Drug Utilization Review Board
Minutes Draft

Name of Meeting: Drug Utilization Review Board
Date of Meeting: March 15, 2012
Length of Meeting: 2 hours 22 minutes
Location of Meeting: DMAS 13th Floor Board Room

Members Present:
Randy Ferrance, MD, Chair
Bill Rock, PharmD
Michele Thomas, PharmD
Jonathan Evans, MD
Cynthia Fagan, FNP
Jane Settle, NP, Vice Chair
Jamie Haight, RPh

Members Not Present:
Renita Driver, PharmD
Sandra Dawson, RPh
Avtar Dhillon, MD

DMAS Attendees:
Rachel Cain, PharmD
Donna Francioni-Proffitt, RPh, Pharmacy Program Manager
Keith Hayashi, RPh
Bryan Tomlinson, Health Care Services Division Director
Tyrone Wall
Scott Cannady

Contractors:
Robert Berringer, PharmD, Senior Clinical Director, ACS/Xerox
Felicia Epps, RPh, Clinical Pharmacy Manager, ACS/Xerox
Eboni Washington, Administrative Assistant, ACS/Xerox

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

Visitors:
Casey Carpenter, Lundbeck
Mike Suto, Genetech
Paul Purdy, Amgen
Susan Matthews, MedImmune
Lisa Pompa, Vertex
Cindy Snyder, GSK
Michele Boykin, GSK
Chijioke Okafor, BMS

Call to Order and Introductions
Dr. Randy Ferrance welcomed everyone and called the meeting to order at 2:16pm. Dr. Ferrance noted that there was a quorum at the start of the meeting.

Minutes—November 17, 2011 Meeting

Dr. Ferrance asked if there were any additions or deletions to the minutes from the November 17, 2011 meeting. Ms. Fagan made the motion for the November 17, 2011 meeting minutes to be approved as written. Ms. Settle seconded; the motion was adopted.

New Drugs

Jakafi™ (ruxolitinib) – after Dr. Berringer presented the ProDUR and RetroDUR criteria, Dr. Evans questioned the monograph where it states "Ruxolitinib has demonstrated a palliative effect in patients with myelofibrosis, but has not been shown to impact survival." Dr. Berringer referenced the endpoints reduction in spleen volume in the efficacy studies included in the monograh. The term, palliative, was based on clinical indicator versus survival. Ms. Settle questioned whether this medication should have service authorization (SA) criteria applied and if applied SA is required, would it result in a time delay that could affect the patient's treatment. Dr. Berringer indicated a SA could take up to 24 hours. Dr. Evans responded that a 24 hour delay should not be an issue and that most other insurers would probably have some sort of authorization on this drug. Dr. Ferrance suggested restricting the medication to patients with myelofibrosis. Dr. Ferrance moved to accept the criteria as presented but implement SA criteria to restrict the medication to patients with a diagnosis of myelofibrosis. Dr. Thomas seconded. The motion was accepted.

Eylea™ (aflibercept) – after Dr. Berringer presented the ProDUR and RetroDUR criteria, Dr. Ferrance stated that this medication should also have a service authorization requirement. Dr. Ferrance suggested restricting the medication to patients with age related macular degeneration. Dr. Ferrance asked for a motion to accept the criteria as presented but implement SA criteria to restrict the medication to patients with a diagnosis of age related macular degeneration. Dr. Evans made the motion to accept this criteria and Ms.Haight seconded. The motion was accepted.

Ferriprox™ (deferiprone) – after Ms. Epps presented the ProDUR and RetroDUR criteria, Dr. Ferrance recommended a SA requirement for this drug. The proposed SA criteria would restrict deferiprone to patients with a diagnosis of thalassemia. In addition, the patient cannot have undergone chelation therapy or has tried and failed chelation therapy. Dr. Evans noted the caution in the monograph regarding using this medication in those at risk of QT prolongation. He suggested that a DD edit be added to include QT prolongation. Dr. Thomas moved to accept the criteria to include the SA criteria and the addition of the drug-drug interaction with QT prolongers. Dr. Evans seconded. The motion was accepted.

Onfi™ (clobazam) – The ProDUR and RetroDUR criteria were presented. Dr. Cain stated that (7) other states have placed criteria on this medication. She

presented the criteria from these states to the Board. Dr. Evans proposed to adopt Georgia's criteria. Ms. Settle seconded. The motion was accepted.

