Drug Use Research & Management Program
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Oregon Drug Use Review / Pharmacy & Therapeutics Committee
Thursday, July 31, 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: Tracy Klein, PhD, FNP; Cathy Zehrung, RPh; Phillip Levine, PhD; James Slater, PharmD;

Members Present by Phone: Dave Pass, MD; Joshua Bishop, 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; Dee Weston; Karina Porter;

Staff Present by Phone: Kathy Sentena, PharmD; Bing-Bing Liang, PharmD; Walter Shaffer, MD; Chris Barber, RN

Audience: Alison Martens, RN (Meda)*; Shall Hall (Purdue); Troy Larsen (Takeda); Seth M. Adams (WVP Health Authority); Ken Fritsche; Deirdre Monroe (Allergan)*; Camille Kerr (Allergan); Ralph Magresh (Merck); David Barba (Forest); Tara Bannow (The Bulletin, Bend OR); Stuart O' Brochta (Gilead)*; Lisa Roessel (Actelion)*; Lori Howarth (Bayer); Elizabeth Skovrow (Bayer)*; Laura Hill (Abbvie); Desiree Allen (Abbvie); Mila Whitem (Lilly); Steve Nemirow *; Bart Benson; Isaac Lloyd; David Barnhoum (Genentech); Amy Jay (Pacific University); Arlette Munoz (OSU/ OHSU COP); Richard McLeod (Pfizer); John McDonald (Meda); Mark Pledger (Novartis); Mike Willett (Pfizer); Trish McDaid-O'Neill (Astra Zeneca); Kristen Harrington (Astra Zeneca); Larry Hinson (Astra Zeneca); Jacki Gethner (Women of a Certain Age)*; Anne Murray (BMS); Shelly Bailey (Central Drugs); Kristi Bronson (Astra Zeneca)*; Jim Graves (BMS); Brad Peacock (Gilead); Lorren Sandt (Caring Ambassadors)*; BJ Cavnor (1 in 4 Org)*; Robert Snediker (J&J)*; Jennifer Morrison (Boehringer Ingelheim); Lauren Kael*; Ruby Grzelecki; Dr. Atif Zaman*; Scott Larson (BMS); John McIlveen, PhD (AMH/ OHA); Judith Leahy (OHA); Caryn Mickelson (WOAH); Diana Dills (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.

b. Mr. Citron reported there are no new conflicts of interest to declare.
Requested any nominations for P&T members to send information to Roger Citron.

c. Approval of agenda and minutes presented by Tracy Klein, (pages 1 - 9)

ACTION: Approved as is.

d. Department updates presented by Dee Weston.
Requested all Pharmaceutical manufacturer meetings be scheduled thru Dee Weston or Linnea Saris.

II. DUR ACTIVITIES

a. Quarterly Utilization Reports presented by Kathy Ketchum, RPh (pages 10 – 14)

b. ProDUR Report presented by Rich Holsapple, RPh (pages 15 – 17)

c. RetroDUR Report presented by Dr. Williams (pages 18 - 23)

d. Oregon State Drug Reviews presented by Dr. Sentena
   1. 2nd Generation Antipsychotics: Are these Drugs effective in treating PTSD? (pages 24 – 25)

   2. New Cholesterol Guidelines: A Significant Shift in Cholesterol Management (pages 26 – 27)

e. FDB Drug File Update presented by Dr. Williams (page 28)

III. DUR BUSINESS

a. Hepatitis C Class Update (pages 29 – 54)
Dr. Zaman presented information from the Hepatitis C Advisory Committee.
Dr. Herink presented the following information:

   1. Recommend including additional changes to PA criteria based on Hepatitis C Advisory Committee Recommendations, including limiting approval to the following patient populations:

      a. Patients with extra hepatic manifestations of HCV who have formal documentation from a relevant specialist that their condition is HDV related.

      b. HCV / HIV co-infected patients with cirrhosis.

      c. HCV infection in the transplant setting (approval needs to be cleared by the DMAP Medical Director).

      d. Cirrhotic (stage 4) patients without ongoing progressive decompensation.

      e. Strike question #5 from original criteria.

      f. Add “and marijuana” to question #11.

g. Revisit at September P&T meeting.

Public Comment:
Stuart O'Brochta from Gilead.
Jacki Gethner from Women of a Certain Age.
Steve Nemirow.
Lorren Sandt from Caring Ambassadors.
BJ Cavnor from 1 in 4 Org.

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

b. Hepatitis C Readiness to Treat (pages 55 – 64)
Dr. Herink presented the following information:
Jude Leahy presented information about the document with revisions to treat information for public health and criteria for physicians.

1. Approve readiness to refer assessment with goal to support patient readiness through actions initiated by primary care providers to prepare patients interested in hepatitis C treatment to engage successfully with specialists.

2. Post resource to the College of Pharmacy website, bring to the CCO Medical Directors meeting and work with public health to facilitate dissemination and education regarding new assessment.

3. Mirror PA Criteria language and consistently call out PCP.

4. Get feedback from hepatologists and primary care physicians on utility of assessment.

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

c. Botulinum Toxins Drug Use Evaluation (pages 65 – 77)
Ms. Ketchum presented the following evaluation:

1. Implement proposed PA criteria in FFS patients to limit use to evidence supported diagnosis.
2. Revisit #4 for clarification at September P&T meeting.

Public Comment:
Deidre Monroe from Allergan.

