



STATE MEDICAID DUR BOARD MEETING
THURSDAY, March 13, 2008
7:00 a.m. to 8:30 a.m.
Cannon Health Building
Room 114



MINUTES

Board Members Present

Mark Balk, PharmD, BCPS
Dominic DeRose, R.Ph.
Tony Dalpiaz, Pharm.D.
Joseph Miner, M.D

Neal Catalano, R.Ph.
Wilhelm Lehmann, M.D.
Bradley Pace, PA-C
Derek Christensen, R.Ph..

Bradford Hare, M.D.
Joseph Yau, M.D.
Colin VanOrman, M.D.

Board Members Excused:

Don Hawley, D.D.S.

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

Rae Dell Ashley, R.Ph.
Tim Morley, R.Ph.
Suzanne Allgaier, RN

Lisa Hulbert, R.Ph.
Nanette Waters
Richard Sorenson, RN

Duane Parke, R.Ph.
Merelynn Berrett, RN

Other Individuals Present:

Steve Farmer, Amgen
Jeff Buel, J&J
Jane Stephen, Allergan
Reed Murdoch, Wyeth
Tony Molchan, Abbott
Barbara Boner, Novartis
Jim Goddard

Craig Boody, Lilly
Linda Craig, AstraZeneca
Steve Hill, Schering Plough
David Block, Shire
Alan Bailey, Pfizer
Cap Ferry, LEC

Peter Yoon, J&J
Joe Heikkinen, AstraZeneca
Rob McGreer, Allergan
Kara Anderson, MHAU
Bryan Larson, DRRC
Rich Heddens, Medimmune

Meeting conducted by: Colin VanOrman, MD

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1. The minutes for February 2008 were reviewed. Mark Balk moved to accept the minutes. The motion passed unanimously with votes by Mark Balk, Neal Catalano, Dr. Hare, Dominic DeRose, Dr. Lehmann, Dr. Yau, Tony Dalpiaz, Bradley Pace, Dr. VanOrman, Derek Christensen, and Dr. Miner.
 2. P&T Committee Update: Duane Parke addressed the Board. The P&T Committee considered the beta agonists for the Preferred Drug List last month. The Albuterol

MDI's, Pirbutolol MDI's, and Albuterol nebulizer solutions will be the preferred short acting agents. For the long acting beta agonists, there will be no change in the solutions for inhalation, and the Salmeterol discus will be preferred. For the LABA/corticosteroid combinations, the Advair and Symbicort product lines will be preferred.

3. Anti-nausea medications: Tim Morley addressed the Board. The DUR Board members were provided with the current criteria for these medications, and some data sheets that represent the class. The DUR Board members were also provided with utilization data for the last 1&1/2 years. All of these agents have indications for highly emetogenic cancer chemotherapies. Most have an indication for post-operative nausea suppression. Most of them also have an indication for nausea associated with radiation therapy. They are basically in two categories: Zofran, Kytril, Anzemet, and the injectable Aloxi; and Emend, which is prescribed almost exclusively to patients on cancer chemotherapy. The DUR Board has also authorized the off-label use of Zofran, Kytril, and Anzemet for hyperemesis associated with pregnancy. Using this drug for hyperemesis in pregnancy after standard therapies have failed seems to be the standard in this community. In addition, both Zofran and Kytril are available generically. The Emend is basically restricted to the highly emetogenic cancer chemotherapies. The PA criteria spell out the chemotherapies that are considered highly emetogenic. However, Emend is very expensive compared to the 5HT3's. The 5HT3's have all been proven safe and effective for this use, but Huntsman Cancer Institute prefers to go straight to Emend. Tim recommended removing the list of highly emetogenic chemotherapy regimens from the Emend sheet and adding Aloxi to the criteria sheet for the other 5HT3's.

Mark Balk stated that Doug Springmeyer had stated that a PA could only be placed on a drug for a medical reason, that it could not decrease the quality of care for the patient, and that there had to be potential for misuse or abuse. How would the DUR Board consider that for this class?

