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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 in Wilsonville, Oregon on Thursday, November 19, 2015. 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 staffⁱ and 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:

Drug Use Review Recommendations:

Intranasal Allergy Drugs PA Criteria

The Committee recommended approving the proposed changes to the Intranasal Allergy Drugs prior authorization (PA) criteria as presented.

LABA/ICS PA Criteria

The Committee recommended adopting the proposed Long-acting Beta-agonist/Corticosteroid Combination PA criteria as presented.

LAMA/LABA PA Criteria

The Committee recommended adopting the proposed Long-acting Muscarinic Antagonist/ Long-acting Beta-agonist Combination PA criteria as presented.

Drugs for Non-Funded Conditions PA Criteria

The Committee recommended adopting the proposed PA criteria as presented.

Drugs Selected for Manual Review PA Criteria

The Committee recommended adopting the proposed PA criteria as presented.

New Drug Policy PA Criteria

The Committee recommended approving the proposed changes to the New Drug Policy PA criteria as presented.

Botulinum Toxins Updated PA Criteria

The Committee recommended approving the proposed changes to the Botulinum Toxin PA criteria after amending to add a request for baseline numbers in questions 6 and 8, as well as baseline number and current number in question 2 in the renewal criteria. The Committee also recommended changing the reduction in question 2 in the renewal criteria to greater than 7 and directed staff to ask HERC to evaluate whether a decrease in the use of pain meds and triptans should also warrant renewal.

Ivabradine New Drug Evaluation

The Committee recommended restricting use of Corlanor® (ivabradine) to populations where it has demonstrated some efficacy and to adopt the proposed PA criteria after amending to: add criteria requiring a hospitalization for heart failure in the previous 12 months based on study inclusion criteria; add a requirement for aldosterone antagonist use or contraindication; and change the ejection fraction in question 3 to match the approved labeling of greater than or equal to 35%.

Ivacaftor/Lumacaftor New Drug Evaluation

The Committee recommended maintaining Orkambi™ (ivacaftor/lumacaftor) as non-preferred on PMPDP and to approve the updated PA criteria as presented after amending the initial approval to 90 days. The Committee also recommended continuing to monitor for patient adherence and to adopt clinical criteria as needed to adequately assess clinical response as further data become available.

Cross-sex hormone Class Review

The Committee recommended including all gonadotropin-releasing hormone (GnRH) analogs in the existing PA criteria for leuprolide and applying to all GnRH treatments for adolescents with gender dysphoria - with the addition of adding the general diagnosis code of endocrine disorders (E34.9) to question 3 in the proposed criteria - to ensure they are used appropriately for puberty suppression.

The Committee also approved the proposed changes to the Testosterone PA criteria and recommended adopting the Estrogen Derivatives PA criteria to allow approval for patients with gender dysphoria. The Committee amended the criteria presented to remove listing the age to align with HERC recommendations and match in all three criteria.

PCSK9 Inhibitor Class Review

The Committee recommended designating Praluent™ (alirocumab) and Repatha™ (evolocumab) as non-preferred in the Other Dyslipidemia Drugs class on the PMPDP and to adopt the proposed PA criteria as amended to restrict use of PCSK9 Inhibitors to the following populations: 1) non-familial hypercholesterolemia unable to achieve at least 50% LDL-C reduction despite high-intensity statin therapy and ezetimibe; or 2) familial hypercholesterolemia.

The Committee amended the proposed PA criteria to remove coronary heart disease risk-equivalent from question 3 and to remove question 7 completely and only approve for patients with documented rhabdomyolysis.

Practitioner-Managed Prescription Drug Plan (PMPDP) Recommendations:

Long Acting Insulin Class Update

The Committee recommended making insulin glargine U300 non-preferred on the PMPDP and subject to clinical PA and to approve the proposed changes to the Insulin PA criteria. After comparative cost consideration in executive session, the Committee recommended no other changes to 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 60 days from the date this notice is posted on the web site.



Lynne Saxton
Director

12-15-15

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 30 calendar days from the date of this notice. 2011 OR law, CH 730 (HB2100) Section 4

¹http://www.orpdl.org/durm/meetings/meetingdocs/2015_11_19/finals/2015_11_19_PnT_Complete.pdf

²http://www.orpdl.org/durm/meetings/meetingdocs/2015_11_19/finals/2015_11_19_WrittenTestimony.pdf