

WY P&T Committee Meeting Minutes
Thursday, November 18, 2010
Cheyenne, WY
9 a.m. – 3 p.m.

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

Excused: Maria Kidner

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

Guests: Kerri Powell (GHS), Brenda Stout, Felicia Fuller (Biogen), John Robinson (Boehringer), Amber McCord (Novartis), Aimee Redhair (Merck), Toya Bowles (Merck), Caroline Hoffman (Pfizer), Paul Engel (Pfizer), Roxanne Meyer (J & J), Gary Bailey (Forest), Karen Bielenberg (Lilly), Kelly Steiner (Merck), John Brokers (Lilly), Ronald Cantrell (Lilly), Rosalynde Finch (Biogen), Brad Buffstalter, Barbara Felt (GSK), Laura Nichols (GSK), Reed Shafer, MD (Cheyenne), Deron Grothe (Teva), Madison Aaberg (Student SOP), Crystal Huntrods (Student SOP)

Dr. Hopfensperger called the meeting to order at 9:10 a.m.

Introductions were made. Aimee announced that Maria Kidner had accepted the open position on the Committee. The dates for 2011 have been set: February 17, May 19, August 18, November 17.

Approval of Minutes

The minutes of the August 19, 2010 meeting were approved as written.

Department of Health

A. Pharmacy Program Manager Report: Issues have been identified with billing of compound medications. Information will be sent to pharmacies regarding how to properly bill for compounds and pharmacies will be given until February 1 to comply. Future non-compliance may result in recovery of paid amounts.

Synagis season has opened. 259 prior authorization requests have been submitted, 129 approved, 21 denied and several deferred for more information. So far there have been no indications of RSV outbreak in the state. Dr. Bush sent a letter reminding prescribers that Synagis should not be used until RSV is circulating. Starting too early will result in reaching the maximum of five doses prior to the end of the season.

The Total Health Record continues to progress. Sites will begin to be operational in January. A task force will be set up to evaluate meaningful use of the system.

B. Psychiatrist Advisory Board Report: No meetings have occurred since the August meeting. Dr. Bush mentioned that the Prescriber Access Line (PAL) is now

open. Any prescriber may call in with pediatric psychiatry questions. An education symposium has been scheduled for December 11 in Cheyenne.

Old Business

A. Intuniv: Per Sara, 34 prior authorization requests were submitted since August. Of those, 16 were approved, 7 completed a trial of guanfacine and were later approved, 8 remain on guanfacine and 3 have not followed criteria and continue to be denied. Dr. Horam indicated that Intuniv is a good second choice. There is some benefit with daily dosing, resulting in better compliance than the recommended three times daily with the generic. The Medical Letter reviewed the medication as well. Dr. Goddik noted that if a patient fails the short-acting they probably won't succeed on the long-acting.

New Business

A. PA Criteria

- i. New Drugs were reviewed.

Silenor: The Committee noted that a TCA marketed as an insomnia agent is concerning for safety reasons. There was a motion, second, and all were in favor of the following criteria.

Silenor: 30-day trial of preferred insomnia agent and 30-day trial of liquid doxepin, followed by manual prior authorization and justification for use of Silenor.

Tobradex ST: No comparative data. The product is formulated to result in less settling in the bottle. There was a motion, second, and all were in favor of the following criteria.

Tobradex ST: 5 day trial and failure of Tobradex, followed by manual prior authorization and justification for use of Tobradex ST.

Gilenya was tabled until the review of the MS category.

Pradaxa: The Committee noted that the trial was a non-inferiority trial, not a superiority trial versus warfarin. There was also note of Pradaxa's expense which may outweigh the costs of INR testing with warfarin.

John Robinson, M.D. (Boehringer Ingelheim) provided public comment. Pradaxa is approved for reduction of stroke and embolism risk in patients with atrial fibrillation and should be dosed 150 mg twice daily with or without food. A non-inferiority trial was conducted for ethics purposes (as opposed to using a placebo-controlled trial). However, the trial was powered to allow for superiority calculations if endpoints were met. As such, Pradaxa 150 mg was superior to warfarin with respect to risk of stroke and systemic embolism.

The Committee raised a question about potential confounding with aspirin use and asked for data separating out these patients. In addition, there was a request for number needed

to treat and number needed to harm for Pradaxa vs. warfarin. There is no recommendation for bridging therapy. Though not studied, the FDA approved the lower dose in renal insufficiency. To determine the dose, modeling was used as the FDA wanted this population to be covered.

There was a motion, second and all were in favor of the following criteria.

Pradaxa: Approve for patients with atrial fibrillation and relative contraindications to warfarin.

ii. Podocon-25. This product is not to be dispensed to the patient. As such, it will require a prior authorization through the pharmacy system.

iii. Aricept. There continues to be use of Aricept in recipients under age 60 for a variety of diagnoses. A literature search was conducted which showed very weak evidence for use. There was a motion, second, and all were in favor of the following criteria.

Aricept: Approve for patients with dementia. All other diagnoses will require prior authorization.

iv. The Committee discussed criteria for new PDL classes. There was a motion, second, and all were in favor of the following criteria.

Welchol: 6 month trial and failure of each unique preferred agent.

Altabax: 7 day trial and failure of two preferred agents in the previous three months.

Topical corticosteroids: 2 week trial and failure of all generics of similar potency in the previous three months.

B. Prevacid solution. As a result of a provider request, Prevacid capsules will be allowed for infants under one year of age for suspension compounding.

C. PDL Class Review

1. Antihistamines. The Committee reviewed the DERP report on Antihistamines. There was no evidence of a significant difference in safety, efficacy or subgroups.

