



STATE MEDICAID P&T COMMITTEE MEETING
THURSDAY, June 18, 2009
7:00 a.m. to 8:30 a.m.
Cannon Health Building
Room 125



MINUTES

Committee Members Present:

Kort DeLost, R.Ph.

Duane Parke, R.Ph.

Jerome Wohleb, PharmD.

Michael Flynn, M.D.

Raymond Ward, M.D.

Board Members Excused:

Karen Gunning, PharmD.

Koby Taylor, PharmD.

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

Jennifer K. Zeleny, CPhT., MPH

Lisa Hulbert, R.Ph.

Tim Morley, R.Ph.,

University of Utah Drug Information Center Staff Present:

John Vu, PharmD.

Other Individuals Present:

John Robinson, Boehringer-Ingelheim

Mary Shefchyk, NNI

Marilyn Semenchuk, GSK

Brett Brewer, EMD Serono

Brady Chournus, Jazz

Roy Lindfield, Schering

Ann Gustafson, GSK

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

1. Minutes for May 2009 were reviewed, corrected, and approved. Jerome Wohleb moved to accept the minutes. Duane seconded the motion. The motion passed with unanimous votes by Dr. Flynn, Kort deLost, Duane Parke, Dr. Ward, and Jerome Wohleb.
2. PDL Update: Duane Parke addressed the Committee. Year-to-date PDL savings were provided to the Committee members.
3. DUR Board Update: Lisa Hulbert addressed the Committee. In June, the DUR Board considered Suboxone, and moved to restrict the use of Suboxone to its approved indication and limiting it to prescribers with the X-DEA number. Hepatitis C agents were also considered, and new limits were placed on Ribavirin and Interferons. In July, the DUR Board will consider topical acne medications, Fibromyalgia, and concomitant use of Statins and Fenofibrates. The DUR Board has also seated some new members.

4. Anti-Parkinson Agents, newer products: Duane Parke addressed the Committee and read copies of letters from providers that had been sent to Medicaid. Copies of most of these letters were provided to Committee members.

Dr. John Vu of the University of Utah DRRC addressed the Committee and summarized the evidence prepared by the University regarding Dopamine Receptor Agonists.

Dr. Daniel Vine, area neurologist, addressed the Committee. He has had the opportunity to treat many Parkinson's agents. Right now, with regard to the Dopamine Receptor Agonists, the only long-acting preparation that is available since the patch was recalled is Requip XL. One of the problems with treating Parkinson's patients is the motor fluctuations, or the so-called "on and off phenomenon". Some of the problems related to lower serum concentration of the drug can be ameliorated using the long-acting formulation. He requested that both Mirapex and Requip should continue to be available, since some patients do better on one than the other. He also requested special consideration for the Requip XL, since it is the only long-acting Parkinson's compound currently available in the United States.

Marilyn Semenchuk, PharmD. with GlaxoSmithKline addressed the Committee regarding the benefits of Requip XL.

Dr. Vine added the "off time" with medication is a scary time for Parkinson's patients, because they know that it is coming between doses. There is an increased morbidity with a risk for falls during that time.

Dr. Ward explained to Dr. Vine that all agents are still available for patients with a Prior Authorization. Dr. Vine stated that this is acceptable, but it adds to the administrative burden for his office. Anything that can be done to streamline that is appreciated by doctor's offices. Dr. Vine asked why it was necessary to even consider this class.

Dr. Ward explained that depending on the contracts that Medicaid can get, some medications in a particular class can be obtained far cheaper. If physicians are at least trying to use the cheaper ones, it leaves more money to cover more medicines or more patients. Dr. Vine said that this makes sense, but based on the demographics he sees in his office, only a very small number of young Parkinson's patients have Medicaid so he was questioning the utility of reviewing this class.

Dr. Flynn asked Dr. Vine if he could talk about his experience with long-acting Sinemet. Dr. Vine stated that long-acting Sinemet is a good product, and the long acting is nice because the patient does not have to take it as often. The problem with Sinemet is that it has a different method of pharmacological activity, and patients lose sensitivity to it over time. Also, Sinemet can induce dyskinesias over time. It is thought that the dopaminergic agonists allow fewer of those.

Dr. Flynn asked Dr. Vine why he would choose a long-acting dopaminergic agonist over long-acting Sinemet. He stated that there seems to be a time frame on the use of Sinemet. The sooner it is started, the sooner the patient loses sensitivity and develops dyskinesia. The dopaminergic agonists seem to prolong the usefulness of Sinemet when it is needed. There is also some evidence, which is soft and not everyone agrees on it, that the dopaminergic agonists may be very slightly disease modifying. However, this is questionable. Most people now are initiating therapy on Parkinson's patients with dopaminergic agonists for reasons that he has tried to explain.

Dr. Flynn stated that it seems reasonable to have it as a second-line option if a patient does not tolerate what is prescribed as a first-line agent or what is prescribed by their internist. This is especially so, if another long-acting agent, such as Sinemet CR, is available, even if it is not equivalent.

Dr. Ward asked Dr. Vine if this was an acceptable option with a PA. He explained where the form is available and how to obtain a Non-Preferred Authorization on Medicaid.

