WY P&T Committee Meeting Minutes
Thursday, November 15, 2012
Cheyenne, WY
9 a.m. – 1 p.m.

Members present: Becky Drnas, Steen Goddik, Joe Horam, Scott Johnston, Maria Kidner, Robert Monger, Scot Schmidt, Brent Sherard, David Sy, Dean Winsch, Tonja Woods (via phone)

Excused: Kevin Robinett

Ex-officio: Melissa Hunter, James Bush, Cori Cooper

Guests: Sara Howe (GHS/WYDUR), Nikki Yost (GHS), Kerri Powell (GHS), Brenda Stout, Sandra Deaver, Dr. Shay (via phone)

Dr. Monger called the meeting to order at 9:01 a.m.

Introductions were made. Aimee welcomed Dr. Sherard to the Committee. He was selected from the group of interested candidates in the closed portion of the August 30th meeting.

Approval of Minutes

The minutes of the August 30, 2012 meeting were approved as revised.

Department of Health

A. Pharmacy Program Manager Report: None

B. Medical Director Report: None

C. DUR Manager Report: The contract with Xerox for the profile review and letter generating module is complete and the new process will begin this quarter. Committee members will no longer be required to review profiles.

Old Business

A. Narcotic Management:

1. Oxycodone max dose was previously set at 90 mg per day. This will impact 73 patients and clarification was needed regarding expectations and next steps for providers when we limit this. The max dose will be increased to 180 mg per day with the twelve patients currently on doses higher than this limit grandfathered and contacted for possible case management. All were in favor of this change.

Dr. Shay called in to discuss his concerns regarding the inability to use buprenorphine sublingual for chronic pain. He indicated that overdose with buprenorphine is very rare, there is a larger therapeutic window than full agonist opioids, less impact on cognitive performance and are therefore safer than full agonists. Dr. Johnston asked what evidence he had to support this safety. Dr. Shay agreed that buprenorphine is being abused, but that it has a better safety profile, particularly in psychomotor performance.

Dr. Horam asked why Dr. Shay did not use Suboxone instead of buprenorphine. Dr. Shay indicated that he is not seeing addicts, and if he is concerned about IV use he would use Suboxone. Dr. Shay prefers to use the sublingual as a tool in addition to Butrans. Patients feel that they have more control if they have an oral pain product instead of a patch.

The Committee asked Dr. Shay to provide evidence to support the use of buprenorphine for chronic pain, particularly in relation to the safety profile. Additional information will be gathered for the March 2013 meeting.

New Business

A. PA Criteria

1. Determine need for criteria

i. New Drugs were reviewed.

a. Tudorza: Phillip Jennings (Forest) provided comment on Tudorza. It is approved for chronic bronchitis and emphysema. Warnings and precautions are similar to the class. Tudorza has a different delivery device than Spiriva that is easy for patients to use. Inspiratory flow necessary to use the device is around 30 ml/min, allowing even the most severely compromised patients to use it. It has less than 6% systemic absorption and no kidney or liver elimination.

The Committee agreed that Tudorza is similar to Spiriva, though it is twice daily. If it is cost-effective, it should be made preferred. All were in favor of this motion.

b. Myrbetriq: Bob Moreland (Astellas) provided comment on Myrbetriq. This medication has a unique mechanism of action in that it relaxes detrusor smooth muscle and improves storage capacity of the bladder.

The Committee felt that there was no evidence that this medication was less safe or efficacious as other medications in the class. All were in favor of this motion.

c. Linzess: Alix Bennett (Forest) provided comment. Linzess is approved for Inflammatory Bowel Disease with predominant constipation and chronic idiopathic constipation. It is minimally absorbed and causes an influx of fluid into the intestine as well as decreasing visceral nerve pain. The most common adverse effect was diarrhea with no evidence of electrolyte imbalance or ECG changes. There is a black box regarding use in children under six and it is contraindicated in patients aged 6 – 17. There is no evidence in opioid-induced constipation, however, Amitiza will be applying for the indication and due to similar result of both drugs (increased fluid in the intestine) it is reasonable to expect Linzess to work if Amitiza works.

The Committee recommended that Linzess and Amitiza be restricted to their indications. Linzess will only be allowed in patients aged 18 and older. Amitiza will be restricted to use in women.

d. Neupro: The Committee saw no evidence of a difference in safety or efficacy between Neupro and the other dopamine agonists. It should be allowed for those who cannot swallow. The existing criteria for non-preferred agents in the restless leg syndrome category is appropriate for Neupro as well. All were in favor of the above.

