



Drug Use Research & Management Program  
OHA Division of Medical Assistance Programs  
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## Oregon Drug Use Review / Pharmacy & Therapeutics Committee

Thursday, November 19, 2015 1:00-5:00 PM

Wilsonville Training Center

29353 SW Town Center

Wilsonville, OR 97070

### MEETING MINUTES

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**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; Bill Origer, MD; Rich Clark, MD, MPH; Caryn Mickelson, PharmD;

**Members Present by Phone:** Dave Pass, MD; Arturo Salazar, MD

**Staff Present:** Megan Herink PharmD, BCPS; Richard Holsapple, RPh; Roger Citron, RPh; Ted Williams, PharmD; Shannon Jasper; Dee Weston; Dave Engen, PharmD; Kathy Sentena, PharmD; Kim Wentz, MD;

**Staff Present by Phone:**

**Audience:** Devin Dufenhorst (Abbot), Kerry Kostman Bonnila (AstraZeneca), Karen Campbell (Allergan)\*, Rick Frees (Vertex), Jamie Tobitt (Vertex)\*, Paul Bonham (Novo Nordisk), Venus Holder (Lilly), Bruce Smith (GlaxoSmith Kline), Dr. McCale (Baxacta), Jeana Colabianchi (Sunovion), Brad Clay (Amgen)\*, Mark Pledger (Novartis), Anthony Ashtag (Novartis)\*, Sylvia Churchill (Amgen), Jennifer Svec (Med Impact), Mary Kemhus (Novartis), Sally Zweber (Novo Nordisk)\*, Merrie Kay Alzola (Novo Nordisk), Margaret Olman (AbbVie), Dean Haxby (OSU), Teresa Chiang (Pacific University), Roger Stephen (Mylan), Mike Powers, MD (OHSU)\*, Brad Clay (Amgen)\*,

(\*) Provided verbal testimony

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### 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 5 - 9)

**ACTION:** Motion, 2<sup>nd</sup>, All in Favor. Approved.

- d. Department updates for OHA.

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## II. DUR ACTIVITIES

- a. Quarterly Utilization Reports (pages 10 - 14)  
Mr. Citron presented the quarterly utilization report.
- b. ProDUR Report (pages 15 – 19)  
Mr. Holsapple presented the quarterly ProDUR reports.
- c. RetroDUR Report (pages 20 – 24)  
Dr. Williams presented the quarterly RetroDUR reports.
- d. Oregon State Drug Reviews (pages 25 – 30)  
Dr. Sentena presented the following reviews:
  - 1. Treating UTIs with the Tried and True
  - 2. Hypertension Guidelines: Do Blood Pressure Goals Change with Age?
  - 3. Is Long-term Proton Pump Inhibitor Treatment for GERD Worth the Risk?

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## III. DUR OLD BUSINESS

- a. Intranasal Allergy Drug Policy (pages 31 - 32)  
Dr. Williams presented the Prior Authorization Criteria.
  - 1. Approve proposed changes to PA criteria.

**ACTION:** Motion, 2<sup>nd</sup>, All in Favor. Approved.

- b. LABA/ICS Drug Policy (pages 33 - 34)  
Dr. Sentena presented the Prior Authorization Criteria.
  - 1. Approve proposed changes to PA criteria.

**ACTION:** Motion, 2<sup>nd</sup>. All in favor. Approved.

- c. LABA/LAMA Drug Policy (pages 35 - 36)  
Dr. Sentena presented the Prior Authorization Criteria.
  - 1. Approve proposed changes to PA criteria.

**ACTION:** Motion, 2<sup>nd</sup>, All in Favor. Approved.

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## IV. DUR NEW BUSINESS

- a. DURM Methods (pages 37 – 53)  
Dr. Herink presented the following review:
  - 1. Methods for DURM Evidence Summary Reviews. (pages 37 – 48)
  - 2. Methods for DURM Abbreviated Drug Reviews. (pages 49 – 53)

3. Approve PA for Drugs for Non-funded Conditions.
4. Approve PA criteria for Drugs Selected for Manual Review.
5. Approve PA criteria for New Drug Policy.

**ACTION:** Motion, 2<sup>nd</sup>, all in Favor. Approved.

b. Botulinum Toxins Drug Policy (pages 54 – 60)

Dr. Williams presented the following updated policy evaluation:

1. Approve proposed changes to PA criteria.
2. No further review or research needed at this time.
3. Revise step 6 add baseline number of headaches.
4. Revise step 8 to add baseline of urinary episodes.
5. Revise step 2 under Renewal Criteria to reduction in >7 headache days per month.

