WY P&T Committee Meeting Minutes
Thursday, August 18, 2011
Cheyenne, WY
9 a.m. – 3 p.m.

Members present: Becky Drnas, Steen Goddik, Kurt Hopfensperger, Joe Horam, Scott Johnston, Richard Johnson, Maria Kidner, Robert Monger, Kevin Robinett, Scot Schmidt, Dean Winsch, Tonja Woods

Ex-officio: James Bush, Antoinette Brown, Donna Artery

Guests: Kerri Powell (GHS), Sara Howe (GHS), Kerri Miller (J&J), Luciano Kolodny (Merck), Roy Lindfield (Sunovion), Lyle Laird (Sunovion), Nic Nielsen (Sunovion), Courtney Smith (Sunovion), Kathleen Karnik (Janssen), Roxanne Meyer (Janseen), Peter Berggren (Janseen), Carol Curtis (AstraZeneca), Rachel Bevis (AstraZeneca), Barbara Felt (GSK), Lisa Borland (Vertex), Pat Wiseman, Anne Marie Licos, Karen Bielenberg (Lilly), Bruce Howard, Dan McCathay (Vertex), Laura Nichols (GSK)

Dr. Hopfensperger called the meeting to order at 9:06 a.m.

Introductions were made.

Approval of Minutes

The minutes of the May 19, 2011 meeting were approved as written.

Department of Health

A. Pharmacy Program Manager Report: The Department is now in the process of finishing supplemental rebate negotiations through the SSDC. In November the 2012 PDL will be presented. GHS Pharmacist, Sara Howe, is updating the Synagis prior authorization form with only minor changes from last year. CMS is doing a national survey on actual acquisition cost (AAC) that is anticipated to start by the end of this year. The Office of Pharmacy Services will be conducting a cost of dispensing survey of all Wyoming Medicaid Pharmacy providers to ensure that all of the necessary information is available if changes to reimbursement methodology are required. The 2nd opinion line through Seattle Children's Hospital has received a total of 47 cases for review, 29 have been completed. The Department is beginning to look for changes in prescribing associated with these reviews. Dr. Goddik commented that the review process is very helpful as they review the entire patient record and are helpful in coordinating care.

Dr. Bush reported results from the Synagis criteria used last year. There was no increase in hospitalizations, length of stay decreased and no deaths were associated with using more stringent criteria for use of Synagis. The Total Health Record continues to roll out. Currently there are 17 physicians, 100 office staff, and 11,000 patiets on the system. They are holding off on connecting to other systems and are focusing on connecting to internal Department of Health databases. The system continues to be offered at no cost to any Medicaid provider. They continue to work on meaningful use

certification. Dr. Bush also reported that the PAL line continues to be used regularly with approximately 400 visits per month.

B. DUR Manager Report: Copies of the Responsible Opioid Prescribing book was provided to pharmacists on the Committee. Anyone wanting extra copies should contact Aimee or Laura. A letter was sent regarding the osteoporosis guidelines recommendation for a drug holiday for patients who have been on bisphosphonates for four or more years. An alert letter was sent to prescribers regarding patients who had used emergency contraceptives more than two times in the last year.

Old Business

A. Long-acting blood pressure medications: Maria reported on her conversations with the cardiologists regarding multi-day dosing of long-acting blood pressure medications. Sometimes low doses will be used multiple times per day by the electrophysiologist. It was also noted that low dose beta blockers are sometimes used for akathesia multiple times per day. There was a motion, second and all were in favor of the following criteria.

Long-acting blood pressure medications will be limited to their labeled dosing frequency. Exceptions will be made to prior authorization for electrophysiology and use in akathesia.

B. Atypical Antipsychotic dose optimization: The following medications will be limited as follows. Exceptions will be made for doses that cannot be achieved within the limitations. Education will be completed before implementation of prior authorization.

Abilify: Limit to 1 tablet or syringe per day.
Invega: Limit to 1 tablet or syringe per day.
Clozapine: Limit to 100 mg and 25 mg strengths.
Fanapt: Limit to 2 tablets per day.
Geodon: Limit to 2 tablets per day.

C. Latuda: Dr. Robinett commented that there were some potential benefits to Latuda including being pregnancy category B, causing less weight gain, and having a favorable metabolic profile. It is similar to Abilify and Geodon without QTc changes. It seems to have a place as a first-line agent for women of child-bearing age.

Lyle Laird (Sunovian) provided public comment. Dr. Johnston asked about studies that were listed on ClinicalTrials.gov but had not been resulted. Dr. Laird indicated that they were in the process of being published. Pearl 3 will be published plus an extension study showing long-term safety with risperidone. It is a pregnancy category B, has long-term safety data showing positive weight gain and metabolic profile effects. There are only small changes in prolactin levels. Latuda is on the formulary at the State Hospital and he requests that the Committee consider it for the PDL.

Dr. Johnston noted that studies were done against Geodon and Seroquel XR which would not be considered comparable drugs.

