



Drug Use Research & Management Program
OHA Division of Medical Assistance Programs
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Oregon Drug Use Review / Pharmacy & Therapeutics Committee

Thursday, March 27, 2014 1:00-5:00 PM

Wilsonville Training Center
29353 SW Town Center
Wilsonville, OR 97070

MEETING MINUTES

NOTE: Any agenda items discussed by the DUR/P&T Committee may result in changes to utilization control recommendations to the OHA. Timing, sequence and inclusion of agenda items presented to the Committee may change at the discretion of the OHA, P&T Committee and staff. The DUR/P&T Committee functions as the Rules Advisory Committee to the Oregon Health Plan for adoption into Oregon Administrative Rules 410-121-0030 & 410-121-0040 as required by 414.325(9).

Members Present: Cathy Zehrung, RPh; Phillip Levine, PhD; William Origer, MD; Zahia Esber, MD; Stacy Ramirez, PharmD; James Slater, PharmD

Members Present by Phone: David Pass, MD

Staff Present: Kathy Ketchum, RPh, MPA:HA; Megan Herink PharmD, BCPS; Richard Holsapple, RPh; Roger Citron, RPh; Ted Williams, PharmD; Trevor Douglass, DC, MPH; Shannon Jasper; Amanda Meeker, PharmD; Dee Weston; Janine Lee, PharmD candidate;

Staff Present by Phone: Kathy Sentena, PharmD, Bing-Bing Liang, PharmD, Brandy Fouts, PharmD; Sherri Willard-Argyres, PharmD

Audience: Stuart O'Brochta (Gilead)*; Richard McLeod; Ralph Magrish (Mercer), Steve Faloon (Otsuka); Kim Laubmeier (Otsuka); Bob Snediker (J & J Stock)*; Theresa Lane (Trillium); Steven Hill (Daiichi Sankyo); Bob Gustafson (Lundbeck); David Barba (Forest); Paul Bonham (Novo Nordisk); Darlene Halverson (Novartis); Mai Duong (Novartis)*; Lance Swanson (Gilead); Kim Clark, PharmD (Grifols); Jason Wideland, PharmD (Gilead); Jamie Damm (Raptor); Connie Brooks (Vertex); Emily Lein, student; Ruby Doan, student; Jeana Colabianchi, PharmD (Sunovion); D.R. McCale (Baxter)*; Kim Clark, PharmD (Grifols); Laura Hill, PharmD (Abbvie); Jim Graves (BMS); David Balhoun (Genentech); Kimberly Blood (WVP); Michelle Bice (Gilead); Matt Willett (Pfizer); B Benson (Merck); Mark Pledger (Novartis); Dr. Walter Shaffer (DMAP); Anne Marie Licos (Med Immune); Dr Kent Benner (OHSU) by phone; Kenneth Ingram, PA (OHSU) by phone;

(*) Provided verbal testimony

I. CALL TO ORDER

- a. The meeting was called to order at approximately 1:00 pm. Introductions of Committee members and staff.
- b. Mr. Citron reported there are no new conflicts of interest to declare.
- c. Approval of agenda and minutes presented by Dr. Origer (pages 1 - 8)

ACTION: Approved as is.

- d. Department updates presented by Dr. Trevor Douglass.
Introduction of Dee Weston to Pharmacy Policy.
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II. DUR OLD BUSINESS

- a. Benzodiazepine Drug Use Evaluation Follow-up (pages 9 – 12)
Ms. Ketchum presented the following information:
 - 1. Edit or delete the 3 mg diazepam dose equivalent from the criteria
 - 2. To avoid false positive identification of new patients from mail order claims, extend the look back period from 100 days to 120 days
 - 3. Send out provider education letters to prescriber when a patient is identified as a new patient to avoid unnecessary gaps in therapy for appropriate patients.

ACTION: Motion, 2nd, All in Favor. Approved.

- b. Lovaza PA Criteria (page 13)
Dr. Herink presented the following information:

Approve Omega-3 Fatty acid PA criteria including documentation of the following:

- 1. Clinically diagnosed hypertriglyceridemia with triglyceride levels > 500
- 2. Failure or contraindication to a fibric acid derivative and niacin OR
- 3. The patient is taking a statin and is unable to take a fibric acid derivative or niacin due to an increased risk of myopathy.
- 4. Add gemfibrozil to table 1.

