DRUG UTILIZATION REVIEW (DUR) BOARD MEETING

Wednesday, June 6, 2007 1:00 P.M. to 4:00 P.M. 1 W. Wilson Street, Room 751 Madison, WI 53701

DUR Board Members Present: Michael Boushon, RPh

Robert M. Breslow, RPh

Ward Brown, MD Daniel Erickson, MD Robert Factor, MD Franklin La Dien, RPh Pamela Ploetz, RPh

Nancy Ranum, MS, RN, CS-ANP, APNP

Lee Vermeulen, Jr., RPh, MS

DHCF: Richard Carr, MD

Carrie Gray Rita Hallett, RN Susan Halfmann Marilyn Howe, RN Lynn Radmer, RPh Kimberly Smithers

James Vavra

APS Healthcare, Inc.: Allan Mailloux, PharmD

Debbie Matitz (squire)

Michael Mergener, RPh, PhD

Guests: Greg Aronin – Johnson and Johnson

Jim Canes – Schering-Plough

Paul Ford – Ortho McNeill-Janssen

Dean Groth - Pfizer

Ken Martin – Botox Therapeutic Div.

Jagdish Shastri – Eli Lilly

Susan Schmitz – Glaxo SmithKline Tim Van DeVilde – Endo Pharm.

Minutes

James Vavra called the meeting to order at 1:05 p.m.

I. Approval of the Agenda

Agenda approved as written.

II. Approval of the Minutes – March 7, 2007 Meeting

Minutes approved as written.

III. Introduction of Jason Helgerson, MA Director

James Vavra introduced Jason Helgerson, the new Medicaid Director. Mr. Helgerson was formerly the Executive Assistant to Helene Nelson, and his primary focus has been on health care and Medicaid reform. He has been involved with the biannual Preferred Drug List (PDL) process. He will be chairing the August PDL meeting, and is looking forward to learning more about what the DUR Board does.

IV. Atypical Antipsychotic Intervention Final Report (Attachment 1)

Dr. Mergener presented the evaluation of the atypical antipsychotic drugs intervention. This intervention resulted from an analysis presented to the DUR Board that determined low-dose monotherapy with antipsychotic drugs to be a significant issue. Claims were aggregated by patient by physician for a four-month period of time, excluding anyone who was taking two doses of a particular drug adding up to a dose that would put them over the low-dose limit and/or anyone who was on more than one atypical antipsychotic. Claims were then aggregated by prescribers, using those with the highest number of claims in that four-month period of time for the intervention letter. The intervention letters were sent out in mid-November 2006. The four months that were used for the post-analysis were December 2006 through March 2007, and compared four months pre to four months post. The intervention group is the group who received the letters and for a comparison group (the "non-intervention group"); the next 100 prescribers were aggregated using the same criteria as was used with the intervention group.

Results indicate that prior to the intervention, \$1.2 million was spent per quarter on low-dose atypical antipsychotic drugs versus the four months post which showed a drop in number of prescriptions and \$500,000 spent, equating to a 57% drop expenditures for low-dose monotherapy atypical antipsychotic drugs. In the non-intervention group, there appeared to be no significant change in the number of prescriptions, but the expenditures increased by 24%. Data for the same two groups was rerun for the period of April 1, 2007 through the last week of May 2007 not looking only for low-dose. Results showed expenditures for the intervention group to be even lower than the post intervention time frame. For the non-intervention group, dose appears to be accelerating as \$390,000 was spent in four months post intervention versus expenditures for new drugs of \$650,000 for April and May. This demonstrates there is definitely a difference in behavior between the two groups.

Pam Ploetz asked about the percentage of patients on monotherapy at low-dose for each drug, particularly Seroquel.

Action Item: Dr. Mergener offered to do a post-analysis on the drugs and report back at the September Board meeting.

Dr. Mergener indicated that this cost is solely for the atypical antipsychotics, but another idea would be to take this list of patients and run all drug costs pre and post to see if costs increased in other areas.

Robert Breslow sees an additional issue as to why the physicians in the intervention group made the change. He feels that when we send out these letters, we need to make an effort to capture the diagnosis.

Mike Boushon suggested, if possible, indicating in the letter the diagnosis Medicaid has on file and asking for verification.

James Vavra agreed that he would like to know what happened with these patients and why the change was made.

Nancy Ranum suggested running the same data for six months. With the new data Mike presented, we already have six months of data.

Pam Ploetz asked if we can instigate a proactive process – meaning if they met this criterion, they automatically get a letter.

It was agreed that prior to doing another intervention, we capture cost information and modify the feedback form to ask for diagnosis. After this, an assessment will be made to look at a mechanism to continue interventions in a proactive manner.

Action Item: For the September meeting, Dr. Mergener will capture all claim expenditures to see if expenditures increased in other areas. The feedback form will be modified to allow for the inclusion of diagnoses, and draft a letter to be sent to the next 100 prescribers.

