



STATE MEDICAID DUR BOARD MEETING
THURSDAY, June 09, 2009
7:00 a.m. to 8:30 a.m.
Cannon Health Building
Room 125



MINUTES

Board Members Present:

Mark Balk, PharmD.
Neal Catalano, R.Ph.
Derek Christensen, R.Ph.
Tony Dalpiaz, PharmD.
Joseph Yau, M.D.

Peter Knudson, DDS
Wilhelm Lehmann, M.D.
Joseph Miner, M.D.
Dominic DeRose, R.Ph.

Board Members Excused:

Bradford Hare, M.D.

Colin VanOrman, M.D.

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

Tim Morley, R.Ph.
Lisa Hulbert, R.Ph.
Jennifer Zeleny, CphT, MPH
Debbie Harrington, R.N.

Merelynn Berrett, R.N.
Duane Parke, R.Ph.
Carol Runia
Richard Sorenson, R.N.

Other Individuals Present:

Carrie Ann Madden, DRRC
Alan Bailey, Pfizer
Lori Howarth, Bayer

Joanne LaFleur, U of U
Sue Heineman, Pfizer

Ann Gustafson, GSK
Chris Sheard, U of U

Meeting conducted by: Wilhelm Lehmann, M.D.

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- 1 Minutes for May 2009 were reviewed. Brad Pace made a motion to approve the minutes. Dominic DeRose seconded the motion. The motion was approved with unanimous votes by Dr. Miner, Neal Catalano, Tony Dalpiaz, Brad Pace, Dominic DeRose, Dr. Lehmann, Derek Christensen, Dr. Yau, and Mark Balk.
 - 2 P&T Committee Report: Duane Parke addressed the Board. Last month the Committee considered nasal corticosteroids and osteoporosis agents. A decision on these classes is pending approval of the administration. The Medicaid Pharmacy website has the PA form for non-preferred drugs. The Prior Approvals have a 24-hour turnaround. The SSDC purchasing pool will be meeting later this month to negotiate PDL rebates at the end of June.
 - 3 Housekeeping: Lisa Hulbert addressed the Board. A few members of the DUR Board have reached their term limits. Awards for service were handed out to Dr. Miner, Dr. Hare, Dr. VanOrman, and Derek Christensen. The Pharmacy Association and Medical Association have nominated new

members that will be seated in a future meeting.

4 Suboxone Review: Joanne Lafleur from the University of Utah College of Pharmacy presented a utilization review of patients who have received Suboxone on Medicaid.

Lisa Hulbert stated that a Medicaid ran a query on Suboxone utilization to determine whether the prescribers ordering the medication had the X-DEA number. No claims that have paid in the last 3 months have had the X-DEA number, but it is difficult to determine whether or not the prescribers ordering the medication have one because Medicaid's claim system does not adjudicate claims based on the DEA number. Medicaid could require this in the future.

In 2006, Jennifer Zeleny worked for on a survey of Suboxone utilization and found that some prescribers self reported ordering it off-label for pain. Additionally, the Pharmacist's Letter has recently published an article about off-label use for pain. The medication has a lot of issues with respiratory depression and hepatotoxicity. Medicaid would like the Board's input on PA criteria or some other controls on this medication. Medicaid is paying a lot of claims on opioids along with Suboxone, which is concerning. With a PA, Medicaid can ensure that patients are tapering the dose. The published guidelines state that the taper schedule should last a maximum of 8 weeks.

Mark Balk asked if Suboxone was addressed in the opioid pain management work group for the state. Tim stated that he did not recall seeing any recommendations on the use of Suboxone for pain.

Dr. Yau stated that this drug is very useful for both treatment and maintenance of opioid dependency, but he does not understand how the drug could be used for pain control. The difference receptors involved have been explained to him, but he still does not understand and would like the expertise of a person who has experience with using it for that.

