Drug Utilization Review Board Meeting Minutes, Open Session July 11, 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., CGP Katie Burenheide Foster, MS, PharmD **KDHE/DHCF/Contractor Staff Present** Annette Grant, RPh Roxanne Chadwell, PharmD, CSP **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, United Health Care Community Plan Lisa Todd, RPh, BBA, Amerigroup	Tim Heston, DO Roger Unruh, DO James Backes, Pharm.D. Margaret O'Donnell, Transcriptionist	**Public Attendees:** Sherry Bearden, CNI; Mildred Jenkins, CNI; Martha Fernandez, CNI; Stephanie Dale, CNI; Susan Slack, AdvanceMed; Melissa Rinehart, AdvanceMed; Jeanie Cavanaugh, United Health Care; Mindy Cameron, Little Hercules; Kim Witte, Avexis; Cheryl Dengue, Sarepta; Pratik Parikh, Sarepta; Haley Gish, Pfizer; Jay Parsons, Pfizer; Jami Sora, Biogen; Tyrone McBayne, Shire; Garth Wright, Genentech; Mike Danze, Genentech; Rick Kayler, Otsuka; Gay Thomas, Bristol-Myers Squibb; Susan Zalenski, Johnson & Johnson; Eric Knisely, Novartis; Matt Bradley, Novartis; Joel Meyer, Novartis; Brent DePriest, GSK; Maggi Olmon, AbbVie; Melissa Basil, AbbVie; Tom Devin, Teva; Ann Modrcin, CMH; Jim Baumann, Pfizer; Rachel Berry, Pfizer; Phil King, Pfizer; Brant Hildebrand, Gilead; Scott Maurice, BI; Mendy Moyer, Syneos; Megn Kerrigan, Merck

TOPIC	DISCUSSION
I. Call to Order	Dr. Mittal called the meeting to order at 10:00am.
Announcements and Introductions	The State announced that the Hepatitis C Agents agenda item was changed from the previously posted (Board & State)-Only Discussion agenda item to an agenda item to be voted on. The State introduced new Board Member, Katie Burenheide Foster, MS, PharmD, and new transcriptionist, Margaret O'Donnell.
II. Old Business **A. Review and approval of January 10, 2018 Meeting Minutes**	**Board Discussion**: None. **Decision and/or Action**: Dr. Unruh moved to accept the minutes as written. Dr. Rice seconded the motion. The motion was approved unanimously.
B. Review and Approval of April 11, 2018 Meeting Minutes	**Board Discussion**: None. **Decision and/or Action**: Dr. Unruh moved to accept the minutes as written. Dr. Heston seconded the motion. The motion was approved unanimously.
III. New Business **A. Medicaid Pharmacy Program Manager overview of prior authorization changes being requested.**	**Summary:** The State discussed the goal for the new PAs is to combine drugs into drug classes or categories and have a PA form per class/category. The new class/category PAs would include key safety requirements needed before a PA approval determination is given, but additional safety criteria would be an attestation only requirement.
B. New Preferred Drug List (PDL) Class 1. Alpha Adrenergic Agonists - Ophthalmic	**Background**: At the June 2018 PDL meeting, the committee approved the addition of ophthalmic alpha adrenergic agonist agents to the PDL. Requesting DUR Board final approval for this PDL class addition to the Master PDL. **Public Comment:** None

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	Board Discussion: None. **Decision and/or Action**: Dr. Backes moved to approve. Dr. Unruh seconded the motion. The motion was approved unanimously.
B. New Preferred Drug List (PDL) Class 2. Beta Blockers – Ophthalmic	**Background:** At the June 2018 PDL meeting, the committee approved the addition of combination ophthalmic beta blocker agents to the PDL. Requesting DUR Board final approval for this PDL class addition to the Master PDL. **Public Comment**: None. **Board Discussion**: None. **Decision and/or Action**: Dr. Heston moved to approve. Dr. Backes seconded the motion. The motion was approved unanimously.
B. New Preferred Drug List (PDL) Class 3. Corticosteroids - Oral	**Background**: At the June 2018 PDL meeting, the committee approved the addition of oral corticosteroid agents to the PDL. Requesting DUR Board final approval for this PDL class addition to the Master PDL **Public Comment**: None. **Board Discussion**: There was some discussion on price differences.

