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: Stacy Ramirez, PharmD; Douglas Carr, MD; Patrick DeMartino, MD; Russ Huffman, PMHNP; Cat Livingston, MD; Caryn Mickelson, PharmD; Robin Moody; Eddie Saito, PharmD

Staff Present: Roger Citron, RPh; David Engen, PharmD; Sara Fletcher, PharmD; Andrew Gibler, PharmD; Deanna Moretz, PharmD; Sarah Servid, PharmD; Kathy Sentena, PharmD; Lan Starkweather, PharmD; Brandon Wells; Trevor Douglass, DC, MPH; Amanda Parish, LCSW; Jennifer Bowen; Dee Weston, JD; Kyle Hamilton; Chris DeMars

Audience: Tara Gonzales, Sobi*; Christine Donahue, CSL Behring*; Rick Kegler, BioMarin*; Lynda Finch, Biogen*; Rochelle Yang, Teva*; Amy Breen, Teva; Cheryl Bondy, Sobi; Jonathan Abdul-Haqq, CSL Behring; Gibby Rodriguez; Madonna McGuire Smith, PNWBD; Kate Ramsay, EOCCO; Cecilia Stewart, EOCCO; Teresa Blair, Ipsen; Katie Vo, Ipsen; Bill McDougall, Biogen; Melissa Snider, Gilead; Melissa Abbott, Eisai; Craig Plauschinat, Eisai; Gary Parenteau, Dexcel; Matt Worthy, OHSU; Tiina Andrews, UHA; Sebastian Branton, student @ UHA; Brandie Feger, Advanced Health CCO; Lori McDermott, Viking HCS; Deron Grothe, Braeburn; Chris Johnson, Biomarin; Georgette Dzwilewski, Indivior; Nirmal Ghuman, Janssen; Susan Lattimore; Michele Sabados, Alkermes; Ann Nelson, Vertex; Alison Bass, CSL Behring; Shauna Wick, Trillium; Jeff White, Sumitomo; Lisa Pulver J&J; Bill Robie, NBDF; Richard Maloy

(*) Provided verbal testimony
I. CALL TO ORDER

A. Roll Call & Introductions
   - Called to order at approx. 1:05 p.m., introductions by Committee and staff
B. Conflict of Interest Declaration – no new conflicts of interest were declared
C. Approval of Agenda and August 2023 Minutes presented by Roger Citron, RPh
   ACTION: Motion to approve, 2nd, all in favor
D. Department Update provided by Andrew Gibler, PharmD

II. CONSENT AGENDA TOPICS

A. CMS Annual Report
B. P&T Annual Report
C. Colony Stimulating Factor (CSF) Class Update and New Drug Evaluation (NDE)
   Recommendation:
   - No PDL changes recommended based on the review of recently published evidence
   - Evaluate costs in executive session
D. Opioid Reversal Agents Class Update
   Recommendation:
   - No PDL changes recommended based on the review of recently published evidence
   - Evaluate costs in executive session
E. Substance Use Disorder Literature Scan
   Recommendation:
   - No PDL changes recommended based on the review of recently published evidence
   - Evaluate costs in executive session
F. Parenteral Antipsychotics Literature Scan
   Recommendation:
   - No PDL changes recommended based on the review of recently published evidence
   - Evaluate costs in executive session
G. Oncology Prior Authorization (PA) Updates
   Recommendation:
   - Add: Elrexfio (elranatamab-bcmm); Akeega (niraparib and abiraterone acetate); Vanflyta (quizartinib); and Talvey (talquetamab-tgvs) to table 1 in the Oncology Agents prior authorization (PA) criteria
H. Orphan Drug Policy Updates
   - Update Table 1 in the Orphan Drugs PA criteria to support medically appropriate use of Sohonos (palovarotene) and Veopo (pozelimab-bbfg) based on FDA-approved labeling
   ACTION: Motion to approve, 2nd, all in favor
III. PREFERRED DRUG LIST (PDL) NEW BUSINESS

A. RSV Prior Authorization Update: Kathy Sentena, PharmD
   Recommendation:
   - Update the clinical PA criteria to align with the Advisory Committee on Immunization
     Practices (ACIP) recommendations for combination use of prophylactic therapies
   Public Comment: Tara Gonzales, Sobi
   ACTION: Motion to approve, 2nd, all in favor

