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

Kansas
Department of Health & Environment

Phone: 785-296-0461
Fax: 785-559-4269
www.kdheks.gov

Darian P. Dernovish, Interim Secretary

Sam Brownback, Governor

Drug Utilization Review Board
Meeting Agenda, Open Session
January 10, 2018 10:00 a.m. – 2:00 p.m.

Meeting Location

DXC Technology, Building #283, Capital Room
6511 SE Forbes Ave, Topeka, KS 66619

Board Members

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

KDHE-DHCF Staff

Annette Grant, RPh
Carol Arace, Administrative Assistant

DXC Technology/HID Staff

Ellen McCaffrey, BSN
Karen Kluczykowski, RPh
Taylor DeRuiter, PharmD

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 11, 2017 Meeting Minutes

III. NEW BUSINESS

A. New Preferred Drug List (PDL) Class

1. **Short-Acting Opioids**
   At the December 2017 PDL meeting, the committee approved the addition of the short-acting opioids 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. **Bydureon® (exentatide)**
   Bydureon is a glucagon-like peptide (GLP-1) receptor agonist indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus. Prior authorization criteria were initially approved in April 2011.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. **Cinryze® (C1 esterase inhibitor, human)**
   Cinryze is a protein C1 inhibitor indicated for the prophylaxis of hereditary angioedema (HAE) attacks. Prior authorization criteria for this agent was last revised in January 2016. 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. **Ruconest® (C1 esterase inhibitor, recombinant)**
   Ruconest is a protein C1 inhibitor indicated for the acute treatment of hereditary angioedema (HAE) attacks. Prior authorization criteria for this agent was last revised in January 2016. HAE is a genetic condition and is commonly diagnosed through a blood test measuring C1 inhibitor levels. 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. **Firazyr® (icatibant)**
   Firazyr is a bradykinin inhibitor indicated for the acute treatment of hereditary angioedema (HAE) attacks. Prior authorization criteria for this agent was last revised in January 2016. HAE is a genetic condition and is commonly diagnosed through a blood test measuring C1 inhibitor levels. 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 January 2017. Since that time, the FDA has approved an expanded indication for Stelara for the treatment of patients 12 years and older with moderate to severe plaque psoriasis who are candidates for phototherapy or systemic therapy. 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

6. **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. Prior authorization criteria for this agent was last revised in January 2017. Since that time, Keytruda has been indicated for the treatment of a) recurrent locally advanced or metastatic gastric or gastroesophageal junction adenocarcinoma with disease progression on or after 2 or more prior lines of therapy; b) relapsed or refractory classical Hodgkin lymphoma; and c) unresectable or metastatic microsatellite instability-high or mismatch repair deficient cancers (solid tumors and colorectal cancer).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

7. **Daraprim® (pyrimethamine)**
   Daraprim had a typographical error during the initial approval in July 2017.
   i. Revised PA Criteria
   ii. *Public Comment
   iii. Board Discussion

8. **Opdivo® (nivolumab)**
   Opdivo is an antineoplastic monoclonal antibody. Prior authorization criteria were last revised in October 2017. Since that time, Opdivo has become indicated for the treatment of hepatocellular carcinoma who have been previously treated with sorafenib. 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

9. **Pegasys® (peginterferon alfa-2a)**
   Pegasys is an alpha interferon, indicated for the treatment of hepatitis B and hepatitis C. Prior authorization criteria were initially approved in July 2013. Since that time, Pegasys has become indicated for the treatment of hepatitis B in noncirrhotic pediatric patients 3 years and older with HBeAg-positive chronic hepatitis B. 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

10. **Sodium-Glucose Cotransporter 2 (SGLT2) Inhibitor Combinations**
    The SGLT2 inhibitor combinations prior authorization criteria was last revised in October 2017. This revision had a typographical error during approval which has since been corrected.
    i. Revised PA Criteria
    ii. *Public Comment
    iii. Board Discussion

11. **Simponi®, Simponi Aria® (golimumab)**
    Simponi is an immunomodulator. Prior authorization criteria were initially approved in April 2016. Since that time, Simponi Aria has become indicated for the treatment of a) psoriatic arthritis and b) active ankylosing spondylitis. 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

12. **Soliris® (eculizumab)**
    Soliris is a complement inhibitor, indicated for the treatment of patients with paroxysmal nocturnal hemoglobinuria to reduce hemolysis, and the treatment of patients with atypical hemolytic uremic syndrome to inhibit complement-mediated thrombotic microangiopathy. Prior authorization criteria were initially approved in October 2013. Since that time, Soliris has become indicated for the treatment of generalized myasthenia gravis who are anti-acetylcholine receptor antibody-positive. 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

13. **Zelboraf® (vemurafenib)**
    Zelboraf is a kinase inhibitor, indicated for the treatment of patients with unresectable and/or metastatic melanoma with a BRAF V600E mutation. Prior authorization criteria were initially approved in October 2015. Since that time, Zelboraf has become indicated for the treatment of Erdheim-Chester disease with BRAF V600 mutation. 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

