



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

Thursday, July 28, 2016 1:00-5:00 PM
Hewlett-Packard Building
Salem, OR 97302

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: Bill Origer, MD; Tracy Klein, PhD, FNP; Rich Clark, MD, MPH; James Slater, PharmD; Walter Hardin, D.O., MBA; Phillip Levine, PhD; Caryn Mickelson, PharmD

Members Present by Phone: Kelley Burnett, D.O.

Staff Present: Andrew Gibler, PharmD; Megan Herink PharmD, BCPS; Richard Holsapple, RPh; Roger Citron, RPh; Ted Williams, PharmD, BCPS; Dee Weston; Dave Engen, PharmD, CGP; Sarah Servid, PharmD; Kim Wentz, MD; Deanna Moretz, PharmD, BCPS; Kim Wentz, MD;

Staff Present by Phone: Kathy Sentena, PharmD;

Audience: Mark Borromeo (Teva)*; Barry Benson (Merck); Jim Graves (BMS); Rick Frees (Vertex); Ellison Suthoff (Vertex); Jamie Tobitt (Vertex); Dwight Cobb (Quintiles); David Barhoum (Genentech); Renee Hasler (Genentech); Jacob White (UCB)*; Greg Boutman (Sunovion)*; Mae Kwong (Janssen)*; Peter Zoob (Vertex); Venus Holder (Lilly); Chris Conner (BMS)*; Steve Isaki (Sunovion); Bobbi Jo Drumm (BMS); Kim Laubmeier (Sunovion)*; Lisa Boyle (WVP); John Schillo (Lundbeck); Pierre Thoumsin (Pfizer); Samantha Sweeney (Otsuka); Jen Lee (AllCare); Betty Tran (Jazz); Jon Bloomfield (Jazz); Sylvia Churchill (Amgen); Christine Oh (Teva); Jennifer Beighle (Janssen); Nik Seifter (GSK)*;

(*) Provided verbal testimony

I. CALL TO ORDER

- A. The meeting was called to order at approximately 1:15 pm. Introductions were made by Committee members and staff.
- B. Mr. Citron reported there were no new conflicts of interest to declare and welcomed Doctor Kelley Burnett to the Committee.
- C. Approval of agenda and May minutes presented by Dr. Origer. (pages 4 - 9)

Dr. Clark said the minutes did not reflect the concern he voiced regarding the “Antidiabetic Treatments and Cardiovascular Implications” newsletter as it appeared to him to indicate that the empagliflozin was clinically superior. Dr. Clark requested the Committee review the newsletter article and provide specific feedback to staff.

Dr. Moretz corrected the minutes to reflect that Elizabeth Le was a PGY2 resident, not a PharmD candidate.

ACTION: Motion to approve as amended, 2nd, All in Favor.

D. Department updates for OHA presented by Ms. Weston.

II. DUR ACTIVITIES

A. Quarterly Utilization Reports (pages 10 - 14)
Presented by Mr. Citron.

B. ProDUR Report (pages 15 – 17)
Presented by Mr. Holsapple.

C. RetroDUR Report (pages 18 - 22)
Presented by Dr. Williams.

D. Oregon State Drug Reviews (pages 23 – 24)
Presented by Dr. Sentena.

1. Autism Spectrum Disorder Still Not Linked to the MMR Vaccine: A Review of the Studies since the 1998 Wakefield Study
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III. DUR OLD BUSINESS

A. Ivacaftro/Lumacaftor (Orkambi™) Concerns (page 25)

1. The Committee discussed the lack of COI disclosure from the CF Foundation, or that of the OHSU specialists being clearly brought to their attention.
2. Updated COI disclosure form was reviewed.
3. The Committee discussed whether the new knowledge of apparent COI would have changed their previous recommendations.

ACTION: The Committee recommended amending the COI disclosure form to include organizations and also requested that experts engaged to review and provide expert opinion on documents being prepared for P&T also be required to complete COI disclosure. The Committee agreed that the current PA criteria should remain in effect and that the anticipated review in November of Orkambi’s expanded FDA indication would suffice. **Motion to approve, 2nd. All in favor. Approved.**

IV. DUR NEW BUSINESS

A. ADHD Drug Policy Evaluation (pages 26-48)

Dr. Herink presented the policy evaluation and following recommendations:

1. Update safety edit to require adults with a history of alcohol abuse or SUD within past 12 months, a mental health specialist consult.
2. Approve lisdexamfetamine for binge eating disorder only for adults with an absence of co-morbid mental health illness and amend PA criteria to require CBT.
3. Require PA for adults 18 years and older
4. Streamline PA processing for stable ADHD regimens for children
5. Perform RetroDUR with change order forms to promote preferred products
6. Evaluate comparative costs in executive session.

ACTION: The Committee did not recommend adopting the update to the safety edit to require a mental health specialist consult for adults with a history of alcohol abuse or SUD within past 12 months, or to require PA for all claims for every adult 18 years and older. The Committee did recommend the OHA adopt the other recommendations.

Motion to approve, 2nd. All in favor. Approved.

