Drug Use Research & Management Program
OHA Division of Medical Assistance Programs
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Oregon Drug Use Review / Pharmacy & Therapeutics Committee
Thursday, May 30, 2013 1:00-5:00 PM
Clackamas Community Training Center
29353 SW Town Center Loop East
Wilsonville, OR 97070

MEETING MINUTES

NOTE: Any agenda items discussed by the DUR/P&T Committee may result in changes to coverage, PDL composition, or 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.

Members Present: David Pass, MD; Phillip Levine, PhD; Stacy Ramirez, PharmD; William Origer, MD; Zahia Esber MD

Members Present by Phone: James Slater, PharmD

Staff Present: Megan Herink PharmD, BCPS; Richard Holsapple, RPh; Roger Citron, RPh; Ted Williams, PharmD; Trevor Douglass, DC, MPH; Shannon Jasper

Staff Present by Phone: Kathy Sentena, PharmD

Audience: Karen Ward (Aegerion), Ann Nielson, Christopher DeSimane (Aegerion), Bruce Howard (Acorda); Gina Guinasso (Acorda); Michelle Bice (Gilead); Chris Haem (Gilead); Danielle Sobel (OMA); Patrick Moty; Kristina Hermach (BMS); Lou LaMarca National Patient Advocate Foundation; Jim Gardner (PhRMA); Bruce Smith; Venus Holder (Lilly); Mary Stumph (Lilly); Holly Batterman, MD ViiV Healthcare; Paul Nielsen (Med Immune); Lorren Sandt (CAP); Jim Hoover (Bayer); Kara Tyler (Amgen); Trish McDaid ONeill (Astra Zeneca); Lisa Valaika (Genzyme); Nancy Martin (Genzyme); Deron Grothe (Teva); Mike Willett (Pfizer); Dianne Vanowski Smith (TMC); Barry Benson (Merck); Dr. Jill Kerrick Walker (Eisai); Paul Barham (NovoNordisk); BJ Cavnor (WWPEW); Carlene Halverson (Novartis)

I. CALL TO ORDER
- a. The meeting was called to order at approximately 1pm.
- b. Mr. Citron reported there are no new conflicts of interest to declare (Other than Dave Pass's Hawaiian shirt)
- c. The March 28th, 2013 meeting minutes were reviewed.
- d. Dr. Douglass introduced new staff: Shannon Jasper

ACTION: Approved as is.

II. DUR ACTIVITIES
- a. HCMB Process Discussion
  1. Draft Procedure and Timeline

ACTION: Approved with the establishment of a subcommittee to act as an advisory committee that includes representation from the P&T committee, as well as the HERC. Depending on the

topic, consider professional or lay experts, a general expert in such areas as statistics, and a patient advocate or patient advocate groups.

2. Public Comment and Testimony:
   Lorren Sandt with Caring Ambassadors including written testimony
   Jim Gardner with Gardner & Gardner Law Firm on behalf of PhRMA (written)
   Lou LaMarca with National Patient Advocate Foundation
   Danielle Sobel with OMA including written memorandum
   Holly Batterman, MD with ViiV Healthcare
   BJ Cavnor with NW Patient Education Network

b. Mr. Holsapple presented the ProDUR report.
c. Dr. Williams stated the RetroDUR report is still being worked on.
d. Mr. Citron presented the Quarterly Utilization Reports.
e. Dr. Sentena presented the Oregon State Drug Review
   1. Management of Gout in the Presence of Chronic Kidney Disease
f. FDB Drug File Updates* - presented by Dr. Williams

III. NEW BUSINESS

a. Makena® (17 alpha-hydroxyprogesterone caproate)*
   Dr. Fouts presented the drug use evaluation for 17 alpha-hydroxyprogesterone caproate recommending required PA criteria and apply quantity limits consistent with PA Criteria. Due to insufficient data to support the compounded product and additional inherent compounding risks, prefer the branded product over the compounded product.