Tim stated that this class could be misused, where other therapies could be equally effective, and that there could be duplication of therapy. It is difficult to tease a PA out of cost issues, since a PA will always result in cost savings. We are also charged in statute with running a cost-effective program. Medicaid is currently discussing how to reconcile these two statutory requirements with the Attorney General's office.

Mark Balk suggested to specifically structure the criteria to not allow the 5HT3's to be prescribed for cases where there is likely to be misuse. As far as duplication of therapy, Emend is indicated and approved to be given as part of a regimen that includes a 5HT3. Looking at the numbers, Emend use appears to be among the lowest. Mark asked if this might be a class that could go to the P&T Committee. This is possible, but it will not be scheduled within the next 5 or 6 months.

Tim stated that if manufacturers don't bid on certain classes of drugs, it makes the P&T Committee less of an issue, since there is no basis for the class to be considered. Tim asked Duane if there are bids available for this drug class.

Duane stated that the P&T Committee's first goal is to not disrupt providers. If a class of drugs goes before the P&T Committee, and the Committee recommends that the class of drugs be placed on a PDL, then the PA requirement should go off.

Tim added that PA is under the purview of the DUR Board, and that the P&T Committee cannot, by statute, use a PA to administer the PDL. If there is a category that has PA, the PA needs to be removed for the class to be considered for the PDL, or the class that has a PA cannot be considered for the PDL. Today, the currently required PA for the class is under consideration for review by the Board.

The Board members wanted to clarify that the drugs would be available to patients who have nausea associated with chemotherapy, radiation, and post-operative nausea, since the 5HT3's are considered first-line drugs for this. PA's can generally be obtained over the telephone for these indications. The Board asked if this could be accomplished by requiring an ICD.9 diagnosis code to be written on the prescription. Medicaid could do this, but does not want to rely on the tool too heavily, since it is too easy to override.

The Board asked if Medicaid has any problems with the current system. This set of criteria has been in use for several years. A majority (approx 2/3) of the requests for PA come in for hyperemesis associated with pregnancy.

Mark Balk asked if it was possible to drop the requirement to try pyridoxine and change the term "phenothiazine" to just phernergan. The PA nurses pointed out that there are other phenothiazines, such as Compazine, available.

The Board stated that it is safer, from the standpoint of pregnancy risk category, to use a 5HT3 than a phenothiazine. Additionally, giving a phenothiazine IV is riskier than a 5HT3.

The Board pointed out that Pyridoxine does have a large body of literature to support its use. OTC doxylamine is also quite effective. The Board was also concerned that allowing 5HT3's for all pregnancies could dramatically raise costs. Derek pointed out that the ACOG guidelines support the use of phenothiazines in pregnancy. The current steps outlined in the PA criteria for the oral 5HT3's in pregnancy are consistent with the ACOG guidelines.

Mark Balk asked if a generic 5HT3 would be required before a name brand would be covered. Medicaid is required to pay for a generic if it is available. A second PA would be needed for the branded 5HT3 to override the mandatory generic requirement.

Dr. Hare moved to remove the list of highly emetogenic chemotherapy regimens from the Emend PA sheet so that it reads, "Patients receiving chemotherapy regimens that are classified as high emetic risk may receive Emend as first-line treatment," and keep the other PA criteria sets are currently written. Derek Christensen seconded this motion. The

motion passed unanimously with votes by Mark Balk, Neal Catalano, Dr. Hare, Dominic DeRose, Dr. Lehmann, Dr. Yau, Tony Dalpiaz, Bradley Pace, Dr. VanOrman, Derek Christensen, and Dr. Miner.

4. Second Generation Antihistamines: Tim Morley addressed the Board. There are two things for the Board to consider. Zyrtec has gone OTC. A prescription cost approximately \$75 for 30 tablets, and OTC is about \$18. Previously, the PA criteria required a failure on Claritin, Alavert, or generic before giving a PA for Zyrtec or Allegra. Liquid Zyrtec was available without restriction until age 10.

The Board asked why the Zyrtec liquid was available without restriction until age 10, when loratadine was available in liquid form for the same age group. Tim stated that there was an issue with children not tolerating loratadine well, but did not remember a specific reason. It was mainly done to accommodate pediatricians.

The Board asked if there was a required time for a trial of the loratadine. There is not, since it should be evident fairly quickly if loratadine will fail.

