Drug Use Research & Management Program
OHA Division of Medical Assistance Programs
500 Summer Street NE, E35; Salem, OR 97301-1079
Phone 503-947-5220 | **Fax** 503-947-1119

Oregon Drug Use Review / Pharmacy & Therapeutics Committee
Thursday, May 26, 2016 1:00-5:00 PM
DHS Barbara Roberts Building
500 Summer St. NE
Salem, OR 97301

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; Bill Origer, MD; Rich Clark, MD, MPH; James Slater, PharmD; Walter Hardin, D.O., MBA; Phillip Levine, PhD; Caryn Mickelson, PharmD; Tracy Klein, PhD, FNP;

Members Present by Phone:

Staff Present: Megan Herink PharmD, BCPS; Richard Holsapple, RPh; Roger Citron, RPh; Ted Williams, PharmD; Dee Weston; Dave Engen, PharmD; Andrew Gibler, PharmD; Kathy Ketchum, RPh. MPA:HA; Kim Wentz, MD; Deanna Moretz, PharmD; Elizabeth Le, PharmD PGY2 Resident

Staff Present by Phone: Kathy Sentena, PharmD;

Audience: Lyle Laird (Sunovion Pharmaceuticals)*; Kim Laubmeier (Sunovion Pharmaceuticals)*; Mary Kemhus (Novartis); Joe Schreck (Allergan); Karen Nishihara (Alkermes)*; Laura Litzenberger (Janssen)*; Laurence Ikeda (Pfizer)*; Mike Willett (Pfizzer); Bobbi Jo Drumm (BMS); Jennifer Svec (MedImpact); Barry Benson (Merck); Ann Neilson (ZS Pharma); Bob Gustafson (Lundbeck); John Schillo (Lundbeck); Steven Hill (Relypsa); Beth Clark (Relypsa)*; Samantha Sweeney (Otsuka); Jacob White (UCB); Mindy Schimpf (UCB); Melissa Snider (Biomarin)*; Jill Kerrick Walker, PharmD (Acorda); Heather Williams-Downing (Acorda); Rick Frees (Vertex); Kelli Strother (Otsuka); Don Stecher (Novartis); Jennifer McElravey, RPh (OHSU); Courtney Strouse (OSU COP); Johnathan Nyo (OSU COP); Dean Haxby (OSU); Amy Burns (AllCare Health); Tony Jelinek (Reckitt Benckiser); Jeana Colabianchi, PharmD (Sunovion); Willram Kennon, Rph (Cascadia Health Alliance); Lisa Boyle, Rph (WVP Health Authority); Jennifer Stout Leyden, Rph (WVP); Rayan Shadralch; Paul Monham (Novo Nordisk); Kerry Bonilla (AstraZeneca); Pierre Thoumsin (Pfizer);

(*) 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.

d. Department updates for OHA.

II. DUR ACTIVITIES

a. Quarterly Utilization Reports (pages 27 – 29)
Presented by Mr. Citron.

b. ProDUR Report (pages 15 – 17)
Presented by Mr. Holsapple.

c. RetroDUR Report (pages 18- 22)
Presented by Dr. Williams.

d. Oregon State Drug Reviews (pages 23 – 26)
Presented by Dr. Sentena.

1. 2015 in Review: Relevant Safety Updates and Ongoing Safety Concerns (23 – 24)
2. Antidiabetic Treatments and Cardiovascular Implications (25 – 26)

Dr. Clark voiced concern that the newsletter appeared to indicate that the results of the empagliflozin study were misrepresented and asked staff to review and consider a retraction or revision.

III. DUR NEW BUSINESS

Abbreviated Clinical Prior Authorization Reviews

a. Ampyra® (dalfampridine) (pages 27 – 29)
Dr. Moretz presented the clinical authorization review.

1. No further research is needed at this time.
2. Maintain current PA policy.

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

b. Kynamro® (mipomersen) and Juxtapid® (lomitapide) (pages 30 – 33)
Dr. Moretz presented the clinical authorization review.

1. No further research is needed at this time.
2. Maintain current PA policy.

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

c. Kuvan® (saproterin) (pages 34 – 36)
Dr. Moretz presented the clinical authorization review.

1. No further research is needed at this time.
2. Maintain PA criteria and update target Phe levels per guideline.

Public Comment:
Melissa Snider from Biomarin gave public comment.

ACTION: Motion to approve as amended, 2nd. All in favor. Approved.

IV. PREFERRED DRUG LIST NEW BUSINESS

a. New Drug Evaluations for COPD

1. Utibron™ Neohaler® (indacaterol/ glycopyrrolate) (pages 37 – 49)
   Dr. Sentena presented the new drug evaluation.

   a. Designate GLY as non-preferred due to insufficient evidence.
   b. Designate IND/ GLY as non-preferred and subject to LAMA/LABA PA criteria.
   c. Evaluate comparative costs in executive session.

   No Changes to PMPDP.

