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
October 11, 2017 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

Taylor DeRuiter, PharmD
Nancy Perry, RN
Ellen McCaffrey, RN
Karen Kluczykowski, RPh
Ariane Casey, 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 July 26, 2017 Meeting Minutes

III. NEW BUSINESS

A. PDL Committee New Business

1. **PDL Pre-Approval**
   At the September 2017 PDL meeting, the committee approved the pre-approval for drug molecule dose form, dose device, IR/ER of CURRENT PDL drug.
   i. Explanation
   ii. *Public Comment
   iii. Board Discussion

B. New Preferred Drug List (PDL) Classes

1. **Hepatitis C Refractory Treatment Agents**
   At the September 2017 PDL meeting, the committee approved the addition of the Hepatitis C Refractory Treatment Agents to the PDL.
   i. Non-Preferred PDL PA Criteria
   ii. *Public Comment
   iii. Board Discussion

2. **Topical Corticosteroids – Mid Potency**
   At the September 2017 PDL meeting, the committee approved the addition of the Topical Corticosteroids – Mid Potency to the PDL.
   i. Non-Preferred PDL PA Criteria
   ii. *Public Comment
   iii. Board Discussion

3. **Topical Corticosteroids – Intermediate Potency**
   At the September 2017 PDL meeting, the committee approved the addition of the Topical Corticosteroids – Intermediate Potency to the PDL.
   i. Non-Preferred PDL PA Criteria
   ii. *Public Comment
   iii. Board Discussion

4. **Topical Corticosteroids – High Potency**
   At the September 2017 PDL meeting, the committee approved the addition of the Topical Corticosteroids – High Potency to the PDL.
   i. Non-Preferred PDL PA Criteria
   ii. *Public Comment
   iii. Board Discussion

5. **Topical Fluorouracil Agents**
   At the September 2017 PDL meeting, the committee approved the addition of the Topical Fluorouracil Agents to the PDL.
   i. Non-Preferred PDL PA Criteria
   ii. *Public Comment
   iii. Board Discussion

6. **Topical Rosacea Agents**
   At the September 2017 PDL meeting, the committee approved the addition of the Topical Rosacea Agents to the PDL.
   i. Non-Preferred PDL PA Criteria
   ii. *Public Comment
   iii. Board Discussion

C. Revised Prior Authorization (PA) Criteria

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

2. **Humira® (Cyltezo® [adalimumab-adbm])**
   Cyltezo is the second biosimilar available for Humira. Biosimilar means that the biological product is approved based on data demonstrating that it is highly similar to an FDA-approved biological product, known as a reference product, and that there are no clinically meaningful differences between the biosimilar product and the reference product. Prior authorization criteria for this agent were last revised in April 2017. Since that time, a new agent has been approved. The prior authorization criteria is being revised to include the new agent, Cyltezo.
   i. Revised PA Criteria
   ii. *Public Comment
   iii. Board Discussion

3. **Kisqali® (ribociclib)**
   Kisqali is a kinase inhibitor. Prior authorization criteria were initially approved in July 2017. Since that time, a new packaging has been approved to include Kisqali in combination with Femara. The prior authorization criteria are being revised to ensure appropriate used based upon the FDA-approved labeling information and be consistent with similar agents and ensure appropriate use. The prior authorization criteria is being revised to include the new agent, Kisqali Femara Pack.
   i. Revised PA Criteria
   ii. *Public Comment
   iii. Board Discussion

4. **Monoamine Depletors (Austedo® [deutetrabenazine], Ingrezza® [valbenazine])**
   Prior authorization criteria were initially approved in March 2009. Since that time, two new agents have been approved. The prior authorization criteria are being revised to ensure appropriate used based upon the FDA-approved labeling information and be consistent with similar agents and ensure appropriate use. The prior authorization criteria is being revised to include the new agents and corresponding indications.
   i. Revised PA Criteria
   ii. *Public Comment
   iii. Board Discussion

5. **Opioid Induced Constipation Agents**
   The agents within the Opioid Induced Constipation Agents PA Criteria have had an update to the wording for the indication. Prior authorization criteria for this agent were last revised in July 2017. The prior authorization criteria are being proposed to ensure appropriate used based upon the FDA-approved labeling information and be consistent with similar agents and ensure appropriate use.
   i. Revised PA Criteria
   ii. *Public Comment
   iii. Board Discussion

6. **Adlyxin® (lixisenatide)**
   Adlyxin is a glucagon-like peptide 1 (GLP-1) receptor agonist. It is being proposed for a change to step therapy. Prior authorization criteria for this agent were initially approved in October 2016. The prior authorization criteria are being proposed to ensure appropriate used based upon the FDA-approved labeling information and be consistent with similar agents and ensure appropriate use.
   i. Revised PA Criteria
   ii. *Public Comment
   iii. Board Discussion

