



STATE MEDICAID DUR BOARD MEETING
 THURSDAY, January 13, 2011
 7:00 a.m. to 8:30 a.m.
 Cannon Health Building
 Room 114



MINUTES

Board Members Present:

Mark Balk, PharmD.
Kathy Goodfellow, R.Ph.
George Hamblin, PharmD.
Peter Knudson, D.D.S.
Cris Cowley, M.D.

Neal Catalano, R.Ph.
Tony Dalpiaz, PharmD.
Brad Hare, M.D.
Joseph Miner, M.D.
Joseph Yau, M.D.

Board Members Excused

Bradley Pace, PA-C

Wilhelm Lehmann, M.D.

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.
Robyn Seely, PharmD.

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

Other Individuals Present:

Gary Oderda, U of U
 Lori Howarth, Bayer
 Mike Crittenden, Pfizer
 Alan Bailey, Pfizer
 Bill White, Lundbeck

Bryan Larson, U of U
 CarrieAnn Madden, U of U
 Camille Kerr, Allergan
 Tony Molchan, Abbott
 Bruce Howard, Accorda

Meeting conducted by: Robyn Seely PharmD.

- 1 Review and Approval of Minutes: The minutes were reviewed. Tony Dalpiaz moved to approve the minutes. Kathy Goodfellow seconded the motion. The motion was approved unanimously by Kathy Goodfellow, Dr. Knudson, Dr. Hare, Dr. Balk, Dr. Yau. Neal Catalano, Dr. Talpiaz, and Dr. Cowley.
- 2 P&T Committee Report: Utah Medicaid is currently in the process of renewing contracts for PDL rebates for 2011. BPH drugs will be reviewed in the February 2011 P&T Committee meeting.
- 3 Metformin Dose Limits: CarrieAnn McBeth addressed the Board and presented research on metformin utilization within the Utah Medicaid population. Safety information for

metformin dosage limits was presented and reviewed. In particular, the black box warning for lactic acidosis was discussed, and a dose limit of 2,550mg daily on metformin and metofmin-containing products was suggested.

Dr. Miner moved to accept the daily limit of 2,550mg.

The Board asked if this will be done through computer programming. Robyn stated that this would be done through computer edits, and that an education article on metformin dosage and safety would be placed in the next MIB and Amber Sheet.

Dr. Hare seconded the motion. The motion was approved unanimously by Kathy Goodfellow, Dr. Knudson, Dr. Hare, Dr. Balk, Dr. Yau, Neal Catalano, Dr. Talpiaz, and Dr. Cowley.

- 4 Combination Products: Dr. CarrieAnn McBeth addressed the Board and presented a report on combination products. Prior Authorization policy and criteria for newly approved combination products were proposed.

Dr. Miner moved to approve the criteria as presented.

Robyn suggested that Medicaid may want to exempt a newly approved combination product from Prior Authorization in the event that there is a cost advantage due to secondary rebates. Dr. McBeth stated that she had intended to address that in her policy recommendation, but may not have done so adequately.

The Board asked if the rebate becomes the primary consideration in the process. Robyn stated that patient wellness is the primary consideration and finances are the lowest consideration.

Mark questioned the availability of secondary rebates when a new drug comes to market, since rebates are solicited annually. Jennifer stated that rebate offers for new-to-market drugs can be submitted at any time during the year. Lisa confirmed that supplemental rebate offers trickle in year-round for this reason.

The Board asked if the policy, as proposed, allows Medicaid to cover new combination products that are cost favorable due to secondary rebates. Robyn stated that she believes that it does, and that the intent to do this is reflected in the deliberations.

Dr. Hare seconded the motion. The motion was approved unanimously by Kathy Goodfellow, Dr. Knudson, Dr. Hare, Dr. Balk, Dr. Yau, Neal Catalano, Dr. Talpiaz, George Hamblin and Dr. Cowley.

- 5 Sabril: Robyn Seely addressed the Board and reviewed indications for Sabril for adults and infantile seizures for children under age 2. Additionally, the black box warning about permanent vision loss in 30% or more of patients taking Sabril was reviewed, and the REMS program requirements called the Sabril Share Program was presented. The FDA approved

ages are 0-2 years of age and then again adults. This is presenting some problems, because many of the patients who would like a Prior Authorization are between the ages of 2-16 years of age.

The DUR Board asked if there were studies available to support the use in the age range of 2-16 years old. Robyn had found some studies, and included abstracts in the DURB materials.

The Board asked what would happen with patients between the ages of 2-18. Robyn stated that those patients would be held to the eye exam requirement. It has been suggested that a majority of clinical improvement as well as vision loss will occur within the first three months of therapy.

The DUR Board asked why the FDA did not approve ages 2-18. Robyn stated that she suspects that it just was not submitted to the FDA.

The DUR Board asked how many requests come in for children in the unapproved age range. Robyn stated that the majority of requests coming in to Medicaid are for that age range, and most of those children have exhausted all of their other therapeutic options.

The DUR Board commented that the studies provided did not provide enough support for use in the age group under discussion.

Dr. Hare wanted to know how efficacious this treatment is, given that it causes blindness in this many patients.

Dr. Miner asked if requests for children in this age range are coming from experts. Robyn stated that most are coming from Dr. VanOrman who is a pediatric neurologist and a former chair of the DUR Board. Additionally, Lisa stated that Medicaid has received two requests to pay for drugs that are imported from Europe to treat Dravet Syndrome due to lack of efficacious agents available in the United States.

Robyn stated that it is important to remember that these children frequently progress to status epilepticus (grand mal seizures) that deprive the brain of oxygen and cause mental retardation that eventually leads to patients requiring a much higher level of care.

The DUR Board asked if the Share Program restricts the age of patients receiving the drug. Anyone between ages 2-18 who is taking the drug is required to register with the Share Program, but it is not restricted to that age.

Dr. Yau stated that he wanted to comment on the observation that status epilepticus causes mental retardation. He stated that he does not believe it is always the case. Certainly it can cause it to progress, but it can also be a reflection of the underlying disorganization of the brain that causes seizures. They often occur together, but one does not necessarily cause the other.

Mark moved to table the discussion on age, imposing quantity limits, and mandating

enrollment in the Share Program. If the Share Program mandates vision testing, it could be eliminated from the PA requirement to reduce the burden on Medicaid staff. Between age 2-18, or 16 since the DUR Board apparently previously approved use that young. Requests in the age gap can be handled by petition until more conclusive studies are presented. The Board also suggested inviting Dr. VanOrman to discuss use of the drug in ages 2-16.

Mark questioned how the current PA allowed age 16 and over. Jennifer stated that the studies presented to the FDA were conducted in ages 16 and older.

Bill White from Lundebeck briefly reviewed the Share Program and described the process of dis-enrolling patients and providers for failing to comply with vision testing every three months.

Dr. Miner seconded the motion. The motion was approved unanimously by Kathy Goodfellow, Dr. Knudson, Dr. Hare, Dr. Balk, Dr. Yau, Neal Catalano, Dr. Talpiaz, George Hamblin and Dr. Cowley.

- 7 Revatio: Robyn Seely stated that Medicaid is proposing the remove the age requirement from the Revatio PA due to the widely accepted use of the drug in this age range.

Dr. Miner moved to remove the age requirement. Neal Catalano seconded the motion.

The next DUR Board meeting was scheduled for Thursday February 10, 2011.

The DUR Board Prior Approval Subcommittee to considered 3 petitions this month. 3 were approved.

Minutes prepared by Jennifer Zeleny