

Oregon Drug Use Review / Pharmacy & Therapeutics Committee

Thursday, March 22, 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; William Origer, MD; Rich Clark, MD, MPH; Walter Hardin, DO, MBA; Jim Slater, PharmD; Caryn Mickelson, PharmD; Stacy Ramirez, PharmD; Cathy Zehrung, RPh

Members Present by Phone: Kelley Burnett, DO

Staff Present: Richard Holsapple, RPh; Roger Citron, RPh; Trevor Douglass, DC, MPH; Sarah Servid, PharmD; Lindsay Newton; Julia Page, PharmD; Jonnaliz Corbett; Deanna Moretz, PharmD; Paige Hook; Emily Hull, PharmD Candidate

Staff Present by Phone: Dean Haxby, PharmD; Kathy Sentena, PharmD

Audience: Rick Frees, Vertex; Chris Stanfield, Supernus; *Amy Everitt, Sunovion; *Kim Laubmeier, Sunovion; Svetlana Cooper, Salud Medical Center; Paul Bonham, Avexis; *Dan Allen, Genzyme; Anthony Wheeler, Eli Lilly; John Goddard, GSK; Tim McFerron, Alkermes; C Johnson, Spark; Diann Matthews, Merck; *Lillian Chen, Spark; Samantha Sweeney, Otsuka; Lisa Boyle, WVP Health; Margaret Olman, Abbvie; *A. Baig, Pfizer; Catie Schlechter, OHSU; *Paul Yang, MD, OHSU; Jeana Colabianchi, Sunovion; Joseph So, Melinta; Jennifer Jordon, Melinta

(*) Provided verbal testimony

Written testimony provided:

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.

C. Dr. Servid provided discussion around the P&T Operating Procedures.

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

II. CONSENT AGENDA TOPICS

A. Approval of agenda and November minutes presented by Mr. Citron. (pages 9-12)

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

- B. Antiepileptics Literature Scan (pages 13-30)
 - 1. No further review or research needed at this time.
 - 2. Review in executive session.

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

III. DUR Activities

- A. Quarterly Utilization Reports (pages 31-36)
- B. ProDUR Report (pages 37-40)
- C. RetroDUR Report (pages 41-44)
- D. Oregon State Drug Reviews
 - 1. Recently published reviews:
 - i. Marketing Claims of Newer Drugs and the Evidence (pages 45-47)
 - ii. Current Landscape of the Antidepressant Class (pages 48-50)
 - 2. Future Topic Recommendations

IV. Preferred Drug List New Business

A. Bone Metabolism drugs class update (pages 51 - 71)

Dr. Moretz presented the class update and recommended:

- 1. Maintain abaloparatide as a non-preferred agent.
- 2. Update clinical PA criteria for bone metabolism agents to include abaloparatide and limit use to women and inclusion criteria from trial including: age of 49-86 years; and fracture and T-score requirements.

ACTION: Committee recommended modifying the proposed PA criteria to add a question after #3 to require a trial or documented contraindication to oral bisphosphonate; add specific language in #8 to include exclusion criteria for abaloparatide from trial (i.e. anticonvulsant use, corticosteroid use) Motion to approve, 2nd. Majority in favor, one opposed. Approved.

B. Oral First and Second Generation Antipsychotics Class Update (pages 72-94) Dr. Servid presented the class update and recommended:

1. No changes to the PDL or safety edits based on the clinical information

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

- C. Luxturna[™] (voretigene neparvovec) New Drug Evaluation (pages 95-105) Dr. Servid presented the evaluation and proposed PA criteria to:
 - 1. Limit use to the population studied.

ACTION: Committee recommended modify the proposed PA criteria to limit approval to requests from a Center of Excellence with confirmation that it will be administered per protocol. Motion to approve, 2nd. Majority in favor, one opposed. Approved. The Committee also recommended referring voretigene neparvovec to the HERC for prioritization consideration as a drug with high cost and marginal benefit. Motion to approve, 2nd. All in favor. Approved.

- D. Atopic Dermatitis DERP Summary (pages 106-138)
 - Dr. Moretz presented the summary with the following recommendations:
 - 1. Revise PA criteria for topical antipsoriatic drugs to include agents used to manage atopic dermatitis. Categorize these 2 classes as "atopic dermatitis drugs" and "antipsoriatics, topical" on the PDL.
 - 2. Designate dupilumab as non-preferred and apply PA criteria to limit use to:
 - a. Moderate-severe atopic dermatitis
 - b. Age ≥ 18 years
 - c. Prescribed by a dermatologist or allergist
 - d. History of inadequate response to ≥ 2 first line agents

ACTION: Committee recommended modifying the proposed PA criteria to require a trial and failure or contraindication to all 3 of the following: topical steroids; topical calcineurin inhibitors; and systemic immunomodulators. Motion to approve, 2nd. All in favor. Approved.

- E. Keveyis® (dichlorphenamide) Drug Evaluation (pages 139-154)
 - Ms. Hill presented the evaluation with the following recommendations:
 - 1. Recommend implementation of PA criteria for dichlorphenamide.

ACTION: Committee recommended modifying the proposed PA criteria to require trial and failure of acetazolamide. Motion to approve, 2nd. All in favor. Approved. The Committee also recommended referring dichlorphenamide to the HERC for prioritization consideration as a drug with high cost and marginal benefit. Motion to approve, 2nd. All in favor. Approved.

- F. Anti-Parkinson's Agents Class Update (pages 155-176)
 - Dr. Page presented the class update with the following recommendations:
 - 1. Modify the PA criteria to:
 - a. Add specific clinical criteria for safinamide which limits use to FDA-approved indication and
 - b. Add renewal criteria which requires physician attestation of condition improvement.
 - C. .

ACTION: Committee recommended modifying the proposed PA criteria to move question #8 prior to #7. Motion to approve, 2nd. All in favor. Approved.

V. EXECUTIVE SESSION

VI. RECONVENE FOR PUBLIC RECOMMENDATIONS * After executive session

A. Antiepileptics Literature Scan (pages 13-30)

*ACTION: No changes to the PMPDP

Motion, 2nd, All in Favor. Approved.

B. Bone Metabolism drugs class update (pages 51 - 71)

*ACTION: No changes to the PMPDP.

Motion, 2nd, All in Favor. Approved.

C. Oral First and Second Generation Antipsychotics Class Update (pages 72-94)

*ACTION: No changes to the PMPDP.

Motion, 2nd, All in Favor. Approved.

D. Atopic Dermatitis DERP Summary (pages 106-138)

*ACTION: Make tacrolimus 0.03% ointment, tacrolimus 0.1% ointment, and pimecrolimus 1% cream preferred.

Motion, 2nd, All in Favor. Approved.

E. Anti-Parkinson's Agents Class Update (pages 155-176)

*ACTION: No changes to the PMPDP.

Motion, 2nd, All in Favor. Approved.

VII. ADJOURN