Drug Utilization Review Board
Minutes Draft

Name of Meeting: Drug Utilization Review Board
Date of Meeting: August 20, 2015
Length of Meeting: 2 hours and 22 minutes
Location of Meeting: DMAS Board Room 13th Floor

Members Present:
Randy Ferrance, MD, Chair
Avtar Dhillon, MD
Seth Brant, MD
Jonathan Evans, MD
Bill Rock, PharmD
Michele Thomas, PharmD
Wendy Nash, PharmD

Members Not Present:
Rhonda Bass, MD
Sandra Dawson, RPh
Jamie Haight, RPh
Denese Gomes, NP

DMAS Attendees:
Rachel Cain, PharmD
Bryan Tomlinson, Health Care Services Division Director
Danielle Adeeb
Tyrone Wall

Contractors:
Donna Johnson, PharmD, Clinical Pharmacy Manager, Xerox
Tina Carter, CPhT, Pharmacy Technician

Vendors:
Debbie Moody, RPh, Magellan Health Services
Nancy Eldin, PharmD, Magellan Health Services

Visitors:
Richard Lomax, Purdue Pharma
Mary Fullerton, Pfizer
Ronnie DePue, Sunovion
Tim Carr, BMS
Ken Jennings, BMS
Michael Brasher, ViiV Healthcare
Patrick Maney, DSI
Alain Porte', Walgreens
Chris Fields, Lundbeck
Leonard Erskine, Avanir
Evonne Stellato, Allergan
Donna Bean, Genentech
Beth Pegram, Vertex

Call to Order and Introductions
Dr. Ferrance called the meeting to order at 2:07pm.

Minutes—November 20, 2014
Meeting minutes were reviewed and approved.

First Data Bank's *Alert Space* Clinical Modules (May Binder)
Dr. Johnson gave a 15-page slide presentation on FirstDataBank (FDB)'s Alert Space and the Alert Management Process. The presentation included: an overview, customizations, modifications, load control, Drug-Drug interactions enhancements, Duplicate Therapy allowances, Drug Disease severity levels and Geriatric, Pediatric and Pregnancy precautions. Dr. Johnson also provided a handout on the Comparison of VAMMIS ProDUR Criteria to FDB AlertSpace Clinical Modules using the following drugs as examples: Jardiance (empagliflozin) and Hetlioz (tasimelteon).

Reports

ProDUR and RetroDUR –Dr. Johnson reviewed the reports provided in the DUR Board binder(s). A request was made to modernize RetroDUR – redefine polypharmacy numbers and reference. Clarify General Assembly language particularly polypharmacy threshold.

Utilization Analysis Reports – Dr. Johnson reviewed the Top 25 Drugs Ranked by Claim Count, by Payment Amount and the Cost of Utilization Analysis by Drug Type provided in the DUR Board binder(s).

Top Diagnoses by Age – Dr. Johnson reviewed the top Diagnoses by Age for all ages provided in the DUR Board binder(s).

AAP Report
Dr. Johnson reviewed the report provided in the DUR Board binder(s). Dr. Johnson noted the large increase (August binder) due to the edit expansion to include patients less than 18 years of age, effective 3/1/15. A request was made to identify the location (facility) of residence for children on AAPs

New Drugs

May Binder

Contrave® (naltrexone/bupropion) – Dr. Johnson presented the drug information and service authorization (SA) criteria recommendations. The motion was made to accept the criteria as written with the additional documentation of "No chronic opioid use". The Board seconded and approved the criteria.

Esbriet® (pirfenidone) – Dr. Johnson presented the drug information and service authorization criteria recommendations. The Board recommended that two

questions be added to the criteria fax form (1) Is the patient's baseline percent predicted forced vital capacity (FVC) greater than or equal to 50% and (2) Does the patient smoke? Debbie Moody with Magellan will collect the submitted fax forms so that the information can be reviewed at the November meeting. The Board may add more specific criteria based on these findings. Until then, SA requests will not be denied based on the responses for these 2 questions. The motion was made to accept the criteria as written; The Board seconded and approved criteria.

Ofev® (nintedanib) – Dr. Johnson presented the drug information and service authorization criteria recommendations. The Board recommended that two questions be added to the criteria fax form (1) Is the patient's baseline percent predicted forced vital capacity (FVC) greater than or equal to 50% and (2) Does the patient smoke? Debbie Moody with Magellan will collect the submitted fax forms so that the information can be reviewed at the November meeting. The Board may add more specific criteria based on these findings. Until then, SA requests will not be denied based on the responses for these 2 questions. The motion was made to accept the criteria as written; The Board seconded and approved criteria.

Lynparza™ (olaparib) – Dr. Johnson presented the drug information and service authorization criteria recommendations. The motion was made to accept the criteria as written with the addition of Drug Interaction question. The Board seconded and approved criteria.

Soolantra® (ivermectin) – Dr. Johnson presented the drug information and service authorization criteria recommendations. The motion was made to accept the criteria as written with the addition of step therapy failure of another agent and quantity limitations to one 30 gram tube. The Board seconded and approved criteria.

Tybost® (cobicistat) – Dr. Johnson presented the drug information with no service authorization criteria recommendations. The Board recommended that a 6 month utilization report be performed to confirm combination therapy with atazanavir or darunavir . The Board will review the results to determine if a service authorization requirement is needed. The motion was made to review service authorization criteria recommendations in 6 months; the Board seconded and approved.

