



Drug Use Research & Management Program
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Oregon Drug Use Review / Pharmacy & Therapeutics Committee

Thursday, September 24, 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; William Origer, MD; Caryn Mickelson, PharmD; Stacy Ramirez, PharmD;

Members Present by Phone:

Staff Present: Kathy Ketchum, RPh, MPA:HA; Richard Holsapple, RPh; Roger Citron, RPh; Ted Williams, PharmD; Andrew Gibler, PharmD; Dee Weston; David Engen, PharmD; Kim Wentz, MD

Staff Present by Phone: Kathy Sentena, PharmD

Audience: Don Stecher (Novartis), Mary Fitzpatrick (Biogen)*, Jeannie Kenyon (AstraZeneca), Dr. Doug Gelowitz (AstraZeneca)*, Bridget Martin (Boehringer Ingelheim), Jenny Morrison (Boehringer Ingelheim), Diann Matthews (Biogen), Kim Copper (AstraZeneca), Kristi Benson (AstraZeneca), Steven Hall (Boehringer Ingelheim)*, Karen Dienko (Boehringer Ingelheim), Kelsey Brink, Megan Carroll, Lisa Ashton (J&J); Margaret Olman (AbbVie), Camille Kerr (Amgen), Dr. McCale (Baxacta), Barry Benson (Merck), Stephanie Lattig (Novo Nordisk), Merrie Kay Alzola (Novo Nordisk), Sally Zweber (Novo Nordisk), Michael Estos (Pfizer)*, Venus Holder (Lilly), Jeana Colabianchi (Sunovion), Nik Seifter (GlaxoSmith Kline)*, Bruce Smith (GlaxoSmith Kline), Becky Gonzales (ViiV Healthcare), David Putelo (ViiV Healthcare), Stella McCaughey (Novartis), Mary Kemhus (Novartis)*, Jon Ward (Novartis), Paul Bonham (Novo Nordisk), Mark Pledger (Novartis),

(*) 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. Origer. (pages 4 - 9)

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

- d. Department updates for OHA.

II. DUR OLD BUSINESS

- a. Initial Pediatric SSRI High Dose Prior Authorization Criteria (pages 10 - 11)
Dr. Williams presented the revised criteria.

ACTION: Motion, 2nd. Approved.

- b. Codeine Prior Authorization Criteria update (page 12)
Dr. Gibler presented the updated criteria.

ACTION: Motion, 2nd. Approved.

III. PREFERRED DRUG LIST NEW BUSINESS

- a. Asthma and COPD Class Updates (pages 13 - 41)
Dr. Sentena presented the following class update:
 - 1. Maintain tiotropium/olodaterol, fluticasone furoate and fluticasone furoate/vilanterol drug products non-preferred.
 - 2. Create new PDL class for long-acting muscarinic antagonist/long-acting beta-agonist (LAMA/LABA) fixed-dose combination inhaler products.
 - 3. Re-organize and modify clinical PA criteria to promote step-therapy that is consistent with Oregon Asthma Guidelines and with medical evidence for COPD:
 - All non-preferred LABA inhalers must go through the LABA PA criteria for appropriate step therapy.
 - All non-preferred inhaled corticosteroids (ICS) must go through the ICS PA criteria for appropriate step therapy.
 - Updated LABA/ICS combination inhalers PA proposed criteria were rejected. Bring back to P&T Committee in November and clarify COPD severity stages in criteria.
 - Proposed new PA criteria for LAMA/LABA products were rejected. Bring back to P&T Committee and clarify evidence for ICS monotherapy prior to LABA/LAMA use and COPD severity stages in criteria.
 - Remove existing clinical PA for “asthma controllers” and indacaterol. Drugs under these PAs will be incorporated into the ICS or LABA PA criteria.
 - Remove clinical PA for leukotriene inhibitors. Non-preferred leukotriene inhibitors will go through the generic non-preferred PDL PA.
 - Clerical changes to the roflumilast clinical PA criteria.
 - 4. Evaluate cost in executive session for PDL decision making.

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

- 5. No changes to PMPDP.

Public Comment:

Nik Seifter from GSK gave public comment.

- b. Diabetic Class Updates (pages 42 - 66)

Dr. Sentena presented the following class update:

1. Include at least one GLP-1 RA on the PDL as a preferred third-line option for T2DM after metformin and a SU.
2. Maintain GLYXAMBI® (empagliflozin and linagliptin) as non-preferred subject to current clinical PA for SGLT-2 inhibitors.
3. Reorganize PDL classes for non-insulin antidiabetic agents to the following:
 - DPP-4 inhibitors
 - GLP-1 Receptor Antagonists
 - Miscellaneous Antidiabetic Agents (metformin, pramlintide, meglitinides, others).
 - SGLT-2 Inhibitors
 - Sulfonylureas
 - Thiazolidinediones
4. No longer require clinical PA for pramlintide.
5. Continue current clinical PAs for DPP-4 inhibitors, SGLT-2 inhibitors, and non-preferred GLP-1 Receptor antagonists.
6. Evaluate cost in executive session for PDL decision making.
7. SGLT-2 inhibitor clinical PA: change duration PA approval to 6 months under #5 so renal function can be re-evaluated. Develop renewal criteria that require re-analysis of renal function in last 6 months for re-approval.
8. ALL GLP-1 receptor antagonists subject to clinical PA.

