



STATE MEDICAID P&T COMMITTEE MEETING
 FRIDAY, December 18, 2008
 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.
 Raymond Ward, M.D.

Karen Gunning, PharmD.
 Duane Parke, R.Ph.

Board Members Excused:

Matthew Rondina, M.D.
 Howard Weeks, M.D.

Koby Taylor, PharmD.
 Jerome Wohleb, PharmD.

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

Jennifer Zeleny, CPhT
 Tim Morley, R.Ph.

Lisa Hulbert, R.Ph.

University of Utah Drug Information Center Staff Present:

Chris Beckwith, PharmD.

Other Individuals Present:

Pam Sardo, Abbott
 Deirdre Monroe, Allergan
 Matt Jackson, Astellas
 Steven Warren, M.D.
 Jay T. Bishof, IHC
 Sam Wilson, Abbott

Tony Molchan, Abbott
 Bryan Gwyn, Novartis
 Dave Case, Astellas
 Aaron Medford
 Alan Bailey, Pfizer
 William Clark, Pfizer

Camille Kerr, Allergan
 Toni Shull, Astellas
 Steven Landau, M.D.
 Ann Gustafson, GSK
 Lisa Stout, Allergan
 Simone Laas

Meeting conducted by: Karen Gunning, PharmD., Chairperson.

1. Minutes for November 2008 were reviewed and approved. Duane Parke stated that there were some clerical corrections that he wanted to make to the minutes, which would not substantially change the meaning of the content. Dr. Harris voted to approve the minutes. Dr. Ward seconded the motion. The motion passed with unanimous votes by Kort DeLost, Duane Parke, Karen Gunning, Raymond Ward, and David Harris.
2. DUR Board Update: Tim Morley addressed the Committee. The DUR Board did not meet this month, so there was no update.

3. Urinary Antispasmodics: Dr. Christina Beckwith addressed the Committee. She presented the Drug Class Review on Agents for Overactive Bladder from the Oregon Health Sciences University Evidence-Based Practice Center completed in December 2005. The agents included in the review were all dosage forms of darifenacin, flavoxate, hyoscyamine, oxybutynin, scopolamine, solifenacin, tolterodine, and tropsium. She noted that hyoscamine is not approved for overactive bladder in the United States, and that the scopolamine product that is approved for overactive bladder is not available in the United States. She also presented a review of the recently approved product fesoterodine, which was prepared by the University of Utah Drug Information Service.

Dr. Ward asked if the Oregon review focused on events other than dry mouth for the adverse drug reactions. Dr. Beckwith stated that they focused on overall rate of any adverse event, and then they focused specifically on dry mouth because these are anticholinergic agents. It is a very common side effect, can be quite severe, and can lead to discontinuation.

Lisa Stout, M.D., community urologist spoke on behalf of Allergan and Sanctura. Overactive bladder is a life-changing disease that can cause people to become shut-ins. She discussed several unique characteristics of Sanctura that make it an important addition to a formulary.

Karen Gunning asked Dr. Stout what her experience is with Medicare Part D formularies with agents for overactive bladder. Dr. Stout stated that the agents are usually a mixture of tier-2 and tier-3. If a drug is not on a Medicare formulary, she will try to work with them to find a drug that will work and will be covered. She feels that it is best to be able to make the decision based on clinical considerations.

Kevin Gwyn, PharmD. of Novartis addressed the Committee on behalf of Novartis and Enablex. He provided the Committee with handouts summarizing pivotal trials, information on prescribing for the elderly, evidence for long-term efficacy, and safety data that he discussed.

Toni Shull, R.N. of AstellasPharma addressed the Committee on behalf of Vesicare. She discussed the disease state of overactive bladder, efficacy, and safety information of Vesicare.

Stuart Landau, M.D., area urologist addressed the Committee on behalf of Pfizer and tolterodine. He stated that he would like to see more than one product on the preferred drug list. He generally starts treatment with tolterodine because it seems to cause less dry mouth, he has good success with it, and has been able to treat children with it.

