



STATE MEDICAID P&T COMMITTEE MEETING
 THURSDAY, January 15, 2009
 7:00 a.m. to 8:30 a.m.
 Cannon Health Building
 Room 114



MINUTES

Committee Members Present:

Kort DeLost, R.Ph.
David Harris, M.D.
Koby Taylor, PharmD.
Jerome Wohleb, PharmD.

Karen Gunning, PharmD.
Duane Parke, R.Ph.
Howard Weeks, M.D.
Raymond Ward, M.D.

Board Members Excused:

Matthew Rondina, M.D.

Dept. of Health/Div. of Health Care Financing Staff Present:

Jennifer K. Zeleny, CPhT., MPH

Tim Morley, R.Ph.

University of Utah Drug Information Center Staff Present:

Chris Beckwith, PharmD.

Other Individuals Present:

Felicia Fuller, Biogen Idec
 Jared Jensen, U of U Student
 Russell Maroc, U of U
 Marilyn Semenchuk, GSK
 Mike Buhler, R.Ph., Merck

Dan Heincy, R.Ph., Merck
 Ann Gustafson, GSK
 Efrain Alton, Merck
 Brett Brewer, EMD Serono

Jerry Johnson, Merck
 Myra Richley, GSK
 Susan Bagley, APRN, U of U
 Barbara Roper, U of U Student

Meeting conducted by: Raymond Ward, M.D., Co-Chairperson.

1. Minutes for November 2008 were reviewed and approved. Dr. Weeks moved to accept the minutes. Duane seconded the motion. The motion passed with unanimous votes by Kort DeLost, Karen Gunning, Duane Parke, Koby Taylor, Dr. Ward, Dr. Weeks, and Jerome Wohleb.
2. DUR Board Update: Tim Morley addressed the Committee. The DUR Board is continuing to review PAs that have been imposed in the past to make sure that they are compliant with the required review process. The Board is also considering some of the issues that have been raised in P&T Committee meetings. During the last P&T meeting, questions were raised about the appropriate use of fibrates and statins, and the DUR Board will address that in the

February 2009 meeting.

3. P&T Committee Housekeeping: Duane Parke addressed the manufacturers in the audience. Medicaid is in the process of rolling over 30+ contracts for the 2009 calendar year. Manufacturers are asked to be patient while the contracts are reviewed and processed within Medicaid, since a number of issues have caused delays.

Dr. Ward addressed the Committee. The Committee is asked to consider some changes to the bylaws regarding lengths of terms, how many terms can be served by members, and the length of term of P&T Committee chairs. A draft of proposed bylaws with articles 12 and 13 added to clarify these points was given to the P&T Committee members.

Dr. Ward stated that the definition of a “term” in article 12 was vague and thought that the article should read, “Committee members shall serve a term of up to three years. Members may volunteer for one additional term.”

Karen Gunning moved to accept the revised bylaws as amended. Dr. Weeks seconded the motion. The motion passed with unanimous votes by Kort DeLost, Karen Gunning, Dr. Harris, Duane Parke, Koby Taylor, Dr. Ward, Dr. Weeks, and Jerome Wohleb.

4. Migraine Agents (Triptans & Triptan Combinations): Dr. Christina Beckwith addressed the Committee, summarizing the OHSU triptan class review from 2005 and clinical information for Treximet that was prepared by the University of Utah Drug Information Service.

The Committee asked if there was a generic Sumatriptan available yet. There is currently a generic that has a 6-month exclusivity on the market.

Duane asked about the onset of action of the orally disintegrating dosage form versus the oral dosage form. The onset of action of an orally disintegrating dosage form may be 3-4 minute faster due to quicker absorption, but there is no significant difference in pain relief at two hours.

Susan Bagley from the U of U Headache Clinic addressed the Committee. She disclosed that she had a consulting agreement with GlaxoSmithKline, but was not attending the meeting on behalf of that company. She clarified that orally disintegrating tablets are not absorbed buccally. They dissolve in the mouth, but still need to be swallowed and get to the duodenum to be absorbed before they will start to work. Efficacy for patient experience may be sooner, however, since patients may perceive that they are getting the drug faster. She also stated that the Oregon review used an 80mg dose of eletriptan, but that strength is not currently available in the United States. When she was involved with triptan FDA trials, they have had to show a 2 point discrimination in the reduction of pain in order to show efficacy. This means that they have to wait until a person has a moderate or severe headache before they can be given the dose. In these trials, when a patient has waited to take medication until they have a severe headache, it may not show the same level of efficacy as if the patient had treated earlier on. When people treat migraines sooner, they also have different safety outcomes, since they do not have the central sensitization that is present in the

