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OFFICIAL WEBSITE NOTICE **Posting Date: June 9, 2021**

RECOMMENDATIONS OF DRUG USE REVIEW / PHARMACY AND THERAPEUTICS COMMITTEE

The Oregon Drug Use Review/Pharmacy and Therapeutics Committee met virtually on Thursday, June 3, 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 most impacted by historic and contemporary injustices and health inequities, ⁱⁱⁱ 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:

Orphan Drug Policy Updates

The Committee recommended updating Table 1 in the Orphan Drugs prior authorization (PA) criteria to support medically appropriate use of NulibryTM (fosdenopterin) based on FDA-approved labeling.

Oncology Policy Updates

The Committee recommended adding the following new FDA-approved antineoplastic agents to Table 1 in the Oncology Agents PA criteria: Fotivda® (tivozanib); Abecma® (idecabtagene vicleucel); Jemperli (dostarlimab-gxly); Pepaxto® (melphalan flufenamide); and ZynlontaTM (loncastuximab tesirine-lpyl).

Antipsychotics in Young Children Safety Edit

The Committee recommended implementing the proposed safety edit to ensure appropriate use of antipsychotics in children 5 years of age or younger and to implement

a retrospective provider outreach program to facilitate access to medications for appropriate children.

Migraine Medications Drug Use Evaluation (DUE)

The Committee recommended making no policy changes for triptan therapy and no PA criteria changes for the CGRP Antagonists at this time based on the DUE. The Committee recommended provider education to increase migraine prophylaxis use in patients taking chronic triptans.

Cystic Fibrosis Prior Authorization Update

The Committee recommended removing the requirement for manual review by the medical director for use of Orkambi® (lumacaftor/ivacaftor) in patients less than 12 years of age - to be consistent with FDA labeling and standard of care - and to add a link to FDA labeling in the Oral CF Modulators PA criteria to ensure all approved CFTR mutations are current.

Practitioner-Managed Prescription Drug Plan (PMPDP) Recommendations:

Colony Stimulating Factors Literature Scan

The Committee recommended making no changes to the PMPDP based on clinical evidence. After comparative cost consideration in executive session, the Committee recommended making NyvepriaTM preferred and Neulasta® non-preferred on the PMPDP.

DRUG	CHANGE	
Nyvepria TM (pegfilgrastim-apgf)	Make preferred on the PMPDP	
Neulasta® (pegfilgrastim)	Make non-preferred on the PMPDP	

Growth Hormone Abbreviated Drug Review and Prior Authorization Update

The Committee recommended adding Sogroya® (somapacitan-beco) to the Growth Hormone class, designating it as non-preferred and limiting use to OHP-covered conditions. The Committee also recommended updating the PA criteria to align with HERC coverage guidance and FDA-approved indications.

Hereditary Angioedema Class Update with New Drug Evaluation

The Committee recommended making no changes to the PMPDP based on clinical evidence and updating the PA criteria to include OrladeyoTM (berotralstat). After

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

Multiple Sclerosis (MS) Class Update with New Drug Evaluation

The Committee recommended implementing the proposed clinical PA criteria for Kesimpta® (ofatumumab) for both physician administered and point of sale pharmacy claims, to limit use to conditions funded by the OHA for patients with a history of inadequate response to at least two disease-modifying drugs approved for MS, and when prescribed by a neurologist. The Committee also recommended updating the Oral MS Drug PA criteria to add PonvoryTM (ponesimod) and recommended modifying the language regarding pregnancy to address all populations of childbearing potential. After comparative cost consideration in executive session, the Committee recommended maintaining ofatumumab and ponesimod as non-preferred and recommended making no other changes to the PMPDP.

Focused Heart Failure Class Update with New Drug Evaluation

The Committee recommended renaming the "ACEIs, ARBs and DRIs" PMPDP class to "Inhibitors of the Renin-Angiotensin-Aldosterone System (RAAS)," including Entresto® (sacubitril/valsartan) and updating the dedicated PA criteria to include the expanded FDA approved indications. The Committee also recommended requiring PA for vericiguat to ensure appropriate use in patients on goal-directed therapy with advanced symptomatic HFrEF (heart failure with reduced ejection fraction), adding a pregnancy question to the PA criteria, and adding an assessment of adherence to the renewal criteria for both sacubitril/valsartan and vericiguat. After comparative cost consideration in executive session, the Committee recommended making Entresto® non-preferred on the PMPDP.

DRUG	CHANGE	
Entresto® (sacubitril/valsartan)	Make non-preferred on the PMPDP	

Platelet Inhibitors Class Update

The Committee recommended making no changes to the PMPDP based on the clinical evidence and recommended updating the PA criteria to include new indications for ticagrelor. After comparative cost consideration in executive session, the Committee recommended making prasugrel preferred and removing from the PA criteria.

DRUG	CHANGE
prasugrel	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

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.

	6/9/2021
Patrick M. Allen	Approval date
Director, Oregon Health Authority	

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/2021 06 03/finals/2021 06 03 PnT Complete.pdf

ii https://www.oregon.gov/OHA/HSD/OHP/Pages/PT-Committee.aspx

These include but are 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.