STATE OF KANSAS

DEPARTMENT OF HEALTH AND ENVIRONMENT
DIVISION OF HEALTH CARE FINANCE
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GOVERNOR JEFF COLYER, M.D.
JEFF ANDERSEN, SECRETARY

Drug Utilization Review Board
Meeting Agenda, Open Session
October 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
Serena Stutzman, APRN
Roger Unruh, DO
LaTonyua Rice, PharmD, CGP
Jennifer Clair, MD
Katie Burenheide Foster, PharmD, MS, BCPS, FCCM

KDHE-DHCF Staff/Contractor

Annette Grant, RPh
Roxanne Chadwell, PharmD, CSP
Markie O'Donnell, Transcriptionist
Dr. Greg Lakin, DO, Chief Medical Officer

DXC Technology/HID Staff

Karen Kluczykowski, RPh
Kathy Kaesewurm, RN, BSN
Taylor DeRuiter, PharmD

MCO Staff

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

I. CALL TO ORDER

A. Announcements and Introductions

II. OLD BUSINESS

A. Review and Approval of July 11, 2018 Meeting Minutes

III. NEW BUSINESS

A. New Preferred Drug List (PDL) Class

1. **Bowel Prep Agents**
   At the September 2018 PDL meeting, the committee approved the addition of bowel prep 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. **Botulinum Toxins**
   Botulinum toxins carry multiple FDA-approved indications for use. Prior authorization criteria were last revised in October 2016. Since that time, the product Xeomin® has been FDA-approved for treatment of chronic sialorrhea in adults. The prior authorization criteria are being revised to be consistent with other agents, ensure appropriate and cost-effective use, and include new indicated uses for these agents.
   i. Revised PA Criteria
   ii. *Public Comment
   iii. Board Discussion

2. **CFTR Modulators**
   Cystic fibrosis transmembrane conductance regulator (CFTR) modulators are indicated for the treatment of cystic fibrosis (CF). The prior authorization criteria were last revised in April 2018. Since that time, Orkambi® has been FDA-approved for the treatment of CF in patients 2 years of age or older. The prior authorization criteria are being revised to ensure appropriate and cost-effective use.
   i. Revised PA Criteria
   ii. *Public Comment
   iii. Board Discussion

3. **Chemotherapy Agents**
   This criteria applies to all oral and injectable chemotherapy agents. The criteria ensures the requested product is being used for FDA-approved indications and in accordance with all dosing and safety recommendations provided in manufacturer labeling, and was initially approved in July 2018. The prior authorization criteria are being revised to include updated indications for use and safety information for the covered agents.
   i. Revised PA Criteria
   ii. *Public Comment
   iii. Board Discussion

4. **Enzyme Replacement Therapy**
   The criteria for enzyme replacement therapies was last revised in October 2014., which included agents for the treatment of type 1 Gaucher disease. Since that time, the new agents Fabrazyme® and Galafold™ have both received FDA approval for the treatment of Fabry disease. The prior authorization criteria are being revised to include new agents and indications for use, as well as ensure appropriate and cost-effective use.
   i. Revised PA Criteria
   ii. *Public Comment
   iii. Board Discussion

5. **Immunomodulators**
   This criteria applies to all immunomodulator agents and their biosimilar products. The criteria ensures the requested product is being used for FDA-approved indications and in accordance with all dosing and safety recommendations provided in manufacturer labeling, and was initially approved in July 2018. The prior authorization criteria are being updated to include step therapy requirements for specific agents and diagnoses, as well as to be consistent with other agents, ensure appropriate and cost-effective use, and include new label information for these agents.
   i. Revised PA Criteria
   ii. *Public Comment
   iii. Board Discussion

6. **Kymriah™**
   Kymriah™ is a chimeric antigen receptor (CAR) T-cell immunotherapy, previously only indicated for the treatment of B-cell precursor acute lymphoblastic leukemia (ALL) that is refractory or in second or later relapse. This criteria was last revised in January 2018. Since that time, Kymriah™ has also been FDA-approved for the treatment of relapsed or refractory diffuse large b-cell lymphoma (DLBCL). The criteria has been updated to include the new indication for use.
   i. Revised PA Criteria
   ii. *Public Comment
   iii. Board Discussion

7. **Opioid Agents**
   This criteria covers all short and long-acting opioids. This criteria was last reviewed in July 2018. The prior authorization criteria are being revised to add the short-acting agent Roxybond™ to the criteria as well as ensure appropriate use based upon the FDA-approved labeling information, CDC guidelines, CMS Best Practices, and input from an internal team composed of members from DXC, KDHE, KDADS, and the MCOs, and to be consistent with similar agents.
   i. Revised PA Criteria
   ii. *Public Comment
   iii. Board Discussion

