



STATE MEDICAID DUR BOARD MEETING
 THURSDAY, August 14, 2008
 7:00 a.m. to 8:30 a.m.
 Cannon Health Building
 Room 125



MINUTES

Board Members Present:

Mark Balk, Pharm, D.
Derek Christensen, R.Ph.
Dominic DeRose, R.Ph.
Joseph Miner, M.D.
Conlin VanOrman, M.D.

Neal Catalano, R.Ph.
Tony Dalpiaz, Pharm.D.
Bradford Hare, M.D.
Wilhelm Lehmann, M.D.
Joseph Yau, M.D.

Board Members Excused:

Peter Knudson, D.D.S.

Bradley Pace, PA-C

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

Richard Sorensen, R.N.
Tim Morley
Lisa Hulbert
Carol Runia

Merelynn Berrett, R.N.
Jennifer Zeleny
Duane Parke

Other Individuals Present:

Craig Boody, Lilly
Erica Brumleve, GSK
Lois Bloebaum, UDOH, MCH
Tony Molchan, Abbott
Rafaele Villella, ALO

Dan Heincy, R. Ph.
Reed Murdoch, Wyeth
Melissa Archer, U of U
Jeff Buel, J&J

Meeting conducted by: Colin VanOrman, M.D.

1. Minutes for July 10, 2008 were reviewed, corrected and approved.
2. Opiate Analgesics - Review of Quantity Limits: Tim Morley addressed the Board. The Board was provided with handouts. There is a great deal of interest in the appropriate usage of opiate analgesics in the state of Utah. There is a prescription pain management task force that has been organized by the Department of Health. It has an advisory committee with many stakeholders throughout the state that participate on this committee. They met on the day before this meeting. Principally, their focus is on appropriate usage of narcotic analgesics. They have come out with some guidelines that they are trying to develop for the state. The Board was provided with a preliminary draft of the guidelines.

Dr. Hare stated that the American Pain Society, the American Academy of Pain Medicine, and a number of governmental agencies wrote very extensive guidelines approximately 10-15 years ago for the treatment of acute and cancer pain management. These have been revised a number of times, most recently one to one and a half years ago. He was concerned that this committee may be working independently of this group. Other states have attempted to do this, and met with controversy. This group should be aware of the other work that has been done throughout the country and the world on this topic.

Tim Morley stated that this draft was included for the Board's information and to allow for comment. Dr. Hare's comments will be relayed to the committee. Many experts and substance abuse centers are represented on this committee.

Dr. Hare mentioned that Dr. Art Lipman, from Utah, has been involved in this at a national level. Tim stated that he is working on this state committee as well.

Tim compiled extensive information on this topic at the request of the Board. This had been prepared for a previous meeting and may not be up to date in all the areas due to the time constraints involved in preparing this material. Medicaid clients go on and off Medicaid coverage, so there may be windows in some of the information that cannot be accounted for. The information is prepared as well as possible under the circumstances. A summary of the current restrictions is included as well. The handouts were reviewed with the Board.

There has been a lot of interest within the prescription pain management task force in methadone and long-acting formulations, particularly when used for treating chronic pain. There is a sense that we have an excessive number of accidental deaths due to legitimate usage. The state epidemiologist was at the pain management meeting. The goal in 18 months or a year is to reduce the number of accidental deaths by 15%. Medicaid's concern is to determine whether we have quantities authorized that may contribute to the problem.

Tim Morley continued to review the handout with the Board. The Board asked if cancer patients were separated from the other patients. The cancer patients were counted separately. Of the 34 patients exceeding monthly limits, it appears that all are cancer patients.

Dr. Yau asked how buprenorphine was counted in these figures. Buprenorphine is included in the total figures for the drug classes, but was separated on the breakdown by individual product in each class.

The Board asked if Medicaid has data for patients who purchase opioid pain medications without using their Medicaid benefit. Medicaid does not have access to these data.

The Board asked if any data were available to indicate whether Medicaid clients were involved in any of the deaths that occurred due to legitimate use of pain medications. This data is not available. However, it is possible that Medicaid is contributing to the "pool" of opioid pain medications in the community that is available for illicit use.

Dr. Hare stated that the original limits were established based on what the Board felt was safe and reasonable. Unfortunately, within the limits that were set, if there are patients or physicians that do not want to use the medications legitimately, it can be done. What the Board can do as a committee is fairly limited.

