



STATE MEDICAID DUR BOARD MEETING  
 THURSDAY, September 10, 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.**  
**Brad Hare, M.D.**  
**Wilhelm Lehmann, M.D.**  
**Joseph Yau, M.D.**

**Neal Catalano, R.Ph.**  
**Dominic DeRose, R.Ph.**  
**Peter Knudson, D.D.S.**  
**Cris Cowley, M.D.**

**Board Members Excused:**

**Tony Dalpiaz, PharmD.**  
**Brad Pace, PA-C**

**Joseph Miner, M.D.**

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

**Lisa Hulbert, R.Ph.**  
**Jennifer Zeleny, CPhT, MPH**  
**Connie Keuffel, R.N.**  
**Merelynn Berrett, R.N.**

**Rick Sorenson, R.N.**  
**Tim Morley, R.Ph.**  
**Amber Kelly, R.N.**  
**Duane Parke, R.Ph.**

**Other Individuals Present:**

Cary Green, Merck  
 Bryan Larson, DRRC  
 Tony Molchan, Abbott  
 Butters, NNI  
 Reed Murdoch, Wyeth  
 Jeff Buel, J&J  
 Koffi Amevor, U of U Student

Mary Shefchyk, NNI  
 Dan Heincy, Merck  
 James Gaustad, Purdue  
 Cap Ferry, LEC  
 Jennifer Stoffel, J&J  
 Marianne Paul-Jensen, DRRC  
 Ashley Campbell, U of U Student

**Meeting conducted by: Wilhelm Lehmann, M.D.**

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1 Review and Approval of Minutes: Minutes from September 2009 were approved. Mark Balk voted to approve the minutes. Neal Catalano seconded the motion. The motion passed with unanimous votes by Neal Catalano, Dr. Lehmann, Dominic DeRose, Mark Balk, Dr. Hare, Kathy Goodfellow, and Dr. Knudson.

2. P&T Committee Report: The P&T Committee has recently reviewed third-generation cephalosporins and targeted immunomodulators. Recommendations have been sent to the director's office, but no response has been received. Next week the P&T Committee will be considering second-generation antihistamines. All new PDL classes will have an effective date

of January 1, 2010, once they are approved.

3. Nucynta Review/Quantity Limits: Lisa Hulbert addressed the Board. Nucynta is a new drug that has come on the drug file. It is indicated for the relief of moderate to severe pain. It has been placed on the cumulative limits, along with the other short-acting opioids that do not contain Tylenol, so the current limit is 180/month. In studies, Nucynta 100mg was compared to Oxycodone 15mg. It may cause less GI upset. No studies submitted to the FDA studied the safety or efficacy of Nucynta beyond 10 days of use. However, one study on Pubmed did take utilization out to 90 days. Concomitant use with serotonergic agents could create a risk for serotonin syndrome, since it works on norepinephrine receptors as well as mu-receptors. Medicaid is looking for a Prior Approval in the Pharmacy Program. Proposed criteria were presented to the Board.

Dr. Hare stated that it is a unique product in that it is both a mu-agonist and a norepinephrine reuptake inhibitor. It is kind of a high-powered version of Ultram. Unfortunately, it is very expensive, and in his experience does not offer a great advantage, except with maybe some of the side-effects with nausea and vomiting. In his experience, though, it is not difficult to match people with a traditional generic opioid for pennies that they can tolerate, without resorting to this product that costs at least ten dollars per day. Norepinephrine blockade seems to play an important role in treating chronic neuropathic pain, so perhaps in the future this drug may provide a benefit for that purpose. For its current indications, it doesn't seem to offer much new or different.

Dr. Yau stated that he is not familiar with this medication, but that serotonin syndrome is not a very frequent concern. Many drugs carry these warnings, but serotonin syndrome is very rare.

Dr. Hare commented on a letter provided by Dr. Lynn Webster. Dr. Webster stated that he feels that this drug has less abuse potential. Dr. Hare has not seen anything in the literature, nor has he had any clinical experience that this is the case. It certainly has not been marketed this way. Dr. Hare felt that the Board should not take this claim into account unless someone can provide good evidence to support it.

Dr. Cowley stated that he has read that it actually has a higher potential than tramadol. Dr. Hare agreed, because it is a much stronger drug. Tramadol is not scheduled, and Nucynta is CII.

Dr. Hare stated that the other limits were put into place to accommodate chronic use. He did not know if this was appropriate for the short-term use for which Nucynta was indicated.

Jennifer Steuffel with Ortho-McNeill addressed the Board. She summarized a 90-day safety study for Nucynta, and other safety information for Nucynta. The 90-day safety study was a flexible dose study.

