Drug Use Research & Management Program
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Oregon Drug Use Review / Pharmacy & Therapeutics Committee
Thursday, May 28, 2015 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; Tracy Klein, PhD., FNP;

Members Present by Phone: Kathryn Lueken, MD; James Slater, PharmD; Caryn Mickelson, PharmD; Dave Pass, MD; James Slater, PharmD; Stacy Ramirez, PharmD;

Staff Present: Kathy Ketchum, RPh, MPA:HA; Megan Herink PharmD, BCPS; Richard Holsapple, RPh; Roger Citron, RPh; Ted Williams, PharmD; Shannon Jasper; Amanda Meeker, PharmD; Andrew Gibler, PharmD; Dee Weston; Jamal Furqan; Linnea Saris;

Staff Present by Phone:

Audience: Barry Benson (Merck), Connie Brooks (Vertex); Gregg Rasmussen (Vertex); Shane Hall (Purdue); Paul Bonham (Novo); Diana Dills (Pfizer)*; Bob Gustafson (Lundbeck); Lee Stout (Chiesi); Steve hall (Boehringer Ingelheim)*; Jim Graves (BMS); Saumya 'Mia' Varghese , student; Theresa Gatti, student; Patrick Moty (Supernus); Samantha Min (Otsuka); Jamie Tobitt (Vertex)*; Don Stecher (Novartis); Mike Willitt (Pfizer); Mary Kernhus (Novartis); Tracey Meeks (Vertex); Jeana Colabianchi (Sunovion); William Davis (Astellas); Venus Holder (Lilly); Stephanie Kendall (J&J); Dr. Michael Powers (OHSU)*;

(*) Provided verbal testimony

I. CALL TO ORDER

a. The meeting was called to order at approximately 1:00 pm. Introductions were made by Committee members and staff.

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

c. Approval of agenda and minutes presented by Dr. Klein after correction of name. (pages 1 - 7)

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

d. Department updates for OHA.

II. DUR ACTIVITIES

a. Quarterly Utilization Reports (pages 8 - 12)
   Mr. Citron presented the quarterly utilization report.
b. ProDUR Report (pages 13 – 15)
   Mr. Holsapple presented the quarterly ProDUR reports.

c. RetroDUR Report (pages 16 – 19)
   Dr. Williams presented the quarterly RetroDUR reports.

d. Oregon State Drug Reviews (pages 20 – 23)
   Dr. Sentena presented the following reviews:
   1. Evaluation of High Dose SSRI Initiation in Pediatrics
   2. The Opioid Epidemic: Are Abuse-deterrent Formulations the Answer?

III. DUR OLD BUSINESS

a. PDL Status of Simeprevir (pages 24 - 29)
   Dr. Herink clarified the following status:

   1. Make Olysio non-preferred on PMPDP.

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

b. Pediatric SSRI High Dose DUE Clarification (pages 30 - 41)
   Dr. Williams presented the following clarification:

   1. Maximum initial dose for children <5 years old.
   2. Will bring back to the July meeting, add criteria for consultation for prescribers that are not psychiatric specialists.

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

c. Tapering Clarification for PPI PA Criteria (pages 42 - 45)
   Dr. Gibler presented the following clarification and PA criteria update:

   1. Approve updated PA criteria.
   2. Retrospective DUR education, contact prescribers thru licensing boards, end grandfather for existing chronic users after one year.

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

IV. DUR NEW BUSINESS

a. Ivacaftor Drug / Policy Update (pages 46 – 55)
   Dr. Herink presented the following updates:

1. Await published data supporting statistically significant improvements in FEV1, or other clinically relevant outcomes, in patients with the R117H mutation in the CFTR gene and in pediatric patients aged 2 to 5 years before approving use in these populations.
2. Expand Cystic Fibrosis Class to include non-inhaled products.

Public Comment:
Jamie Tobitt from Vertex.
Dr. Michael Powers from OHSU.

***ACTION:** After executive session. All in Favor. Approved
3. *Defer action, request clinical criteria improvement for specific to age group 2-5.
4. *Bring back to the July meeting for follow up.

b. Oral Anticoagulants Class Update / Policy Evaluation (pages 56 – 88)
Dr. Sentena and Ms. Ketchum presented the following class update and policy evaluation:

1. Discontinue the clinical PA requirement for all DOACs.
2. Develop a Retrospective DUR program to monitor appropriate dosing and use in the presence of contraindications.
3. Review utilization in one year.

***ACTION:** After executive session. All in favor. Approved.

4. *Make all DOACs preferred.

Public Comment:
Dr. Diana Dills from Pfizer.
Steve Hall from Boehringer Ingelheim.

c. Leuprolide Drug / Policy Update (pages 89 – 93)
Dr. Meeker presented the following drug update and policy:

1. Modify PA criteria allow approval of leuprolide in adolescents with documented gender dysphoria at the beginning of puberty confirmed by pubertal levels of hormone but no earlier than Tanner stages 2-3.
2. Add must be “Prescribed by Pediatric Endocrinologist” to criteria.

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

V. PREFERRED DRUG LIST NEW BUSINESS

a. Otic Antibiotics Class Update (pages 94 – 101)
Dr. Gibler presented the following class update:

1. Keep either ofloxacin or ciprofloxacin / dexamethasone as a preferred product for treatment of acute otitis media in patients with tympanostomy tubes.
2. Keep at least one ototopical aminoglycoside antibiotic as an option for otitis externa.
3. Maintain finafloxacin as non-preferred due to its limited indication for otitis externa only and lack of comparative evidence, unless it is cost-effective.
4. Evaluate comparative costs in executive session.