Dr. Yau also felt that the cumulative quantities are correct. He was also concerned about the concomitant use of benzodiazepines. He feels that this has probably led to more deaths. Tim stated that the pain committee talked about this yesterday, as well. The Board has not yet restricted the concomitant use of benzodiazepines. The data on concomitant use provided to the Board did include benzodiazepines in the CIV category.

Dr. Hare felt that the limits that have been established are reasonable. Most patients can be managed within the guidelines. A patient should not need more than one long acting and one short acting pain medication at a time. If a patient is difficult to treat and needs an unusual combination of medications to achieve pain control, they can petition the Board. The Board will consider exceptions to policy in these cases. The one other drug that has become available since these limits were established is Actiq. There should be a hard and fast rule that there is no place for Actiq outside the treatment of cancer pain. Dr. Hare sees a lot of it being prescribed for non-cancer pain. He feels it is inappropriate for that purpose.

Tim Morley stated that Medicaid requires an ICD.9 diagnosis code for cancer for payment of both Actiq and Fentora. Medicaid also waives quantity limits for a cancer diagnosis, and allows for only one long acting and one short acting agent at a time. The only limitation that Medicaid does not have of what has been discussed is a restriction of the concomitant use of a benzodiazepine and a CII pain medication.

Dr. Hare felt that regulating the concomitant use of CII pain medications and benzodiazepines would be fairly difficult. Many chronic pain patients have comorbid anxiety disorders. It is not standard to immediately put them on a benzodiazepine, but some patients do seem to benefit from longer acting benzodiazepines with their pain medications. It can be a potentially dangerous combination, but is sometimes also safer. To have an absolute restriction is going to be difficult. Certainly, Medicaid should educate on the dangers of the combinations with muscle relaxants, CNS depressants, sleep drugs, etc.

Derek asked if it is possible to restrict the use of benzos to one agent at a time. They are restricted to 120 units per month. Dr. Yau felt that the quantities limits are reasonable, but one cannot stop a patient from taking them inappropriately once a correct number is prescribed.

Mark Balk stated that on the combinations with CIV medications, in looking at the numbers it seems that 5% of the total number that are on CIIs are receiving CIVs and 3% of the total number on CIIIs are receiving CIVs. He asked if these are small enough percentages to tolerate. Tim stated that the Board should determine whether this is reasonable.

The Board asked for the total number of deaths that the coroner's office was looking at. There were 519 deaths that were drug related.

Tim Morley asked that the Board determine whether or not the current limits were adequate. He also asked that the Board determine whether Medicaid has appropriate limits for methadone.

The Board noticed that there were certain recommendations being made as to the qualifications of physicians prescribing methadone. It is not within the purview of the Board to control that. It would need to happen at the state level.

Dr. Hare stated that years ago the Board attempted to set a threshold for reasonable doses. The Board needs to determine whether or not the limits were still reasonable. Some people were unhappy with the limits. Other physicians were relieved when Medicaid established these limits so they would not need to write for them.

Tim stated that there is some question as to whether or not it is reasonable for the same 90 tablet per month limits to be applied to 10mg tablets and 80mg tablets. In the past, Medicaid would need to override to get to doses like 60mg before those tablets were made. The Board felt that those exceptions should be fairly easy to deal with. The limits were originally set to prevent doses exceeding certain number of milligrams per day. The Board tried to use equianalgesic doses of common drugs when establishing these limits. Medicaid did not use these limits exactly as established. Medicaid only counts total numbers of pills rather than total numbers of milligrams.

Duane Parke stated that the limitations of the computer system have only allowed for Medicaid to track the total number of pills. He did not know if the system could handle this higher-level computation at this time. All of the limitations are tied to the point of sale computer system. It may be possible to expand the limitations, but a discussion with the programmers would need to take place to determine what could be done.

Mark Balk asked if the computer system was capable of counting up the total number of milligrams. Tim stated that the computer system will need to identify and differentiate the strengths for the NDCs. This would require a fairly sophisticated algorithm. The computer system can expend a maximum of 3 seconds adjudicating a single claim. This is a national standard that Medicaid cannot exceed. The last time that the programmers attempted to set this up, Medicaid was over the maximum amount of time. Medicaid still has an old system. Five years from now, there should be a new point of sale system that may be capable of carrying out this calculation.

Dr. Hare stated that for long-term use, it makes more clinical sense to limit the number of short acting opioid analgesics to 4 doses per day. The computer system could probably be changed to limit the number of short acting opioids to 120 if the patient has had a long acting opioid medication in the last 30 days. However, the Board did not feel that the data provided demonstrated a need to change this limitation.

