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, November 21, 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: Mark Helm, MD, MBA, FAAP; Russell Huffman, DNP, PMHNP; Tracy Klein, PHD, FNP; Caryn Mickelson, PharmD; William Origer, MD; Cathy Zehrung, RPh

Members Present by Phone: Dave Pass, MD; James Slater, PharmD; Kelley Burnett, DO;

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

Staff Present by Phone: Kathy Sentena, PharmD

Audience:
Rick Frees, Vertex Pharmaceuticals; Tim McFerron, Alkermes; Hiten Patadia, Otsuka; Brandon Yip*, Sanofi; Sean Staff, Aimmune Therapeutics; Paul Thompson*, Alkermes; Trent Taylor, Johnson & Johnson; Mae Kwong, Johnson & Johnson*; Mario Aguiar*, Sanofi Genzyme ; Jie Ferg, Sanofi Genzyme; Ann Wheeler*, Indivior; Bobbi Jo Drum, BMS; Ellen Chow, BMS; Roy Lindfield, Sunovion; Duke Piyathasee*, Takeda; Andrea Willetts, Takeda; Devin Cram, Takeda; Lori McDermott, Supernus; Anna Breckeisler; Patrick Maxy, Horizion Pharmaceuticals; Holly Mousa; Ann Neilson, Tricida; Dennis Schaffer, Sanofi Genzyme; Amy Yang*, OHSU; Chi Kohlhoff, Vida pharmaceuticals;
(*) 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 September 2019 minutes presented by Mr. Citron
ACTION: Motion to approve, 2nd, all in favor
D. Department Update – Trevor Douglass

II. CONSENT AGENDA TOPICS

A. Quarterly Utilization Reports
B. Antifungal Class Update
C. Anticoagulant Class Update
Recommendation:
1. Make no changes to the preferred drug list (PDL) based on clinical evidence.
2. Evaluate comparative drug costs in executive session.

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

III. DUR ACTIVIES

A. ProDUR Report - Mr. Holsapple presented the ProDUR report
B. RetroDUR Report - Dr. Engen presented the RetroDUR Report
C. Oregon State Drug Reviews
1. Oregon Health Authority Mental Health Clinical Advisory Group (MHCAG) Recommendations for Treatment of Schizophrenia
2. Stimulant Use in Excessive Somnolence Disorders

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

IV. DUR NEW BUSINESS

A. Substance Use Disorders Literature Scan and Prior Authorization (PA) Update
Dr. Moretz presented the literature scan and proposal to:
1. Make no changes to the PDL or PA criteria based on the review of recent clinical evidence.

Dr. Servid presented the policy proposal and recommended PA criteria updates to:
2. Remove the PA requirement for all OUD products except for dose limit of 24 mg buprenorphine per day for transmucosal products.

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3. Designate products as either preferred or voluntary non-preferred based on evaluation of costs in executive session.
4. Continue to monitor use of substance use disorder products to assess potential changes in medically appropriate use.

ACTION: The Committee recommended implementing the proposed changes to the PA criteria. As part of ongoing monitoring for this class the Committee recommended soliciting input from prescribers of MAT and to assess efficacy or treatment discontinuation between agents.
Motion to approve, 2nd, 7 in favor, 1 opposed

B. Antidepressant Use in Children Drug Use Evaluation (DUE)
Dr. Servid presented the proposal to:
1. Implement a safety edit for initiation of TCA therapy in children younger than the FDA-approved minimum age limit with the goal of preventing off-label use.
2. Automatically approve requests for:
    - Prescriptions identified as being written by a mental health specialist, or
    - Ongoing TCA therapy, or
    - Evidence of a recent trial of a SSRI.

