STATE MEDICAID P&T COMMITTEE MEETING

THURSDAY, September 17, 2009
7:00 a.m. to 8:30 a.m.
Cannon Health Building
Room 125

MINUTES

Committee Members Present:

Ellie Brownstein, M.D.
Michael Flynn, M.D.
Koby Taylor, PharmD.
Jerome Wohleb, PharmD.
Kort DeLost, R.Ph.
Duane Parke, R.Ph.
Raymond Ward, M.D.

Board Members Excused:

Karen Gunning, PharmD.

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

Jennifer Zeleny, CPhT., MPH
Tim Morley, R.Ph.
Lisa Hulbert, R.Ph.

University of Utah Drug Information Center Staff Present:

Chris Beckwith, PharmD.
Elyse MacDonald
Mike Brown
Michael, Katsounkis
Diane Laaza

Other Individuals Present:

David Walters, J&J
Tony Molchan, Abbott
Marc Jensen, UCB
Lori Howarth, Bayer
Kristina Callis-Duffin, U of U Dematology
Deborah Griffis, Abbott
Bobby White, UCB
Ann Gustafson, GSK
Gordon Harmston, Mtn West GI
Rich Gremillion, M.D.

Meeting conducted by: Koby Taylor, PharmD., Co-Chairperson.

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1. Minutes for July 2009 were reviewed, corrected, and approved. Dr. Ward moved to approve the minutes. Dr. Wohleb seconded the motion. The motion was unanimously approved by Dr. Wohleb, Dr. Flynn, Dr. Ward, Dr. Taylor, Kort DeLost, and Dr. Brownstein.

2. DUR Board Update. Lisa Hulbert addressed the Committee. Proceedings from the September 10, 2009 DUR Board meeting were summarized.

3. Housekeeping: Duane Parke addressed the Committee. The PDL for the osteoporosis class was revised to include alendronate as the only preferred agent. Medicaid Pharmacy staff made recommendations for the third generation cephalosporin class, and are awaiting management approval. On

the agenda, the December topic that includes "dipyridamole, aspirin" as agents in the drug class should read "dipyridamole/aspirin", as the agent under discussion will be a combination agent.

4. Targeted Immunomodulators: Duane Parke addressed the Committee. He read a letter from Dr. Radlin from Granger Medical Clinic in favor of having Cimzia on unrestricted access through Utah Medicaid.

Dr. Christina Beckwith of the University of Utah Drug Information Service addressed the Committee. The primary document used in the presentation was from the Oregon Health Sciences University, and updates for new agents and indications from the University of Utah Drug Information Service were presented.

Dr. Gordon Harmston addressed the Committee. He is a local gastroenterologist who practices in a group of 14 gastroenterologists. He is in favor of having Humira on the PDL due to its ease of use and efficacy for patients with Crohn's Disease. There is no mixing for patients, since the drug comes in a pen. The fact that the patients can self-administer is also very helpful. His practice treats many Medicaid patients and Crohn's patients.

Dr. Rich Gremillion, area rheumatologist, addressed the Committee. About 80% of use of these agents is in rheumatoid arthritis, where they are used extensively. He spoke in favor of the Anti-TNF class and its superiority over existing agents. He also spoke in favor of having at least 2 Anti-TNF agents on the PDL so that patients have several choices if their first Anti-TNF fails or stops working.

Duane Parke advised Dr. Gremillion that all agents in the class will still be available and under clinical PA. However, the preferred drugs will have to have been tried before a non-preferred.

Dr. Wohleb asked Dr. Gremillion about side-effects of the agents in this class. He stated that the biggest side effect was localized injection site reactions in about 1/3 of the people, but that none of them result in scarring and go away after 24-48 hours. There is a risk of about 3/20 of developing infections. Life-threatening infections can be avoided with proper screening. The other side effects are extremely rare, and the MS reactions tend to go away when the agents are stopped.

