

**Drug Utilization Review Board  
Minutes  
November 18, 2010**

**Length of Meeting:** 2:09 PM – 4:21 PM

**Location of Meeting:** DMAS 13<sup>th</sup> Floor Board Room

**Members Present:**

Geneva Briggs, PharmD, Chair  
Sandra Dawson, RPh, MSHA  
Renita Driver, PharmD  
Jonathan Evans, MD, MPH  
Cynthia Fagan, FNP  
Bill Rock, PharmD  
Jane Settle, NP

**Members Not Present:**

Avtar Dhillon, MD; Randy Ferrance, MD; Michele Thomas, PharmD; Jamie Haight, RPh; Jason Lyman, MD

**DMAS Attendees:**

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

**Contractors:** Rob Berringer, PharmD, ACS/Xerox; Wendy Nash, PharmD, ACS/Xerox; Debbie Moody, RPh, Provider Synergies/Magellan; Nancy Eldin, RPh, Provider Synergies/Magellan

**Visitors:**

Elenee Argentinis, BI  
Tim Carr, BMS  
Brenda Evans, UCB  
Rick Meidlinger, J&J  
Jason Richardson, Forest  
Bruce Song, AZ  
Cindy Snyder, GSK  
Fred Whitten, Merck

## **Call to Order and Introductions**

Chair Geneva Briggs welcomed everyone and called the meeting to order. Dr. Briggs noted that the agenda would be shifted and items that did not require a vote would be addressed first until a quorum was met.

## **RetroDUR Reports**

Dr. Wendy Nash, ACS/Xerox, presented the RetroDUR reports for the last quarter. She directed the Board to the results on the RetroDUR response grid. Letters for the Polypharmacy and Abuse reviews were mailed in June and July during the transition take over period. Two hundred forty nine (249) letters were sent for the Polypharmacy review with an 8% response rate. There were 509 letters sent for the Abuse review, with an 11% response rate. Beta Blockers in Heart Failure lettering was conducted in August 2010, with 212 letters sent and a 17% response rate. Most prescribers responded they were aware of the situation and there was no adjustment in therapy. Dr. Nash explained that a response of "other" meant the provider handwrote his/her response on the returned form instead of checking one of the designated boxes. Dr. Berringer noted that letters were sent to prescribers reminding them to recommend their high risk patients receive an annual influenza vaccine was sent in September. Dr Nash added that Dulera letters were sent as well and that the responses for Influenza and Dulera will be presented at the next meeting.

## **ProDUR Reports**

Dr. Nash presented the quarterly ProDUR reports. According to *The Summary of ProDUR Alerts for FFY 2010*, under History Alerts, Drug Drug interactions constituted the largest number at 917,697 followed by Therapeutic Duplication with 332,555. Patient Age was the leading Non-History alert at 40,501. Dr. Nash also noted that 33.5% of all claims have a ProDUR alert.

*The Cost of Utilization Analysis by Drug Type for FFY 2010* demonstrated that 64% of claims were filled generically. Review of *The Top 25 Drugs by Payment Amount September 2010* revealed that the atypical antipsychotics aripiprazole and quetiapine ranked number one and number two, respectively. As a group the atypical antipsychotics held 4 of the top 9 slots. Dr. Nash brought to the Board's attention that clopidogrel ranked 24<sup>th</sup> and thus may warrant RetroDUR analysis. And lastly, Dr. Nash reviewed *The Top 25 Drugs Ranked by Claim Count September 2010*. OTC products factored in heavily in this report, constituting 10 of the 25. Loratadine ranks number one, followed closely by hydrocodone/acetaminophen and aspirin at number three.

## **Dose Optimization Reports**

Given that DMAS has performed drug optimization for years, Dr. Cain asked that Dr. Berringer, ACS/Xerox, look to see if ACS/Xerox could provide any new ideas for the August 2010 meeting. At August 2010 meeting, Dr. Berringer presented the *Dose*

*Optimization Report*, which identified an extensive list of opportunities and he was asked to do further analysis of potential cost savings for several of the opportunities and present at the November meeting. These savings could then be weighed against the impact on the Call Center, which provides service authorization (SA) service.

