Drug Use Research & Management Program
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Oregon Drug Use Review / Pharmacy & Therapeutics Committee
Thursday, November 17, 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; Walter Hardin, D.O., MBA; Cathy Zehrung, RPh; Phil Levine, PhD

Members Present by Phone: James Slater, PharmD

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; Lindsay Newton; Emily Church; Jim Rickards, MD

Staff Present by Phone: Kathy Sentena, PharmD

Audience: Luis Velasquez/Vertex; Venus Holder/Lilly; Tony Hasan/Lilly; *Lisa Allen/Vertex; *Anthony Wheeler/Lilly; David Barhoum/Genentech; Jan Leach/Genentech; Lindsay Bahr/Mallinckrodt; Becky Hanson/Quintiles IMS; Melissa Snider/Biomarin; Kerry Bonilla/AstraZeneca; Risa Reuscher/Amgen; *Sylvia Churchill/Amgen; *Margaret Olmon/Abbvie; *Lynda Finch/Biogen; Diann Matthews/Biogen; Jennifer Shidler/SanofiGenayone; Stephanie Roberts/Acorda; Jeana Colabianchi/Sunovion; Rick Frees/Vertex; Lisa Boyle/WVP Health Authority; Matt Medina/Purdue; Brianna Mendoza; *Kari Rose; *Talon Hyatt; *Kim Osmus/Katie's Kause for CF; *Mike Powers/OHSU CF Center; Paul Nielsen/Alkermes; Deron Grothe/Teva;

(*) Provided verbal testimony

Written testimony provided: Sue Landgraf/Cystic Fibrosis Research Inc.; Bruce Marshall & Lisa Feng/Cystic Fibrosis Foundation

I. CALL TO ORDER

A. The meeting was called to order at approximately 1:05 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 September minutes presented by Mr. Citron. (pages 4 - 7)

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

D. Department updates for OHA presented by Dr. Rickards and Ms. Weston.

II. DUR ACTIVITIES

A. CMS Annual Report – presented by Ms. Weston
B. Quarterly Utilization Report (pages 8-12) – presented by Mr. Citron
C. ProDUR Report (pages 13-15) – presented by Mr. Holsapple
D. RetroDUR Report (pages 16-20) – presented by Dr. Williams
E. Oregon State Drug Reviews (pages 21-30) – presented by Dr. Sentena
   1. Who Benefits from Calcium and Vitamin D Supplementation?
   2. Pharmacist Prescribed Contraceptives
   3. Vaccine Update 2016
   4. Endocrine Therapy for Breast Cancer

Dr. Clark voiced his concern with reporting statistical significance vs. clinical significance in the newsletters. Dr. Gibler highlighted the importance of real outcomes such as mortality, fractures, etc. and recommended we will include NNT when possible. Dr. Clark seemed satisfied with the recommendation.

F. Dose Consolidation Lettering Proposal (pages 31-42) – presented by Dr. Williams

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

III. PREFERRED DRUG LIST NEW BUSINESS

A. Synagis ® (palivizumab) Drug Policy (pages 43 - 47)
Dr. Engen presented the class update and following recommendation:

1. Update current clinical prior authorization criteria to require that the patient's parent/caregiver and prescriber comply with all case management services, including obtaining current patient weight throughout approved treatment period.

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

B. Procysbi ® (cysteamine delayed-release) Drug Policy (pages 48 - 51)
Dr. Moretz presented the class update and the following recommendation:

1. No changes to the current clinical prior authorization criteria are recommended.

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

C. H.P. Acthar Gel® (repository corticotropin inj) Drug Policy (pages 52 - 56)
Dr. Moretz presented the scan and following recommendation:

1. No changes to the current clinical prior authorization criteria are recommended.

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

D. Oral Cystic Fibrosis Modulators Class Update (pages 57 - 72)
Dr. Herink presented the class update and the following recommendations:

1. No changes to the PDL are recommended.
2. Continue to require clinical prior authorization for approval in appropriate patients and amend criteria to reflect FDA approval for use of Orkambi (lumacaftor/ivacaftor) in children ages 6 through 11 years. If clinical PA criteria are fulfilled, refer claims for this age group to the Medical Director for approval.