Tim stated that there is also a new entry into the class of non-sedating antihistamines. Xyzal, which is levocetirizine, is new to the market. The cost on the generic OTC Zyrtec has come way down. Xyzal cost remains high.

The Board asked if Zyrtec OTC and generic Zyrtec OTC will be available without PA. Tim stated that this is something that the Board needs to consider.

The Board felt that it was reasonable to ask clients to try both of the OTC alternatives before authorizing a higher cost prescription antihistamine.

Mark Balk made a motion to add Xyzal to the list of antihistamines requiring a PA, and requiring documentation of a failure on both a loratadine product and a cetirizine product. Derek Christensen seconded the motion. The motion passed unanimously with votes by Mark Balk, Neal Catalano, Dr. Hare, Dominic DeRose, Dr. Lehmann, Dr. Yau, Tony Dalpiaz, Bradley Pace, Dr. VanOrman, Derek Christensen, and Dr. Miner.

5. Quinine Sulfate: Tim Morley addressed the Board. Quinine Sulfate was a pre-1962 drug. The FDA did not have a lot of data on it until someone decided to file a New Drug Application, and submit safety and efficacy studies. This immediately invalidated all previous copies of the drug, and created one manufacturer for quinine sulfate. The problem with this is that the only labeled indication is for malaria, and it states specifically in the approved labeling that it is not approved for the treatment or prevention of nocturnal leg cramps. Quaaluan is approximately 6 times more expensive than quinine used to be. This category has seen a substantial rise in cost for a treatment that is really not approved. The other reason that the FDA accepted this data is because it is not an innocuous drug and there are some problems with side effects. The data is not available to support its use for nocturnal leg cramps. Medicaid is requesting to restrict the use of

Quaaluaquin for the treatment of malaria.

Dr. Miner stated that he agrees with restricting the off label use because of the potential for adverse effects. He moved to accept the PA criteria as proposed by Medicaid.

Bradley Pace seconded the motion. The motion passed unanimously with votes by Mark Balk, Neal Catalano, Dr. Hare, Dominic DeRose, Dr. Lehmann, Dr. Yau, Tony Dalpiaz, Bradley Pace, Dr. VanOrman, Derek Christensen, and Dr. Miner.

6. Epocrates Update: Medicaid has been given the opportunity to purchase the Epocrates system and program it with Medicaid coverage and limitations for covered products. Medicaid will be able to input whether a drug needs a PA, if it has quantity limits, if it is preferred or non-preferred. This will make Medicaid information available at the point of care, since this will be available through a smart phone or a laptop. Medicaid employees have gone through training on how to input that information, and are now beginning to program that. The information will be available for a free download. There will be a link to the download from the Medicaid Pharmacy website, or it can be downloaded directly from the Epocrates website. There are 17 other states that have their Medicaid coverage information available through Epocrates.
7. Bladder Drugs: Tim Morley addressed the Board. The Board has reviewed this class. There is a new entry to this class - Sanctura XR. Since the advent of Medicare Part D, usage among Medicaid clients has dropped significantly. This is a category of drugs for which there are bids for the PDL, and could be considered in the P&T Committee. In view of the fact that usage has dropped, the PA could be removed from this class, and could be moved over to the PDL.

Mark Balk stated that these are not typically drugs of abuse or misuse, and that the usage has been quite low during the time period for which data is provided. He moved to remove the PA from the class.

The Board asked when this class was scheduled for review by the P&T Committee. It has not yet been scheduled. No action would be taken on this class of drugs until the P&T Committee considers the class.

Mark Balk re-stated his motion to remove the PA from the class immediately, even if the P&T Committee will not consider the class for some time. Bradley Pace seconded the motion. The motion passed unanimously with votes by Mark Balk, Neal Catalano, Dr. Hare, Dominic DeRose, Dr. Lehmann, Dr. Yau, Tony Dalpiaz, Bradley Pace, Dr. VanOrman, Derek Christensen, and Dr. Miner.