7. **Sodium-Glucose Cotransporter 2 (SGLT2) Inhibitor Combinations**
   SGLT2 inhibitor combinations is being proposed for a change to step therapy. Prior authorization criteria for this agent were initially approved in October 2016. The prior authorization criteria are being proposed to ensure appropriate used based upon the FDA-approved labeling information and be consistent with similar agents and ensure appropriate use.
   i. Revised PA Criteria

ii. *Public Comment
iii. Board Discussion

8. **H.P. Acthar® (corticotropin)**
H.P. Acthar is adrenocortical steroid. Prior authorization criteria were initially approved in July 2013. Step therapy and appropriate dosing is being proposed. The prior authorization criteria are being revised to ensure appropriate used based upon the FDA-approved labeling information and be consistent with similar agents and ensure appropriate use.
    i. Revised PA Criteria
    ii. *Public Comment
    iii. Board Discussion

9. **Actemra® (tocilizumab)**
Actemra is an interleukin-6 (IL-6) receptor antagonist. Prior authorization criteria were last revised in July 2017. Since that time, the medication has become indicated for the treatment of cytokine release syndrome (CRS). The prior authorization criteria are being revised to ensure appropriate used based upon the FDA-approved labeling information and be consistent with similar agents and ensure appropriate use.
    i. Revised PA Criteria
    ii. *Public Comment
    iii. Board Discussion

10. **Darzalex® (daratumumab)**
Darzalex is a CD38-directed cytolytic antibody. Prior authorization criteria were last revised in April 2017. Since that time, the medication has become indicated for the treatment of with multiple myeloma as combination therapy with pomalidomide and dexamethasone after at least 2 prior therapies including lenalidomide and a proteasome inhibitor. The prior authorization criteria are being revised to ensure appropriate used based upon the FDA-approved labeling information and be consistent with similar agents and ensure appropriate use.
    i. Revised PA Criteria
    ii. *Public Comment
    iii. Board Discussion

11. **Imbruvica® (ibrutinib)**
Imbruvica is a kinase inhibitor. Prior authorization criteria were last revised in April 2017. Since that time, the medication has become indicated for the treatment of chronic graft versus host disease (cGVHD) after failure of one or more lines of systemic therapy. The prior authorization criteria are being revised to ensure appropriate used based upon the FDA-approved labeling information and be consistent with similar agents and ensure appropriate use.
    i. Revised PA Criteria
    ii. *Public Comment
    iii. Board Discussion

12. **Mekinist® (trametinib)**
Mekinist is a kinase inhibitor. Prior authorization criteria were last revised in April 2014. Since that time, the medication has become indicated for the treatment of metastatic non-small cell lung cancer (NSCLC) with BRAF V600E mutation in combination with dabrafenib. The prior authorization criteria are being revised to ensure appropriate used based upon the FDA-approved labeling information and be consistent with similar agents and ensure appropriate use.
    i. Revised PA Criteria
    ii. *Public Comment
    iii. Board Discussion

13. **Opdivo® (nivolumab)**
    Opdivo is a programmed death receptor-1 (PD-1) blocking antibody. Prior authorization criteria were last revised in April 2017. Since that time, the medication has become indicated for the treatment of adult and pediatric (12 years and older) patients with microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) metastatic colorectal cancer that has progressed following treatment with a fluoropyrimidine, oxaliplatin, and irinotecan. The prior authorization criteria are being revised to ensure appropriate used based upon the FDA-approved labeling information and be consistent with similar agents and ensure appropriate use.
    i. Revised PA Criteria
    ii. *Public Comment
    iii. Board Discussion

14. **Orencia® (abatacept)**
    Orencia is a T cell costimulation modulator. Prior authorization criteria were last revised in April 2016. Since that time, the medication has become indicated for the treatment of adult psoriatic arthritis (PsA). The prior authorization criteria are being revised to ensure appropriate used based upon the FDA-approved labeling information and be consistent with similar agents and ensure appropriate use.
    i. Revised PA Criteria
    ii. *Public Comment
    iii. Board Discussion

15. **Lynparza® (olaparib)**
    Lynparza is a poly (ADP-ribose) polymerase (PARP) inhibitor indicated for the maintenance treatment of adult patients with recurrent epithelial ovarian, fallopian tube or primary peritoneal cancer and for the treatment of adult patients with deleterious or suspected deleterious germline BRCA-mutated advanced ovarian cancer. Prior authorization criteria were initially approved in July 2017. A new formulation (tablet) has been approved that have additional indications than the capsule. The prior authorization criteria are being revised to ensure appropriate used based upon the FDA-approved labeling information and be consistent with similar agents and ensure appropriate use.
    i. Revised PA Criteria
    ii. *Public Comment
    iii. Board Discussion

