommended designating sofosbuvir/velpatasvir/voxilaprevir (Vosevi®) non-preferred on the PMPDP and to continue to reserve it for treatment-experienced individuals

Practitioner-Managed Prescription Drug Plan (PMPDP) Recommendations:

Sickle Cell Disease Literature Scan

The Committee recommended making no changes to the PMPDP based on clinical evidence and to update the PA criteria to include the expanded age indication for

voxelotor. The Committee further recommended modifying criteria to remove documentation of baseline pain crises for voxelotor use, to clarify language regarding hydroxyurea use, and to clarify documentation of benefit required upon renewal. After comparative cost consideration in executive session, the Committee recommended making no changes to the PMPDP.

Fabry Disease Literature Scan

The Committee recommended revising the PA criteria to reflect the expanded indication for agalsidase beta.

VoxzogoTM (vosoritide) New Drug Evaluation (NDE)

The Committee recommended implementing the proposed PA criteria to ensure appropriate use.

Vyvgart™ (efgartigimod alfa-fcab) NDE

The Committee recommended designating efgartigimed as non-preferred on the PMPDP and subject to the proposed PA criteria to ensure appropriate use.

DRUG	CHANGE
Vyvgart [™] (efgartigimod alfa-fcab)	Make non-preferred on the PMPDP

Fluoroquinolone Drug Class Update

The Committee recommended designating moxifloxacin as preferred on the PMPDP based on the clinical evidence. After comparative cost consideration in executive session, the Committee recommended making no additional changes to the PMPDP.

DRUG	CHANGE
moxifloxacin	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.

APPROVAL BY THE DIRECTOR OF THE OREGON HEALTH AUTHORITY

Recommendations regarding hepatitis C virus (HCV) direct-acting antivirals (DAAs) are approved as clarified below:

Remove PA criteria and required case management for preferred DAA regimens for patients without prior claims history for a DAA. Designate sofosbuvir/velpatasvir/voxilaprevir (Vosevi®) non-preferred on the PMPDP and continue to reserve it for treatment-experienced individuals.

Implementation of HCV DAA recommendations shall occur as soon as practicable, after consultation with CCOs to identify and address operational barriers, and no later than January 1, 2023.

All other 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

4/21/2022

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).

i https://www.orpdl.org/durm/meetings/meetingdocs/2022 04 07/finals/2022 04 07 PnT Complete.pdf

iihttps://www.orpdl.org/durm/meetings/meetingdocs/2022_04_07/finals/2022_04_07_WrittenTestimony.pdf