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 in accordance with Oregon Revised Statute 183.333

Members Present: Mark Helm, MD, MBA, FAAP; Caryn Mickelson, PharmD; Russell Huffman, DNP, PMHNP; Tracy Klein, PhD, FNP; William Origer, MD; James Slater, PharmD; Stacy Ramirez, PharmD; Cathy Zehrung RPh;

Staff Present: Roger Citron, RPh; David Engen, PharmD; Andrew Gibler, PharmD; Richard Holsapple, RPh; Deanna Moretz, PharmD; Sarah Servid, PharmD; Sara Fletcher, PharmD; Kathy Sentena, PharmD; Dee Weston, JD; Brandon Wells; Jennifer Bowen

Audience: Karen Einbinder, Greenwich Biosciences; Adam Kopp, Zogenix Inc.; Amiee Weems, Acorda Therapeutics; Amy Burns, Allcare; Andrea Wilcuts, Takeda; Anthony Wheeler, Eli Lilly; Brandon Yip, Sanofi; Bruce Wallace, Azurity; Camille Kerr, Regeneron; Chi Kohloff, Viela Bio; Christina Hartmann; Dan Allen, Sanofi-Genzyme; Dave Huges; David Nagarkatti-Gude; Debbie Sheppe, Neurelis; Dennis Schaffner, Sanofi-Genzyme; Deron Grothe, Teva Pharmaceuticals; Elise Conlee, Greenwich Boisciences; Jena Ritter; Jeanne Vander Zanded; Jeffery Mussack, Braeburn Inc.; Jennifer Shear, Teva; Kaite Scheelar; Keely Larson, Bayer Healthcare; Kim Tran; Lori Howarth, Bayer; Lori McDermott, Supernus; Margaret Olmon, AbbVie; Marissa Tabile; Mark Kantor, AllCare; Timothy McFerron, Alkermes; Michael Fifer, Providence; Michael Foster, BMS; Nena Hartman, Neurocrine Biosciences; Nick Kashey; Carrie Johnson, Amgen; Nichole Robline, Otsuka; Paul Thompson, Alkermes; Robb Host Neurelis; Robin Traver, Umpquah Health; Roy Lindfield, Sunovion; Shannon Lee, Trillium; Shirley Quach, Novartis; Sibin Stephen, Zogenix; Stephanie Kennedy, Greenwich Biosciences; Suzanne Gauen, Providence; Terry Cadenasso, Acorda Therapeutics; Venus Holder, Eli Lilly; William O’Neill, Sunovion; Amanda Parrish
I. CALL TO ORDER

A. The meeting was called to order at approximately 1:05 pm. Introductions were made by Committee members and staff
B. Conflict of Interest Declaration - No new conflicts of interest were declared
C. Approval of August 2020 minutes presented by Mr. Citron
   ACTION: Motion to approve, 2nd, all in favor
D. Department Update provided by Dee Weston
E. Covid-19 Updates

II. CONSENT AGENDA TOPICS

A. Oncology Policy Update
B. Orphan Drug Policy Update
   ACTION: Motion to approve, 2nd, all in favor

III. DUR NEW BUSINESS

A. Bipolar Drug Use Evaluation (DUE)
   Doctors Nick Kashey, MD and David Nagarkatti-Gude, MD from the Mental Health Clinical Advisory Group (MHCAG) presented the MHCAG Acute Bipolar Depression and Acute Bipolar Mania treatment algorithms.

   Doctor Sarah Servid, PharmD presented the Bipolar DUE and proposal to:

   1. Implement a targeted profiled review of patients with bipolar disorder who have frequent hospitalization or emergency room visits for psychiatric reasons to identify areas for optimization of medications and notify prescribers if opportunities to improve care are identified
   2. Prioritize patients with 3 or more hospitalizations or ED visits over 6 months for psychiatric reasons and who: 1) appear non-adherent to current therapy; or 2) are prescribed regimens not recommended by the OHA and Mental Health Clinical Advisory Group. Non-recommended regimens may include patients with 3 or more bipolar medications, patients prescribed antidepressant monotherapy, or patients who use aripiprazole for bipolar depression

(*) Provided verbal testimony

Written testimony: Posted to OSU Website
IV. PREFERRED DRUG LIST NEW BUSINESS

A. Atopic Dermatitis (AD) Literature Scan
Dr. Moretz presented the proposal to:
1. Revise the prior authorization (PA) criteria for AD and topical antipsoriatics to reflect the expanded indication for crisaborole in children aged 3 months and older with moderate AD
2. Revise the PA criteria for dupilumab to reflect expanded indication for management of moderate-to-severe AD not well controlled by topical prescription medications in children older than 6 years of age

ACTION: Motion to approve, 2nd, all in favor

B. Asthma COPD Class Update
Dr. Sentena presented the proposal to:
1. Make no changes to the PMPDP based on clinical evidence
2. Update the clinical definition of severe and very severe COPD in the roflumilast PA criteria
3. Clarify the age recommendations for use of monoclonal antibodies