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	Decision and/or Action: Dr. Backes moved to approve. Dr. Unruh seconded the motion. The motion was approved unanimously.
B. New Preferred Drug List (PDL) Class 4. Desmopressin Products	**Background:** At the June 2018 PDL meeting, the committee approved the addition of desmopressin products to the PDL. Requesting DUR Board final approval for this PDL class addition to the Master PDL. **Public Comment**: None. **Board Discussion**: None. **Decision and/or Action**: Dr. Unruh moved to approve. Dr. Heston seconded the motion. The motion was approved unanimously.
B. New Preferred Drug List (PDL) Class 5. Non-steroidal Atopic Dermatitis Agents	**Background:** At the June 2018 PDL meeting, the committee approved the addition of non-steroidal atopic dermatitis agents to the PDL. Requesting DUR Board final approval for this PDL class addition to the Master PDL. **Public Comment**: None. **Board Discussion**: It was noted that the State will place these medications as preferred or Non-preferred and that non-preferred will have to meet the standard non-preferred PDL criteria. **Decision and/or Action**: Dr. Backes Moved to approve. Dr. Heston seconded the motion. The motion was approved unanimously.

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B. New Preferred Drug List (PDL) Class 6. Glaucoma Combination Products - Ophthalmic	**Background:** At the June 2018 PDL meeting, the committee approved the addition of combination ophthalmic agents used for the treatment of glaucoma to the PDL. Requesting DUR Board final approval for this PDL class addition to the Master PDL. **Public Comment:** None. **Board Discussion:** None. **Decision and/or Action:** Dr. Heston moved to approve. Dr. Unruh seconded the motion. The motion was approved unanimously.
C. Revised Prior Authorization (PA) Criteria 1. Non-Preferred Preferred Drug List (PDL) Prior Authorization	**Background**: The criteria for Non-preferred PDL drugs were last updated in January 2017. Revisions include editorial updates, adding requirements for documentation of previous medication use, and specific criteria for non-preferred, oral, non-solid dosage formulations. **Public Comment**: None. **Board Discussion:** None. **Decision and/or Action:** Dr. Unruh moved to approve. Dr. Backes seconded the motion. The motion was approved unanimously.

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C. Revised Prior Authorization (PA) Criteria 2. Exondys 51 (eteplirsen)	**Background:** Exondys 51 is an antisense oligonucleotide 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 were last revised in April 2017. Discussion and possible revision of criteria is being proposed. **Public Comment**: Pratik Parikh, Sarepta, commented that Exondys 51 patients are exon 51 skippers and a percentage of exon 44 patients where there is no drug available have a natural exon skipping that occurs in their body and they have trace levels of Dystrophin. Data has shown exon 44 skippers ambulate two years longer than other patients with different mutations suggesting trace levels of Dystrophin may have a clinical benefit. Ann Modrcin M.D., recommends giving Exondys 51 to patients as young as possible as soon as safety data is available and suggests adding pulmonary function studies to baseline criteria. Mindy Cameron, Little Hercules, who has a 17-year-old son with DMD, notes that even though the boys in the trial are non-ambulatory, they look better, move better, breathe better and speak better and thanked the Board for making the changes. **Board Discussion:** There was discussion on adding pulmonary function studies and switching the word "or" to the word "and". **Decision and/or Action:** Dr. Heston moved to approve as amended. Dr. Backes seconded the motion. The motion was approved unanimously as amended.
C. Revised Prior Authorization (PA) Criteria 3. Makena (hydroxyprogesterone caproate)	**Background:** 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 births. The criteria was last revised in January 2018. The prior authorization criteria are being revised to include quantity limits for the subcutaneous formulation of Makena.

