



STATE MEDICAID DUR BOARD MEETING
 THURSDAY, April 14, 2011
 7:00 a.m. to 8:30 a.m.
 Cannon Health Building
 Room 125



MINUTES

Board Members Present:

Neal Catalano, R.Ph.
 Tony Dalpiaz, PharmD.
 Cris Cowley, M.D.

Kathy Goodfellow, R.Ph.
 Wilhelm Lehmann, M.D.
 Joseph Yau, M.D.

Board Members Excused

Mark Balk, PharmD.
 Brad Hare, M.D.
 Joseph Miner, M.D.

George Hamblin, R.Ph.
 Peter Knudson, D.D.S.
 Bradley Pace, PA-C

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

Richard Sorenson, R.N.
 Tim Morley, R.Ph.
 Marisha Kissell, R.N.
 Lisa Hulbert, R.Ph.

Robyn Seely, PharmD.
 Jennifer Zeleny, CPhT, MPH
 Heather Santacruz, R.N.

Other Individuals Present:

Lori Howarth, Bayer
 Sabrina Aery, BMS
 Cap Ferry, LEC

David Luke, Merck
 Brett Brewer, EMD Serono

Meeting conducted by: Wilhelm Lehmann, M.D.

- 1 Review and Approval of Minutes: The meeting room for March was changed to 125. Neal Catalano moved to accept the minutes. Kathy Goodfellow seconded the motion. The motion passed with unanimous votes by Dr. Lehmann, Dr. Yau, Kathy Goodfellow, Neal Catalano, Dr. Cowley, and Tony Dalpiaz.
- 2 P&T Committee Report: Lisa Hulbert addressed the Board. In February, the P&T Committee looked at BPH drugs, and a recommendation is being taken forward to upper management. There will be no meeting in April due to Spring Break.
- 3 Tim Morley addressed the Board and congratulated Kathy Goodfellow for receiving the Bowl of Hygeia award at the recent pharmacy convention. This is a national award given at the state level.
- 4 Housekeeping: Robyn Seely addressed the Board. Mark Balk has accepted a second term

with the DUR Board. Dr. Lehmann has just completed a second term, and is ineligible for continued service. Medicaid thanked him for his service.

- 5 Review of Selected Treatments for Type 2 Diabetes: Robyn Seely addressed the Board, and presented research prepared for the DUR Board meeting. Proposed PA criteria were included.

Kathy Goodfellow asked if the separate ingredients for Kombiglyze are more cost-effective for Utah Medicaid, and how Janumet is being treated. Jennifer stated that the access to Janumet is unrestricted due to its PDL status. It is available unrestricted, as is Januvia, based on cost status.

Sabrina Aery stated that there is price parity between Onglyza and Kombiglyze. Robyn stated that failure on Januvia or Janumet would be required prior to Onglyza or Kombiglyze based on the current PDL status. The DUR Board was asked to look at clinical considerations only.

Dr. Yau asked the members of the Board who are more experienced in treating diabetes if any dose adjustments would be required for these drugs while taking metformin. Robyn stated that these drugs are dosed independently of metformin.

Dr. Lehmann felt that Cycloset is a surprising product, given the side-effects of bromocriptine. The Board members have also not seen very good results with Victoza, but are aware that there is a concern with use for weight loss.

The Board asked Robyn about the relative risk for tumors. That was an increase in relative risk, and the absolute risk was very small.

The DUR Board asked if there is an A1C requirement for Byetta. Jennifer stated that the A1C requirement for therapy initiation was an A1C > 7. This was to prevent abuse for weight loss. The Board expressed concern about therapy being discontinued if the A1C went below 7. Jennifer stated that this was not the case. If the A1C drops below 7, that means that the therapy is working, and Medicaid has no reason to discontinue therapy that is effective. The A1C > 7 was only required for therapy initiation.

Jennifer stated that Byetta criteria also preclude concomitant use with insulin. The Board felt that there may be individual circumstances where an endocrinologist may wish to use both, but this has not been studied.