The Committee agreed that it is a reasonable option for women of child-bearing age so prior authorization requests will be approved for these requests.

D. Low dose Seroquel: A response from Dr. Jane Robinett regarding the proposed criteria for low-dose Seroquel was reviewed. The Committee agreed that low-dose Seroquel was reasonable for use in patients with mood disorder who could not tolerate higher doses. The final criteria are as follows:

Seroquel: Prior authorization will be required for use of doses at or below 100 mg for greater than 30 days without a diagnosis of mood disorder.

New Business

A. PA Criteria
   i. New Drugs were reviewed.
      a. Incivek
      b. Victrelis

The efficacy of both of these drugs for Hepatitis C is great. They should only be used in combination with peg-interferon and ribavirin. Public comment from Dr. Peter Perakos was reviewed and Aimee noted that a letter had been sent to physicians who are currently prescribing peg-interferon and ribavirin with no preference for either drug noted.

Lisa Borlund (Vertex) provided comment for Incivek. It is an antiviral indicated for Hepatitis C-1 for treatment naive patients as well as prior partial responders and null responders. Three trials have been conducted and two published including the ADVANCE trial.

Dr. Kolodny (Merck) provided comment for Victrelis which has the same indication as Incivek. Victrelis should always be used in combination therapy, never alone. Response guided therapy is used with a few exceptions. Victrelis does have notable drug interactions due to its interaction with CYP3A4/5.

The Committee discussed the similarity of the drugs and recommended that prior authorization should be used to ensure triple therapy is being used per indication. All were in favor of this criteria. A discussion of cost differences between the two drugs was tabled for the closed session due to the sensitivity of this information.

c. Zytiga: Roxanne Meyer (Janssen) provided comment on Zytiga. This drug has very limited distribution, mostly through specialty pharmacies. Dr. Johnston noted that no trial data was available in clinicaltrials.gov. Maria noted concern over the need for an echocardiogram to determine ejection fraction which may not always be done. The drug also requires monthly potassium checks, and frequent LFT checks. There was a motion, second, and all were in favor of limiting Zytiga to its

approved indication, castration-resistant prostate cancer in those who have received prior chemotherapy containing docetaxel. A letter will be drafted and sent to prescribers following prior authorization approval regarding the need to be aware of ejection fraction.

d. Lazanda will be limited to patients with a cancer diagnosis and will be limited by age and quantity per indication, similar to all other immediate release fentanyl products.

e. Xarelto: Kathy Karnick (Janssen) provided comment on Xarelto, which is a new Factor XA inhibitor approved for prophylaxis of DVT which can lead to PE in patients undergoing hip or knee replacement. This is an oral, once daily product, requiring no routine monitoring. There was a motion, second and all were in favor of limiting Xarelto to its approved indication.

f. Viibryd will be non-preferred until an updated DERP review can be reviewed.

g. Brilinta: This drug came on the market with head to head trials which is a positive aspect. Effient and Brilinta can be used with any proton pump inhibitor which is an advantage over Plavix. The Committee recommended similar status as Plavix. There was a motion, second and all were in favor of limiting Brilinta to its approved indication, to reduce thrombotic cardiovascular events in patients with acute coronary syndrome.

ii. Immunoglobulins were discussed, particularly their growing cost and the appropriateness of the medication being provided through a pharmacy when proper temperature control cannot be assured until administration. Scot has worked with this product with home health and has never had an issue. The physicians are unaware of issues of product integrity. The Committee asked for additional information on the subject.

iii. The use of ondansetron in pregnancy was discussed. A letter regarding its use in nausea gravidarum versus hyperemesis gravidarum was sent prior to the meeting and responses were reviewed. At this point, it seems that the medication is being used appropriately and no changes are necessary.

B. PDL Class Review

1. Restless leg syndrome. Barbare Felt (GSK) provided comment on Horizant and requested the Committee allow use of Horizant without failing gabapentin first. Horizant is a prodrug that releases gabapentin internally, dose proportionately, even with extended exposure. It has a higher Cmax, Tmax and AUC than immediate release gabapentin, though the clinical significance of this is not yet known. The Committee discussed the length of a trial which had been set at two months at the last meeting. This length is based on the time required to adequately titrate the dopamine agonists. It was noted that while drug absorption is different between Horizant and immediate release

gabapentin, it is not being use at a saturable dose (>3600 mg). Barbara also noted that studies in DPNP failed and there are no plans to move forward with that indication. There was a motion, second and all were in favor of upholding the criteria agreed upon at the last P&T Committee meeting, thus generic gabapentin will be allowed for restless leg syndrome. Additional review of this class will occur if necessary when the Cochrane Review is published.

Other: There were no other items for discussion.

Open Comments: There were no open comments.

The open portion ended at 11:35 am and the Committee met in closed session to review patient profiles and hold their annual planning session.

There being no further business, the meeting adjourned at 2:00 p.m.

Respectfully submitted,

Aimee Lewis
WYDUR Manager