Mark Balk stated that one of the pieces of the PA was to rule out concomitant use of serotonergic agents. He suggested narrowing down the criteria to rule out concomitant use of MAOI's. Brad Hare also stated that requiring a failure of oxycodone was too narrow. All conventional analgesics should be included with an "or" statement in the failure requirement. A broad

statement of requiring failure of a short-acting opioid should be sufficient.

Dr. Hare moved to accept the PA criteria as amended. Dr. Yau seconded the motion. The motion passed with unanimous votes by Neal Catalano, Dr. Lehmann, Dominic DeRose, Mark Balk, Dr. Hare, Kathy Goodfellow, Dr. Yau, Dr. Cowley, and Dr. Knudson.

4. Candes class Review: Mariann Paul of the University of Utah Drug Regimen Review Center addressed the Board, and presented the University of Utah's evidence for the echinocandin class and PA review for Candes. They recommended that the echinocandins be treated as a class, rather than singling out Candes for PA.

Mark Crosby from IHC home care addressed the Board. He presented data from IHC, and stated that the medications are usually started in the inpatient setting. All of the 53 patients over 2 years served by his organizations that received it in the last year had been started on an inpatient basis, and were ordered with an infectious disease consult. He questioned the need for a PA under the circumstances, and because the FDA labeled indications had changed so much since it was introduced.

Cary Green, Hospital Customer Manager from Merck, addressed the Board. He gave a history of the indications of Candes since it was introduced in 2001. He presented new evidence for safety and efficacy.

Mark Balk said that he thought it was appropriate to consider echinocandins as a class, but other antifungals as well, due to the treatment guidelines. He proposed either having a class PA or removing the PA altogether. He was concerned that keeping the class PA could delay care for a very serious infection. There are very few PA requests for Candes with a very low denial rate, so he questioned whether or not a PA was necessary. The Board agreed.

Mark moved to remove the Candes / echinocandin PA. Neal seconded the motion. The motion passed with unanimous votes by Neal Catalano, Dr. Lehmann, Dominic DeRose, Mark Balk, Dr. Hare, Kathy Goodfellow, Dr. Yau, Dr. Cowley, and Dr. Knudson.

Duane commented that the PA was originally placed to guard against inappropriate prophylactic use. The Board agreed to review utilization at a later date to make sure that this was not occurring.

5. Insulin Quantity Limits: Lisa Hulbert addressed the Board. Insulin utilization was reviewed, and some very high quantity prescription quantities were found, with up to 15 pens or 8 or 9 vials. Furthermore, it has been discovered that there is a secondary market for diabetes test strips. This raises the concern for fraud, and Medicaid would like to place a quantity limit that could be overridden with a phone call to the pharmacy team in cases of medical necessity. Lisa proposed a number of four vials per month.

Some Board members have had clinical experience with doses up to 100 units per day in cases of severe insulin resistance, and examples of these cases were given. They also thought that there may be cases of billing errors rather than fraud, but agreed that some sort of limit could be

helpful to prevent that.

Kathy Goodfellow suggested setting the limit on the lower side to err on the side of caution, and raising it if the phone calls to force claims became excessive.

Tim asked the Board if there was a standard for daily numbers of glucose tests. The higher end of the range for pumpers is 8-10 times per day when making dosage adjustments. People that are well-controlled may test 3-4 times per day or as low as twice per week.

Mark Balk asked if test strips needed to be addressed. That has already been done.

The Board did not feel that the diversion with insulin would be as severe as with test strips, due to legal implications.

Jennifer Zeleny asked about the 6-8 vial prescriptions for the U-500. Tony felt that this was excessive.

Dr. Knudson asked if there was another use for test strips that he was not aware of. It seemed strange to him that it would be diverted. Jennifer explained the research that she and Alex Yei had done into the Cash For Diabetes Strips site, and provided an overview of his internet business model. Other Board members talked about how people who were getting strips on insurance were re-selling them at the Redwood Road swap meet.

A member of the audience stated that he had experiences when he owned his pharmacy where Medicaid eligible clients would come in to buy large quantities of insulin and share with their non-Medicaid family members.

Dr. Yau stated asked if there is a combined total daily dose that would be appropriate for a limit. The Board did not think that this was a good way to control it, because some patients with pumps use only short acting. Five vials or five boxes of three pens should be an adequate number to cover most peoples' monthly needs.

Neal moved to make the limit for each type of insulin up to 5 vials or 15 pens per month. Kathy seconded the motion. The motion passed with unanimous votes by Neal Catalano, Dr. Lehmann, Dominic DeRose, Dr. Hare, Kathy Goodfellow, Dr. Yau, Dr. Cowley, and Dr. Knudson. Mark Balk recused himself from voting because Sanofi has an insulin product.

Next meeting set for November 12, 2009

Meeting adjourned.

There were no petitions for the DUR Board Prior Approval Subcommittee to consider this month.

Minutes prepared by Jennifer Zeleny