Public Comment: Jennifer Shear, Teva Pharmaceuticals

ACTION: The Committee amended the proposed Roflumilast PA criteria to include that the request be from or in consultation with pulmonary specialist
Motion to approve, 2nd, all in favor

C. Antiepileptic (non-injectable) Class Update and New Drug Evaluation (NDE)
Dr. Moreetz presented the proposal to:
1. Designate fenfluramine as non-preferred on the PMPDP and to implement the proposed PA criteria to ensure medically appropriate utilization
2. Revise the PA criteria for cannabidiol to reflect the expanded indication and appropriate dosing for tuberous sclerosis complex (TSC) in patients 1 year of age and older
3. Rename Antiepileptics class from “oral and rectal” to “non-injectable” to account for nasal formulations
Public Comments: Sibin Stephen, Zogenix; Debbie Sheppe, Neurelis; Stephanie Kennedy Greenwich Biosciences

ACTION: Motion to approve, 2<sup>nd</sup>, all in favor

D. Antacids: Proton Pump Inhibitors and H2 Receptor Antagonists Class Update
Dr. Sentena presented the proposal to:
   1. Make no changes to the PMPDP based on clinical evidence
   2. Modify PPI PA criteria to clarify durations of therapy

ACTION: Motion to approve, 2<sup>nd</sup>, all in favor

E. Parkinson’s Disease Class Update and NDEs
Dr. Gibler presented the proposal to:
   1. Designate istradefylline, opicapone and apomorphine sublingual as a non-preferred on the PMPDP based on the clinical evidence and availability of several first-line agents
   2. Update the Anti-Parkinson’s Agents PA criteria to ensure safe and appropriate use of the new agents

Public Comment: William O’Neill, Sunovion Pharmaceuticals

ACTION: Motion to approve, 2<sup>nd</sup>, all in favor

F. Biologics for Autoimmune Conditions DERP Summary and Policy Evaluation
Dr. Moretz presented the DERP summary and proposal to:
   1. Make no changes to the PMPDP based on clinical evidence
   2. Modify the PA criteria to reflect updated indications for the Targeted Immune Modulator agents as proposed

Dr. Servid presented the Policy Evaluation and recommended:
   1. Make no policy changes based on current utilization data
   2. Continue to monitor trends in utilization

Public Comment: Shirley Quach, Novartis; Margaret Olmon, AbbVie; Anthony Wheeler, Eli Lilly; Carrie Johnson, Amgen

ACTION: Motion to approve, 2nd, all in favor
V. DUR NEW BUSINESS (continued)

B. Modafinil/armodafinil Drug Use Evaluation (DUE)
ACTION: Committee reviewed the DUE and recommended modifying the modafinil/armodafinil PA criteria to prevent inappropriate use during pregnancy and in women of childbearing age.
ACTION: Motion to approve, 2nd, all in favor

VI. EXECUTIVE SESSION

Members Present: Mark Helm, MD, MBA, FAAP; Caryn Mickelson, PharmD; Russell Huffman, DNP, PMHNP; Tracy Klein, PHD, FNP; William Origer, MD, James Slater, PharmD; Stacy Ramirez, PharmD; Cathy Zehrung RPh

Staff Present: Roger Citron, RPh; David Engen, PharmD; Richard Holsapple, RPh; Deanna Moretz, PharmD; Sarah Servid, PharmD; Sara Fletcher, PharmD; Kathy Sentena, PharmD; Dee Weston, JD; Brandon Wells; Jennifer Bowen

VII. RECONVENE for PUBLIC RECOMMENDATIONS

A. Parkinson’s Disease Class Update and NDEs:
Recommendation: Make amantadine capsules and tablets preferred
ACTION: Motion to approve, 2nd, all in favor

B. Asthma/COPD Class Update
Recommendation: Make Tudorza® Pressair non-preferred and make AirDuo RespiClick®, Anoro Ellipta, and Stiolto® Respimat® preferred
ACTION: Motion to approve, 2nd, all in favor

C. Antiepileptics (non-injectable) Class Update and NDE
Recommendation: make fenfluramine non-preferred
ACTION: Motion to approve, 2nd, all in favor

D. PPI and H2Ras Update
Recommendation: Make famotidine complete chew tablets nizatidine solution, Aciphex®, Dexilant®, Prevacid® DR capsules, and Pylera™ and lansopra/amoxicil/clarithro combo pack preferred
ACTION: Motion to approve, 2\textsuperscript{nd}, all in favor

E. Atopic Dermatitis Literature Scan
   \textbf{Recommendation:} Make no changes to the PMPDP
   \textbf{ACTION:} Motion to approve, 2\textsuperscript{nd}, all in favor

F. Biologics for Autoimmune Conditions
   \textbf{Recommendation:} Make secukinumab non-preferred
   \textbf{ACTION:} Motion to approve, 2\textsuperscript{nd}, all in favor

IX. ADJOURN