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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 Salem, Oregon on Thursday, January 26, 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 [i] 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:

Buprenorphine Clinical PA Criteria

The Committee recommended removing the prior authorization (PA) for buprenorphine/naloxone sublingual tablets and film - unless the average daily dose exceeds 24 mg of buprenorphine - and to remove the pharmacy lock-in requirement since prescribers are asked to routinely check the Oregon Prescription Drug Monitoring Program (PDMP).

Vivitrol® (naltrexone ER injection) Clinical PA Criteria

The Committee recommended removing the PA for naltrexone ER injection.

Oral Multiple Sclerosis Drugs Clinical PA Criteria

The Committee recommended amending the PA criteria to deny use of an oral MS agent if no form of relapsing multiple sclerosis has been diagnosed.

Practitioner-Managed Prescription Drug Plan (PMPDP) Recommendations:

Gout Drugs Class Update

The Committee recommended no changes to the PMPDP based on the clinical evidence and to maintain the preferred status for allopurinol. The Committee also recommended approving the clinical PA criteria for non-preferred drugs as amended to require a trial of allopurinol, or have a contraindication to allopurinol, before approving febuxostat. After comparative cost consideration in executive session, the Committee recommended no other changes to the PMPDP.

Conventional Antiemetics Class Review

The Committee recommended adding the conventional antiemetic class to the PMPDP and to designate scopolamine, dimenhydrinate, and meclizine as non-preferred as these drugs are primarily prescribed for unfunded conditions on the Prioritized List. The Committee also recommend consolidating the current clinical PA criteria for newer antiemetics and dronabinol into one policy - which will also apply to non-preferred conventional antiemetics - after amending the proposed criteria to ask whether the diagnosis is an OHP-funded condition at the beginning of PA. After comparative cost consideration in executive session, the Committee recommended making promethazine and prochlorperazine tablets, syrups and rectal suppositories preferred; metoclopramide tablets and oral solutions preferred; and phosphoric acid/dextrose/fructose preferred agents on the PMPDP. The Committee also recommended making dronabinol, nabilone, metoclopramide rapid dissolving tablets and trimethobenzamide non-preferred agents.

DRUG	CHANGE
Scopolamine	Make non-preferred on the PMPDP
Dimenhydrinate	Make non-preferred on the PMPDP
Meclizine	Make non-preferred on the PMPDP
Promethazine tabs, syrup & supp.	Make preferred on the PMPDP
Prochlorperazine tabs, syrup & supp.	Make preferred on the PMPDP
Metoclopramide tabs & oral soln.	Make preferred on the PMPDP
Phosp. acid/dextrose/fructose oral soln.	Make preferred on the PMPDP
Dronabinol	Make non-preferred on the PMPDP
Nabilone	Make non-preferred on the PMPDP
Metoclopramide rapid dissolving tabs	Make non-preferred on the PMPDP
Trimethobenzamide	Make non-preferred on the PMPDP

Hormone Replacement Therapy Class Update

The Committee recommended combining the progestin agents into one class on the PMPDP and to designate at least one preferred product for FDA-approved indications funded by the OHP (i.e., endometriosis, endometrial cancer, endometrial hyperplasia,

abnormal bleeding disorders, and prevention of preterm birth) based utilization and comparative drug costs in the executive session. The Committee recommended requiring PA for ospemifene to only cover for OHP-funded conditions and approved the proposed update to the clinical PA criteria for hydroxyprogesterone caproate, which will apply to brand and generic products for both pharmacy and physician-administered claims. After comparative cost consideration in executive session, the Committee recommended making medroxyprogesterone acetate tablets, micronized progesterone capsules, norethindrone acetate tablets, and Depo-Provera® injection preferred on the PMPDP and to make all other progestins non-preferred.

DRUG	CHANGE
Depo-Provera® injection	Make preferred on the PMPDP
Medroxyprogesterone acetate tabs	Make preferred on the PMPDP
Micronized progesterone caps	Make preferred on the PMPDP
Norethindrone acetate tabs	Make preferred on the PMPDP
Progesterone	Make non-preferred on the PMPDP

Antidiarrheals Class Review

The Committee recommended adding the antidiarrheal medications to the PMPDP and to designate all drugs except loperamide as non-preferred to restrict use to OHP-funded conditions. The Committee also recommended implementing the following quantity limits to insure safe and appropriate use:

- Loperamide = maximum 16 mg per 24 hours
- Diphenoxylate/atropine = maximum 20 mg/0.2 mg per 24 hours
- Crofelemer = maximum 500 mg per 24 hours

DRUG	CHANGE
Loperamide	Make preferred on the PMPDP
Diphenoxylate/atropine	Make non-preferred on the PMPDP
Crofelemer	Make non-preferred on the PMPDP

Vitamin D Analogs Class Review

The Committee recommended adding the Vitamin D analog class to the PMPDP, to maintain calcitriol as the only preferred vitamin D analog and to designate paricalcitol, doxercalciferol and calcifediol non-preferred.

DRUG	CHANGE
Paricalcitol	Make non-preferred on the PMPDP
Doxercalciferol	Make non-preferred on the PMPDP
Calcifediol	Make non-preferred on the PMPDP

Ocaliva® (obeticholic acid) New Drug Evaluation

The Committee recommended incorporating the Bile Therapy drugs: obeticholic acid, ursodiol, and cholic acid into one class on the PMPDP and to designate ursodiol as preferred and obeticholic acid as a non-preferred. The Committee also approved clinical PA criteria for all non-preferred bile therapy drugs - which restricts use of obeticholic acid to populations that may benefit from this therapy without undue harm - after amending the proposed criteria to re-phrase wording for question #4 to ask if patient has no evidence of complications from cirrhosis or hepatic decompensation and re-phrase wording for question #5 to ask if the total bilirubin level is less than 2-times the upper limit of normal and to deny the claim if either criteria is not met.

DRUG	CHANGE
ursodiol	Make preferred on the PMPDP
obeticholic acid	Make non-preferred on the PMPDP

Adlyxin® (lixisenatide) New Drug Evaluation

The Committee recommend maintaining lixisenatide as non-preferred on the PMPDP and subject to current clinical prior authorization (PA) criteria for GLP-1 receptor agonists.

Zinbryta™ (daclizumab) New Drug Evaluation

The Committee recommended maintaining daclizumab as non-preferred on the PMPDP and approved the proposed clinical PA criteria to limit use to adult patients with relapsing MS, without hepatic disease, who have higher degree of ambulatory ability (EDSS $\leq$5), with a history of inadequate response to at least 2 disease modifying agents approved for MS, when prescribed by a neurologist.

Nuplazid™ (pimavanserin) New Drug Evaluation

The Committee recommended adopting the proposed safety edit to restrict use of pimavanserin to populations that may benefit without undue harm.

Xiidra™ (lifitegrast) New Drug Evaluation

The Committee recommended requiring PA for lifitegrast ophthalmic solution to only approve for OHP funded conditions.

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

2/24/17
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

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[i] http://www.orpdl.org/durm/meetings/meetingdocs/2017_01_26/finals/2017_01_26_PnT_Complete.pdf
[ii] http://www.orpdl.org/durm/meetings/meetingdocs/2017_01_26/finals/2017_01_26_WrittenTestimony.pdf