



**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.**  
**Bradley Pace, PA-C**  
**Cris Cowley, M.D.**

**Wilhelm Lehmann, M.D.**  
**Tony Dalpiaz, PharmD.**  
**Dominic DeRose, R.Ph.**  
**Joseph Yau, M.D.**

**Board Members Excused:**

**Neal Catalano, R.Ph.**  
**Joseph Miner, M.D.**

**Peter Knudson, D.D.S.**  
**Brad Hare, 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.**  
**Thomas Jones, M.D.**

**Rick Sorenson, R.N.**  
**Tim Morley, R.Ph.**  
**Amber Kelly, R.N.**  
**Carol Runia**

**Other Individuals Present:**

Roy Lindfield, Schering  
 Steve Farmer, Amgen  
 Jeff Buel, J&J  
 Alan Bailey, Pfizer  
 Mark Crosby, IHC

Reed Murdoch, Wyeth  
 Ben Campbell, DRRC  
 Bruno Frampton, Genentech  
 Katy Ramsay, U of U  
 Adam Sosa, DMJSA

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

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- 1      **Review and Approval of Minutes:** Tony Dalpiaz moved to approve the minutes. Brad Pace seconded the motion. The motion was approved with unanimous votes by Kathy Goodfellow, Mark Balk, Dominic DeRose, Wilhelm Lehmann, Brad Pace, and Tony Dalpiaz.
  
- 2      **P&T Committee Update:** Duane Parke addressed the Committee and provided an update on the PDL. The P&T Committee reviewed 3<sup>rd</sup> generation cephalosporins last month, and recommendations for the class are currently with management.
  
- 3      **Avastin PA Criteria Review:** Lisa Hulbert addressed the Board and provided updated information regarding the FDA approved indications. A proposed changed PA form was provided to the Board.

Mark Balk stated that the macular degeneration criteria should be removed from the oncology criteria

for ease of use of the form. He did not have any changes to suggest for the criteria, but wanted to change the format of the proposed PA criteria sheet.

Mark Balk moved to adopt the proposed criteria changes and formatting changes. Kathy Goodfellow seconded the motion. The motion was approved with unanimous votes by Kathy Goodfellow, Mark Balk, Dominic DeRose, Wilhelm Lehmann, Brad Pace, Joseph Yau, and Tony Dalpiaz.

4 Lamisil PA Criteria Review: Lisa Hulbert addressed the Board. Lamisil is up for the 9 month review of PA criteria. The Board was provided with before and after utilization figures for the drug. The Board was also provided with the criteria that were approved 9 months ago.

Kathy Goodfellow asked if it was worth it for Medicaid to keep the drug on PA now that it had gone generic and was so inexpensive.

Rick Sorensen stated that when Lamisil first went on PA there were a small number of requests for off-label use. That has slowed down significantly. Most of the requests are pretty straightforward.

Lisa Hulbert stated that originally people were being put on the drug and left on it for long periods of time. This was a safety concern. Dominic asked if this could be controlled with a computer edit rather than a PA. Lisa stated that the computer system was obsolete, and handling such an edit might not be feasible. Handling it through a PA would be easiest.

Dominic DeRose moved to keep the PA as is. Mark Balk seconded the motion. The motion was approved with unanimous votes by Kathy Goodfellow, Mark Balk, Dominic DeRose, Wilhelm Lehmann, Brad Pace, Joseph Yau, Cris Cowley, and Tony Dalpiaz.

5 17-P Alphahydroxy PA Criteria Review: Dr. Thomas Jones of Utah Medicaid addressed the Board. He has no conflicts of interest to disclose. The purpose of 17-p is that it is a synthetically produced progesterone. Progesterone is produced throughout pregnancy until the end when it drops off rapidly and has some participation in the onset of labor. There comes a time when keeping a pregnancy viable inside the uterus is problematic. About 12% of all pregnancies will end up delivering before the 37<sup>th</sup> week. A lot of those are ones that are classified as iatrogenic, or due to some other illness that caused the doctor to intervene and have the child come prematurely. Of the 12%, about 20% fall into that category. Some of them are due to failure of the cervix. About 80% are spontaneous. The concern is to be able to prevent this 80%. Progesterone has come in and out of use since the 1950's.

There have always been questions about what can be done to prevent premature labor. Some interventions have included shortening workers' shifts, discouraging smoking during pregnancy, having children at least 1 year apart, and managing infections. There are other risk factors that are non-modifiable, such as race, age, problems with the cervix, etc. One of the ways to modify these risks is to administer progesterone.

Medicaid has a Prior Authorization available for 17-p for clients with a history of prior pre-term labor, to be started between 16-23 weeks. One of the things that is known about progesterone is that once a client goes into labor, administering progesterone will not stop it. If, however, there is a history, then it does effect. The question is when to start and stop administering it. The University of Utah has statistics available showing that a 34 week pregnancy is just as viable in their hands as a

full-term pregnancy. In the rural districts, patients need to be sent out.

