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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, March 27th, 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 staffⁱ 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:

Benzodiazepine Drug Use Evaluation (DUE)

The P&T Committee agreed with the recommendations to delete the 3 mg diazepam dose equivalent from the prior authorization (PA) criteria and to extend the look back period from 100 days to 120 days to avoid false positive identification of new patients from mail order claims. The Committee also recommended the OHA send out provider education letters to prescribers when a patient is identified as a new patient to avoid unnecessary gaps in therapy for appropriate patients.

Omega-3 Fatty Acid PA Criteria

The Committee recommended approving the dedicated Omega-3 Fatty acid PA criteria including documentation of the following:

- Clinically diagnosed hypertriglyceridemia with triglyceride levels > 500
- Failure or contraindication to a fibric acid derivative and niacin OR

- The patient is taking a statin and is unable to take a fibric acid derivative or niacin due to an increased risk of myopathy.

The Committee asked staff to add gemfibrozil to Table 1 on the PA criteria.

Diclofenac Safety Evaluation

Due to limited evidence on safety data associated with diclofenac therapy and the inherent risks associated with all NSAIDs, the Committee recommended no PA be applied at this time and no changes to the PMPDP. The Committee also requested staff reevaluate this topic in one year.

Antipsychotic Adherence Monitoring Proposal

The Committee approved the plan to create a weekly RetroDUR provider fax notification campaign of potentially non-adherent patients with a recent diagnosis of schizophrenia with the following reporting metrics:

- Provider satisfaction responses
- HEDIS 2013 Adherence to Antipsychotic Medications for individuals with Schizophrenia (SAA)
- Hospitalization rates by antipsychotic adherence level
- Pre/post hospitalization and prescription utilization rates for patients identified by program for intervention

The Committee also recommended collaborating with CCO Pharmacy Directors regarding initiative content, timing and inclusion of CCO patients and providers, as well as to start by targeting a specific pharmacy and asking providers what information would be most helpful to them (e.g. utilization of other mental health related medications including seizure medications, benzodiazepines, and antidepressants).

The Committee directed staff to evaluate use of injectable antipsychotics to determine if adherence rates differ between injectable and oral agents and to add schizoaffective disorder to the inclusion criteria.

Zolpidem DUE

The Committee recommended limiting zolpidem monthly consumption to 15 units/ 30 days by prior authorization to discourage continuous daily use. The Committee also recommended implementation of a prior authorization for women on zolpidem 10mg and 12.5mg due to safety concerns and to evaluate the approved sedative benzodiazepine continuous therapies for frequently approved comorbidities so they may be included as approved step therapy edits for zolpidem.

Immunoglobulin DUE

The Committee recommended staff perform a retrospective quarterly audit and report to P&T for all IgG claims to verify billing accuracy, evidence supporting diagnosis and appropriate dosing.

Delayed Release Cysteamine New Drug Evaluation

The Committee recommended requiring prior authorization for cysteamine DR to limit its use to patients with documentation of nephropathic cystinosis and intolerance or nonadherence to cysteamine IR or inability to achieve a WBC cysteine level $<1 \text{ nmol } \frac{1}{2}$ cysteine per mg protein, preferably from a physician experienced in managing nephropathic Cystinosis.

Practitioner-Managed Prescription Drug Plan (PMPDP) Recommendations:

Immunoglobulin Abbreviated Class Review

The Committee recommended IVIG products are similar in efficacy and should be prescribed based on the risk of adverse events with each formulation, cost, and history of IgG use.

The choice of IVIG or SCIG should account for the individual patient's ability to administer IgG at home, compliance, availability and ease of IV access, and comorbid conditions. After comparative cost consideration in executive session, the Committee recommended adding the class to PMPDP for subcutaneous (sub-q) point of sale agents, designate Gamunex-C as preferred and all other sub-q agents non-preferred. The Committee also recommended not creating a PDL class or requiring PA for physician administered IVIG agents at this time.

