**Drug Utilization Review Board**
**Minutes Draft**

**Name of Meeting:** Drug Utilization Review Board
**Date of Meeting:** September 29, 2011
**Length of Meeting**: 2 hours 15 minutes
**Location of Meeting**: DMAS 13th Floor Board Room

**Members Present:**
Geneva Briggs, PharmD, Chair
Avtar Dhillon, MD
Randy Ferrance, MD
Jamie Haight, RPh
Bill Rock, PharmD
Jane Settle, NP
Michele Thomas, PharmD

**Members Not Present:**
Jonathan Evans, MD
Cynthia Fagan, FNP
Sandra Dawson, RPh. MSHA
Renita Driver, PharmD

**DMAS Attendees:**
Cindi Jones, Agency Director
Cheryl Roberts, Chief Deputy for Operations
Rachel Cain, PharmD
Scott Cannady, Senior Health Policy Analyst
Donna Francioni-Proffitt, RPh, Pharmacy Program Manager
Tyrone Wall, Compliance Specialist
Bryan Tomlinson, Health Care Services Division Director

**Contractors:**
Robert Berringer, PharmD, Senior Clinical Director, ACS/Xerox
Ebony Washington, Administrative Assistant, ACS/Xerox

**Vendors:**
Nancy Eldin. PharmD, Magellan Medicaid
Debra Moody, RPh, Magellan Medicaid

**Visitors:**
Judy Buchanan, Gilead
Marie Furride, AstraZenecca
Julie Garner, MedImmune
Eric Kimelblatt, Gilead
Restin King, AstraZenecca
Dan McCall, Astra Zenecca
Rick Meidlinger, J&J
Jason Richardson, Forest
Cherie Robertson, Pfizer
Troy Schantz, Abbott
Bruce Song, AstraZenecca
Cindy Snyder, GSK

**Call to Order and Introductions**

Dr. Geneva Briggs welcomed everyone and called the meeting to order at 2:02pm. She noted that a quorum was in attendance and each member of the DUR Board introduced themselves.

Mr. Tomlinson announced that this was Dr. Briggs' last DUR Board meeting as Chair and a member of the DUR Board. He discussed all the work the DUR Board has done during his eight year tenure including such activities as early refill, , edit activity, and the interchange between the DUR Board and P&T Committee. Mr. Tomlinson thanked Dr. Briggs for all the work she has done. Cindi Jones, Agency Director at DMAS then presented Dr. Briggs with a plaque and also thanked her for all her work over the years. Ms Jones also thanked the entire DUR Board for all the work it has done. Cheryl Roberts, Chief Deputy for Operations at DMAS commented on the resurgence of the DUR Board under Dr. Brigg's tenure and also thanked Dr. Briggs for all her work over the years.

**Minutes—May 19, 2011 Meeting**

Dr. Rock noted that the DMAS Attendees Not Present was incorrectly worded and recommended it be worded as DMAS Not Present. Dr. Ferrance made motion for the May 19, 2011 meeting minutes to be approved as amended. Dr. Thomas seconded; the minutes were accepted with noted correction.

**New Drugs**

**Caprelsa™ (vendetanib) -** Dr. Rock requested the drug to diagnosis criteria of Steven–Johnsons, pneumonitis, hypothyroidism, hypertension, hemoptysis, and torsades be added to the RetroDUR ADR criteria. Dr. Ferrance also requested that toxic epidermal necrolysis (TEN) be added to the RetroDUR ADR criteria. Dr. Ferrance moved to accept the criteria as amended. Dr. Rock seconded. The motion was adopted.

**Daliresp™ (roflumilast) -** Dr. Thomas asked if ICD-9 diagnosis codes included in the suidical ideation drug to diagnosis ProDUR criteria were for suicidal ideation or suicide attempt. Dr. Thomas also requested that the description reflect those specific codes in the edit. She also requested they be added to the RetroDUR ADR criteria. Dr. Rock moved to accept the criteria as amended. Ms. Settle seconded. The motion was adopted.

