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OFFICIAL WEBSITE NOTICE Posting Date: June 9, 2020

RECOMMENDATIONS OF DRUG USE REVIEW / PHARMACY AND THERAPEUTICS COMMITTEE

The Oregon Drug Use Review / Pharmacy and Therapeutics Committee met virtually on Thursday, June 4, 2020. 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 finally, substantial differences in costs of drugs within the same therapeutic class. Based upon the clinical information presented by staff ⁱand all public comment offered, ⁱⁱ while considering the impact on special populations, the Committee makes the following recommendations for the Oregon Practitioner-Managed Prescription Drug Plan (PMPDP) or for any other preferred drug list established by the Oregon Health Authority:

Practitioner-Managed Prescription Drug Plan (PMPDP) Recommendations:

Acne Class Update with New Drug Evaluation (NDE)

The Committee recommended making no changes to the PMPDP based on clinical evidence and to update the prior authorization (PA) criteria as proposed. After comparative cost consideration in executive session, the Committee recommended making AltrenoTM (tretinoin) and ArazloTM (tazarotene) non-preferred and unassigned benzoyl peroxide products preferred on the PMPDP, but subject to the acne PA criteria.

DRUG	CHANGE
Altreno TM (tretinoin)	Make non-preferred on the PMPDP
Arazlo TM (tazarotene)	Make non-preferred on the PMPDP
unassigned benzoyl peroxide	Make preferred on the PMPDP

Antiepileptics Class Update with NDE

The Committee recommended designating Xcopri® (cenobamate) as non-preferred on the PMPDP based on clinical evidence. After comparative cost consideration in executive session, the Committee recommended making no other changes to the PMPDP.

DRUG	CHANGE
Xcopri® (cenobamate)	Make non-preferred on the PMPDP

Oral Diuretics Class Update

The Committee recommended designating chlorthalidone as preferred on the PMPDP based on clinical evidence. After comparative cost consideration in executive session, the Committee recommended making generic triamterene/hydrochlorothiazide (HCTZ) products preferred.

DRUG	CHANGE
chlorthalidone	Make preferred on the PMPDP
generic triamterene/HCTZ	Make preferred on the PMPDP

Sickle Cell Disease (SCD) Class Review with NDE

The Committee made the following recommendations: 1) create a PMPDP class for the SCD drugs, 2) make a hydroxyurea formulation a preferred treatment and 3) designate OxbrytaTM (voxelotor) and Adakveo® (crizanlizumab-tmca) as non-preferred. The Committee also recommended implementing the proposed SCD PA criteria after amending the version posted in the packet to also apply to L-glutamine. After comparative cost consideration in executive session, the Committee recommended making generic hydroxyurea capsules preferred and Droxia®, Hydrea®, Siklos®, and EndariTM (L-glutamine) non-preferred on the PMPDP.

DRUG	CHANGE
generic hydroxyurea capsules	Make preferred on the PMPDP
Droxia® (hydroxyurea)	Make non-preferred on the PMPDP
Hydrea® (hydroxyurea)	Make non-preferred on the PMPDP
Siklos® (hydroxyurea)	Make non-preferred on the PMPDP
Endari TM (L-glutamine)	Make non-preferred on the PMPDP
Adakveo® (crizanlizumab-tmca)	Make non-preferred on the PMPDP
Oxbryta TM (voxelotor)	Make non-preferred on the PMPDP

Drugs for Duchenne Muscular Dystrophy (DMD) Class Update with NDE

The Committee recommended updating the DMD PA criteria to incorporate Vyondys 53® (golodirsen).

Idiopathic Pulmonary Fibrosis Class Update

The Committee recommended updating the PA criteria as proposed and to expand and rename the PMPDP class to cover approved indications for Interstitial Lung Disease, which includes idiopathic pulmonary fibrosis. No changes to the PMPDP were recommended based on the clinical evidence.

