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: Bill Origer, MD; Rich Clark, MD, MPH; Walter Hardin, D.O., MBA; Phil Levine, PhD; Caryn Mickelson, PharmD

Members Present by Phone: Tracy Klein, PhD, FNP; Dave Pass, MD; Kelly Burnett, DO; Stacy Ramirez, PharmD

Staff Present: Andrew Gibler, PharmD; Kathy Sentena PharmD; Richard Holsapple, RPh; Roger Citron, RPh; Dee Weston; Sarah Servid, PharmD; Kim Wentz, MD; Deanna Moretz, PharmD, BCPS; Sarah Servid, PharmD; Kim Wentz, MD; Deanna Moretz, PharmD, BCPS; Lindsay Newton;

Staff Present by Phone:

Audience: *Deb Profant/Alkermes; Joe Schreck/Allergan; *Martin Klos/MD; *Curtis Sianchuk/Intercept; *Rajesh Patel/Intercept; Georjette Dawilewski/Indivior; *Harish Thiagaraj/Rph; KJ Jackson/Trividia Health; *Margaret Olmon/AbbVie; *Tim Murphy/Bridgeway Recovery Services; *Eric Geisler MD/Serenity Lane Treatment Center; Lisa Boyle/ WVP Health Authority; Melissa Smith/OSU; Jennifer Srec/Medimpact; Dean Hayley/OSU; Jeana Colabianchi/Sunovion; Kerry Kostman Bonilla; *Alex Cuyler/Lane County

(*) Provided verbal testimony

Written testimony provided:

I. CALL TO ORDER

A. The meeting was called to order at approximately 1:01 pm. Introductions were made by Committee members and staff.
B. Mr. Citron reported there were no new conflicts of interest to declare.

C. Election of chair and vice chair for 2017. Bill Origer was nominated as chair and Tracy Klein was nominated as vice chair.

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

D. Approval of agenda and November minutes presented by Mr. Citron. (pages 5 - 9)

ACTION: Motion to approve, 2nd, All in Favor.

E. Department updates for OHA presented by Ms. Weston.

II. DUR ACTIVITIES

A. Buprenorphine and Vivitrol Drug Policies (pages 10-14) – presented by Dr. Gibler
   1. Remove PA for Suboxone (buprenorphine/naloxone) sublingual tablets unless average daily dosage exceeds 24 mg of buprenorphine
   2. Remove pharmacy lock-in requirement since prescribers are asked to routinely check the Oregon Prescription Drug Monitoring Program (PDMP)
   3. Remove PA for Vivitrol ® (naltrexone ER injection) and add the agent to the PDL

ACTION: Motion to approve proposal, 2nd. 8 in favor, 1 opposed. Approved.

B. Oral Multiple Sclerosis Drug Policy (pages 15-17) – presented by Dr. Gibler
   1. Deny use of an oral MS agent if no form of relapsing multiple sclerosis is present.

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

III. PREFERRED DRUG LIST NEW BUSINESS

A. Gout Drugs Class Update (pages 18 - 32)
   Dr. Sentena presented the class update and following recommendation:

   1. Continue preferred status for allopurinol on the PDL.
   2. Approve clinical PA criteria for non-preferred drugs as presented with the addition of question 8 added back in.

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

B. Conventional Antiemetics Class Review (pages 33 - 61)
   Dr. Moretz presented the class update and the following recommendation:

   1. Add conventional antiemetics to the OHP FFS PMPDP.
2. Designate scopolamine, dimenhydrinate, and meclizine as non-preferred since these drugs are primarily prescribed for nonfunded conditions.

3. Consolidate the current clinical PA criteria for newer antiemetics and dronabinol into one policy which requires approval by the Committee. Move question #11 to the #2 spot. Non-preferred conventional antiemetics will also be subject to this PA.

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

C. Hormone Replacement Therapy Class Update (pages 62 - 97)

Dr. Servid presented the scan and following recommendation:

1. Combine progestin agents into one PDL class and designate at least one preferred product for FDA-approved indications funded by the OHP (i.e., endometriosis, endometrial cancer, endometrial hyperplasia, abnormal bleeding disorders, and prevention of preterm birth) based utilization and comparative drug costs in the executive session.

2. Restrict non-funded use of ospemifene by PA.

3. Update clinical PA criteria for hydroxyprogesterone caproate that will apply to both branded and generic products and apply to pharmacy and physician-administered claims.

