Drug Utilization Review Board
Meeting Minutes, Open Session October 10, 2018

Drug Utilization Review Board
Meeting Location: DXC Technology,
Building #283, Capital Room 6511
SE Forbes Ave, Topeka, KS 66619

DUR Board Members Present
Moneeshindra Mittal, MD, Chair
LaTonyua Rice Pharm.D.
Katie Burenheide Foster, PharmD
Jennifer Clair, MD
Serena Stutzman, APRN
Tim Heston, DO
Roger Unruh, DO
James Backes, Pharm.D.

KDHE/DHCF/Contractor Staff Present
Annette Grant, RPh.
Dr. Wayne Wallace
Margaret O'Donnell, Transcriptionist

DXC Technology Staff Present
Karen Kluczykowski, RPh
Kathy Kaesewurm, RN, BSN

HID Staff Present
Taylor DeRuiter, Pharm.D.

MCO Staff Present
Angie Zhou, Pharm.D., Sunflower Health Plan
Jennifer Murff, RPh, UnitedHealthcare
Lisa Todd, RPh, Amerigroup

Public Attendees: Donna Osterlund, Lance Webb, Genzyme; Meghan Kerrigan, Merck; Jennifer Stoffel, Erin Hohman, Janssen; Eric Gardner, Vertex, Jeff Knappen, Spark; Mike Pratsner, Osiris; Camille Kerr, Amgen; Keith Wisdom, Aetna; Dan Swanson, Anil Kalie, Antony Kimthi, Lily Staab, Cerner; Aaron Zimmerman, Teva; Teresa Blair, Ipsen; Jim Baumann, Pfizer; Jeff Osmundson, Novartis; Jill Conner, Sanofi; David Horsch, Takeda; Harry Vu, Valerie Ng, Brent Hildebrand, Heather Whisnant, Krishna Moorthy, Richard McDermott, Matt Goodrich, Delos DeCelle

*Illegible names on the sign-in sheet were not included.

TOPIC	DISCUSSION
I. Call to Order	Dr. Mittal called the meeting to order at 10:11 a.m.
Announcements and Introductions	Ms. Grant introduced new Board Members, Serena Stutzman, APRN and Jennifer Clair, MD.
II. Old Business **A. Review and approval of July 11 2018 Meeting Minutes**	**Board Discussion:** None. **Decision and/or Action:** Dr. Unruh moved to accept the minutes as written. Dr. Foster seconded the motion. The motion was approved unanimously.
III. New Business **A. New Preferred Drug List (PDL) Class** 1. **Bowel Prep Agents**	**Background:** 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. **Public Comment:** None **Board Discussion**: None. **Decision and/or Action:** Dr. Backes moved to approve. Dr. Unruh seconded the motion. The motion was approved unanimously.

TOPIC	DISCUSSION
B. Revised Prior Authorization (PA) Criteria 1. Botulinum Toxins	**Background:** 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. **Public Comment:** None. **Board Discussion:** There was a question about identifying the specialist in consultation with and if that would be able to be identified on the form. The State replied that the PA form would say "Is this being prescribed by or in conjunction with a neurologist?" Most of the PA forms then list the different specialists to choose from, which are part of the PA criteria. **Decision and/or Action:** Dr. Backes moved to approve. Dr. Heston seconded the motion. The motion was approved unanimously.
B. Revised Prior Authorization (PA) Criteria 2. CFTR Modulators	**Background:** 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. **Public Comment:** Eric Gardner with Vertex mentioned to the Board that there was an update and FDA approval for Kalydeco® 12 months and older, on August 17th.

TOPIC	DISCUSSION
B. Revised Prior Authorization (PA) Criteria 2. CFTR Modulators **(Continued)**	This was verified by the DUR pharmacist and State pharmacist via a package insert search. The PA was amended to reflect that update. **Board Discussion:** There was discussion regarding the number of patients and the annual cost per patient. The annual cost was $300,000 for 35 patients. **Decision and/or Action:** Dr. Unruh moved to approve as amended. Dr. Rice seconded the motion. The motion was approved unanimously.
B. Prior Authorization (PA) Criteria 3. Chemotherapy Agents	**Background:** 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 a 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. **Public Comment:** None. **Board Discussion:** None. **Decision and/or Action:** Dr. Heston moved to approve. Dr. Foster seconded the motion. The motion was approved unanimously.

TOPIC	DISCUSSION
B. Revised Prior Authorization (PA) Criteria 4. Enzyme Replacement Therapy	**Background:** 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. **Public Comment:** Lance Webb with Genzyme Corporation spoke to the Board about Fabrazyme®. **Board Discussion:** None. **Decision and/or Action:** Dr. Rice moved to approve. Ms. Stutzman seconded the motion. The motion was approved unanimously.
B. Revised Prior Authorization (PA) Criteria 5. Immunomodulators	**Background:** This criteria applies to all immunomodulatory 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 I n 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. **Public Comment:** None.

