



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

Thursday, November 21, 2013 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; William Origer, MD, Tracy Klein, PhD, FNP;

Members Present by Phone: Stacy Ramirez, PharmD; William Nunley, MD; James Slater, 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;

Staff Present by Phone: Kathy Sentena, PharmD, Bing-Bing Liang, PharmD

Audience: Kimberly Blood, (WVP Health Authority); Venus Holder, (Lilly); Paul Barham (NovoNordisk); Jeana Colabianchi, (Sunovion); Kathleen Rogers, FNP, MSN, (Sunovion); Anne Marie Licos, PharmD (MedImmune); Bruce Smith (GSK); Barry Benson, (Merck); Barbara Felt (GSK)*; Kyle Linhard (Upsher-Smith); Theresa Lane (Trillium Community Health Plan); Jo Crawford (Serenity Lane); Tammy Grasty (Serenity Lane); Amy Burns (AllCare CCO); Gina Guinasso (Acorda); Bruce Howard (Acorda); Phillip Kenner (Accorda)*; Joe Chan (Otsuka America); Patrick Moty (Supernus); Dean Haxly (OSU); John McIlveen, PhD, LMHC (OHA – Addictions & Mental Health)*

(*) Provided verbal testimony

I. CALL TO ORDER

- a. The meeting was called to order at approximately 1:10 pm. Introductions of Committee members and staff.
- b. Mr. Citron reported there are no new conflicts of interest to declare.
- c. The July 25th meeting minutes were reviewed. (pages 3 - 8)

ACTION: Motion, Approved as is.

- d. Department updates by Dr. Trevor Douglass.
Dr. Douglass announced OHA is currently seeking and will be hiring a new Policy Manager for the Pharmacy Division. This will occur by the end of December. Mr. Citron explained the state is looking at the implementation of the policy regarding sanctioned providers and how that would affect the Point of Sale system for Pharmacy.
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II. DUR ACTIVITIES

- a. Quarterly Utilization Reports (page 9) Third quarter 2013
Drug Utilization Review, Federally required, for state Medicaid that provide coverage. (Hand out given) Changes on report include (1) encounter data from CCO's; (2) Quarterly rebates invoiced CMS and supplemental rebates; (3) Physician administered drugs.
 - b. ProDUR Report (page 13) also 2 page hand out
Mr. Holsapple gave the highest volume of ProDUR alerts. Reports generated provide early refill, therapy changes, and or loss of medication. Pharmacies do have ability to override with clarification code.
 - c. RetroDUR report (page 14-16)
Dr. Williams stated there will be a new format effective in January.
 - d. Oregon State Drug Reviews
 - 1. Managing Metabolic Side Effects in Children Receiving Antipsychotics. (Page 17 - 18) Ms. Sentena presented the newsletter.
 - 2. Updates and Comparisons of Type 2 Diabetes Guidelines. (Page 19-20)
Ms. Sentena presented the second part of the newsletter.
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III. PREFERRED DRUG LIST NEW BUSINESS

- a. Vivitrol® (naltrexone) New Drug evaluation (Page 21-34)
Dr. Liang presented the following information: Naltrexone injection is indicated for the treatment of alcohol dependence in patients who are able to abstain from alcohol in an outpatient setting prior to initiation of treatment with naltrexone. It is also indicated for the prevention of relapse to opioid dependence following opioid detoxification. It should be part of a comprehensive management program that includes psychosocial support.

Conclusion was:

- 1. Evaluate comparative costs of injectable extended release naltrexone in executive session and require prior authorization for the use in opioid dependence requiring:
 - 2. The failure of other oral agents for the treatment of opioid dependency OR the patient requires injectable therapy
 - 3. The member is part of a comprehensive treatment program for substance abuse that includes a psychosocial support system.
 - 4. Patients be opioid free for 7 days prior to administration.
- b. Allow for use in alcohol dependence until a subsequent full evidence review is done.

Public Comment: Dr. McIlveen offered to help with any information and or studies regarding the pharmaceuticals for Alcohol and drug dependence. He is also going to help with the language for the Prior Authorization.

Jo Crawford from Serenity Lane (Alcohol and Drug Treatment Program) testified regarding the success they have had at their clinic using Vivitrol® with certain clients.

- c. *(After Executive Session) Make Vivitrol non-preferred. Will bring back full alcohol dependence review when literature is fully published. Committee and staff will work with Dr. John McIlveen to clarify and tighten PA criteria.

IV. HCMB Subcommittee Follow-Up

- a. Subcommittee Report (Page 35-36)
Dr. Douglass stated that if medication is not on a list, there will be a pathway for Coverage for that drug that has appropriate criteria.
- b. Ampyra® (dalfampridine)
- c. Kuvan® (saproterin)

Public Comment: Phillip Kenner testified the studies showed improvement in walking for clients. An MSW S12 study validated the outcome with improvement in all 12 areas tested, they updated safety data, and there were no new safety signals. There is value if patients are able to try the product.

1. Add Kuvan® (saproterin) to the HCMB list.
2. Add Ampyra® (dalfampridine) to the HCMB list.
3. Change the language in the Kuvan® PA criteria to criteria #4 to: *Is the patient "compliant" with a Phe-restricted diet.*

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

V. DUR OLD BUSINESS

- a. Juxtapid® (lomitapide) and Kynamro® (mipomersen) (Page 37-38)
Ms. Ketchum presented the following updates:
 1. Approve modified PA criteria to remove language approving treatment if LDL-C apheresis is not available to them and changing the length of approval from 6 months to 1 year.