V. Dr. Ward Brown Presentation – Post Myocardial Infarction Protocol (Attachment 2)

Dr. Ward Brown presented on "Core Measure Success – Acute Myocardial Infarction Care". This protocol was implemented at Gundersen Lutheran in 1994 as a result of published statements indicating that nationwide, 60 to 65% of MI patients were receiving what was then considered a standard of care at time of discharge. Gundersen reviewed approximately 500 of their patients from the prior year and 61% of their patients were receiving standard therapy, so they initiated systems to improve their care with the hope of improving patient outcomes. As a result, they looked at all the phases dealing with acute myocardial infarction ending with discharge, and developed preprinted admission orders (printed up similar to a record) and triggers for providers to follow the standard of care. Starting in 1994, every patient that came in having a myocardial infarction was standardized and went through the same process. Dr. Brown commented this has proven to be a continuous educational process and one that is continuously reviewed.

Their Priority 1 Program has been in place for almost two years. The program includes protocols for getting these patients to an angioplasty suite quickly with as few obstacles as possible. Gundersen has partnered with other hospitals that agree to take on Gundersen's protocol. A patient that presents with an ischemic event goes directly to their facility, and is registered with just name and birth date (no insurance cards necessary). Gundersen has decreased the average time in addressing patients to under

100 minutes from time they get in the door at the referring hospital until they arrive at Gundersen. Once the patient arrives, it is 12 minutes to begin the angioplasty.

To date, they have been very successful in improving care and outcomes. However, one problem is that once patients go back to their primary care provider, their provider feels the need to change medication, so Gundersen is currently working on changing these behaviors as well. No formal evaluation has yet been done looking at these patients six months later to see if they are still on the discharge medications.

Lee Vermeulen commented from the public reported measures he has seen, there appears to be a disconnect from what hospitals are reporting and what the insurance plans are expected to report publicly for post-MI care. Medicaid has a unique opportunity to demonstrate that this disconnect can be overcome. Pam Ploetz asked if the Board could make that recommendation. James Vavra responded that Jason Helgerson would like DUR to look at a package for the next 12 months of interventions, similar to what managed care plans do, to promote quality and get cost savings. This looks like a good starting point.

VI. Break

VII. Pharmacy Policy Overview (Attachment 3)

Rita Hallett presented on "Wisconsin Medicaid Pharmacy – Program & Policy". The difference between Medicaid and HMOs is Medicaid cannot have formularies per se – there are federal laws about the kinds of drugs that are covered.

Rita reported the Deficit Reduction Act of 2005 has been passed at the federal level and has some new requirements, e.g., it requires that manufacturers report their average manufacturer price to CMS federally and that is what will be used by CMS to set federal upper limits on generic drugs. The final rule will result in drug pricing changes. Effective 1/1/08, the Act will also require that all physician-administered drug claims include the national drug coding information (NDC field). One of the main reasons for that is drug rebate.

There are two kinds of drug rebates which require minimum amounts to be paid. For a brand name product, manufacturers must submit to the State 15.1% of their average manufacturer price and in addition, any time a manufacturer raises a drug price above CPI, that incremental difference gets tacked onto the 15.1%; with generic drugs, their requirement is 11% with no other requirements attached to it. Supplemental rebates came along when the State initiated a contract with Provider Synergies, an organization that deals with supplemental rebates for a number of states around the country.

Pharmaceutical Care is part of a budget initiative started in 1996 for the 1995 budget. Therapeutic substitution is the most frequently billed code. An insufficient quantity pharmaceutical care code allowing up to a 100-day supply has been recently approved for PCC billing. This code allows a pharmacy to dispense a 100-day supply that saves Medicaid dispensing fees. Recipient co-pays also decrease. Suboptimal regimen is the code used for dose consolidation and tablet splitting.

Rita distributed a handout for the Drug Effectiveness Review Project (DERP) which displays the finalized reports that are available for viewing on the website.

Comprehensive NeuroScience (CNS) is a national organization that looks particularly at behavioral health prescribing. A grant was given to CNS by Eli Lilly to look at these practices in the state of Wisconsin; started in May 2005 and ended in November 2006. One of the discussion items for the September DUR Board meeting is to discuss the criteria that was found to be very useful and how those may be used in retrospective and/or prospective DUR.

Mike Boushon asked with the PDL, is there a report showing dollars and percent spent per non-preferred drug in each class? Dr. Mergener responded there is data available – the PDL Core Team and Provider Synergies track utilization data on a quarterly basis. The State also tracks utilization in particular classes where decisions have been made to make some drugs non-preferred.