ACTION: Motion, 2nd, All in Favor. Approved.

III. DUR NEW BUSINESS

- a. Antipsychotic Adherence Monitoring RetroDUR Proposal (pages 20 – 35)
Dr. Williams presented the following proposal:
 - 1. Create a weekly RetroDUR provider fax notification campaign of potentially non-adherent patients with a recent diagnosis of schizophrenia with the following reporting metrics:
 - a. Provider satisfaction responses.
 - b. HEDIS 2013 Adherence to Antipsychotic Medications for individuals with Schizophrenia (SAA).
 - c. Hospitalization rates by antipsychotic adherence level.
 - d. Pre/post hospitalization and prescription utilization rates for patients identified by program for intervention.

2. Outreach

- a. Collaborate with CCO Pharmacy Directors regarding initiative content and timing and inclusion of CCO patient's providers.
- b. Start with targeting a specific pharmacy and asking providers what information would be most helpful to them (utilization of other mental health related medications including seizure medications, benzodiazepines, and antidepressants).
- c. Evaluate use of injectable antipsychotics to determine if adherence rates differ between injectable and oral agents.
- d. Add schizoaffective disorder as inclusion criteria.

ACTION: Motion, 2nd, All in Favor. Approved.

b. Zolpidem Drug Use Evaluation (pages 36 – 42)

Ms. Ketchum presented the following information:

1. Limit Zolpidem monthly consumption to 15 units / 30 days by prior authorization to discourage continuous daily use.
2. Place a prior authorization for women on Zolpidem 10 mg and 12.5 mg.
3. Evaluate the approved sedative benzodiazepine continuous therapies for frequently approved comorbidities and include those as approved step therapy edits for zolpidem.

ACTION: Motion, 2nd, All in Favor. Approved.

c. Immunoglobulin Abbreviated Class Review (pages 43 – 55)

Dr. Fouts presented the class review and the following recommendations:

1. IVIG products are similar in efficacy and should be prescribed based on the risk of adverse events with each formulation, cost, and history of IIG use.
2. 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.
3. After executive session, add Sub-Q class to PDL, and designate Gamunex C as only preferred point of sale agent and all other Sub-Q agents as non-preferred.
4. Do not create a PDL class or require PA for PADs at this time.

Public Comment:

D.R. McCale III from Baxter Bioscience presented testimony regarding IG review.

***ACTION:** After Executive Session, all in favor.

d. Immunoglobulin Drug Use Evaluation (pages 56 – 67)

Ms. Lee presented the evaluation and following recommendation:

1. Perform a retrospective quarterly audit and report to P&T for all IgG claims to verify billing accuracy, evidence supporting diagnosis and appropriate dosing.

ACTION: Motion, 2nd, all in favor. Approved.

e. Diclofenac Safety Evaluation (14 – 19)

Dr. Sentena presented the evaluation and following recommendations:

1. Due to limited evidence on safety data associated with diclofenac therapy and the inherent risks associated with all NSAIDs, no changes to preferred drug list are recommended at this time.
2. Revisit in one year.

ACTION: Motion, 2nd, All in Favor. Approved.

IV. PREFERRED DRUG LIST OLD BUSINESS

a. Hepatitis C Class Update (pages 68 – 90)

Dr. Herink presented new guidelines and the following recommendations:

1. Revise 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.
2. Restrict sofosbuvir and simeprevir treatment to Fibrosis stage 3 and 4 patients at this time, consistent with recommendations from the hepatology workgroup.
3. Make telaprevir and boceprevir non-preferred due to increased safety concerns and guideline recommendations.
4. Continue to evaluate new evidence as it comes out for further revisions.
5. Develop and present a Readiness to Treat document at May P&T.
6. Explore opportunity to leverage 340B sole-source contract.

Public Testimony:

Dr. Kent Benner and PA Kenneth Ingram reported the community standard discussed with the Hepatitis C workgroup.

Robert Snediker from J&J Stock provided public comment.

Stuart O'Brochta from Gilead provided public comment.

ACTION: Motion, 2nd, All in Favor. Approved.