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	Public Comment: None. **Board Discussion:** None. **Decision and/or Action:** Dr. Heston moved to approve. Dr. Backes seconded the motion. The motion was approved unanimously.
C. Revised Prior Authorization (PA) Criteria 4. Opioid Products Indicated for Pain Management	**Background:** This criteria covers all short and long-acting opioids. The criteria was last reviewed in April 2018. The prior authorization criteria are being revised to address patients living in facilities where unit dose packaging and custodial care is being given, as well as outlier situations where a secondary prescriber of opioids would be approved. Both requests are based upon provider feedback. **Public Comment:** None. **Board Discussion:** The Board had questions about the 14-day PA requirement, the 21-day approval duration, and the definition of long-term care criteria, as there are different levels of assisted living. There was a recommendation to use the wording "facility-administered medications". **Decision and/or Action:** Dr. Heston moved to approve as amended. Dr. Backes seconded the motion. The motion was approved unanimously as amended.
C. Revised Prior Authorization (PA) Criteria 5. Opioid Dependence Agents	**Background:** This criteria was last revised in April 2017. Buprenorphine/naloxone combination agents are being removed from PA, therefore requiring criteria revision of the single agent buprenorphine (Subutex®) **Public Comment:** None.

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	Board Discussion: None. **Decision and/or Action:** Dr. Heston moved to approve. Dr. Rice seconded the motion. The motion was approved unanimously.
D. New Prior Authorization (PA) Criteria 1. Diabetic Agents	**Background:** This criteria will combine and supersede all previous criteria for diabetic agents including SGLT2 Inhibitors, GLP-1 Receptor Agonists, and their combination products. The criteria also includes updates from prescribing information of the above mentioned products as well as criteria for Steglatro. The prior authorization criteria are being consolidated to ensure criteria consistency between similar agents and ensure appropriate use. **Public Comment:** None. **Board Discussion:** A member of the Board asked if there was a requirement to recheck baseline eGFR The State summarized that they want to put this back in the hands of the physicians and then check on the backside through Retro-Drug Utilization Review (RDUR) to see if the physicians are doing the extra safety criteria. **Decision and/or Action:** Dr. Backes moved to approve. Dr. Heston seconded the motion. The motion was approved unanimously.
D. New Prior Authorization (PA) Criteria 2. Immunomodulators for Inflammatory Conditions	**Background:** This criteria will combine and supersede all previous criteria for immunomodulatory agents and their biosimilar products including Actemra, Amevive, Cimzia, Cosentyx, Enbrel, Entyvio, Humira, Inflectra, Kevzara, Kineret, Orencia, Otezla, Remicade, Rituxan, Siliq, Simponi, Stelara, Taltz, Tremfya, Tysabri, and Xeljianz. The criteria also includes updates to indications of the above mentioned products as well as criteria for the new immunomodulatory products Ilaris, Ilumya, Ixifi, and Olumiant. The prior authorization

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	criteria are being consolidated to ensure criteria consistency between similar agents and ensure appropriate use. **Public Comment:** None. **Board Discussion:** The Board brought up the complexity of the document and asked the MCOs if they have systems in place to make it operational. An MCO replied that the reviews are all manual and it only requires someone to read through the document and find the correct drug and suggested adding a bullet on checking the PDL. The State added that they are open to feedback on the Prior Authorization (PA) forms. **Decision and/or Action:** Dr. Backes moved to approve. Dr. Heston seconded the motion. The motion was approved unanimously.
D. New Prior Authorization (PA) Criteria) 3. Multiple Sclerosis Agents	**Background:** This criteria will combine and supersede all previous criteria for multiple sclerosis agents including Ampyra, Aubagio, Avonex, Betaseron, Copaxone,, Extavia, Gilenya, Lemtrada, Ocrevus, Plegridy, Rebif, Tecfidera, and Tysabri. The criteria also includes updates from product labeling of the above mentioned products as well as criteria for the new agent, Glatopa. The prior authorization criteria are being consolidated to ensure criteria consistency between similar agents and ensure appropriate use. **Public Comment:** None. **Board Discussion:** The Board had concerns that the forms will make it harder for the physician, that the form needs to make the process seamless, and a "mock run" at the next DUR meeting for feedback would be helpful. One Board member felt that less documentation required up front should make the process easier.