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

IV. PREFERRED DRUG LIST NEW BUSINESS

a. Alcohol Dependence Class Review (pages 78 – 97)
Dr. Liang presented the following review:

1. Combine the alcohol dependence agents and opioid dependence into one PDL class. Oral naltrexone and acamprosate should be preferred on the PDL based on moderate level evidence to support the similar efficacy and safety for the treatment of alcohol use disorder.

2. Maintain injectable naltrexone non-preferred and reserve as a treatment option for those patients unable or unwilling to take oral therapy or are not likely to adhere with oral naltrexone therapy.

3. Maintain naltrexone depot injection prior authorization criteria.

4. Designate disulfiram non-preferred and grandfather current clients for 12 months.

Public Comment:
Dr. John McIlveen from OHA – Addictions and Mental Health

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

b. Androgens Class Update (pages 98 – 106)
Dr. Liang presented the following update:

1. Re-evaluate safety of testosterone therapy once FDA concludes its review.

2. Remove ovarian failure from list of covered diagnosis in PA criteria.

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

3. Evaluate comparative costs in executive session.

4. Designate Aveed non-preferred and no grandfathering.

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

c. Pulmonary Arterial Hypertension (pages 107 – 128)
Dr. Sentena presented the following update:

1. Prior authorize riociguat to ensure appropriate use by qualified providers.

2. Prior authorize macitentan to ensure appropriate use by qualified providers.

3. Limited evidence is insufficient to prefer macitentan over bosentan for placement on PDL.

4. Prior authorize oral treprostinil to ensure appropriate use by qualified providers.

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

5. Continue to include an agent from each class on the PDL and evaluate comparative costs in executive session.

6. *After executive session. No changes to the PMPDP.

Public Comment:
Stuart O'Brochta from Gilead.
Lisa Roessel NP from Actelion.
Elizabeth Skovrow from Bayer.

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

d. Anticoagulant Class Update (pages 129 – 158)
Dr. Sentena presented the following update:

1. Atrial Fibrillation: Recommend warfarin as first-line therapy and offer dabigatran and apixaban as non-preferred agents subject to PA approval. No changes to the PDL are recommended.

2. VTE treatment: Recommend warfarin or enoxaparin first line with dabigatran, rivaroxaban and apixaban as non-preferred options if clinical criteria are met. Recommend adding apixaban to current PA criteria as a second line option.

3. Orthopedic Prophylaxis: Recommend LMWH as an appropriate first-line treatment option. Recommend rivaroxaban and apixaban as non-preferred options if clinical criteria are met. Recommend adding apixaban to current PA criteria as a second line option.

4. Medically Ill: If continued anticoagulation is warranted in medically ill patients recommend warfarin as first-line option. Fourteen day supply of rivaroxaban allows transition to preferred therapy in current PA criteria. No changes to the PDL are recommended.

5. Add "difficulty obtaining INR monitoring" to questions #5 and #9 in Oral Direct Factor Xa Inhibitors criteria, and questions #3 and #8 in Oral Direct Thrombin Inhibitors.

6. *After executive session. No changes to the PMPDP.

Public Comment:
Diane Dills from Pfizer.
Robert Snediker from J&J.

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

e. Antiplatelet Class Update (pages 159 – 179)
Ms. Ketchum presented the following update:

1. Continue to list aspirin and clopidogrel as preferred drugs due to high level evidence of benefit for multiple indications (Coronary Artery Disease [CAD], ACS, stroke and PAD).

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

2. Evaluate other antiplatelet drugs in executive session for potential inclusion.

3. Add Vorapoxar to antiplatelet criteria.

4. *After executive session, no changes to PMPDP.

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

f. Asthma / COPD Class Update (pages 180 – 202)
Dr. Meeker presented the following update:

1. Due to no evidence demonstrating clinical superiority of umeclidinium / vilanterol over current agents, recommend making it non-preferred.

2. Recommend including umeclidinium / vilanterol in the prior authorization criteria to ensure it is being used appropriately and limiting to patients who have COPD.

3. Due to no evidence demonstrating clinical superiority of safety of umeclidinium over current agents, recommend making it non-preferred.

4. Due to no evidence demonstrating clinical superiority of safety of mometasone HFA over current agents, recommend making it non-preferred.

5. Due to no strong comparative effectiveness of superiority between other agents, recommend comparing costs in executive session.

6. Reorganize PDL classes bases on drug class as followed:
   a. Long-acting Bronchodilators
   b. Short-acting Beta Agonists
   c. Anticholinergic Inhalers
   d. Combination Inhalers
   e. Inhaled Corticosteroids
   f. Miscellaneous Pulmonary Drugs

7. Due to no evidence demonstrating clinical superiority, designate flunisolide HFA as non-preferred on the PMPDP.

8. No changes to any of the listed PMPDP classes.

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

Public Comment:
Alison Martens RN from Meda Pharmaceuticals.
Kristi Bronson from Astra Zeneca.

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

g. First Generation Antidepressants (pages 203 – 220)

   Deferred

h. Insomnia Class Update (pages 221 -231)

   Deferred

i. Drug Class Scans

   1. Insulins (pages 232 – 253)

   Deferred

   2. Skeletal Muscle Relaxants (pages 254 – 266)

   Deferred

   3. NSAIDs (pages 267 – 286)

   Deferred

4. Oral Hypoglycemics (pages 287 – 306)

Deferred

5. New Antiemetics (pages 307 – 348)

Deferred

V. EXECUTIVE SESSION

VI. RECONVENE for PUBLIC RECOMMENDATIONS

Mr. Citron announced the next P & T meeting will be held Tuesday Sept. 23rd.

VII. ADJOURN