



STATE MEDICAID DUR BOARD MEETING
 THURSDAY, August 13, 2009
 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.
Dominic DeRose, R.Ph.
Peter Knudson, D.D.S.
Joseph Miner, M.D.
Joseph Yau, M.D.

Neal Catalano, R.Ph.
Tony Dalpiaz, PharmD.
Bradford Hare, M.D.
Wilhelm Lehmann, M.D.
Cris Cowley, M.D.

Board Members Excused:

Bradley Pace, PA-C

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

Jennifer Zeleny, CPhT., MPH
Tim Morley, R.Ph.
Lisa Hulbert, R.Ph.
Amber Kelly, R.N.
Brenda Strain

Richard Sorenson, R.N.
Debbie Harrington, R.N.
Merelynn Berrett, R.N.
Connie Keuffel, R.N.
Carol Runia

Other Individuals Present:

Felicia Fuller, Biogen Idec
 Cary Green, Merck
 Jenny Blackham, Lilly
 Gary Bailey, Forrest
 Gordon Taltersall, Pfizer
 Sue Heineman, Pfizer
 Ben Campbell, DRRC
 Anne Marie Licos, Medimmune
 Scott Latimer, Pfizer

Dan Heincy, Merck
 Candi Arce-Larrea, Pfizer
 Scott Clegg, Lilly
 Peter McFarland, Forrest
 Derek Butters, Novo
 Lori Howarth, Bayer
 Jackie Lehman, UMA
 Mark Crosby, IHC

John Stockton, Genentech
 Mary Shefchyk, Novo
 Tracy Davies, Lilly
 Judy Christensen, Pfizer
 Tim Rutti, Gilead
 Marianne Paul, DRRC
 Pat Wiseman, Medimmune
 Gary Oderda, U of U

Meeting conducted by: Wilhelm Lehmann, M.D.

- 1 P&T Committee Update: Duane Parke addressed the Board. Medicaid has gotten the approval to move ahead on anti-parkinson agents, Hepatitis C agents, and on the osteoporosis class.
- 2 Minutes for July 2009 were reviewed. Dr. Knudson moved to approve the minutes. Neal Catalano seconded the motion. The motion was passed with unanimous votes by Mark Balk, Neal Catalano, Kathy Goodfellow, Tony Dalpiaz, Dominic DeRose, Bradford

Hare, Peter Knudson, Wilhelm Lehmann, Joseph Miner, Cris Cowley, and Joseph Yau.

- 3 Fibromyalgia: Ben Campbell, PharmD. addressed the Board. He reviewed the presentation from the previous DUR Board meeting, and presented clarification of some information from the previous month.

One of the recommendations is to limit the daily dose of Lyrica to 600mg per day. This could be overridden at the pharmacy team level in cases where evidence of medical necessity has been received. Dr. Miner recommended that the maximum daily dose be limited to 600mg per day. Mark Balk seconded the motion. The motion was passed with unanimous votes by Mark Balk, Neal Catalano, Kathy Goodfellow, Tony Dalpiaz, Dominic DeRose, Bradford Hare, Peter Knudson, Wilhelm Lehmann, Joseph Miner, Cris Cowley, and Joseph Yau.

- 4 Lyrica, Cymbalta, and Savella Review: Carrie Ann Madden, PharmD. addressed the Board and presented evidence compiled by the University of Utah's Drug Regimen Review Center on the new Fibromyalgia drug Savella, and on the usefulness of requiring ICD.9 codes through the Pharmacy POS system. Recommendations for coverage conditions of Savella were presented to the DUR Board.

The Board asked how Medicaid could prevent concomitant use of Savella and SSRI's, SNRI's and Tricyclics without a PA. Lisa Hulbert stated that a cumulative edit could be placed on the class to halt the claim in the point of sale system.

Dr. Hare stated that he sees many potential applications for Savella in pain and depression, in addition to Fibromyalgia. There may be some good literature to support these off-label uses since the drug has been available for 10 years in Europe.

Tim Morley provided utilization statistics for the three Fibromyalgia drugs for the 2009 fiscal year.

Mark Balk stated that with four SNRI's on the market, there should be some consistent way to treat the same drugs in the class. The same recommendations could be extended to Cymbalta, venlafaxine and desvenlafaxine. The Board could table this discussion for a month and try to review it as a class for internal consistency. Also, the Board could drop the recommendation about putting a hard halt on claims with other concomitant antidepressants, because it could open up a can of worms in terms of how other antidepressant claims are handled.

