



STATE MEDICAID DUR BOARD MEETING
 THURSDAY, December 14, 2006
 7:00 a.m. to 8:30 a.m.
 Cannon Health Building
 Room 125



MINUTES

Board Members Present

Mark Balk, PharmD
Derek G. Christensen, R.Ph.
Tony Dalpiaz, Pharm.D.
Joseph Miner, M.D.

Neal Catalano, R.Ph.
Bradley Pace, PA-C
Dominic DeRose, R.Ph.
Colin B. VanOrman, M.D.

Bradford Hare, M.D.
Wilhelm T. Lehmann, M.D.
Don Hawley, D.D.S.
Joseph Yau, M.D.

Board Members Excused:

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

Rae Dell Ashley, R.Ph.
Tim Morley, R.Ph.
Jennifer Zeleny, CPhT.
Lisa Hulbert, R.Ph.

Sue Allgaier R.N.
Merelynn Berrett, R.N.
Richard Sorenson, R.N.
Duane Parke, R.Ph.

Other Individuals Present:

Craig Boody, Lilly
Jeff Buel, Johnson&Johnson

Gene Farmer, Amgen
Tony Molchan, Abbott

Alan Bailey, Pfizer

Meeting conducted by: Colin VanOrman

1. Minutes for November 8, 2007 were reviewed, corrected, and approved. Dominic DeRose made the motion to approve the minutes. Dr. Hare seconded the motion. The motion passed with a unanimous vote from Mark Balk, Tony Dalpiaz, Dr. Miner, Neal Catalano, Bradley Pace, Dominic DeRose, Dr. VanOrman, Dr. Hare, Dr. Hawley, and Dr. Yau.
2. Business Items: Tim Morley thanked the Board members for their service. The Division will give the Board members Christmas gifts. However, the gifts have not yet arrived.
3. P&T Committee Update: Duane Parke addressed the Board. Last month the P&T Committee reviewed opioids. The Board members were provided with some handouts. One handout shows the percentage of deaths caused by opioid analgesics, which was worrisome. The University of Utah Drug Information Service also attempted to create a

dose conversion chart for opioid analgesics. There is a lot of disagreement among the available data. Nevertheless, the University of Utah did prepare a chart, which was presented to the Board for use.

The Board asked if there was a decision made by the P&T Committee. The Committee concluded that all of the opioid analgesics are equally safe and efficacious, and recommended that the Division proceed based on price.

4. Selzentry: Dr. VanOrman addressed the Board. Selzentry was discussed at a previous DUR Board meeting. When Selzentry was last under discussion, the need for a tropism test to determine whether or not the drug was appropriate for the HIV strain was discussed. There is currently only one lab in the country that can perform this test. Action on Selzentry was deferred until the Division could review the pertinent laws surrounding the need for this tropism test. The Board members were provided with two pertinent legal references.

Tim Morley addressed the Board. After reviewing the law and looking at the arrangement that the manufacturer has with this test, Medicaid has determined that the manufacturer is not requiring this test as a condition of obtaining the drug. The manufacturer is not selling the test. Monogram is the only lab that makes a validated test for Selzentry. They have an agreement with the University of Utah to provide this test. The Medicaid Pharmacy Program does not pay for tests. The question comes down to whether or not the test is available for someone wishing to have it performed. Last month, the Board was mainly concerned that the patient had the test prior to obtaining the drug due to the large number of HIV patients who do not have the CCR-5 conversion. In terms of the law, the manufacturer is not seeking to require the test as a condition of the sale of the drug, so the laws do not apply.

RaeDell Ashley asked the Board if they would like to have Dr. Kristen Rees from the University of Utah come and give testimony to the Board as to whether or not she is using the drug and performing the tropism tests prior to prescribing it. The Board felt that she probably is doing the test if she is prescribing the drug, since the drug would be useless for patients who do not have the CCR-5 conversion.

Mark Balk moved that the Prior Authorization criteria for Selzentry, which require the tropism test as a condition for coverage, be accepted. Dr. Mineer seconded the motion. The motion passed unanimously with votes from Mark Balk, Tony Dalpiaz, Dr. Miner, Neal Catalano, Bradley Pace, Dominic DeRose, Dr. VanOrman, Dr. Hare, Dr. Hawley, Derek Christensen, Dr. Lehmann, and Dr. Yau.

