



500 Summer St NE E20 Salem OR 97301 Voice: 503-947-2340 Fax: 503-947-2341 www.Oregon.Gov/OHA

www.health.oregon.gov

OFFICIAL WEBSITE NOTICE Posting Date: April 30, 2018

RECOMMENDATIONS OF DRUG USE REVIEW / PHARMACY AND THERAPEUTICS COMMITTEE

The Oregon Drug Use Review / Pharmacy and Therapeutics Committee met in Salem, Oregon on Thursday, March 22, 2018. 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 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:

Practitioner-Managed Prescription Drug Plan (PMPDP) Recommendations:

Antiepileptics Literature Scan

The Committee recommended that no further review or research is needed at this time. After comparative cost consideration in executive session, the Committee recommended making no changes to the PMPDP.

Bone Metabolism Drugs Class Update

The Committee recommended maintaining abaloparatide as a non-preferred agent and to update the clinical prior authorization (PA) criteria to limit use to women matching the inclusion criteria from the clinical trial including: age of 49-86 years; and fracture and Tscore requirements. The Committee also recommended modifying the proposed PA criteria to require a trial or documented contraindication to oral bisphosphonates and add specific exclusion criteria for anticonvulsant use that can affect vitamin D metabolism, chronic heparin use within six months prior to screening, or daily treatment with corticosteroids within the previous 12 months. After comparative cost consideration in executive session, the Committee recommended making no changes to the PMPDP.

Oral First and Second Generation Antipsychotics Class Update

The Committee recommended no changes to the PDL or safety edits based on the clinical information. After comparative cost consideration in executive session, the Committee recommended making no changes to the PMPDP.

<u>Luxturna™</u> (voretigene neparvovec) New Drug Evaluation

The Committee agreed with the proposal to limit use to the population studied and recommended modifying the proposed PA criteria to limit approval to requests from a Center of Excellence with confirmation that it will be administered per protocol. The Committee also recommended referring voretigene neparvovec to the Health Evidence Review Commission (HERC) for prioritization consideration as a drug with high cost and marginal benefit.

Atopic Dermatitis DERP Summary

The Committee recommended revising the PA criteria for topical antipsoriatic drugs to include agents used to manage atopic dermatitis and to categorize these two classes as "atopic dermatitis drugs" and "antipsoriatics, topical" on the PMPDP. The Committee also recommended designating dupilumab as non-preferred and to apply PA criteria to limit use to moderate-severe atopic dermatitis for members 18 years and older when prescribed by a dermatologist or allergist and to require a trial and failure or contraindication to all three of the following: topical steroids; topical calcineurin inhibitors; and systemic immunomodulators. After comparative cost consideration in executive session, the Committee recommended making tacrolimus 0.03% ointment, tacrolimus 0.1% ointment, and pimecrolimus 1% cream preferred on the PMPDP.

DRUG	CHANGE
tacrolimus 0.03% ointment	Make preferred on the PMPDP
tacrolimus 0.1% ointment	Make preferred on the PMPDP
pimecrolimus 1% cream	Make preferred on the PMPDP

Keveyis® (dichlorphenamide) Drug Evaluation

The Committee recommended adopting the proposed PA criteria after amending to require a trial and failure of acetazolamide. The Committee also recommended referring dichlorphenamide to the HERC for prioritization consideration as a drug with high cost and marginal benefit.

Anti-Parkinson's Agents Class Update

The Committee recommended adopting the proposed changes to the PA criteria which add specific clinical criteria for safinamide to limit use to the FDA-approved indication and add renewal criteria which requires physician attestation of condition improvement. The Committee also recommended reordering questions #8 prior to #7 in the proposed PA criteria. After comparative cost consideration in 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.

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.

The recommendation to refer voretigene neparvovec and dichlorphenamide to the Health Evidence Review Commission (HERC) for prioritization consideration as drugs with high cost and marginal benefit will be taken under further advisement. The Director accepts the other PA criteria recommendations detailed above.

Patrick Allen

Director

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

http://www.orpdl.org/durm/meetings/meetingdocs/2018_03_22/finals/2018_03_22_PnT_Complete.pdf

iihttp://www.orpdl.org/durm/meetings/meetingdocs/2018 03 22/finals/2018 03 22 WrittenTestimony.pdf