2. Multiple Sclerosis drugs. Reed Shafer, M.D. provided comment on his experience. He has 130 MS patients in his practice. He agrees with the previous recommendations in which Tysabri and Novantrone are 2nd tier. Gilenya shows efficacy between the interferons and Tysabri and should be used for people who have trouble with injectables or who cannot take Tysabri.

Amber McCord (Novartis) gave comment on Gilenya. It showed superiority to Avonex in a head to head trial. It has the best safety evidence in MS history. It is approved for three out of four forms of MS. It is the first and only oral immunomodulator.

Rosalynde Finch (Biogen Idec) gave comment on Avonex and Tysabri. She noted that in the Gilenya trial, patients had to be failing therapy to enter the study. There was no difference in disability reduction, which is the primary outcome in MS. There are over 6 million patient-years with Avonex and over 100,000 patient-years with Tysabri. She pointed out that the FDA does not say that more than one drug should be failed prior to Tysabri, which is different from WY's current criteria.

Amber McCord (Novartis) responded to Ms. Finch's comments regarding the Gilenya trial. Most of the patients in the trial were treatment-naïve. The trial showed Class 1 superiority which is the highest level of superiority evidence. The dose approved is the lower of the two studied as it has more safety data, having been studied for ten years in renal transplant patients.

Dr. Hopfensperger noted that Dr. Shafer's recommendation closely fits treatment in Wyoming. We do require a trial of an interferon and Copaxone before moving on to Tysabri. Gilenya should not be used first-line. He requested that Rebif, Beta-seron or Extavia, Avonex and Copaxone remain on the PDL. There was a motion, second and all were in favor of the following criteria for Gilenya.

Gilenya: Non-preferred MS agent. Trial and failure of an interferon, Copaxone and Tysabri, or an inability to use Tysabri.

3. Triptans. Reed Shafer, M.D. provided his thoughts on triptans. He would like to be able to use any of the triptans. Some patients respond to one and not others. They are all not quite the same and they require trial and error in individual patients. Treximet is particularly helpful.

Tonya Bowles (Merck) provided comment on Maxalt MLT. She requested that Maxalt MLT remain preferred. Maxalt was similar or superior to sumatriptan in four head to head trials and superior on many measures against naratriptan in one trial. Maxalt did cause more adverse effects in the trial with naratriptan. In patient preference studies, more patients preferred the orally disintegrating tablet.

Barbara Felt (GSK) gave comment on Treximet. It treats multiple mechanisms and has proven safety and efficacy over sumatriptan.

The Committee requested that an orally dissolving form remain on the PDL. There is no preference for zolmitriptan over rizatriptan. Non-preferred agents will require trial and failure of one preferred agent and the lookback period will be increased.

4. ADHD medications. Dr. Johnston commented that none have been shown to be better than short-acting methylphenidate. Dr. Horam noted that the long-acting medications are a great advancement in treatment of kids with ADHD. The Committee did not see evidence in the DERP report which supported a change to the existing criteria or PDL.

Adam Sosa (J&J) indicated that the long-acting data is robust, particularly when looking at the economic data. Long-acting methylphenidate is preferable to short-acting due to a lower abuse potential.

5. Overactive bladder agents. Caroline Hoffman (Pfizer) provided comment on Toviaz. It has been studied head to head against Ditropan and Detrol and showed superiority. Superiority did not continue in long-term extensions on all outcomes.

The Committee did not see evidence supporting a change to existing criteria and PDL.

6. Proton pump inhibitors. There is no evidence supporting a change in PDL or criteria in the PPI class.

7. Statins. Maria Kidner had provided written comments regarding the statin class. She requested that Crestor be allowed for patients at risk for drug interactions with the other statins, particularly those on amiodarone and Multaq.

John Brokars (Lilly) gave comment on Livalo. It showed superiority to pravastatin and against atorvastatin in diabetics. The risk for drug-drug interactions is much less with Livalo than other statins.

There is no evidence supporting a change in the PDL. The criteria will be altered to allow a non-preferred agent when a patient is at risk for drug-drug interaction with a preferred statin.

8. Erythropoiesis agents. Roxanne Meyer (Ortho Biotech) provided comment on Procrit. It is a well-established product with four labeled indications including labeled pediatric dosing. There is a REMS program in place. Dr. Johnston asked if there was concern over misuse and if we should limit to its approved uses. Epogen and Procrit are the same product. Both are made in the same plant with the label being the only difference. Procrit will be the preferred product with a manual prior authorization required for Epogen.

D. Gabapentin for sleep and headache. The Committee reviewed evidence for the use of gabapentin for sleep and for headache. The evidence for both uses is very poor and the Committee agreed that prior authorizations should be denied for these uses.

E. Cymbalta for chronic pain. John Brokars (Lilly) provided comment. There was one study in which the endpoints were not met in back pain, however, there are four positive studies in back pain and osteoarthritis of the knee. Dr. Johnston questioned several studies that had not been included. John will follow up on the studies as he is not aware of any that were not published. Pain and depression are closely intertwined and norepinephrine affect is tied to pain relief. The Committee expressed concern that a patient would be started on Cymbalta for pain and then another agent for depression or mood disorder which would result in duplicate therapy and potential adverse reactions. The Committee agreed to allow Cymbalta for pain related to osteoarthritis of the knee as this is where the strongest evidence lies.

Other: Aimee provided a brief overview of the changes made to the 2011 PDL.

Open Comments:

Dr. Johnston expressed his concern regarding chronic pain management. He believes something needs to be done regarding the amounts of narcotics that are inappropriately dispensed. We will ask the Rx Abuse Task Force to come to a meeting and discuss the issue.

The Committee met in closed session to review patient profiles.

There being no further business, the meeting adjourned at 2:45 p.m.

Respectfully submitted,

Aimee Lewis
WYDUR Manager