Dr. Rob Berringer presented a follow-up to the *Dose Optimization August 2010 Report*. Dr. Berringer reviewed each of the six drug classes for dose consolidation. He explained that Maximum Annual Savings assumed that all prescriptions would be converted and twelve prescriptions would be filled per year. Saving cost per RX is calculated by taking the cost of the higher strength and subtracting the cost of two of the lower strength. Dr. Berringer gave the example of SSRI 50 mg two tablets given once daily versus 100 mg daily. Maximum annual savings assumes the prescription will be filled monthly over 12 months. Exceptions are the number patients in a 30 day time period that have that opportunity.

Though the number of exceptions is the highest for lisinopril, the savings is lower and thus may not justify the additional call center costs. Dr. Berringer noted with some of these drugs there still may be a quality issue; however, the cost benefit is diluted. This is particularly true where there is significant generic penetration.

A lengthy discussion followed regarding Proton Pump Inhibitors (PPIs) and dose optimization. Dr. Berringer explained for PPI BID dosing the ACS/Xerox clinical analytics tool has removed recipients with GERD, Zollinger Ellis Syndrome, GI Bleed where BID is clinically appropriate. The savings are potentially \$1.4 million annually. The actual conversion rate would probably be 30 to 50%, even so that would be a considerable amount of money. Dr. Geneva Briggs clarified that the model assumes the recipient will take one unit of the current strength per day instead of two units per day (one unit twice daily). Dr. Jonathan Evans noted that duration of proton pumps was often longer than recommended, frequently there is a lack of indication, there is cost differential between drugs, and there is a recently identified drug interaction with clopidogrel. Dr. Evans explained that a number of studies have shown that 2/3 or 3/4 of patients in hospitals are on PPIs with no indication, and that upon discharge from acute care, 90% of patients continue on a prescription with a PPI prescription. Further, a study in Long Term Care (LTC) found that 91% remained on a PPI six months after admission. He noted that the frequency is just one domain of the appropriateness of PPI therapy. Dr. Briggs suggested that a RetroDUR analysis may be an option. Dr. Evans stated that most private insurers have a tiered system due to the cost differential amongst agents and that is a prospective approach with prior authorization. It was noted that PPIs are on the PDL and therefore a PA would be an option, and that for a recipient to receive BID dosing this would require a SA. Dr. Evans stated that by decreasing the frequency the state could save \$1.4 million and speculated that by discontinuing the drug for those who don't need it, perhaps, up to \$2 million. Rachel explained the dose optimization process. The prescriber does have to call the call center. This would require a substantial number of calls at first, approximately 2600. Dr. Evans noted that some physicians change their behavior just by having to submit a SA. Therefore, there will not be 2600 total calls. He stated that prescriber considers the

following: what can we switch to, what's the issue and what's the alert. Ms. Settle noted that at least one Medicaid HMO will reimburse for Prilosec 20mg bid but not Prilosec 40mg daily. She further stated that it would be useful for providers for the DUR Board to look at some of the other Virginia Medicaid HMOS and what they do and attempt to standardize. Dr. Evans asked if it would be possible to allow the original prescription and then requiring a SA after 60 days.

Dr. Berringer stated that there is additional data, separate from dose optimization, which reveals recipients who have been on PPI for longer than six months with NO diagnosis, not even GERD, PUD or ZE. This number is about 1,500. Dr. Briggs suggested a RetroDUR review for those.

Dr. Evans noted that PPIs are highly useful and highly effective drugs but no one is recommending high dose and for long period unless exceptional circumstances.

Dr. Evans stated that his vision of the DUR Board is that part of its charge is Patient Safety Committee. The DUR Board has a commitment to the recipients to advocate for their safety and an obligation to industry to make sure their products are used in an appropriate manner. Dr. Briggs noted osteoporosis with long term administration. Dr. Evans stated much of these issues can be blamed on fragmented care.

The Board turned its' attention to meloxicam and Selective Serotonin Reuptake Inhibitors (SSRIs). Dr. Briggs noted that these did not involve a call center issue, but rather necessitated a call from the dispensing pharmacist. Dr. Evans says there is a significant amount of polypharmacy with antidepressants. He noted the people paying for and the people taking them need an explanation. Dr. Evans stated that as a prescriber he would like to know if he could save Virginia Medicaid a lot of money. That would change his behavior. Unfortunately the prescribers don't know what medications cost. He doesn't think it is unreasonable for the DUR Board to help with that education.