The Board asked how much the test cost. Tim Morley stated that he thought it was around \$1600.

5. Isentress: Dr. VanOrman addressed the Board. Information for Isentress has been provided to the Board. Medicaid has not made a request for Prior Authorization criteria

for this drug.

Tim Morley addressed the Board. Isentress is approved for combination therapy with other antiretroviral agents. Medicaid has not requested any Prior Authorization requirements. If the Board finds that it is not to be used as a first-line agent, a very simple PA may be considered. It is not approved for pediatric use.

The Board asked if there are any other agents that are not meant to be used as first-line treatment or monotherapy. In the class of HIV drugs, the only drug with a PA requirement is Selzentry. Other drugs or classes of drugs do have these requirements, in some cases.

The Board asked how many that Prior Authorizations may be seen with these drugs. Medicaid has not had PA requirements on HIV drugs in the past, so there is no way to tell. However, the new HIV drugs, unlike the HIV drugs that are already on the market, are being approved as add-on therapy to existing drug regimens. There has been no need to encourage appropriate utilization with PA's in the past, but there may be a need with these newer drugs. The question is whether or not the Board feels the need to ensure that patients are on optimal therapy prior to starting these new agents.

Dr. Hawley moved that Medicaid proceed without a PA, and bring the issue back to the Board if it is found that the drug is being prescribed inappropriately in the future. Mark Balk seconded the motion. The motion passed unanimously with votes by Mark Balk, Tony Dalpiaz, Dr. Miner, Neal Catalano, Bradley Pace, Dominic DeRose, Dr. VanOrman, Dr. Hare, Dr. Hawley, Derek Christensen, Dr. Lehmann, and Dr. Yau.

6. Pro-Drug or Metabolic "Me-Too" Policy: Dr. VanOrman addressed the Board. In previous DUR Board meetings, the Board has considered new drugs that are either pro-drugs or metabolic "me-too's", and the question has been asked whether they are really of benefit to the patient, or if they are just a means for patent extension. Medicaid has provided a proposed Prior Authorization policy for these drugs. The PA essentially says that unless there is a compelling reason to approve the drug is shown, it would not be immediately approved. The parent compound would be shown unless there was a compelling reason, such as increased safety and efficacy, decreased side-effects, decreased hospitalization, decreased emergency room visits, decrease in overall costs. The alternative to that would be placement of an MAC price.

Tim Morley addressed the Board. This has been discussed rather extensively within the Division. There are a number of drugs that have come to the market recently. These drugs are either active metabolites of existing drugs, or drugs that have to be metabolized into an active component of a drug that already exists. In light of the fact that many drugs like this are coming out, the Division feels that it is necessary to have a policy to handle these drugs on a reasonable basis. There is already a Brand Name PA policy that is used when a generic comes on the market. In that case, a PA is automatically placed on the brand. There is a policy that if a new entry to an existing category that has PA restriction,

the new drug automatically gets placed on PA pending review. The same position is being pursued with the pro-drugs. Is there a method or approach that the Division can use to govern the use of these products? Sometimes they come out so quickly that the Division does not have time to bring them to the Board. This would be a global policy that would become effective with today's meeting, and allow the Division to place PA's across the Board as pro-drugs or metabolic "me-too's" become available. Generally, they are more expensive medications. They always come out about a year before a generic comes to market. One must consider if they offer a significant advantage over currently available therapies. Medicaid is responsible for providing lower-cost alternatives when available. This would allow Medicaid to do that.

The Board asked if the alternative would be to bring all new drugs before the Board before restricting them with a PA, unless there was some sort of an appeal or discussion of benefits to using the new drug. Medicaid would eventually bring all of these to the Board, because that would be important to do. They just would not go 6-8 months before PA was placed on it.

Dr. Yau asked if the term pro-drug or "me-too" was defined clearly enough. There may be some cases where the drugs are similar, but they are different enough that the Board would not authorize it automatically. Finding the lower-cost alternative is an important role of the Board. The question is whether the new drug would come before the Board as an appeal from the manufacturer or other means of appeal. Another comment is regarding the phrase "significant therapeutic advantage" over the parent compound. Oftentimes, this is hard to come by. The manufacturers themselves will not compare that, so where will the Board gain the experience to make this determination? The Board will never have that information. In general, the PA policy is good in principle.