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	Decision and/or Action: Dr. Heston moved to approve. Dr. Foster seconded the motion. The motion was approved unanimously.
D. New Prior Authorization (PA) Criteria 4. Chemotherapy Agents.	**Background:** This criteria will combine and supersede all previous criteria for chemotherapy agents including 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. The prior authorization criteria are being consolidated to ensure criteria consistency between similar agents and ensure appropriate use. **Public Comment:** None. **Board Discussion:** The State commented that it is important to remember that the original use of PAs stemmed from fraud, waste, abuse and patient safety needs, in addition to cost effective medication use. One Board member asked if the oncologist is the one doing this PA would they even have the list of QT prolonging medications. **Decision and/or Action:** Dr. Unruh moved to approve. Dr. Backes seconded the motion. The motion was approved unanimously.
D. New Prior Authorization (PA) Criteria 5. Step-Therapy Criteria	**Background:** This criteria will combine and supersede all previous criteria for agents requiring step-therapy including Amrix, Avandaryl, Bonjesta, Diclegis, Dymista, Fortamet, Glumetza, GoNitro, Motofen, nitrogylycerin sublingual spray, non-steroidal atopic dermatitis agents, proton-pump inhibitors, Vimovo, Yosprala, and Zegerid. Newly added step-therapy required agents include Aimovig (erenumab-aooe), Consensi (amlodipine\celecoxib), Esomep-EZS (esomeprazole), and the carbinoxamine products Arbinoxa, Karbinal ER,

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	and RyVent. The criteria contains agent-specific criteria for diagnosis and safety, as well as required step-therapy for each agent. **Public Comment:** None. **Board Discussion:** There was discussion about how a provider would know how to find the step-therapy criteria. The Board had concerns about whether the framework would be ready in 60 days and the need to table this until the framework is ready. A suggested option of approving the step therapies on an individual basis, if we moved this agenda item to the end of the agenda to discuss in more detail then. There was a question about whether all three MCOs would be using these PA forms. **Decision and/or Action:** The Board agreed to move this to the end of the agenda and review for approval the individual components one at that time.
D. New Prior Authorization (PA) Criteria 6. Hepatitis C Agents	**Background:** This criteria will combine and supersede all previous criteria for hepatitis C agents including Daklinza, Epclusa, Harvoni, Mavyret, Olysio, Sovaldi, Technivie, Viekira Pak, Viekira XR, Vosevi, and Zepatier. Additional changes are being proposed as well. **Public Comment:** None. **Board Discussion:** None. **Decision and/or Action:** Dr. Heston moved to approve. Dr. Unruh seconded the motion. The motion was approved unanimously.

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E. Mental Health Medication Advisory Committee (MHMAC) 1. ADHD Medications - Safe Use for All Ages	**Background:** At the May 2018 MHMAC meeting, the committee approved criteria that combines and supersedes all previous criteria for ADHD products. The criteria has been revised to allow for an initial written peer-to-peer consultation when needed, and includes the newer agents Adzensys ER, Adzensys XR-ODT, Mydayis, and Cotempla XR-ODT. **Public Comment:** None. **Board Discussion:** None. **Decision and/or Action:** Dr. Unruh moved to approve. Dr. Heston seconded the motion. The motion was approved unanimously.
E. Mental Health Medication Advisory Committee (MHMAC) 2. Antidepressant Medication - Safe Use for All Ages	**Background:** At the May 2018 MHMAC meeting, the committee approved criteria that combines and supersedes all previous criteria for antidepressants. The criteria has been revised to allow for an initial written peer-to-peer consultation when needed, and includes the newer agents Khedezla, Prozac Weekly, Luvox CR, and Trintellix. **Public Comment:** None. **Board Discussion:** A request was made for the State to summarize the Mental Health Medication Advisory Committee (MHMAC) process. The State reviewed all the pharmacy committee processes to help the new board member understand the DUR Board relationship to the other state pharmacy committees. **Decision and/or Action:** Dr. Heston moved to approve. Dr. Unruh seconded the motion. The motion was approved unanimously.

