Drug Use Research & Management Program
OHA Division of Medical Assistance Programs
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Oregon Drug Use Review / Pharmacy & Therapeutics Committee
Thursday, January 29, 2015 1:00-5:00 PM
Wilsonville Training Center
29353 SW Town Center
Wilsonville, OR 97070

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 as required by 414.325(9).

Members Present: Cathy Zehrung, RPh; Phillip Levine, PhD; William Origer, MD; Kathryn Lueken, MD; James Slater, PharmD; Caryn Mickelson, PharmD; Stacy Ramirez, PharmD; Tracey Klein, PhD., FNP;

Members Present by Phone: David Pass, MD; Arturo Salazar, MD;

Staff Present: Kathy Ketchum, RPh, MPA:HA; Megan Herink PharmD, BCPS; Richard Holsapple, RPh; Roger Citron, RPh; Ted Williams, PharmD; Shannon Jasper; Linnea Saris; Amanda Meeker, PharmD; Andrew Gibler, PharmD; Dee Weston,

Staff Present by Phone: Kathy Sentena, PharmD;

Audience: Barry Benson (BMS), Leslie Mann (Celgene), Pat Wiseman (AstraZeneca), Bruce Smith (GlaxoSmithKline), Ann Marie Licos (AstraZeneca), Carrie Johnson (AstraZeneca), Mark Handley (AstraZeneca), Venus Holder (Lilly), Michelle Widolff (Lundbeck)*, Bill Ferguson (Lundbeck), Patrick Moty (Supennus), Margaret Olman (Daiichi Sankyo), Steve Hill (PSI), Paul Bonham (Novo), Becky McReynolds (Abbvie), Michelle Bice (Gilead), Georgette Dewilewski (Indivior), Steve Nemirow*, Pamela Vincent (Indivior), Meg Nguyen (Teva)*, Deron Grothe (Teva), Mary Kemhus (Navartis), Dean Haxby (OSU), Cynthia Patterson ()*, Sarah Day (RCG & Associates)*, Jenna Colabianchi, PharmD (Sunovian), Stuart O'Brochta (Gilead)*, Kim Blood (WVCH), Stacy Eria (FamilyCare), Bob Sneidker (Janssen)*, Jeannie Kenyon (Amgen), Mark Pledger (Novartis), Scott Larson (BMS), Kent Benner, MD (Oregon Clinic)*, Pat Trifinor (VBG), Lincoln Alexander (Student), Desiree Allen (Abbvie), Allen Hammagren (Abbvie), Lorren Sandt (Caring Ambassadors)*, Don Stecher (Novartis), BJ Cavnor (One in Four)*, Dr. Atif Zaman (OHSU)*, David Byram (Orexo US)*

(*) Provided verbal testimony

I. CALL TO ORDER

a. The meeting was called to order at approximately 1:00 pm. Introductions of Committee members and staff.

b. Election of Chair and Vice Chair for the P&T Committee.

Elected Dr. Bill Origer for Chair. Motion, Second, all in favor. Approved.
Elected Tracy Klein PhD., FNP elected for Vice Chair. Motion, Second, all in favor. Approved.

c. Mr. Citron reported there are no new conflicts of interest to declare.

d. Approval of agenda and minutes presented by Dr. Origer (pages 1 - 8)

ACTION: Approved as is.

e. Department updates presented by Linnea Saris.

II. DUR ACTIVITIES

a. Quarterly Utilization Reports (pages 9 - 13)
Presented by Mr. Citron.

b. ProDUR Report (pages 14 - 15)
Presented by Mr. Holsapple.

c. RetroDUR Report (pages 16 - 18)
Presented by Dr. Williams.

d. Oregon State Drug Reviews
Presented by Dr. Sentena.
    1. What's New with Oral Anticoagulants? (pages 19 - 21)
    2. Guidance Update for Prophylaxis of Respiratory Syncytial Virus (pages 22 – 24)

III. DUR NEW BUSINESS

a. Droxidopa (Northera™) (pages 25 - 40)
Dr. Gibler presented the following new drug evaluation:

1. The committee requires prior authorization for patients limiting to the following:
    a. Treating diagnosis must be an OHP funded condition, **AND**
    b. Patient must have a diagnosis of symptomatic orthostatic hypotension due to primary autonomic failure, dopamine beta-hydoxylase deficiency, or non-diabetic autonomic neuropathy**, AND**
    c. Patient must not be currently receiving antihypertensive therapy, **AND**
    d. Patient must have a documented trial of appropriate therapy for orthostatic hypotension, including both fludrocortisone and midodrine, unless physician provides justification (e.g., contraindications, concern for adverse effects, etc.).