Karen Gunning reminded the audience that Utah Medicaid does not have a closed formulary with the preferred drug list, and that the preferred drug list can be easily overridden. If a prescriber has a medical reason for prescribing a non-preferred product for a patient, the prescriber can write "Medically Necessary – Dispense as Written" on the prescription and document medical necessity in the chart in order to get a paid pharmacy claim.

Mark Balk, PharmD., Medical Liaison with Pfizer addressed the Committee about

tolteridine. Its efficacy and safety have been extensively studied. It has also been studied for compliance, persistence, and quality of life. It has been studied in men with OAB and can be safely taken with the alpha blocker tamsulosin. It has the highest usage of the branded OAB agents in Utah. Both the immediate release and extended release formulations of tamsulosin will be going generic around 2019.

Steven Warren, M.D. addressed the Committee. He is a local provider who works extensively with nursing homes and assisted living. One of the biggest costs in nursing homes is briefs, and prescribing OAB agents decreases the costs of the briefs. A big cause of hip fractures both at home and in nursing homes is falls when a patient is hurrying to the bathroom. He had experienced problems with patients discontinuing due to dry mouth or constipation with oxybutynin products, but he does not find this to be the case with Detrol LA. He also uses the Oxytrol patch for patients who cannot swallow due to dementia or stroke, and does not seem to have as severe side effects with it. Approximately 20-30% of his patients in nursing homes are under 65 years of age.

Kort DeLost asked if he has seen problems with mental status or confusion with any of the other OAB drugs. Dr. Warren stated that he has seen this problem, as well as constipation and severe dry mouth with generic oxybutynin. Even though it is a very cheap drug, patients do not seem to tolerate it well and frequently discontinue it. Having a patient take a more expensive OAB drug that they are willing to stick with saves money in the long run.

Dr. Beckwith stated that CNS side-effects were evaluated by the Oregon review as well. The only information that was available to include was analysis of a trial of tolteridine extended release versus oxybutynin immediate release. There were no statistically significant differences found in this review.

Karen Gunning stated that since Medicaid is paying for an under-65 population, problems that may occur in very elderly patients with pre-existing dementia with these drugs are not as significant of a consideration with these drugs in a Medicaid population.

Karen Gunning asked what stand the DUR Board has taken with these drugs. The DUR Board had allowed generic oxybutynin to be covered without a PA and required a PA on all of the new agents that had come out. However, the DUR Board retired all of these PAs so that the P&T Committee could consider the entire group for PDL status. When the PAs were removed, there was a big shift in prescription volume towards newer agents in the class. Tim was not certain what percentage of PA requests were approved or denied for the newer OAB agents when a PA was required. Utilization of the class as a whole also decreased with the advent of Medicare Part D.

Karen Gunning stated that when she was on the DUR Board when the PA criteria were crafted for OAB drugs. They did extensive research into the adverse effects at that time. It is hard to say which drug is better, because they can all cause dry mouth. It is also hard to determine which drug is most efficacious, because they all reduce symptoms but they don't seem to reduce symptoms by very much.

Karen Gunning stated that she received several emails all advocating for a variety of different

products. In terms of the letters, there is not much further information than what was stated by the speakers today. There were three letters in favor of Sanctura and two for Detrol.

Dr. Ward made a motion that all of the urinary antispasmodics are equally effective; the long acting agents, as a group, have a lower rate of adverse events; therefore, the PDL should include at least one long acting agent, meaning any agent that is dosed once per day; otherwise Medicaid can decide based on cost. Duane seconded the motion. The Oxytrol patch would be considered a long-acting agent.

Kort DeLost asked if the PDL should include more than one long-acting agent, so that at least one would be an oral dosage form. Karen Gunning felt that the PA was working well and should not have been removed given the current economy. Duane stated that the motion should also include the finding that all of the agents are equally safe.

Dr. Ward stated that he would modify his original motion to state that at least one of the long acting dosage forms on the PDL should be an oral dosage form, and that all of the agents were equally safe. Kort DeLost seconded the revised motion. The motion passed with unanimous votes by Kort DeLost, Duane Parke, Karen Gunning, Raymond Ward, and David Harris.