ACTION: The Committee recommended implementing the proposed safety edit and to also implementing a retrospective DUR safety net program to identify patients with denied claims and no subsequent follow-up in order to minimize interruptions and delays in therapy
Motion to approve, 2nd, All in favor

C. Dupixent® (dupilumab) Prior Authorization Update
Dr. Moretz presented the proposal to:
1. Revise the dupilumab PA criteria to include chronic rhinosinusitis with nasal polyposis as an FDA-approved indication for dupilumab as add on therapy to standard of care

ACTION: The Committee recommended implementing the proposed changes to the dupilumab PA criteria after amending to specifying the duration of the required steroid course for step therapy and to change “inhaled” steroid in question #15 to “intranasal”.
Motion to approve, 2nd, All in favor

V. PREFERRED DRUG LIST NEW BUSINESS

A. Aemcolo™ (rifamycin) New Drug Evaluation
Dr. Sentena presented the proposal to:
1. Designate rifamycin as non-preferred on the PDL.

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2. Add rifamycin to PA criteria for rifaximin to ensure appropriate utilization of both medications.

ACTION: The Committee recommended implementing the proposed recommendations after amending the proposed PA criteria to add a question to approve only if there is a contraindication to azithromycin and fluoroquinolones.
Motion to approve, 2nd, 7 in favor – 1 opposed

B. Arikayce® (amikacin) New Drug Evaluation
Dr. Engen presented the proposal to:
1. Designate amikacin liposome inhalation suspension as non-preferred on the PDL.
2. Implementing the proposed clinical PA criteria.

ACTION: The Committee recommended implementing the proposed recommendations after modifying question #4 to confirm the patient has been adherent for the past 6 months to a 3-drug regimen.
Motion to approve, 2nd, All in favor

C. Drugs for Gaucher Disease Class Review
Dr. Servid presented the proposal to:
1. Create a class for lysosomal storage disorders and designate miglustat as non-preferred based on FDA labeling as second-line therapy and eliglustat as non-preferred based on need for additional enzymatic testing.
2. Recommend PA for all targeted therapies for Gaucher disease to ensure medically appropriate use.
3. Evaluate comparative costs in executive session.

ACTION: The Committee recommended adopting the proposals after amending to refer requests for Type 3 patients to the Medical Director for review.
Motion to approve, 2nd, 6 in favor, 2 opposed

D. Ruzurgi® and Firdapse® (amifampridine) New Drug Evaluations
Dr. Engen presented the proposal to:
1. Create a new PDL class for Lambert-Eaton Myasthenic Syndrome (LEMS) agents.
2. Implementing the proposed clinical PA criteria for amifampridine.
3. Evaluate comparative costs in executive session.

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

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E. Cholbam® (cholic acid) New Drug Evaluation
Dr. Moretz presented the proposal to:
1. Designate cholic acid as non-preferred on the PDL.
2. Implementing the proposed clinical PA criteria.

ACTION: The Committee recommended adopting the proposals after modifying the initial approval to 3 months and to include assessment of liver function tests (LFTs) in the renewal criteria.
Motion to approve, 2nd, All in favor

VI. EXECUTIVE SESSION

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

Members Present by Phone:
Dave Pass, MD; James Slater, PharmD; Kelley Burnett, DO;

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

Staff Present by Phone: Kathy Sentena, PharmD

VII. RECONVENE for PUBLIC RECOMMENDATIONS

A. Antifungal Class Update
Recommendation: make no changes to the PDL

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

B. Anticoagulant Class Update
Recommendation: make no changes to the PDL

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

C. Substance Use Disorders

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Recommendation: make buprenorphine injection (Sublocade™) preferred and buprenorphine sublingual tablets, disulfiram tablets, buprenorphine/naloxone film (Bunavail®) voluntary non-preferred on the PDL.

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

D. Drugs for Gaucher Disease
Recommendation: make taliglucerase alfa preferred all other agents for Gaucher disease as non-preferred on the PDL

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

E. Amifampridine New Drug Evaluations
Recommendation: make Ruzurgi® preferred and Firdapse® non-preferred on the PDL

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

IX. ADJOURN

X. OHA Rules Advisory Committee