2. For approval beyond 30 days, require documentation that:
    a. Patient must have a documented response to therapy (e.g., improvement in dizziness, lightheadedness, etc.).

3. After evaluation presentation, the committee agreed to change initial approval from 1 month to 14 days, and each subsequent approval from 1 year to 3 months.

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Public Comment:
Michelle Widolff from Lundbeck gave public comment.

ACTION: Motion, 2nd, All in Favor. Approved.

IV. PREFERRED DRUG LIST NEW BUSINESS

a. Hepatitis C Class Update and New Drug Evaluation (pages 41 - 72)
Dr. Herink presented the following update and new drug evaluation:

Dr. Zaman and Dr. Benner presented to the members and public the outcome from the Hepatitis C Advisory Group and the current recommendations.

1. Implement PA criteria to prioritize use so that patients defined by the AASLD guidelines as "highest priority" who are at high risk for liver-related complications and severe extrahepatic hepatitis are treated.

    a. Stage 3 or 4 fibrosis without decompensated cirrhosis, **OR**
    b. Those receiving an organ transplant, **OR**
    c. Patients with extrahepatic manifestations, including:
        i. Type 2 or 3 cryoglobulinemia with end-organ manifestations (e.g., vasculitis)
        ii. Proteinuria, nephrotic syndrome, or membranoproliferative glomerulonephritis.

2. Evaluate cost in executive session for PDL decision.

3. *After executive session, approved Harvoni (ledipasvir/ sofosbuvir) as a preferred product on the PDL. Amend PA criteria so Harvoni is preferred over Sovaldi for Genotypes 1 and 3. PA criteria effective as soon as supplemental rebate is in place.

Public Comment:
BJ Cavnor from One in Four gave public testimony.
Steve Nemirow self employed gave public testimony.
Lorren Sandt from Caring Embassadors gave public testimony.
Stuart O'Brochta from Gilead gave public testimony.
Bob Snediker from J&J gave public testimony.

***ACTION:** After executive session. All in favor. Approved.

b. Hypoglycemic Agents New Drug Evaluations (pages 73 - 135)
Dr. Sentena presented the following new drug evaluations:

1. Albiglutide (Tanzeum™) (pages 73 – 87)
    a. Add albiglutide to current PA criteria for GLP-1 analogs.
2. Dulaglutide (Trulicity™) (pages 88 – 102)
    a. Add dulaglutide to current PA criteria for GLP-1 analogs.
3. Empagliflozin (Jardiance) (pages 103 – 118)
    a. Add empagliflozin to current PA criteria for SGLT2s.
4. Canagliflozin / Metformin (Invokamet™) (pages 119 – 135)
    a. Add canagliflozin-metformin to current PA criteria for SGLT2s.
5. No changes to oral hypoglycemic PDL classes recommended at this time.

Public Comment:

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Bob Snediker form J&J gave public comment.

ACTION: Motion, 2nd, All in favor. Approved.

c. Colony Stimulating Factor Class Updates (pages 136 – 152)
Ms. Ketchum presented the following class updates:

1. Consider a DUE of the Colony Stimulating Factors to assess adherence to NCCN* guidelines and Guideline Note 11 of the OHP List of Prioritized Services.
*National Comprehensive Cancer Network
2. Evaluate PDL placement of tbo-filgrastim after evaluating costs in executive session.
3. *After executive session, make Granix (tbo-filgrastim) preferred on the PDL.
4. *After executive session, no DUE necessary at this time.

Public Comment:
Meg Nguyen from Teva gave public comment.

***ACTION:** After executive session. All in favor. Approved.

d. Ophthalmic VEGF for Glaucoma Class Update (pages 153 – 161)
Dr. Herink presented the following class update:

1. Maintain pegaptanib and aflibercept as non-preferred due to lower strength of evidence.
2. Evaluate comparative costs in executive session.
3. * After executive session, no changes to the PDL.