16. **Trokendi XR® (topiramate extended-release)**
    Trokendi is an anticonvulsant. Prior authorization criteria were initially approved in January 2014. Since that time, the medication has become indicated for the prophylaxis of migraine headache in adults and adolescents 12 years of age and older and as monotherapy in those with partial onset seizures or primary generalized tonic-clonic seizures in those who are at least 6 years of age. The prior authorization criteria are being revised to ensure appropriate used based upon the FDA-approved labeling information and be consistent with similar agents and ensure appropriate use.
    i. Revised PA Criteria
    ii. *Public Comment
    iii. Board Discussion

17. **Daklinza® (daclatasvir)**
    Daklinza is a direct acting antiviral agent indicated for the treatment of hepatitis C virus (HCV). Prior authorization criteria were last revised in January 2017. There is a black box warning for the risk of hepatitis B reactivation. With new agents approved for other genotypes, consistent wording for using the preferred agent is being added. The prior authorization criteria are being revised to ensure appropriate used based upon the FDA-approved labeling information and be consistent with similar agents and ensure appropriate use.
    i. Revised PA Criteria
    ii. *Public Comment
    iii. Board Discussion

18. **Epclusa® (sofosbuvir/velpatasvir)**
    Epclusa is a direct acting antiviral agent indicated for the treatment of hepatitis C virus (HCV). Prior authorization criteria were last revised in January 2017. There is a black box warning for the risk of hepatitis B reactivation. With new agents approved for other genotypes, consistent wording for using the preferred agent is being added. The prior authorization criteria are being revised to ensure appropriate used based upon the FDA-approved labeling information and be consistent with similar agents and ensure appropriate use.
        i. Revised PA Criteria
        ii. *Public Comment
        iii. Board Discussion

19. **Zepatier® (elbasvir/grazoprevir)**
    Zepatier is a direct acting antiviral agent indicated for the treatment of hepatitis C virus (HCV). Prior authorization criteria were last revised in April 2017. There is a black box warning for the risk of hepatitis B reactivation. With new agents approved for other genotypes, consistent wording for using the preferred agent is being added. The prior authorization criteria are being revised to ensure appropriate used based upon the FDA-approved labeling information and be consistent with similar agents and ensure appropriate use.
        i. Revised PA Criteria
        ii. *Public Comment
        iii. Board Discussion

20. **Olysio® (simeprevir)**
    Olsyio is a direct acting antiviral agent indicated for the treatment of hepatitis C virus (HCV). Prior authorization criteria were last revised in January 2017. There is a black box warning for the risk of hepatitis B reactivation. The prior authorization criteria are being revised to ensure appropriate used based upon the FDA-approved labeling information and be consistent with similar agents and ensure appropriate use.
        i. Revised PA Criteria
        ii. *Public Comment
        iii. Board Discussion

21. **Viekira® (ombitasvir/paritaprevir/ritonavir/dasabuvir)**
    Viekira is a direct acting antiviral agent indicated for the treatment of hepatitis C virus (HCV). Prior authorization criteria were last revised in January 2017. There is a black box warning for the risk of hepatitis B reactivation. The prior authorization criteria are being revised to ensure appropriate used based upon the FDA-approved labeling information and be consistent with similar agents and ensure appropriate use.
        i. Revised PA Criteria
        ii. *Public Comment
        iii. Board Discussion

22. **Harvoni® (ledipasvir/sofosbuvir)**
    Harvoni is a direct acting antiviral agent indicated for the treatment of hepatitis C virus (HCV). Prior authorization criteria were last revised in July 2017. With new agents approved for other genotypes, consistent wording for using the preferred agent is being added. The prior authorization criteria are being revised to ensure appropriate used based upon the FDA-approved labeling information and be consistent with similar agents and ensure appropriate use.
        i. Revised PA Criteria
        ii. *Public Comment
        iii. Board Discussion

23. **Sovaldi® (sofosbuvir)**
    Sovaldi is a direct acting antiviral agent indicated for the treatment of hepatitis C virus (HCV). Prior authorization criteria were last revised in April 2017. With new agents approved for other genotypes, consistent wording for using the preferred agent is being added. The prior authorization criteria are being

revised to ensure appropriate used based upon the FDA-approved labeling information and be consistent with similar agents and ensure appropriate use.

i. Revised PA Criteria
ii. *Public Comment
iii. Board Discussion

24. **Vosevi® (sofosbuvir/velpatasvir/voxilaprevir)**
Vosevi is a direct acting antiviral agent indicated for the treatment of hepatitis C virus (HCV). Prior authorization criteria were initially approved in July 2017. With new agents approved for other genotypes, consistent wording for using the preferred agent is being added. The prior authorization criteria are being revised to ensure appropriate used based upon the FDA-approved labeling information and be consistent with similar agents and ensure appropriate use.

