



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

Thursday, January 30, 2014 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; William Origer, MD; Zahia Esber, MD

**Members Present by Phone:** David Pass, MD; Joshua Bishop, PharmD; James Slater, PharmD; William Nunley, MD

**Staff Present:** Kathy Ketchum, RPh, MPA:HA; Megan Herink PharmD, BCPS; Richard Holsapple, RPh; Roger Citron, RPh; Ted Williams, PharmD; Trevor Douglass, DC, MPH; Hank Hickman; Amanda Meeker, PharmD;

**Staff Present by Phone:** Kathy Sentena, PharmD, Bing-Bing Liang, PharmD; Sherri Argyres, PharmD; Shannon Jasper

**Audience:** Tim McFerron, (Alkermes); Jeana Colabianchi (Sunovion); Lyle Laird (Sunovion)\*; Aaron Shaw (Sunovion); Kim Laubmeier (Otsuka)\*; Justine Overman (Astra Zeneca); Tom McLeon (Gilead)\*; Amy Bauman (Gilead); Troy Larsen (Takeda); Barry Benson (Merck); Paul Barham (Novo Nordisk); Kyle Linhardt (Upsher Smith); D.R. McCale (Baxter); Venus Holder (Eli Lilly); Amy Everitt (Otsuka); Leslie Mann (Celgene); Mike Willett (Pfizer); Amy Burns (AllCare); Kim Blood (WVCH); Caryn Mickleson (WOAH); Lorren Sandt (Caring Ambassadors)\*; Annie Ogostalick; Bruce Smith (GlaxoKlineSmith); Steve Faloon (OAPI); Kurt Turner (OAPI); Ha Trinh (Salud Pharmacy intern); Dean Haxby (OSU / OHSU); Troy Pendegraft (Nipro Diagnostics); Ann Marie Licos (MedImmune)

(\* ) Provided verbal testimony

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### 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.
- c. Election of Chair and Vice Chair for P&T Committee (page 3)  
Bill Origer, MD reelected Chair, Tracy Klein reelected Vice Chair

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

- d. Approval of Agenda and Minutes (pages 4 – 9)

**ACTION:** Approved as is.

- e. Department updates by Dr. Trevor Douglass  
The insulin pens on the PDL are not changing. The PA criteria will stay current.

Dr. Douglass also announced OHA is currently seeking and will be hiring a new Policy Manager for the Pharmacy Division and directed anyone interested to contact him directly.

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## II. DUR ACTIVITIES

- a. Quarterly Utilization Reports (pages 10-14)  
Mr. Citron presented the current reports for the utilization summary reports for July 2012 – June 2013. The changes to the report now include the encounter data, rebate data, and physician administered drugs.
- b. ProDUR Report (page 15 - 18)  
Mr. Holsapple provided a high level summary for 4<sup>th</sup> quarter 2013. Reports generated provide early refill, therapy changes, and or loss of medication.
- c. RetroDUR Report (page 19)  
Dr. Williams presented the report for 1<sup>st</sup> quarter Intervention History.
- d. Oregon State Drug Reviews (pages 20 – 21)
  - 1. Update on the New Oral Anticoagulants with a focus on Apixaban®.  
Dr. Sentena presented the newsletter.

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## III. PREFERRED DRUG LIST

- a. Fish Oil (pages 22 – 52)  
Dr. Liang presented the class review regarding the Omega-3 Fatty Acids under the PDL class “Other Lipid Lowering Agents”.

Recommendations:

- Keep omega-3 fatty acids as non-preferred agent on PDL, applying the “Non-preferred drugs in PDL classes” prior authorization criteria.
- Consider listing all over-the-counter fish oil products as non-preferred.

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

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## IV. DUR NEW BUSINESS

- a. Fish Oil Drug Use Evaluation (DUE) (pages 53 – 61)

Ms. Ketchum presented the drug use review report for Omega-3 fatty acids. The following recommendations were given:

- Retain legend omega-3 acid ethyl esters (Lovaza®) as non-preferred.
- Put all over-the-counter FO/O3 products on the "Excluded Drug List". Drugs on this list used for funded diagnoses will be approved through the administrative appeals process.
- Publish an Oregon State Drug Review on FO/O3 detailing the lack of evidence and announcing the policy prior to implementation.
- Bring back Lovaza® as old business to evaluate PA, as we may see a shift in use.

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

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## V. PREFERRED DRUG LIST CONTINUED

b. Hepatitis C Abbreviated New Drug Evaluations (pages 77 – 89)

1. Olysio® (simeprevir) NDE

Dr. Herink presented the review for simeprevir.

The following recommendations were given:

- Apply HepC Protease Inhibitor / Triple Therapy prior authorization criteria and limit use to:
  1. Patients with HCV genotype 1
  2. Without Q80K polymorphism virus
  3. Patients also on peginterferon alfa and ribavirin
  4. Compensated liver disease
  5. Prescribed by a specialist
- Bring back entire class for further PDL decision making.
- After executive session:  
Make preferred on PDL and bring back to March P&T meeting as old business. Review report of Hepatitis workgroup. Have staff look into the potential of using a sole source provider.

