Drug Use Research & Management Program
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Oregon Drug Use Review / Pharmacy & Therapeutics Committee
Thursday, July 30, 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; Tracy Klein, PhD., FNP; James Slater, PharmD; William Origer, MD; Caryn Mickelson, PharmD;

Members Present by Phone:

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

Staff Present by Phone: Sherri Willard Argyres, PharmD

Audience: Jamie Tobitt (Vertex)*; Connie Brooks (Vertex); Gregg Rasmussen (Vertex); Shane Hall (Purdue); Steve Hall (Boehringer Ingelheim)*; Jim Graves (BMS); Don Stecher (Novartis); Mary Kernhus (Novartis)*; Jeana Colabianchi (Sunovion); Stephanie Kendall (J&J); Tina Andrews, PharmD; Lisa Allen (Vertex); Leslie Fox (J&J); David Engen; Dana Evans (Genentech)*; Jody Daniels (GSK); Amy Burns (AllCare Health); Bonnie Jiron (AllCare Health); Jo Choi (AllCare Health); Pat Wiseman (Astra Zeneca)*; Joshua Lee (Astra Zeneca)*; Deron Grothe (Teva); Cheryl Fletcher (AbbVie); Stuart O'Brochta (Gilead)*; Christine Oh (Teva)*; Mark Fledger (Novartis); Rich Thorpe (Astellas)*; Shelly Dhir (VIIV)*; Shawn Madison (VIIV); Mike Powers (OHSU)*; Gopal Allada (OHSU)*; Signe Fransen (BMS)*; Bobbi Joe D (BMS); Chris Conner (BMS); Chris Hoem (Gilead); Stephanie Persaud (OSU); Irena Surina (Pacific U); Mindy Schimpf (UCB); George Dela Corda (Mylan); Soumi Gupta (Janssen)*; Joe Schieck (Allergen); Geoffrey L'Heurrux (HIV Aliance)*; Darlene Halverson (Novartis); Debby Parish; BJ Cavnor (One in Four)*; Timothy McFerron (Alkermes); Brandie Feger (Western Oregon Advanced Health); David Barhoum (Genentech)

(*) Provided verbal testimony

I. CALL TO ORDER

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

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

c. Approval of agenda and minutes presented by Dr. Origer. (pages 5 - 10)

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

d. Department updates for OHA.

II. DUR ACTIVITIES

a. Quarterly Utilization Reports (pages 11 - 15)
Mr. Citron presented the quarterly utilization report.

b. ProDUR Report (pages 16 - 18)
Mr. Holsapple presented the quarterly ProDUR reports.

c. RetroDUR Report (pages 19 - 22)
Dr. Williams presented the quarterly RetroDUR reports.

III. DUR OLD BUSINESS

a. Ivacaftor Prior Authorization Criteria (pages 23 - 35)
Dr. Herink presented the following criteria changes:

1. Approve use for and include those ages 2 – 5 years with gating mutations in the proposed PA Criteria.
2. Refer PA requests for R117H to Medical Director for manual review.
3. Change the length of authorization on header from 30 days to 60 days and include a 10% change from baseline to the BMI renewal criteria.

Public Comment:
Jamie Tobitt from Vertex presented public comment.
Mike Powers presented public comment.
Gopal Allada presented public comment.

ACTION: Motion, 2nd. Approved.

b. Pediatric SSRI High Dose DUE Clarification (pages 36 - 37)
Dr. Williams presented the following revised criteria:

1. Approve updated PA criteria as presented for children <5 years old.

ACTION: Motion, 2nd. Approved.

c. Rifaximin Prior Authorization Criteria (pages 38 - 39)
Dr. Gibler presented the following clarification and PA criteria update:

1. Approve updated PA criteria as presented. Change approval from lifetime to one year.

ACTION: Motion, 2nd. Majority, 1 opposed. Approved.

d. Codeine Prior Authorization Criteria (pages 40 – 42)
Dr. Gibler presented the following revised criteria:

1. Approve PA criteria as presented for children <18 years old.
2. Change question #2 to #3 and instead ask if it is for an OHP funded condition. Perform RetroDUR for age and prescriber education.

ACTION: Motion, 2nd. Approved.

e. Leuprolide Hormone Therapy Prior Authorization Criteria (pages 43 – 44)
Dr. Gibler presented the proposed updated criteria.

1. The committee rejected the updated PA criteria as presented.
2. Committee asked staff to solicit input from a pediatric endocrinologist and to evaluate cross-sex hormone treatments.

ACTION: Motion not approved, and one abstained.

IV. DUR NEW BUSINESS

a. HIV Class Review / Drug Use Evaluation (pages 45 – 77)
Dr. Gibler and Ms. Ketchum presented the following review and evaluation:

1. Create voluntary Preferred Drug List (PDL) class for all HIV antiretroviral drugs and combination products.
2. Designate all drugs as preferred at this time.
3. Work with established, high Medicaid volume HIV clinics to try and identify ARV regimens with broad tolerability and high viral response rates in most patients and that have favorable or equivalent comparative price (preferred) and try to identify ARV regimens with common tolerability problems or lower viral response rates in most patients and with an unfavorable comparative price (non-preferred).

Public Comment:
Stuart O'Brochta from Gilead provided public comment.
Soumi Gupta from Janssen provided public comment.
Signe Fransen from BMS provided public comment.
Dr. Geoffrey L'Heurex from HIV Alliance provided public comment.
BJ Cavnor from One in Four proved public comment.

