



OFFICE OF THE DIRECTOR

John A. Kitzhaber, MD, Governor

Oregon
Health
Authority

500 Summer St NE E20

Salem OR 97301

Voice: 503-947-2340

Fax: 503-947-2341

www.Oregon.Gov/OHA

www.health.oregon.gov

OFFICIAL WEBSITE NOTICE

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RECOMMENDATIONS OF DRUG USE REVIEW / PHARMACY AND THERAPY COMMITTEE

The Oregon Drug Use Review / Pharmacy and Therapeutics Committee met in Wilsonville, Oregon on Thursday, January 30th, 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 and all public comment offered,ⁱⁱ 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:

Fish Oil Drug Use Evaluation

The Committee recommended retaining legend omega-3 acid ethyl esters (Lovaza®) as non-preferred on the PMPDP and putting all over-the-counter fish oil (FO)/omega-3 (O3) fatty acid products on the "Excluded Drug List". Drugs on this list used for funded diagnoses will be approved through the administrative appeals process.

The Committee approved the DUR proposal for staff to publish an Oregon State Drug Review on FO/O3 detailing the lack of evidence and announcing the policy prior to implementation and to bring back Lovaza® as old business at the March P&T meeting to evaluate the proposed prior authorization (PA) criteria.

Practitioner-Managed Prescription Drug Plan (PMPDP) Recommendations:

Fish Oil Class Review

The Committee recommended retaining legend omega-3 acid ethyl esters (Lovaza®) as non-preferred on the PMPDP and putting all over-the-counter fish oil (FO)/omega-3 (O3) fatty acid products on the "Excluded Drug List".

Bedaquiline (Sirturo™) New Drug Evaluation

The Committee recommended requiring prior authorization for bedaquiline to limit its use to patients infected with active pulmonary MDR M. tuberculosis when an effective antimycobacterial regimen cannot otherwise be provided and the drug is used in association with an MDR-TB regimen that includes at least 3 drugs to which the patient's MDR-TB isolate is susceptible to in vitro or, if in vitro testing is unavailable, 4 other drugs to which the patient's isolate is likely susceptible. The Committee also recommended requiring documentation of the following:

- diagnosis of active pulmonary MDR-TB (i.e., not latent or drug-sensitive TB)
- resistance of the patient's isolate to at least isoniazid and rifampin
- susceptibility of the patient's isolate to bedaquiline
- prescriptions for 3 or 4 concomitant medications used to treat MDR-TB
- the use of expert medical consultation

The Committee recommended making bedaquiline non-preferred and to consider reviewing the entire class in the future to identify preferred options.

Sofosbuvir (Solvadi®) New Drug Evaluation

The Committee recommended making sofosbuvir preferred on the PMPDP and to implement prior authorization criteria to limit use to:

- Patients also on peginterferon and ribavirin with HCV genotype 1 or 4
- Patients also on ribavirin with HCV genotypes 2 and 3
- Prescribed in consultation with a specialist
- Patients with evidence of moderate to severe fibrosis
- Patients with a history of compliance to previous hepatitis C treatment

The Committee asked staff to bring back a class update to the March P&T meeting as old business and to review a report of the Hepatitis workgroup. The Committee also recommended the Department look into the potential of using a sole source provider.

Simeprevir (Olysio®) New Drug Evaluation

The Committee recommended making simeprevir preferred on the PMPDP and to apply the Hep C. Protease Inhibitor/Triple Therapy prior authorization criteria limiting use to:

- Patients with HCV genotype 1
- Without Q80K polymorphism virus
- Patients also on peginterferon alfa and ribavirin
- Patients with compensated liver disease and moderate to severe fibrosis
- When prescribed by a specialist
- Patients with a history of compliance to previous hepatitis C treatment

The Committee asked staff to bring back a class update to the March P&T meeting as old business and to review a report of the Hepatitis workgroup. The Committee also recommended the Department look into the potential of using a sole source provider.

Second Generation Antipsychotics (SGA) Class Update

Based on the lack of long-term effectiveness and safety data, the Committee recommended listing aripiprazole long-acting injection as non-preferred on the voluntary Mental Health (MH) Preferred Drug List (PDL). After comparative cost consideration in executive session, the Committee recommended making ziprasidone non-preferred on the voluntary mental health (MH) (PDL)

DRUG	CHANGE
aripiprazole (Abilify® Maintena)	Make non-preferred on voluntary MH PDL
ziprasidone	Make non-preferred on voluntary MH PDL

Gout Medications

The Committee agreed that therapy with xanthine oxidase inhibitors remains first-line therapy for chronic gout/hyperuricemia and that there is insufficient evidence of any significant difference between allopurinol and feboxostat in clinical outcomes such as gout flares. As the American College of Rheumatology guidelines give no preference to either agent and both are recommended as first line treatment. The Committee also agreed that there is insufficient evidence for the use of intra-articular corticosteroids for the treatment of acute gout.

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 PMPDP

Oral HSV Antiviral 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 PMPDP.

Hormone Replacement Therapy Scan

The Committee recommended that no further research is needed at this time as there is no new significant comparative evidence on the efficacy and safety of hormone replacement therapy medications.

After comparative cost consideration in executive session, the Committee recommended making Vivelle-Dot and Alora preferred on the PMPDP and FemHRT, Jinteli and their generics non-preferred on the PMPDP and to grandfather current patients for 12 months.

DRUG	CHANGE
estradiol patch (Vivelle Dot®)	Make preferred on PMPDP
estradiol transdermal (Alora®)	Make preferred on PMPDP
norethindrone acetate/ethinyl estradiol (FemHRT)	Make non-preferred on PMPDP
norethindrone acetate/ ethinyl estradiol (Jinteli®)	Make non-preferred on PMPDP

Calcium Channel Blockers 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 PMPDP.

Beta Blockers Scan

The Committee recommended that no further research is needed at this time and after comparative cost consideration in executive session, the Committee recommended Make nadolol NP on PMPDP and to grandfather current patients for 12 months.

DRUG	CHANGE
nadolol	Make non-preferred on PMPDP

ACEI/ARBs/DRI's Scan

The Committee agreed that there is insufficient evidence evaluating azilsartan/chlorthalidone combination therapy on long term clinical outcomes and recommended it be maintained as non-preferred.

The Committee recommended that no further research is needed at this time as there is no new comparative efficacy or safety evidence for preference of one agent over another within each class.

After comparative cost consideration in executive session, the Committee recommended making captopril, fosinopril, moexilpril, quinapril and trandolapril and the HCTZ combination products non-preferred on the PMPDP due to low use and high relative price and to grandfather current patients for 12 months.

DRUG	CHANGE
captopril, captopril/HCTZ	Make non-preferred on PMPDP
fosinopril, fosinopril/HCTZ	Make non-preferred on PMPDP
moexilpril, moexilpril /HCTZ	Make non-preferred on PMPDP
quinapril, quinapril/HCTZ	Make non-preferred on PMPDP
trandolapril, trandolapril/HCTZ	Make non-preferred on 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.



Tina Edlund
Acting Director, Oregon Health Authority

03/04/14
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

ⁱhttp://pharmacy.oregonstate.edu/drug_policy/sites/default/files/pages/dur_board/meetings/meetingdocs/2013_07_25/finals/2013_07_25_PnT_Complete.pdf

ⁱⁱhttp://pharmacy.oregonstate.edu/drug_policy/sites/default/files/pages/dur_board/meetings/meetingdocs/2013_07_25/finals/2013_07_25_WrittenTestimony.pdf