



STATE MEDICAID DUR BOARD MEETING
 THURSDAY, January 13, 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.
Wilhelm Lehmann, M.D.
Joseph Yau, M.D.

Neil Catalano, R.Ph.
Tony Dalpiaz, PharmD.
Joseph Miner, M.D.

Board Members Excused

George Hamblin, R.Ph.
Peter Knudson, D.D.S.
Cris Cowley, M.D.

Bradford Hare, M.D.
Bradley Pace, PA-C

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

Richard Sorenson, R.N.
Lisa Hulbert, R.Ph.
Marisha Kissell, R.N.
Amber Kelly, R.N.
Robyn Seely, PharmD.

Tim Morley, R.Ph.
Merelyn Berrett, R.N.
Heather Santacruz, R.N.
Jennifer Zeleny, CPhT., MPH

Other Individuals Present:

Felicia Fuller, Biogen Idec
 Bruce Howard, Acorda
 Julie Porter, Novartis
 Matt Anderson, Alkermes
 Brett Brewer, EMD Serono
 Lori Howarth, Bayer
 Mary Jo McMillen, USARA

Mark German, Novartis
 Greg Hoke, Reckitt Benkiser
 Barbara Boner, Novartis
 Roy Lindfield, Sunovion
 Darlene Petersen, PGU
 Sean Ponce, MD

Brian Hutchinson, Acorda
 Vern Stacey, GSK
 Robert Belaski, Alkermes
 Gary Oderda, U of U
 CarrieAnn Madden, U of U
 Efrain Alton, Merck

Meeting conducted by: Wilhelm Lehmann, M.D.

- 1 Review and Approval of Minutes: Dr. Miner moved to approve the minutes. Neal Catalano seconded the motion. The motion was approved by Kathy Goodfellow, Mark Balk, Dr. Lehmann, Neal Catalano, Tony Dalpiaz, and Dr. Miner. Dr. Yau abstained, as he was not in attendance last month.
- 2 P&T Committee Report: Lisa Hulbert addressed the Board. The DURB members and guests were provided a handout of classes that are scheduled for review by the P&T Committee.

The Board asked when the P&T Committee meets. The P&T Committee meets the third Thursday of every month at 7AM at the Cannon Health Building. It is a public meeting like the DUR Board meetings.

- 3 Pradaxa Off-Label Uses: Dr. CarrieAnn Madden addressed the Board and provided some additional information and an evidence table of published trials discussing off-label uses of Pradaxa.

Mark Balk asked about the accuracy of the enoxaparin study that was provided. Dr. Madden stated that needed to be corrected as noted by Dr. Balk.

The Board asked Robyn to remind them the action that was taken last month. They did not feel it was necessary to revise their previous decisions based on the evidence presented.

- 4 Oral Multiple Sclerosis Therapies: Dr. CarrieAnn Madden addressed the Board and presented evidence and proposed PA criteria for Ampyra and Gilenya.

Mark Balk asked for clarification on the indications for Ampyra. It is not indicated only for relapsing-remitting MS, so Dr. Madden stated that she did not intend to put that into the criteria.

Brian Hutchinson from Accorda Therapeutics addressed the DUR Board in favor of the benefits of Ampyra for MS patients with several forms of MS.

Dr. Julie Porter from Novartis addressed the DUR Board in favor of the benefits of Gilenya for patients with MS.

Mark Balk asked if the drug would be initiated through samples in the office. If that is the case, would it be necessary for physicians to provide information about bradycardia monitoring. The representative from Novartis indicated that patients enrolled in the REMS program would be sent a 14 day supply for dose initiation. Therefore, patients would have already been started by the time they are requesting the PA.

Kathy Goodfellow asked if all patients need to be enrolled in the REMS program to receive the medication. They do not, so it is possible to get medications outside of the REMS program.

The Board felt that the monitoring requirement was reasonable, considering that the patient is required to be watched for six hours after the initial dose, so the physician does need to plan ahead. The Novartis representative added that there is an average wait time of 14-28 days before the patient is placed in queue to receive therapy to when therapy is initiated, so the additional PA requirement is not likely to delay this.

Mark stated that the only other thing he would add to the Gilenya is an age requirement of 18.

Mark moved that for fingolemod the PA be modified to include 18 years minimum age, and that for dalfamperdine the requirement for relapsing-remitting be removed. Accept the PA criteria with these changes.

The Board asked what would be done with the requirement for bradycardia monitoring. The Board felt that it was not necessary to have a formal requirement if therapy was already initiated with samples. It was suggested that a check-box for the provider to acknowledge that monitoring has occurred or will occur might be sufficient. Lisa stated that Medicaid would take this into consideration when operationalizing this requirement.

Dr. Miner seconded the motion. The motion was approved by Kathy Goodfellow, Mark Balk, Dr. Lehmann, Neal Catalano, Tony Dalpiaz, Dr. Yau, and Dr. Miner.

Mark Balk asked about placing MS injectables on PA, due to requirements for baseline CBC's, LFTs, and thyroid levels. Many of these drugs have testing requirements that the DUR Board could consider. Jennifer explained that the Interferons and Copaxone did, historically, require a PA, but that was removed when the class was placed on the PDL before PDL classes could be placed on PA. Utilization has not really increased, suggesting that there is no huge problem with off-label use. She did not know if any of the PDL bids would allow for a PA, but Medicaid staff could look into it. Mark thought that the drugs have been available long enough that perhaps it would not be necessary.

Tim added that the DUR Board can consider oral MS drugs and oral MS drugs as separate classes, and can even consider drugs singly rather than by class.

- 5 Vivitrol: Robyn Seely addressed the Board. Robyn reviewed material provided to the DUR Board related to the new and existing indications for Vivitrol.

Robert Belaski of Alkermes spoke to the DUR Board in favor of making Vivitrol available to prevent relapse of opioid dependence.

Dr. Sean Ponce addressed the DUR Board in favor of making Vivitrol available to Medicaid clients wishing to receive treatment outside of methadone clinics.

Robyn read a letter submitted by Dr. Elizabeth Howell to the DUR Board.

Dr. Yau stated that he believes this medication is clinically useful. He stated that the half life stated in the handout may be misleading, because the depo formulation maintains blood levels over a month even though the chemical naltrexone only has a half life of 5-10 hours.

Robyn also stated that Dr. Michael Measom was unable to attend the meeting, but provided an article for the Board to review.

Dr. Miner asked if a 6 months prior authorization was enough, or if it should be for 1 year. The Board felt that 6 months was adequate.

Dr. Miner moved to adopt the criteria as proposed. Dr. Balk seconded the motion. The motion was approved by Kathy Goodfellow, Mark Balk, Dr. Lehmann, Neal Catalano, Tony Dalpiaz, Dr. Yau, and Dr. Miner.

Dr. Oderda suggested that Medicaid consider a block on opioid prescriptions for patients receiving Naltrexone.

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

The DUR Board Prior Approval Subcommittee did not meet this month.

Minutes prepared by Jennifer Zeleny