***ACTION:** After executive session. All in favor. Approved.

e. Ophthalmic Drugs for Glaucoma Class Update (pages 162 – 179)
Dr. Gibler presented the following class update:

1. Maintain unoprostone and the brinzolamide / brimonidine fixed-combination product as non-preferred.
2. Continue to include a medication from each category on PDL, including miotics, alpha-adrenergic agonists, beta-blockers, carbonic anhydrase inhibitors, and prostaglandin analogs.
3. Evaluate comparative costs in executive session.
4. * After executive session, no changes to the PDL.

***ACTION:** After executive session. All in favor. Approved.

f. Opioid Dependence Class Update (pages 180 – 201)
Dr. Gibler presented the following class update:

1. No further research or review needed at this time.
2. Evaluate comparative costs in executive session.
3. * After executive session, no changes to the PDL.

Public Comment:
Pamela Vincent from Reckitt Benhiser gave public comment.
Cynthia Patterson from BioDelivery Sciences gave public comment.
David Byram from Orexo US gave public comment.

***ACTION:** After executive session. All in favor. Approved.

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g. Olodaterol New Drug Evaluation (pages 202 – 212)
Dr. Meeker presented the following drug evaluation:

1. Designate olodaterol as non-preferred due to lack of quality evidence demonstrating clinical effectiveness.
2. Evaluate comparative costs in executive session.

***ACTION:** After executive session. All in favor. Approved.

h. Drug Class Scans

1. Ophthalmic Antibiotics (pages 213 – 218)
Dr. Meeker presented the following drug scan:

a. No further research or review needed at this time.
b. Evaluate comparative costs in executive session.
c. *After executive session, no changes to the PDL.

***ACTION:** After executive session. All in favor. Approved.

2. Ophthalmic Antibiotics / Corticosteroids (pages 219 – 220)
Dr. Meeker presented the following drug scan:

a. No further research or review needed at this time.
b. Evaluate comparative costs in executive session.
c. *After executive session, make gentamicin / prednisolone ophthalmic suspension and ointment preferred on PDL.
d. *After executive session, make Maxitrol (neomycin, polymyxin B, and dexamethasone) ophthalmic ointment preferred on PDL.

***ACTION:** After executive session. All in favor. Approved.

3. Cephalosporins (pages 221 – 227)
Dr. Gibler presented the following drug scan:

a. Maintain at least one oral agent from 1st, 2nd, and 3rd generation cephalosporins and amoxicillin / clavulanate, as well as age appropriate dosage formulations.
b. No further research or review needed at this time.
c. Evaluate comparative costs in executive session.
d. *After executive session, make cefuroxime oral suspension preferred on PDL.

***ACTION:** After executive session. All in favor. Approved.

4. Topical Psoriasis (pages 228 – 235)
Dr. Herink presented the following drug scan:

a. No further research or review needed at this time.
b. Evaluate comparative costs in executive session.
c. *After executive session, no changes to the PDL.

***ACTION:** After executive session. All in favor. Approved.

5. Drug Effectiveness Review Project (DERP) Scans:

a. ADHD (pages 236 – 254)

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Dr. Gibler presented the following DERP scan:

1. No further research or review needed at this time.
2. Evaluate comparative costs in executive session.
3. *After executive session, no changes to the PDL.

***ACTION:** After executive session. All in favor. Approved.

b. ACE-Inhibitors, Angiotensin Receptor Blockers, Direct Renin Inhibitors (pages 255 – 295)
Dr. Gibler presented the following DERP scan:

1. No further research or review needed at this time.
2. Evaluate comparative costs in executive session.
3. *After executive session, no changes to the PDL.

Public Comment:
Sarah Day from Silvergate Pharmaceuticals gave public comment.

***ACTION:** After executive session. All in favor. Approved.

c. Statins (pages 296 – 360)
Dr. Gibler presented the following DERP scan:

1. No further research or review needed at this time.
2. Evaluate comparative costs in executive session.
3. *After executive session, no changes to the PDL.

***ACTION:** After executive session. All in favor. Approved.

d. Macrolides (pages 361 – 372)
Dr. Gibler presented the following DERP scan:

1. No further research or review needed at this time.
2. Evaluate comparative costs in executive session.
3. *After executive session, no changes to the PDL.

***ACTION:** After executive session. All in favor. Approved.

V. EXECUTIVE SESSION

VI. EXECUTIVE SESSION

VII. RECONVENE for PUBLIC RECOMMENDATIONS

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