DRUG	CHANGE
Gamunex-C®	Make preferred on PMPDP
All other sub-q agents	Make non-preferred on the PMPDP

Hepatitis C Class Update

The Committee recommended revising the sofosbuvir PA criteria for more appropriate patient selection, including criteria to avoid in patients with significant renal impairment and those who would be noncompliant for a variety of reasons. The Committee also recommended restricting sofosbuvir and simeprevir treatment to Fibrosis stage 3 and 4 patients at this time, consistent with recommendations from the hepatology workgroup. Due to increased safety concerns and guideline recommendations the Committee recommended making telaprevir and boceprevir non-preferred on the PMPDP.

The Committee directed staff to continue to evaluate new evidence as it comes out for further revisions, explore opportunity to leverage 340B sole-source contract and to develop and present a “Readiness to Treat Document” as old business at May P&T meeting.

DRUG	CHANGE
telaprevir (Incivek®)	Make non-preferred on PMPDP
boceprevir (Victrelis®)	Make non-preferred on PMPDP

Multivitamins (MVI) and Antioxidants Abbreviated Class Review

Based on evidence of no benefit on mortality, CVD, or cancer outcomes with multivitamins or antioxidant multivitamin supplements, the Committee recommended prior authorizing agents and approving for documented nutritional deficiency, or for diagnoses associated with nutritional deficiency.

For mono vitamin supplements including calcium, vitamin D, folic acid, vitamin B, and the ferrous salt formulations with evidence to support their use or insufficient evidence to make strong conclusions, the Committee moved to evaluate comparative costs in executive session due to no evidence of superiority of individual products over another.

After comparative cost consideration in executive session, the Committee recommended making products without an AAC and no utilization non-preferred. The Committee also recommended making Nascobal®, ferrous sulfate oral suspension and drops, pyridoxine lozenge and lozenge HD, vitamin D3 wafers, and vitamin D2 & D3 Drops non-preferred on the PMPDP and to not grandfather current patients. The Committee recommended making all other products preferred on the PMPDP.

The Committee asked staff to develop and present dedicated PA criteria as old business at May P&T meeting and to bring back a review of other minerals and electrolytes at a future P&T meeting for further decision-making.

DRUG	CHANGE
Nascobal®	Make non-preferred on PMPDP
products without an AAC and no utilization	Make non-preferred on PMPDP
ferrous sulfate oral suspension & drops	Make non-preferred on PMPDP
pyridoxine lozenge and lozenge HD	Make non-preferred on PMPDP
vitamin D3 wafers	Make non-preferred on PMPDP
vitamin D2 & D3 drops	Make non-preferred on PMPDP
all other products	Make preferred on the PMPDP

Inhaled Antibiotics Class Update

The Committee found that there is no new clinical evidence of effectiveness or safety resulting in recommended changes to current PMPDP agents and to maintain tobramycin inhalation solution as a preferred agent. After comparative cost consideration in executive session, the Committee recommended maintaining tobramycin inhalation powder (Tobi® Podhlaer™) as non-preferred on the PMPDP and to require step therapy with tobramycin inhalation solution before approval. The Committee recommended making no changes to the PMPDP.

Topical Antifungal Abbreviated Class Update

Due to lack of long term clinical outcomes data and direct comparative data to suggest better tolerability or efficacy than currently available agents, the Committee recommended maintaining luliconazole (Luzu™) as non-preferred topical antifungal medication on the

PMPDP. After comparative cost consideration in executive session, the Committee recommended making no changes to the PMPDP.

Smoking Cessation 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 the PMPDP.

Quick relief Medications for Asthma Scan

The Committee recommended that no further research is needed at this time and after comparative cost consideration in executive session, the Committee recommended removing Pirbuterol Acetate from the PMPDP as it is no longer available and add Ventolin® HFA if it does not jeopardize existing SR contracts.

DRUG	CHANGE
Pirbuterol Acetate	Remove name from PMPDP
Ventolin® HFA	Make preferred on PMPDP if possible

Long Acting Opioid Scan

The Committee found insufficient comparative evidence of efficacy and due to important safety concerns, recommended maintaining hydrocodone ER (Zohydro® ER) as non-preferred on the PMPDP. 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 the PMPDP.

Proton Pump Inhibitor 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 the PMPDP.

Digestive Enzyme 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 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.

Tina Edlund

Tina Edlund
Acting Director

4-17-14

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