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## OFFICIAL WEBSITE NOTICE

Posting Date: December 20<sup>th</sup>, 2013

### RECOMMENDATIONS OF DRUG USE REVIEW / PHARMACY AND THERAPEUTICS COMMITTEE

The Oregon Drug Use Review / Pharmacy and Therapeutics Committee met in Wilsonville, Oregon on Thursday, November 21<sup>st</sup>, 2013. 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<sup>i</sup> and all public comment offered,<sup>ii</sup> while considering the impact on special populations, the Committee makes the following recommendations for the Oregon Prescriber-Managed Prescription Drug Plan (PMPDP) or for any other preferred drug list established by the Oregon Health Authority:

#### Drug Use Review Recommendations:

##### High Cost Marginal Benefit (HCMB) Subcommittee Follow-Up

The P&T Committee agreed with the recommendation made by the sub-committee and recommended sapropterin (Kuvan) and dalfampridine (Ampyra) be added to the HCMB list.

The Committee also recommended changing the language in step #4 of the Kuvan PA criteria to: Is the patient "compliant" with a Phe-restricted diet.

##### Lomitapide (Juxtapid) & mipomersen (Kynamro)

The Committee recommended approving the modified PA criteria to remove language approving treatment if LDL-C apheresis is not available to the patient and to change the length of approval from 6 months to 1 year.

##### Benzodiazepine DUE

In an effort to prevent inappropriate long-term benzodiazepine use, the Committee recommended to require prior authorization of patients newly started on benzodiazepine (no history within last

100 days) with prescriptions extending beyond an initial 4 weeks. Approval would be granted in any of the three situations:

- Diagnosis of malignant neoplasm or other end of life diagnosis OR
- Diagnosis of epilepsy OR
- OHP Covered Indication and all of the following:
  - Clinical rationale to support long-term BZO use for the supplied indication(s) AND
  - No concurrent sedative/hypnotic or opioid AND
  - Dose < 3mg diazepam equivalents

The Committee directed staff to bring back a policy evaluation after the first quarter of implementation.

The Committee also requested staff bring back more data regarding geographic location and provider specialties prescribing long-term benzodiazepines and to develop targeted education intervention to those at high risk of mortality and to pilot this intervention at a high risk clinic.

**Practitioner-Managed Prescription Drug Plan (PMPDP) Recommendations:**

Vivitrol (Naltrexone extended release) New Drug Evaluation

The Committee recommended making Vivitrol a non-preferred agent and to require prior authorization for the use in opioid dependence requiring:

- The failure of other oral agents for the treatment of opioid dependency OR the patient requires injectable therapy
- The member is part of a comprehensive treatment program for substance abuse that includes a psychosocial support system
- Patients be opioid free for 7 days prior to administration

Allow for use in alcohol dependence until a subsequent full evidence review can be presented when literature is fully published.

Work with John McIlveen within the Oregon Health Authority to clarify and tighten PA criteria.

Diabetes Class

After comparative cost consideration in executive session, the Committee recommended making the new combination products alogliptin/pioglitazone (Oseni) and alogliptin/metformin (Kazano) non-preferred agents on the PMPDP.

DRUG	CHANGE
alogliptin/pioglitazone (Oseni)	Make non-preferred on PMPDP
alogliptin/metformin (Kazano)	Make non-preferred on PMPDP

### First Generation Antipsychotic (FGA) Review

To reduce the copay burden the Committee recommended adding the FGA class to the voluntary PDL list to promote the use of cost-effective and individualized treatment options for schizophrenia and bipolar disorder. After comparative cost consideration in executive session, the Committee recommended making all FGA preferred on PMPDP. The Committee also agreed that staff should further review the second generation antipsychotics at an upcoming meeting for comparative effectiveness and safety.

DRUG	CHANGE
all first generation antipsychotics	Make preferred on PMPDP

### Chronic Obstructive Pulmonary Disease

Due to no evidence demonstrating clinical superiority of fluticasone/vilanterol over current agents, the Committee recommended making it non-preferred on the PMPDP and to amend guidelines to fit with new GOLD COPD classification. The Committee also recommended adding fluticasone/vilanterol to the LABA/ICS prior authorization criteria and limiting to patients who have COPD.

The Committee recommended maintaining tiotropium as a preferred agent due to evidence of superiority over ipratropium, however, due to no strong comparative effectiveness of superiority between other agents, costs were reviewed in executive session. After comparative cost consideration in executive session, the Committee recommended no changes to the PMPDP.

DRUG	CHANGE
fluticasone/vilanterol (Breo Ellipta)	Make non-preferred on PMPDP

### Parkinson's Disease

The Committee determined that there is insufficient evidence that rotigotine is more efficacious or safer than other oral dopamine agonists in the treatment of PD. After comparative cost consideration in executive session, the Committee recommended making Neupro non-preferred on the PMPDP and no other PDL changes.

DRUG	CHANGE
rotigotine (Neupro)	Make non-preferred on PMPDP

### Statin Medications

The Committee found there is insufficient comparative evidence on long term clinical outcomes or evidence that one agent is safer than another. After comparative cost consideration in executive session, the Committee recommended no changes to the PDL.

### Newer Antiemetics Scan

The Committee recommended that no further research is needed at this time and after comparative cost consideration in executive session, the Committee recommended making no changes to PDL.

### Newer Drugs for Insomnia Scan

The Committee recommended that no further research is needed at this time and after comparative cost consideration in executive session, the Committee recommended making no changes to the PDL.

The Committee also asked staff to bring back a zolpidem DUE with potential safety recommendations.

### Nonsteroidal Anti-inflammatory Drugs Scan

The Committee recommended that no further comparative effectiveness research is needed at this time, but did direct staff to bring back information to assess the safety of diclofenac at a future meeting. After comparative cost consideration in executive session, the Committee recommended making no changes to the PDL.

### Skeletal Muscle Relaxants Scan

The Committee recommended that no further research is needed at this time and after comparative cost consideration in executive session, the Committee recommended making no changes to PDL.

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.

*Tina Edlund*

Tina Edlund  
Director, Oregon Health Authority

12/20/13

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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<sup>1</sup>[http://pharmacy.oregonstate.edu/drug\\_policy/sites/default/files/pages/dur\\_board/meetings/meetingdocs/2013\\_07\\_25/finals/2013\\_07\\_25\\_PnT\\_Complete.pdf](http://pharmacy.oregonstate.edu/drug_policy/sites/default/files/pages/dur_board/meetings/meetingdocs/2013_07_25/finals/2013_07_25_PnT_Complete.pdf)

<sup>ii</sup>[http://pharmacy.oregonstate.edu/drug\\_policy/sites/default/files/pages/dur\\_board/meetings/meetingdocs/2013\\_07\\_25/finals/2013\\_07\\_25\\_WrittenTestimony.pdf](http://pharmacy.oregonstate.edu/drug_policy/sites/default/files/pages/dur_board/meetings/meetingdocs/2013_07_25/finals/2013_07_25_WrittenTestimony.pdf)