Drug Utilization Review Board
Minutes Draft

Name of Meeting:	Drug Utilization Review Board
Date of Meeting:	November 17, 2011
Length of Meeting:	2 hours 24 minutes
Location of Meeting:	DMAS 13th Floor Board Room

Members Present:

Randy Ferrance, MD, Chair
Sandra Dawson, RPh. MSHA
Avtar Dhillon, MD
Jonathan Evans, MD
Cynthia Fagan, FNP
Bill Rock, PharmD
Jane Settle, NP, Vice Chair

Members Not Present:

Renita Driver, PharmD
Jamie Haight, RPh
Michele Thomas, PharmD

DMAS Attendees:

Rachel Cain, PharmD
Donna Francioni-Proffitt, RPh, Pharmacy Program Manager
Keith Hayashi, RPh
Bryan Tomlinson, Health Care Services Division Director

Contractors:

Robert Berringer, PharmD, Senior Clinical Director, ACS/Xerox
Eboni Washington, Administrative Assistant, ACS/Xerox

Vendors:

Nancy Eldin, PharmD, Magellan Health Services

Visitors:

Drew Bernstein, MedImmune
Cindy Snyder, GSK
Brenda Evans, VCB
Robert Kearley, Sunovion
Susan Matthews, MedImmune
Kurtis McDonald, BMS
Rick Meidlinger, J&J
Rick Pace, Purdue
Jason Richardson, Forest
Bruce Song, AstraZenecca

Call to Order and Introductions

Dr. Randy Ferrance welcomed everyone and called the meeting to order at 2:06pm. Dr. Ferrance noted that there was not a quorum at the start of the meeting but additional members were expected to arrive.

Minutes—September, 29, 2011 Meeting

Dr. Ferrance stipulated that the September 29, 2011 meeting minutes be accepted by acclamation since there was not a quorum.

ProDUR Edits

Celexa and abnormal heart rhythms FDA Warning – the recent FDA warning related to Celexa that Dr. Rock requested at the last DUR Board meeting was presented. It was initially discussed that the MMIS system currently has an edit that denies for doses greater than 60mg and Dr. Berringer asked the board if they wanted to change the edit to 40mg. Dr. Rock asked about a review and sending letters to providers for patients currently prescribed more than 40mg per day. Dr. Rock discussed that this warning is somewhat controversial amongst psychiatrics and that the VA Medical Center's policy includes informed consent and additional EKGs being done. Dr. Rock suggested sending letters to make providers aware of the issue. Dr. Berringer then corrected his previous statement and said that the current ProDUR edit messages only at doses greater than 60mg and does not deny. Dr. Cain recommended that an analysis be conducted that identifies the number of patients at the different doses (e.g., > 80mg/day, 60-80mg/day, etc.) and bring those numbers to the next meeting for discussion on next steps (e.g., ProDUR edit, service authorization, provider letters, etc.).

Drospirenone containing Oral Contraceptives (OC) FDA Warning- the FDA warning related to drospirenone containing OCs as requested by Dr. Thomas at the September DUR Board meeting was presented. Currently, there is no edit in VAMMIS that checks against thromboembolism history for any of the OCs. Dr. Ferrance discussed that while all OCs have a thromboembolic risk, these drugs have a higher risk. He suggested that a ProDUR edit be added to address this issue but was pended because the DUR Board did not have a quorum.

Ondansetron and arrhythmias FDA Warning – the FDA warning related to ondansetron and risk of abnormal heart rhythms was presented. Dr. Berringer discussed that there are a number of QT Prolonging edits in the system but ondansetron is not included in any of them. Currently there are both drug-disease and drug-drug interaction ProDUR edits that address these issues and it was suggested that ondansetron be added to them. The Board agreed with the recommendation but could not vote since a quorum was not present.

CYP450 Inducers - During the last meeting there were a number of drugs presented that had CYP450 interactions and Dr. Rock suggested bringing a list of those drugs to the next meeting. Dr. Berringer presented the Cytochrome P450 Drug Interactions table published by the Pharmacist Letter as the reference for these drugs. Dr. Cain suggested adding to the glossary, so the Board can refer to it and use it to define what drug to enter into the edits. A motion was not

necessary to add this document to the DUR Board binder Glossary but the Board agreed to add it.

Dr. Dhillon arrived at the meeting. Dr. Ferrance welcomed Dr. Dhillon and mentioned that Dr. Evans is expected and that his presence would provide enough for a quorum.

