



STATE MEDICAID DUR BOARD MEETING
 THURSDAY, September 9, 2010
 7:00 a.m. to 8:30 a.m.
 Cannon Health Building
 Room 114



MINUTES

Board Members Present:

Joseph Miner, M.D.
Wilhelm Lehmann, M.D.
Brad Hare, M.D.
Joseph Yau, M.D.

Neal Catalano, R.Ph.
Dominic DeRose, R.Ph.
Mark Balk, PharmD.
Cris Cowley, M.D.

Board Members Excused

Peter Knudson, DDS
Bradley Pace, PA-C

Kathy Goodfellow, R.Ph.
Tony Dalpiaz, PharmD.

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

Jennifer Zeleny, CPhT., MPH
Lisa Hulbert, R.Ph.
Richard Sorenson, R.N.
Marisha Kissell, R.N.

Tim Morley, R.Ph.
Merelynn Berrett, R.N.
Angela Handrahan, R.N.
Heather Santacruz, R.N.

Other Individuals Present:

Alan Sawitzke, U of U
 Tim Smith, Pfizer
 Bryan Larson, U of U
 Lori Howarth, Bayer
 Tony Molchan, Abbott

Vern Stacey, GSK
 Mikko Laitinen, Pfizer
 Pat Wiseman, Medimmune
 Jay Jennings, S-A
 Reed Barker, UPhA

Roy Palmer, Pfizer
 Alan Bailey, Pfizer
 Anne Marie Licos, Medimmune
 Dave Harper, S-A

Meeting conducted by: Wilhelm Lehmann, M.D.

- 1 Review and Approval of Minutes: The minutes were reviewed. Dr. Miner moved to approve the minutes. Neal Catalano seconded the motion. The motion passed unanimously by Dr. Miner, Neal Catalano, Dr. Lehmann, Dominic DeRose, Dr. Hare, Dr. Balk, and Dr. Yau.
- 2 P&T Committee Report: The P&T Committee reviewed antihistamine eye drops and nasal sprays last month, and found them to be equally safe and efficacious. Next week, the P&T Committee will review the new additions to the Statin Class, and review Health Care Reform.
- 3 Multaq Place in Therapy: Dr. Bryan Larson addressed the Board and presented updated material on dronedarone and its place in therapy, which was prepared by the University of Utah College of Pharmacy.

Mark Balk stated that one of the issues raised last time was that it was difficult to compare agents within the class. Mark asked what the indications are for the various agents. Dr. Larson stated that he was not aware of all of the FDA indications, but that amiodarone and the other agents are widely used for the different indications presented. Dr. Balk stated that he thought that the DUR Board would need to review the evidence in support of using all of the agents off-label.

Dr. Balk also pointed out that the guidelines presented had up to 53 authors, half of whom had conflicts of interest. Dr. Larson agreed that this is not uncommon, but that the conflict of interest with the author of one of the dronedarone articles who was also serving on the advisory board of Sanofi-Aventis was particularly disturbing. Dr. Balk clarified that he is employed by Sanofi-Aventis.

Dr. David Harper of Sanofi-Aventis addressed the DUR Board in favor of dronedarone and its safety advantages.

Neal Catalano asked Lisa to reiterate the guidelines for off-label use of drugs. Lisa stated that Medicaid will accept one large randomized multi-center controlled clinical trials, or three smaller trials, or listed in recognized compendia. Lisa clarified that it is not a problem to place unapproved drugs as first-line over approved drugs if there is ample evidence to support their use. Dr. Balk stated that the DUR Board should also consider if other drugs with contraindications should be considered for PA for appropriate use as well.

Dr. Hare stated that he does not think it is necessary to re-write the guidelines, since guidelines written by experts in the field already exist. The 2006 and 2010 guidelines are available to prescribers to resolve conflicting evidence on the existing therapy in deciding which agent or agents to use first line over Multaq.

Dr. Miner thought that it would be appropriate to require not just failure, but also possibly contraindication or medical justification against using another antiarrhythmic agent.