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

D. Antidiarrheals Class Review (pages 98 - 110)

Dr. Moretz presented the class update and the following recommendations:

1. Add antidiarrheal medication class to the OHP FFS PMPDP and designate all drugs except Loperamide as non-preferred to restrict use to only funded conditions.

2. Add quantity limits to loperamide, diphenoxylate/atropine, and crofelemer to insure safe and appropriate use:
   a. Loperamide: maximum 16 mg per 24 hours
   b. Diphenoxylate/atropine: maximum 20 mg/0.2 mg per 24 hours
   c. Crofelemer: maximum 500 mg per 24 hours

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

E. Vitamin D Analogs Class Review (pages 111-125)

Dr. Sentena presented the following class update and recommendations:

1. Add Vitamin D analogs to the OHP FFS PMPDP.

2. Continue to keep calcitriol as the only preferred vitamin D analog and designate paricalcitol, doxercalciferol and calcifediol non-preferred.

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

F. Ocaliva® (obeticholic acid) New Drug Evaluation (pages 126-139)
Dr. Servid presented the class update along with the following recommendations:

1. Incorporate STC 05 Bile Therapy drugs (obeticholic acid, ursodiol, cholic acid) into one PDL class.
2. Designate ursodiol as a preferred agent and obeticholic acid as a non-preferred agent. No other recommendations for other bile therapy medications will be made at this time.
3. Approve proposed clinical PA criteria as amended below* for all non-preferred drugs which restricts use of obeticholic acid to populations that may benefit from this therapy without undue harm.

*In the PA for obeticholic acid, re-phrase wording for #4 to ask if patient has no evidence of complications from cirrhosis or hepatic decompensation; re-phrase wording for #5 to ask if the total bilirubin level is less than 2-times the upper limit of normal. Deny claim if either criteria is not met.

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

G. Adlyxin® (lixisenatide) New Drug Evaluation (pages 152-163)
Dr. Sentena presented the class update along with the following recommendation:

1. Designate lixisenatide non-preferred and subject to current prior authorization (PA) criteria for GLP-1 receptor agonists.

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

H. Zinbryta™ (daclizumab) New Drug Evaluation (pages 164-179)
Dr. Moretz presented the class update along with the following recommendations:

1. Designate daclizumab as non-preferred and approve proposed clinical PA criteria which limit use to:
   a. Adult patients with relapsing MS; and
   b. Without hepatic disease; and
   c. Higher degree of ambulatory ability (EDSS ≤ 5); and
   d. History of inadequate response to at least 2 disease modifying agents approved for MS; and
   e. Prescribed by a neurologist.

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

I. Nuplazid™ (pimavanserin) New Drug Evaluation (pages 180-191)
Dr. Servid presented the class update along with the following recommendation:

1. Approve proposed safety edit to restrict use of the drug to populations that may benefit without undue harm.

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

J. Xiidra™ (lifitegrast) New Drug Evaluation (pages 192-202)
Dr. Sentena presented the class update along with the following recommendation:

1. Restrict non-funded use of lifitegrast ophthalmic solution by PA.

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

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**V. EXECUTIVE SESSION**

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**VI. RECONVENE FOR PUBLIC RECOMMENDATIONS * After executive session**

A. Gout Drugs Class Update (pages 18 - 32)
   * **ACTION:** No changes to the PDL.
   Motion, 2nd, All in Favor. Approved.

B. Conventional Antiemetics Class Review (pages 33 - 61)
   * **ACTION:** Make dronabinol and nabilone non-preferred, subject to approved clinical PA criteria. Make metoclopramide rapid dissolving tablets non-preferred. Make trimethobenzamide non-preferred. Make promethazine and prochlorperazine tablets, syrups and rectal suppositories, metoclopramide tablets and oral solutions and phosphoric acid/ dextrose/fructose preferred on the PDL.
   Motion, 2nd, All in Favor. Approved

C. Hormone Replacement Therapy Class Update (pages 62 - 97)
   * **ACTION:** No PDL changes to the estrogen classes recommended. Make medroxyprogesterone acetate tablets, micronized progesterone capsules, norethindrone acetate tablets, and Depo-Provera injection preferred on the PDL. Keep Makena (hydroxyprogesterone caproate) preferred and make all other progestins non-preferred.
   Motion, 2nd, All in Favor. Approved

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**VII. ADJOURN**