Reports

Dr. Berringer discussed the RetroDUR reports for monthly topics in the third quarter of 2011. These reports include statistics on members and providers included in addition to comments received from each intervention mailed since summer of 2010. The Polypharmacy (400 members and 1,050 provider letters) 267 members and 284 provider letters) and clopidogrel intervention stats were highlighted while the Abuse intervention was on hold. The RetroDUR Letter Response Report by Response Code was also discussed and it was reported that the average response was about 18%. Dr. Ferrance asked why the Abuse intervention was on hold and Dr. Berringer explained that the criteria that was run was the same as that done in June 2010 instead of what was approved at the May 2011 meeting. Dr. Cain had noticed that during the final letter approval review. Ms. Dawson questioned as to the average response rate across other ACS clients and Dr. Berringer stated that it was similar to what ACS has seen at about 20%.

The AAP in Children < 6 report for the time period of July through September 2011 was also discussed. For July, August, and September 2011, DMAS had 130, 128, and 140, respectively, children less than 6 years old with history of atypical antipsychotic use. Dr. Ferrance discussed that Dr. Sonenklar with Magellan will be conducting the reviews for the AAP in Kids < 6 years old SA program. Dr. Cain distributed the Medicaid Memo that was mailed to providers on November 9th. The memo highlighted the program and that it will be implemented on December 1st and also included the SA criteria. Dr. Cain also distributed the original prior authorization form that the DUR Board voted on in addition to a copy that has additional criteria that Dr. Sonenklar would like to add for Board consideration. She also distributed the SA form.

Dr. Cain then reviewed the timeline for this program and discussed that DMAS has been reviewing this issue in some capacity since 2005. At the November 2010 meeting, the DUR Board approved the August 2010 meeting minutes and psychiatric criteria changes that included adding olanzapine and removing PTSD. At the March 2011 and May 2011 DUR Board meeting, no changes were made to the criteria. At the September 2011 DUR Board meeting, the board voted to implement the program on 12/1/11 and remove reference to “pediatric” in pediatric psychiatrist. The memo was mailed on November 9, 2011. DMAS also contracted with Magellan to provide a pediatric psychiatrist who will review these requests. Dr. Cain also discussed that DMAS will allow a 30-day supply for

those requests that do not meet the criteria for approval. Dr. Cain notified the DUR Board that Dr. Sonenklar also requested that Adjustment Reaction Disorder, PTSD, Intermittent Explosive Disorder, and Other-Reactive Attachment Disorder of Infancy or Early Childhood be added to the list of ICD-9 codes for approval.

Children currently on AAP therapy will be grandfathered for 6 months from December 1, 2011. For patients who have not recently received therapy, the respective physician will need to submit an SA form. Requests could be in writing or verbally. Dr. Cain explained all patients must meet the four criteria (i.e., A, B, C, and D on the SA form) and their respective provider must complete and submit an SA form.

If criteria are met, therapy will be approved for 6 months. If criteria A, B, C, and D are not met, the patient may obtain a 30-day supply and the request will be forwarded to Dr. Sonenklar for peer to peer review.

Dr. Cain also discussed the proposed approval lengths for provider types listed in "A" (i.e., psychiatrist, neurologist, developmental/behavioral pediatrician) to be 1 year while approvals for prescribers not included in section "A" to be 6 months. Dr. Evans suggested that a disclaimer be added to section B since none of the diagnoses listed are actually FDA-approved diagnoses and some providers may not understand what "allowable diagnosis" means. Dr. Dhillon agreed that there currently aren't any FDA-approved indications for these medications in children less than 6 years old.

Dr. Evans also suggested that the approval length be 6 months for all prescribers keeping it in line with other drugs of concern (e.g., Class III drugs, long-term care regulations). Dr. Dhillon felt that 6 months would allow time to develop a plan and obtain a consultation. Dr. Ferrance noted that "supply proof of a psychiatric consultation or assessment" in section A should actually be done by a psychiatrist, neurologist, or developmental/behavioral pediatrician. Ms. Fagan felt that those prescribers in A have more expertise and that the approval lengths should be 1 year instead of 6 months for those prescribers. Dr. Evans rebutted that 6 months approvals will ensure patients are being seen more frequently. Dr. Evans then made a motion to change the approval length to 6 months for all prescribers. Bill Rock seconded. The motion was accepted.

Dr. Ferrance then asked the Board to consider the additional diagnoses (Adjustment Reaction Disorder, PTSD, Intermittent Explosive Disorder, and Other-Reactive Attachment Disorder of Infancy or Early Childhood) that Dr. Sonenklar added in section B. Dr. Cain suggested that the Board discuss with Dr. Sonenklar when he is available via conference call later in the meeting.

