Drug Use Research & Management Program
OHA Division of Medical Assistance Programs
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Oregon Drug Use Review / Pharmacy & Therapeutics Committee
Thursday, September 26, 2013 1:00-5:00 PM
HP Corporate Office
4070 27th Court SE
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: Cathy Zehrung, RPh; Phillip Levine, PhD; William Origer, MD, Tracy Klein, PhD, FNP; Zahia Esber, MD

Members Present by Phone: David Pass, MD; Joshua Bishop, PharmD; Stacy Ramirez, PharmD;

Staff Present: Kathy Ketchum, RPh, MPA:HA; Megan Herink PharmD, BCPS; Richard Holsapple, RPh; Roger Citron, RPh; Ted Williams, PharmD; Trevor Douglass, DC, MPH; Shannon Jasper; Amanda Meeker, PharmD; Kala Berkey, PharmD Candidate

Staff Present by Phone: Kathy Sentena, PharmD, Bing-Bing Liang, PharmD

Audience: Christine Curry, (Genentech)*; Arti Baig (Pfizer)*; Isabel Lloyd, (Vertex); Don Stetcher (Novartis); Cheryl Fletcher, (Abbvie); Laura Hill, (Abbvie)*; Kimberly Blood, (WVP Health Authority); David Barhoum, (Genentech); Lynda Finch, (Biogen Idec)*; Venus Holder, (Lilly); Janet Fox, (Pfizer)*; Patty Harwood, (MedImmune); Kerrie Fowler,(UHA); Michael Estos (Pfizer); Michelle Bice, (Gilead); Laura Litzenberger; (Johnson & Johnson)*; Lori Howarth, (Bayer); Jim Hoover, (Bayer); Brad Peacock, (Gilead); Karen Ward, (Aegerion); Tzeli Triantafillon (VIIV); Paul Barham (NovoNordisk); Mark Cummings, Forest; Deborah Profant, PhD, (Teva)*; Bob Gustafson (Lundbeck); Jamie Damm, (Vertex); Jeana Colabianchi, (Sunovion); Lyle Laird, (Sunovion); Anne Marie Licos, (MedImmune); Bruce Smith (GSK); Caryn McKesin (Western Oregon Advanced Health); Bill Lavia, (MedImmune); Darlene Halverson, (Novartis); Mark Alden, (Genentech); Barry Benson, (Merck); Stephanie Pugh, (Novo Nordisk); Nathan Wood, (Merck)

(*) Provided verbal testimony

I. CALL TO ORDER

a. The meeting was called to order at approximately 1:10 pm. Introductions of Committee members and staff.

b. Mr. Citron reported there are no new conflicts of interest to declare.

c. The July 25th meeting minutes were reviewed. (pages 4 – 6)

ACTION: Approved as is.

d. Department updates by Dr. Trevor Douglass.

II. HCMB Subcommittee Approval

The P & T members agreed to include at least one (1) HERC member, three (3) P & T members, and one (1) Statistician. During the first meeting, the members will elect a chair and vice chair for the committee. Mr. Citron stated they will post and agenda and meeting times on the OSU College website for interested parties.

ACTION: Motion, 2nd, All in Favor. Approved.

III. DUR OLD BUSINESS

a. Kuvan® (saproterin) (page 7)
Dr. Herink presented modifications to the PA criteria to include clinical target ranges and specification for use in both adults and children.

ACTION: Motion, 2nd, All in Favor. Approved.

b. Juxtapid® (lomitapide) & Kynamro® (mipomersen) (page 8)
Ms. Ketchum presented to modify the PA criteria to include more details on optimal combination therapy. Added to #4, See Clinical Notes below. Refer to an expert on necessity of #5, allowing coverage if LDL apheresis is not available to them.

ACTION: Motion, 2nd, All in Favor. Approved.

IV. DUR NEW BUSINESS

a. DUR report: RetroDur for the use of Psychotropic Medications in Children. (pages 32 – 46) Order changed from original agenda. Dr. Williams presented the following:
   1. Send providers an annual request for additional clinical data for children receiving any of the following regimens:
      a. Five or more chronic psychotropics in children
      b. Two or more chronic antipsychotics in children
      c. Psychotropics in children under years old
         i. Non-stimulants under 6 years old
         ii. CNS stimulants under 4 years old
   2. Add the definitions for “chronic” and “concurrent therapy” on provider message that will be faxed.

