

Oregon Drug Use Review / Pharmacy & Therapeutics Committee

Thursday, July 26, 2018, 1:00-5:00 PM DXC Building Salem, OR 97301

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; Phil Levine, PhD; Walter Hardin, DO, MBA; Jim Slater, PharmD; Caryn Mickelson, PharmD; Stacy Ramirez, PharmD; Cathy Zehrung, RPh; Kelley Burnett, DO; William Origer, MD

Members Present by Phone:

Staff Present: Richard Holsapple, RPh; Roger Citron, RPh; Trevor Douglass, DC, MPH; Sarah Servid, PharmD; Lindsay Newton; Dee Weston; Renae Wentz, MD; Julia Page, PharmD; Jonnaliz Corbett; Deanna Moretz, PharmD; Megan Herink, PharmD; David Engen, PharmD; Amanda Parish

Staff Present by Phone: Kathy Sentena, PharmD

Audience: Rick Frees, Vertex; Greg Rasmussen, Vertex; *Lisa Allen, Vertex; Bobbi Jo Drum, BMS; Stephanie Lattig, NovoNordisk; *Anthony Hoovier, NovoNordisk; Andrew Tschernia, OSU; Mike Moore, Otsuka; Aaron Fitzcharles, Pacific University; Dan Allen, Sanofi Genzyme; Mike Ketcher, Sanofi Genzyme; Julie Brown, Harmony Biosciences; *Mae Kwong, Janssen; Van Ann, Vu; Katie Peters, Salud Medical Center; Tim McFerron, Alkermes; Kelly Wright, Lupin Pharma; *Anthony Wheeler, Lilly; Venus Holder, Lilly; Nancy Yuguna, Lilly; Laura Jeffcoat, Abbvie; Anthony Mckenzie, OSU; Sierra Carpenter, OSU; Amy Burns, AllCare; Danielle Shannon, WVP Health Authority; *Kara Shirley, Care Oregon/MHCAG; *Amy Garee; *Forrest Bell; *Marilyn Hartell; Sheila Stidal Collari; John Goddard, GSK

(*) Provided verbal testimony

Written testimony provided: Forrest Bell

I. CALL TO ORDER

- A. The meeting was called to order at approximately 1:04 pm. Introductions were made by Committee members and staff. No new conflict of interests were declared.
- B. Dr. Douglass provided a department update and legislative update.

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

II. CONSENT AGENDA TOPICS

A. Approval of agenda and May minutes presented by Mr. Citron. (pages 4-7)

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

- B. P&T Methods
- C. CMS Annual Report
- D. P&T Annual Report
- E. Quarterly Utilization Reports

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

III. DUR ACTIVITIES

- A. ProDUR Report (pages 8-16)
- B. RetroDUR Report (pages 17-23)
- C. Oregon State Drug Reviews (pages 24-25)
 - 1. A Review of Implications of FDA Expedited Approval Pathways, Including the Breakthrough Therapy Designation

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

IV. PREFERRED DRUG LIST NEW BUSINESS

- A. Oral Cystic Fibrosis Modulators Class Update (pages 26-51)

 Dr. Herink presented the class update and recommended:
 - Continue to require PA for approval in appropriate patients. No changes to the PDL. Remove the requirement of an FDA-approved CF gene mutation test from PA criteria.

ACTION: The Committee amended the proposed PA criteria to remove question #21 (case management) and instead document in the criteria an acknowledgement that if therapy is approved, a referral will be made to case management; remove question #13 (FEV1 restriction); and modify question #17 to correlate with the FDA-approved mutations for tezacaftor/ivacaftor. Motion to approve, 2nd. All in favor. Approved.

B. Newer Diabetes Class Update (pages 52-100)Dr. Sentena presented the class update and recommended:

- 1. No changes to the PDL based on efficacy and safety data. Add new formulations to existing PA criteria.
- 2. Evaluate comparative costs in executive session.

ACTION: The Committee amended the proposed PA criteria to remove amylin analog (sub-item 5) from question #6 in SGLT-2 PA criteria. Motion to approve, 2nd. All in favor. Approved.

