Drug Use Research & Management Program
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Oregon Drug Use Review / Pharmacy & Therapeutics Committee
Tuesday, September 23, 2014 1:00-5:00 PM
Wilsonville Training Center
29353 SW Town Center
Wilsonville, OR 97070

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; Stacy Ramirez, PharmD; Tracy Klein, PhD., FNP; Kathryn Lueken, MD;

Members Present by Phone:

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; Linnea Saris; Amanda Meeker, PharmD; Dee Weston; Kaylin Winden, PharmD Candidate; Andrew Gibler, PharmD;

Staff Present by Phone: Kathy Sentena, PharmD, Brandy Fouts, PharmD;

Audience: Deborah Profant (Teva)*; Diana Lein (Bristol-Myers Squibb)*; Lori Howarth (Bayer); Deron Grothe; Camille Kerr (Allergan); Deirdre Monroe (Allergan)*; Jazz Ferreira, Lynda Finch (Biogen Idec)*; Dean Haxby (OSU); Barry Benson (Merck); BJ Cavnor (One in Four)*; Venus Holder (Lilly); Melissa Walsh (Novartis)*; Leslie Mann (Celgene); Jason Alm (Celgene)*; Derek Traister (Biogen Idec); Anne Marie Licos, PharmD (MedImmue)*; Paul Nielsen (AstraZeneca); Paul Bonham (NN1); Scott Larson (BMS); Laura Hill (Abbvie); Cheryl Fletcher (Abbvie); Shane Hall (Purdue); Michelle Bice (Gilead); John Peterson (Gilead)*; Linda Simpson (Gilead); Richard McLeod (Pfizer)*; Arti Baig (Pfizer)*; Brett Marett (BMS); Bill Strynk (J&J); Amy Bauma (Gilead); Brad Peteuck (Gilead); Allison Gille (OSU); Shelley Bailey (Central Drugs); Bob Snediker (J&J)*; Tricia Bourne (Gilead); Dianne Matthews (J&J); Steve Nemirow (Kartini Clinic); Shannon Noel (FCI); Bruce Howard (Acorda); Gina Guinasso (Acorda); Caryn Mickelson (WOAH); Kimberly Blood (WVCH); Stephanie Kendall (J&J); Michael Weingarten (J&J); Michael Estes (Pfizer);

(*) Provided verbal testimony

I. CALL TO ORDER

a. The meeting was called to order at approximately 1:00 pm. Introductions of Committee members and staff. Introductions of new committee members included Dr. Kathryn Lueken and Dr. Arturo Salazar.

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

c. Approval of agenda and minutes presented by Dr. Origer (pages 4 - 10)

ACTION: Approved as is.

d. Department updates presented by Trevor Douglass.

II. DUR OLD BUSINESS

a. Hepatitis C Class update (pages 11 - 25)
Dr. Herink presented the following class update:

1. Recommend including additional changes to PA criteria (Appendix 1):
   - Excluding patients who have had previous treatment with an oral direct acting antiviral
   - Requiring an HCV RNA level at week 4 to determine response. If the HCV RNA is detectable at week 4 or at any time point thereafter, reassess HCV RNA in 2 weeks. If the HCV RNA increases or if the 8 week HCV RNA is detectable, discontinue treatment.
   - Excluding GT1 interferon ineligible patients due to insufficient evidence in this population.

2. With evolving pipeline of medications for treatment of hepatitis C, create general Hepatitis C prior authorization criteria to ensure new treatments are being used appropriately until they can be reviewed in full by the Pharmacy & Therapeutics Committee.

3. The sale and distribution of telaprevir has been discontinued; remove from PDL.

Public Comment:
John Peterson from Gilead Sciences.
Steven Nemirow spoke about his treatment using Sovaldi.
BJ Cavnor from One in Four.

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

b. Botulinum Toxins PA Criteria (pages 26 – 29)
Ms. Ketchum presented the following information:

1. Approve updated PA criteria to include overactive bladder syndrome and neurogenic detrusor over-activity.

Public Comment:
Deirdre Monroe from Allergan.

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

III. DUR NEW BUSINESS

a. Synagis ® (pages 30 - 42)
Dr. Sentena presented the following update:

1. Amend the current PA to align recommendations with those of the 2014 AAP guideline.

2. Continue to allow for geographic variations in RSV activity.

3. Remove the requirement in #16 of the PA criteria for a pediatric cardiologist for those with cyanotic heart defects.

Public Comment:
Anne Marie Licos, PharmD from MedImmune.

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

IV. PREFERRED DRUG LIST NEW BUSINESS

a. Drug Class Scans
   1. Parkinson's Medications (pages 43 – 51)
      Dr. Herink presented the following information:

      a. No further review or research needed at this time.

      b. Evaluate comparative costs in executive session.

      c. No changes to the PDL.