The question is whether or not a patient has to be started between 16-23 weeks, or whether it could be started later. One paper that Lisa showed him indicated that a patient could start as late as 26 weeks. This appears to be the case, although there are some studies that indicate that a patient could go into labor before that. A literature search showed that ACOG recommended initiation of therapy as early as possible after 16 weeks, and discontinuing after 35 weeks or later. The main function of progesterone is to calm down the uterus to prevent early contractions.

Dr. Jones presented an article from Up to Date showing an article that supports current Utah Medicaid PA criteria. This is one of the best articles he was able to find on the subject. He also presented a handout from a Utah Medical Association Practicing Physicians' Forum. It was presented by Dr. Scott Barton in support of using 17-p to reduce costs.

In summary, he believes that Utah Medicaid should be providing coverage for the drug. He believes that the PA criteria are in order, and he believes that the timeframe for initiating therapy is appropriate. It does work through the 34<sup>th</sup> week or later until other factors come into play in determining whether or not it is time to get the baby out.

Tim Morley asked if there is any advantage demonstrated by later term administration of the drug, for example 24-29 weeks. Dr. Jones stated that if the patient has had one premature baby, it is recommended that the patient starts early. If the patient has a history of premature labor and they have not yet gone into labor at 30 weeks, it should be started.

Lisa Hulbert asked if he would support initiation of therapy even at 30 weeks. Dr. Jones stated that if they have a history of pre-term labor, it would be appropriate to start it if they have not yet gone into labor. Once they have gone into labor, it is no longer appropriate to initiate therapy. There are other treatment options that are available once the mother goes into labor.

The Board was provided with the current Medicaid PA criteria, and a copy of the article that a provider sent requesting that therapy could be started later. Dr. Jones indicated that he would be in favor of allowing initiation later during the course of pregnancy.

Mark Balk stated that provisions for coverage were allowed by the DUR Board, in this case, for a non-FDA approved drug based on the fact that one large randomized controlled clinical trial was available showing that this therapy is efficacious if started during weeks 16-23 of gestation. The article provided in support of initiating therapy was interesting, but was an observational trial. Expanding PA criteria based on that evidence would be precedent setting and he does not believe that the DUR Board should do that.

Dr. Jones stated that the big problem with requiring a randomized controlled clinical trial in this day and age is that no one will do it for fear of getting sued. The only way that data will be gathered in this patient population will be through retrospective analyses. Mark Balk stated that the original article in the New England Journal of Medicine was prospective.

Dr. Jones thought that there might be many reasons for a woman to not show up for prenatal care until the 25<sup>th</sup> week or later, so it would be advisable for Medicaid to provide initiation of therapy later. Even though the best time to start it would be at the 16<sup>th</sup> week, it could be started and have an

effect if started before the woman goes into labor. He did not feel that practicing physicians would be willing to go through an appeal process, or than an appeal process could be handled promptly enough for a woman past 23 weeks gestational age who is asking for therapy to be initiated past 23 weeks. Dr. Jones stated that he will look into how commercial payors are handling initiation of therapy for this product and let the DUR Board next month.

Mark stated that he does not necessarily want to deny coverage for this product for a woman past 23 weeks of gestational age, but that he does not want to set a precedent by changing criteria without a prospective randomized controlled clinical trial. The Board agreed, and stated that they would like to look at an appeal for a patient past 23 weeks gestational age to set a precedent to handle an appeal outside of criteria for this particular product, rather than set a precedent on changing criteria with inadequate evidence.

Dr. Lehmann stated that there are also a fair number of pregnancies handled by family practitioners. He asked the Board to think about whether or not the PA should be extended to family practitioners. Lisa stated she will see if any requests have been denied due to specialty.

Duane suggested that if this discussion is tabled, Medicaid could see how other states are handling the PA process. Mark Balk stated that the last time he looked into this, only South Carolina was providing coverage and using the same criteria.

The Board also suggested re-evaluating the process for deciding whether or not to only use randomized controlled clinical trials. Lisa stated that this was based on OBRA 90 legislation, and that the exact wording of this legislation was not randomized controlled clinical trial necessarily. She will bring back the exact wording of the legislation. She was also asked to provide a legal opinion on expanding coverage based only on observational studies.

Dr. Cris Cowley moved that this discussion be tabled until OBRA 90 language and a legal opinion on extending coverage could be provided by Medicaid. Mark Balk seconded the motion. The motion was approved with unanimous votes by Kathy Goodfellow, Mark Balk, Dominic DeRose, Wilhelm Lehmann, Brad Pace, Joseph Yau, Cris Cowley, and Tony Dalpiaz.

6 Federal DUR Report: Lisa Hulbert addressed the Board. The Board was provided with the DUR Annual Report that was submitted to the federal government. She offered to answer questions pertaining to the report.

Next meeting set for October 8, 2009  
Meeting adjourned.

The DUR Board Prior Approval Subcommittee convened and considered 2 petitions and approved 1. The second petition was tabled pending the receipt of more information from the requesting physician.

Minutes prepared by Jennifer Zeleny