Since meloxicam is not the drug of choice for any conditions, Dr. Evans wanted to know if one prescriber or one group of prescribers was using it or if the use was widespread. If one prescriber or group is utilizing it, then that prescriber or group could be targeted for intervention letters. Dr. Berringer stated that a prescriber or group of prescribers could be targeted as an educational mailing instead of formalized dose optimization.

Finally the Board discussed the effectiveness of lettering and the costs involved. Dr. Nash explained that the cost of lettering is included in the contract. Ms. Settle prefers notification by emails. Dr. Evans noted, however, letters from the Commonwealth of Virginia usually get opened and read. Dr. Nash related the low response rate to the RetroDUR letters historically and the current ones just presented. Dr. Berringer noted that he has seen these types of mailings before and even though the response rate is low, a 50% switch rate on the consolidation has been seen.

Dr. Briggs called for a motion. Since there was no quorum, Dr. Evans made a recommendation to letter on all SSRIs meloxicam. Mr. Tomlinson reminded the Chair

that she could call for a “Sense of the Group” regarding this recommendation since a quorum was not present. Dr. Bill Rock seconded the recommendation. The recommendation was unanimously carried.

### **Atypical Antipsychotic Use in Children Under Six Years of Age**

Dr. Cain gave a brief update on the Atypical Antipsychotic (AAPs) Use in Children Less Than 6 Years Old project. DMAS was charged by the DUR Board to bring criteria for implementation and engage a physician consultant, which is still pending. Bryan Tomlinson stated that recommendations from the DUR Board for criteria and a physician consultant have been accepted, but not implemented yet. Therefore, Mr. Tomlinson stated DMAS was not prepared to present the physician consultant today. He stated this is not an automatic mechanism, but rather a separate contracting process and the Department is exploring different options for contracting with a physician consultant. The first option, the Department of Psychiatry at VCU, would constitute a joint venture between DMAS and another state agency. There are also other contracting possibilities.

Dr. Nash reviewed the *AAPs in Children Less Than 6 Years Old Report*. She explained that the report was being converted to a calendar month basis to make the reporting more consistent and logical. The time frames for previous reports have varied from 2 to 5 months, which has made comparisons difficult. She further noted it will take 3-4 months of data reported by the calendar month before any comparisons can be made using the data. Dr. Nash reviewed the age breakdown with most recipients being 5 year olds. She explained the categories new, old and prior for the calendar month September 2010 spreadsheet. Prior means that the recipient was on an AAPs in the previous month; however, the prescription has not been filled during the current month. The concern with looking at just the one month is if a patient is not strictly being adherent, but is still taking the medication, the refill could move over into the next month or perhaps the recipient didn't take during the summer. Therefore, to interpret the data, the Board needs to look at trends. When looking at all categories, males predominate over females, by a little over 2 to 1. Dr. Evans wanted to know about rates as well, i.e. numerator and denominator, for the total number of antipsychotics. Dr. Cain has also requested additional data elements, such as diagnosis codes for inclusion in the report, which will be presented at a later date.

Dr. Evans asked if DMAS was aware of any changes in other states that relate to AAP use in general. Dr. Evans noted that in 2 weeks the US Senate will hold hearings on AAP use in the elderly. He anticipates more activity nationwide with this class of drugs, given the Senate's and CMS' interest. He stated the public reaction will be against this class of meds, particularly as chemical restraints. He stated that the determining factor as to whether a resident, with dementia, remains on an AAP for a year is the LTC facility where they reside.

Dr. Cain provided the history of the DUR Board's interest in AAPs during the time when there was a Comprehensive NeuroScience (CNS) program. At first the Board started

with the entire population, children and adults. Then the population was split and letters to children and adults were alternated monthly. Lastly, the Board decided to look at children, take the data and do something worthwhile. Dr. Evans stated this is a public safety issue and that the manufacturers don't want inappropriate use either.