Dr. Yau asked if a prescriber needed by law the X-DEA number to prescribe it. This is a requirement to prescribe it for opioid dependence, but any prescriber with a DEA number can prescribe it off-label for pain. Dr. Miner felt that Medicaid should not pay for this without the X-DEA number, since Medicaid should not be covering off-label use.

Dr. Yau stated that the X-DEA number indicates that the prescriber has attended training on how to induce and manage opioid withdrawal. His second concern about limiting the amount of time for which Suboxone is paid goes back to the question of whether or not treatment for an addiction should be episodic or should be treated as a chronic condition. Tapering could certainly be tried, but some people will need to be maintained chronically. His third concern relates to concomitant opioid use. The state has recently had some good news reported with opioid-related deaths declining. Certainly there is a relationship between deaths and concomitant use of benzodiazepines and opioids, because the combination is deadly. To control the concomitant use of opioids would certainly address some of the concerns related to respiratory depression. He was

wondered, getting back to his concern about the usefulness of Suboxone in pain control, if concomitant use of Suboxone and opioids would provide adequate pain control and possibly prevent some of the respiratory depression. He stated that he does not understand the chemistry of it.

The Board felt that the ICD.9 code was a nuisance for the pharmacies, and did not generate accurate data for Medicaid. A PA would be preferable. Also, an X-DEA number is as accurate as an ICD.9 code.

The Board stated that if Medicaid imposes a PA, it should be given for at least a year to address Dr. Yau's concern of chronic management. Lisa replied that based on the guidelines provided by the manufacturer of Suboxone, the most lenient taper schedule should last 8 weeks. The problem is that Medicaid is seeing this medication used for pain, and continued concomitant use of opioid narcotics. Also, the DOPL controlled substance database is not as current as Medicaid claims data, so treating physicians do not always have access to whether or not a patient is continuing to seek opioid pain medications.

Tim stated that there was obviously a perception that this agent required special handling skills for a prescriber to use it effectively and responsibly. Does Medicaid want to direct its use in that fashion to make sure that the dangers associated with inappropriate prescribing are being avoided?

Dr. Yau stated that the training associated with this drug has more to do with the office-based induction of this drug. With that, there is a sense of how safe this medication can be. There is really no skill training with how to maintain this medication over time. In that respect, it is like other medications. The skill that is taught is how to have a patient to come into the office and have the medication induced for detoxification. The tapering guidelines relate to how to reduce and discontinue the medication safely. This does not mean that the medication needs to be tapered and discontinued. Some patients will require chronic treatment for their addiction. He feels that this is a better medication for that purpose than methadone.

The Board did not feel, based on the fact that Medicaid should not be paying for off-label use, that use for pain management should even be addressed. That being said, physicians should have the X-DEA number that indicates that they have some training in managing opioid addiction. Additionally, Medicaid may want to consider whether or not the physician has the training to deal with addressing the lifestyle issues of the patient that usually go along with addiction.

Mark Balk stated that Medicaid does always have the option of approving off-label use on a case-by-case basis if evidence is available to support the use. For labeled use, the prescriber does need the X-DEA number, so he is comfortable restricting its use to those prescribers.

The Board felt that Medicaid should contact Dr. Hare for his opinion, since he is usually very outspoken and willing to provide advice on issues related to pain management. It is possible that some of the off-label use comes from patients requesting the medication for pain, and he would know about such trends.

Mark Balk stated that Talwin NX, if it is still available, still provides an option for an agonist/antagonist combination for pain relief. The community pharmacists on the Board confirmed that it is still available.

Dr. Miner moved that Medicaid only cover Suboxone if it is prescribed under an X-DEA number, and if no other opiates are being prescribed with it. Mark Balk seconded the motion.

Lisa stated, as a point of clarification, that the only way to enforce this would be through a prior authorization. Dr. Miner and Mark Balk stated that this was fine.

Dr. Yau stated that this will probably lead to petitions for use for pain, and concomitant use with opioids. Dr. Hare should advise how best to handle those. Lisa stated that the analgesic component of Suboxone is available for pain as Subutex.