Dr. Cowley asked how many total a-fib patients are being treated on Medicaid. This was not available; only dronedarone patients were counted. These are usually miserable on drug therapy and most of them go through several different drugs. None of them are very efficacious long-term, and he believes that catheter ablation is going to become more favorable.

Neal Catalano thought that the utilization was very low, all of the medications are risky, and a PA may be another extra step that is not needed. The utilization is very small on this drug.

Dr. Larson stated that the utilization is very small, but the Board may still wish to consider limiting use so that patients with Class III and IV heart failure do not get it. This drug was initially rejected by the FDA due to increasing deaths in patients with heart failure. Three of the Medicaid patients who received the drug did have heart failure, but the class of heart failure was unknown.

Mark Balk clarified that the Black Box warning was only against use in patients with Class

IV heart failure. Dr. Larson agreed, but stated that limiting Class III would be out of caution due to the review articles warning against it, and dronedarone's known risk to worsen heart failure.

Dr. Lehmann summarized that the recommendations have been to leave this alone, to PA this drug to require medical justification for its use, or a PA to limit its use by people with Class III or IV heart failure.

The Board asked if this drug would increase volume of PA. The PA nurses did not feel like it would be burdensome due to the low volume of this drug.

Dr. Hare did not even think that a PA to restrict use in heart failure, because of the prominence of the black box warning.

Dr. Miner moved to leave this drug without PA. Dr. Hare seconded the motion. The motion passed unanimously by Dr. Miner, Neal Catalano, Dr. Lehmann, Dominic DeRose, Dr. Hare, Dr. Cowley, and Dr. Yau. Dr. Balk abstained.

- 4 Celebrex: Lisa Hulbert addressed the Board and presented evidence prepared by Utah Medicaid in favor of placing Celebrex on PA. A letter from the Utah Rheumatology Alliance was provided, which had been sent in response to the P&T Committee review.

The Board asked how long the PA had been off of Celebrex. The PA was removed two years ago, when it was placed on the PDL. Concerns about possible overuse of Celebrex were raised by Brian Hardy, who is not present to follow up. Evidence from the Oregon review and AHRQ guidelines were encapsulated in the PA suggestions.

Mark Balk asked if Medicaid stands to lose PDL rebates by requiring PA. Lisa stated that Medicaid staff will consider this when deciding on the PA.

Dr. Roy Palmer, Medical Director from Pfizer addressed the Board in favor of Celebrex.

Dr. Sawitzke from the University of Utah addressed the Board. He stated that the criteria proposed are very good, but it is what he already uses. He felt that requiring him to supply paperwork to prove it is another unnecessary step.

Lisa Hulbert responded that the PA would be reviewed after 9 months to see if it is appropriate to keep it.

Neal Catalano wondered if requiring a PA would drive use towards opioids, which are already over-utilized. Tim stated that the intent of the PA was more to drive appropriate use within the NSAID class.

Dr. Hare stated that the one thing missing from the guidelines was the lack of effect on platelets. The drug is used during a post-op period because it has a lower bleeding risk, and is a unique agent in that regard. Jennifer Zeleny and Rick Sorenson stated that a ten-day post

operative was available by telephone PA the last time that Celebrex was on PA. That could be included if the PA is reinstated. Dr. Hare asked if it could be available for a short supply without a telephone PA, due to the burden associated with getting a PA. Based on the relatively small volume of prescriptions, the necessity of a PA on this drug is questionable.

Lisa suggested a quantity limit, requiring a PA for beyond ten days of use. The Board felt that this was problematic. However, the Board felt that a quantity limit for BID use (#60 per month) was reasonable. This is already in place.

Dr. Miner moved to keep Celebrex off of PA. Neal Catalano seconded the motion. The motion passed unanimously by Dr. Miner, Neal Catalano, Dr. Lehmann, Dominic DeRose, Dr. Hare, Dr. Cowley, Dr. Balk, and Dr. Yau.

The next DUR Board meeting was scheduled for Thursday October 14, 2010.

The DUR Board Prior Approval Subcommittee to considered 1 petitions this month. 1 was approved.

Minutes prepared by Jennifer Zeleny