Dr. Vine asked if the authorization was a shoe-in? Dr. Ward said that his patients have always been approved. Dr. Vine asked why it was even necessary then. Lisa Hulbert stated that the NPA was not just a paper tiger and that it is reviewed by nurses. However, the NPA was not meant to be onerous or burdensome.

Dr. Ward asked John if there were better patient outcomes on longer acting forms. John stated that there was no evidence to support this. He also stated that the American Academy of Neurology practice parameters do not recommend using Sinemet CR over the standard formulation as far as reducing "off time".

Dr. John Robinson addressed the Committee on behalf of Boehringer Ingelheim and the benefits of Mirapex.

The Committee asked Dr. Vine how many of his patients are adequately controlled on long-acting versus short-acting dopaminergic agonists. He stated that it is about a 50/50 split. It is nice to be able to take one dose per day. The rest of the agents are usually TID or more frequently.

Dr. Ward asked if Dr. Vine sees many Medicaid patients. He has worked with Medicaid since he began practicing Medicine.

Kort deLost asked Dr. Vine if he could quantify the increase in hip fractures or falls in his practice due to the off-phenomenon. He stated that he does see an increase, but cannot quantify it.

Dr. Ward pointed out that Medicaid only had 5 patients on the Requip XL last year, so it appears that many patients are being well controlled without the need for a long-acting agent.

Dr. Ward stated that he did not believe based on the evidence presented, that there is a difference in safety or efficacy of the agents.

Dr. Flynn moved that the oral agents in this class are equally safe and efficacious. Duane Parke seconded the motion. The motion passed with votes by Dr. Flynn, Kort deLost, Duane Parke, and Dr. Ward. Jerome Wohleb opposed the motion.

Dr. John Vu presented evidence on the COMT inhibitor class that was prepared by the University of Utah DRRC.

There was no public comment on this class of agents.

Dr. Ward stated that there do not appear to be significant differences in efficacy between the two agents under consideration. Also, only 3 clients have received agents in this class last year.

Jerome Wohleb stated that he would like to at least entertain the possibility of restricting the use of these agents to neurologists by PA. Utilization is very limited, and some of these agents have side-effect profiles that are concerning.

Dr. Ward asked if it is even in the Committee's purview to require a clinical PA on this class. He suggested a motion that states that there is no difference in the agents, and that the Committee suggests that it is not necessary agent in this class.

The Committee felt that this was not an appropriate motion, since one of those agents clearly has a safety issue due to the black box warning.

The Committee asked Dr. Vine how he usually prescribes these agents. He generally uses the combination product Stalevo as the disease progresses. He does not have any patients on tolcapone.

Dr. Flynn made motion that if Medicaid choose a preferred agent, that it not be tolcapone due to safety concerns. Jerome seconded the motion. The motion passed with unanimous votes from Dr. Flynn, Kort deLost, Duane Parke, Dr. Ward, and Jerome Wohleb.

The Committee considered whether or not a second motion was needed to restrict the use of COMT inhibitors to neurologists to dissuade primary care physicians from using this class. This should be a moot point, due to the low utilization in the class.

Jennifer Zeleny stated that occasionally, based on Committee recommendations, the DUR Board considers classes for stricter management through a clinical PA. The Committee can consider whether this is a recommendation that should be made for this class. Jerome said that this is what he was interested in doing.

Dr. Flynn and Dr. Ward did not feel that primary care physicians would be likely to write prescriptions for this class, since it requires some expertise in the disease state.

Kort deLost stated that he has never dispensed Comtan, and has 2 patients in his whole practice on Stalevo. He did not feel that there was a big concern with its utilization.

Dr. Ward asked Jerome if he wanted to make a motion, but he was fine with the Committee's decision.

John Vu addressed the Committee on the MAOI inhibitors and presented evidence prepared by the University of Utah DRRC.

There was no public comment on these agents.

The class has very low utilization. Dr. Ward asked if the Committee wanted to consider recommending to Medicaid to not bring a class for consideration if there are less than 30 patients on medications in the class.

Jerome Wohleb agreed and made a motion that if a class has a small population, to be defined by the Division, Medicaid should evaluate the cost-effectiveness of bringing a class to the Committee.

Duane said that he has bids for all 3 classes.

Kort thought that it would be opening a can of worms to make such a recommendation.

Duane stated that if this recommendation was made independent of any drug class, he would be happy to take it to the Division.

Jennifer Zeleny stated that she did not feel that the motion should be tied to a specific quantity of patients since some drug classes are comprised of very costly agents. Dr. Ward agreed and said that the Committee would recommend that the Division recommend whether there is any cost savings to be had, based on a small amount of usage, before sending the class to the Committee to review.

Jerome made the motion as stated by Dr. Ward. Duane Parke seconded the motion. Duane Parke, Dr. Ward, and Jerome Wohleb voted in favor of the motion. Kort deLost and Dr. Flynn opposed.

5. Kort deLost moved that the agents in this class are equally safe and efficacious. Dr. Flynn seconded the motion. The motion passed with unanimous votes by Dr. Flynn, Kort deLost, Duane Parke, Dr. Ward, and Jerome Wohleb.

Next Meeting Set for Thursday, July 16, 2009
Meeting Adjourned.

Minutes prepared by Jennifer Zeleny