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, September 26, 2019 1:00 - 5:00 PM

DXC Conference Room

4070 27th Ct. SE

Salem, OR 97302

MEETING AGENDA

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: Tracy Klein, PhD, FNP; Bill Origer, MD; Cathy Zehrug RPh; James Slater PharmD; Mark Helm MD, MBA, FAAP; Russell Huffman, DNP, PMHNP; Stacy Ramirez, PharmD,

Members Present by Phone: Dave Pass, MD; Caryn Mickelson, PharmD; Kelley Burnett, DO;

Staff Present: Roger Citron, RPh; David Engen, PharmD; Richard Holsapple, RPh; Megan Herink, PharmD; Deanna Moretz, PharmD; Sarah Servid, PharmD; Deborah Weston; Trevor Douglass, DC, MPH; Brandon Wells; Jennifer Torkelson; Jennifer Bowen;

Staff Present by Phone: Kathy Sentena, PharmD;

Audience: Russ Rahimtoola PTC Therapeutics; Tena Aadel PTC Therapeutics; Alexis Russell PTC Therapeutics*; Lydia Shenouda, Avexis, Inc.*; Keith Dilly, Avexis Inc.; Paul Bonham, Avexis Inc.; Bobbi Jo Drum, BMS; Lisa Borland, Sarepta*; Kevin Ho, Sanofi Genzyme*; Gregg Resnick, Vertex Pharmaceuticals; Laura Jeffcoat, AbbVie; Angela Walter, Sanofi Genzyme*; Joseph Triong, Vertex Pharmaceuticals*; Keri Smith, ViiV; Michelle Bice, Gilead Sciences; Lauren Nelson, Sanofi Genzyme*; Stuart O'Brochta , Gilead Sciences*; John O'Malley, Sanofi Genzyme; Brad Peacock, Gilead Sciences; Austin Landerville,; Zulema Lescas; Paul Williams, Genentech; Jesse McCoy, Genzyme; Bill McDougal, Biogen; Gloria Montesanto, Sanofi Genzyme; Kaysei Bam, Biogen; Deanne Calvert, Sanofi Genzyme*; Kathleen Mullane, Safeway; Camille Kerr, Amigen; Lisa Knutson, Sanofi Genzyme; Lauren Sandt, Caring Ambassadors; Lori McDermott, Supernus; Kim Bennett; Danielle Shannon, WVP Health Authority; Erika Finanger*; Desiree Allen, AbbVie; Jon Taylor , Alnylam; Diann Matthews, Merck; Chris Johnson, Spark; Geetika Gupta, Merck; Amy Yang*, OHSU;

(*) Provided verbal testimony

Written testimony provided: Posted to OSU Website

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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 July 2019 minutes presented by Mr. Citron
ACTION: Motion to approve, 2nd , all in favor
D. Department Update: Trevor Douglas – Mental Health Clinical Advisory Group – Amanda Parrish appointed to coordinator

II. CONSENT AGENDA TOPICS

A. Oral Muscle Relaxants Literature Scan
B. Herpes Simplex Virus Literature Scan
C. Insulins Class Update
D. Antidepressants - Reviewed in July 2019
Recommendation:
- Make no changes to the PMPDP based on clinical evidence
- Evaluate comparative drug costs in executive session

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

III. PREFERRED DRUG LIST NEW BUSINESS

A. Drug Class Literature Scans
1. Hepatitis C, Direct-Acting Antivirals
Dr. Herink presented the proposal to:
- Approve updated prior authorization (PA) criteria
- Recommend maintenance of Table in the PA criteria to reflect ongoing updates to FDA-approved regimens for preferred regimens
- Make no changes to the PMPDP based on clinical evidence
- Evaluate comparative drug costs in executive session

ACTION: The Committee recommended moving the request for baseline RNA level to question #2 when asking about diagnosis (ie through positive detection of HCV viral load)
Motion to approve, 2nd, all in favor

2. Tobacco Smoking Cessation
Dr. Engen presented the proposal to:
- Update PA criteria to implement an age limit for varenicline
- Make no changes to the PMPDP based on clinical evidence
- Evaluate comparative drug costs in executive session

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

3. Drugs for Duchenne Muscular Dystrophy

Dr. Servid presented the proposal to:

- Update PA criteria to include updated FDA-approved ages and assessment of immunization status prior to initiation of treatment with deflazacort

ACTION: The Committee recommended modifying questions #7 to specify 2 MMR and 2 varicella vaccinations and #9 to clarify which mutations are amenable to exon 51 skipping

