Curtis State Office Building
1000 SW Jackson St., Suite 540
Topeka, KS 66612-1367

Kansas
Department of Health & Environment

Phone: 785-296-0461
Fax: 785-368-6368
www.kdheks.gov

Susan Mosier, MD, Secretary

Sam Brownback, Governor

Drug Utilization Review Board
Meeting Agenda, Open Session
January 11, 2017 10:00 a.m. – 2:00 p.m.

Meeting Location
HP Enterprise Services, Building #283, Capital Room
6511 SE Forbes Ave, Topeka, KS 66619

Board Members

Lauren Morton, PharmD, BCPS
James Backes, PharmD
Tim Heston, DO
John Kollhoff, PharmD
Judy Dowd, PA-C
Roger Unruh, MD
Moneeshindra Mittal, MD
LaTonyua Rice, PharmD, CGP

KDHE-DHCF Staff

Annette Grant, RPh
Carol Arace, Administrative Assistant

HP Enterprise Services/HID Staff

Ariane Casey, PharmD
Karen Kluczykowski, RPh
Nancy Perry, RN

MCO Staff

Angie Zhou, PharmD, **Sunflower State Health Plan**
Jennifer Murff, RPh, **UnitedHealthcare Community Plan**
Lisa Todd, RPh, **Amerigroup**

I. CALL TO ORDER

A. Announcements

II. OLD BUSINESS

A. Review and Approval of October 12, 2016 Meeting Minutes

III. NEW BUSINESS

A. Preferred Drug List (PDL)

1. The PDL criteria were last approved in October 2006. Revisions include requirements for PDL agents as well as editorial updates.
    i. Non-Preferred PDL PA Criteria
    ii. *Public Comment
    iii. Board Discussion

B. Revised Prior Authorization (PA) Criteria

1. **Weight Loss Drugs [Belviq® XR (lorcaserin extended release)]**
   Belviq XR is an extended release formulation of lorcaserin, a non-stimulant medication used as an adjunct to diet and exercise for weight loss in overweight and obese individuals. Belviq XR is an addition to the Weight Loss PA Criteria. The prior authorization criteria are being revised to be consistent with similar agents and ensure appropriate use.
   i. Revised PA Criteria
   ii. *Public Comment
   iii. Board Discussion

2. **Diclegis® (Bonjesta® [doxylamine-pyridoxine])**
   Bonjesta is an extended-release formulation of doxylamine and pyridoxine indicated for the short-term treatment of pregnancy related nausea/vomiting. The prior authorization criteria are being revised to be consistent with similar agents and ensure appropriate use.
   i. Revised PA Criteria
   ii. *Public Comment
   iii. Board Discussion

3. **Enbrel® (etanercept)**
   Enbrel is a tumor necrosis factor inhibitor that interrupts the inflammatory pathway and is used for the treatment of many immune-mediated chronic diseases. Enbrel was recently approved for use in pediatric patients (four years of age or older) who require systemic therapy for plaque psoriasis. The prior authorization criteria are being revised to be consistent with similar agents and ensure appropriate use.
   i. Revised PA Criteria
   ii. *Public Comment
   iii. Board Discussion

4. **Ilaris® (canakinumab)**
   Ilaris is a biologic immunomodulator. Prior authorization criteria for this agent was last revised in April 2016. Since that time, Ilaris has 3 new indications: Tumor Necrosis Factor Receptor Associated Periodic Syndrome (TRAPS) in adult and pediatric patients, Hyperimmunoglobulin D Syndrome (HIDS)/Mevalonate Kinase Deficiency (MKD) in adult and pediatric patients, and Familial Mediterranean Fever (FMF) in adult and pediatric patients. The prior authorization criteria are being revised to be consistent with similar agents and ensure appropriate use.
   i. Revised PA Criteria
   ii. *Public Comment
   iii. Board Discussion