IV. PREFERRED DRUG LIST NEW BUSINESS

A. Smoking Cessation Drug Class Update (pages (49 – 73)

Dr. Herink presented the class update and following recommendations:

1. No changes to the PDL based on the clinical evidence
2. Allow initial treatment with varenicline for 24 weeks
3. Evaluate whether current PA policy is meeting goal
4. Evaluate comparative costs in executive session

ACTION: The Committee did not support allowing continued treatment with varenicline for 24 weeks without PA, but did recommend the OHA adopt the other recommendations.

Motion to approve, 2nd. All in favor. Approved.

B. Drug Class Literature Scans

1. Antidepressants (pages 74 – 87)

Dr. Moretz presented the scan and following recommendations:

- a. No further research is needed at this time
- b. Evaluate comparative costs in executive session

ACTION: Motion to approve, 2nd. All in favor. Approved.

2. Erythropoiesis Stimulating Agents (pages 88 – 94)

Dr. Moretz presented the scan and following recommendations:

- a. No further research is needed at this time
- b. Maintain current PA criteria
- c. Evaluate comparative costs in executive session

ACTION: Motion to approve, 2nd. All in favor. Approved.

3. Antivirals for Herpes Simplex Virus (pages 95 – 102)

Dr. Sentena presented the scan and following recommendations:

- a. No further research is needed at this time
- b. Adopt proposed changes to PA criteria
- c. Evaluate comparative costs in executive session

ACTION: Motion to approve, 2nd. All in favor. Approved.

4. Drugs for BPH (pages 103 – 111)

Dr. Sentena presented the scan and following recommendations:

- a. No further research is needed at this time
- b. Evaluate comparative costs in executive session

ACTION: Motion to approve, 2nd. All in favor. Approved.

5. Anti-Parkinson's Agents (pages 112 – 123)

Dr. Engen presented the scan and following recommendations:

- a. No further research is needed at this time
- b. Evaluate comparative costs in executive session

ACTION: Motion to approve, 2nd. All in favor. Approved.

6. Bone Resorption Inhibitors (pages 124 – 135)

Dr. Gibler presented the scan and following recommendations:

- a. No further research is needed at this time
- b. Evaluate comparative costs in executive session

ACTION: Motion to approve, 2nd. All in favor. Approved.

C. Antiepileptic Drug Class Update (pages 136 – 163)

Dr. Moretz presented the class update and following recommendations:

1. No further research is needed at this time
2. Maintain brivaracetam as a non-preferred on the PMPDP
3. Evaluate comparative costs in executive session

Public Comment:

Jacob White from UCB Pharma gave public comment

Kim Laubmeier and Greg Broutman from Sunovion Pharmaceuticals Inc. gave public comment

ACTION: Motion to approve, 2nd. All in favor. Approved.

D. Direct-acting Oral Anticoagulants Class Update (pages 164 – 176)

Dr. Sentena presented the class update and following recommendations:

1. No changes to the PMPDP based on the DERP report
2. Continue open access to all DOACs without PA

Public Comment:

Christopher Conner with Bristol-Myers Squibb gave public comment
Mae Kwong with Janssen gave public comment

ACTION: Motion to approve, 2nd. Majority in favor with one opposed. Approved.

E. Lesinurad New Drug Evaluation (pages 177 – 186)

Dr. Engen presented the NDE and following recommendations:

1. Due to limited evidence and unknown long-term safety risks maintain lesinurad as non-preferred on the PMPDP

ACTION: Motion to approve, 2nd. All in favor. Approved.

F. Monoclonal Antibodies for Asthma Class Review (pages 187 – 210)

Drs. Herink and Gibler presented the class review and following recommendations:

1. Maintain mepolizumab and reslizumab as a non-preferred on the PMPDP
2. Adopt proposed PA criteria as amended to require age ≥12 years for Nucala

Public Comment:

Nik Seifter, PharmD with GSK gave public comment.
Mark Borromeo with Teva gave public comment

ACTION: Motion to approve, 2nd. Majority in favor with two opposed. Approved.

V. EXECUTIVE SESSION

VI. RECONVENE FOR PUBLIC RECOMMENDATIONS * After executive session

A. ADHD Drug Policy Evaluation (pages 26 - 48)

***ACTION:** recommend making Daytrana non-preferred on the PMPDP
Motion, 2nd, All in Favor. Approved.

B. Smoking Cessation Drug Class Update (pages (49 – 73)

***ACTION:** Recommend no changes to the PMPDP.
Motion, 2nd, All in Favor. Approved.

C. Drug Class Literature Scans

1. Antidepressants (pages 74 – 87)
2. Erythropoiesis Stimulating Agents (pages 88 – 94)
3. Antivirals for Herpes Simplex Virus (pages 95 – 102)
4. Drugs for BPH (pages 103 – 111)
5. Anti-Parkinson's Agents (pages 112 – 123)
6. Bone Resorption Inhibitors (pages 124 – 135)

***ACTION:** Recommend no changes to the PMPDP.
Motion, 2nd, All in Favor. Approved.

D. Antiepileptic Drug Class Update (pages 136 – 163)

***ACTION:** Recommend no changes to the PMPDP.

Motion, 2nd, All in Favor. Approved.

VII. ADJOURN