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## OFFICIAL WEBSITE NOTICE

Posting Date: August 29<sup>th</sup>, 2014

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

The Oregon Drug Use Review / Pharmacy and Therapeutics Committee met in Wilsonville, Oregon on Thursday, July 31<sup>st</sup>, 2014. 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:

##### Hepatitis C Class Update

The P&T Committee agreed with the proposed changes to PA criteria based on the Hepatitis C Advisory Committee Recommendations, including limiting approval to the following patient populations: patients with extrahepatic manifestations of HCV who have formal documentation from a relevant specialist that their condition is HCV related; HCV/HIV co-infected patients with cirrhosis; HCV infection in the transplant setting (approval needs to be recommended by the OHSU Liver Transplant Program and approved by the DMAP Medical Director); and Cirrhotic (stage 4) patients without ongoing progressive decompensation.

The Committee also recommended that question #5 be removed from the PA criteria and #4 be clarified so that outreach will occur when prescribed by a gastroenterologist or infectious disease specialist to determine whether they have experience with Hepatitis C. The Committee also recommended that marijuana use be added to question #11. Finally, they asked that we revisit the criteria at the September P&T meeting.

### Hepatitis C Readiness to Refer Assessment

The Committee approved the Readiness to Refer assessment with the goal to support patient readiness through actions initiated by primary care providers, to prepare patients interested in hepatitis C treatment to engage successfully with specialists. The Committee recommended that the language mirror that used in the PA criteria and to consistently call out PCP.

The Committee also recommended getting feedback from hepatologists and primary care physicians on utility of the assessment and to make these resources available on the College of Pharmacy website, present it to the CCO Medical Directors, and to work with public health to facilitate dissemination and education regarding this new assessment.

### Botulinum Toxins DUE

The Committee recommended implementing the proposed PA criteria in FFS patients to limit use to evidence supported diagnoses and to research and revisit question #4 at the September P&T meeting.

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

#### Alcohol Dependence Class Review

The Committee recommended combining the alcohol dependence agents and opioid dependence into one PDL class and to include oral naltrexone and acamprosate on the PMPDP based on moderate level evidence to support the similar efficacy and safety for the treatment of alcohol use disorder. The Committee also recommended maintaining injectable naltrexone as a treatment option for those patients unable or unwilling to take oral therapy, or are not likely to adhere with oral naltrexone therapy and to maintain naltrexone depot injection prior authorization criteria. The committee recommended designating disulfiram nonpreferred on the PMPDP and to grandfather current clients for one year.

DRUG	CHANGE
disulfiram	Make nonpreferred on PMPDP and grandfather current clients for 12 months

#### Androgen Class Update

The Committee recommended re-evaluating the safety of testosterone therapy once the FDA concludes its review and to remove ovarian failure from the list of covered diagnoses in the PA criteria. After comparative cost consideration in executive session, the Committee recommended making Aveed™ nonpreferred on the PMPDP and to not grandfather current patients.

DRUG	CHANGE
Aveed™	Make nonpreferred on the PMPDP

### Pulmonary Arterial Hypertension Class Update

The Committee recommended requiring prior authorization for riociguat, macitentan and oral treprostinil to ensure they are prescribed by either a pulmonologist or cardiologist. The Committee recommended continuing to include an agent from each class on the PDL and agreed that the limited evidence is insufficient to recommend macitentan be preferred over bosentan on the PMPDP. After comparative cost consideration in executive session, the Committee recommended making no changes to the PMPDP.

### Anticoagulant Class Update

The Committee recommended the following:

- Atrial Fibrillation: Recommend warfarin as first-line therapy and offer dabigatran and apixaban as non-preferred agents subject to PA approval. No changes to the PMPDP were recommended.
- VTE treatment: Recommend warfarin or enoxaparin first line with dabigatran, rivaroxaban and apixaban as non-preferred options if clinical criteria are met. Recommend adding apixaban to current PA criteria as a second line option.
- Orthopedic Prophylaxis: Recommend LMWH as an appropriate first-line treatment option. Recommend rivaroxaban and apixaban as non-preferred options if clinical criteria are met. Recommend adding apixaban to current PA criteria as a second line option.
- Medically Ill: If continued anticoagulation is warranted in medically ill patients recommend warfarin as first-line option. Fourteen day supply of rivaroxaban allows transition to preferred therapy in current PA criteria.

The Committee recommended adding "difficulty obtaining INR monitoring" to questions #5 and #9 in Oral Direct Factor Xa Inhibitors PA criteria, and questions #3 and #8 in Oral Direct Thrombin Inhibitors PA criteria. After comparative cost consideration in executive session, the Committee recommended no changes to the PMPDP.

### Antiplatelet Class Update

The Committee recommended that aspirin and clopidogrel continue to be listed as preferred drugs on the PMPDP due to high level evidence of benefit for multiple indications (e.g. Coronary Artery Disease (CAD), ACS, stroke and PAD). The Committee also recommended vorapaxar be added to Antiplatelet criteria. After comparative cost consideration in executive session, the Committee recommended no changes to the PMPDP.

### Asthma/COPD Class Update

Due to no evidence demonstrating clinical superiority of umeclidinium/vilanterol over current agents, the Committee recommended making it non-preferred on the PMPDP and to apply prior authorization criteria to ensure it is being used appropriately and limited to patients who have COPD.

Due to no evidence demonstrating clinical superiority or safety of mometasone HFA over current agents, the Committee recommended making it non-preferred. Due to no evidence demonstrating clinical superiority the Committee also recommended designating flunisolide HFA as non-preferred on the PMPDP.

The Committee agreed with the staff recommendation to reorganize the PMPDP drug classes into:

- Long-acting Bronchodilators
- Short-acting Beta Agonists
- Anticholinergic Inhalers
- Combination Inhalers
- Inhaled Corticosteroids
- Miscellaneous Pulmonary Drugs

After comparative cost consideration in executive session, the Committee recommended 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.



Suzanne Hoffman  
Interim Director, Oregon Health Authority

8-29-2014  
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

<sup>i</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)