Drug Use Research & Management Program
OHA Health Systems Division
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, December 2nd, 2021 1:00 - 5:00 PM

Via Zoom webinar

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 in accordance with Oregon Revised Statute 183.333

Members Present: Cathy Zehrung, RPh; Cat Livingston, MD; Stacy Ramirez, PharmD; Tim Langford, PharmD; Caryn Mickelson, PharmD; Robin Moody, MPH; William Origer, MD; Mark Helm, MD; Russell Huffman, PMHNP; Patrick DeMartino, MD

Staff Present: Jennifer Bowen, Admin; Roger Citron, RPh; David Engen, PharmD; Sara Fletcher, PharmD; Lan Starkweather, PharmD; Deanna Moretz, PharmD; Sarah Servid, PharmD; Megan Herink, PharmD; Brandon Wells; Kyle Hamilton; Andrew Gibler, PharmD; Trevor Douglass, DC, MPH; Kathy Sentena, PharmD; Deborah Weston, JD

Audience: Becky Gonzales, ViiV Healthcare; Brandie Feger, Advanced Health; Donald Nopper, Apellis Pharmaceuticals; Edward Saito, Pacific University/Virginia Garcia; **Emily Smith, Zealand Pharma**; Haley Bruce, Artia Solutions; **Jamie Tobitt, Apellis Pharmaceuticals**; Jean Ritter, Zealand Pharma; Jeremy Strand, Alexion; Jody Legg; **Jonathan Frochtzwajg, Cascade AIDS project**; Katie Scheelar, EOCCO/Moda; Kelly Wright, Gilead Oncology; Laura Jeffcoat, Abbive; Mark Kantor, AllCare Health; Matt Worthy, OHSU; Matthew Ito, Regeneron; Melissa Snider; Michael Donabedian; Michael Foster, BMS; Olaf Reinwald, GBT; Rick Frees, Vertex Pharmaceuticals; Rob Perallon, Alexion; Roy Linfield, Sunovion; Shirley Quach, Novartis; **Sophia Yun, Janssen Scientific Affairs**; Stormy Cameron, Artia Solutions; **Stuart O'Brochta, Gilead**; Tanya Frost, Sites of Care; Tiina Andrews, Umpqua Health Alliance; Trent Taylor, JNJ; **Andrew Ahmann, OHSU; Maggi Olmon, AbbVie**

(*) Provided verbal testimony
Written testimony: Posted to OSU Website

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I. CALL TO ORDER

A. Roll Call & Introductions
   - Called to order at approx. 1:05 p.m., introductions by staff and Committee
B. Approval of Agenda
C. Conflict of Interest Declaration – no new conflicts of interest were declared
D. Approval of August 2021 Minutes presented by Roger Citron
   ACTION: Motion to approve, 2nd, all in favor
E. Department Update provided by Trevor Douglass

II. CONSENT AGENDA TOPICS

A. Oncology Prior Authorization (PA) Updates
Recommendations:
- Add the following new FDA-approved antineoplastic agents to Table 1 in the Oncology Agents prior authorization (PA) criteria: Scemblix® (asciminib); Exkivity™ (mobecertinib); Tivdak™ (tisotumab vedotin-tftv)

B. Orphan Drug Policy Updates
Recommendations:
- Update Table 1 in the Orphan Drugs PA criteria to support medically appropriate use of Tavneos™ (avacopan), Livmarli™ (maralixibat), and Bylvay™ (odevixibat) based on FDA-approved labeling

C. Inhaled Cystic Fibrosis Drugs Literature Scan
Recommendations:
- No PDL changes recommended based on the clinical evidence
- Maintain inhaled mannitol as non-preferred
- Evaluate costs in executive session

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

III. DUR ACTIVITIES

A. **ProDUR Report**: Lan Starkweather, PharmD
B. **RetroDUR Report**: Dave Engen, PharmD
C. **Oregon State Drug Review**: Kathy Sentena, PharmD
   - **Covid-19 Vaccine Update**
   - **Deprescribing Techniques to Minimize Safety Issues Associated with Inappropriate Polypharmacy**

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IV. DUR OLD BUSINESS

A. **Evkeeza™ (evinacumab-dgnb) Prior Authorization Update:** Megan Herink, PharmD
Recommendation:
- Update PA criteria to include renewal criteria
Public Comment: Matthew Ito, Regeneron
ACTION: The Committee recommended updating the PA criteria as proposed after amending to better assess clinical need by updating question #3 of the initial approval to require 12 weeks of maximally tolerated therapy. The Committee also recommended adding the proposed renewal PA criteria, but with an added question to evaluate pregnancy risk
Motion to approve, 2nd, All in favor