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

2. Sovaldi® (sofosbuvir) NDE (pages 90 – 104)

Dr. Herink presented the review for sofosbuvir.

The following recommendations were given:

- Make preferred on the PDL and implement prior authorization criteria and limit to:
  1. Patients also on peginterferon and ribavirin with HCV genotype 1 or 4
  2. Patients also on ribavirin with HCV genotypes 2 and 3
  3. Prescribed in consultation with a specialist
  4. Has evidence of moderate to severe fibrosis
- After executive session:  
The committee decided to bring back to March P&T meeting as old business. Review report of Hepatitis workgroup. Have staff look into the potential of using a sole source provider.

**Public comment:**

Loren Sandt provided public comment on HepC. The presented guidelines are great and please go by the ASLD and ISD recommendations when discussing prices.

Tom McLean from Gilead provided public comment about his company's product for HepC.

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

a. Situro™(bedaquiline) New Drug Evaluation (pages 62 – 76)

Dr. Argyres presented the review for bedaquiline.

The following recommendations were given:

1. Prior authorize bedaquiline to limit its use to patients infected with active pulmonary MDR M. tuberculosis when
  - a) an affective antimycobacterial regimen cannot otherwise be provided and
  - b) the drug is used in association with an MDR-TB regimen that includes at least 3 drugs to which the patient's MDR-TB isolate is susceptible to in vitro or, if in vitro testing is unavailable, 4 other drugs to which the patient's isolate is likely susceptible.
2. Documentation of the following should be approved:
  - a) Diagnosis of active pulmonary MDR-TB (i.e., not latent or drug sensitive TB)
  - b) Resistance of the patient's isolate to at least isoniazid and rifampin
  - c) Susceptibility of the patient's isolate to bedaquiline
  - d) Prescriptions for 3 or 4 concomitant medications used to treat MDR-TB
  - e) The use of expert medical consultation
3. Make bedaquiline non-preferred and consider reviewing the entire class in the future to identify preferred options.
4. Approve as printed.

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

c. Second Generation Antipsychotics (pages 105 – 126)

Dr. Meeker presented the class update for Second Generation Antipsychotics.

The following recommendations were given:

1. Based on the lack of long-term effectiveness and safety data, recommend listing aripiprazole long-acting injection as non-preferred on the voluntary PDL.
2. Evaluate costs in executive session.

After executive session:

Make ziprasidone Non-Preferred on the Voluntary MH PDL.

**Public comment:**

Dr. Lyle Laird from Sunovion spoke in regards to the Second Generation Antipsychotics and the statistics regarding Bipolar disorder, Bipolar depression, measures of anxiety, quality of life and measure of suicide.

Dr. Kim Laubmeier from Otsuka spoke regarding Abilify®, the boxed warnings and asked if there were questions.

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

d. Gout Medications (pages 127 – 133)

Dr. Herink presented the review for Analgesics for Gout.

The following recommendations were given:

1. Therapy with xanthine oxidase inhibitors remains first-line therapy for chronic gout / hyperuricemia 1.
2. There is sufficient evidence of any significant difference between allopurionol and feboxostat in clinical outcomes such as gout flares 2. The American College of

Rheumatology guidelines give no preference to either agent and both are recommended as first line treatment 1.

3. There is insufficient evidence for the treatment of intra-articular corticosteroids for the treatment of acute gout.
4. No further review or research needed. Evaluate comparative costs in executive session.

After executive session, no changes to PMPDP were recommended.

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

e. Drug Class Scans

1. Oral Antivirals HSV

Dr. Herink presented the review.

The following recommendations were given:

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

After executive session, there were no changes recommended to the PMPDP.

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

2. Hormone Replacement Therapy

Dr. Herink presented the review.

The following recommendations were given:

- There is no new significant comparative evidence on the efficacy and safety of hormone replacement therapy medications; no further research or review needed at this time.
- Evaluate comparative costs in executive session.

After executive session:

- Make FemHRT, Jintelli and their generics non preferred on PMPDP and grandfather for 12 months.
- Make Vivelle-Dot and Alora preferred on PMPDP.

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

3. Calcium Channel Blockers

Dr. Herink presented the review.

The following recommendations were given:

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

After executive session, there are no changes to PMPDP.

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

4. Beta-Blockers

Dr. Herink presented the review.

The following recommendations were given:

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

After executive session:

- Make nadolol nonpreferred on PMPDP and grandfather for 12 months.

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

5. ACEI / ARBs / DRIs

Dr. Herink presented the review.

The following recommendations were given:

- No further research or review needed at this time.
- There is insufficient evidence evaluating azilsartan / chlorthalidone combination therapy on long term clinical outcomes. Maintain as non-preferred and evaluate comparative costs in executive session.
- There is no new comparative efficacy or safety evidence for preference of one agent over another within each class.

After executive session:

- Make captopril, fosinopril, moexilpril, quinapril, trandolapril and their HCTZ combination products non-preferred due to low use and high relative price and grandfather for 12 months.

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

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**VI. EXECUTIVE SESSION**

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**VII. RECONVENE for PUBLIC RECOMMENDATIONS**

Mr. Citron confirmed the next P & T meeting will be held on March 27, 2014.

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**VII. ADJOURN**