Mr. Tomlinson stated that the population enrolled in Virginia Medicaid will change in 2014 as a result of federal health care reform. To date, recipients have primarily been women and children. Under health reform, it is anticipated that there will be another one-half million childless adults. This will translate into different utilization patterns. He stated Virginia Medicaid has already experienced significant increases in Medicaid enrollment on a monthly basis.

### **Minutes—August 19, 2010 Meeting**

The Board reviewed the minutes from the August 18, 2010 meeting. Sandra Dawson moved to accept the minutes with no corrections and Dr. Evans seconded.

### **New Drugs**

Dr. Wendy Nash, presented criteria for the new drugs, Beyaz® (drospirenone/ethinyl estradiol/levomefolate calcium tablets and levomefolate calcium tablets), Gilenya® (fingolimod) and Tekamlo® (aliskiren and amlodipine).

The Board had the ensuing discussions and made the following recommendations:

- Beyaz®: Dr Evans noted that the fourth indication for Beyaz—in women who choose to use an oral contraceptive as their method of contraception to raise folate levels for the purpose of reducing the risk of a neural tube defect in a pregnancy conceived while taking the product or shortly after discontinuing the product—was interesting, has an FDA indication, but had no clinical indication. He noted the company would have had to pay extra money to obtain extra data to obtain the indication and thus it must be a benefit to somebody.

Dr. Rock suggested placing an edit to code for smokers since the incidence of thromboembolic events increases dramatically in smokers who are 35 years old. The logistics were discussed and the Board decided to add a drug-disease (MC) if the patient has a history of tobacco dependence ICD-9 and a patient age edit (PA) if >35 years of age. Ms. Dawson made a motion to accept the edits with adding Tobacco Dependence to MC. Ms. Settle seconded it. The motion carried unanimously.

- Tekamlo®:  
Aliskiren was added to TD, (2)  
DD: ACEIs, ARBs, and combinations of ACEIs and ARBs, potassium, pironolactone, potassium sparing diuretics, Yaz, BeYaz (2)

PA: Add an alert for patient <16 or 18 years of age based on other VA MMIS PA alerts that are based on a pediatric population and age not specifically defined in package labeling.

Ms. Dawson made a motion to accept the edits with the noted additions. Dr. Evans seconded. The motion carried unanimously.

- Gilenya®: Dr. Nash noted that Gilenya received priority review from the FDA as it is the first oral disease modifying drug for relapsing forms of Multiple Sclerosis (MS). She instructed the members to listen carefully to the warnings as these would have an impact on the distribution system and the mandatory monitoring of the patient for 6 hours after the first dose. Prior to voting on the edits, there was extensive discussion about Gilenya. Donna Proffitt explained the “Free Care Rule”. Basically the rule states that a provider cannot provide free care to other patients and then charge Medicaid if Medicaid recipients receive the same care. Dr. Evans noted that rebates are an even broader concern as they influence prescribing behavior. From a policy perspective, Medicaid has been concerned about free drugs since the costs may be shifted to Medicaid.

Dr. Cain noted that Dr. Nash had proactively contacted Novartis, setting up a conference call that included Donna Johnson and herself at which time Novartis presented their distribution system for Gilenya. Dr. Nash explained that Novartis has partnered with specialty pharmacy, TheraCom, a CVS Caremark company, to handle the limited distribution. Novartis outlined the following model during the conference call. After determining that a patient should have Gilenya, the prescriber will contact TheraCom, submit paperwork with patient details and a prescription for Gilenya. After TheraCom determined eligibility, a free 14 day blister pack will be filled and labeled for the patient, and will be mailed to the prescriber’s office. The prescriber must monitor the patient for 6 hours either in the prescriber’s office, an ambulatory care center, an infusion center or rheumatology clinic. In addition to determining eligibility and filling the free prescription, TheraCom will provide a comprehensive program involving patient education and adherence aids, including calling the patient if a prescription has not been filled nearing the 14 day mark. This comprehensive program is to “match the expectations” of what is provided for other MS drugs.