The Board asked if it was possible to place a limitation that would not allow greater than 120 dosage units for more than 3 months in a row, to account for acute injury needs. Medicaid would need to ask the programmers if the computer system could be programmed for this.

Dr. Hare asked if the limitation placed on Actiq and Fentora, requiring an ICD.9 diagnosis code for cancer, was working. The limitation appears to be working, although there was some initial concern in the provider community when the limitation was first placed.

Dominic DeRose made a motion to leave the limits as they are. Mark Balk seconded the motion. The motion passed with unanimous votes by Mark Balk, Neal Catalano, Derek Christensen, Tony Dalpiaz, Dominic DeRose, Bradford Hare, Joseph Miner, Wilhelm Lehmann, Colin VanOrman, and Joseph Yau.

3. 17-p Information and Discussion: Tim Morley addressed the Board. The Board has previously considered this item. The Board had requested that Medicaid return with

information. This is the injectable formulation compounded by 4 compounding pharmacies on the Wasatch Front, used to prevent pre-term labor. There used to be a commercial product available; there isn't any more. The pharmacies are using a bulk compound powder and compounding it. The pharmacies that are doing it have been USP 797 criteria certified to do that. Medicaid has included their certifications for the Board, and some of the information that was associated with their certifications. This product seems to fill a need, and there is a lot of interest in it. Even though that powder does not carry an FDA approved indication for that, there is enough experience in the medical community with its use that it would probably warrant Medicaid paying for it. Medicaid has been paying for one of the bulk products in the interim to meet the needs that have been highly critical. Medicaid would like the DUR Board to at least weigh in on it. If Medicaid is going to pay for a non-FDA approved use, it would be nice to have DUR Board support.

Dr. Hare asked if there were studies to support the use of this compound. The ACOG guidelines regarding this product were provided to the Board. There are also some studies supporting the use of the product. That has not been the problem. The real issue is whether Medicaid can justify this non-FDA approved use.

The Board stated that Altius has a high-risk OB case manager to manage patients on this product. Does Medicaid have something similar? The Medical Director of Medicaid is a former OB. There is no one set up specifically for case management. The Board wondered if there was a potential for abuse for this drug because it is the "hip" new drug, if it was not used by an experienced specialist. This drug needs to be used in a very controlled fashion, so it should not be available to everyone.

Mark Balk stated that this is part of the criteria for the PA process. Looking at the three questions: Does it impact quality of care to put a PA on it?; Is there potential for abuse or misuse?; Is there a medical reason? If the answer is yes to all of those, then the Board should probably put a PA on it. The Board needs to go through all of those steps in the process, but this is a great example of where a PA would be very appropriate. There are specific criteria on when this therapy should be initiated at 16-21 weeks. There needs to be a history of pre-term labor at 20-36 weeks gestation. Looking at pharmacies that are putting this together, the pharmacies need to be 797 certified. Initially, payment could be limited to the 4 pharmacies that have supplied evidence of 797 certification. Eventually, payment could be expanded to other pharmacies that can demonstrate 797 compliance. North Carolina Medicaid has a 17-p project that has a lot of education built around it. Medicaid could look at those criteria and formulate proposed criteria for the Board.

Tim Morley stated that Medicaid is recommending 4 criteria for a PA that were provided in a handout to the DUR Board.

Dr. Miner asked if it was necessary to limit initiation of therapy to between 16-20 weeks gestation. Certainly it should not be started prior to 16 weeks gestation, but it could be started after 20 weeks gestation. Mark Balk stated that if someone comes in late for prenatal care, it could be started as late as 23 weeks. The injections need to be given for a minimum of 5 weeks. The injections should be given through the end of the pregnancy.

The Board asked if the patient would be responsible for compounding fees, or if that would be included in Medicaid's payment structure. Compounding fees would be included in the payment structure by Medicaid.

Dr. Miner moved that Medicaid pay for 17-p under the proposed criteria, with the change that therapy be initiated between 16-23 weeks gestation. Mark Balk seconded the motion. The motion passed with unanimous votes by Mark Balk, Neal Catalano, Derek Christensen, Tony Dalpiaz, Bradford Hare, Joseph Miner, Wilhelm Lehmann, Colin VanOrman, and Joseph Yau.

Next meeting set for September 11, 2008

Meeting adjourned.

The DUR Board Prior Approval Subcommittee convened and considered two petitions.