Cystic Fibrosis (CF) Class Update with NDE

The Committee recommended maintaining TrikaftaTM (elexacaftor/tezacaftor/ivacaftor) as non-preferred on the PMPDP and to update the Oral CF Modulators PA as outlined in the proposed criteria changes. The Committee also recommended updating the PA criteria as proposed - including initial approvals for 6 months and subsequent approvals for 12 months – after amending to remove the required sweat chloride test from the renewal criteria for ivacaftor.

Laxatives for Chronic Constipation Class Update

The Committee recommended revising the Drugs for Constipation PA criteria to include MotegrityTM (prucalopride), Zelnorm® (tegaserod), and Ibsrela® (tenapanor) and to designate all three non-preferred on the PMPDP to assure use for OHP funded conditions. After comparative cost consideration in executive session, the Committee recommended making no other changes to the PMPDP.

DRUG	CHANGE
Motegrity TM (prucalopride)	Make non-preferred on the PMPDP
Zelnorm® (tegaserod)	Make non-preferred on the PMPDP
Ibsrela® (tenapanor)	Make non-preferred on the PMPDP

GamifantTM (emapalumab-lzsg) NDE

The Committee recommended creating a PMPDP class for the hemophagocytic lymphohistiocytosis (HLH) drugs and to designate Gamifant® (emapalumab-lzsg) as non-preferred. The Committee also recommended implementing the proposed Emapalumab PA criteria.

DRUG	CHANGE
Gamifant® (emapalumab-lzsg)	Make non-preferred on the PMPDP

Drug Use Review (DUR) Recommendations:

Fluoroquinolone Drug Use Evaluation (DUE)

The Committee reviewed the DUE and recommended no policy changes at this time.

Orphan Drug Policy Updates

The Committee recommended adding Crysvita® (burosumab-twza), Brineura® (cerliponase alfa), and Reblozyl® (luspatercept) to the Orphan Drugs PA criteria to support medically appropriate use based on their Food and Drug Administration (FDA) labeling.

Oral Multiple Sclerosis Drugs

The Committee recommended updating the Oral Multiple Sclerosis Drugs PA criteria to reflect expanded FDA approved indications and include all new fumarate salts. The Committee also approved removing Daclizumab from the Ocrelizumab PA criteria - as it has been voluntarily recalled from the U.S. market - and to modify the goals to clarify that primary progressive multiple sclerosis (PPMS) does not require step therapy.

Oncology Prior Authorization Policy Proposal

The Committee recommended implementing the proposed Oncology Agents PA criteria and to apply to: all antineoplastic drugs originally approved by the FDA on 1/1/2008 or later; all new molecular entities and new formulations of antineoplastic drugs that already require PA; and all new FDA approved antineoplastic agents. The Committee will be notified of new drugs added to the policy at a subsequent P&T meeting.

Hepatitis C, Direct-Acting Antivirals (DAA) Policy Evaluation and Literature Scan

The Committee recommended amending the DAA PA criteria to include new FDA approved indications in pediatric patients and to remove the requirement for a pregnancy test. Case management was instead proposed to address risks associated with birth control and pregnancy. The Committee also recommended updating the Table of Recommended Treatment Regimens to accommodate any expanded or new FDA-indications for current recommended regimens and to add guidance for patients that have contraindications or intolerances to ribavirin.

Dose Consolidation Policy Proposal

The Committee recommended implementing pharmacy point of sale (POS) edits to consolidate medications with fixed prices across various strengths, in conjunction with a safety net RetroDUR - including a form letter for pharmacies to notify providers when they make a change to the prescription.

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

6/9/2020

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. 2019 OR law, HB 2692

¹ https://www.orpdl.org/durm/meetings/meetingdocs/2020 06 04/finals/2020 06 04 PnT Complete.pdf

ii https://www.orpdl.org/durm/meetings/meetingdocs/2020_06_04/finals/2020_06_04_WrittenTestimony.pdf