The Board asked if the other drugs should require an A1C. The Board felt that it was unnecessary, because the other agents under consideration are not likely to be abused for weight loss.

The Board asked if the lab work for A1C was really required for Byetta. Dr. Lehmann felt that the requirement to fax the actual lab report was onerous. He proposed a check-box requirement. Neal Catalano moved to accept the Victoza criteria as proposed, with the

addition of a check-box to require the physician to acknowledge an A1C > 7. Kathy Goodfellow seconded the motion. The motion passed with unanimous votes by Dr. Lehmann, Dr. Yau, Kathy Goodfellow, Neal Catalano, Dr. Cowley, and Tony Dalpiaz.

Tony Dalpiaz moved to accept the Cycloset criteria as proposed. Neal Catalano seconded the motion. The motion passed with unanimous votes by Dr. Lehmann, Dr. Yau, Kathy Goodfellow, Neal Catalano, Dr. Cowley, and Tony Dalpiaz.

The DUR Board felt that the PDL structure will manage Kombiglyze. It is an entry into an existing class; the P&T Committee has already reviewed the individual ingredients, and deemed them equally safe and efficacious. The question is whether or not the DUR Board feels that it is warranted to have clinical criteria in addition to the PDL criteria. The Board may also wish to give Medicaid the ability to clinically manage these drugs outside of the PDL. The Board felt that the cost-effectiveness bullet in the proposed criteria was already addressed by the PDL.

The Board felt that the proposed maximum of #150 tablets was cost-ineffective and unsafe. #60 tablets could be achieved for the maximum daily dose through dose consolidation, and prevent overdosage of saxagliptin at the higher strengths. The proposed criteria were amended to a maximum of #60 tablets per 30 days.

Neal Catalano moved to accept the Kombiglyze criteria with the proposed changes. Tony Dalpiaz seconded the motion. The motion passed with unanimous votes by Dr. Lehmann, Dr. Yau, Kathy Goodfellow, Neal Catalano, Dr. Cowley, and Tony Dalpiaz.

Dr. Lehmann asked if the Board wanted to amend the criteria for Byetta to not require a lab report. The PA nurses stated that they accept an A1C value reported in the progress notes. Medicaid has historically requested documentation in one form or another, rather than a check box. The Board felt that it was important to keep the Byetta and Victoza requirements for lab work needed to be the same.

Rick Sorenson stated that he was happy with documentation in the form of a lab report, or in the progress notes. He did not like the idea of the check-box because it does not require supporting documentation. The Board members agreed that this is a tool that can be abused.

The Board members asked if it was possible to transmit the A1C value electronically. Medicaid may be able to take that eventually, but that is not possible now.

Dr. Cowley suggested that the form include a line that can be filled out with the current A1C value and signed. This system of documenting on the form and faxing in is currently in use for the NPA form, but that is often filled out by the MA or nurse and returned by Medicaid because it is unsigned. Additionally, there are other criteria for Byetta and Victoza that require more extensive documentation.

Tim felt that if the system of accepting notes rather than a check box has been working well, perhaps that should be left alone. Rick thought that a check box would add more steps,

because the other criteria on the form require additional documentation.

Jennifer stated that perhaps the Board should get back to the original concern, which is that the requirement fax the original lab report is too onerous. The PA nurses do not care whether that is in the form of a letter, in the progress notes, written on a signed form, as long as there is a date and a value provided somewhere. We will let the minutes reflect that the three requirements are a date, a value, and a provider signature, and the providers will have some latitude in how they provide that in their PA request.

Neal also suggested to amend the Victoza criteria to require no concomitant insulin use, to be consistent with Byetta, and the labeled uses. He also moved that the requirement to provide the A1C for Byetta and Victoza should be met with a date, value, and provider signature, as discussed. He moved to make the amendment. Dr. Cowley seconded the motion. The motion passed with unanimous votes by Dr. Lehmann, Dr. Yau, Kathy Goodfellow, Neal Catalano, Dr. Cowley, and Tony Dalpiaz.

The next DUR Board meeting was scheduled for Thursday May 12, 2011.

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

Minutes prepared by Jennifer Zeleny