**Dificid™ (fidaxomicin) -** Dr. Briggs requested injectable vancomycin be added to the therapeutic duplication criteria. Dr. Thomas moved to accept the criteria as amended. Dr. Rock seconded. The motion was adopted.

**Edurant™ (rilpivirine) –** Ms. Settle requested that NNRTIs be added to the therapeutic duplicate therapy criteria. She discussed that standard of care is not to use multiple NNRTIs concurrently. Ms Settle moved to accept the criteria as amended. Dr. Rock seconded. The motion was adopted.

**Fluzone Intradermal™ (influenza virus vaccine) –** Ms. Settle moved to accept the criteria as presented. Dr. Rock seconded. The motion was accepted.

**Horizant™ (gabapentin enacarbil) -** Dr. Berringer explained that gabapentin is currently included in a therapeutic duplicate edit that includes gabapentin and pregabalin. Dr. Briggs requested that gabapentin enacarbil be added to this edit. Dr. Rock requested that the suicidal ideation be added to the RetroDUR ADR criteria. Dr. Briggs requested the high dose be set at doses greater than 600mg instead of the recommended > 1,200mg/day. Dr. Briggs also recommended that the drug to diagnosis edits with renal impairment and renal dysfunction be added as severity 2. Ms. Settle moved to accept the criteria as amended. Ms. Haight seconded. The motion was adopted.

**Incivek™ (telaprevir) -** Dr. Ferrance requested that Stevens Johnson, toxic epidermal necrolysis (TEN), Drug Rash with Eosinophilia and Systemic Symptoms (DRESS) be added to the RetroDUR ADR criteria. Dr. Ferrance discussed that while the incidence is < 1%, it is an ADR that should not be missed. There was also discussion regarding duration of therapy for 12 weeks. Dr. Berringer explained that VAMMIS is not able to accommodate duration of therapy edits but one could be added as RetroDUR criteria. It was suggested to report on this duration of > 12 weeks of therapy at the next DUR Board meeting. Dr. Thomas moved to accept the criteria as amended. Ms Haight seconded. The motion was adopted.

**Mononine™ (coagulation factor IX, human monoclonal) -** Dr. Ferrance requested that hemophilia A be added to the drug to diagnosis (MC) criteria as a severity 1 edit. Ms. Haight moved to accept the criteria as amended. Ms. Settle seconded. The motion was adopted.

**Nulojix™ (belatacept) -** Dr. Briggs requested that history of Epstein Barr virus (EBV) be added as a severity 1 to the drug to diagnosis criteria. She later asked that it not be added since the package labeling has it listed as a contraindication/warning if EBV seronegative or with unknown EBV serostatus. Ms Settle moved to accept the criteria as amended. Ms. Haight seconded. The motion was adopted.

**Phoslyra™ (calcium acetate) -** Dr. Ferrance moved to accept the criteria as presented. Ms. Haight seconded. The motion was adopted.

**Sprix™ (ketorolac tromethamine) -** Dr. Ferrance requested that Sprix be added to the pregnancy criteria with the other ketorolac products with a severity 1 edit set to deny. Dr. Briggs also requested that an excessive quantity edit be added for > 5 bottles every 30 days. Ms. Settle moved to accept the criteria as amended. Ms. Haight seconded. The motion was adopted.

**Tradjenta™ (linagliptin) -** Dr. Ferrance requested that GLP1 agonists (i.e., exenatide and liraglutide) be added to the therapeutic duplicate criteria. Ms. Settle moved to accept the criteria as amended. Dr. Thomas seconded. The motion was adopted.

**Viibryd™ (vilazodone) -** Dr. Dhillon requested the suicidal ideation/attempts be added to the RetroDUR ADR criteria. Ms Haight moved to accept the criteria as amended. Dr. Thomas seconded. The motion was adopted.

