Landon State Office Building
900 SW Jackson Street, Room 900-N
Topeka, KS 66612

Kansas Department of Health and Environment
Division of Health Care Finance

Phone: 785-296-3981
Fax: 785-296-4813
www.kdheks.gov/hcf/

Robert Moser, MD, Secretary

Sam Brownback, Governor

REVISED 10/7/2014

Drug Utilization Review Board
Meeting Agenda, Open Session
October 8, 2014 10:00 a.m. – 2:00 p.m.

Meeting Location
HP Enterprise Services, Capital Room
6700 SW Topeka Blvd, Bldg. 283 J, Topeka, KS 66619

Board Members
James Backes, PharmD
Tim Heston, DO
John Kollhoff, PharmD
Judy McDaniel Dowd, PA-C
Russell Scheffer, MD
Kevin Waite, PharmD
Roger Unruh, DO

KDHE-DHCF Staff
F.E. Bustillo, III, MD
Kelley Melton, PharmD
Liane Larson, PharmD

HP Enterprise Services/HID Staff
Nicole Ellermeier, PharmD
Nancy Perry, RN
Karen Kluczykowski, RPh

MCO Staff
Jonalan Smith, PharmD, FASCP, **Sunflower State Health Plan**
Jennifer Murff, RPh, **United Healthcare Community Plan**
Lisa Todd, RPh, **Amerigroup**

I. CALL TO ORDER

A. Announcements

II. OLD BUSINESS

A. Review and Approval of July 9, 2014 Meeting Minutes

III. NEW BUSINESS

A. New Preferred Drug List Classes

1. **Fixed Dose Combination Products for Hyperlipidemia**
   At the September 2014 PDL meeting, the committee approved the addition of the Fixed Dose Combination Products to the PDL. Standard non-preferred prior authorization criteria are being proposed for this new class to allow access to non-preferred agents.
   - i. Non-Preferred PDL PA Criteria
   - ii. *Public Comment
   - iii. Board Discussion

2. **Anti-Infective/Steroid Otic Combination Products**
   At the September 2014 PDL meeting, the committee approved the addition of the Anti-Infective/Steroid Combination Products to the PDL. Standard non-preferred prior authorization criteria are being proposed for this new class to allow access to non-preferred agents.
   i. Non-Preferred PDL PA Criteria
   ii. *Public Comment
   iii. Board Discussion

3. **Oral Immune Disease Modifying Agents**
   At the September 2014 PDL meeting, the committee approved the addition of the Oral Immune Disease Modifying Agents to the PDL. Standard non-preferred prior authorization criteria are being proposed for this new class to allow access to non-preferred agents.
   i. Non-Preferred PDL PA Criteria
   ii. *Public Comment
   iii. Board Discussion

B. Revised Prior Authorization (PA) Criteria

1. **Testosterone Agents (Vogelxo® (testosterone gel))**
   Prior authorization criteria for testosterone agents were last revised in July 2014. Since that time, a new agent has been approved—Vogelxo testosterone gel. Prior authorization criteria are being revised to include this new agent as well as testosterone powder for compounding.
   i. Revised PA Criteria
   ii. *Public Comment
   iii. Board Discussion

2. **Sodium-Glucose Co-Transporter 2 (SGLT2) Inhibitors (Jardiance® (empagliflozin))**
   Prior authorization criteria for the SGLT2 Inhibitors were approved in April 2014. Since that time, a new agent has been approved—Jardiance. Prior authorization criteria are being revised to include this new agent.
   i. Revised PA Criteria
   ii. *Public Comment
   iii. Board Discussion

3. **Enzyme Replacement Therapy (Cerdelga® (eliglustat))**
   Prior authorization criteria for enzyme replacement therapy were initially approved in July 2014. Since that time, a new agent has been approved—Cerdelga. Prior authorization criteria are being revised to include this new agent.
   i. Revised PA Criteria
   ii. *Public Comment
   iii. Board Discussion

4. **Promacta® (eltrombopag)**
   Prior authorization criteria for Promacta was initially approved in July 2009 and last revised in July 2014. Since that time, the FDA-approved indications have been expanded to include severe aplastic anemia in patients who have had an inadequate response to immunosuppressive therapy. Prior authorization criteria are being revised to include this new indication.
   i. Revised PA Criteria
   ii. *Public Comment
   iii. Board Discussion

5. **Decubitus & Wound Care Products**
   Prior authorization criteria for decubitus and wound care products were initially approved in December 1994 and have been revised several times. Prior authorization criteria are being revised to include expanded approval for patients with severe partial thickness burns.
   i. Revised PA Criteria
   ii. *Public Comment
   iii. Board Discussion

6. **Xolair® (omalizumab)**
   Prior authorization criteria for Xolair was last revised in July 2014 to include the new FDA-approved indication for chronic idiopathic urticaria in patients 12 years of age and older who remain symptomatic despite antihistamine treatment. At that time the criteria for that indication was approved to require Xolair be prescribed by or in consultation with an allergist or immunologist. Prior authorization criteria are being revised to include "dermatologist" on the list of provider specialties that may prescribe Xolair for chronic idiopathic urticaria.
   i. Revised PA Criteria
   ii. *Public Comment
   iii. Board Discussion

