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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 Salem Oregon on Thursday, June 28th, 2012. 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, 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:

May Meeting Minutes

The Committee reviewed and approved the minutes from the May meeting. It was noted however, that the OHA recommendations that were posted for the May P&T meeting needed to be amended to accurately reflect the Committee's recommendation that Lovaza be designated non-preferred.

Fidaxomicin (Dificid®) Follow-up

The Committee reviewed the infectious disease consult regarding C. Difficile and based upon the information presented recommended continuation of the prior authorization criteria recommended at the April P&T Meeting.

Ivacaftor (Kalydeco®) New Drug Evaluation

The Committee reviewed the new drug evaluation of ivacaftor and proposed PA criteria. Based upon the clinical evidence presented the Committee approved the proposed criteria to limit use to patients six years of age and older who have been diagnosed with CF and have the G551D mutation in the CFTR gene, when

prescribed by or in consultation with a pulmonologist or by a practitioner from an accredited CF center. The Committee recommended a trial of standard medication therapy should be tried if indicated and/or tolerated and that renewals meeting criteria should be approved for six months.

Erythropoiesis Stimulating Agent (ESA) Class

The Committee reviewed the ESA class update and proposed PA criteria. Based on the clinical evidence presented the Committee approved the updated PA criteria and recommended modifying the initial PA approval lengths for anemia associated with CKD and chemotherapy induced anemia to 8 weeks to assess adequate response in congruence with the OHP list. The Committee amended the proposed PA criteria recommending removal of HCT and requiring a reduction in ribavirin dose to 600mg/day for patients on triple therapy for Hep.C.

The Committee recommended HERC be contacted to update OHP Guideline Note 7 to reflect twelve weeks which is current FDA labeling and was also recommended by expert reviewers. The Committee also recommended listing peginesatide as non-preferred on the PMPDP until more safety and efficacy data are available.

Based upon confidential pricing reviewed in executive session the Committee recommended deferring changes to the PMPDP until September when the 2012 supplemental rebate bids can be reviewed.

Nitrate Class

The Committee reviewed the Nitrates abbreviated class review. Based on the clinical evidence presented the Committee agreed with the recommendation to add Nitrates as a class on the PMPDP and approved the staff recommendations to: include a short acting nitrate for angina prevention and treatment; include a long-acting nitrate agent for angina prophylaxis and treatment and include isosorbide dinitrate ER for the management of heart failure; and to require prior authorization for approved OHP diagnosis only.

Following review of confidential pricing in executive session the Committee recommended including as preferred agents on the PMPDP: nitroglycerin SL tabs, isosorbide dinitrate tabs and SL tabs, isosorbide mononitrate tabs, isosorbide mononitrate ER 24H tabs, isosorbide dinitrate ER caps, nitroglycerin ER caps and nitroglycerin patches. The Committee recommended making isosorbide dinitrate ER tablets, nitroglycerin spray and ointments non-preferred.

Targeted Immune Modulators (TIMs)

The Committee reviewed the TIMs drug class review which included the DERP Executive Summary and P&T Committee Brief. Based on the clinical evidence presented the Committee agreed with staff recommendations to maintain golimumab, tocilizumab, and ustekinumab as non-preferred on the PMPDP due to limited comparative evidence and lack of clinical benefit compared to currently available TIMs. The Committee recommended adding clinical criteria for prior authorization of non-preferred TIMs to include a step therapy requirement of a trial and inadequate response to methotrexate and to limit approval to the appropriate FDA indications for each non-preferred drug. The Committee recommended DMAP coordinate coverage in the pharmacy and medical programs and directed staff to perform a DUE to evaluate preferred products for off-label use or use inconsistent with current clinical guidelines.

Iron Chelators

The Committee reviewed the Iron Chelators new drug review. Based on the clinical evidence presented and following the review of confidential pricing in executive session the Committee agreed with the recommendation to add deferoxamine as a preferred agent on the PMPDP. The Committee recommended making the oral agents deferasirox and deferiprone non-preferred agents and to apply the default non-preferred PA criteria to utilize them as second line agents.

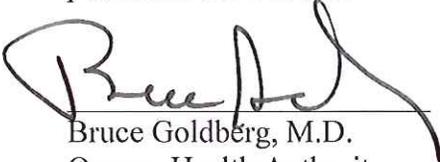
Hepatitis B Recommendations from April P&T meeting

The Hepatitis B class review originally performed at the February P&T meeting was revisited at the April 26th P&T meeting and Dr. Atif Zaman was appointed as an ad-hoc expert for the re-review. Based on the clinical evidence presented the Committee agreed with the recommendation to implement the proposed PA criteria for the non-preferred agents in this class, to promote the use of preferred and recommended treatments. Following the review of confidential pricing in executive session the Committee recommended making entecavir non-preferred.

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 and will be put into place no earlier than 60 days from the date this notice is posted on the web site.


Bruce Goldberg, M.D.
Oregon Health Authority

7/24/2012
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