B. **Spravato® (esketamine) Safety Edit**: Sarah Servid, PharmD
Recommendation:
- Update the esketamine safety edit to clarify appropriate maintenance dose and use in patients with a history of substance use disorder
Public Comment: Sophia Yun, Janssen Scientific Affairs
ACTION: Motion to approve, 2nd, all in favor

V. DUR NEW BUSINESS

A. **HIV Pre-Exposure Prophylaxis Drug Use Evaluation**: Sarah Servid, PharmD
Recommendation:
- Develop an educational retrospective drug use review (DUR) program to improve provider knowledge of PrEP for patients with a recent STI, diagnosis of high-risk sexual behavior, or potential viral exposure
Public Comment: Jonathan Frochtzwajg, Cascade AIDS Project; Stuart O'Brochta, Gilead
ACTION: Motion to approve, 2nd, all in favor

VI. PREFERRED DRUG LIST NEW BUSINESS

A. **Glucagon Class Update with New Drug Evaluation (NDE)**: Kathy Sentena, PharmD
Recommendations:
- Make no changes to the PDL based on the review of recent clinical evidence
- Maintain dasiglucagon as non-preferred on the PDL
- Evaluate costs in executive session
Public Comment: Emily Smith, Zealand Pharma; Andrew Ahmann, OHSU
ACTION: Motion to approve, 2nd, all in favor

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B. **Paroxysmal Nocturnal Hemoglobinuria (PNH) Class Update and NDE**:
Deanna Moretz, PharmD
Recommendations:
-Revise ravulizumab PA criteria to reflect expanded indication for use in pediatric patients aged 1 month and older with PNH or atypical hemolytic uremic syndrome
- Revise dosing (Table 1) to reflect updated indications
- Add pegcetacoplan to the "Biologics for Rare Diseases" drug class on the PDL
- Implement PA criteria for pegcetacoplan to limit use to FDA-approved indications funded by the OHP
- Evaluate costs in executive session
Public Comment: Jamie Tobitt, Apellis Pharma
ACTION: The Committee recommended implementing the proposed recommendations after adding a question to require providers assess for uncontrolled hypertension prior to initiation of therapy for applicable agents - including Aimovig®
Motion to approve, 2nd, all in favor

C. **Gonadotropin-Releasing Hormone (GnRH) Modifiers Class Update and NDE:**
Deanna Moretz, PharmD
Recommendations:
- Implement new PA criteria for GnRH modifiers to evaluate GnRH antagonists separately from GnRH agonists
- Evaluate costs in executive session
Public Comment: Maggi Olmon, AbbVie
ACTION: Motion to approve, 2nd, all in favor

D. **Growth Hormone Class Update and NDE**: David Engen, PharmD
Recommendations:
- Maintain lonapegsomatropin as non-preferred in the Growth Hormone PDL class
- Update PA criteria for GH agents to include lonapegsomatropin
- Evaluate costs in executive session
ACTION: Motion to approve, 2nd, all in favor

E. **Bile Therapy Literature Scan and Prior Authorization Update**: Deanna Moretz, PharmD
Recommendations:
- Make no changes to the PDL based on the review of recent clinical evidence
- Modify obeticholic acid PA criteria to include recommended dosing parameters and safety precautions
- Evaluate costs in executive session
ACTION: Motion to approve, 2nd, all in favor

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VII. EXECUTIVE SESSION

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VIII. RECONVENE for PUBLIC RECOMMENDATIONS

A. **Inhaled Cystic Fibrosis Drugs Literature Scan**
Recommendation: Make tobramycin in sodium chloride (NaCl) nebulized solution preferred; Kitabis® Pak and its generic tobramycin nebulizer solution non-preferred on the PDL
ACTION: Motion to approve, 2nd, all in favor

B. **Glucagon Class Update and NDE**
Recommendation: No changes to the PDL are recommended
ACTION: Motion to approve, 2nd, all in favor

C. **Paroxysmal Nocturnal Hemoglobinuria (PNH) Class Update and NDE:**
Recommendation: Maintain pegcetacoplan as non-preferred on the PDL
ACTION: Motion to approve, 2nd, all in favor

D. **GnRH Modifiers Class Update and NDE**
Recommendation: Maintain relugolix/estradiol/norethindrone as non-preferred on the PDL
ACTION: Motion to approve, 2nd, all in favor

E. **Growth Hormone Class Update and NDE**
Recommendation: No changes to the PDL are recommended
ACTION: Motion to approve, 2nd, all in favor

F. **Bile Therapy Lit Scan and PA Update**
Recommendation: No changes to the PDL are recommended
ACTION: Motion to approve, 2nd, all in favor

VII. ADJOURN