7. **Topical Acne Agents (Retin-A Micro® (tretinoin microspheres), Tretin-X® & Avita® (tretinoin))**
   Prior authorization criteria for topical acne agents were initially approved in June 2011 and revised in July 2012. At that time, several agents were overlooked that should have been included in the criteria. Prior authorization criteria are being revised to add Retin-A Micro, Tretin-X, and Avita.
   i. Revised PA Criteria
   ii. *Public Comment
   iii. Board Discussion

8. **Synagis® (palivizumab)**
   Prior authorization criteria for Synagis was last revised in October 2012 to follow the American Academy of Pediatrics (AAP) guidelines for the prophylaxis of RSV. In July 2014, the AAP released new guidelines, and prior authorization criteria are being revised to align more closely with the revised guidelines for RSV prophylaxis.
   i. Revised PA Criteria
   ii. *Public Comment
   iii. Board Discussion

C. New PA Criteria

1. **Alpha-1 Proteinase Inhibitors (Aralast NP®, Glassia®, Prolastin® C & Zemaira® (Alpha$_1$ proteinase inhibitor (human)))**
   Alpha-1 proteinase inhibitors are indicated for chronic augmentation therapy in adults with clinically evident emphysema due to severe congenital deficiency of Alpha$_1$-PI (alpha$_1$-antitrypsin deficiency). Prior authorization criteria are being proposed for these agents to ensure appropriate use based upon the FDA-approved indications.
   i. Prior Authorization Criteria
   ii. *Public Comment
   iii. Board Discussion

2. **Zykadia® (ceritinib)**
   Zykadia is a kinase inhibitor indicated for the treatment of patients with anaplastic lymphoma kinase-positive metastatic non-small cell lung cancer who have progressed on or are intolerant to crizotinib. Prior authorization criteria are being proposed to ensure appropriate use based upon the FDA-approved indication.
   i. Prior Authorization Criteria
   ii. *Public Comment
   iii. Board Discussion

3. **Afrezza® (insulin human inhalation)**
   Afrezza is a rapid-acting inhaled insulin indicted to improve glycemic control in adult patients with diabetes. Prior authorization criteria are being proposed to ensure appropriate use based upon the FDA-approved indications.
   i. Prior Authorization Criteria
   ii. *Public Comment
   iii. Board Discussion

4. **Anoro® Ellipta® (umeclidinium/vilanterol)**
   Anoro Ellipta is a combination anticholineric/long-acting beta$_2$-adrenergic agonist indicated for long-term, once-daily, maintenance treatment of airflow obstruction in patients with chronic obstructive pulmonary disease (COPD), including chronic bronchitis and/or emphysema. Prior authorization criteria are being proposed to ensure appropriate use based upon the FDA-approved indications.
   i. Prior Authorization Criteria
   ii. *Public Comment
   iii. Board Discussion

5. **Qudexy® XR (topiramate)**
   Qudexy XR is a topiramate extended-release capsule indicated for the treatment of partial onset or primary generalized tonic-clonic seizures and seizures associated with Lennox-Gastaut syndrome. Prior authorization criteria are being proposed to ensure appropriate use based upon the FDA-approved indications.
   i. Prior Authorization Criteria
   ii. *Public Comment
   iii. Board Discussion

6. **Zydelig® (idelalisib)**
   Zydelig is indicated for the treatment of relapsed chronic lymphocytic leukemia, relapsed follicular B-cell non-Hodgkin lymphoma, and relapsed small lymphocytic lymphoma. Prior authorization criteria are being proposed to ensure appropriate use based upon the FDA-approved labeling information.
   i. Prior Authorization Criteria
   ii. *Public Comment
   iii. Board Discussion

7. **Ruconest® (C1 esterase inhibitor [recombinant])**
   Ruconest is indicated for the treatment of acute attacks in adults and adolescent patients with primary hereditary angioedema (HAE). Prior authorization criteria are being proposed to ensure appropriate use based upon the FDA-approved labeling information and to remain consistent with other agents used to treat HAE.
   i. Prior Authorization Criteria
   ii. *Public Comment
   iii. Board Discussion

8. ~~**Sofosbuvir/Ledipasvir**~~

~~The newest hepatitis C direct-acting agent is the combination of sofosbuvir/ledipasvir. FDA approval is anticipated in early October 2014. Prior authorization criteria are being proposed to ensure appropriate utilization.~~

~~i. Prior Authorization Criteria~~

~~ii. *Public Comment~~

~~iii. Board Discussion~~

D. Miscellaneous Items

1. **Fee-for-Service Annual Program Assessment**

The annual program assessment for the Medicaid fee-for-service population will be presented to show drug trends over the past state fiscal year.

i. Presentation

ii. Board Discussion

IV. OPEN PUBLIC COMMENT

V. ADJOURN

Lunch will be provided for the DUR Board members.
The next DUR Board meeting is scheduled for January 14, 2015.

*Public comment is limited to five minutes per product; additional time will be allowed at the DUR Board's discretion.
Informal comments will be accepted from members of the audience at various points in the agenda.
****THIS AGENDA IS SUBJECT TO CHANGE****