TOPIC	DISCUSSION
B. Revised Prior Authorization (PA) Criteria 5. Immunomodulators **(Continued)**	**Board Discussion**: None. **Decision and/or Action:** Dr. Foster moved to approve. Dr. Heston seconded the motion. The motion was approved unanimously.
B. Revised Prior Authorization (PA) Criteria 6. Kymriah™ (tisagenlecleucel)	**Background:** 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. **Public Comment:** Jeff Osmudson with Novartis spoke about Kymriah™ and the fact that it may be restrictive to say that there's no active infections at the time of PA and it should instead be at the time of infusion. **Board Discussion:** The criteria for all diagnoses were amended to remove infection and inflammatory limitation requirements at the time of PA approval. The duration of approval was changed from one year to 12 months, for verbiage consistency with other drug PAs. **Decision and/or Action:** Ms. Stutzman moved to approve as amended. Dr. Backes seconded the motion. The motion was approved unanimously.

TOPIC	DISCUSSION
B. Revised Prior Authorization (PA) Criteria **7.** Opioid Agents	**Background:** 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. **Public Comment:** None. **Board Discussion:** None. **Decision and/or Action:** Dr. Heston moved to approve. Dr. Rice seconded the motion. The motion was approved unanimously.
B. Revised Prior Authorization (PA) Criteria 8. Somatropin Products	**Background:** 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**.** **Public Comment:** None.

TOPIC	DISCUSSION
B. Revised Prior Authorization (PA) Criteria 8. Somatropin Products **(Continued)**	**Board Discussion:** None. **Decision and/or Action:** Dr. Foster moved to approve. Dr. Unruh seconded the motion. The motion was approved unanimously.
B. Revised Prior Authorization (PA) Criteria 9. Spinraza (nusinersen)	**Background:** Spinraza™ is a survival motor neuron-2 (SMN2)-directed and 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. **Public Comment:** None. **Board Discussion:** None. **Decision and/or Action:** Due to new drug study results very recently brought to the state pharmacy team, the State requested to table this agenda item.

TOPIC	DISCUSSION
C. New Prior Authorization (PA) Criteria 1. CGRP Antagonists	**Background:** 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. **Public Comment:** None. **Board Discussion:** None. **Decision and/or Action:** Dr. Heston moved to approve. Dr. Rice seconded the motion. The motion was approved unanimously.
C. New Prior Authorization (PA) Criteria 2. Orilissa™ (elagolix)	**Background:** Orilissa™ is a gonadotropin-releasing hormone (GnRH) receptor antagonist indicated for the moderate to severe pain from endometriosis. The prior authorization criteria are being proposed to ensure appropriate use based upon the FDA-approved labeling information and be consistent with similar agents and ensure appropriate use. **Public Comment:** Laura Hill with AbbVie spoke about dosing and suggested having the dyspareunia language taken out.

TOPIC	DISCUSSION
C. New Prior Authorization (PA) Criteria 2. Orilissa™ (elagolix) **(Continued)**	**Board Discussion:** There was discussion that symptoms shouldn't be part of the criteria and the doctor is the judge of it, not the pharmacy or the insurance company. The State commented that it would be best to not leave it open, but rather should parallel other PA criteria for the basic safety needs. The State recommended removing the information in table 3 and edit the 5th bullet down to say "the prescribed dose is not to exceed 200 mg". **Decision and/or Action:** Dr. Heston moved to approve as amended. Ms. Stutzman seconded the motion. The motion was approved unanimously.
C. New Prior Authorization (PA) Criteria 3. Trogarzo™ (ibalizumab-ulyk)	**Background:** 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 use based upon the FDA-approved labeling information and be consistent with similar agents and ensure appropriate use. **Public Comment:** None. **Board Discussion:** The MCOs questioned whether verbiage should be added around the baseline, something about improvement from the original baseline. An MCO recommended using the verbiage "or maintain". Amendments were made to reflect this discussion. **Decision and/or Action:** Ms. Stutzman moved to approve as amended. Dr. Foster seconded the motion. The motion was approved unanimously.

TOPIC	DISCUSSION
C. New Prior Authorization (PA) Criteria 4. Advanced Medical Hold Manual Review PA	**Background:** 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. **Summary:** Follows current Medical Hold Manual Review process. During the manual review PA process, the PA reviewer will use the specific Advanced Medical Hold Manual Review (AMHMR) PA Criteria as directed by the KDHE Pharmacy Team using a template as proposed. The rest of the current Medical Hold process will continue from this point forward. Each drug with an AMHMR PA will be presented to the DUR Board for proposal of permanent PA criteria at the earliest opportunity, but no later than 180 days after being placed on Advanced Medical Hold Manual Review. **Public Comment:** None. **Board Discussion:** There was discussion regarding patients not being started on samples of a medication that would be given long term, when it is not known if the patient's insurance covered that drug. **Decision and/or Action:** Dr. Foster moved to approve. Ms. Stutzman seconded the motion. The motion was approved unanimously.