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

   2. Growth Hormones (pages 52 – 58)
      Dr. Herink presented the following updates:

      a. No further review or research needed at this time.

      b. Evaluate comparative costs in executive session.

      c. Update PA criteria to ask physicians to switch to a preferred product in the continuation criteria.

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

   3. Insulins (pages 59 – 84)
      Dr. Herink presented the following updates:

      a. There is low quality evidence of no significant differences in change in HbA1C or overall and severe hypoglycemia between insulin determir and insulin glargine and high quality evidence that insulin determir is associated with less weight gain and low quality evidence of more injection site reactions compared to insulin glargine.

      b. There is no significant new comparative evidence on the efficacy and safety of other agents on the PDL.

c. Continue to include at least one agent from each subgroup (short acting, rapid acting, etc.) as preferred on the PDL and evaluate comparative costs in executive session.

d. Due to no evidence showing an advantage in efficacy or safety with insulin human inhalation powder (Afrezza) when compared to injectable insulin products for which long term data is available, make Afrezza non-preferred.

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

4. Alzheimer Drugs (pages 85 – 114)
   Dr. Herink presented the following updates:

   a. No further research or review needed at this time.

   b. Evaluate comparative costs in executive session.

   c. Make Namenda XR® preferred.

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

5. Other Lipotropics (pages 115 – 122)
   Dr. Herink presented the following updates:

   a. No further research or review needed at this time.

   b. Evaluate comparative costs in executive session.

   c. Make niacin non-preferred due to lack of cardiovascular outcome benefit and possible harm.

   d. Make fenofibrate tablets preferred and Tricor® and Trilipix® non-preferred.

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

b. Diabetes Class Update (pages 123 – 140)
   Dr. Sentena presented the following updates:

   1. Evidence of SGLT2 inhibitors supports the current PA criteria. Dapagliflozin should be added to the criteria and maintained as non-preferred.

   2. There is no new evidence on the comparative efficacy/ effectiveness or safety for the oral hypoglycemic PDL class. Evaluate comparative costs in executive session.

   3. Make Fortamet and generic equivalents non-preferred

Public Comment:
Bob Snediker form J&J.

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

c. Multiple Sclerosis Class Update (pages 141 – 157)
   Dr. Sentena presented the following updates:

   1. Limited evidence suggests glatiramer 40 mg three times weekly is effective in preventing relapses in patients with RRMS; maintain as non-preferred.

2. Recommend requiring a prior authorization for peginterferon beta-1a.

3. Evaluate costs in executive session.

4. No changes to the PDL.

Public Comment:
Melissa Walsh from Novartis.
Deborah Profant, PhD from Teva.
Lynda Finch from Biogen Idec.

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

d. First Generation Antidepressants (pages 158 – 174)
Dr. Herink presented the following class review:

1. The selection of the appropriate medication for a patient should be chosen based on the properties of an individual drug, as opposed to a drug group.

2. In alignment with treatment guidelines, first and second generation antidepressants should be accessible to patients, with the selection of the individual agent dependent on severity of condition, comorbidities, medication history, and tolerability of side effects for the individual patient.

3. Recommend including first generation antidepressants to the voluntary MH PDL and evaluate costs in executive session. Consider a non-preferred status for MAOIs, given the known safety concerns including high risks of drug-drug and drug-food interactions. Also maintain nefazodone as non-preferred due to hepatic safety concerns.

4. Evaluate costs in executive session.

5. No other changes to the PDL.

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

e. TIMS Class Update (pages 175 – 194)
Dr. Herink presented the following class update:

1. Modify prior authorization criteria to include new FDA approved indications and new medications.

2. Evaluate comparative costs of newly approved agents in executive session.

3. Make Simponi non-preferred.

Public Comment:
Arti Baig from Pfizer.
Jason Alm from Celgene.
Diana Lein from Bristol-Myers Squibb.

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

f. Topical Antifungals Class Update (pages 195 – 208)
Ms. Ketchum presented the following class update:

1. Evaluate comparative costs in executive session.

2. No changes to the PDL.

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

g. Vitamins & Electrolytes Abbreviated Class Review (pages 209 – 216)
Dr. Herink presented the following class review:

1. Evaluate comparative costs in executive session to list specific agents as preferred and non-preferred.

2. Include a formulation of the different potassium salt supplements due to different clinical considerations.

3. Potassium chloride packets make non-preferred on the PMPDP.

4. Potassium gluconate make non-preferred on the PMPDP.

5. Magnesium ER and DR make non-preferred on PMPDP.

6. Magnesium IR make preferred on the PMPDP.

7. Phosphorus make preferred on the PMPDP.

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

V. EXECUTIVE SESSION

VI. RECONVENE for PUBLIC RECOMMENDATIONS

VII. ADJOURN
