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, June 04, 2020 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: Mark Helm, MD, MBA, FAAP; Caryn Mickelson, PharmD; Russell Huffman, DNP, PMHNP; Tracy Klein, PhD, FNP; William Origer, MD, James Slater, PharmD; Patrick DeMartino, MD, MPh; Stacy Ramirez, PharmD; Cathy Zehrung RPh; David Pass, MD

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

Audience: Alexandra Lachmann, Gilead; Amy Hamdan; Andrea Willcuts, Takeda; Andrew Yu, Novartis; Bill McDougall, Biogen; **Brandon Yip, Sanofi-Genzyme*;** Brook Goobic, Vertex; Bruce Wallace, Azurity; Carmen Oliver, BioHaven; Chelsea Leroue, PhD, BioHaven; Chi Kohlhoff, Viela Bio; Chris DeSimone; Christina Hartmann, Jazz Pharma; Crystal Henderson, Global Blood Therapeutics; Dennis Schaffner, Sanofi-Genzyme; Edward Eldridge, Gilead; **Erica Finanger, OHSU*;** Gregg Rasmussen, Vertex; **Jaime Smutko, Global Blood Therapeutics*;** Jean Ritter, Zealand Pharma; Jeanne Vander Zaden, Biocodex MSL; Jenny Todenhagen, Genentech; Jill Johnson, Genentech; Kara Tyelr, Kite Pharma; Kelly Maynard, Little Hercules Foundation; Ken Orr, Global Blood Therapeutics; Kevin Black, SK Life Science; Kristen Kross, Sobi; Lance Swanson; Laura Jeffcoat, AbbVie; Lee Stout, Chiesei; LeeAnna Hoskins; **Lisa Allen, Vertex*; Lisa Borland, Sarepta Therapeutics***; Lynda Finch, Biogen; **Margaret Olmon, Abbvie***; Mark Kantor, AllCare; Matt Metcalf, Sobi; Timothy McFerron, Alkermes; Michael Foster, BMS; Michelle Bice, Gilead Sciences; Mike Donabedian, Sarepta; Nichole Roblin, Otsuka; Oyinda Osibanjo, YVFWC; Paul Genentech; Rick Frees, Vertex; Robb Host; **Robert Ahlstrom, PhD, Sobi*;** Roy Lindfield, Sunovion;

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Shari Yamada, Agios; Steve Hall Genentech; Steve Isaki, Lundbeck; **Stuart O'Brochta, Gilead***; Subrat Roychoudhary, Novartis; Tom Arnhart, UltragenRx; Tracy Copeland, Sarepta; Troy Pendergraft, IQVIA; Any Burns, AllCare; Carrie Johnson, PharmD, Amgen; Jeff Odell, UltragenRx; Jennifer Shear, Teva Pharmaceuticals, Mike Willet, Pfizer; Norm Navarro, Providence; Wendy Bibeau

(*) Provided verbal testimony

Written testimony: Posted to OSU Website

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 February 2020 minutes presented by Mr. Citron
ACTION: Motion to approve, 2nd, all in favor
D. Department Update provided by Dee Weston

II. CONSENT AGENDA TOPICS

A. Quarterly Utilization Reports
B. P&T Annual Report
C. Acne Class Update w/ New Drug evaluation (NDE):
Make no changes to the PMPDP based on clinical evidenced; update the prior authorization (PA) criteria as proposed; and evaluate costs in executive session
D. Antiepileptics Class Update w/ NDE:
Designate Xcopri® (cenobamate) as non-preferred on the PMPDP based on clinical evidence and evaluate costs in executive session
E. Fluoroquinolones Drug Use Evaluation (DUE):
No policy changes were recommended at this time based on the DUE
F. Oral Diuretics Class Update:
Designate chlorthalidone as preferred on the PMPDP based on clinical evidence and evaluate costs in executive session
G. Orphan Drug Policy Update:
Add Crysvita® (burosumab-twza), Brineura® (cerliponase alfa), and Reblozyl® (luspatercept) to the Orphan Drugs PA criteria to support medically appropriate use based on their Food and Drug Administration (FDA) labeling

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

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III. DUR ACTIVITIES

A. ProDUR Report - Mr. Holsapple presented the ProDUR report
B. RetroDUR Report – Dr. Engen presented the RetroDUR Report
C. Oregon State Drug Reviews
   1. CGRP Antagonists in Migraine Prophylaxis
   2. Evidence for Drugs that are Heavily Marketed

   Dr. Sentena presented two recently published newsletters, thanked the Committee for reviewing the draft versions and solicited ideas for future newsletters

IV. DUR OLD BUSINESS

A. Oral Multiple Sclerosis Drugs
   Dr. Servid presented the proposed PA criteria updates:

   ACTION: The Committee recommended updating the Oral Multiple Sclerosis Drugs PA criteria to accommodate expanded FDA approved indications and to include all new fumarate salts. The Committee also approved removing Daclizumab from the Ocrelizumab PA criteria - as it has been voluntarily recalled from the U.S. market - and to modify the goals to clarify that primary progressive multiple sclerosis (PPMS) does not require step therapy
   Motion to approve, 2nd, all in favor