The Board asked if any hard halts go out to the pharmacies now when multiple classes of antidepressants are filled for the same patient. Lisa Hulbert stated that DUR alerts currently go to pharmacies, but the claims still pay. Medicaid would like to place a hard halt on Savella because it is a new medication.

Dr. Yau felt that it is a good recommendation to halt claims for Savella combined with other antidepressants. There is a safety issue because Savella preferentially has a much higher affinity for norepinephrine. Norepinephrine is associated with many concerning

side-effects. It has not gotten much attention. Now we talk about serotonin syndrome, because the SSRI's came out with such a big push. Norepinephrine is associated with many concerns, like heart rate and seizures. He feels that the recommendation to halt claims is a good one, but how to execute it is another question. The TCA's have been used and there is no accounting of it at all. This could be an education effort. This is not the usual SNRI, because the preferential affinity is so much higher. It is almost like a TCA, like desipramine. Before we have experience with it, there are a lot of safety issues.

The Board agreed that clients' uses of multiple pharmacies can make it difficult to track dangerous drug interactions, but agreed that perhaps restricting concomitant antidepressant use should apply to the whole class, if adopted.

Dr. Madden stated that the DRRC sees a lot of concomitant use of antidepressants that does not make a lot of sense. The DRRC could do an analysis of how common this is in Utah Medicaid.

Mark Balk stated that this may support the need for reviewing concomitant use of all antidepressants. However, realistically, this would be best handled through an educational approach rather than a hard halt.

Dr. Yau stated that the combined use of antidepressants is very common. Serotonin syndrome happens; adverse effects due to norepinephrine happen. A hard halt on claims would be very difficult to enforce and create a large workload. Education may be the best approach.

Jenny Blackham of Eli Lilly addressed the DUR Board about the indications of Cymbalta, and its use in treating Fibromyalgia with and without comorbid depression.

Peter McFarland of Forrest addressed the DUR Board about the indication of Savella and its use in treating Fibromyalgia.

Dr. Yau asked what is a reasonable clinical response time for the 100mg daily dose of Savella. Peter McFarland stated that in clinical trials, patients showed improvements at week two and maximum benefit at 9 weeks.

Dr. Yau asked if any safety data was available for concomitant use with other antidepressant classes from overseas. Peter McFarland stated that this drug has been used for many years overseas, but did not have any specific safety data. Dr. Yau stated that he felt like he would like to see overseas safety data before discussing any hard halts to prevent concomitant use with other antidepressants.

Lisa said that Medicaid would like to implement a limit of 100mg per day, with the possibility of a 200mg per day dose to be overridden at the pharmacy team level. Also, she recommended that Medicaid make Savella consistent with other agents in the class by capturing ICD.9 diagnosis codes through the point of sale. Medicaid can also do an educational piece in the Amber Sheet about the concomitant use of SNRI's and other antidepressants.

Dr. Hare stated that people with significant depression were excluded from many of the Fibromyalgia studies. He believes that the results with these drugs in clinical practice will be worse than in the studies because of this. Fibromyalgia requires a multi-faceted approach to for treatment, and this may not happen in the primary care setting. Dr. Bateman talked about this at the last meeting as well. Drugs are certainly a treatment for Fibromyalgia, but they are not the only treatment. An educational piece about the disease state is needed as well for this reason.

Lisa Hulbert asked Dr. Hare if he would work with Medicaid on an educational piece for the Amber Sheet. He stated that he works with many experts on this issue, and would be happy to come up with an educational article.

Mark Balk made a motion to limit the quantity of Savella to 100mg per day with the possibility of override, to require an ICD.9 code, and an educational piece on the treatment of Fibromyalgia and drug-drug interactions. Dr. Miner seconded the motion. The motion was passed with unanimous votes by Mark Balk, Neal Catalano, Kathy Goodfellow, Tony Dalpiaz, Dominic DeRose, Bradford Hare, Peter Knudson, Wilhelm Lehmann, Joseph Miner, Cris Cowley, and Joseph Yau.

Mark Balk clarified that a 2 month trial of 100mg per day would be needed on Savella before a 200mg daily dose should be authorized.

Next meeting set for September 10, 2009
Meeting adjourned.

The DUR Board Prior Approval Subcommittee convened and considered 5 petitions and approved 3.

Minutes prepared by Jennifer Zeleny