8. **Somatropin Products**
   Somatropin products are used for several indications in both children and adults. Prior authorization criteria were last revised in April 2018. Since then, Zomacton® has been FDA-approved for use in pediatric patients that are short for gestational age, as well as for treatment of short stature homeobox-containing gene (SHOX) deficiency, and Turner syndrome. The prior authorization criteria are being revised to ensure appropriate use based upon the FDA-approved labeling information and be consistent with similar agents.
   i. Revised PA Criteria
   ii. *Public Comment
   iii. Board Discussion

9. **Spinraza™**
   Spinraza™ is a survival motor neuron-2 (SMN2)-directed antisense oligonucleotide indicated for the treatment of spinal muscular atrophy (SMA) in pediatric and adult patients. Prior authorization criteria for this agent was last revised in July 2017. The prior authorization criteria are being updated to ensure appropriate use in adult patients based upon the FDA-approved labeling and available drug information.
   i. Revised PA Criteria
   ii. *Public Comment
   iii. Board Discussion

C. New Prior Authorization (PA) Criteria

1. **CGRP Antagonists**
   Calcitonin gene-related peptide receptor (CGRP) antagonists are a new class of medications indicated for the prevention of migraine. During the July 2018 meeting, the Board approved prior authorization criteria for the CGRP antagonist Aimovig™. Since that time, another CGRP antagonist, Ajovy™, has been FDA-approved for the prevention of migraine. This PA utilizes the criteria for Aimovig™ to create a new class criteria for these agents for the purpose of consolidation, to ensure criteria consistency between similar agents and ensure appropriate use.
   i. Prior Authorization Criteria
   ii. *Public Comment
   iii. Board Discussion

2. **Orilissa™**
   Orilissa™ is a gonadotropin-releasing hormone (GnRH) receptor antagonist indicated for the treatment of moderate to severe pain from endometriosis. 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. **Trogarzo™**
   Trogarzo™ is a new recombinant monoclonal antibody, indicated for the treatment of HIV in treatment-experienced 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

4. **Advanced Medical Hold Manual Review PA**
   This criteria would be applicable to new-to-market-drugs that are FDA Approved after October 15, 2018 that are not referenced in any approved drug or drug-class specific prior authorization criteria in place. The criteria is meant to function as a pre-approval management process for new-to-market drugs and drug formulations until the DUR Board can give a full review to the newly approved agent and make a determination on permanent PA criteria for the agent.
   i. Prior Authorization Criteria
   ii. *Public Comment
   iii. Board Discussion

D. Mental Health Medication Advisory Committee (MHMAC)

1. **ADHD Medications**
   At the August 2018 MHMAC meeting, the committee revised the criteria for use of ADHD products. The criteria were initially approved in July 2018 and have been revised to include the agents Evekeo®, Jornay PM™, and Relexxii® to ensure criteria consistency between similar agents and ensure appropriate use.
   i. Prior Authorization Criteria
   ii. *Public Comment
   iii. Board Discussion

2. **Antidepressant Medications**
   At the August 2018 MHMAC meeting, the committee revised the criteria for use of multiple concurrent antidepressant products. The criteria were initially approved in July 2018 and have been revised to remove mirtazapine and trazodone agents from the list of drugs that the criteria applies to.
   i. Prior Authorization Criteria
   ii. *Public Comment
   iii. Board Discussion

3. **Antipsychotic Medications**
   At the August 2018 MHMAC meeting, the committee revised the criteria for use of antipsychotic agents. The criteria were initially approved in July 2018 and have been revised to include the agents Aristada Initio™ and Perseris™, as well as clarify language present in the criteria for use in patients greater than 65 years of age.
   i. Prior Authorization Criteria
   ii. *Public Comment
   iii. Board Discussion

4. **Benzodiazepine Medications**
   At the August 2018 MHMAC meeting, the committee revised the criteria for use of benzodiazepine medications. The criteria were initially approved in July 2018 and have been revised to update specific criteria for use of an opioid in combination with high-dose benzodiazepine agents.
   i. Prior Authorization Criteria
   ii. *Public Comment
   iii. Board Discussion

E. Miscellaneous Items

1. **Pharmacy Committee Summaries & General Program Updates**
   i. Presentation
   ii. Board Discussion

2. **PA Process – Updates and Demonstration**
   i. Presentation
   ii. Board Discussion

3. **Fee-for-Service Annual Program Assessment**
   The annual program assessment for the Medicaid fee-for-service population will be presented to show utilization and cost trends over the past state fiscal year.
   i. Presentation
   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 January 9, 2019.

*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****