The Board further discussed adding a disclaimer for "allowable" in section B such as the DUR Board recognizes all uses are off label. Dr. Rock recommended

removing “allowable” and Dr. Ferrance stated that was redundant. Dr. Rock made a motion to strike “allowable” in B, add for the off label use of these medications to the end of D, and allow the inclusion of the three additional diagnoses recommended by Dr. Sonenklar. Ms. Fagan seconded. The motion was accepted.

New Drugs

Adcetris (brentuximab vedotin) – after Dr. Berringer presented the ProDUR and RetroDUR criteria, Dr. Ferrance questioned if claims for this drug would even be filled or submitted by retail pharmacies. Although these are intravenous medications, they could be filled by specialty pharmacies and be submitted into VAMMIS. Ms. Settle moved to accept the criteria as presented. Ms. Fagan seconded. The motion was accepted.

Arcapta™ (indacaterol) – Dr. Rock suggested that the word “not” be removed from first sentence on page two under “Excessive Use of Arcapta and Use with Other Long-Acting $Beta_2$-Agonists” in the update. Dr. Evans asked if there was a way to alert if the patient was using Arcapta on an as needed basis. Dr. Berringer explained that VAMMIS is not able to message or deny based on the prescription’s directions. Ms. Fagan moved to accept the criteria as presented. Dr. Evans seconded. The motion was accepted.

Arzerra™ (ofatumumab) – Dr. Evans felt this drug would be mostly administered in a physician’s practice and that not many claims would be submitted by retail pharmacies. Ms. Dawson moved to accept the criteria as presented. Dr. Rock seconded. The motion was accepted.

Brilinta™ (ticagrelor) – Dr. Rock recommended that rivaroxaban and low molecular weight heparins be added as a drug-drug interaction (Severity 2). Dr. Ferrance also recommended that the severity level for the NSAID and warfarin to be a “2”. Ms. Settle moved to accept the criteria as amended. Ms. Fagan seconded. The motion was accepted.

Complera™ (emtricitabine/rilpivirine/tenofovir) – Ms. Settle recommended that the therapeutic duplication edit be removed and Dr. Ferrance agreed. After further discussion, the Board agreed to add a therapeutic duplication edit for Atripla and the individual components included in Complera (emtricitabine, rilpivirine, and tenofovir). Dr. Evans moved to accept the criteria as amended. Ms. Settle seconded. The motion was accepted.

Firazyr™ (icatibant acetate) –Dr. Evans asked how DMAS could ensure this drug was used only for hereditary angioedema. Dr. Ferrance recommended that this drug require a service authorization to ensure the patient has history of the disease. Dr. Evans moved to accept the criteria as presented but require service authorization for this drug. Ms. Fagan seconded. The motion was accepted.

AAP in Children < 6 Years Old (cont'd)

At this point in the meeting, Dr. Sonenklar was conferenced into the meeting via phone. Dr. Dhillon questioned Dr. Sonenklar about the Adjustment Disorders diagnosis and whether he felt everyone would be approved if those diseases were added for approval. Dr. Sonenklar did not think everyone would be approved. He explained he included them to provide mental health providers a diagnosis for behaviors instead of an actual mental health diagnosis (e.g., schizophrenia, bipolar, etc.). Dr. Sonenklar agreed to remove the diagnosis if the Board decided to remove them. Dr. Ferrance explained that the Board's initial intent was to prevent these being used as chemical restraints in children with behavior issues.

Ms. Fagan then discussed the different approval lengths (6 month and 1 year) based on the prescriber type. Dr. Sonenklar stated that he thought it was 6 months for all providers and Dr. Ferrance confirmed that was approved by the Board earlier in today's Board meeting. Dr. Sonenklar agreed with the Board's decision on a 6 month approval.

Dr. Evans recommended removing the diagnoses (i.e., Adjustment Reaction Disorder, PTSD, Intermittent Explosive Disorder, and Other-Reactive Attachment Disorder of Infancy or Early Childhood) that Dr. Sonenklar previously asked to be added. Dr. Dhillon stated there is some literature that mentions the use of these agents for the diagnoses of PTSD and Intermittent Explosive Disorder. Ms. Settle then made the motion to remove the Adjustment Reaction Disorders and Other – Reactive Attachment Disorder of Infancy or Early Childhood from the SA form. Ms. Fagan seconded. The motion was accepted.

New Drugs (cont'd)

Lazanda™ (fentanyl citrate nasal spray) – Dr. Ferrance recommended that the proposed therapeutic duplicate criteria with long acting narcotics be removed since it is short acting product. Dr. Evans also recommended that this drug have service authorization due to its one indication for breakthrough pain in cancer patients and safety concerns. Dr. Cain stated that this drug has a REM program and will be reviewed by the P&T Committee. Ms. Proffitt then stated that it will automatically go to a nonpreferred status and require service authorization. Dr. Evans and Dr. Ferrance asked that the REMs program be reviewed and presented at the next DUR Board meeting. Ms. Fagan moved to accept the criteria as amended. Ms. Dawson seconded. The motion was accepted.

