



STATE MEDICAID DUR BOARD MEETING
THURSDAY, January 15, 2008
7:00 a.m. to 8:30 a.m.
Cannon Health Building
Room 114

MINUTES

Board Members Present:

Mark Balk, PharmD.
Wilhelm Lehmann, M.D.
Colin VanOrman, M.D.
Joseph Yau, M.D.

Neal Catalano, R.Ph.
Tony Dalpiaz, PharmD.
Bradford Hare, M.D.

Board Members Excused:

Peter Knudson, D.D.S.
Joseph Miner, M.D.
Dominic DeRose, R.Ph.

Derek Christensen, R.Ph.
Bradley Pace, PA-C

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

Lisa Hulbert, R.Ph.
Debbie Harrington, RN
Tim Morley, R.Ph.

Rick Sorenson, RN
Merelynn Berrett, RN
Carol Runia

Other Individuals Present:

Gary Oderda, U of U
Todd Burrows, Lilly
Alan Bailey, Pfizer

Ann Gustafson, GSK
Lori Howarth, Bayer
Pat Wiseman, Medimmune

Note: There were others in attendance, but the roll did not complete circulation.

Meeting conducted by: Colin VanOrman, M.D., DUR Board Chairman

1. The minutes for November 18, 2008 were reviewed, corrected, and approved. Dr. Lehmann moved to approve the minutes and Mark Balk seconded the motion. The motion passed with unanimous votes by Mark Balk, Neal Catalano, Dr. Lehmann, Tony Dalpiaz, Dr. VanOrman, Dr. Hare, and Dr. Yau.
2. DUR Board Annual Report: Tim Morley addressed the Board. The DUR Board members were provided with a copy of the DUR Board Annual Report to the State Legislature. Tim reviewed some of the highlights from the report, including a new section dealing with PDL savings.

Dr. Oderda addressed the Board regarding the role of the DRRC in retrospective DUR reviews. There are some changes in Medicaid's contract with the DRRC. In

the past, the DRRC has identified patients who are the highest utilizers in the drug program based on the number of prescriptions that they have received. Now, patient drug use will be analyzed to identify the patients who are at the highest risk for adverse events. There will also be a more focused intervention based on the patient's disease state. The interventions will also become more personal in order to attempt to more actively engage the prescribers.

Tim stated that the State has a new website for public notice announcements. That address will be provided upon request to the DUR Board members, and is available on the February P&T Committee agenda.

3. Nexavar PA Review: Tim Morley addressed the Board. Nexavar was initially reviewed in 2006, and is being brought back to the DUR Board for the mandatory follow-up review. Utilization data for this and the other drugs being reviewed today was provided to the DUR Board members. The current Prior Authorization is specific to the FDA approved indication that was in place when the drug was first reviewed. Since the initial PA was approved, the FDA has added another indication for unresectable hepatocellular carcinoma.

Neal moved that Medicaid add the new FDA approved indication of unresectable hepatocellular carcinoma to the PA criteria. Dr. Hare seconded the motion. The motion passed with unanimous votes by Mark Balk, Neal Catalano, Dr. Lehmann, Tony Dalpiaz, Dr. VanOrman, Dr. Hare, and Dr. Yau.

4. Sutent PA Review: Tim Morley addressed the Board. Sutent was also initially reviewed in 2006, and is being brought back to the DUR Board for the mandatory follow-up review. The original PA was approved according to the FDA approved indication for renal cell carcinoma for patients who have had disease progression on or are intolerant to Gleevec. Since the initial PA was approved, the FDA has added another indication for gastrointestinal stromal tumor for patients who have had disease progression on or are intolerant to Gleevec. All approved indications are still only for post-Gleevec usage, which is a major reason that this drug was originally put on PA. Medicaid is recommending that the DUR Board update the PA criteria with the new FDA approved indications.

Mark Balk recommended dropping the bullet point in the PA criteria requiring documentation of treatment history, since the following bullet point asks for documentation for disease progression on Gleevec or documentation of Gleevec intolerance. He also recommended adding the diagnosis of GIST.

The Board asked if it was appropriate to require Gleeve failure for a diagnosis of advanced renal cell carcinoma, since it was not specifically addressed in the FDA labeling, and the labeling did include studies for treatment-naïve patients. Mark Balk pointed out that the clinical information provided by Medicaid includes a study that demonstrates that Sunitinib is effective in a first-line setting.

The Board recommended that Gleevec failure not be required for advanced renal cell carcinoma since it is no longer part of the FDA approved indications.

Tony moved to accept the PA criteria with the recommended changes. Dr. Yau

seconded the motion. The motion passed with unanimous votes by Mark Balk, Neal Catalano, Dr. Lehmann, Tony Dalpiaz, Dr. VanOrman, Dr. Hare, and Dr. Yau.

5. Increlex PA Review: Tim Morley addressed the Board. Increlex is Insulin-like Growth Factor 1. The current criteria were provided to the DUR Board.

Mark Balk recommended changing the criteria on bullet point 4 that states “normal to low GH levels” to “normal to elevated GH levels” as stated in the FDA approved indications.

Dr. VanOrman asked if the Board recommended that the other contraindications outlined in the package insert should be included in the PA criteria. Mark suggested consolidating the requirement to rule out secondary forms of IGF deficiency into one bullet point and including the examples from page 7 in the PI in parenthesis.

Mark moved to accept the amended criteria. Tony seconded the motion. The motion passed with unanimous votes by Mark Balk, Neal Catalano, Dr. Lehmann, Tony Dalpiaz, Dr. VanOrman, Dr. Hare, and Dr. Yau.

Next meeting set for February 12, 2009

Meeting adjourned.

The DUR Board Prior Approval Subcommittee considered 2 petitions this month.

Minutes prepared by Jennifer Zeleny