V. PREFERRED DRUG LIST NEW BUSINESS

a. Vitamins Abbreviated Class Review - MVI and Antioxidant Supplements (pages 91-105)

Dr. Herink presented the review and following recommendations:

1. Based on evidence of no benefit on mortality, CVD, or cancer outcomes with multivitamins or antioxidant multivitamin supplements, prior authorize agents and

approve for documented nutritional deficiency or diagnosis associated with nutritional deficiency.

2. For mono vitamin supplements with evidence to support their use or insufficient evidence to make strong conclusions, evaluate comparative costs in executive session due to no evidence of superiority of individual products over another. This includes calcium, vitamin D, folic acid, vitamin B, and the ferrous salt formulations.
3. Bring back a review of other minerals and electrolytes for further decision-making.
4. Bring back as old business to the May P&T meeting and present PA criteria.
5. After review in executive session, make products without AAC and not utilization non-preferred.
6. After executive session, make the following non-preferred and do not grandfather:
 - Nascobal
 - Ferrous Sulfate Oral Susp and Drops
 - Vitamin D3 Wafers, Vitamin D2 & D3 Drops

Make all other products preferred.

***ACTION:** After Executive Session, all in favor.

- b. Inhaled Antibiotics Class Update (Cystic Fibrosis) (pages 106 – 115)
Dr. Herink presented the class update and following recommendations:

1. There is no new clinical evidence of effectiveness or safety resulting in recommended changes to current PDL agents. Maintain tobramycin inhalation solution as a preferred agent and evaluate comparative costs of other agents in executive session.
2. Make tobramycin inhalation powder (Tobi Podhaler) non-preferred and require step therapy with tobramycin inhalation solution before approval.

Public Comment:

Stuart O'Brochta from Gilead gave public comment.

Mai Duong from Novartis gave public comment and presented the Tobi Podhaler.

***ACTION:** After Executive Session, no changes to PDL, all in favor.

- c. Procysbi® (delayed release cysteamine bitartrate) (pages 116 – 126)
Dr. Willard-Argyres presented the new drug evaluation and following recommendations:

1. Prior authorize 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 nmol ½ cysteine per mg protein, preferably from a physician experienced in managing nephropathic cystinosis.

***ACTION:** After Executive Session, all in favor.

- d. Topical Antifungals Class Update (pages 127 – 138)
Dr. Liang presented the new drug evaluation and following recommendations:

1. Maintain luliconazole (Luzu) a non-preferred topical antifungal medication on the PDL due to lack of long term clinical outcomes data and direct comparative data to suggest better tolerability or efficacy than currently available agents.
2. Evaluate comparative costs in executive session.

***ACTION:** After Executive Session, no changes to the PDL, all in favor.

e. Drug Class Scans

Dr. Herink presented the reviews and following recommendations:

1. Smoking Cessation (pages 139 – 146)
 - a. No further research or review needed at this time; update PA criteria based on HP feedback.
 - b. Evaluate comparative costs in executive session.

***ACTION:** After Executive Session, no changes to the PDL, all in favor.

2. Quick Relief medications for asthma (pages 147 – 160)
 - a. No further research or review needed at this time.
 - b. Evaluate comparative costs in executive session.
 - c. Remove Maxair Autoinhaler as it is no longer manufactured.
 - d. Add Ventolin HFA as preferred if it does not jeopardize existing contracts.

***ACTION:** After Executive Session, all in favor.

3. Long acting opioids (pages 161 – 191)
 - a. Due to insufficient comparative evidence of efficacy and important safety concerns, maintain hydrocodone ER (Zohydro ER) as non-preferred.
 - b. Evaluate comparative costs in executive session.

***ACTION:** After Executive Session, no changes to the PDL, all in favor.

4. Proton Pump Inhibitors (pages 192 – 206)
 - a. No further research or review needed at this time.
 - b. Evaluate comparative costs in executive session.

***ACTION:** After Executive Session, no changes to the PDL, all in favor.

5. GI – digestive enzymes (pages 207 – 210)
 - a. No further research or review needed at this time,
 - b. Evaluate comparative costs in executive session.

***ACTION:** After Executive Session, no changes to the PDL, all in favor.

VI. EXECUTIVE SESSION

VII. RECONVENE for PUBLIC RECOMMENDATIONS

Mr. Citron confirmed the next P & T meeting will be held May 29, 2014 at 1:00 pm.

VII. ADJOURN