



STATE MEDICAID DUR BOARD MEETING
 THURSDAY, June 9, 2011
 7:00 a.m. to 8:30 a.m.
 Cannon Health Building
 Room 125



MINUTES

Board Members Present:

Mark Balk, PharmD.
 Kathy Goodfellow, R.Ph.
 Bradford Hare, M.D.
 Kumar Shah

Neal Catalano, R.Ph.
 George Hamblin, R.Ph.
 Joseph Miner, M.D.
 Joseph Yau, M.D.

Board Members Excused

Cris Cowley, M.D.
 Peter Knudson, D.D.S.

Tony Dalpiaz, PharmD.

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

Lisa Hunt, R.Ph.
 Robyn Seely, PharmD.
 Richard Sorenson, R.N.
 Annette Leonard, R.N.
 Jennifer Zeleny, CPhT., MPH

Tim Morley, R.Ph.
 Heather Santacruz, R.N.
 Merelynn Berrett, R.N.
 Marisha Kissell, R.N.

Other Individuals Present:

Carrie Ann Madden, U of U
 Mary Colburn, J&J
 Gary Oderda, U of U
 Audra Robinson, Savient
 Lori Howarth, Bayer
 Brooks Hubbard, BI

Kerri Miller, J&J
 Scott Clegg, Lilly
 Charissa Anne, J&J
 Nancy Wilson, Savient
 Cap Ferry, LEC
 Jeff Buell, J&J

Meeting conducted by: Robyn Seely, PharmD.

- 1 DUR Board Member Changes: Mark Balk as reinstated for a second term. Brad Pace retired as consumer representative on the DUR Board. Kumar Shah was introduced as the new consumer representative on the Board.

Primary Care representative and DUR Board chairman Wilhelm Lehman retired from the Board. A new DUR Board chairman was elected. Dr. Hare nominated Neal Catalano. Dr. Miner seconded the motion. Neal Catalano as unanimously elected by Dr. Miner, Mr. Shah, Mr. Hamblin, Dr. Balk, Dr. Hare, and Ms. Goodfellow. Robyn voted for Neal Catalano on behalf of Tony Dalpiaz.

- 2 Review and Approval of Minutes: Neal Catalano moved to approve the minutes. Kathy Goodfellow seconded the motion. The motion was approved unanimously by Dr. Miner, Mr. Shah, Mr. Hamblin, Dr. Balk, Dr. Hare, and Ms. Goodfellow.
- 3 P&T Committee Update: There are a number of individuals also leaving the P&T Committee and new people coming onto the Committee. Some new members should be introduced at the next meeting. The P&T Committee will be looking at oral systemic antifungals, and topical antifungal agents in July. In August the Committee will review platelet aggregation inhibitors, and in September the Committee will review androgens. Some new classes will be coming onto the PDL shortly. An updated annual savings report was presented to the Board.
- 4 Krystexxa: Robyn Seely presented research and information on Krystexxa, an infused treatment for gout.

Dr. Hare commented that this seems like this is a very dangerous drug due to the potential for anaphylaxis. Anaphylaxis is a life-threatening condition, and 6.5% of individuals seem to have this reaction. He recommended that PA criteria require that the infusion take place in a facility that is capable of managing this.

Dr. Miner agreed, and stated that this should only be used by expert nephrologists and rheumatologists.

Dr. Robinson from Savient pharmaceuticals addressed the Board, and clarified the nature of the so-called anaphylactic reactions during the clinical trials. He also described the REMS program in place for Krystexxa, the skills of the specialists who are being targeted for marketing for the drug, and discussed which patients should receive this drug.

Neal Catalano asked if the REMS program has a certification program for prescribers. Dr. Robinson stated that there is not. It is more of a physician education by the drug company, instructing them which of the minority of chronic gout patients are appropriate for this drug.

Robyn asked about which specialists are appropriate. Dr. Robinson stated that nephrologists and rheumatologists who work with severe gout patients are most appropriate. Most of the patients in the clinical trials were long-term severe gout patients with numerous comorbidities related to their gout.

Mr. Shah suggested that there be a separate bullet point or category for prescribing limitations for the PA criteria.

Dr. Robinson also stated that the company recommends screening for G6PD deficiency prior to receiving Krystexxa due to a specific contraindication in prescribing in this population.

Lisa stated that in clinical trials gout patients who lost response or had anaphylaxis had serum uric acid levels greater than 6 two times. Was that within the first three months? Dr. Robinson stated that patients could lose response at any time.

Jennifer asked how soon after infusion the serum uric acid level should be measured? Dr. Robinson stated that the level should be measured 48 hours prior to the next infusion. Naturally, chronic gout patients will be well above 6 prior to beginning Krystexxa.

Dr. Miner stated the he is ready to accept the PA criteria as proposed, with limiting the use of the drug to nephrologists, rheumatologists, or other specialists trained in managing gout using Krystexxa.

Dr. Hare suggested adding wording to limit administration to a facility equipped to manage anaphylaxis.

The Board clarified that infusion should occur every 14 days, not 7. Also, the Board requested to include G6PD screening.

Robyn added that reauthorization criteria should include serum uric acid levels, and preclude reauthorization for patients who have had 2 or more tests greater than 6.

Dr. Robinson added that patients in clinical trials were not required to fail on the drugs listed in the PA criteria. It was sufficient to have a contraindication to these drugs.

Gary Oderda stated that the criteria read that the drug has to be administered by a rheumatologist. At the infusion centers, nurses typically administer the drug. The PA criteria should read “prescribed by”.

Dr. Miner moved to accept the PA criteria with the changes as summarized. Dr. Hare seconded the motion. The motion was approved unanimously by Dr. Miner, Mr. Shah, Mr. Hamblin, Dr. Balk, Dr. Hare, and Ms. Goodfellow.

- 5 Grandfathered Drugs: Carrie Ann Madden from the University of Utah Pharmacy Outcomes Research Center summarized research presented on grandfathered drugs. Prior Authorization criteria for newly approved branded versions of grandfathered drugs were suggested for the Board.

Dr. Balk stated that the PA recommendations were reasonable, but he was interested in some exceptions. He wanted to define “substantially different” dosage form and suggested only calling it “different”. He also wanted to add that if, upon FDA review, some safety parameter (e.g. black box warning) were discovered, that parameter should be applied to all existing generic similar drugs. Dr. Miner seconded the motion. The motion was approved unanimously by Dr. Miner, Mr. Shah, Mr. Hamblin, Dr. Balk, Dr. Hare, and Ms. Goodfellow.

Dr. Miner also stated that it would be nice to define “significantly” more costly and put numbers to that, but the PA criteria can stand without an official motion on that.

The next DUR Board meeting was scheduled for Thursday July 14, 2011.

The DUR Board Prior Approval Subcommittee considered 2 petitions this month. One petition was approved.

Minutes prepared by Jennifer Zeleny