



OFFICE OF THE DIRECTOR

Kate Brown, Governor

Oregon
Health
Authority

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: August 9, 2017

RECOMMENDATIONS OF DRUG USE REVIEW / PHARMACY AND THERAPEUTICS COMMITTEE

The Oregon Drug Use Review / Pharmacy and Therapeutics Committee met in Salem, Oregon on Thursday, July 27, 2017. 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:

Practitioner-Managed Prescription Drug Plan (PMPDP) Recommendations:

Biologics Class Update

The Committee reviewed the proposed prior authorization (PA) criteria – with updated FDA approved ages and indications and recommended step therapy – and recommended adopting after amending to: change the list of drugs requiring PA to “all biologics” and remove the list of indications; change the order of the questions; add to the list of other potent immunosuppressants in question #14; and to add a question requiring a quantiferon gold test to evaluate for tuberculosis before approval of these agents. The Committee also recommended designating brodalumab as non-preferred on the PMPDP and to revise Table 1 of the PA criteria to state brodalumab is indicated for plaque psoriasis. After comparative cost consideration in executive session the Committee recommended no other changes to the PMPDP.

Spinraza® (nusinersen) New Drug Evaluation

The Committee recommended revising the PA criteria to limit coverage of nusinersen to the SMA populations in which the drug has been studied after amending to: add the Upper Limb Module to the list of functional assessments in question #4; add a note in question #5 to clarify that this criteria does not apply to patients who have ventilator

assistance; to change the length of approval to 5 doses within 8 months for initial approvals and 1 year for renewals; and to separate question #7 into renewal criteria and re-order the numbering as appropriate. The Committee also recommended referring nusinersen to the Health Evidence Review Commission (HERC) for prioritization consideration, assessing its health benefits as a medication with high cost.

Emflaza™ (deflazacort) New Drug Evaluation

The Committee recommended approval of the proposed PA criteria which restricts use to patients with Duchenne Muscular Dystrophy (DMD) and documented contraindication or serious intolerance to oral corticosteroids after amending the criteria to: remove “or other corticosteroid” from question #6; clarify that age restrictions of only apply to deflazacort; and to change the deflazacort approval to 12 months. The Committee also recommended referring deflazacort to the HERC for prioritization consideration as a drug with high cost and marginal benefit compared to currently available low-cost oral corticosteroids.

Exondys 51™ (eteplirsen) New Drug Evaluation

The Committee recommended adopting the proposed PA criteria which limits approval to the population studied and continuation of therapy criteria after amending to: remove the requirement of ambulatory status; revise question #10 to require documentation of a baseline functional assessment and examples of validated functional assessment tools such as the 6-minute walk test or North Star Ambulatory Assessment; and change the wording of the renewal criteria to ask “Has the patient’s baseline functional status been maintained at or above baseline level or not declined more than expected given the natural disease progression?”. The Committee also recommended referring eteplirsen to the HERC for prioritization consideration as a medication with high cost and no clinically meaningful benefit.

Abbreviated Drug Reviews

Trulance™ (plecanatide)

The Committee recommended that no further research or review was needed and to require PA to restrict use to OHP-funded conditions. The Committee also recommended adding plecanatide to the “Drugs for Constipation” PA criteria.

Symproic® (naldemedine)

The Committee recommended that no further research or review was needed and to require PA to restrict use to OHP-funded conditions. The Committee also recommended adding naldemedine to the “Drugs for Constipation” PA criteria.

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, with any exceptions noted below. 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

8-9-17

Approval date

Exception(s) to approval of the recommendations: The recommendation to refer Spinraza® (nusinersen) to HERC for prioritization consideration be postponed until after the P&T Committee has reviewed additional published evidence expected in Spring 2018.

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

ⁱhttp://www.orpdl.org/durm/meetings/meetingdocs/2017_07_27/finals/2017_07_27_PnT_Complete.pdf

ⁱⁱhttp://www.orpdl.org/durm/meetings/meetingdocs/2017_07_27/finals/2017_07_27_WrittenTestimony.pdf