ACTION: Motion, 2nd, All in Favor. Approved.

b. DUR report: Metabolic Monitoring of Antipsychotics in Children. (pages 9 – 21) Dr. Williams presented the following updates:
   1. Fax quarterly reports to providers addressing the absence of glucose monitoring in children receiving antipsychotics. Reports to contain the following information:
      a. Dashboard comparing the target provider to other Medicaid providers and providers within their specialty.
      b. Educational materials highlighting recommendations for monitoring and management of metabolic abnormalities in children.
      c. List patients without claims for glucose monitoring within the past 12 months.

d. Form indicating the status of metabolic monitoring for each patient for the provider to complete and return to the Medical Assistance Program.

2. Change from annual reminder for children without glucose monitoring to reminder every 6 months.

ACTION: Motion, 2nd, All in Favor. Approved.

c. DUR report: Follow up for Children prescribed their first ADHD Medication. (page 22 – 31) Dr. Williams presented the following updates:

1. Fax reports biweekly to promote follow up care for children prescribed their first ADHD medication. Reports to contain the following information
   a. Dashboard comparing the target provider to other Medicaid providers and providers with their specialty.
   b. A list of patients with their first ADHD prescription within the last 2 weeks.
   c. A Form indicating the status of a scheduled follow up visit for each patient for the provider to complete and return to the Medial Assistance Program.
   d. Educational materials highlighting recommendations for monitoring and management of ADHD pharmacotherapy in children.

ACTION: Motion, 2nd, All in Favor. Approved.

d. Synagis® (palivizumab) Policy Evaluation (pages 47 – 59) Ms. Berkey presented the following updates:

1. Continue the palivizumab PA for the 2013 – 2014 RSV season with no adjustments.
2. Follow-up study needed in December or January to ensure safety indicators remain acceptable.

ACTION: Motion, 2nd, All in Favor. Approved.

V. PREFERRED DRUG LIST (PDL classes will be reviewed for annual pricing update

a. Diabetes Class updates (page 60 – 88)
Dr. Sentena presented the following updates:

1. Prior authorize canagliflozin as a third-line treatment option for patients unable to tolerate or have contraindications to metformin and / or sulfonylurea therapy.
2. Prior authorize alogliptin as a third-line treatment option for patients unable to tolerate or have contraindications to metformin and / or sulfonylurea therapy.
3. Sulfonylurea therapies should be considered a preferred second-line treatment option for patients without contraindications or tolerance issues.
4. Evaluate comparative costs in executive session.
5. * (After executive session) Make canagliflozin and alogliptin non preferred.
6. * (After executive session) Prior authorize canagliflozin as a fourth-line treatment option for patients unable to tolerate or have contraindications to metformin, sulfonylurea therapy, and other third line treatments.
7. * (After executive session) Add hypoglycemic risk in Incretin Mimetics PA criteria as a contraindication to sulfonylureas.

Public Comment: Laura Litzenberger, Johnson & Johnson

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

b. Other Lipotropics (page 89 – 103)
Dr. Herink presented the following updates:

1. Make isocapent ethyl a non-preferred lipotropic agent and use the non-PDL prior authorization criteria due to its use as an alternative to a fibric acid derivative and niacin for hypertriglyceridemia.

2. Evaluate comparative costs of other agents in executive session for further PDL decisions.
3. * (After executive session) Make Trilipix preferred and brand Tricor preferred over its generic alternatives.
4. * (After executive session) Make Vascepa, Restora, Inositol and Lipogen non-preferred.

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

c. Parkinson's Disease (page 104 – 116)
Dr. Liang presented the following updates:
1. No further research or review needed at this time.
2. Evaluate comparative costs in executive session.
3. Add Neupro to the Parkinson's class and evaluate price in November.
4. * (After executive session) Make carbidopa / levodopa ER preferred.
5. * (After executive session) Fix clerical issues in PA criteria.