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

9. *Make Byetta® PDL = Y.

Public Comment:

Bob Snediker from J&J gave public comment.
Dr. Doug Gelowitz from AstraZeneca gave public comment.
Steve Hall from Boehringer Ingelheim gave public comment.

ACTION: Motion, 2nd. Approved.

c. Drug Class Literature Scans

1. Oral Multiple Sclerosis Drugs (pages 67 – 78)\
Dr. Gibler presented the updated scan.
 - a. No further research or review needed at this time.
 - b. Evaluate comparative costs in executive session.
 - c. #2 in clinical PA, for No: “not funded under the OHP” and refer to guideline.

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

Public Comment:

Mary Fitzpatrick from Biogen gave public comment.
Mary Kemhus from Novartis gave public comment.

2. Growth Hormones (pages 79 – 85)
Dr. Gibler presented the updated scan.
 - a. No further research or review needed at this time.
 - b. Evaluate comparative costs in executive session.

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

- c. *#2 in clinical PA: Leave definition of adult as “older than 18 years of age”.

Public Comment:

Micheal Estos from Pfizer gave public comment.

3. Inflammatory Bowel Agents (pages 86 – 92)
Dr. Gibler presented the updated scan.
 - a. At least one oral corticosteroid formulation should be available on the PDL for adjunctive management of mild Crohn’s disease.
 - b. Budesonide rectal foam should not be a preferred agent at this time due to limited short-term evidence.
 - c. No further research or review needed at this time.
 - d. Evaluate comparative costs in the executive session.

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

4. Alzheimer’s Agents (pages 93 – 100)
Dr. Gibler presented the updated scan.
 1. No further research or review needed at this time.
 2. Evaluate comparative costs in executive session.

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

- d. Sacubitril/Valsartan New Drug Evaluation (pages 101 - 114)
Dr. Gibler presented the following new drug evaluation:
 1. Restrict use of sacubitril/valsartan to populations where it has demonstrated efficacy.
 2. Approve proposed prior authorization.
 3. #1 clinical PA: “Is this a request for renewal of a prior approved PA”?

ACTION: Motion, 2nd. Approved.

Public Comment:

Mary Kemhus from Novartis gave public comment.

- e. Ivabradine New Drug Evaluation (pages 115 - 128)
Dr. Gibler presented the following new drug evaluation:

Evaluation was deferred to the November meeting.

- f. Influenza Class Update (pages 129 – 142)
Dr. Gibler presented the following class update:

The class update was deferred to the November meeting.

IV. DUR NEW BUSINESS

- a. Modafinil/Armodafinil Drug Use Evaluation (pages 143 – 167)
Ms. Ketchum presented the following review and evaluation:

1. Implement proposed prior authorization criteria for patients initiated on modafinil or armodainil (no claims evidence within 102 days) and without previous claims evidence of narcolepsy or obstructive sleep apnea.
2. Grandfather current modafinil/armodafinil users for one year.
3. Clerical amendments: Remove “or other CNS stimulants” from Yes under #3, Remove “Pass to RPH” from Yes under #4.

ACTION: Motion, 2nd. Approved.

- b. Tetracyclines Drug Use Evaluation (pages 168 – 177)
Dr. Williams presented the following drug use evaluation:

1. Restrict use of all tetracycline antibiotics to a 14-day supply every 6 months.
2. Make tetracycline antibiotic therapy exceeding 14 days every 6 months subject to prior authorization to verify the presence of an OHP funded condition.

ACTION: Motion, 2nd. Approved.

- c. Low Dose Quetiapine Policy Evaluation (pages 178 – 189)
Ms. Ketchum presented the following drug evaluation:

1. Automatically approve for:
 - Patients with a claim for a second generation antipsychotic in the past six months.
 - Patients with prior medical claims evidence of schizophrenia or bipolar disorder.
 - Prescriptions identified as being written by a mental health provider when the claims system has the capability.

ACTION: Motion, 2nd. Approved.

- d. Clinical Review of Existing Prior Authorization Criteria
 1. Tesamorelin for injection (pages 190 – 191)
Dr. Gibler presented the following clinical review for the existing PA.
 - a. No further research or review needed at this time.
 - b. No changes to the current PA criteria.

ACTION: Motion, 2nd. Approved.

2. Becaplermin topical gel (pages 192 – 193)
Dr. Gibler presented the following clinical review for the existing PA.
 - a. No further research or review needed at this time.
 - b. No changes to the current PA criteria.

ACTION: Motion, 2nd. Approved.

V. EXECUTIVE SESSION

VI. RECONVENE for PUBLIC RECOMMENDATIONS

VII. ADJOURN