Derek stated that in his conversations with psychiatrists treating patients with Suboxone, and there are instances where these patients have an episode of acute pain that needs to be treated. He asked if this motion would exclude coverage for prescriptions of short-term opioids for acute pain.

Tim stated that prescriptions for this group could be overridden on a case-by-case basis. Criteria would be developed to accommodate these overrides.

Lisa summarized that the PA would be limited to prescribers with an X-DEA number, rule out the concomitant use of opioids except for acute pain on a case-by-case basis, and be limited to a taper schedule of 8 weeks.

The Board wondered how emergency supplies of opioids for acute pain would be handled when Medicaid was closed. One way to handle it would be to guarantee payment under the 72-hour emergency supplies. The other way would be to allow small quantities of short-acting opioids with no restriction. The Board felt that it would be appropriate to allow small quantities of short-acting opioids. Tim felt that the computer system could handle such an edit, and that the system could check utilization of opioids prior to paying a Suboxone claim.

Duane suggested that the University of Utah do a retrospective report on opioid utilization after a Suboxone PA is placed.

Lisa stated that Medicaid would report on utilization 9 months after a PA is placed anyway.

Dr. Lehmann asked Dr. Miner to restate the motion with the adjustments that were made during discussion. Dr. Miner stated that Suboxone will only be paid if the prescriber has an X-DEA number, if there are no ongoing long-term opioids prescribed with it, short-term opioids for acute pain will be permitted. Mark Balk seconded the motion. The motion was approved with unanimous votes by Dr. Miner, Neal Catalano, Tony Dalpiaz, Brad Pace, Dominic DeRose, Dr. Lehmann, Derek Christensen, Dr. Yau, Dr. Knudson and Mark Balk.

5 Hepatitis C Class Review: Dr. Joanne Lafleur and Dr. CarrieAnn Madden from the University of Utah addressed the Board, summarized information prepared by the University on the topic, and outlined policy recommendations.

Duane Parke asked if the subset of patients who would respond at 72 weeks could somehow be identified. Joanne stated that these patients could be identified by their viral response at 12 and 24 weeks of therapy. If there was a PA requirement, the physician would need to check the patient for a viral response and document that.

Mark asked if the response at 24 weeks in late responders is the same as the 2 log drop seen in rapid responders. CarrieAnn and JoAnne were not sure about the exact decrease that should be seen and at what point in the late responders. They will research this.

The Board asked about the need for quantity limits on the Pegasys kits. The University discovered some irregularities in that 4 kits were sometimes being billed as a 4 week supply. This is believed to be either fraudulent or a billing error, since one kit of 4 syringes is supposed to be a 4 week supply.

Dr. Lehmann asked if the University provided specific recommendations for the use of growth factors for patients in Hepatitis C. Recommendations were provided. Mark Balk did not feel that the PA on the growth factors should be dropped, but that the Board should make them available when needed on an individual basis. This can be accomplished through the PA process.

Dr. Miner moved to adopt the summary of recommendations as presented by the University. Derek wanted to also add that Medicaid should do an educational piece in the Amber Sheet on Pegasys billing. He felt that most of the excessive quantities were due to legitimate errors rather than fraud. Mark Balk seconded the motion. The motion was approved with unanimous votes by Dr. Miner, Tony Dalpiaz, Dr. Lehmann, Derek Christensen, Dr. Yau, Dr. Knudson and Mark Balk.

6 Vitamin D Coverage: Lisa Hulbert addressed the Board. Medicaid has identified two NDCs that are pay rebates through CMS. These will be opened up for coverage in the system as per the DUR Board recommendations.

7 Proposed Resolution on Cost Issues: Tim Morley addressed the Board. The Division Director of Medicaid requested that a resolution to be able to discuss cost be provided to him. He will then forward it to the Legislature. A draft proposal was provided to the Board, but it will not be discussed until next month due to time constraints.

Next meeting set for July 9, 2009
Meeting adjourned.

The DUR Board Prior Approval Subcommittee convened and considered 5 petitions.

Minutes prepared by Jennifer Zeleny