Evotaz™ (atazanavir sulfate/cobicistat) – Dr. Johnson presented the drug information with no service authorization criteria recommendations. The Board recommendation is a 6 month utilization review to confirm combination therapy with other antiretroviral agents before service authorization approval. The motion was made to review service authorization criteria recommendations in 6 months; the Board seconded and approved.

Prezcobix™ (darunavir/cobicistat) – Dr. Johnson presented the drug information with no service authorization criteria recommendations. The Board recommendation is a 6 month utilization review to confirm combination therapy with other antiretroviral agents before service authorization approval. The motion was made to review service authorization criteria recommendations in 6 months; the Board seconded and approved.

Vitekta® (elvitegravir) – Dr. Johnson presented the drug information with no service authorization criteria recommendations. The Board recommendation is a 6 month utilization review to confirm combination therapy with other antiretroviral agents and coadministered with ritonavir before service authorization approval. The motion was made to review service authorization criteria recommendations in 6 months; the Board seconded and approved.

Farydak® (panobinostat) – Dr. Johnson presented the drug information and service authorization criteria recommendations. The motion was made to accept the criteria as written with the addition of concurrent therapy of Velcade (bortezomib) and dexamethasone. The Board seconded and approved criteria.

Ibrance® (palbociclib) – Dr. Johnson presented the drug information and service authorization criteria recommendations. The motion was made to accept the criteria as written; the Board seconded and approved criteria.

Lenvima™ (lenvatinib) – Dr. Johnson presented the drug information and service authorization criteria recommendations. The motion was made to accept the criteria as written with the addition of pregnancy question; the Board seconded and approved criteria.

New drugs: PDL-eligible; physician-administered injectables. All were tabled until the November DUR Board Meeting.

August Binder

Corlanor® (ivabradine) – Dr. Johnson presented the drug information with no Service Authorization Recommendations because it may become PDL eligible. The motion was made to accept with ***no*** service authorization recommendations; The Board seconded and approved.

Jadenu™ (deferasirox) – Dr. Johnson presented the drug information and service authorization criteria recommendations. The motion was made to accept criteria as written with the revision of service authorization approval period of 6 months. The Board seconded and approved criteria.

Natpara® (parathyroid hormone) – Dr. Johnson presented the drug information and service authorization criteria recommendations. The motion was made to accept the criteria as written with the following additions: require endocrinologist or

nephrologist to prescribe and service authorization period of 6 months. The Board seconded and approved criteria.

Orkambi™ (lumacaftor/ivacaftor) – Dr. Johnson presented the drug information and service authorization criteria recommendations. The motion was made to accept criteria as written with the following additions: Bilirubin testing be required at baseline and for renewals, requesters must provide evidence of Liver Function testing. The Board seconded and approved criteria.

Saxenda® (liraglutide) – Dr. Johnson presented the drug information and service authorization criteria recommendations. The motion was made to accept criteria as written with the additional requirement that patient not be on Victoza or other GLP-1 inhibitors. The Board seconded and approved criteria.

New Drugs: PDL-eligible; physician-administered injectables. All were tabled until the November DUR Board Meeting.

Service Authorizations

Jakafi – Dr. Johnson presented new FDA approved indication for polycythemia vera. The Board reviewed the service authorization form to include additional criteria of polycythemia vera diagnoses and inadequate/intolerant therapy of Hydroxyurea. The motion was made to accept the addition to the criteria; the Board seconded and approved criteria.

Kalydeco – Dr. Johnson presented new FDA approval for patients age 2 years and older with Cystic Fibrosis who have one of 10 specific gene mutations. The Board reviewed the service authorization form to include additional criteria. The motion was made to accept the addition to the criteria; the Board seconded and approved criteria.

Imbruvica – Dr. Johnson presented new FDA approved indication for Waldenström's macroglobulinemia. The Board reviewed the service authorization form to include the addition of Waldenström's macroglobulinemia diagnoses and patient to have received at least one prior therapy. The motion was made to accept the addition to the criteria; the Board seconded and approved criteria.

Promacta – Dr. Johnson presented new FDA approval for patients age 6 years and older with chronic immune idiopathic thrombocytopenia (ITP). The Board reviewed the service authorization form to include additional criteria. The motion was made to accept the addition to the criteria; the Board seconded and approved criteria.

<u>Topics for Discussion</u> (All Tabled until November DUR Board Meeting)

Analysis of Compounded Medications – follow up
Morphine Equivalent Dosing for Narcotics
Synagis utilization
New DUR Quarterly Newsletter - draft

<u>Other Business</u>

Dr. Ferrance stated that he will continue on as Chair but the Board needed a Vice Chair to replace Jane Settle.
Bill Rock, PharmD received nominations for Vice Chair and motion was made to accept by Dr. Evans, seconded by Dr. Dhillon. The Board unanimously approved Dr. Rock's nomination for vice chair.

A review of the Board's bylaws was tabled until March 2016.

Meeting was adjourned at 4:29 pm.

The next DUR Board meeting is scheduled for November 12, 2015. A request was made to change the meetings to the 2nd Thursday of each month that the Board is scheduled to meet.