



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

Thursday, May 29, 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: Tracy Klein, PhD, FNP; Cathy Zehring, RPh; Phillip Levine, PhD; Zahia Esber, MD;

Members Present by Phone: Dave Pass, MD; James Slater, PharmD;

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

Staff Present by Phone: Kathy Sentena, PharmD; Brandy Fouts, PharmD; Walter Shaffer, MD

Audience: Cheryl Fletcher (AbbVie); Michelle Bice (Gilead); Vantana Slater (Amgen)*; Mark Pledger (Novartis); Camille Kerr (Allergan); Chris Doyle (Allergan); Deirdre Monroe (Allergan)*; Venus Holder (Lilly); Paul Bonham (Novo Nordisk); Kimberly Blood (WVP Health Authority); Seth Adams (WVP Health Authority); Bob Snediker (J & J)*; Alyssa Tuttle; Phillip Do; Jeana Colabianchi, PharmD (Sunovion); Greg Broutman, PhD (Sunovion)*; Jamilyn Perez Aragon (Astellas); Cory Bradley (CareOregon); Shannon Betty (MedImmune); Paul Nielsen (Astra Zeneca); Mike Willett (Pfizer); Shane Hall (Purdue); Scott Larson (BMS); Amy Bauman (Gilead); Stuart O'Brochta (Gilead)*; Emily Van Woerden (AbbVie); Stephanie Kendall (J&J); Bill Struyk (J&J)*; Barry Benson (Merck); Jenny Morrison (BIPi); Michael Estes (Pfizer); Brad Peacock (Gilead); Ann Neilson (Amgen); Jim Davidson (Myers and Stauffer); Adrienne McCormick (Myers and Stauffer); Dean Haxby (OSU); David Barba (Forrest); Troy Larsen; Molly Meeker (Hyperion); Lorren Sandt (Caring Ambassadors Program)*; Brett Masett (Bristol Myers Squibb)*; Darlene Halverson (Novartis)

(*) 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 Tracy Klein (pages 3 - 9)

ACTION: Approved as is.

- d. Department updates presented by Dr. Trevor Douglass.
Introduction of Linnea Saris to Pharmacy Policy.
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II. DUR ACTIVITIES

- a. Quarterly Utilization Reports (pages 10-14)
- b. ProDUR Report presented by Rich Holsapple, RPh (pages 15 - 17)
- c. RetroDUR Report presented by Ted Williams, PharmD (pages 18 - 21)
- d. Oregon State Drug Reviews presented by Kathy Sentena
 - 1. Strategies for Effective Monitoring and Management of Psychotropics in Children (pages 22 – 23)
 - 2. Evidence Based Review of Fish Oil: Going Beyond the Headlines (pages 24 – 25)
- e. FDB Drug File Update presented by Ted Williams, PharmD (page 26)

Public Comment:

III. DUR OLD BUSINESS

- a. Multivitamin PA Criteria (pages 27 – 28)
Dr. Herink presented the following proposal:

Approve PA criteria to cover multi-vitamins and antioxidants MVI combinations for documented nutritional deficiency or diagnosis associated with nutritional deficiency only.

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

- b. Hepatitis C “Readiness to Treat” (pages 29 - 42)
Dr. Herink presented the following information:
 - 1. Develop a Hepatitis C readiness to treat assessment to supplement the drug prior authorization process, to help identify red flags that may affect treatment adherence and cure rates of hepatitis D virus.
 - 2. Screen Hepatitis C patients to ensure the follow:
 - a. The patient is motivated to start treatment and understand the general goals of therapy.
 - b. Identify any potential barriers to treatment
 - c. The patient is not homeless or has a high-risk home status.
 - d. The patient has not had alcohol or drug abuse in the past 6 – 12 months.
 - e. The patient is getting adequate psychiatric support and treatment if applicable.

- f. The patient has access to care and support system, including such things as transportation to appointments.
- g. The patient meets the criteria in the prior authorization criteria.
- 3. Presentation from Cory Bradley, PharmD of CareOregon presented the studies and research.
- 4. Clerical changes on document
 - Point system identity risk factor, but not denying treatment
 - Non-emergent medical assistance and transportation
 - Non compliance contract between client and provider
 - Risk of reinfection
 - Medical coverage or loss of eligibility

Public Comment:

Stuart O’Brochta, RPh from Gilead provided comment regarding adherence and the readiness to treat document.

Bill Struyk from Johnson and Johnson just asked if document was for all products.

Lorren Sandt from Caring Ambassador’s presented comment and provided data sheets regarding the epidemic of patients with Hepatitis C.

ACTION: Defer action to incorporate feedback and bring back to the July meeting a couple of proposals to be considered.

IV. DUR NEW BUSINESS

- a. Botulinum Toxins (pages 43 - 67)
 - Dr. Herink presented the following new guidelines:
 - 1. Manually review claim profiles for patients not associated with evidence-supported diagnosis to determine if BoNT was used appropriately.
 - 2. Consider implementing prior authorization criteria to limit use to evidence supported diagnosis.