Dr. Cain outlined the distribution logistics in more detail. Upon further questioning, Novartis stated that the company would **not** be able to provide the free 14 day blister pack to Medicaid recipients. Dr. Nash asked Novartis to send the procedure that would be followed for Virginia Medicaid recipients. How will recipients get the drug? From a 7 day sample pack at the prescribers office or by 28 day prescription filled at a pharmacy that has specialty status? Novartis stated they were unable to provide a procedure at this point in time.

There are two packaging sizes with NDC numbers that are listed in the Product Information (PI)—2x14 blister packs for 28 day supply and a 7 day blister pack. Novartis stated that the 7 day blister packs will be used by Novartis nurse

educators for samples in the prescriber offices. Only the 2x14 day blister pack is listed in the VAMMIS computer system.

Ms. Settle requested clarification on how the prescriber administered drug will be reimbursed. Dr. Cain stated that if the prescriber administers the drug, then a medical claim should be filed. The other injectable MS drugs that are administered by a prescriber should also to be billed on a medical claim form.

Dr. Cain restated the two main points:

1. The only package size that is billable in the VAMMIS system is the 28 day pack and that is what will be submitted on POS
2. Since this is an MS drug, this class is on the PDL and the P&T Committee will handle the clinical questions involved.

Dr. Evans noted that fingolimod is interesting in several ways. The mechanism by which this drug works is immunosuppression and its ability to sequester lymphocytes. The utility is not unique to MS. Epstein Barr and Chronic Lymphocytic Leukemia could all be studied. So the utilization of this drug will probably expand. It is the first of that class which also makes it interesting.

Chair Briggs stated the price of Gilenya is \$140 per capsule, which is the daily dose. The Board discussed the costs involved if the prescription is filled for 28 days, the patient is unable to tolerate the drug after the first dose and thus the other 27 pills will have to be discarded. Dr. Evans commented on how the safety system would be compromised if the steady supply of the medication was not maintained. The first dose effect could become a factor again.

Chair Briggs noted two points for this committee:

1. The DUR Board would vote on edits for the fingolimod.
2. Since this class of drugs is on the PDL, the P&T Committee will review it at the next meeting.

Dr. Cain stated she is checking the Medicaid list to see how other states are handling the edits.

The following edits were added:

HD >1/day (2)

TD: interferon  $\beta$  (2), glatiramer acetate (2), natalizumab (2), mitoxantrone (2)

DD: immunosuppressants (2), verapamil (2), digoxin (2)

ADR:

PA: <18 yo (1)

MC: sick sinus (1), av blocks (1)

LR: yes, (2)

Ms. Dawson made a motion to accept the edits with the noted changes. Dr. Evans seconded. The motion passed unanimously.

## **Approval of future RetroDUR reviews for next quarter**

Dr Briggs reviewed the list of topics for the Board to consider for upcoming RetroDUR reviews—Plavix, Dose Optimization with SSRIs, Meloxicam and PPIs long duration with a documented diagnosis and a suite of HIV reports.

Dr. Nash reviewed the HIV handout that was provided. Indicators for consideration are HIV no Hepatitis B Vaccine, no influenza vaccine and no pneumococcal vaccine. For HIV Lab monitoring, the two indicators are HIV no CD4 count and no viral load. Dr. Nash was asked to explain the definition of “candidate” and “exceptions”. Dr. Nash explained that candidates refer to the number of recipients with HIV. Exceptions are the ones who didn’t receive a Hep B vaccine, for example. Dr. Berringer further explained that candidates include recipients who have a diagnosis of HIV, are currently treated and are >19yo. He stated that claims data for the last two years were searched for Hep B and pneumococcal vaccines, and claims data for the last year was searched for influenza.

Ms. Settle discussed the difficulties involved with the HIV population (e.g., the patients’ degree of immunosuppression, changing State of Virginia Aids Drug Assistance Program (ADAP) guidelines, recipients transitioning in and out of care, care provided by Primary Care Providers (PCP) and differing clinical opinions on CD4 counts). Dr. Evans estimated it costs the State of Virginia a minimum of \$10,000 annually in health care benefits for an HIV beneficiary. Ms. Settle stated it would be useful to know where the recipient receives care and by provider type.

Dr Evans stated he is grateful to learn if his patient is not taking their medications as prescribed.