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E. Mental Health Medication Advisory Committee (MHMAC) 3. Antipsychotic Medications - Safe Use for All Ages	**Background:** At the May 2018 MHMAC meeting, the committee approved criteria for use of antipsychotic agents that combines and supersedes all previous MHMAC criteria. The criteria has been revised to allow for an attestation of attempts to gather needed lab values, and includes the newer agents Abilify Discmelt, Versacloaz, and Loxitane. This revision also includes a criteria for use in the Long-Term Care setting. **Public Comment:** None. **Board Discussion:** There was some concern about the necessity to be able to see the patient and what constitutes "severe" in the criteria. A suggestion was made to take out the word "severe" and leave in "danger to self and others". Also, there was a question if the criteria applied to every patient over 65, not just those in long-term care. The State recommended the Board approve this version today and the State would revisit this at the MHMAC meeting next month for any modification. **Decision and/or Action:** Dr. Heston moved to approve. Dr. Burenheide Foster seconded the motion. The motion was approved unanimously.
E. Mental Health Medication Advisory Committee (MHMAC) 4. Benzodiazepine Medications – Safe Use for All Ages	**Background:** At the May 2018 MHMAC meeting, the committee approved criteria that combines and supersedes all previous criteria for benzodiazepines. The criteria has further been revised to allow for an initial written peer-to-peer consultation when needed. **Public Comment:** None. **Board Discussion:** The Board suggested the benzodiazepine PA verbiage match the opioid policy benzodiazepine verbiage and to add language about adjusting dosing limits if they are on both medications The State will suggest changes at the next MHMAC meeting in August.

TOPIC	DISCUSSION
	Decision and/or Action: Dr. Unruh moved to approve. Dr. Heston seconded the motion. The motion was approved unanimously
Step-Therapy Criteria **Aimovig**	**Public Comment:** None. **Board Discussion**: None. **Decision and/or Action:** Dr. Heston moved to approve. Dr. Unruh seconded the motion. The motion was approved unanimously.
Step-Therapy Criteria **Carbinoxamine Products**	**Public Comment:** None. **Board Discussion**: None. **Decision and/or Action:** Dr. Heston moved to approve. Dr. Backes seconded the motion. The motion was approved unanimously.
Step-Therapy Criteria **Bonjesta and Diclegis**	**Public Comment:** None. **Board Discussion**: Dr. Rice asked how the prescriber would know if the patient has tried the OTC medications. **Decision and/or Action:** This revision will be tabled at this time and brought back to the Board at the next DUR Meeting.

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Step-Therapy Criteria **Consensi™ (amlodipine/celecoxib)**	**Public Comment:** None. **Board Discussion**: None. **Decision and/or Action:** Dr. Heston moved to approve. Dr. Backes seconded the motion. The motion was approved unanimously.
Step-Therapy Criteria **Non-Steroidal Atopic Dermatitis Agents** - Elidel® (pimecrolimus) - Eucrisa® (crisaborole) - Protopic® (tacrolimus)	**Public Comment:** Phil King of AbbVie commented that frequently patients will be prescribed Hydrocortisone 1% as a first-time agent, which can be prescription or OTC. Mr. King asked if it's not filled through the pharmacy and just purchased OTC, can the physician attest to the trial and failure of the Hydrocortisone. **Board Discussion:** The State stated that prescription strength Hydrocortisone will be required. **Decision and/or Action:** Dr. Heston moved to approve. Dr. Unruh seconded the motion. The motion was approved unanimously.
Step-Therapy Criteria **Esomeprazole product**	**Public Comment:** None. **Board Discussion:** None. **Decision and/or Action:** Dr. Unruh moved to approve. Dr. Foster seconded the motion. The motion was approved unanimously.

TOPIC	DISCUSSION
F. Miscellaneous Items 1. Appointment of the new Chairperson for the DUR Board.	A motion and a second was made for Dr. Mittal to continue as the DUR Board Chairperson. A vote was taken and passed unanimously.
F. Miscellaneous Items 2. Managed Care Organization Annual Drug Utilization Review Reports	i. Sunflower Individual Report - Angie Zhou, PharmD PowerPoint ii. United Healthcare Individual Report - Jennifer Murff, RPh PowerPoint iii. Amerigroup Individual Report – Lisa Todd, RPh PowerPoint
IV. Open Public Comment	**Public Comment:** Susan Zalenski, Johnson & Johnson, requested that the State post the draft criteria to the website prior to the meeting. She recommended having a cut-off period for agenda changes. Melissa Basil, AbbVie, asked clarifying questions about Prep-C requirements. **Board Discussion:** The State said that they are open to the request of posting the draft criteria to the website, but doing so would happen after the documents were sent to the DUR Board, which is one week prior to the meeting day. An agenda change cut-off period will also be considered. The meeting adjourned at 2:05pm.
V. Adjourn	Dr. Unruh moved to adjourn. Dr. Heston seconded the motion.

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