i. Revised PA Criteria
ii. *Public Comment
iii. Board Discussion

D. New Prior Authorization (PA) Criteria

1. **Mavyret® (glecaprevir/pibrentasvir)**
Mavyret is a direct acting antiviral agent indicated for the treatment of hepatitis C virus (HCV). The prior authorization criteria are being proposed to ensure appropriate used based upon the FDA-approved labeling information and be consistent with similar agents and ensure appropriate use.

i. Prior Authorization Criteria
ii. *Public Comment
iii. Board Discussion

2. **Haegarda® (C1 esterase inhibitor [human])**
Haegarda is a plasma-derived concentrate of C1 Esterase Inhibitor (Human) (C1-INH) indicated for routine prophylaxis to prevent Hereditary Angioedema (HAE) attacks in adolescent and adult patients. The prior authorization criteria are being proposed to ensure appropriate used based upon the FDA-approved labeling information and be consistent with similar agents and ensure appropriate use.

i. Prior Authorization Criteria
ii. *Public Comment
iii. Board Discussion

3. **Idhifa® (enasidenib)**
Idhifa is an isocitrate dehydrogenase-2 inhibitor indicated for the treatment of adult patients with relapsed or refractory acute myeloid leukemia (AML) with an isocitrate dehydrogenase-2 (IDH2) mutation. The prior authorization criteria are being proposed to ensure appropriate used based upon the FDA-approved labeling information and be consistent with similar agents and ensure appropriate use.

i. Prior Authorization Criteria
ii. *Public Comment
iii. Board Discussion

4. **Motofen® (difenoxin/atropine)**
Motofen is indicated as adjunctive therapy in the management of acute nonspecific diarrhea and acute exacerbations of chronic functional diarrhea. The prior authorization criteria are being proposed to ensure appropriate used based upon the FDA-approved labeling information and be consistent with similar agents and ensure appropriate use.

i. Prior Authorization Criteria
ii. *Public Comment
iii. Board Discussion

5. **Ocrevus® (ocrelizumab)**
   Ocrevus is CD20-directed cytolytic antibody indicated for the treatment of patients with relapsing or primary progressive forms of multiple sclerosis. The prior authorization criteria are being proposed to ensure appropriate used based upon the FDA-approved labeling information and be consistent with similar agents and ensure appropriate use.
   i. Prior Authorization Criteria
   ii. *Public Comment
   iii. Board Discussion

6. **Tremfya® (guselkumab)**
   Temfya is an interleukin-23 blocker indicated for the treatment of adult patients with moderate-to-severe plaque psoriasis who are candidates for systemic therapy or phototherapy. The prior authorization criteria are being proposed to ensure appropriate used based upon the FDA-approved labeling information and be consistent with similar agents and ensure appropriate use.
   i. Prior Authorization Criteria
   ii. *Public Comment
   iii. Board Discussion

7. **Triptodur® (triptorelin)**
   Triptodur is a gonadotropin releasing hormone (GnRH) agonist indicated for the treatment of pediatric patients 2 years and older with central precocious puberty. The prior authorization criteria are being proposed to ensure appropriate used based upon the FDA-approved labeling information and be consistent with similar agents and ensure appropriate use.
   i. Prior Authorization Criteria
   ii. *Public Comment
   iii. Board Discussion

8. **Bineura® (cerliponase alfa)**
   Brineura is a hydrolytic lysosomal N-terminal tripeptidyl peptidase indicated to slow the loss of ambulation in symptomatic pediatric patients 3 years of age and older with late infantile neuronal ceroid lipofuscinosis type 2 (CLN2), also known as tripeptidyl peptidase 1 (TPP1) deficiency. The prior authorization criteria are being proposed to ensure appropriate used based upon the FDA-approved labeling information and be consistent with similar agents and ensure appropriate use.
   i. Prior Authorization Criteria
   ii. *Public Comment
   iii. Board Discussion

9. **Rydapt® (midostaurin)**
   Rydapt is kinase inhibitor indicated for the treatment of adult patients with acute myeloid leukemia (AML) with a positive FLT3 mutation, aggressive systemic mastocytosis (ASM), systemic mastocytosis with associated hematological neoplasm (SM-AHN), or mast cell leukemia (MCL. The prior authorization criteria are being proposed to ensure appropriate used based upon the FDA-approved labeling information and be consistent with similar agents and ensure appropriate use.
   i. Prior Authorization Criteria
   ii. *Public Comment
   iii. Board Discussion

E. Mental Health Medication Advisory Committee (MHMAC)

1. **Multiple Concurrent Mood Stabilizers**
   At the August 2017 MHMAC meeting, the committee approved the criteria for use of multiple concurrent mood stabilizers.
   i. Prior Authorization Criteria
   ii. *Public Comment
   iii. Board Discussion

F. 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 10, 2018.

*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****