5. **Stelara® (ustekinumab)**
   Stelara is a biologic immunomodulator. Prior authorization criteria for this agent was last revised in April 2016. Since that time, Stelara has become indicated for the treatment of moderately to severely active Crohn disease in adults who have failed or were intolerant to immunomodulatory or corticosteroid therapy, but never failed tumor necrosis factor (TNF) blocker therapy, or who have failed or were intolerant to treatment with 1 or more TNF blockers. The prior authorization criteria are being revised to be consistent with similar agents and ensure appropriate use.
   i. Revised PA Criteria
   ii. *Public Comment
   iii. Board Discussion

6. **Tecentriq® (atezolizumab)**
   Tecentriq is an antineoplastic monoclonal antibody. Prior authorization criteria were initially approved in October 2016. Since that time, Tecentriq has become indicated for the treatment of metastatic non-small cell lung cancer who have disease progression during or following platinum-containing chemotherapy. Patients with EGFR or ALK genomic tumor aberrations should have disease progression on FDA-approved therapy for these aberrations prior to receiving this medication. The prior authorization criteria are being revised to be consistent with similar agents and ensure appropriate use.
   i. Revised PA Criteria
   ii. *Public Comment
   iii. Board Discussion

7. **Keytruda® (pembrolizumab)**
   Keytruda is a PD-L1 receptor targeted therapy for melanoma, non-small cell lung cancer and squamous cell carcinoma of the head and neck. The prior authorization criteria are being revised to update approved indications and place in therapy.
   i. Revised PA Criteria
   ii. *Public Comment
   iii. Board Discussion

8. **Non-Preferred Metformin ER (Glumetza® [metformin ER], Fortamet® [metformin ER])**
   Prior authorization criteria is being revised to remove the term “Brand” from the prior authorization criteria to be consistent with similar agents and ensure appropriate use.
   i. Revised PA Criteria
   ii. *Public Comment
   iii. Board Discussion

9. **Daklinza® (daclatasvir)**
   Prior authorization criteria is being revised to include step therapy for Daklinza, to ensure cost-effective use.
   i. Revised PA Criteria
   ii. *Public Comment
   iii. Board Discussion

10. **Epclusa® (sofosbuvir/velpatasvir)**
    Prior authorization criteria is being revised to include step therapy for Epclusa, to ensure cost-effective use.
    i. Revised PA Criteria
    ii. *Public Comment
    iii. Board Discussion

11. **Harvoni® (ledipasvir/sofosbuvir)**
    Prior authorization criteria is being revised to include step therapy for Harvoni, to ensure cost-effective use.
    i. Revised PA Criteria
    ii. *Public Comment
    iii. Board Discussion

12. **Olysio® (simeprevir)**
    Prior authorization criteria is being revised to include step therapy for Olysio, to ensure cost-effective use.
    i. Revised PA Criteria
    ii. *Public Comment
    iii. Board Discussion

13. **Sovaldi® (sofosbuvir)**
    Prior authorization criteria is being revised to include step therapy for Sovaldi, to ensure cost-effective use.
    i. Revised PA Criteria
    ii. *Public Comment
    iii. Board Discussion

14. **Technivie® (ombitasvir/paritaprevir/ritonavir)**
    Prior authorization criteria is being revised to include step therapy for Technivie, to ensure cost-effective use.
    i. Revised PA Criteria
    ii. *Public Comment
    iii. Board Discussion

15. **Viekira® (ombitasvir/paritaprevir/ritonavir/dasabuvir)**
    Prior authorization criteria is being revised to include step therapy for Viekira Pak and Viekira XR, to ensure cost-effective use.
    i. Revised PA Criteria
    ii. *Public Comment
    iii. Board Discussion

16. **Zepatier® (elbasvir/grazoprevir)**
    Prior authorization criteria is being revised to include step therapy for Zepatier, to ensure cost-effective use.
    i. Revised PA Criteria
    ii. *Public Comment
    iii. Board Discussion