Asclera™ (polidocanol) – The ProDUR and RetroDUR criteria were presented by Ms. Epps. Dr. Ferrance questioned the medical indication for treating spider veins. Dr. Cain responded that claims for this medication submitted through point-of-sale (POS) are currently being paid since there are no edits in the system to deny the claim. Ms. Fagan requested that ACS bring this drug back to the next meeting for further discussion. The Board requested additional information about the drug and a utilization report. In addition the Board asked if Medicaid pays for other antisclerosing agents (e.g.,Scleromate or Sotradecol).

Promacta™ (eltrombopag) –The ProDUR and RetroDUR criteria were presented by Ms. Epps. Ms. Settle recommended a SA requirement for this drug to include criteria for the diagnosis of chronic immune (idiopathic) thrombocytopenia (ITP) and insufficient response to corticosteroids, immunoglobulins or splenectomy. Dr. Thomas moved to accept the SA criteria as presented, and add Nplate (romiplostim) as a TD in the ProDUR edits. Ms. Settle seconded. The motion was accepted.

Edarbyclor™ (azilsartan and chlorthalidone) – The ProDUR and RetroDUR criteria were presented by Ms. Epps. Dr. Evans suggested adding diuretic (SEV 2) to the TD edit and ACE inhibitors, potassium, and potassium sparing diuretics to DD for this medication and all other ARBs in the system. Dr. Evans moved to accept the criteria to include the addition of the drug-drug interactions and therapeutic duplication criteria to this drug and all other ARBs. Ms. Thomas seconded. The motion was accepted.

Kalydeco™ (ivacaftor) – The ProDUR and RetroDUR criteria were presented. Dr. Ferrance suggested a SA was needed for this medication. Ms. Settle questioned whether DMAS would require a genetic test documenting the gene mutation for the SA or if the doctor's word would be taken. Dr. Berringer clarified that the SA criteria was accepted with one change (to state that the genetic test documenting the gene mutation must be included). Dr. Evans moved to accept the criteria to include the addition of the SA criteria with the results of the genetic test attached to the request. Ms. Settle seconded. The motion was accepted.

Old Business

Celexa and abnormal heart rhythms FDA Warning – This information was originally presented during the November meeting. The edit currently in place is based on doses above 60mg per day. The new warning also states there is no difference in efficacy above 40mg. Dr. Berringer presented the Citalopram Daily Dose report and explained there were 452 recipients on doses >40mg/day in the last quarter of 2011. Dr. Berringer suggested the edit read 40mg/day as

opposed to 60mg/day. The motion was presented by Ms. Fagan and Dr. Evans seconded. The motion was accepted.

Firazyr™ (icatibant) -- During the November meeting, the Board requested SA criteria be presented at the March meeting for discussion. The proposed criteria were presented by Ms. Epps. Dr. Ferrance suggested that the initial 3 criteria were acceptable, but the "additional criteria or other questions to consider (last 4)" were not necessary. Dr. Ferrance recommended that a RetroDUR review be conducted in a couple of months to evaluate utilization. Dr. Cain stated that the drug's cost, a utilization report, and a query on how other states manage this medication would be brought back to the May meeting. Ms. Settle presented the motion to accept the first 3 stated SA criteria with a change from "supply lab reports" to "supply lab results" in sentence #2 and a change to #1 to restrict the quantity to 6 doses per month. Ms. Fagan seconded. The motion was accepted.

Lazanda™ (fentanyl citrate) – This medication was presented during the November meeting. The Board requested REMS criteria be brought back to the March meeting. The REMS program was reviewed by the Board.

Xalkori™ (crizotinib) – During the November meeting, the Board requested SA criteria be brought to the March meeting. Dr. Cain indicated that criterion #2 should state lab report instead of lab results. The lab work needs to be sent in with the request. It was also requested that #6 not be removed since Dr. Ferrance feels that cancer patients are normally getting regular lab work. Dr. Evans proposed a three month authorization. The motion was presented by Dr. Evans and Ms. Fagan seconded. The motion was accepted.

Zelboraf™ (vemurafenib) –During the November meeting, the Board requested SA criteria to be brought to the March meeting. Dr. Evans proposed the SA criteria be accepted with the addition that the authorization will only be for three months. The motion was presented by Ms. Settle and Ms. Fagan seconded. The motion was accepted.