Mark Balk stated that perhaps some of the terms in the proposed PA policy are being used inappropriately. For example, the term pro-drug is generally used to mean any drug that is not active until the body does something to it. For example, codeine is metabolized into morphine; levodopa is metabolized into dopamine; enalapril into enalaprilate. The concept of having a PA on a new entry into the market that is a pro-drug may be a good concept, but the language in the proposed policy does not handle it well. Additionally, the Board is being asked to treat all biosimilars and "me-too's" as a class, when they are not really a class, rather they are an entity. The concept of having a PA may be a good one, but it should be handled on a class-by-class basis rather than on such a broad category of drugs. Lastly, as for the "compelling reasons", all that the FDA mandates when a drug comes out is that it be superior to placebo. Unfortunately, the Board cannot have the information for years after the drug comes onto the market. It would be better to handle these new drugs on a class-by-case basis.

The Board asked if they would eventually see the drugs on a case-by-case basis anyway. Tim Morley stated that the Board would eventually see all of these drugs. This policy would allow the Division to place a PA on these drugs as they come out, before they are brought to the Board. In many cases, these new drugs are significantly more expensive

than the parent compounds. When Medicaid is thinking of a pro-drug, they are referring to a drug that is either the active metabolite of an existing drug, or it is currently existing chemical entity that is used. An example of this is Vyvanse, which is cleaved by the body in to Dextroamphetamine. Dextroamphetamine is already available on the market.

Duane Parke stated that the issue that Medicaid is trying to address is patent extension. In many cases, when a drug company finds a profitable drug, they will patent the isomers, active metabolites, and pro-drugs to be able to extend their patent and their cash flow. When a drug goes of patent, the price goes into free-fall. Medicaid's goal is to take advantage of the generics that come out on the primary product.

The Board asked if they can remove the word "pro-drug" from the policy and replace it with the term "patent-extender". The Board suggested something like "similar compound with no therapeutic advantage". The Board also asked what "me-too" means. Tim Morley stated that this refers to a drug that is metabolized into a currently existing entity.

The Board stated that they would want to be careful to craft terminology so that these drugs that can be considered patent-extenders, but without overstepping to allow Medicaid to restrict new drugs that do not have a comparable compound already on the market.

The Board asked if Medicaid has a sufficient workforce to be able to implement a policy such as this, and what would the timeframe be to bring the drug or individual cases before the Board. Tim Morley stated that part of the problem is that these types of drugs must be brought to the Board along with all of the other new drugs that are entering the market. Of course, if there are PA requests, there may be denials before the drug is brought before the Board. Of course, there will also be approvals. With all of the new drugs coming to the market, it may be several months before a new drug is brought before the Board. Duane Parke stated that the industry standard is that if the drug is not brought before the Board, the PA would sunset in 6 months.

The Board asked how new drugs are handled, in general. First, Medicaid looks at whether or not the new drug fits into an existing category. If they are going to present an issue of duplicate therapy, or if they are substantially more costly than currently available therapy, Medicaid tries to bring them to the Board as soon as possible. If there are no significant issues, Medicaid can delay bringing the drug before the Board, since there really is nothing to discuss. In this particular case, that could apply as well. If Medicaid decided that a drug really fit this category, Medicaid could place it on PA until DUR Board review. If the new drug does not pose significant challenges and does not need a PA, Medicaid would not even need to bring it before the DUR. What Medicaid is looking at is an opportunity to say that a particular drug does not bring forth any advances; all it does is provide a therapy that is already available in another form. In those cases, the Division could protect itself from a higher cost by utilizing a PA.

The Board asked if there was a better term that could be used. A proposal was made to

drop the term “pro-drug” altogether. Dr. Lehmann proposed the term “newly marketed metabolically and therapeutically equivalent drug to an existing class of medications”. Looking at the end runs on the patent expirations, there are different approaches: the isomer, the XR, and the pro-drug. The judgement would be that they are metabolically and therapeutically equivalent to drugs that are on the market. The Board felt that “therapeutically equivalent” may be too broad. The term “chemically equivalent” may be more appropriate. The term “chemically identical” may be even better. Another proposal was the term “newly marketed medications or entities chemically identical or metabolites of medications currently available or marketed as either brand or generic products”.