**Victrelis™ (boceprevir) –** Dr. Berringer pointed out an error on the first page of the New Drug Update that should read 200mg capsules instead of 300mg capsules. The ProDUR and RetroDUR criteria were presented. Ms. Haight moved to accept the criteria as presented. Ms. Settle seconded. The motion was adopted.

**Xarelto™ (rivaroxaban) -** Dr. Rock requested the dabigatran (Pradaxa) and heparin be added to the therapeutic duplicate criteria. Dr. Ferrance requested that spinal deformities be removed from the drug to diagnosis criteria. Ms. Settle moved to accept the criteria as amended. Dr. Ferrance seconded. The motion was adopted.

**Zutripro™ (hydrocodone bitartrate/chlorpheniramine maleate/pseudoephedrine hydrochloride) -** Dr. Briggs requested that phenylephrine combination products be added to the therapeutic duplication criteria. Dr. Briggs also requested that phenylpropanolamine be removed from the drug to drug interaction since these products have been removed from the market. Dr. Ferrance moved to accept the criteria as amended. Ms. Haight seconded. The motion was adopted.

**Zytiga™ (abiraterone acetate) -** Dr. Ferrance moved to accept the criteria as presented. Ms. Settle seconded. The motion was adopted.

**ProDUR Reports**

Dr. Berringer discussed recent simvastatin label changes. These included an FDA warning posted on June 8th, 2011 notifying providers not to start new patients on Simvastatin 80mg and updating simvastatin drug to drug interactions. ACS has updated their RetroDUR criteria to reflect these changes and the following reflect the number of DMAS recipients hitting on the respective criteria.

| Clinical Indicator | Number of patients |
|---|---|
| Prescribed simvastatin 80mg for < 9 months | 237 |
| Drug to drug interactions | |
| • Simvastatin and antifungals | 3 |
| • Simvastatin and protease inhibitors | 0 |
| • Simvastatin and macrolides | 14 |
| • Simvastatin and nefazodone | 3 |

| | |
|---|---|
| • Simvastatin and gemfibrozil | 157 |
| • Simvastatin and cyclosporine | 4 |
| • Simvastatin and danazol | 0 |
| • Simvastatin > 10mg and amiodarone | 22 |
| • Simvastatin > 10mg and calcium channel blockers | 166 |
| • Simvastatin > 20mg and amlodipine | 353 |
| • Simvastatin > 20mg and ranolazine | 24 |

Ms. Settle requested that the simvastatin and protease inhibitor be added as a ProDUR drug to drug interaction. Dr. Ferrance seconded. The motion was adopted

**RetroDUR Reports**

Dr. Berringer discussed that the RetroDUR database has 2 years of pharmacy and medical claims history (i.e., ICD-9, CPT, and HCPCS codes) and includes only those claims paid by Medicaid. Dr. Berringer also explained the medications not paid by Medicaid (e.g., samples) are not included in the database. While the CPT codes for a laboratory test paid by Medicaid is in the database, results or other clinical data (e.g., vital signs) are not included. Dr. Berringer also discussed limitations of administrative claims data such as billing entry errors and gaps in history due to patients moving on and off of Medicaid.

**AAP in Children**

Ms. Francioni-Proffitt described the Service Authorization (SA) Requirement for the Use of Atypical Antipsychotics in Children under the Age of 6 program. DMAS has contracted with Magellan to review antipsychotic use in children under the age of 6 years using the following criteria:

- The drug must be prescribed by a pediatric psychiatrist or pediatric neurologist or the prescriber must supply proof of a psychiatric consultation AND,
- The recipient must have an appropriate diagnosis AND,
- The recipient must be participating in a behavioral management program AND,
- Written, informed consent for the medication must be obtained from the parent or guardian.