Public Testimony:

Deirdre Monroe from Allergan, clarification of injection of botox for migraine.

ACTION: Defer action to conduct DUE with CCO utilization and bring back PA recommendations.

- b. ADHD DUE (pages 68 – 82)
 - Dr. Williams presented the following new guidelines:
 - 1. Create a safety edit for:
 - Prescribing of ADHD medications by non-psychiatrists, psych mental health Nurse practioners, and pediatrician’s with developmental specialty when the regimen is:
 - 1. Outside of the standard ages
 - 2. Outside of the standard doses
 - 3. Non-standard polypharmacy
 - 2. Develop retrospective program to survey providers and educational campaign.

3. Do a RetroDUR analysis to follow denials.
4. Bring back information on OPAL-K (Oregon Psychiatric Access Line for Kids) as it progresses.

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

V. PREFERRED DRUG LIST NEW BUSINESS

- a. Cystic Fibrosis Abbreviated Update (pages 83 - 97)
Dr. Herink presented the following review:

1. Update Kalydeco PA criteria to include additional FDA approved CFTR mutations.
2. Evaluate comparative costs of tobramycin 300 mg/ 4 ml (Bethkis) in executive session for PDL (Y) placement.
3. *After executive session make Bethkis preferred.

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

- b. Antidepressants Class Update (pages 98 - 128)
Dr. Meeker presented the following review:

1. Evidence does not support superiority of vortioxetine or levomilnacipran over other agents in this drug class. Recommend that both be listed as non-preferred agents.
2. Based upon current comparative effectiveness research, no changes are recommended for the second generation antidepressant preferred drug class list based on safety and efficacy. Costs should be reviewed in executive session.
3. *After executive session. Make generic escitalopram oxalate tablets preferred.
4. *After executive session. Make imipramine pamoate and clomipramine HCL non-preferred on the voluntary PDL and when dispensed require brand name Anafranil (clomipramine).

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

- c. Inflammatory Bowel Agents (pages 129 - 135)
Dr. Herink presented the following new class updates:

1. Continue to maintain topical and oral options as preferred on the PDL.
2. No further review of research needed at this time and review comparative costs in executive session.
3. *After executive session. No changes to PDL.

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

- d. Phosphate Binders (pages 136 - 143) presented early

Ms. Fouts presented the following new drug evaluation:

1. Phosphate binders should be selected based on each patient's specific clinical needs.
2. Maintain a non-calcium based phosphate binder to the preferred class, based on cost.
3. Evaluate comparative costs in executive session.
4. *After executive session. Make calcium acetate generic tablets preferred.

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

e. Antiepileptic Class Update (pages 144 – 152)

Ms. Ketchum presented the following updates:

1. No further research required at this time. Evaluate comparative costs in executive session.
2. *After executive session. Maintain Aptiom as non-preferred.

Public Comment:

Greg Broutman from Sunovion regarding antiepileptic drugs.

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

f. Drug Class Scans

1. Bone Metabolism (pages 153 – 161)

Ms. Ketchum presented the following updates:

- a. No further research or review needed at this time.
- b. Evaluate comparative costs in executive session.
- c. *After executive session. No changes to the PDL.

Public Comment:

Vandanna Slatter from Amgen gave public comment about the drug class review.

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

2. Erythropoiesis Stimulating Agents (pages 162 – 167)

Ms. Ketchum presented the following updates:

- a. Peginesatide was removed from the market in February 2013 due to 19 reports of anaphylaxis following first dose (including 3 deaths) in patients receiving dialysis. It is recommended it be removed entirely from the PDL.
- b. No further research or review is needed at this time. Evaluate comparative costs in executive session.
- c. *After executive session. No changes to the PDL.

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

3. Hepatitis B Antivirals (pages 168 - 179)
Dr. Herink presented the following updates:
 - a. No further research or review is needed at this time. Update PA criteria to specify HBV undetectable levels and include a caveat for patients with decompensated cirrhosis.
 - b. Update pediatric age restriction of entecavir on PA criteria.
 - c. Evaluate comparative costs in executive session.
 - d. *After executive session no changes to the PDL.

Public Comment:

Brett Marett from Bristol Myers Squibb gave public comment about updates.

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

4. BPH (pages 180 – 190)
Dr. Herink presented the following updates:
 - a. No further research or review needed at this time. Evaluate comparative costs in executive session.
 - b. *After executive session. No changes to PDL.

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

5. Overactive Bladder (pages 191- 213)
Dr. Herink presented the following updates:
 - a. No further research or review needed at this time. Evaluate comparative costs in executive session.
 - b. *After executive session. No changes to PDL.

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

6. Triptans (pages 214 – 239)
Dr. Herink presented the following updates:
 - a. No further research or review needed at this time. Evaluate comparative costs in executive session.
 - b. *After executive session. Make Imitrex Brand only injectable preferred over its generic.

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

VI. EXECUTIVE SESSION

VII. RECONVENE for PUBLIC RECOMMENDATIONS

Mr. Citron confirmed the next P & T meeting will be held July 31, 2014.

VII. ADJOURN