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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, November 21, 2019. 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 (PDL) established by the Oregon Health Authority:

Practitioner-Managed Prescription Drug Plan (PMPDP) Recommendations:

Antifungals Class Update

The Committee recommended making no changes to the PMPDP based on clinical evidence. After comparative cost consideration in executive session, the Committee recommended making no changes to the PMPDP.

Anticoagulants Class Update

The Committee recommended making no changes to the PMPDP based on clinical evidence. After comparative cost consideration in executive session, the Committee recommended making no changes to the PMPDP.

Rifamycin New Drug Evaluation

The Committee recommended designating rifamycin as non-preferred on the PMPDP based on clinical evidence. The Committee also recommended adding rifamycin to the rifaximin prior authorization (PA) criteria, after amending the proposed criteria to add a question to approve only if there is a contraindication to azithromycin and fluoroquinolones.

DRUG	CHANGE
Rifamycin (Aemcolo™)	Make non-preferred on the PMPDP

Amikacin New Drug Evaluation

The Committee recommended designating amikacin liposome inhalation suspension as non-preferred on the PMPDP based on the clinical evidence. The Committee also recommended implementing the proposed clinical PA criteria to ensure appropriate utilization after modifying question #4 to confirm the patient has been adherent for the past 6 months to a 3-drug regimen.

DRUG	CHANGE
amikacin liposome (Arikayce®)	Make non-preferred on the PMPDP

Drugs for Gaucher Disease Class Review

The Committee recommended creating a PMPDP class for lysosomal storage disorder drugs and to designate miglustat as non-preferred based on FDA labeling as second-line therapy and eliglustat as non-preferred based on need for additional enzymatic testing. The Committee recommended implementing the proposed PA criteria for all targeted therapies for Gaucher disease to ensure medically appropriate use and to refer requests for Type 3 patients to the Medical Director for review. After comparative cost consideration in executive session, the Committee recommended making taliglucerase alfa preferred and all other agents for Gaucher disease as non-preferred on the PMPDP.

DRUG	CHANGE
taliglucerase alfa (Elelyso®)	Make preferred on the PMPDP
miglustat (Zavesco®)	Make non-preferred on the PMPDP
eliglustat (Cerdelga®)	Make non-preferred on the PMPDP
velaglucerase alfa (Vpriv®)	Make non-preferred on the PMPDP
imiglucerase (Cerezyme®)	Make non-preferred on the PMPDP

Amifampridine New Drug Evaluations

The Committee recommended creating a PMPDP class for Lambert-Eaton Myasthenic Syndrome (LEMS) agents and to implement the proposed PA criteria for amifampridine. After comparative cost consideration in executive session, the Committee recommended making Ruzurgi® preferred and Firdapse® non-preferred on the PMPDP.

DRUG	CHANGE
amifampridine (Ruzurgi®)	Make preferred on the PMPDP
amifampridine (Firdapse®)	Make non-preferred on the PMPDP

Cholic Acid New Drug Evaluation

The Committee recommended designating cholic acid as non-preferred on the PMPDP based on the clinical evidence. The Committee also recommended implementing the proposed clinical PA criteria to ensure use according to FDA-approved indications, after modifying initial approval to 3 months and to include assessment of liver function tests (LFTs) in the renewal criteria.

DRUG	CHANGE
cholic acid (Cholbam®)	Make non-preferred on the PMPDP

Drug Use Review (DUR) Recommendations:

Substance Use Disorder Literature Scan and Prior Authorization (PA) Update

The Committee recommended making no changes to the PMPDP based on clinical evidence. In response to House Bill 2257 form the 2019 legislative session, the Committee recommended removing the PA requirement for all opioid use disorder (OUD) products, except for the dose limit of 24 mg buprenorphine per day for transmucosal poducts. The Committee also recommended staff continue to monitor use of OUD products to assess potential changes in medically appropriate use. After comparative cost consideration in executive session, the Committee recommended making: buprenorphine injection (Sublocade™) preferred; and changing buprenorphine sublingual tablets, disulfiram tablets, buprenorphine/naloxone film (Bunavail®) from non-preferred to voluntary non-preferred on the PMPDP. Voluntary non-preferred designation results in no PA being required simply for PDL status. New products coming to market included in the class will be designated voluntary non-preferred until reviewed by the P&T Committee.

DRUG	CHANGE
buprenorphine injection (Sublocade™)	Make preferred on the PMPDP

Antidepressant Use in Children Drug Use Evaluation (DUE)

After consideration of the clinical evidence and input from the Mental Health Clinical Advisory Group (MHCAG), the Committee recommended implementing a safety edit for initiation of tricyclic antidepressant (TCA) therapy in children younger than the FDA-approved minimum age limit with the goal of preventing off-label use, but to automatically approve requests for:

- Children with prescriptions identified as being written by a mental health specialist, or
- Children with ongoing TCA therapy, or
- Children with a recent trial of a SSRI

The Committee also recommended implementing a retrospective DUR safety net program to identify patients with denied claims and no subsequent follow-up in order to minimize interruptions and delays in therapy.

Dupilumab Prior Authorization Update

The Committee recommended revising the dupilumab PA criteria to include chronic rhinosinusitis with nasal polyposis as an FDA-approved indication when prescribed as add-on therapy to standard of care. The Committee also recommended specifying the duration of the required steroid course for step therapy and to change "inhaled" steroid in question #15 to "intranasal".

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 7 days from the date this notice is posted on the web site.

_____ 11/26/2019

Patrick Allen — Approval date

Director, Oregon Health Authority

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 7 calendar days from the date of this notice. 2019 OR law, HB 2692

[i] https://www.orpdl.org/durm/meetings/meetingdocs/2019_11_21/finals/2019_11_21_PnT_Complete.pdf

[ii] https://www.orpdl.org/durm/meetings/meetingdocs/2019_11_21/finals/2019_11_21_WrittenTestimony.pdf