Motion to approve, 2nd, all in favor

B. Oral Cystic Fibrosis Modulators Prior Authorization Update

Dr. Herink presented the proposal to:

- Update PA criteria to reflect recent changes in FDA approved labels for ivacaftor and tezacaftor/ivacaftor
- Revise PA criteria to list FDA-approved indications and ages in a table which will facilitate more streamlined PA updates for expanded indications

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

C. Opioid Class Update

Dr. Herink presented the proposal to:

- Revise PA criteria as follows:
    - Add dihydrocodeine morphine milliequivalents to opioid conversion chart listed in SAO PA criteria
    - Add pain associated with sickle cell disease and severe burn injury as an exclusion to SAO and LAO PA criteria
    - Add concomitant benzodiazepine/CNS depressant use as an assessment to SAO and LAO PA criteria
    - Remove taper plan for patients using chronic SAO's for back and spine, based on HERC guidance
    - Retire codeine PA criteria and add a question about use of codeine and tramadol to the SAO PA criteria to insure appropriate use in patients under the age of 19 years based on FDA safety alerts
- Make no changes to the PMPDP based on clinical evidence
- Evaluate comparative drug costs in executive session

ACTION: The Committee recommended: modifying the question on the Prescription Drug Monitoring Program (PDMP) to verify that opioid prescribing is appropriate rather than from a single provider; add PEG score to the list of examples documenting improvement in question #17 in the SAO criteria; and to add a note recommending against pediatric use for tramadol in the dosing table

Motion to approve, 2nd, all in favor

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D. Vyndaqel® and Vyndamax® (tafamidis) New Drug Evaluation

Dr. Herink presented the proposal to:

- Designat Vyndaqel and Vyndamax as non-preferred medications in the Amyloidosis Agents class
- Modify PA criteria for Drugs for Transthyretin-Mediated Amyloidosis to ensure appropriate use of tafamidis

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

E. Spinal Muscular Atrophy Class Update and New Drug Evaluation

Dr. Moretz presented the proposal to:

- Implement PA criteria to ensure one time administration of onasemnogene abeparvovec in appropriate SMA pediatric populations per the FDA labeling
- Revise nusinersen PA criteria to include an assessment of onasemnogene abeparvovec administration prior to nusinersen initiation
- Evaluate comparative drug costs in executive session

ACTION: The Committee recommended adding language to the nusinersen renewal criteria regarding stabilization in a meaningful manner

Motion to approve, 2nd, all in favor

F. Bone Metabolism Drugs Class Update and New Drug Evaluation

Dr. Moretz presented the proposal to:

- Maintain romosozumab as a non-preferred agent on the PMPDP
- Update clinical prior authorization (PA) criteria for bone metabolism agents to include romosozumab
- Evaluate comparative drug costs in the executive session

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

G. Drugs for Fabry Disease Class Review

Dr. Moretz presented the proposal to:

- Designate agalsidase beta and migalastat as non-preferred agents on the PMPDP
- Implement PA criteria for the Fabry disease treatments to ensure use according to FDA-approved indications

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

H. Aemcolo™ (rifamycin) New Drug Evaluation

Topic Deferred to a Future Meeting

IV. EXECUTIVE SESSION

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V. RECONVENE for PUBLIC RECOMMENDATIONS

A. Oral Muscle Relaxants Literature Scan
Recommendation: make methocarbamol preferred on the PDL

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

B. Herpes Simplex Virus Literature Scan
Recommendation: make valacyclovir tablets preferred on the PDL

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

C. Insulins Class Update
Recommendation: make insulin glulisine (pens and vials); insulin regular, human U-500 pen; Humalog Mix 75/25 and 50/50 KwikPens; and insulin detemir vials preferred on the PDL

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

D. Antidepressants
Recommendation: make no changes to the PDL

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

E. Hepatitis C, Direct-Acting Antivirals
Recommendation: make Zepatier non-preferred on the PDL

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

F. Tobacco Smoking Cessation
Recommendation: make no changes to the PDL

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

G. Opioid Class Update

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Recommendation: make no changes to the PDL

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

H. Spinal Muscular Atrophy Class Update and New Drug Evaluation
Recommendation: add the class to the PDL and designate Zolgensma as preferred and nusinersen non-preferred

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

I. Bone Metabolism Drugs Class Update and New Drug Evaluation
Recommendation: make no changes to the PDL

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

VI. ADJOURN

VII. OHA RULES ADVISORY COMMITTEE