8. Invega: Tim Morley addressed the Board. In discussion with the manufacturer, Medicaid made some modifications to the PA criteria. Previously, the PA criteria stated minimum age of 18 years old, diagnosis of schizophrenia, no prior failure on risperidone, could not be used prior to risperidone trial, and patient fails to take multiple daily doses of antipsychotics and cannot tolerate a single daily dose of risperidone. Medicaid proposes

to remove to the two criteria in the middle that state no prior failure on risperidone, and could not be used prior to risperidone trial. These criteria were very confusing and difficult to administer. The last criteria is still a little bit confusing. It could be broken into two separate criteria stating that patient fails to take multiple daily doses, and separately that the patient cannot tolerate a single daily dose of risperidone.

Dr. Yau stated that the advantage of a once-daily medication in a mental health client is that it improves compliance. Thinking about the advantage of the pro-drugs is that they do not have to go through another metabolic step, and that there are drug interaction issues. This may be something to be considered.

Tim stated that from an efficacy and safety standpoint, the data are similar. The Board needs to consider if there is a duplication of available therapy. Invega represents a duplication of therapy with risperidone. Risperidone is going to go off patent, and Invega came to market right before that. Invega and Risperdal are made by the same manufacturer, and an argument could be made to move all patients on risperidone over to Invega prior to the generic coming out. If all Medicaid patients currently on risperidone were moved over to Invega, it would have cost the Department an additional \$16million dollars. Medicaid did feel that the once-daily dosing form needed to be available for this type of drug, though. The manufacturer of Invega felt that the revised PA criteria were acceptable. Was the availability of a once-daily dosage form really so important that the Board needs to reconsider this drug?

Dr. Yau felt that the once-daily dosing is very important. There are also depo injections available for this class of drugs, because non-adherence is such a huge problem for this class (approximately 50%).

Tim asked if any other drugs have a single daily dose indication. There are other atypicals that are dosed once daily. Mark Balk said that there are patients in this class who do end up switching from drug to drug, and the availability of multiple once-daily agents is important because of the problems associated with adherence in this class.

Medicaid did restrict this drug because it is a prodrug, and therefore duplicates currently available therapy. The literature does not indicate that it offers any significant advantage over currently available therapy, other than the once-daily dosing.

Dr. Yau added that the added advantage of the prodrug is that it does not have to go through the same metabolic channel. Particularly in patients on multiple drugs, it is difficult to predict how they will effect each other in the body.

The Board stated that restricting the use of Invega to only a diagnosis of schizophrenia should keep usage low, since Invega will not be used for the other mood disorders like the other atypicals.

Peter Yoon from Johnson and Johnson addressed the Board. If these drugs were similar,

one would not expect patients who failed on risperidone to do well on Invega. There is evidence that some patients who fail on risperidone do end up doing well on Invega. These patients do need other options for treatment. These patients do not change their drugs without a reason, and they usually need another drug as a result of a relapse. It is important to have other options in the event of a relapse.

Duane Parke stated that if he understood that a prodrug is metabolized into the active drug (in this case risperidone). Dr. Yoon clarified that risperidone is not a prodrug; it is the active metabolite.

Dr. Yoon stated that it is difficult to find a study that says one way or the other that any drug in this class is better. The trial that was supposed to answer questions like this- the CATIE trial- actually left more questions than answers.

Dr. Yau felt that it would be reasonable to leave in the criteria that the patient cannot tolerate a single daily dose of risperidone. Tim asked how the PA would handle patients who take other drugs at multiple daily doses. It will be difficult to prove that the other antipsychotic is failing due to the frequency of dose, or if it will be a therapeutic failure.

Mark suggested that the PA criteria be further revised to say on the third bullet, "Cannot tolerate a single daily dose of risperidone." This was Dr. Yau's motion. Mark Balk seconded it. The motion passed unanimously with votes by Mark Balk, Neal Catalano, Dr. Hare, Dominic DeRose, Dr. Lehmann, Dr. Yau, Tony Dalpiaz, Bradley Pace, Dr. VanOrman, Derek Christensen, and Dr. Miner.

Next meeting set for April 10, 2008

The DUR Board Prior Approval Sub-committee convened and considered 7 petitions. Drug histories were for 12 months unless otherwise noted.

Minutes prepared by Jennifer K. Zeleny