VIII. DUR 2007 Annual Projects

• Anticholinergic Burden (Attachment 4)

Dr. Mergener presented on the Anticholinergic Burden project. Published literature was utilized to develop rankings to perform some moderate correlation with actual serum anticholinergic titers (certain drugs get 3 points vs. 2 points vs. 1 point). That protocol was reapplied to data previously pulled to calculate a weighted burden score for patients. Dr. Mergener accumulated top-ranked prescribers by number of patients with the burden score and the frequency of the prescribers. The second attachment is a draft of the prescriber letter with reference made to the article used. Dr. Mergener would like feedback from the Board on whether or not to proceed with this intervention. If the decision is to proceed, additional feedback on the prescriber letter and determining a reasonable cut-off for the anticholinergic burden to send letters on is needed.

Dr. Mergener gave an example of the definition of burden of 10. For the anticholinergic drugs, it is either a 3, 2, or 1 – meaning for the person getting a 10, they would have 4 drugs – this is the number of prescriptions per month. For example, if a person got two prescriptions for Benadryl (which would have 3s), they got 6 points.

Robert Breslow expressed his concern that this literature only addresses potency equivalence. We have to be careful that while it does increase an inherent risk of adverse consequences, we cannot say with certainty that CNS effects will be produced because we have no clear evidence. Dr. Mergener responded that the letter is intended to be informational. Prescribers will be informed that their patients are receiving a number of anticholinergic drugs, even though the prescriber may only be prescribing a couple of those drugs.

Lee Vermeulen commented that even if the expectation is that we are going to see a lower drug cost, it would be nice to look at other outcomes. This cannot be done

unless you look at total cost of care. A huge factor contributing to hospitalizations is the use of over-the-counter drugs. Dr. Mergener indicated within our population, there is greater likelihood we will have information about over-the-counter drugs because Wisconsin Medicaid pays for many OTC drugs with a prescription. He further indicated the data given to the prescribers will include **all** drugs that Medicaid pays for the patient.

Suggestions for the letter include:

- Ask for diagnosis (e.g. add a section to the feedback form for this)
- Add a brief introductory line to explain what the letter is about, or switch the order of the letter to say "You are getting this because..."
- Letters be sent to the prescribers who have patients with the most burden

Action Item: Dr. Mergener recommends drawing the burden line at 7 (approximately 2,500 patients) and see how many prescribers that includes. He will get this out to the Board within the next month in order to get the intervention letters out prior to the September Board meeting.

• Choice of Second Project

The second project recommendation was to use the Atypical Intervention and mail letters to the next 100 prescribers to determine if the same cause and effect is seen in the next set of prescribers.

IX. Feedback on Preferred Drug List Mental Health Classes (Attachment 5)

Dr. Mergener explained that both the PA Advisory Committee and the Mental Health Advisory Committee provide additional input to the State on the PDL's mental health drugs. There has been some debate as to whether or not certain classes are considered to be true mental health classes. The State is looking for an external source to recommend whether or not they think these drugs actually belong in the mental health category or truly are not mental health drugs.

James Vavra indicated the first two (anti-depressants, SSRIs and anti-depressants, others) and the last two (atypical antipsychotics and stimulants and related agents) classes on the list generate the most discussion by the mental health advocates. They have little to say about the other classes. An inquiry was made regarding gabapentin and Dr. Mergener responded that gabapentin does not have any mental health indications as it has been proven to be ineffective in bipolar disease.

The Board agreed that only the first two and last two classes on the list belong in the mental health category.

X. Migraine Prophylaxis Intervention (Attachment 6)

Dr. Mergener presented on the Migraine Prophylaxis Intervention. The Util A drugs are used in migraine; the Util C is the negating drugs. The issue is people that are over utilizing drugs to treat migraines (listed under Util A) should be put on prophylactic therapy to try to decrease their use of triptans. An alert would be sent if it is determined

that use of drugs to stop migraine is too frequent. An alert would **not** be sent if patients were also taking a drug for migraine prophylaxis (listed until Util C). The letter would read "We have identified your patient is on too much X and we don't see any drug on the list being used for prophylaxis. Therefore, you should consider adding a prophylactic drug to the patient's regimen." Dr. Mergener indicated we have the ability to turn this alert on in retrospective DUR in the test mode, look at a couple months of data, and see what is actually happening. He has an older, less exclusive criterion he can use as well.

Action Item: Based upon the Board's recommendation to activate this in the next DUR cycle, Dr. Mergener will run both criteria in test mode in the next cycle and report back the numbers at the September Board meeting.

Miscellaneous

- For the September 5, 2007 Board meeting, it was suggested to have Bob Factor do his presentation on "Costs of Antipsychotics and Antidepressants". Mr. La Dien will then present at the December meeting.
- Anticholinergic Burden Intervention Mike Boushon inquired if it is within the realm of this group to pay somebody to look at these and make recommendations to go further, or should this be considered a follow-up? Dr. Mergener recommended this be a follow-up.

XI. Adjournment

James Vavra adjourned the meeting at 3:55 p.m.