V. DUR NEW BUSINESS

A. Oncology Prior Authorization (PA) Policy Proposal
   Dr. Servid presented the policy proposal and proposed PA criteria:

   ACTION: The Committee recommended implementing the proposed Oncology Agents PA criteria and to apply to: all antineoplastic drugs originally approved by the FDA on 1/1/2008 or later; all new molecular entities and new formulations of antineoplastic drugs that already require PA; and all new FDA approved antineoplastic agents. The Committee will be notified of new drugs added to the policy at subsequent meetings
   Motion to approve, 2nd, all in favor

B. Hepatitis C, Direct-Acting Antivirals Policy Evaluation and Literature Scan
   Dr. McKenzie presented the Policy Evaluation and Dr. Herink presented the Literature Scan and proposed updates to the DAA PA criteria:

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ACTION: The Committee recommended amending the DAA PA criteria to include new FDA approved indications in pediatric patients and to remove the requirement for a pregnancy test. Case management was instead proposed to address risks associated with birth control and pregnancy. The Committee also recommended updating the Table of Recommended Treatment Regimens to accommodate any expanded or new FDA-indications for current recommended regimens and to add guidance for patients who have a contraindication or intolerance to ribavirin
Motion to approve, 2nd, all in favor

C. Dose Consolidation Policy Proposal
Dr. Fletcher presented the policy proposal:

ACTION: The Committee recommended implementing pharmacy point of sale (POS) edits to consolidate medications with fixed prices across various strengths, in conjunction with a safety net RetroDUR - including a form letter for pharmacies to notify providers when they make a change to the prescription
Motion to approve, 2nd, all in favor

VI. PREFERRED DRUG LIST NEW BUSINESS

A. Sickle Cell Disease (SCD) Class Review and New Drug Evaluation (NDE)
Dr. Sentena presented the proposal to:
1. Create a PMPDP class for the SCD drugs
2. Make a hydroxyurea formulation a preferred treatment
3. Designate Oxbryta™ (voxelotor) and Adakveo® (crizanlizumab-tmca) as non-preferred
4. Implement the proposed SCD PA criteria
5. Evaluate comparative costs in executive session

ACTION: The Committee amended to the proposed SCD PA criteria posted in the packet to also apply to L-glutamine.
Motion to approve, 2nd, all in favor

B. Drugs for Duchenne Muscular Dystrophy (DMD) Class Update w/ NDE
Dr. Servid presented the proposal to:
1. Update the DMD PA criteria to incorporate Vyondys 53® (golodirsen) as proposed

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

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C. Idiopathic Pulmonary Fibrosis Class Update
Dr. Gibler presented the proposal to:
1. Update the PA criteria as proposed
2. Expand and rename the PMPDP class to cover approved indications for Interstitial Lung Disease - which includes idiopathic pulmonary fibrosis
3. Make no changes to the PMPDP based on the clinical evidence

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

D. Cystic Fibrosis Class Update with NDE
Dr. Herink presented the proposal to:
1. Maintain Trikafta™ (elexacaftor/tezacaftor/ivacaftor) as non-preferred and add to the Oral CF Modulators PA criteria as proposed
2. Update the PA criteria for initial approval of 6 months and 12 months for subsequent approval

ACTION: The Committee also recommended removing the required sweat chloride test from the renewal criteria for ivacaftor
Motion to approve, 2nd, all in favor

E. Laxatives for Chronic Constipation Class Update
Dr. Moretz presented the proposal to:
1. Revise the Drugs for Constipation PA criteria to include Motegrity™ (prucalopride), Zelnorm® (tegaserod), and Ibsrela® (tenapanor)
2. Designate all three non-preferred on the PMPDP to assure use for OHP funded conditions
3. Evaluate comparative costs in executive session

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

F. Gamifant™ (emapalumab-lzsg) New Drug Evaluation
Dr. Engen presented the proposal to:
1. Create a PMPDP class for the hemophagocytic lymphohistiocytosis (HLH) drugs
2. Designate Gamifant® (emapalumab-lzsg) as non-preferred
3. Implement the proposed Emapalumab PA criteria

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

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VII. 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; Patrick DeMartino, MD, MPh; Stacy Ramirez, PharmD; Cathy Zehrung RPh; David Pass, MD

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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

VIII. RECONVENE for PUBLIC RECOMMENDATIONS

A. Acne Class Update w/ New Drug evaluation (NDE):
Recommendation: make Altreno™ (tretinoin) and Arazlo™ (tazarotene) non-preferred and make unassigned benzoyl peroxide products preferred and subject to acne PA
ACTION: Motion to approve, 2nd, all in favor

B. Antiepileptics Class Update w/ NDE:
Recommendation: make no changes to the PMPDP

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

G. Oral Diuretics Class Update:
Recommendation: make chlorthalidone and generic triamterene/hydrochlorothiazide products preferred on the PMPDP

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

H. Sickle Cell Disease (SCD) Class Review and New Drug Evaluation (NDE)
Recommendation: make generic hydroxyurea capsules preferred and Droxia®, Hydrea®, Siklos®, and Endari™ (L-glutamine) non-preferred on the PMPDP

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

I. Laxatives for Chronic Constipation
Recommendation: make no changes to the PMPDP

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

IX. ADJOURN

X. OHA Rules Advisory Committee