



STATE MEDICAID P&T COMMITTEE MEETING
THURSDAY, November 18, 2010
7:00 a.m. to 8:30 a.m.
Cannon Health Building
Room 114



MINUTES

Committee Members Present:

Karen Gunning, PharmD.
Kort DeLost, R.Ph.
Lisa Hulbert R.Ph.

Brandon Jennings, PharmD.
Raymond Ward, M.D.
Michael Flynn, M.D.

Committee Members Excused:

Ellie Brownstein, M.D.

Beth Johnson, R.Ph.

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

Robyn Seely, PharmD.
Jennifer Zeleny, CPhT, MPH

Tim Morley, R.Ph.
Richard Sorenson, R.N.

University of Utah Drug Information Center Staff Present:

Gary Oderda, PharmD.

Other Individuals Present:

Vern Stacey, GSK
Scott Clegg, Lilly
David Young, U of U

Tony Molchan, Abbott
Sabrina Aery, BMS
Pamela Sardo, Abbott

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

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1. Review and Approval of Minutes: The minutes from September 2010 were reviewed. Brandon Jennings moved to approve the minutes. Dr. Flynn seconded the motion. The motion was approved unanimously by Karen Gunning, Brandon Jennings, Kort DeLost, Dr. Ward, Dr. Flynn, and Lisa Hulbert.
 2. DUR Board Update: In September 2010, the DUR Board met and reviewed Multaq and Celebrex. In October the Board considered, Cambia, Forteo, and novel dosage forms. The November meeting was cancelled, and the December meeting will be held on December 9.
 3. Housekeeping: Lisa Hulbert stated that the P&T Committee is moving into some smaller dollar classes for PDL consideration. The Committee was asked about order for classes to review. The Committee felt that it should be left to the discretion of the organization preparing clinical reviews. The Committee requested to be advised when new classes would be added to the PDL and what the preferred agents would be.

4. Digestive Enzymes: Lisa Hulbert of Utah Medicaid addressed the Committee and presented research prepared by Medicaid Pharmacy staff on the topic of Digestive Enzymes.

The Committee asked if unapproved products were considered in this review. Unapproved products were not included, and should not be considered by the P&T Committee today.

Lisa also read a letter from the Cystic Fibrosis Foundation asking the Committee for to not limit coverage to one product.

Dr. Flynn asked if there were any head-to-head studies of the products. There was only one systematic review, but the studies submitted to the FDA were placebo controlled. This cannot be determined by the approval process.

David Young of the University of Utah Cystic Fibrosis Center addressed the Committee on the necessity of enzyme replacement products for Cystic Fibrosis patients. He agreed that Medicaid should not pay for unapproved products, and stated that they will completely cease to be available shortly.

The Committee asked about how switching occurred between unapproved products and currently available products. Generally lipase units are used because efficacy can be measured through fecal fat content and patient weight.

Dr. Young discussed that the manufacturing process and dosage forms of the different products varies. The branded products dissolve at different rates. This can make switching between the three branded products problematic, and occasionally causes adverse events. Dr. Young stated that there is now also a generic of Zenpep called Exgen. It is an approved generic that should become widely available in the future. All generics will be held to the same standard as approved products in the future.

Dr. Ward asked if there are any reasons that treatment naïve patient would have to start on one product rather than another. Dr. Young agreed that there are no reasons to start a brand new patient on one drug or another. In the adult center, most patients come already started on product. CF patients are typically started on enzyme replacement under 6 months of age.

Karen Gunning asked how many patients in Utah have CF. Dr. Young stated that there are about 30,000 individuals in the U.S. with CF, and the U has one of the larger treatment centers. More adult individuals are being diagnosed with atypical CF or very mild disease due to expanded genetic screening, but they would not necessarily receive the same types of treatments.

Karen pointed out that there are a lot of non-CF individuals receiving pancreatic enzymes. There is no way to determine how many Medicaid patients receiving enzymes do have CF due to the quality of Medicaid data.

Dr. Ward asked if it was reasonable to have a preferred agent for new starts. Even with a preferred agent, the other agents are still available. It was explained that there

are other classes on the PDL where switching patients could be unsafe, and there is no fail-first requirement for a PA in those cases. That could be applied to CF patients receiving pancreatic enzymes. Dr. Young stated that it was acceptable if the PA process did not require a significant amount of work.

Robyn asked if there are dosage forms that are easier to give to pediatric patients. Dr. Young stated that these products went away with the unapproved products, and the current recommendations are to open the capsules and sprinkle the beads into applesauce, tube feeds, etc.

The Committee asked if the current adults CF patients were done transitioning from unapproved products to approved products. There are still some adults who need to be transitioned, since they have stockpiled products that they know and can rely on.

Dr. Ward and Karen Gunning both have some experience with non-CF patients receiving pancreatic enzymes, and they have not experienced problems with switching patients or heard of the problems that Dr. Young has experienced in his practice.

The Committee asked if Medicaid is still paying for unapproved products. Tim Morley stated that CMS issued a letter on November 16, 2010, instructing Medicaid to cease paying for unapproved products.

Dr. Ward asked if commercial insurers have preferred products, and if they allow PA for CF patients. Dr. Young stated that commercial insurers do have preferred products, but sometimes impose unreasonable PA criteria for non-preferred products.

Pamela Sardo, PharmD., of Abbott addressed the Committee on the benefits of Creon.

Karen Gunning asked if Abbott has a sense with non-CF related pancreatic insufficiency. Dr. Sardo did not know the statistics, but stated that she could look into it further.

Karen asked if there was a more pediatric or tube friendly formulation coming. Dr. Sardo stated that she was not sure of the pipeline and stated that she was not aware of a different formulation since the capsules can be opened.

Dr. Flynn moved that for new starts the medications are equally safe and efficacious and a decision can be made based on cost. Patients with CF who are currently on an approved product need to be allowed to remain on the product without a treatment failure in the preferred product. Brandon Jennings seconded the motion. The motion was approved unanimously by Karen Gunning, Brandon Jennings, Kort DeLost, Dr. Ward, Dr. Flynn, and Lisa Hulbert.

Next Meeting Set for Thursday, December 16, 2010
Meeting Adjourned.

Minutes prepared by Jennifer Zeleny