Dr. Neil Sonenklar is a Pediatric Psychiatrist in the Richmond area who will review service authorizations requests for antipsychotics in children under the age of six that do not meet the approved criteria. He will provide peer to peer consultations with the prescribing providers. This program will be implemented on December 1, 2011. For requests that do not meet the criteria, Magellan will authorize a SA for a period of 15-30 days (to be determined by Dr. Sonenklar) so that the child can receive the medication while Dr. Sonenklar reviews the request and consults with the prescribing provider. Ms Moody from Magellan also discussed that some of the process is still in discussion including such things as

emergency fills allowed for requests on the weekend to provide therapy until Dr. Sonenklar's review. Ms. Francioni-Proffitt also discussed that Dr. Sonenklar was scheduled to attend the DUR Board meeting but had a conflict with the reschedule date. He is on the agenda for the November meeting.

Dr. Dhillon discussed the practicality of the criteria in the first bullet (i.e., "The drug must be prescribed by a pediatric psychiatrist or pediatric neurologist or the prescriber must supply proof of a psychiatric consultation AND") due to the low number of pediatric psychiatrists in the state. The Board discussed the aforementioned criteria, possible impact on members, and potential changes. Ms. Francioni-Proffitt reviewed the process and that the call center will use the criteria to approve the request. She explained that the claim will go through if the drug is prescribed by a pediatric psychiatrist OR has proof of a psychiatric consultation. If the criteria are not met, the claim will be flagged for Dr. Sonenklar to review. He will provide a consult with the prescriber and make a service authorization decision.

Dr. Briggs suggested using provider types of psychiatrist or neurologist. Dr. Thomas was concerned about making the provider types too broad and suggested that Dr. Sonenklar recommend changes based on experience during implementation of the program. Dr. Dhillon suggested that criteria number one be "the drug must be prescribed by a psychiatrist or neurologist or the prescriber must supply proof of a psychiatric consultation AND". Dr. Briggs noted that the request still must meet the other criteria to be approved and that any of the criteria can be changed at a future date. Mr. Tomlinson summarized that the references to "pediatric" would be struck from criteria number one. Dr. Briggs also noted that children currently on therapy get a 6-month grandfather after which time they will be reviewed.

**Synagis**

Dr. Cain discussed that the Medicaid memorandum was published on June 1st for the new edit on Synagis and that there have been thirty one requests to date. Two requests are currently pending for review and three have been referred to the Medical Director at Magellan. A total of eight have been denied to date. Two have been denied because the request did not meet Synagis criteria and a faxed form was sent and a follow up call was made to the prescribers. Six providers received faxed letters notifying the provider that the patient did not meet the criteria and follow up phone calls are pending.

Deb Discenza was introduced to provide public comment. Ms. Discenza is a parent advocate who represents parents of premature children (i.e., less than 37 weeks gestation) and who herself has a daughter that was born at 30 weeks. Ms. Discenza discussed how grateful she was for the drug and issues regarding helping others understand the importance of keeping the babies healthy. On the national scene there are groups that have come forward and said they do not agree with the AAP guidelines. Ms. Discenza stated that she supports the drug

and is requesting another review of the criteria. She further discussed that new data on late preterm infants and lung development has come out. Ms. Discenza closed with a request for a scientific review of the criteria.

**FFY 2010 CMS Annual Report**

The report was included with the DUR Board binders and each member was asked to review the report on their own.

**Other Business**

- Ms. Settle made motion to nominate Dr. Ferrance as Chair. The motion to elect Dr. Ferrance for Chair was approved.
- Dr. Ferrance made a motion to nominate Ms. Settle as Vice Chair. The motion to elect Ms. Settle for Vice Chair was approved.
- Dr. Rock requested that ACS review current DUR criteria relative to Celexa and compare current criteria to the recent FDA warnings specifically doses at greater than 40mg per day. Dr. Berringer will compare and present findings at the November DUR Board meeting.
- Dr. Thomas requested that ACS also review the oral contraceptive criteria specific to drug to disease edit related to thromboembolism risk. ACS will research the current drug to disease oral contraceptive/thomboembolism criteria to see if it is set to deny or a change should be made based on this new risk.

**The next DUR Board Meeting is scheduled in November.**

**Meeting was adjourned at 4:17 pm.**