Use of medications for restless leg syndrome will be reviewed for appropriateness.

e. Aubagio: The Committee recommended that Aubagio be made non-preferred and limited to its indications. All were in favor of this recommendation.

ii. Sedative/hypnotic use in pediatrics was reviewed. There is very limited data on safety and efficacy of these medications in children under age 18. For chronic insomnia, clonidine and trazodone are typically used in children with good effect. The use of sedative/hypnotics will be further explored with the prescribers using them and additional information brought to the next meeting.

iii. Use of Truvada for prophylaxis in those at high risk of contracting HIV was discussed. Michelle Puyear (Gilead) provided public comment. She indicated that the anticipated use is low. There is a REMS program in place which has an education component, though distribution is not limited. Ms. Puyear shared concerns that limiting for this indication could delay or prevent treatment of post-exposure prophylaxis or treatment of HIV positive patients. High risk patients are defined by the CDC and in the product labeling. The Committee recommended that Truvada require prior authorization with the following criteria:

Truvada will be allowed for those with an HIV diagnosis or HIV medications on file. A negative HIV test and pregnancy test will be required for prophylaxis. The prior authorization will be in place for three months, at which time a new PA will be required showing negative HIV and pregnancy tests.

iv. Cymbalta use with SSRIs, SNRIs, triptans, MAOIs and haloperidol were discussed. Starting these drugs together at the same time is the real concern. The Committee felt that nothing needed to be done at this time. GHS will monitor new requests to determine if there is concerning use of these medications together.

2. Review existing criteria:

i. A request was received to consider the use of modafinil for ADHD for patients with a history of substance abuse. The literature was reviewed for this indication. The Committee agreed that it is reasonable to allow modafinil for patients with ADHD and a history of substance abuse. All were in favor of this addition to the existing modafinil criteria.

ii. Adderall immediate release has been approved for use in children aged 3 – 5 years old. The Committee agreed that the age limit should be adjusted for this medication only and dose limits should be applied at 150% of labeled maximum. All were in favor of this change to criteria.

iii. A new class of CIII/CIV long-acting medications was discussed, specifically for Butrans and tramadol ER. Rupa Shah (Purdue) provided comment on Butrans. It is a 7 day patch approved for treatment of moderate to severe chronic pain. It should not be used as needed or for mild, acute or short-term pain. Doses higher than 20 mcg/hour should not be used due to a risk of QT interval prolongation.

The Committee asked about use with another opioid. Ms. Shah indicated that it is indicated for patients who are taking between 30 and 80 mg morphine equivalent and short-acting analgesics are recommended for the first three days until the drug reaches its full effect. It was noted that there is a study in osteoarthritis in which Butrans was no better than placebo. Ms. Shah provided the study as requested but cannot comment on why the results were not significant as it would be speculation.

The Committee agreed that a long-acting CIII/CIV class should be developed. Tramadol IR is preferred, followed by tramadol ER and finally Butrans. A 14 day trial of each agent will be required before moving to the next step. Butrans will be allowed for patients with a high risk or history of seizures.

iv. Nucynta has recently received an indication for neuropathic pain. The Committee agreed to allow Nucynta for diabetic peripheral neuropathy and for patients with significant gastrointestinal concerns with other CII narcotics. All were in favor of this recommendation.

Medications for neuropathic pain will be reviewed at the next P&T Committee meeting.

v. Exalgo 32 mg has been approved. This is a very high dose of opioid and should be monitored closely. The Committee recommended a dose limit of 16 mg twice daily (32 mg daily). Anything above this does will require prior authorization.

C. 2013 PDL Review: Changes to the PDL for 2013 were presented. Use of Zetia as monotherapy was discussed. At this time, there is no need for criteria, however, utilization will be monitored.

1. The prior authorization criteria for triptans was reviewed. The Committee agreed that the criteria should be updated to require a trial of both preferred medications prior to use of a non-preferred.

2. The antiplatelet class was reviewed. The most recent DERP report was provided to the Committee along with a summary of all studies published after the DERP report cutoff. Breanna Buckley (Lilly) provided comment on Effient. Effient has a black box warning against use in patients greater than

75 years old. Its efficacy was proven in the Triton study. No drug interactions were noted. Effient is not approved for medically managed patients.

Effient is used in specific STEMI and acute coronary syndrome patients and is started in the cath lab. Brilinta is similarly started in the cath lab.

There is no evidence of significant differences in safety or efficacy for STEMI and ACS patients. A limit of one year should be applied to all antiplatelet drugs. All were in favor of this recommendation.

3. Xopenex will be non-preferred beginning January 1, 2013. The Committee agreed that Xopenex should be allowed for patients with significant tachycardia associated with albuterol use. All were in favor of this recommendation.

D. Other: Dr. Johnston is working on the antibiotic information. Aimee asked for additional information and he is hoping to present the data at the next meeting.

There being no further business, the open portion of the meeting adjourned at 12:15 p.m.

The Committee met in closed session, adjourning at 1:00 p.m. During the closed session, Butrans was further discussed. It was determined that it did not make sense to require a patient who is on a narcotic analgesic to try tramadol prior to use of Butrans. As a result, the existing pathway to Butrans (trial and failure of morphine ER or low-dose fentanyl) will remain in place in addition to the tramadol pathway.

Respectfully submitted,

Aimee Lewis
WYDUR Manager