pathophysiology of a more severe migraine. When these side-effects are reported, they may be due to the migraine rather than the drug. Clinically, she has had good experience with Treximet, since people get more lasting relief with the combination product, leading to less triptan use. Also, safety concerns about inappropriately combining Treximet with NSAIDs do not appear to be valid in her clinical experience. Migraines should be treated with triptans, since they are a more disease specific treatment. People get into trouble when taking some of the other headache products, such as Fiorinal/Fioricet compounds, and need to be weaned off. Frovatriptan and Naratriptan have longer half lives, and will not show the 2 hour relief like the other triptans. Also, injectibles can be followed with oral dosage forms for more lasting pain relief.

Karen Gunning asked if there is one particular drug that would typically be used first-line. Susan Bagley stated that rizatriptan and sumatriptan are used more readily, because prescribers have more experience using them. In menstrual migraines, a longer-acting triptan may be considered.

Duane Parke stated that the DUR Board has set a limit of 9 tablets per 30 days of triptans. Susan Bagley felt that this was appropriate for most people. The general thought is that a migraine can be treated 2-3 times per week with no rebound. Rebound is a greater problem for people who take small doses of Fioricet each day.

The Committee asked how to define whether a patient requires acute rescue versus prophylactic treatment. According to the American Headache Society, more than 2 headaches per month is deemed enough to start a patient on prophylactic treatment. In clinical practice, however, the need for prophylaxis is more defined by the level of disability caused by the headaches. Also, patients need to be made completely headache-free to avoid a kindling effect with headache gathering more headache. That way, they can treat when they know that they are getting a headache, rather than taking something because they feel funny or waiting until they have a very severe headache.

The Committee asked what types of drugs are used for prophylaxis. She usually starts with tricyclics or trazodone. Topamax, beta blockers, and calcium channel blockers also work well.

Karen Gunning recommended that the DUR Board look at the number of patients receiving 9 triptans a month to check on whether or not they are on prophylaxis.

Jerry Johnson, Neuroscience Health Science Advisor from Merck, addressed the Committee in favor of Maxalt and Maxalt MLT on the PDL. He cited clinical trials in support of keeping this family of drugs on the PDL.

Marilyn Semenchuk, Regional Medical Scientist with GlaxoSmithKline addressed the Committee in favor of Treximet. She provided historical background into GlaxoSmithKline's research into migraines and the development of Treximet, as well as citations of clinical trials in support of the product.

Dr. Ward asked if taking Treximet would be superior to taking Sumatriptan 100mg plus Naproxen 500mg. That has not been studied, and GlaxoSmithKline does not plan to study it.

Duane remarked that he felt that the Oregon review for this class was extremely critical of how many of the studies were conducted. Dr. Ward agreed that it was evident that drug companies do not use equivalent dosages in their studies when their goal is to demonstrate superiority. Another way to look at it is that the drugs will accomplish the same thing at equipotent doses, which is what they were designed to do.

Karen asked Susan if it is correct to consider all of the triptans together. Due to kinetics, frovatriptan and naratriptan should be considered long-acting. Treximet could be considered along with the longer acting ones, due to the duration of relief that it provides.

Karen did not feel that Treximet was greater than the sum of its components. For the purposes of the P&T Committee, it really cannot be considered along with the rest of the triptans. It may be more appropriate to take it to the DUR Board.

Dr. Beckwith added that because sumatriptan injection has a unique indication for cluster headaches, it should be considered as its own special category.

Jerome Wohleb moved to recommend that Medicaid have an injectable, a short acting, and a long acting triptan on the PDL. Dr. Harris seconded the motion. The motion passed with unanimous votes by Kort DeLost, Karen Gunning, Dr. Harris, Duane Parke, Koby Taylor, Dr. Ward, Dr. Weeks, and Jerome Wohleb.

Duane Parke moved that all of the triptans are equally safe and efficacious. Dr. Weeks seconded the motion. The motion passed with unanimous votes by Kort DeLost, Karen Gunning, Dr. Harris, Duane Parke, Koby Taylor, Dr. Ward, Dr. Weeks, and Jerome Wohleb.

The Committee recommended that the DUR Board consider not paying Fiorinal/Fioricet. Susan Bagley agreed that butalbital containing compounds should not be paid at all for headaches.

Next Meeting Set for Thursday, February 19, 2009
Meeting Adjourned.

Minutes prepared by Jennifer Zeleny