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

2. Seebri™ Neohaler® (glycopyrrolate) (pages 37 – 49)
   Dr. Sentena presented the new drug evaluation.

   a. Designate GLY as non-preferred due to insufficient evidence.
   b. Designate IND/ GLY as non-preferred and subject to LAMA/ LABA PA criteria.
   c. Evaluate comparative costs in executive session.

   No Changes to PMPDPD.

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

b. Antipsychotics Drug Class Update (pages 50 – 88)
   Dr. Gibler presented the following class updates.

   1. No changes to the PDL based on the clinical evidence.
   2. Perform and present DUE.
   3. Evaluate comparative costs in executive session.

Public Comment:
Lyle K. Laid, PharmD from Sunovion Pharmaceuticals Inc. gave public comment.
Kim Laubmeier from Sunovion Pharmaceuticals Inc. gave public comment.
Karen Nishihara from Alkermes gave public comment.
Laura Litzenberger from Janssen gave public comment.

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

c. Long-acting Opioids Drug Class Update (pages 89 – 120)
   Dr. Gibler presented the following class update.

   1. No changes to the PDL based on the clinical evidence.
   2. Approve proposed opioid analgesics PA criteria as amended, including:

a. Ask if the opioid prescription is for pain diagnosis associated with back or spine conditions as defined by the OHP list of Prioritized Services, or for migraine headache.
b. Add examples of validated tools that assess functions as outlined in Guideline Note 60 of the OHP List of Prioritized Services

3. Discontinue PAs for Methadone, Opioid/non-opioid fixed dose combination products, and short-acting fentanyl products.
4. Present plan to P&T of how to reach ultimate coverage goal, monitor impact and perform provider education.
5. Evaluate comparative costs in executive session

Public Comment:
Laurence Ikeda from Pfizer gave public comment.

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

d. Smoking Cessation Drug Class Update (pages 121 – 144)
Deferred to future meeting.

e. Cough and Cold Drug Class Update (pages 145 – 156)
Ms. Ketchum presented the following class update.

1. Prefer no expectorants and remove all guaifenesin single ingredient products (HSN = 000271) from the PMPDP.
2. Ensure there is a minimum of 1 product with codeine and 1 with dextromethorphan preferred on the PDL for refractory cough.
3. Expand the pediatric restriction (children 13 years of age and older) to all cough and cold products.
4. Restrict codeine cough products to adults (19 years of age and older) and update Codeine PA criteria to reflect.
5. Evaluate comparative costs in executive session.

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

f. Vyvanse™ (lisdexamfetamine) New Indication Evaluation (pages 157 – 165)
Ms. Ketchum presented the following new indication.

Updated the current PA criteria to include BED indication.

The committee deferred taking action on the proposed changes to the ADHD PA criteria until July when the ADHD DUE will be presented. The committee asked that options be considered for restricting use of Vyvanse for BED to second line therapy in the PA criteria.

ACTION: Deferred to July.

g. Veltassa® (patiromer) New Drug Evaluation (pages 166 – 180)
Dr. Herink presented the following new drug evaluation.

1. Defer PDL decisions until a review of sodium polystyrene sulfonate and zirconium cyclosilicate (awaiting FDA approval) at future P&T meeting.
2. Approve proposed PA criteria to prevent use in the emergent setting or in scenarios not supported by the medical literature.

Public Comment:
Elizabeth Clark from Relypsa gave public comment.

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

h. Zurampic® (lesinurad) New Drug Evaluation (pages 181 – 190)
Deferred to future meeting.

i. Briviact® (brivaracetam) New Drug Evaluation (pages 191 – 200)
Deferred to future meeting.

j. Drug Class Literature Scans

1. Erythropoiesis Stimulating Agents (pages 201 – 207)
Scan deferred to future meeting.

2. Antivirals for Herpes Simplex Virus (pages 208 – 217)
Scan deferred to future meeting.

V. EXECUTIVE SESSION

VI. RECONVENE FOR PUBLIC RECOMMENDATIONS * After executive session

a. New Drug Evaluations for COPD (pages 37 - 49)
***ACTION:** recommend no changes to the PMPDP
Motion, 2nd, All in Favor. Approved.

b. Antipsychotics Drug Class Update (pages 50 – 88)
***ACTION:** Make Latuda™ preferred contingent upon SR.
Make Saphris™ preferred contingent upon SR.
Make Abilify Maintenna preferred contingent upon SR.
Monitor market shift.
Make chlorpromazine voluntary non-preferred (no PA required)
Perform change form request.
Maintain brexpiprazole Voluntary non-preferred.
Maintain cariprazine Voluntary non-preferred.
Motion, 2nd, All in Favor. Approved.

c. Long-acting Opioids Drug Class Update (pages 89 – 120)
ACTION: ~~Approved PA criteria changes~~.
Recommend no changes to the PMPDP.
Motion, 2nd, All in Favor. Approved.

d. Cough and Cold Drug Class Update (pages 145 – 156)
***ACTION:** Make benzonatate non-preferred.
Motion, 2nd, All in Favor. Approved.

VII. ADJOURN