TOPIC	DISCUSSION
D. Mental Health Medication Advisory Committee (MHMAC) 1. ADHD Medication	**Background:** 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. **Public Comment:** None. **Board Discussion:** There was discussion about what the word "stable" means. The State said that this was the verbiage that the MHMAC members agreed was an acceptable reason to continue the treatment as was prescribed. **Decision and/or Action:** Dr. Backes moved to approve. Dr. Unruh seconded the motion. The motion was approved unanimously
D. Mental Health Medication Advisory Committee (MHMAC) 2. Antidepressant Medications	**Background:** 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. **Public Comment:** None

TOPIC	DISCUSSION
D. Mental Health Medication Advisory Committee (MHMAC) 2. Antidepressant Medications **(Continued)**	**Board Discussion:** There was discussion about the new formulation of Trazodone and if it would be excluded and what it means to strike the two sentences. The State explained that operationally we cannot know if these two drugs are being used as a sleep aid or as an anti-depressant, until after the PA hits and the physician requests a PA. Therefore, the addition of these two drugs to the PA was delayed to discuss with the MHMAC members to determine if this was really their intention. With this knowledge, the MHMAC members requested to have data first to determine how many patients this would affect, prior to permanently adding these two drugs to the PA. **Decision and/or Action:** Ms. Stutzman moved to approve. Dr. Backes seconded the motion. The motion was approved unanimously
D. Mental Health Medication Advisory Committee (MHMAC) 3. Antipsychotic Medications	**Background:** 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. **Public Comment:** None. **Board Discussion:** The Board had questions about the exact definition of long-term care and about patients with both schizophrenia and dementia. The State discussed that even though schizophrenia is a valid diagnosis, it would seem unlikely to be a new diagnosis in the elderly. The State said that there were around 270 patients not in the LTC setting with the diagnosis of dementia. The Board requested to find out how many of these patients had a valid diagnosis on file for an anti-psychotic.

TOPIC	DISCUSSION
D. Mental Health Medication Advisory Committee (MHMAC) 3. Antipsychotic Medications **(Continued)**	**Decision and/or Action:** Dr. Heston moved to approve. Dr. Foster seconded the motion. The motion was approved unanimously.
D. Mental Health Medication Advisory Committee (MHMAC) **4.** Benzodiazepine Medications	**Background:** 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. **Public Comment:** None. **Board Discussion:** There was discussion about long-term care, about KTRACS use, if there was a chart for dosing limitations if opioids and benzodiazepines are used together, and if both the benzodiazepine and opioid PAs had the same language regarding concurrent use. The State said that the Opioid PA does have a dosing chart, but that the system coding doesn't allow for tracking of the benzodiazepine dose and the opioid dose at the same time. The original language in the opioid PA was based upon the CDC's recommendation for a patient on concurrent benzo and opioids, the opioid dose should be adjusted first; not the benzo. Both PAs do address the concurrent use of both drug classes, even though the language is not exactly the same on both PAs. **Discussion and/or Action:** Dr. Heston moved to approve. Dr. Backes seconded the motion. The motion was approved unanimously.

TOPIC	DISCUSSION
E. Miscellaneous Items 1. Pharmacy Committee Summaries & General Program Updates	The State gave results from a report comparing data from January 1, 2015 through June 30, 2015 to January 1, 2018 through June 30, 2018. There was a 28.8% decrease in the number of children under 6 yrs. old on any mental health drug. The number of mental health drugs per child for children under 6 decreased from 4.74 to 3.17. There was a decrease in the number of children under 6 who received above the maximum antipsychotic dose. There was a 47.7% decrease in the total number of children under 6 on an antipsychotic. There was up to eight times more children, depending on age bracket, who received antipsychotics, that underwent metabolic testing, compared to pre-PA implementation. (The last data point was based on dates 2014&2017 vs 2015&2018).
2. PA Process – Updates and Demonstration	The State gave a demonstration of how to fill out a PA form, using the Opioid Products Indicated for Pain Management PA form.
3. Fee-for-Service Annual Program Assessment	The annual program assessment for the Medicaid fee-for-service population was presented to show drug trends over the past state fiscal year. Dr. DeRuiter presented the annual report.
IV. Open Public Comment	Phil King with Pfizer spoke about Xeljianz® and that the double step-therapy puts it at a disadvantage to the other agents based on their package insert criteria and asked the Board to reconsider the step therapy change for Xeljanz®. The State agreed with this request, as a disadvantage to the other agents in this PDL class was not intended.
Revised Prior Authorization (PA) Criteria Immunomodulators	Dr. Unruh moved to bring Revised Prior Authorization Criteria for Immunomodulators back to vote on an amendment. Ms. Stutzman seconded the motion. The motion was approved unanimously. Step-therapy for Xeljianz® was changed from two to one conventional therapy.

TOPIC	DISCUSSION
Revised Prior Authorization (PA) Criteria Immunomodulators **(Continued)**	Dr. Backes moved to approve the amendment. Ms. Stutzman seconded the motion. The motion to amend was approved unanimously.
V. Adjourn	Dr. Unruh moved to adjourn. Ms. Stutzman seconded the motion. The meeting adjourned at 1:13 p.m.

All approved PA criteria are posted to the KDHE website- http://www.kdheks.gov/hcf/pharmacy/pa criteria.htm