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

VI. DUR NEW BUSINESS

- a. Benzodiazepine Drug Use Evaluation (Page 39-51)
Ms. Ketchum to presented the following updates:
 1. To prevent inappropriate long-term use, require prior approval for exceeding 4 weeks on newly started patients only. (no history within the last 100 days)
 2. Approval would be granted in any of the following situations:
 - i. Clinical Rationale to support long-term BZO use for supplied indication(s)
 - ii. No concurrent sedative / hypnotic or opioid
 - iii. Dose <3 mg diazepam equivalents

Recommendations to OHA:

1. Approve amended prior approval and bring back more data and information. Consider targeted education to those at high risk of mortality and piloting these interventions at a high risk clinic.
2. Bring back a policy evaluation after the first quarter of implementation.
3. Change “evidence to support” to Clinical Rationale.

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

VII. PREFERRED DRUG LIST OLD BUSINESS

a. Diabetes Class Clarification (Pages 52 -80)

Mr. Citron gave the following updates:

1. In addition to requiring prior authorization as decided upon in the September P&T meeting, make the new combination products alogliptin / pioglitazone (Oseni®) and alogliptin / metformin (Kazano®) non-preferred.
2. *(After executive session) - Keep the new combination products alogliptin / pioglitazone (Oseni®) and alogliptin / metformin (Kazano®) non-preferred.

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

VIII. PREFERRED DRUG LIST NEW BUSINESS (continued)

a. First Generation Antipsychotic Review (Pages 81-102)

Dr. Herink presented the following information:

1. To reduce the copay burden, first generation antipsychotics should be included on the voluntary PDL list to promote the use of cost-effective and individualized treatment options for schizophrenia and bipolar disorder. Evaluate comparative costs in executive session.
2. Further review the second generation antipsychotics at an upcoming meeting for comparative effectiveness and safety.
3. *(After executive session) Add class to PDL and make all FGA preferred.

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

b. Chronic Obstructive Pulmonary Disease (COPD) (Pages 103-132)

Dr. Meeker presented the following information:

1. Due to no evidence demonstrating clinical superiority of fluticasone / vilanterol over current agents, recommended making it non preferred.
2. Recommend adding fluticasone / vilanterol to the LABA/ ICS prior authorization criteria and limiting to patients who have COPD.
3. Due to strong comparative effectiveness of superiority between other agents, recommend comparing costs in executive session and maintaining tiotropium as preferred due to evidence of superiority over ipratropium.
4. *(After executive session) – Guidelines to be amended to fit with new GOLD COPD classification.
5. *(After executive session) – No changes to the PDL.

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

c. Parkinson's Disease Drugs (Pages 133-146)

Dr. Herink presented the following information:

1. There is insufficient evidence that rotigotine (Neupro®) is more efficacious or safer than other oral dopamine agonists in the treatment of Parkinson's Disease. Evaluate in executive session for relative cost.

2. *(After executive session) – No changes to the PDL.

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

d. Statin Medications (Pages 147-163)

Dr. Herink presented the following information:

1. There is insufficient comparative evidence on long term clinical outcomes or evidence that one agent is safer than another. Evaluate comparative costs in executive session.
2. *(After executive session) – No changes to the PDL.

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

e. Drug Class Scans

1. Newer Antiemetics (Pages 164-174)

Dr. Herink presented the following information:

- i. There is evidence that palonosetron may be superior to other 5HT3 antagonists in the treatment of chemotherapy induced nausea and vomiting for moderately emetogenic chemotherapy and that ondansetron, dolasetron, and granisetron are equally effective.
- ii. There is low quality evidence that the combination of doxylamine / pyridoxine led to significantly greater improvement in nausea vomiting symptoms as compared with placebo (-4.8 PUQE score vs 3.9; p=0.006) but insufficient comparative evidence compared to other available agents. Maintain as non-preferred.
- iii. Evaluate comparative costs in executive session.
- iv. *(After executive session) – No changes to the PDL.

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

2. Newer Drugs for Insomnia (Pages 175-200)

Dr. Herink presented the following information:

- i. No further research or review needed at this time.
- ii. Evaluate comparative costs in executive session.
- iii. Consider DUR evaluation and safety edit for zolpidem.
- iv. *(After executive session) – Bring back zolpidem DUE with potential safety recommendations. No PDL changes.

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

3. Nonsteroidal Antiinflammatory Drugs (Pages 201-216)

Dr. Herink presented the following information:

- i. No further research or review needed at this time.
- ii. Evaluate comparative costs in executive session.
- iii. *(After executive session) – Bring back information to assess the safety of diclofenac. No PDL changes at this time.

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

4. Skeletal Muscle Relaxants (Pages 217-230)

Dr. Herink presented the following information:

- i. No further research or review needed at this time.
- ii. Evaluate comparative costs in executive session.
- iii. *(After executive session) – No PDL changes at this time.

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

IX. EXECUTIVE SESSION

X. RECONVENE for PUBLIC RECOMMENDATIONS

Mr. Citron confirmed to the public of the next P & T meeting will be held in November.

VII. ADJOURN