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## OFFICIAL WEBSITE NOTICE

Posting Date: February 18, 2015

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

The Oregon Drug Use Review / Pharmacy and Therapeutics Committee met in Wilsonville, Oregon on Tuesday, January 29, 2015. 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 Practitioner-Managed Prescription Drug Plan (PMPDP) or for any other preferred drug list established by the Oregon Health Authority:

#### Drug Use Review Recommendation:

##### Droxidopa (Northera™) New Drug Evaluation

The Committee recommended requiring prior authorization (PA) limiting use to patients with an OHP funded condition with a diagnosis of symptomatic orthostatic hypotension due to primary autonomic failure, dopamine beta-hydroxylase deficiency, or non-diabetic autonomic neuropathy, who are not currently receiving antihypertensive therapy and that have had a documented trial of appropriate therapy for orthostatic hypotension, including both fludrocortisone and midodrine - unless physician provides justification (e.g., contraindications, concern for adverse effects, etc.). The Committee recommended the initial approval be limited to 14 days and approval beyond two weeks be limited to three months, requiring documentation of a response to therapy (e.g., improvement in dizziness, lightheadedness, etc.) for subsequent approvals.

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

##### Hepatitis C Class Update and New Drug Evaluation

The Committee recommended implementing the proposed PA criteria to prioritize use so that patients defined by the AASLD guidelines as "highest priority" who are at high risk for liver-related complications and severe extrahepatic hepatitis are treated, including:

- Stage 3 and 4 fibrosis without decompensated cirrhosis, OR
- Those receiving an organ transplant, OR
- Patients with extrahepatic manifestations, including:
  - Type 2 or 3 cryoglobulinemia with end-organ manifestations (e.g., vasculitis)
  - Proteinuria, nephrotic syndrome, or membranoproliferative glomerulonephritis.

After comparative cost consideration in executive session, the Committee recommended making Harvoni™ (ledipasvir/sofosbuvir) a preferred product on the PMPDP and to amend the PA criteria so Harvoni™ (LED/SOF) is preferred over Sovaldi® (sofosbuvir) for Genotypes 1 and 3.

| DRUG                  | CHANGE                      |
|-----------------------|-----------------------------|
| ledipasvir/sofosbuvir | Make preferred on the PMPDP |

#### Hypoglycemic Agents New Drug Evaluations

The Committee recommended no changes to oral hypoglycemic PMPDP classes at this time and to add albiglutide and dulaglutide to the current PA criteria for GLP-1 analogs. The Committee also recommended adding empagliflozin and canagliflozin-metformin to the current PA criteria for SGLT2s.

#### Colony Stimulating Factor Class Update

The Committee agreed that the evidence on CSFs supported previous recommendations regarding efficacy, effectiveness and harms. After comparative cost consideration in executive session, the Committee recommended making Granix® (tbo-filgrastim) preferred on the PMPDP.

| DRUG           | CHANGE                      |
|----------------|-----------------------------|
| tbo-filgrastim | Make preferred on the PMPDP |

#### Ophthalmic VEGF Inhibitor Class Update

The Committee recommended maintaining pegaptanib and aflibercept as non-preferred agents on the PMPDP due to lower strength of evidence. After comparative cost consideration in executive session, the Committee recommended no changes to the PMPDP.

#### Ophthalmic Drugs for Glaucoma Class Update

The Committee recommended that no further research was needed at this time and to maintain unoprostone and the brinzolamide/brimonidine fixed-combination product as non-preferred on the PMPDP. The Committee also recommended continued inclusion of a medication from each category on PMPDP, including: miotics; alpha-adrenergic agonists; beta-blockers; carbonic anhydrase inhibitors and prostaglandin analogs. After comparative cost consideration in executive session, the Committee recommended no changes to the PMPDP.

#### Opioid Dependence Class Update

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



### Olodaterol (Striverdi® Respimat®) New Drug Evaluation

Due to lack of quality evidence demonstrating clinical effectiveness, the Committee recommended maintaining olodaterol as non-preferred on the PMPDP.

### Ophthalmic Antibiotic Scan

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

### Ophthalmic Antibiotic/Corticosteroid Scan

The Committee recommended that no further research is needed at this time and after comparative cost consideration in executive session, recommended making gentamicin/prednisolone ophthalmic suspension and ointment, as well as neomycin/polymyxin B/dexamethasone ophthalmic ointment preferred on the PMPDP.

| DRUG   | CHANGE                      |
|--|-----------------------------|
| gentamicin/prednisolone ophthalmic suspension and ointment | Make preferred on the PMPDP |
| neomycin, polymyxin B, and dexamethasone ointment          | Make preferred on the PMPDP |

### Cephalosporin Scan

The Committee recommended that no further research is needed at this time and to continue to include at least one agent from the 1<sup>st</sup>, 2<sup>nd</sup>, and 3<sup>rd</sup> generation cephalosporins and amoxicillin/clavulanate, as well as age appropriate dosage formulations as preferred on the PMPDP. After comparative cost consideration in executive session, the Committee recommended making cefuroxime oral suspension preferred on the PMPDP.

| DRUG                       | CHANGE                      |
|----------------------------|-----------------------------|
| cefuroxime oral suspension | Make preferred on the PMPDP |

### Topical Psoriasis Scan

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

#### ADHD Scan

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

#### ACE-Inhibitor, Angiotensin Receptor Blocker, Direct Renin Inhibitor Scan

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

#### Statin Scan

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

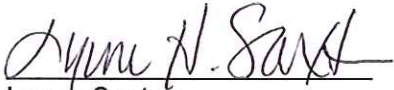
#### Macrolide Scan

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



Lynne Saxton  
Director, Oregon Health Authority

2-18-15  
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>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)