Reports

ProDUR and RetroDUR – Dr. Ferrance asked if anyone had any questions or concerns regarding the reports. Dr. Berringer stated the reports were included in the members' notebooks for their review.

Future Topics

Intervention Topic	Clinical Indicators
Atypical Antipsychotics: Coordination of Care in Adults	• Duplicate therapy: Multiple Prescribers • Use in Type 1 or 2 diabetic patients • Use in morbidly obese patients • Ziprasidone and cardiac concerns • Long-acting injection options for non-adherent, chronically psychotic patients
Gastrointestinal Drug Usage Evaluation (DUE)	• Extended duration of H2RA or PPI therapy with an unknown diagnosis • Extended duration of PPI therapy in patients with PUD • Duplicate anti-secretory 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: Concomitant H2RA and NSAID therapy in patients at high risk of PUD • Patient safety issue: Bisphosphonate therapy in patients with GERD • Patient safety issue: Medications potentially aggravating GERD • Twice daily PPI dosing

Dr. Berringer discussed the Atypical Antipsychotics: Coordination of Care report, stating each performance indicator and the number of exceptions found (the number of patients who met those perspective criteria). This report was proposed as a future monthly report topic. Dr. Berringer stated information regarding the CSBs could be included. Dr. Cain stated that the adult population has not been followed in some time. The focus has been mainly on children. Dr. Thomas questioned the basis of the metabolic syndrome indicators stating that patients on atypicals should undergo specific screenings. Dr. Berringer stated that ACS can include the screenings in the RetroDUR review. Dr. Ferrance proposed that criteria be accepted as stated. It was decided to accept the criteria except for the change regarding the metabolic syndrome indicators, letters will be sent and then a review by the Board 6 months later.

Ms. Epps discussed Gastrointestinal Agents Drug Utilization Evaluation (DUE) performance indicators and the number of exceptions found. Dr. Cain stated that BID dosing not captured in the DMAS system. It was decided to letter all performance indicators except for twice daily dosing.

Other Business

Atypical antipsychotics in children <6 years:

Explanation of new program: Dr. Cain explained the new Behavioral Program at DMAS (with Mendy Meeks and Sandra Brown). Dr. Cain explained that Ms. Meeks and Ms. Brown are responsible for the therapy side of the program and review the same reports to ensure no one is missing out on therapy.

Dr. Sonenklar'Update: Dr. Sonenklar reported on the SA requests submitted to the call center. He stated that he has consulted with a few prescribers and from his perspective, the program is going well. It appears that most of the SA requests have met criteria and have been processed. A few did indicate additional mental health intervention was either taking place or planned and should be documented.

ACS' Update: Dr. Berringer presented data from October 2012 to February 2012. In reviewing this report, he noted that status categories included NEW (children that have not been on the medication prior to the indicated month and their first claim showed up in that particular month), OLD (children that have claims during the specified month PLUS claims during the 16 weeks before the indicated month), and PRIOR (children that have NO claims during the specified month (not currently on therapy) with claims during the 16 weeks before the indicated month). Two trends are shown on the report for months October 2011 to February 2012. First, the total number of kids on atypicals is decreasing. Second, the number of new starts has decreased.

Synagis Report – Dr. Cain summarized numbers provided in a Magellan report. This report contains data from September 2011 to February 2012.

- There were a total of 540 claims approved in this time period.
- There were 77 denied claims.
- Dr. Kraft(pediatric specialist) reviewed 97 of the 540 claims
- Of the 97 cases reviewed by Dr. Kraft, 85 were approved and 12 were denied.
- DMAS has received one appeal during this time period, which was an error. Upon review the appeal should have gone to the recipient's primary insurer not DMAS.

DMAS received the question of whether the Synagis season should be extended past March 31st due to the unusually warm weather this past winter in Virginia.

Dr. Ferrance stated he had not heard anything about extending the season in Virginia. Dr. Cain contacted the CDC and the State Health Department. The CDC informed Dr. Cain that they did not have a recommendation to extend the season. The Virginia Health Department recommended that DMAS not extend the season.

Ms Proffitt ran a utilization report which revealed patients are not receiving more than 5 doses. In addition, a second report was run comparing September 2011 to February 20, 2011 to the same time period last year and there was a $2 million drug spend save.

Meeting was adjourned at 4:38 pm.

The next DUR Board Meeting is scheduled on May 17th.