



OFFICIAL WEBSITE NOTICE

Posting Date: October 3, 2019

RECOMMENDATIONS OF DRUG USE REVIEW / PHARMACY AND THERAPEUTICS COMMITTEE

The Oregon Drug Use Review / Pharmacy and Therapeutics Committee met in Salem, Oregon on Thursday, September 26, 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 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:

Practitioner-Managed Prescription Drug Plan (PMPDP) Recommendations:

Oral Muscle Relaxants Literature Scan

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

DRUG	CHANGE
methocarbamol	Make preferred on the PMPDP

Herpes Simplex Virus Literature Scan

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

DRUG	CHANGE
valacyclovir tablets	Make preferred on the PMPDP

Insulins 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: insulin glulisine (pens and vials) preferred; insulin regular, human U-500 pen preferred; Humalog Mix 75/25 and 50/50 KwikPens preferred; to remove the prior authorization (PA) requirement for these preferred pens; and to make insulin detemir vials preferred on the PMPDP.

DRUG	CHANGE
insulin glulisine pens and vials	Make preferred on the PMPDP
insulin regular, human U-500 pen	Make preferred on the PMPDP
Humalog Mix 75/25 & 50/50 KwikPens	Make preferred on the PMPDP
insulin detemir vials	Make preferred on the PMPDP

Antidepressant Class

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

Hepatitis C, Direct-acting Antivirals Literature Scan

The Committee approved the proposed updates to the PA criteria after amending to move the request for baseline RNA level to question #2 when asking about diagnosis (i.e. through positive detection of HCV viral load) and to delegate to staff the ability to make minor changes consistent with FDA labeling to the recommended regimens table. After comparative cost consideration in executive session, the Committee recommended making Zepatier non-preferred on the PMPDP.

DRUG	CHANGE
Zepatier	Make non-preferred on the PMPDP

Tobacco Smoking Cessation Literature Scan

The Committee recommended updating the PA criteria to implement an age limit for varenicline and to make 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.

Drugs for Duchenne Muscular Dystrophy Literature Scan

The Committee recommended updating the PA criteria to include updated FDA-approved ages and assessment of immunization status prior to initiation of treatment with deflazacort after modifying questions #7 to specify 2 MMR and 2 varicella vaccinations and #9 to clarify which mutations are amenable to exon 51 skipping.

Oral Cystic Fibrosis Modulators Prior Authorization (PA) Update

The Committee recommended updating the PA criteria to reflect changes in FDA approved labels for ivacaftor and tezacaftor/ivacaftor and to revise the PA criteria to list the FDA-approved indications and ages in a table to facilitate more streamlined PA updates for expanded indications.

Opioid Class Update

The Committee recommended revising the opioid PA criteria as follows:

- Add dihydrocodeine morphine milliequivalents to opioid conversion chart listed in Short-acting Opioid (SAO) PA criteria
- Add pain associated with sickle cell disease and severe burn injury as an exclusion to SAO and Long-acting Opioid (LAO) PA criteria
- Add concomitant benzodiazepine/CNS depressant use as an assessment to SAO and LAO PA criteria
- Remove taper plan for patients using chronic SAO's for back and spine, based on updated HERC guidance
- Retire codeine PA criteria and add a question about use of codeine and tramadol to the SAO PA criteria to insure appropriate use in patients under the age of 19 years based on FDA safety alerts

The Committee also recommended: modifying the question on the Prescription Drug Monitoring Program (PDMP) to verify that opioid prescribing is appropriate rather than from a single provider; adding PEG score to the list of examples documenting improvement in question #17 in the SAO criteria; and to add a note recommending against pediatric use for tramadol in the dosing table. No changes to the PMPDP were recommended based on the clinical evidence. After comparative cost consideration in executive session, the Committee recommended making no changes to the PMPDP.

Tafamidis New Drug Evaluations (NDE)

The Committee recommended designating Vyndaqel and Vyndamax as non-preferred medications in the Amyloidosis Agents class and to modify the Drugs for Transthyretin-Mediated Amyloidosis (ATTR) PA criteria to ensure appropriate use of tafamidis.

DRUG	CHANGE
Vyndaqel	Make non-preferred on the PMPDP
Vyndamax	Make non-preferred on the PMPDP

Spinal Muscular Atrophy Class Update and NDE

The Committee recommended implementing the proposed PA criteria to ensure one-time administration of onasemnogene abeparvovec occurs in appropriate SMA pediatric populations per the FDA labeling and to revise the nusinersen PA criteria to include an assessment of onasemnogene abeparvovec administration prior to initiation. The Committee also recommended adding language to the nusinersen renewal criteria regarding stabilization in a meaningful manner. After comparative cost consideration in executive session, the Committee recommended adding the class to the PMPDP and to designate onasemnogene abeparvovec preferred and nusinersen non-preferred.

DRUG	CHANGE
Zolgensma (onasemnogene abeparvovec)	Make preferred on the PMPDP
Spinraza (nusinersen)	Make non-preferred on the PMPDP

Bone Metabolism Drugs Class Update and NDE

The Committee recommended maintaining romosozumab as a non-preferred agent on the PMPDP and to update the PA criteria for bone metabolism agents to include romosozumab. After comparative cost consideration in executive session, the Committee recommended making no changes to the PMPDP.

Drugs for Fabry Disease Class Review

The Committee recommended designating agalsidase beta and migalastat as non-preferred agents on the PMPDP and to implement proposed PA criteria for the Fabry disease treatments to ensure appropriate use according to FDA-approved indications.

DRUG	CHANGE
agalsidase beta	Make non-preferred on the PMPDP
migalastat	Make non-preferred on 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 7 days from the date this notice is posted on the web site.



Patrick M. Allen
Director, Oregon Health Authority

10/3/2019

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

ⁱ https://www.orpdl.org/durm/meetings/meetingdocs/2019_09_26/finals/2019_09_26_PnT_Complete.pdf

ⁱⁱ https://www.orpdl.org/durm/meetings/meetingdocs/2019_09_26/finals/2019_09_26_WrittenTestimony.pdf