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OFFICIAL WEBSITE NOTICE **Posting Date: March 6, 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, November 30, 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 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:

Drug Use Review Recommendations:

New Drug Policy Prior Authorization (PA) Criteria

The Committee approved the proposed changes to the New Drug Policy PA criteria to apply to drugs not in a PMPDP class, or for which no existing clinical PA criteria could be applied, which cost more than \$5,000 per claim or per month. The Committee recommended approval be limited to FDA-approved indications and dosing, for OHP-funded treatments for that indication, but to not apply to drugs with an orphan drug designation which are the only FDA-approved therapy for the funded condition.

Biosimilar Policy PA Criteria

The Committee recommended that biosimilar drugs that become available for a drug that has been reviewed for the PMPDP be designated as non-preferred until the P&T Committee reviews the product.

Drugs for Duchenne Muscular Dystrophy

The Committee recommended updating the PA criteria to require that the requested treatment is funded by the OHP for that condition and to add a link to the Prioritized List.

Antiemetics Clinical PA Criteria

The Committee recommended updating the PA criteria to eliminate quantity limits for all drugs in the class, with the exception of dronabinol.

Low-dose Quetiapine Safety Edit

The Committee recommended modifying the safety edit to apply to only patients with a daily dose of 50 mg or less.

Pediatric Antipsychotic Drug Use Evaluation

The Committee recommended developing a RetroDUR program to provide new start patients access to care coordination and referral for expert consultation.

Practitioner-Managed Prescription Drug Plan (PMPDP) Recommendations:

Bevyxxa® (betrixaban) New Drug Evaluation

The Committee recommended maintaining betrixaban as a non-preferred drug in the anticoagulant PDL class and to apply the non-preferred drug PA criteria.

Multiple Sclerosis (MS) Class Update

The Committee recommended applying clinical PA criteria to ocrelizumab for both physician administered and point of sale pharmacy claims to:

- limit use to MS conditions that are above the funding line on the Prioritized List
- require a trial or history of inadequate response to at least 2 disease modifying agents approved for MS
- require it be prescribed by a neurologist

The Committee amended the proposed PA criteria to add a question to verifying Hepatitis B status and also recommended referring ocrelizumab, when prescribed for primary progressive MS, to the Health Evidence Review Commission (HERC) for prioritization consideration.

The Committee approved the proposed clinical PA criteria for natalizumab - separate from the biologic PA criteria – after amending to require screening for tuberculosis only for Crohn's disease and not for multiple sclerosis.

The Committee recommended amending the PA criteria for oral multiple sclerosis drugs to remove the requirement of a trial of interferon beta 1a or interferon 1b, and glatiramer and to change the approval duration to 6 months. After review in executive session the Committee recommended no other changes to the PMPDP.

Antidepressant DERP Summary Review

Due to clinical and implementation concerns with the Pediatric SSRI Antidepressant PA criteria, the Committee recommended removal of daily dose limits for pediatric patients on antidepressants. 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 ocrelizumab to the Health Evidence Review Commission (HERC) will be taken under further advisement. The Director accepts the other PA criteria elements outlined in the Multiple Sclerosis Class update.

3/6/18

Patrick M. 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

ⁱhttp://www.orpdl.org/durm/meetings/meetingdocs/2017_11_30/finals/2017_11_30_PnT_Complete.pdf ⁱⁱhttp://www.orpdl.org/durm/meetings/meetingdocs/2017_11_30/finals/2017_11_30_WrittenTestimony.pdf