The Committee asked if there is any off-label use in pediatrics of the agents that do not have pediatric indications. He is not a pediatric rheumatologist, so he does not have experience in this area.

The Committee asked if he preferred any agents. Dr. Gremillion prefers Enbrel due to the short half-life and the fact that it can be out of the patient's system quickly if stopped due to infection. All of the agents have systems that are easy to use with crippled hands.

Tim Morley asked if he has experience with dose creep. He stated that he has

not had much trouble. Most drugs, once they started to work effectively continue to work in an effective manner. If patients complain that it stopped working, it is usually due to disease progression, not because the medication has stopped. Some of the medications stimulate antibody production, but concomitant administration with Methotrexate can prevent that.

Dr. Kristina Callis-Duffin, area dermatologist, addressed the Committee. Her practice is about 30-50% psoriasis patients, of which ¼ have psoriatic arthritis. She agreed with Dr. Gremillion that these agents are superior over older agents used to treat psoriasis and psoriatic arthritis. She uses primarily Humira and Enbrel for her practice, and she considers them quite comparable in safety. There is no rhyme or reason why some people will respond to one better than the other, and she felt that they both should be preferred. She did not want to have to switch patients off their current therapies.

The Committee asked if there is any guideline as to what to use first. There is not. She stated that the Obama administration has made study of comparative effectiveness a priority. The University has applied for a challenge grant for funding such studies. Eventually, there may be good comparative effectiveness research.

Deb Griffiths, PharmD., from Abbott Laboratories addressed the Committee. She spoke in favor of the outcomes with Humira across many indications.

Mark Jensen, PharmD. from UCB Pharma addressed the Committee in favor of Cimzia. He passed out a syringe to demonstrate its ease of use.

Koby Taylor asked Dr. Beckwith if it was reasonable to be comparing the agents to one another due to their differing indications. Dr. Beckwith stated that with these agents their labeled indications mostly match well with what has been studied and how they are used in clinical practice.

Dr. Ward stated that he would recommend making a two-part motion that the agents are all equally safe and efficacious, and that each disease state should be represented in the agents included. Dr. Beckwith agreed, and suggested that the Committee not consider ulcerative colitis, since Remicade is not being considered and that is the only approved agent. Dr. Ward agreed.

Dr. Wohleb asked if the cost of administering Remicaid in a clinic setting would affect how the class as a whole is managed. Dr. Ward thought that the amount of work involved in getting a PA versus administering IV drugs would not drive people over to Remicaid. Dr. Callis-Duffin agreed.

Dr. Ward stated that based on the question that this Committee is supposed to answer, about differences in safety and efficacy, he does not feel that there is a difference in these. The Committee suggested that there may be a grandfather clause for the class. Duane stated that Medicaid does not consider grandfathering. Utilization data demonstrates that the vast utilization is between Enbrel and Humira, and so there are many drugs to be grandfathered OUT of the process, if anything.

Dr. Brownstein asked if any of the agents besides Enbrel and Humira have been studied in children. Dr. Beckwith said no.

Dr. Ward moved that the agents are all equally safe and efficacious. Duane Parke seconded the motion. Dr. Wohleb seconded the motion. The motion was unanimously approved by Dr. Wohleb, Dr. Flynn, Dr. Ward, Dr. Taylor, Kort DeLost, and Dr. Brownstein.

Dr. Ward moved that there are differences in labeled indications, and therefore, of the agents, there needs to be at least one agent indicated for Rheumatoid Arthritis, Crohn's Disease, Juvenile Rheumatoid Arthritis, Psoriatic Arthritis, Ankylosing Spondylitis, and Plaque Psoriasis, and that there need to be at least 2 preferred agents. Dr. Flynn seconded the motion. The motion was unanimously approved by Dr. Wohleb, Dr. Flynn, Dr. Ward, Dr. Taylor, Kort DeLost, and Dr. Brownstein.

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

Minutes prepared by Jennifer Zeleny