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

d. Multiple Sclerosis (page 117 – 136)
Ms. Berkey presented the following updates:
1. Include dimethyl fumarate on the oral MS drug prior authorization criteria to limit to patients who have tried and failed first line agents including beta interferons and / or glatiramer.
2. Include either interferon beta-1a subQ or interferon beta-1b subQ as a preferred option due to evidence demonstrating improved efficacy compared to interferon beta-1a IM in relapse related outcomes.
3. Evaluate costs in executive session for further PDL decision-making.
4. * (After executive session) Make Betaseron and Rebif preferred.
5. * (After executive session) Amend PA criteria to include pathway for Tecfidera.

Public Comment: Dr. Deborah Profant, Teva Pharameuticals; Lynda Finch, Biogen Idec

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

e. Long Acting Opioids (page 137 – 143)
Ms. Ketchum presented the following updates:
1. Evaluate relative cost of tramadol ER in executive session.
2. Set maximum daily dose to 300 mg per drug label.
3. * (After executive session) Make Ultram ER and Conzip non-preferred.

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

f. Hepatitis C Agents (page 144 – 162)
Dr. Herink presented the following updates:
1. Recommended to maintain either one or both of peginterferon alfa-2a and peginterferon alfa-2b as preferred pegylated interferon products.
2. Consider removing criteria #9 of protease inhibitor PA criteria which currently denies for patients with HIV coinfection.
3. Evaluate comparative costs in executive session.
4. * (After executive session) Make Pegasys preferred.
5. * (After executive session) Allow approval of protease inhibitors for patients with HIV / HCV coinfection if under supervision of an HIV specialist.

Public Comment: Dr. Christine Curry, Genentech

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

g. Drug Class Scans
1. Topical Androgens (page 163 – 169)
Dr. Herink presented the following updates:

a. There is no new evidence that there is a difference in efficacy between the different testosterone products; No further research or review needed at this time.
b. Evaluate comparative costs in executive session, including relative costs of new formulations (Axiron, Androgel 1.62%, and Fortesta).
c. * (After executive session) Make Androgel preferred.
d. * (After executive session) Make Androderm non-preferred and grandfather current patients.

Public Comment: Laura Hill, Abbvie

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

2. Topical Antiparasites (page 170 – 174)
Dr. Herink presented the following updates:
a. No further research or review needed at this time.
b. Evaluate comparative costs in executive session.
c. *(After executive session) Make Natroba non-preferred.

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

3. COPD (page 175 –189)
Dr. Meeker presented the following updates:
a. Add Breo Ellipta to the class and bring back more detailed drug review in November.
b. Evaluate comparative costs in executive session.
c. * (After executive session) Make both Combivent Respimat and Combivent MDI preferred and remove step edit.

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

4. Growth Hormones (page 190 – 197)
Dr. Herink presented the following updates:
a. No further research or review needed at this time.
b. Evaluate comparative costs in executive session.
c. * (After executive session) Make Norditropin preferred.

Public Comment: Janet Fox, Pfizer

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

5. Alzheimer's Agents (page 198 – 205)
Dr. Herink presented the following updates:
a. No further research or review needed at this time.
b. Evaluate comparative costs in executive session.

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

6. Public Comment
7. Discussion of Clinical Recommendations to OHA

h. Classes Under Consideration for Annual PDL Pricing Review.
1. TIMS
a. Evaluate comparative costs in executive session
b. * (After executive session) Make Simponi preferred.

Public Comment: Arti Baig, Pfizer

2. Antiepileptic Medications
a. Evaluate comparative costs in executive session
b. * (After executive session) Make valproic acid solution preferred.
3. Ulcerative Colitis Agents
a. Evaluative comparative costs in executive session.
b. * (After executive session) Make Lialda preferred.

4. Public Comment
5. Discussion of clinical recommendations to OHA.

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

VI. EXECUTIVE SESSION

VII. RECONVENE for PUBLIC RECOMMENDATIONS

Mr. Citron confirmed to the public of the next P & T meeting will be held in November.

VII. ADJOURN