C. New Prior Authorization (PA) Criteria

1. **Exondys 51® (eteplirsen)**
   Exondys 51 is a central nervous system agent indicated for the treatment of Duchenne muscular dystrophy (DMD) in patients who have a confirmed mutation of the DMD gene that is amenable to exon 51 skipping. Prior authorization criteria is being proposed to ensure appropriate use based upon the FDA-approved labeling information and to remain consistent with other agents used for the approved indication.
   i. Prior Authorization Criteria
   ii. *Public Comment
   iii. Board Discussion

2. **Zinplava® (bezlotoxumab)**
   Zinplava is a human monoclonal antibody that binds to *Clostridium difficile* toxin B and is indicated to reduce recurrence of infections in adults who are receiving antibiotic treatment for *Clostridium difficile* infection (CDI). Prior authorization criteria is being proposed to ensure appropriate use based on approved indications.
   i. Prior Authorization Criteria
   ii. *Public Comment
   iii. Board Discussion

3. **Aspirin/Proton Pump Inhibitor Combination Step Therapy (Yosprala® [aspirin/omeprazole])**
   Step therapy for aspirin/proton pump inhibitor combination therapies is being proposed to ensure cost-effective use.
   i. Prior Authorization Criteria
   ii. *Public Comment
   iii. Board Discussion

4. **Nitroglycerin sublingual (GoNitro® [nitroglycerin sublingual powder])**
   GoNitro is a sublingual nitroglycerin powder used for the acute treatment of angina pectoris (“chest pain”) in those with underlying cardiovascular disease. Prior authorization is being proposed to ensure therapeutic appropriateness and cost-effective use.
   i. Prior Authorization Criteria
   ii. *Public Comment
   iii. Board Discussion

5. **Sulfonylurea/Thiazolidinedione Combination Step Therapy (Avandaryl® [rosiglitazone/glimepiride])**
   Step therapy for sulfonylurea/thiazolidinedione combination therapies is being proposed to ensure cost-effective use.
   i. Prior Authorization Criteria
   ii. *Public Comment
   iii. Board Discussion

6. **Amrix® (cyclobenzaprine extended-release)**
   Amrix is an extended-release formulation of cyclobenzaprine indicated for the treatment of muscle spasm associated with musculoskeletal injury. Step therapy is being proposed to ensure therapeutic appropriateness and cost-effective use.
   i. Prior Authorization Criteria
   ii. *Public Comment
   iii. Board Discussion

7. **Zolpimist® (zolpidem tartrate oral spray)**
   Zolpimist is an oral spray formulation of zolpidem tartrate, indicated for the treatment of insomnia in adults. Prior authorization criteria is being proposed to ensure appropriate use based on approved indications.
   i. Prior Authorization Criteria
   ii. *Public Comment
   iii. Board Discussion

8. **Zegerid® (omeprazole/sodium bicarbonate)**
   Zegerid is a reformulated version of omeprazole, a proton pump inhibitor used for gastroesophageal reflux disease. Step therapy is being proposed for cost-effective use of this formulation.
   i. Prior Authorization Criteria
   ii. *Public Comment
   iii. Board Discussion

D. Mental Health Medication Advisory Committee (MHMAC)

1. **Use of Multiple Concurrent Tricyclic Antidepressants**
   At the November 2016 MHMAC meeting, the committee approved the criteria for the concurrent use of two or more different TCAs used concurrently for greater than sixty days.
   i. MHMAC PA Criteria
   ii. *Public Comment
   iii. Board Discussion

2. **Opioid Dependence Agents**
   At the November 2016 MHMAC meeting, the committee approved the revised criteria for opioid dependence agents.
   i. MHMAC PA Criteria
   ii. *Public Comment
   iii. Board Discussion

E. Miscellaneous Items

1. **Fee-for-Service Retrospective Drug Utilization Review Topic Selections**
   The DUR Board will select topics for the two (2) RDUR intervention topics between February and June 2017.
   i. Topic Presentations
   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 April 12, 2017.

*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****