



Office of the Director

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OFFICIAL WEBSITE NOTICE

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

The Oregon Drug Use Review / Pharmacy and Therapeutics Committee met in Wilsonville, Oregon on Thursday, August 30th, 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:

Oral Direct Factor X Inhibitors: Rivaroxaban (Xarelto®)

The Committee reviewed and approved the proposed updated prior authorization criteria to allow for a 14 days of rivaroxaban, or until patients are adequately anticoagulated while switching to other oral anticoagulants.

Targeted Immune Modulators

The Committee reviewed the TIMs drug use evaluation and proposed prior authorization criteria. Based on the clinical evidence presented the Committee agreed with staff recommendations for non-preferred TIMs to be used for FDA approved indications, with a previous trial of DMARD therapy when appropriate, and dose limits to ensure maximum recommended doses are not exceeded. The Committee recommended removal of the requirement for PA for preferred products for non-approved indications as well as questions #3 and #5 in the proposed criteria.

The Committee recommended coordination of coverage for this class between the medical and pharmacy programs. Based upon confidential pricing reviewed in executive session the Committee recommended maintaining Humira and Enbrel as preferred agents on the PMPDP and to designate Remicade as non-preferred as it requires IV administration.

Antipsoriatics

The Committee reviewed and approved the proposed updated antipsoriatic prior authorization criteria to require a trial of standard systemic therapies including cyclosporine, methotrexate, or acitretin if appropriate, before use of a non-preferred biologic agent should be authorized.

Fingolimod (Gilenya®) New Drug Evaluation

The Committee reviewed and approved the proposed updated prior authorization criteria to include new FDA safety warnings regarding use in patients with preexisting cardiac disease.

Erythropoiesis Stimulating Agents

The Committee reviewed and approved the proposed updated prior authorization criteria to ensure adequate Fe repletion and adequate ESA dosing (#13 on PA criteria) and extend initial length of authorization to 12 weeks when Guideline Note 7 on the Prioritized List is updated.

Based upon confidential pricing reviewed in executive session the Committee recommended making Procrit and Aranesp preferred and Epogen non-preferred on the PMPDP.

Inhaled Antibiotics and Dornase Alfa for Cystic Fibrosis

The Committee reviewed the abbreviated class review. Based on the clinical evidence presented the Committee agreed with the recommendation to make tobramycin inhalation solution a preferred agent on the PMPDP due to more long term efficacy and safety evidence with a quantity limit of 56 vials/56 days (for cycles of 28 days on followed by 28 days off therapy). The Committee also

recommended making aztreonam inhalation solution a non-preferred agent and limit to patients with cystic fibrosis with a quantity limit of 84 vials/56 days (for cycles of 28 days on followed by 28 days off therapy)

The Committee deferred taking action on Dornase Alfa and asked that it be brought back to the September P&T meeting with 2yr data.

Ranolazine (Ranexa®)

The Committee reviewed the abbreviated drug evaluation of ranolazine. Based on the clinical evidence presented the Committee agreed with staff recommendations to make non-preferred on the PMPDP due to the lack of comparative effectiveness data that ranolazine is more effective or safer than other antianginal agents for managing the risk of cardiovascular events or death.

Diuretics

The Committee reviewed the diuretic agent abbreviated class review. Based on the clinical evidence presented the Committee agreed with the recommendation to add loop, thiazide/thiazide like and potassium sparing diuretics as a class on the PMPDP and to include aldosterone antagonists due to mortality benefit in select patients with heart failure. The Committee agreed that there was a lack of clinical distinction in efficacy or harms and to include agents from each class as preferred on the PMPDP.

Based upon confidential pricing reviewed in executive session the Committee recommended making all multisource agents preferred except: amiloride, chlorothiazide, chlorthalidone, furosemide solution 40mg/5ml, eplerenone, methyclothiazide, triamterene/HCTZ tablets, metolozone and ethacrynic acid.

Ophthalmic Glaucoma Agents

The Committee reviewed the ophthalmic glaucoma agent abbreviated class update and tafluprost (Zioptan®) new drug evaluation. Based on the clinical evidence presented the Committee recommend continuing to include a medication from each category including miotics, sympathomimetics, beta blockers, carbonic anhydrase inhibitors, and prostaglandin analogues as preferred on the PMPDP and had no changes to recommend to current PDL status based on new clinical

evidence or differences in efficacy/effectiveness or harms between members within each class. Due to lack of evidence for a benefit in efficacy or safety of tafluprost over currently available prostaglandins the Committee agreed to evaluate comparative costs with other agents in executive session.

Based upon confidential pricing reviewed in executive session the Committee recommended making generic latanoprost drops preferred and apraclonidine, Alphagan P, travoprost and tafluprost non-preferred on PMPDP.

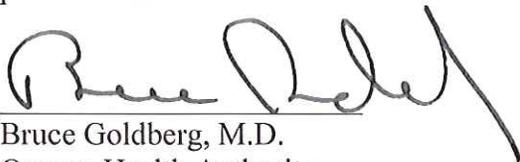
Vascular Endothelial Growth Factor (VEGF) Inhibitors

The Committee reviewed the VEGF abbreviated class review. Due to a new FDA approval the Committee deferred taking action and asked that it be brought back to the November P&T meeting.

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

9-24-12

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