



Drug Use Research & Management Program

OHA Health Systems Division

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Oregon Drug Use Review / Pharmacy & Therapeutics Committee

Thursday, July 27, 2017, 1:00-5:00 PM

Human Services 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: Rich Clark, MD, MPH; Tracy Klein, PhD, FNP; Caryn Mickelson, PharmD; Cathy Zehring, RPh; Stacy Ramirez, PharmD

Members Present by Phone: James Slater, PharmD

Staff Present: Richard Holsapple, RPh; Roger Citron, RPh; Dee Weston; Sarah Servid, PharmD; Deanna Moretz, PharmD, BCPS; Lindsay Newton; Dave Engen, PharmD, CGP; Kathy Sentena, PharmD; Kim Wentz, MD; Julia Verhulst, PharmD

Staff Present by Phone: Megan Herink, PharmD, MBA

Audience: *Helen Kim, Synergy; Rick Frees, Vertex; *Drew Gragham, *Wren Graham, Olivia Washington, *Jamie Saukko; *Dustin Saukko; Joe Schrek, Allergan; Bobbie Duim, DMS; *Susara Arroyo, Mario Arroyo, Russ Rahimtoola, Shawn Moncrieff, Heather Romero, *Skip Miller; Krista Pickett; Magdalene Miller; Diego Hayon; *Tanner Odom, Biogen; *Jon D. Moulton; Jennifer Shidler, Genzyme; Karsen Bala, Biogen; Bob Gustofer, Avexis; Mindy Schimpf, UCB; Chioma Ezenduka, UCB; *Michelle Mui, UCB; Matt Seibet, BioGen; Venus Holder, Lilly; Anthony Wheeler, Lilly; *Christine Getman; *Scott Foertmeyer; Kelsey Svaren; Bill McDougall, BioGen; Cheryl Fletcher, Abbvie; *Meghal Khakherms, Abbvie; Leo Yasmski, Merck; *Celia Vander Velden; Mary Kemhus, Novartis; Virgil Guthrre, OSU; Nena Hartman; Sylvia Churchill; Mike Donabedian, Sarepta Therapeutics; *Lisa Borland, Sarepta Therapeutics; *Jesse Hong, Purdue; Wilmon Grant, Biogen; Stephanie Yamamoto, Johnson & Johnson; Robert Snediker, Johnson & Johnson; JR Roe Mallinkrodt; *Erika Finanger, OHSU; *C. Shepherdson; H. Shepherdson; I. Shepherdson; H. McBroom; L. McBroom; E. McBroom; N. McBroom; J. McBroom; R. McBroom; *Tammy, Christopher and Emily Hay; *Miriam Ischander; Tim McFerron, Alkermes; *Anthony Hager, BMS; Jeanna Colabianchi, Sunovion; Robert Snediken, Janssen; Amy Burns, AllCare; Kayla Burnette, AllCare; DJ Clark, AllCare; Darren Coffman, HERC; Cathy Gross, Purdue

(*) Provided verbal testimony

Written testimony provided:

I. CALL TO ORDER

- A. The meeting was called to order at approximately 1:03 pm. Introductions were made by Committee members and staff.
- B. Mr. Citron reported there were no new conflicts of interest to declare.
- C. Approval of agenda and May minutes presented by Mr. Citron. (pages 5 - 8)

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

II. DUR OLD BUSINESS

- A. CMS Annual Report (separate handout)
Mr. Citron presented the annual report and explained that CCOs will be required to complete it effective January 2019
- B. Prioritization of PA Criteria Implementation
Mr. Citron presented prior authorization (PA) criteria awaiting implementation and bandwidth from DXC with recommendations for implementation prioritization.

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

III. PREFERRED DRUG LIST NEW BUSINESS

- A. Biologics Class Update (pages 9 - 59)
Dr. Moretz and Dr. Servid presented the new drug evaluation and class update with the following recommendations:
 - 1. Update PA criteria with updated FDA approved ages and indications as presented.
 - 2. Approve recommended step therapy as presented.
 - 3. Designate brodalumab as non-preferred drug on the PDL.
 - 4. Amend original proposed criteria to include: change the list of drugs requiring PA to “all biologics” and remove the list of indications; change the order of the questions; add to the list of other potent immunosuppressants in question #14; and to add a question requiring a quantiferon gold test to evaluate for tuberculosis before approval of these agents. The Committee also recommended to revise Table 1 of the PA criteria to state brodalumab is indicated for plaque psoriasis.

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

- B. Emflaza® (deflazacort) (pages 113-128)
Dr. Servid presented the new drug evaluation and proposed PA criteria with the following recommendations:

1. Adopt proposed PA criteria which restricts use to patients with DMD and documented contraindication or serious intolerance to oral corticosteroids.
2. Refer deflazacort to the Health Evidence Review Commission (HERC) for prioritization consideration as a drug with high cost and marginal benefit compared to currently available low-cost oral corticosteroids.
3. Amend original proposal to include: remove “or other corticosteroid” from question #6; clarify that age restrictions of only apply to deflazacort; and to change the deflazacort approval to 12 months.
- 4.

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

C. Exondys 51® (eteplirsen) (pages 129-139)

Dr. Servid presented the new drug evaluation and proposed PA criteria with the following recommendations:

1. Adopt proposed PA criteria to limit use to the population studied and continuation of therapy criteria.
2. Refer eteplirsen to the Health Evidence Review Commission (HERC) for prioritization consideration as a medication with high cost and no clinically meaningful benefit.
3. Amend original proposal to: remove the requirement of ambulatory status; revise question #10 to require documentation of a baseline functional assessment and examples of validated functional assessment tools such as the 6-minute walk test or North Star Ambulatory Assessment; and change the wording of the renewal criteria to ask “Has the patient’s baseline functional status been maintained at or above baseline level or not declined more than expected given the natural disease progression?”.

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

D. Spinraza® (nusinersen) (pages 98 - 112)

Dr. Moretz presented the new drug evaluation and proposed PA criteria with the following recommendations:

1. Revise PA criteria to insure nusinersen utilization in SMA populations in which the drug has been studied.
2. Refer nusinersen to the Health Evidence Review Commission (HERC) for prioritization consideration as a medication with high cost and marginal clinical benefit.
3. Amend original proposal to include: revising the PA criteria to limit coverage of nusinersen to the SMA populations in which the drug has been studied after amending to: add the Upper Limb Module to the list of functional assessments in question #4; add a note in question #5 to clarify that this criteria does not apply to patients who have ventilator assistance; to change the length of approval to 5 doses within 8 months for initial approvals and 1 year for renewals; and to separate question #7 into renewal criteria and re-order the numbering as appropriate.

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

E. Abbreviated Drug Reviews (pages 202 - 204)

Dr. Servid presented the class update and following recommendation:

1. Trulance™ (plecanatide) (page 202)
 - a. Require PA to restrict use to OHP-funded conditions.
 - b. Add plecanatide to “drugs for constipation” PA criteria.
2. Symproic® (naldemedine) (page 203-204)
 - a. Require PA to restrict use to OHP-funded conditions.
 - b. Add naldemedine to “drugs for constipation” PA criteria.

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

VI. EXECUTIVE SESSION

VII. RECONVENE FOR PUBLIC RECOMMENDATIONS * After executive session

A. Biologics Class Update (pages 9 - 59)

***ACTION:** No changes to the PMPDP

Motion, 2nd, All in Favor. Approved.

VIII. ADJOURN