Juvisync™ (sitagliptan/simvastatin) – Ms. Settle moved to accept the criteria as presented. Dr. Evans seconded. The motion was accepted.

Nucynta ER™ (tapentadol HCL) – Dr. Berringer noted that the label has a maximum dose of 500mg but this was not included in the proposed DUR criteria. Dr. Evans suggested that tramadol be added to the therapeutic duplicate criteria. Dr. Evans moved to accept the criteria as amended. Ms. Settle seconded. The motion was accepted.

Dr. Rock also made a motion that a therapeutic dup edit be added to include Nucynta immediate release. Ms. Settle seconded. The motion was accepted.

Xalkori™ (crizotinib) – Ms. Settle recommended that this drug require service authorization based on single indication. Ms. Settle moved to accept the criteria as presented but require service authorization for the drug. Ms. Fagan seconded. The motion was accepted.

Zelboraf™ (vemurafenib) – Dr. Ferrance recommended this drug be place on service authorization. Dr. Evans moved to accept the criteria as presented and place this drug on service authorization. Ms. Fagan seconded. The motion was accepted.

Future Topics

Dr. Ferrance requested that Dr. Berringer present potential future RetroDUR topics that ACS has done in other states.

Intervention Topic	Clinical Indicators
Atypical Antipsychotics: Coordination of Care in Adults	• Duplicate antipsychotic therapy • Atypical antipsychotic use in patients with diabetes • Atypical antipsychotic use in morbidly obese patients • Ziprasidone use with a cardiovascular disease history • Long-acting injection options for non-adherent patients
Gastrointestinal Drug Usage Evaluation (DUE)	• Extended duration of H2RA or PPI therapy with an unknown diagnosis • Duplicate therapy • Patient safety issue: Concomitant H_2 receptor antagonist and NSAID therapy in patients with PUD • Patient safety issue: Concomitant anti-secretory therapy and NSAID therapy in patients with PUD from multiple prescribers • Patient safety issue: Bisphosphonate therapy in patients with GERD

	• Patient safety issue: Medications potentially aggravating GERD • Twice daily PPI dosing
Treatment of Chronic Noncancer Pain	• Excessive dose of tramadol or opiate analgesics containing acetaminophen or ibuprofen • Tramadol use with renal or hepatic disease • Pediatric use of tramadol • Use of meperidine • Underutilization of long acting opiates (titration or initiation of long acting therapy) • Coordination of care (multiple opiates from multiple prescribers)

Dr. Evans felt these were good topics but felt the duplicate antipsychotic use is a common practice amongst specific circles and questioned if this behavior would change. Dr. Berringer explained this indicator identifies duplicate therapy for a single prescriber and multiple prescribers. Dr. Ferrance requested that these be presented at the next DUR Board meeting with numbers of patients that meet the clinical indicators

Other Business

Synagis Report – Dr. Cain summarized numbers provided in a Magellan report.

- September – a total of 33 approved. Some approved by a pharmacist at the call center for those patients that met Synagis criteria. Also, four were approved by Magellan-contracted pediatrician physician.

- October – a total of 144 approved. Of these, 112 were approved by the call center pharmacist and 29 were approved by the physician.

- November (half of the month) – a total of 54 approved. Of these, 43 were approved by the call center pharmacist and 11 were approved by the physician.

Dr. Ferrance asked if Magellan could provide the total number submitted in order to compare to the approval numbers. Dr. Evans commented that he hoped that the Call Center would not continue to see claims deny for the same reasons over time. Ms. Proffitt explained that Magellan calls each physician explaining the reason for denial and also sends a letter for those requests that are denied. Currently, all denial requests are being sent to the physician for further review.

ProDUR Edits
Since the ProDUR edits related to FDA warning were discussed when the DUR Board did not have a quorum, the Board reconsidered these.

- Drospirinone – Dr. Rock made a motion to add a drug disease ProDUR edit for drospirinone containing oral contraceptives with thromboembolic disorders. Ms. Settle seconded. The motion was accepted.

- Ondansetron – Ms Fagan made a motion to add ondansetron to the existing QT prolonging drug-drug interaction and drug-disease interaction between QT prolonging agents and QT prolong disease history. Dr. Rock also recommended ondansetron be added to the list of QT prolonging agents. Ms. Settle seconded. The motion was accepted.

The next DUR Board Meeting is scheduled on March 15th.

Meeting was adjourned at 4:30 pm.