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

E. Opioid Analgesics Class Update (pages 73-108)
Dr. Gibler presented the following class update and recommendations:

1. Review comparative short-acting opioid costs in the executive session to inform PDL status of this class.
2. Maintain non-preferred status for Troxyca ER (oxycodone/naltrexone) extended-release capsules.
3. Approve the proposed clinical prior authorization criteria for short- and long-acting opioid analgesics:
    a. Patients with a terminal diagnosis or cancer diagnosis are exempt from prior authorization.
    b. All non-preferred short-acting opioids and preferred short-acting opioids prescribed for more than 7 days are subject to prior authorization.
    c. All long-acting opioid analgesics are subject to prior authorization.
    d. Update quantity limits for new long-acting opioid approvals.
4. Oregon Health Authority to work with the Pharmacy Benefits Manager (HPE) on timing of implementation of these new drug policies. This will need to include an educational component.

The Committee recommended modify question #8 of the proposed short-acting opioid clinical PA criteria to remove restriction that opioid analgesics be prescribed by a single prescriber or prescribing practice. Instead request prescriber simply review the scheduled substances the patient has been recently prescribed. For long-acting opioids, the

Committee recommended making clerical or visual changes to Table 1 of the proposed PA criteria to separate and highlight methadone as being a uniquely different opioid than the other agents.

The Committee debated lowering the maximum prescribed amount from 90 daily MME to 50 daily MME. Consensus could not be reached so a vote was taken and Dr. Clark voted for lowering to 50 daily MME, while the majority voted to keep it at 90 daily MME.

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

F. Multiple Sclerosis Drug Class Update (pages 109-133)
Dr. Moretz presented the class update along with the following recommendations:

1. No changes recommended to the PDL based on evidence from the DERP report. Evaluate comparative drug costs in the executive session.
2. Revise clinical prior authorization criteria to require assessment of lymphocyte counts before initiating therapy with Tecfidera (dimethyl fumarate).

The Committee recommended modifying question #9 of the clinical PA criteria to also require confirmation of a negative pregnancy test prior to initiation of teriflunomide.

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

G. Taltz (ixekizumab) New Drug Evaluation (pages 134-151)
Dr. Gibler presented the class update along with the following recommendations:

1. Incorporate Taltz (ixekizumab) into current prior authorization criteria for Biologics. No changes to the clinical criteria recommended.
2. Evaluate comparative drug costs in the executive session to determine PDL status for Taltz (ixekizumab).

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

H. Non-statin Lipid-lowering Agents Class Update (pages 152-182)
Dr. Moretz presented the class update along with the following recommendations:

1. No changes to the PDL recommended based on updated evidence. Review comparative drug costs in the executive session.
2. Revise current clinical prior authorization criteria for omega-3 fatty acids to remove requirement of failure or contraindication to niacin therapy as condition for approval.
3. No changes to clinical prior authorization criteria for PCSK9 Inhibitors, mipomersen or lomitapide recommended.

The Committee recommended modifying the goal for the PA of omega-3 fatty acids to state it is to restrict use of omega-3 fatty acids to patients at increased risk for pancreatitis.

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

V. EXECUTIVE SESSION

VI. RECONVENE FOR PUBLIC RECOMMENDATIONS * After executive session

A. Opioid Analgesics Class Update (pages 73-108)
*__ACTION:__ Recommend no changes to the PMPDP.
Motion, 2nd, All in Favor. Approved.

B. Multiple Sclerosis Drug Class Update (pages 109-133)
*__ACTION:__ Make Glatopa non-preferred, request pharmacies dispense Copaxone brand.
Motion, 2nd, All in Favor. Approved

C. Taltz (ixekizumab) New Drug Evaluation (pages 134-151)
*__ACTION:__ Maintain TALTZ PDL=N. Recommend no changes to the PMPDP.
Motion, 2nd, All in Favor. Approved

D. Non-statin Lipid-lowering Agents Class Update (pages 152-182)
*__ACTION:__ Recommend no changes to the PMPDP.
Motion, 2nd, All in Favor. Approved

VII. ADJOURN