4. **Fibric Acid Derivatives:** Dr. Beckwith addressed the Committee. The class review of the Fibric Acid Derivatives was prepared by the University of Utah Drug Information Service, and included agents containing fenofibrate and gemfibrozil. This review was presented to the Committee. A table of available products and therapeutic equivalents, where available, was also provided to the Committee.

Pam Sardo, PharmD., Government Regional Clinical Executive with Abbott Laboratories addressed the Committee about Tricor. She stated that the mechanism of action of the fibric acid derivatives is unknown, but there are some hypotheses as to why gemfibrozil may have a higher rate of adverse events. Trilipix was approved 48 hours ago. It is the first and only fibrate approved for use with a statin. She asked for the opportunity to provide additional information on Trilipix to the Committee, and asked the Committee to consider tabling a decision until Trilipix could be included in the review.

Sam Wilson, M.D. addressed the Committee. He is a family practice physician in Bountiful and is in the process of becoming a certified lipidologist. Taking lipid medications is difficult for patients, since they cannot feel the symptoms and the medications require frequent blood tests. Absorption of the fenofibrates is problematic, since they are required to be taken with a high fat meal. Tricor does not require this. Trilipix is even better, because it can be taken without regards to meals, and has an improved safety profile. Many patients require multiple agents to control lipids, and the preferred product should be well absorbed, safe, and well tolerated. Prescribers who deal with lipids do not like gemfibrozil due to the higher frequency of adverse events, and high amount of drug interactions.

Karen Gunning asked if there were any case reports of rhabdomyolysis with the combination of fenofibrate products and statins. Dr. Beckwith stated that fenofibrate products do interact

with pravastatin, but not with fluvastatin, simvastatin, or lovastatin. Gemfibrozil has been shown to interact with everything except for fluvastatin. Part of this may be due to the fact that fenofibrate has not been on the market as long, and sometimes it takes a while for these things to be reported. Rhabdomyolysis is a very rare event, so a high number of patients may need to be treated before the adverse event or drug interaction is discovered.

Karen clarified if the micronized or non-micronized products need to be taken with food. Dr. Beckwith stated that the non-micronized products can be taken without regard to meals, and the micronized products need to be taken with meals. Dr. Wilson disagreed.

Dr. Ward asked if there were any outcomes data on micronized versus non-micronized fenofibrate products. Dr. Beckwith stated that they were not able to locate any direct comparisons between these products.

Karen Gunning stated that the number of fenofibrate formulations on the market is confusing. She felt that it would be an interesting study to determine the continuity of the products given to patients. There is a potential to decrease confusion by selecting only one product.

A member of the audience offered to present an outcomes study on different fenofibrate products. Karen stated that she had a hard time looking at outcomes studies on drugs that she considered to be the same product (fenofibrate vs. fenofibrate).

Dr. Beckwith wanted to respond to Dr. Sardo's request that a decision on the fibric acid derivatives be delayed until information was available on Trilipix. She stated that she had been unable to find any studies in Medline within the last couple of days. Dr. Sardo offered to provide her with recently published journal articles.

Dr. Ward made a motion that the P&T Committee found that both of the agents in this class have generics available, and the Committee has not found that any of the branded agents have superior outcomes to the generic forms. Therefore, a decision should be made based on cost. If the product companies feel that they have additional information that would be helpful to the Committee, the class could be put back on the schedule for a later date.

Karen Gunning asked if it was possible to put a hard edit on co-prescription of a statin plus gemfibrozil, and asked that Tim have the DUR Board consider recommending that edit be placed. Karen also felt that there was some opportunity to decrease confusion by streamlining prescriptions to one preferred product.

Duane Parke seconded Dr. Ward's motion. The motion passed with unanimous votes by Kort DeLost, Duane Parke, Karen Gunning, Raymond Ward, and David Harris.

Next Meeting Set for Thursday, January 15, 2009
Meeting Adjourned.

Minutes prepared by Jennifer Zeleny