**ACTION:** Motion, 2<sup>nd</sup>, all in favor. Approved.

**Public Comment:**

Karen Campbell pharmacist from Allergan gave public testimony.

c. Ivabradine (Corlanor<sup>®</sup>) New Drug Evaluation (pages 61 – 74)

Dr. Herink presented the following drug evaluation:

1. Restrict use of ivabradine to populations where it has demonstrated some efficacy.
2. Approve amended criteria.
3. Change criteria #3 to 35%.
4. Include criteria of hospitalization within the past 12 months.
5. Additional criteria sites patient must be on an aldosterone antagonist.

**ACTION:** Motion, 2<sup>nd</sup>, All in Favor. Approved.

**Public Comment:**

Brad Clay from Amgen gave public testimony.

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## V. PREFERRED DRUG LIST NEW BUSINESS

a. Ivacaftor/Lumacaftor (Orkambi<sup>™</sup>) (pages 75 – 91)

Dr. Herink presented the following drug evaluation:

1. Maintain Orkambi<sup>™</sup> as non-preferred on PMPDP.
2. Approve updated PA criteria as presented.
3. Continue to monitor for patient adherence and adopt clinical criteria as needed to adequately assess clinical response as further data become available.
4. Changed minimum length of authorization from 60 to 90 days.

**ACTION:** Motion, 2<sup>nd</sup>, majority in favor, one opposed. Approved.

**Public Comment:**

Dr. Michael Powers from OHSU gave public comment.

Dr. Gopal Allada from OHSU gave public comment.

Jamie Tobitt PharmD from Vertex gave public comment.

b. Cross-sex Hormone Class Review (pages 92 – 111)

Dr. Sentena presented the following class review:

1. Include all GnRH analogs in the existing PA criteria for leuprolide and apply to all GnRH treatments for adolescents with GD to ensure they are used appropriately for puberty suppression.
2. Approve changes to testosterone PA criteria to allow approval for patients with GD.
3. Adopt estrogen derivatives PA criteria to allow approval for patients with GD.
4. Amend criteria 3 to include option for any other endocrine disorder.
5. Remove age restriction criteria of 16 years of age and older for testosterone and estrogen derivatives.

**ACTION:** Motion, 2<sup>nd</sup>, all in favor. Approved.

c. PCSK9 Inhibitor Class Review (pages 112 – 124)

Dr. Herink presented the following class review:

1. Due to limited evidence of long-term CV benefit and harms designate alirocumab and evolucumab as non-preferred in the “Other Dyslipidemia Drugs” class.
2. Approve proposed PA criteria to restrict use of PCSK9 Inhibitors to the following populations: 1) non-familial hypercholesterolemia unable to achieve at least 50% LCL-C reduction despite high-intensity statin therapy and ezetimibe; 2) familial hypercholesterolemia; or 3) persistent myopathy or myalgia with several adequate trials of statin therapy.
3. Remove CHD risk-equivalent from #3 (patient has to have clinical ASCVD).
4. Remove #7 completely and only approve for patients with documented rhabdomyolysis.

**ACTION:** Motion, 2<sup>nd</sup>, All in Favor. Approved.

**Public Comment:**

Brad Clay pharmacist from Amgen gave public comment.

d. Long-acting Insulin Class update (pages 125 – 133)

Dr. Herink presented the following class update:

1. Make insulin glargine U300 non-preferred and subject to clinical PA.
2. Approve changes to Insulin PA criteria. Maintain at least one preferred long-acting insulin product on the PDL.
3. Review insulin degludec (Tresiba<sup>®</sup>) and insulin degludec/ aspart (Ryzodeg<sup>®</sup> 70/30) as separate new drug evaluations at a later time.
4. Evaluate comparative costs in the executive session.

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

**Public Comment:**

Dr. Sally Zweber from Novo Nordisk will come back to give public comment.

e. Antiemetic Drug Class Update (pages 134 – 154)

Review of class deferred.

- f. Influenza Antiviral Class Update (pages 155 – 167)  
Review of class deferred.
- g. Iron Chelator Drug Class Update (pages 168 – 180)  
Review of class update deferred.
- h. Drug Class Literature Scans
  - 1. Immunosuppressants (pages 181 – 189)  
Review of class deferred.
  - 2. Topical Analgesics (pages 190 – 194)  
Review of class deferred.

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## **VI. EXECUTIVE SESSION**

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## **VII. RECONVENE for PUBLIC RECOMMENDATIONS**

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## **VIII. ADJOURN**