***ACTION:** After executive session. All in favor. Approved.

5. Make finafloxacin non-preferred when added to the drug file.

b. Oxazolidinone Antibiotic Class Review (pages 102 – 111)
Ms. Ketchum presented the following class review:

1. Create a new Preferred Drug List Oxazolidinone Antibiotics Class including linezolid and tedizolid.
2. Prefer linezolid because of proven benefit.
3. Implement proposed PA criteria.

ACTION: Motion, 2nd, all in favor. Approved.

4. *Make tedizolid non-preferred.

c. Rifaximin New Drug Evaluation (pages 112 – 123)
Dr. Gibler presented the following drug evaluation:

1. Implement proposed criteria after removing criteria #3 of PA criteria.

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

d. Drug Class Literature Scans

1. Antibiotics for *Clostridium difficile* infection (pages 124 – 132)
Dr. Gibler presented the following class scan:

a. No further review or research needed at this time.
b. Evaluate comparative costs in executive session.

***ACTION:** After executive session. All in favor. Approved.

c. *No PMPDP changes recommended.

2. Fluoroquinolones (pages 133 – 142)
Dr. Gibler presented the following class scan:

a. Continue to maintain at least one FQ with broad coverage of gram-negative bacteria (ciprofloxacin, levofloxacin) and at least one “respiratory” third generation FQ (gemifloxacin, levofloxacin, moxifloxacin).
b. No further review or research needed at this time.
c. Evaluate comparative costs in executive session.

***ACTION:** After executive session. All in favor. Approved.

d. *No PMPDP changes recommended.

3. Ophthalmic Anti-inflammatory Drugs (pages 143 – 160)
Dr. Gibler presented the following class scan:

a. No further review or research needed at this time.
b. Evaluate comparative costs in executive session.

***ACTION:** After executive session. All in favor. Approved.

c. *No PMPDP changes recommended.

4. Inhaled Cystic Fibrosis Drugs (pages 161 – 165)
   Dr. Herink presented the following class scan:

   a. Maintain at least one formulation of either inhaled tobramycin or aztreonam as preferred on the PDL for the treatment of chronic infection with *P. aeruginosa*.
   b. Evaluate comparative cost in executive session.

***ACTION:** After executive session. All in favor. Approved.

   c. *Make Tobi Podhaler and KITABIS PAK preferred and accept SR and make Kalydeco non-preferred.

5. Gout Agents (pages 166 – 170)
   Dr. Herink presented the following class scan:

   a. Continue to include one xanthine oxidase inhibitor as preferred on the PMPDP for the treatment of chronic gout and hyperuricemia.
   b. No further review or research needed.
   c. Evaluate comparative costs in executive session.

***ACTION:** After executive session. All in favor. Approved.

   d. *No PMPDP changes recommended.

6. Short-acting Opioids (pages 171 – 182)
   Dr. Meeker presented the following class scan:

   a. Update current PA criteria for excessive dose limits on opioid / non-narcotic combination products and remove deleted products.
   b. No further review or research needed at this time.
   c. Evaluate comparative costs in executive session.

***ACTION:** After executive session. All in favor. Approved.

   d. *Make all rectal subclass products, all ACETAMINOPHEN WITH CODEINE products and all ibuprofen containing products preferred on the PMPDP and make all butalbital products non-preferred.
   e. *Maintain liquid hydrocodone / APAP 500 mg formulation in table.
   f. *Age restrictions on all codeine products from 0 – 6 years of age. PA required.
   g. *Add hydrocodone / APAP solution as a preferred agent.

7. Tetracyclines (pages 183 – 189)
   Dr. Williams presented the following class scan:

   a. Recommend inclusion of one or more agents from this class including doxycycline.
   b. No further review or research needed at this time.
   c. Evaluate comparative costs in executive session.

***ACTION:** After executive session. All in favor. Approved.

   d. *No PMPDP changes recommended.

8. DERP Scan Summaries
    a. Second-generation Antihistamines (pages 190 – 208)
    Dr. Gibler presented the following class scan:

        1. Update PA criteria with minor administrative edits.
        2. No further review or research needed at this time.
        3. Evaluate comparative costs in executive session.

***ACTION:** After executive session. All in favor. Approved.

        4. *No PMPDP changes recommended.

    b. Beta-blockers (pages 209 – 224)
    Dr. Gibler presented the following class scan:

        1. Based on previous recommendations, prefer either carvedilol or metoprolol succinate; as well as either acebutolol, carvedilol, metoprolol tartrate, propranolol or timolol; and either atenolol, nadolol, propranolol or propranolol extended-release.
        2. No further review or research needed.
        3. Evaluate comparative costs in executive session.

***ACTION:** After executive session. All in favor. Approved.

        4. *Add metoprolol succinate to the PMPDP as preferred.

    c. Overactive Bladder Drugs (pages 225 – 238)
    Dr. Gibler presented the following class scan:

        1. No further review or research needed.
        2. Evaluate comparative costs in executive session.

***ACTION:** After executive session. All in favor. Approved.

        3. *No PMPDP changes recommended.

VI. EXECUTIVE SESSION

VII. RECONVENE for PUBLIC RECOMMENDATIONS

VIII. ADJOURN