***ACTION:** All in favor.

b. Fycompa ® (Perampanel)*
   Dr. Liang presented the drug evaluation for Perampanel for adjunctive therapy for treatment of partial-onset seizures with or without secondary generalized seizures in patients with epilepsy aged 12 years and older. Designate Perampanel a second line non-preferred oral anticonvulsant to ensure appropriate use as adjunct treatment when previous treatment with AEDs has not provided adequate response or has not been tolerated.
   Testimony given by Dr. Jill Walker.

***ACTION:** All in favor.

c. Aubagio ® (teriflunomide)*
   Dr. Argyres presented the drug evaluation for teriflunomide and recommends non-preferred and limit use to confirmed patients with documentation of prior failed use of an interferon for MS or glatiramer acetate. Prior authorization required. Add proof of contraception for women of childbearing age to criteria.

***ACTION:** All in favor.

d. Acthar Gel ® (Repository corticotropin injection)*
   Dr. Herink presented the new drug evaluation for Acthar Gel ®. Recommendation is Prior Authorize to allow coverage for the treatment of infantile spasms in patients less than 2 years of age and restrict other use for those who cannot tolerate appropriate glucocorticoid therapy. Requires manual review of claims for patients > 2 years of age.

***ACTION:** All in favor.

e. CF Vitamins Abbreviated Class Review (after executive seesion)*
   Dr. Herink presented the evaluation for Cystic Fibrosis vitamins. Due to the consensus among CF practitioners of routine supplementation with fat-soluble vitamin preparations in patients with CF, compare and add appropriate formulations to the list of supplements that are included in the rebate exception policy. Make a broader recommendation to encourage CCO's to evaluate their CF vitamin utilization

and adopt similar coverage guidelines. Information will be shared through the medical and/or pharmacy director meetings.

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

f. Juxtapid ® (lomitapide)*

Dr. Herink presented the new drug evaluation for Juxtapid ®. Recommendation to designate Juxtapid ® as non-preferred and prior authorize criteria to limit use to genetically confirmed HoFH only who have a medical contraindication to lipid lowering therapy and LDL apheresis and which is prescribed in consultation with a specialist. Requires manual review. Reach out to gather information and bring back to the committee on the reliability of genetic testing and more specific criteria that defines apheresis failure.

Testimony by Dr. Karen Ward from Aegerion.

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

g. Kynamro ® (mipomersen)*

Dr. Herink presented new drug evaluation for Kynamro ®. Recommendation to designate Kynamro ® as non-preferred and prior authorize criteria to limit use to genetically confirmed HoFH only who have a medical contraindication to lipid lowering therapy and LDL apheresis and which is prescribed in consultation with a specialist. Requires manual review. Reach out to gather information and bring back to the committee on the reliability of genetic testing and more specific criteria that defines apheresis failure.

Testimony by Nancy Martin from Genzyme.

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

h. Drug Class Scans*

1. Cough and Cold Products (after executive session)

Dr. Herink stated no further research or review is needed at this time. Evaluate comparative costs in executive session.

Recommendations to make this a PDL class. Preference only these lower cost GSN's Guaifenesin liquid 100mg/5ml, guafenesin/dextromethorphan syrup, guafenesin/codeine phosphate liquid, psedoephedrine HCL tablets 30mg and 60mg. Consider addition of benzoate capsules as a preferred alternative to Mucinex tablets.

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

2. Topical Antibiotics (after executive session)

Dr. Herink stated no further research or review is needed at this time. Evaluate comparative costs in executive session.

Recommendations to designate double-antibiotic ointment as preferred and designate Centany AT Kits non-preferred.

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

3. Oral Immunosuppressants (after executive session)

Dr. Herink stated no further research or review is needed at this time. Evaluate comparative costs in executive session.

Recommendations to designate Myfortic and Sandimmune solution as preferred to be consistent with previous recommendations.

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

IV. The meeting was adjourned at approximately 4:30pm.

**Agenda items will be discussed by Committee members for the purpose of making recommendations to the Oregon Health Plan for adoption into Oregon Administrative Rules 410-121-0030 & 410-121-0040 as required by 414.325(9)*