The Board asked if Medicaid could quantify the number of these drugs that come out each year. If there are only about 3-4 per year, it would not be burdensome for Medicaid to bring each drug to the DUR Board. Generally, it takes 6-8 weeks between the time that the drug is approved, and the time that it is marketed. This should give Medicaid ample time to bring a new drug to the DUR Board. Tim Morley stated that new drugs are coming out at such a fast rate that this may not be realistic. Medicaid needs to handle these rationally both from a financial standpoint as well as a therapeutic standpoint.

Tim Morley stated that once a global policy is approved, some broad PA criteria also would need to be approved. Medicaid would only ask that the requirement be that a lower cost parent compound be tried prior to approval of the new pro-drug.

The Board felt that continued discussion of this issue was counterproductive. In some classes of drugs, it would not be unreasonable to have a patient try a lower-cost alternative first. However, in some drug classes, a pro-drug could have real therapeutic value. The Board should still consider these drugs on a case-by-case basis.

Tim Morley stated that currently there is a 90-day period before a new PA could go into effect. Medicaid must give 30 day notice before bringing a new drug before the DUR Board. After the DUR Board discusses a new drug, Medicaid must wait 90 days before putting the PA into effect. During this time, Medicaid can potentially waste a significant amount of resources. In the event of a federal audit, Medicaid could get into trouble for paying unnecessarily for high-cost drugs.

The Board felt that this discussion should be tabled while someone works on wording, and the Board members have time to think about the issue. Neal Catalano moved that the DUR Board postpone this discussion. Mark Balk seconded the motion. The motion passed unanimously with votes by Mark Balk, Tony Dalpiaz, Dr. Miner, Neal Catalano, Bradley Pace, Dominic DeRose, Dr. VanOrman, Dr. Hare, Dr. Hawley, Derek Christensen, Dr. Lehmann, and Dr. Yau.

7. Aranesp, Procrit, Epogen - Criteria Review: Dr. VanOrman addressed the Board. The review of existing PA criteria for this class is being brought to the DUR Board because of an update from the FDA. The Board was provided with current PA criteria. The FDA is now recommending that if the patient is receiving these agents for chronic renal failure,

their hemoglobin should be between 10-12. For cancer patients, they are saying that the hemoglobin should not go above 12 due to an increased cancer risk. The dose should be targeted to avoid transfusion, but to keep it below 12. The question is if the Board should revise the PA criteria based on the FDA guidelines.

Tim Morley addressed the Board. The current PA criteria is actually instigating therapy at the level where the therapeutic goal should be. The FDA also splinters apart cancer patients and chronic renal failure patients, but Medicaid's criteria does not.

One alternative could be that the Board recommend that the hemoglobin levels in the PA reflect the FDA guidelines. This would allow Medicaid to change the PA requirements after the FDA is finished with its review.

The Board asked the PA nurses for input on this PA. Putting a range of hemoglobins could broaden the PA criteria a little bit, and that would not be a problem. However, the having an endpoint in the PA may incorrectly suggest that it is the responsibility of the PA nurses to monitor the therapeutic outcomes. This is the responsibility of the provider.

Dr. Yau stated that the PA criteria for Epogen/Procrit and Aranesp are not uniform, and this could be confusing. Also, the statements that patients cannot be on hemodialysis or having an active GI Bleed are placed in a confusing place on the PA form. Lastly, the FDA indication for HIV is for anemia as a result of AZT, so the Board may wish to consider this specific indication for the PA criteria rather than allowing it for all HIV patients. Tim Morley clarified that the HIV indication was only FDA approved for Epogen/Procrit. This is why it is not on the Aranesp PA form. Procrit and Epogen are also indicated for reducing transfusions perioperatively.

The Board asked if there was anything objectionable in the FDA guidelines. All that the FDA is saying is that the threshold for starting therapy is a lower hematocrit and hemoglobin. The Board suggested that the PA form should state that initial approval requires a hemoglobin < 10 and a hematocrit < 30, as per FDA guidelines. Re-authorization would require a hemoglobin < 12 and a hematocrit < 36, as per FDA guidelines. Dr. Mineer made this motion. Mark Balk seconded this motion. The motion passed with a unanimous vote by Mark Balk, Tony Dalpiaz, Dr. Miner, Neal Catalano, Bradley Pace, Dominic DeRose, Dr. VanOrman, Dr. Hare, Dr. Hawley, Derek Christensen, Dr. Lehmann, and Dr. Yau.

Next meeting set for January 10, 2008.
Meeting adjourned.

Minutes prepared by Jennifer Zeleny.