14. **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 were initially approved in January 2017. The criteria is being updated to address the use of Zinplava in patients with a diagnosis of HIV/AIDS or those that are receiving chemotherapy.
        i. Revised PA Criteria
        ii. *Public Comment
        iii. Board Discussion

15. **Makena® (hydroxyprogesterone caproate)**
    Makena is a progestin indicated for the prevention of preterm birth in women with a singleton pregnancy who have a history of singleton spontaneous preterm birth. Prior authorization criteria were last revised in July 2016. The criteria is being updated to allow for treatment with Makena to begin in patients up to 26 weeks, 6 days of gestation.
        i. Revised PA Criteria
        ii. *Public Comment
        iii. Board Discussion

C. New Prior Authorization (PA) Criteria

1. **Cabometyx® (cabozantinib)**
    Cabometyx is a pro-invasive receptor tyrosine kinase inhibitor, indicated for the treatment of advanced renal cell carcinoma in patients who have received prior anti-angiogenic therapy. Prior authorization criteria is being proposed to ensure appropriate use based upon the FDA-approved labeling information.
        i. Prior Authorization Criteria
        ii. *Public Comment
        iii. Board Discussion

2. **Calquence® (acalabrutinib)**
   Calquence is a second-generation Bruton's tyrosine kinase (BTK) inhibitor, indicated for the treatment of mantle cell lymphoma (MCL) in patients who have received at least 1 prior therapy. Prior authorization criteria is being proposed to ensure appropriate use based upon the FDA-approved labeling information.
   i. Prior Authorization Criteria
   ii. *Public Comment
   iii. Board Discussion

3. **Elaprase® (idursulfase)**
   Elaprase is a recombinant form of iduronate-2-sulfatase, indicated for patients with Hunter syndrome (mucopolysaccharidosis type II [MPS II]) to improve walking capacity in patients 5 years and older. Prior authorization criteria is being proposed to ensure appropriate use based upon the FDA-approved labeling information.
   i. Prior Authorization Criteria
   ii. *Public Comment
   iii. Board Discussion

4. **Kymriah® (tisagenlecleucel)**
   Kymriah is a T cell immunotherapy, indicated for the treatment of B-cell precursor acute lymphoblastic leukemia (ALL) that is refractory or in second or later relapse. Prior authorization criteria is being proposed to ensure appropriate use based upon the FDA-approved labeling information.
   i. Prior Authorization Criteria
   ii. *Public Comment
   iii. Board Discussion

5. **Lyrica® and Lyrica®CR (pregabalin and pregabalin CR)**
   Lyrica is an anti-epileptic medication, indicated for the treatment of fibromyalgia, postherpatic neuralgia, partial-onset seizures, and neuropathic pain associated with diabetic peripheral neuropathy and spinal cord injury. Prior authorization criteria is being proposed to ensure appropriate use based upon the FDA-approved labeling information and includes step therapy to ensure cost-effective use.
   i. Prior Authorization Criteria
   ii. *Public Comment
   iii. Board Discussion

6. **Trelegy Ellipta® (fluticasone/umeclidinium/vilanterol)**
   Trelegy Ellipta is a combination product consisting of an inhaled corticosteroid, anticholinergic, and long-acting beta agonist. It is indicated for chronic obstructive pulmonary disease (COPD), including chronic bronchitis and/or emphysema. 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

7. **Trelstar® (triptorelin)**
   Trelstar is a gonadotropin releasing hormone (GnRH) agonist, indicated for the palliative treatment of advanced prostate cancer treatment. Prior authorization criteria is being proposed to ensure appropriate use based upon the FDA-approved labeling information.
   i. Prior Authorization Criteria
   ii. *Public Comment
   iii. Board Discussion

8. **Verzenio™ (abemaciclib)**
   Verzenio is a cyclin-dependent kinase (CDK) inhibitor, indicated for the treatment of hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative advanced or metastatic breast cancer in women with disease progression following endocrine therapy. 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

9. **Opioids**
   This criteria will combine and supersede all previous criteria for past opioid PAs, for both short and long acting opioids. The prior authorization criteria are being proposed to ensure appropriate use based upon the FDA-approved labeling information and be consistent with similar agents. CDC guidelines, CMS Best Practices, and input from an internal team composed of members from DXC, KDHE, KDADS, and the MCOs was used for guidance in this draft.
   i. Prior Authorization Criteria
   ii. *Public Comment
   iii. Board Discussion

D. 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 2018.
   i. Topic Presentations
   ii. Board Discussion

IV. OPEN PUBLIC COMMENT

V. ADJOURN

ACRONYMS: CDC = CENTER FOR DISEASE CONTROL, CMS = CENTERS FOR MEDICAID AND MEDICARE, KDHE = KANSAS DEPT. OF HEALTH AND ENVIRONMENT, KDADS = KANSAS DEPARTMENT FOR AGING AND DISABILITY SERVICES, MCO = MANAGED CARE ORGANIZATION

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****