ACTION: Motion, 2nd. Approved.

b. Antiplatelet Class Update and Policy Evaluation (pages 78 – 105)
Dr. Herink and Ms. Ketchum presented the following class update and policy evaluation:

1. Continue to PA policy and update with proposed changes.
2. Implement a retrospective safety net program to identify patients that do not start antiplatelet therapy within 14 days for additional transition assistance with a focus on insuring patients qualifying for DAPT are not discontinued prematurely.
3. Continue to list aspirin and clopidogrel as preferred drugs due to high level evidence of benefit.
4. Evaluate comparative costs of other antiplatelet drugs in executive session for PDL changes.

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

5. *Make cilostazol preferred.
6. *No other changes to PMPDP.

Public Comment:
Joshua Lee from Astrazeneca provided public comment.

c. Tetracyclines Drug Use Evaluation (pages 106 – 116)
Dr. Williams presented the following drug evaluation:

DUE not presented, deferred, will be added to the September P&T agenda.

d. Low Dose Quetiapine Policy Evaluation (pages 117 – 128)
Dr. Meeker and Dr. Herink presented the following policy evaluation:

Policy Evaluation not presented, deferred, will be added to the September P&T agenda.

e. Modafinil / Armodafinil Drug Use Evaluation (pages 129 – 153)
Ms. Ketchum presented the following drug use evaluation:

DUE not presented, deferred, will be added to the September P&T agenda.

f. Clinical Review of Existing Prior Authorization Criteria (pages 154 – 157)
Dr. Gibler presented the following criteria review:

Criteria not presented, deferred, will be added to the September P&T agenda.

V. PREFERRED DRUG LIST NEW BUSINESS

a. Secukinumab New Drug Evaluation (pages 158 – 173)
Dr. Willard presented the following new drug evaluation:

1. Approve modifications to the Oregon Health Plan (OHP) for Prior Authorization (PA) criteria for systemic Biologicals and topical drugs for psoriasis. For ease of administration, PA criteria for topical therapies were removed from the systemic biological PA criteria and incorporated into the topical drugs for proposed psoriasis PA criteria.
2. Incorporate secukinumab into the OHP PA criteria for Biologicals and limit its use to patients with moderate to severe psoriasis, as diagnosed by a dermatologist and defined by the OHA, who have failed first-line therapies as defined by the OHA.
3. Evaluate relative costs in executive session for PDL decision making.

Public Comment:
Mary Kemhus from Novartis provided public comment.

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

4. *Maintain secukinumab as non-preferred.
5. *No changes to the PMPDP.

b. Idiopathic Pulmonary Fibrosis (IPF) New Drug Evaluation (pages 174 – 198)

Dr. Gibler presented the following new drug evaluation:

1. Pirfenidone New Drug Evaluation (pages 174 – 187)
   Recommended adopting Idiopathic Pulmonary Fibrosis (IPF) Agents PA criteria and apply to pirfenidone to assure appropriate utilization.

2. Nintedanib New Drug Evaluation (pages 188 – 198)
   Recommend requiring prior authorization for nintedanib to limit use to appropriate patients.

3. Add IPF Class to PMPDP and review comparative costs in the executive session.

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

4. *Make pirfenidone and nintedanib non-preferred, no grandfathering necessary.

c. Intranasal Allergy Inhalers Class Review (pages 199 – 215)
   Dr. Gibler presented the following drug class review:

1. Create PDL class for “Intranasal Allergy Drugs” and prefer at least one intranasal corticosteroid due to evidence of effectiveness for OHP-funded conditions.
2. Approve updated PA criteria as presented.
3. Review comparative costs in executive session.

Public Comment:
Christine Oh from Teva provided public comment.

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

4. *Make non-steroid products PDL = N due to lack of data
5. *Make FLUTICASONE PROPIONATE (Legend) PDL = Y
6. *Make all other steroid products PDL = N, no grandfathering

d. Antifungals Class Update (pages 216 – 241)
   Ms. Ketchum presented the following class update:

1. Update the prior authorization criteria as proposed to reflect changes to the OHP prioritized list.
2. Maintain open access to fluconazole.
3. Maintain clinical prior authorization requirement for griseofulvin, itraconazole, and terbinafine.
4. Make ketoconazole non-preferred due to increased risk.
5. Allow hematology, oncology and infectious disease specialty prescribers approval for voriconazole to cover invasive aspergillosis.
6. Review comparative costs in executive session.

Public Comment:
Richard Thorpe from Astellas provided public comment.

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

7. *Make ketoconazole non-preferred and no grandfathering.
8. *No other PMPDP changes recommended.

e. Calcium Channel Blockers Class Update (pages 242 – 253)
   Dr. Wu presented the following class update:

1. Create a “Combination Antihypertensive” PDL class to include fixed-dose combination products containing two antihypertensive drugs and combinations containing an antihypertensive drugs with a non-hypertensive drug (e.g., statin)
2. Evaluate comparative costs in executive session.

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

3. *Make the following fixed dose combinations preferred:
    - AMLODIPINE-ALMESARTAN
    - ENALAPRIL-HYDROCHLOROTHIAZIDE
    - LISINOPRIL-HYDROCHLOROTHIAZIDE
    - LOSARTAN-HYDROCHLOROTHIAZIDE
    - METOPROLOLSUCCINATE-HYDROCHLOROTHIAZIDE
    - OLMESARTAN-AMLODIPINE-HYDROCHLOROTHIAZIDE
    - OLMESARTAN-HYDROCHLOROTHIAZIDE
    - PROPRANOLOL-HYDROCHLOROTHIAZIDE
4. *Make all other products in Combination Antihypertensives class non-preferred.
5. *No other PMPDP changes recommended.

VI. EXECUTIVE SESSION

VII. RECONVENE for PUBLIC RECOMMENDATIONS

VIII. ADJOURN