B. Gene Therapies for Hemophilia A, Hemophilia B, and Beta-thalassemia DERP Summary
   & NDE: Sara Fletcher, PharmD
   Recommendations:
   - Designate betibeglogene autotemcel, etranacogene dezaparvovec, and valoctocogene
     roxaparvovec-rvox non-preferred on the PDL
   - Apply PA to ensure clinically appropriate utilization
   Public Comment: Christine Donahue, CSL Behring; Rick Kegler, BioMarin
   ACTION: The Committee modified the proposed betibeglogene autotemcel clinical PA
   criteria to allow for approval in people over 35 years of age with beta thalassemia
   Motion to approve, 2nd, all in favor

C. SGLT-2 Inhibitors Class Update: Kathy Sentena, PharmD
   Recommendations:
   - No PDL changes recommended based on the review of recently published evidence
   - Update PA criteria to allow for preferred SGLT2 therapies to be used first-line in
     treatment of T2D
   - Maintain bexagliflozin and sotagliflozin as non-preferred
   - Evaluate costs in executive session
   ACTION: Motion to approve, 2nd, all in favor

D. Alzheimer’s Drugs Class Update and New Drug Evaluation: Dave Engen, PharmD
   Recommendations:
   - Create a new PDL class: Monoclonal Antibodies for Alzheimer’s Disease
   - Designate lecanemab as non-preferred on the PDL
   - Implement PA criteria for lecanemab and update existing criteria as proposed
   Public Comment: Lynda Finch, Biogen
   ACTION: The Committee recommended removing the requirement for amyloid imaging
   in renewal criteria
   Motion to approve, 2nd, all in favor
E. **VMAT-2 Inhibitors Class Update:** Deanna Moretz, PharmD

**Recommendations:**
- No PDL changes recommended based on the review of recently published evidence
- Revise PA criteria as proposed
- Evaluate costs in executive session

**Public Comment:** Rochelle Yang, Teva

**ACTION:** After considering input from the Mental Health Clinical Advisory Group (MHCAG), the Committee recommended revising the proposed clinical PA criteria to remove the requirement of a specialist for initial approval and to update the renewal criteria to require a clinically significant reduction in symptoms of tardive dyskinesia from baseline

**Motion to approve, 2nd, all in favor**

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**IV. DUR NEW BUSINESS**

A. **Asthma Rescue Inhalers Drug Use Evaluation:** Sara Fletcher, PharmD

**Recommendations:**
- Implement one-time targeted provider fax notifications requesting SABA therapy reassessment for specific patients as proposed
- Implement targeted RetroDUR to fax provider notification when 3 SABA inhalers are filled within 6 months (Exclude patients with COPD diagnosis)
- Implement a quantity limit of 6 SABA claims in 6 months (Exclude patients with COPD diagnosis)

**ACTION:** The Committee rejected the proposed SABA quantity limit

**Motion to approve, 2nd, all in favor**

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**V. EXECUTIVE SESSION**

**Members Present:** Stacy Ramirez, PharmD; Douglas Carr, MD; Patrick DeMartino, MD; Russ Huffman, PMHNP; Tim Langford, PharmD; Cat Livingston, MD; Caryn Mickelson, PharmD; Robin Moody; Eddie Saito, PharmD

**Staff Present:** Roger Citron, RPh; David Engen, PharmD; Sara Fletcher, PharmD; Andrew Gibler, PharmD; Deanna Moretz, PharmD; Sarah Servid, PharmD; Kathy Sentena, PharmD; Lan Starkweather, PharmD; Brandon Wells, Dee Weston, JD; Kyle Hamilton
VI. RECONVENE for PUBLIC RECOMMENDATIONS

A. CSF Class
   Recommendation: Make Nyvepria (pegfilgrastim-apgf) non-preferred
   ACTION: Motion to approve, 2nd, all in favor

B. Opioid Reversal Agents
   Recommendations: Add OTC reversal agents as covered products and make Opvee (nalmefene) and naloxone cartridge preferred
   ACTION: Motion to approve, 2nd, all in favor

C. Substance Use Disorder
   Recommendations: Make Brixadi preferred and Sublocade Voluntary non-preferred
   ACTION: Motion to approve, 2nd, all in favor

D. Parenteral Antipsychotics
   Recommendations: Make Uzedy (risperidone) preferred
   ACTION: Motion to approve, 2nd, all in favor

E. SGLT-2 Inhibitors
   Recommendations: Make no changes to the PDL
   ACTION: Motion to approve, 2nd, all in favor

F. Alzheimer’s Drugs
   Recommendations: Make no changes to the PDL
   ACTION: Motion to approve, 2nd, all in favor

G. VMAT-2 Inhibitors
   Recommendations: Make no changes to the PDL
   ACTION: Motion to approve, 2nd, all in favor

VII. ADJOURN