- C. Asthma Biologics DERP Summary (pages 101-124)
 Dr. Moretz presented the class update and recommended:
 - 1. No changes to the PDL based on evidence.
 - 2. Add benralizumab to PA criteria for monoclonal antibodies for asthma.
 - 3. Revise PA criteria to include expanded indication for mepolizumab in patients experiencing eosinophilic granulomatosis with polyangiitis (EGPA).
 - 4. Evaluate comparative costs in executive session.

ACTION: The Committee amended the proposed PA criteria to add a new question around co-prescribing auto-injectable epinephrine; require at least one hospitalization or 2 ED visits in the past 12 months while receiving a maximally dosed inhaled corticosteroid AND 2 additional controller drugs; modify question #4 to go to #10 if answered "yes"; and change wording from "another" monoclonal antibody to "newly approved" monoclonal antibody in question #4. Motion to approve, 2nd. All in favor. Approved.

- D. Radicava® (edaravone) New Drug Evaluation (pages 125-137) Dr. Engen presented the drug evaluation and recommended:
 - 1. Implement PA criteria for edaravone.

ACTION: The Committee amended the proposed PA criteria to remove the age requirement in question #2; remove question #5; move #4 (asking if continuation) to after #1; modify renewal criteria question #2 to say "prescriber" and add questions identical to #8 and #9 to the renewal criteria. Motion to approve, 2nd. All in favor. Approved.

- E. Neuropathic Pain DERP Summary (pages 138-163)

 Dr. Moretz presented the drug evaluation and recommended:
 - 1. No further review or research needed at this time.
 - 2. Maintain pregabalin extended-release tablets as non-preferred on the PMPDP.
 - 3. Apply clinical PA criteria to pregabalin extended-release tablets.
 - 4. Evaluate comparative costs in executive session.

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

V. DUR OLD BUSINESS

A. Sedatives (pages 164-167)

Dr. Page presented the proposed updates to the Sedatives PA criteria with the following recommendation:

1. Update PA criteria to clarify FDA-recommended initial and maximum daily dose recommendations as well as use in palliative care settings.

ACTION: The Committee amended the proposed PA criteria to modify the approval duration for palliative care to lifetime. Motion to approve, 2nd. All in favor. Approved.

- B. New Drug Policy (pages 168-170)
 - Dr. Servid presented the proposed updates to the New Drug Policy PA criteria with the following recommendation:
 - 1. Modify PA criteria.

ACTION: Motion to approve, 2nd. Majority in favor, one opposed. Approved. The Committee asked that the policy be brought back for additional information on how this may be able to be applied to oncology.

VI. EXECUTIVE SESSION

Present in room: Tracy Klein, PhD, FNP; Phil Levine, PhD; Walter Hardin, DO, MBA; Jim Slater, PharmD; Caryn Mickelson, PharmD; Stacy Ramirez, PharmD; Cathy Zehrung, RPh; Kelley Burnett, DO; William Origer, MD; Richard Holsapple, RPh; Roger Citron, RPh; Trevor Douglass, DC, MPH; Sarah Servid, PharmD; Lindsay Newton; Dee Weston; Renae Wentz, MD; Julia Page, PharmD; Jonnaliz Corbett; Deanna Moretz, PharmD; Megan Herink, PharmD; David Engen, PharmD; Amanda Parish; Anthony McKenzie; Sierra Carpenter; Katie Peters, Aaron Fitzcharles; Andrew Tschernia

VII. RECONVENE FOR PUBLIC RECOMMENDATIONS * After executive session

- A. Newer Diabetes Class Update (pages 52-100)
 - *ACTION: No changes to the PMPDP.
 - Motion, 2nd, All in Favor. Approved.
- B. Asthma Biologics DERP Summary (pages 101-124)
 - *ACTION: No changes to the PMPDP.
 - Motion, 2nd, All in Favor. Approved.
- C. Neuropathic Pain DERP Summary (pages 138-163)
 - ***ACTION:** No changes to the PMPDP.
 - Motion, 2nd, All in Favor. Approved.

VIII. ADJOURN