Dr. Evans stated the broad concept we are talking about is quality measures and the DUR Board should be focused on quality measures. He asked if DMAS has a quality measure dashboard that goes beyond medications. He gave the example in LTC, where the percentage of residents receiving immunizations is tracked. He further stated that if DMAS has a broader quality program, we want to ensure the DUR Board is supporting that program, working in concert and not duplicating it. Mr. Tomlinson explained that beyond the DUR Board, FFS does not have a quality program. Medicaid does, however, have quality measures for the managed care population and that is the largest population in Virginia Medicaid.

Ms. Settle stated that there are standard labs obtained every six months in order for participation in the states ADAP. Dr. Berringer stated that CD4 counts claim data is reviewed for last nine months and for viral load six months. Ms. Settle noted that if the patient is hepatitis surface antibody positive, the patient will not need a Hep B vaccine.

Ms. Settle wanted to know if there is a way to match up recipients getting medications and labs being done for those recipients. She noted a lot of patients who wander in and

out of receiving care may have only received their medication nine months ago; however, the disease is still active.

Ms. Settle stated it would be useful to know where the HIV patient with problems is receiving care; whether it involves an HIV specialist or Primary Care Physician (PCP), who simply is not keeping tight control. Dr. Berringer stated that the DUR Review Panel will be asked to review the demographics of those doctors treating these patients and prescribing medications to see if they are ID specialists (e.g. MCV/VCU clinics).

Dr. Evans wanted letters sent and to know where they are being treated. He surmised that Medicaid resources are being wasted. He stated that clinics need to know about the utilization issues as well as the individual providers. Ms. Settle concurred and stated that her clinic would want a heads up call, for example, if 30% of patients don't meet criteria which could indicate a clinic wide problem. This would be useful information that we can work on. She thought that not only VCU HIV clinics would be interested but UVA as well and Dr. Evans agreed.

Dr. Nash asked for clarification. Were the time frames to be changed for CD4 counts and viral loads or were they to be left at nine months and six months respectively? Ms. Settle stated to leave them as is.

Dr. Nash provided statistics from a compliance and discontinuation report that was not available to be distributed. Approximately 100 recipients who have a diagnosis of HIV and are not receiving an antiretroviral were identified. Again Ms. Settle noted that these recipients may not need to be on it as the recommendations continue to be in flux. Dr. Evans stated he likes to know if his patients are doing what he thinks they are doing because it affects what he does next. If medications are increased or added, this could harm the patient. He recommended leaving this component. Ms. Settle stated that their clinic has access to a computerized database as to when the patient last filled their prescription.

There was no formal voting on these topics. The Board discussed the topics and reached a consensus.

### **Ad Hoc Reports**

Dr. Cain stated that Synagis use for prevention of Respiratory Syncytial Virus (RSV) has been under consideration by the Department for a couple of years. A number of states have been monitoring Synagis use. These states have made it a seasonal drug and put added parameters so that recipients can only receive the drug from September to March. Additionally, some states limit the number of doses and have age restrictions. Dr. Cain noted that Medicaid does have some older patients that receive the drug and there is some literature now indicating high risk groups in the elderly need it. The American Academy of Pediatrics (AAP) has guidelines, which will be brought to the next meeting, as well as the results of a state Medicaid survey describing what other states are doing. Dr. Cain explained that it would be beneficial for the Board to look at the

preliminary report on Synagis® utilization which was distributed. Dr. Nash reviewed the monthly claims and reported that from 10/2009 to 9/2010 the total claims paid was \$4,572,520 and that Synagis® ranks number one in it's Generic Therapeutic Class. She pointed out that 80 recipients received Synagis® in April, three in May and 17 in September. Implementing seasonal edits could reduce utilization. The average cost per RX is \$1,900, so even a few doses could make a significant impact.

Dr. Evans stated there may be other seasonal drugs that the Board could review.

**Other Business:**

Chair Briggs instructed the Board that the bylaws had not been reviewed recently. A copy of the bylaws will be distributed for review prior to the next meeting at which time they would be discussed and voted on.

The next meeting is scheduled for March 17, 2010. There will not be a meeting in February because of the General Assembly.

The meeting in May is scheduled for May 19, 2010.

**Adjournment:** Chair Briggs adjourned the meeting at 4:21PM.