



STATE MEDICAID DUR BOARD MEETING
 THURSDAY, April 12, 2007
 7:00 a.m. to 8:30 a.m.
 Cannon Health Building
 Room 125



MINUTES

Board Members Present:

Don Hawley, DDS.
Lowry Bushnell, M.D.
Derek G. Christensen, R.Ph.
Dominic DeRose, R.Ph.

Bradley Pace, PAC.
Wilhelm T. Lehmann, M.D.
Colin VanOrman, M.D.

Board Members Excused:

Mark Balk, PharmD.
Bradford Hare, M.D.
Joseph K. Miner, M.D.

Karen Gunning, PharmD.
Jeff Jones, R.Ph.

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

Rae Dell Ashley, R.Ph.
Tim Morley, R.Ph.
Richard Sorenson, R.N.
Lisa Hulbert
Nanette Epstein

Suzanne Allgaier, R.N.
Merelynn Berrett, R.N.
Nanette Waters
Duane Parke, R.Ph.

Other Individuals Present:

Elizabeth Stoltz, J&J
Craig Boody, Lilly
Von Wood, Merck
Roy Linfield, Schering
Lori Howarth, Bayer
Linda Craig, Astrazeneca
Matthew C. Hansen, MD
Michael Measom, MD

Jeff Buell, J&J
John Stockton, Genentech
Tom Holst, Schering-Plough
Trish McDaid-O'Neill, Astrazeneca
David Stallward, AG
Mike Soltan, Astrazeneca
Rob Wood, Pfizer
Tim Smith, Pfizer

Erica Brumleve, GSK
Steve Farmer, Amgen
Barbara Boner, Novartis
Gerry Shiohita, Schering
Gwen Boyer, Pfizer
James Gaustad, Purdue
John T. Nielsen, Astrazeneca
Pierre Toumlin, Amgen

Meeting conducted by: Lowry Bushnell

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1. Minutes for March 8, 2007 were reviewed, corrected and approved.
 2. Housekeeping: Board members will be contacted during the upcoming month with information regarding DUR Board terms. New Medicaid employees Lisa Hulbert, who will

be working on the Transformation Grant, and Duane Parke, who will direct the PDL Project for the Department of Health. Duane Parke will be managing the P&T Committee.

3. Preferred Drug List: Tim Morley addressed the Board. A packet containing information showing the relationship of the DUR Board to the P&T Committee and a time line for the implementation of the PDL was distributed to the Board. The Preferred Drug List will be an evolving tool. Medicaid anticipates starting with two drug classes on August 1, 2007. A complete PDL will not be implemented all at once; Medicaid intends to implement a PDL for six drug classes by the end of the current year. Six potential PDL categories had been publicized during the legislative session. Medicaid anticipates that the first six categories to be implemented will resemble the list of six categories that has been publicized. However, no firm decisions have been made, and it is possible that drug categories other than the six that have been publicized will have a PDL implemented. Through the legislation for the PDL, atypical and typical antipsychotics will not be included in the PDL. .

Typical progression for a PDL will be as follows:

- The Division selects a drug class.
- Pertinent data is compiled from databases and manufacturers.
- Compiled data is presented in a P&T Committee hearing.
- P&T Committee makes a recommendation to the division about a preferred drug.
- The division will craft Prior Authorization criteria for non-preferred drugs and present it to the DUR Board.

In the case of the first two classes, the process will be worked backwards. These are homogeneous classes, so Prior Authorization criteria for non-preferred agents will look the same for all drugs in that class. When preferred drug(s) are selected for the classes, they will not be subject to the Prior Authorization criteria that is discussed today. Public testimony is received during the DUR meeting, and 90 days are required by statute before a PDL Prior Authorization can be implemented. After the 90 days have passed, the PDL for the class can be implemented.

The Board asked Medicaid if other behavioral health drugs such as antidepressants or ADHD drugs could be included in a PDL. Medicaid's understanding is that these drugs could be included under a PDL, but Medicaid does not anticipate implementing a PDL for these classes in the near future.

The Board asked what six classes would initially be subject to a PDL. Tim Morley replied that he did not know with certainty. The six drug classes that had been selected for fiscal analysis for the legislature were PPI's, Statins, NSAIDS, Opiate analgesics, anti epileptics, and sedative hypnotics.

The Board asked how many drug classes there were in total. There are over 100 drug classes, and Medicaid only anticipates implementing a PDL for six classes during the first six months.

4. P&T Committee: Tim Morley addressed the Board. The information that will be covered regarding the P&T Committee has been crafted in Rule and is currently out for public comment as of 4/11/07. P&T members are appointed by the division and serve two year terms. Their terms will be renewable at the option of the division. Nominations for potential appointees will be requested by the Division from appropriate professional organizations

within the state. The P&T Committee will consist of four physicians, one from each of the following specialties: internal medicine, family medicine, psychiatry, and pediatrics; four pharmacists, one from each of the following areas: academia, independent pharmacy, chain pharmacy, and hospital pharmacy. The Committee manager will be a voting member and appointed from the Division. There will be two non-voting ad hoc specialists participating at the invitation of the committee depending on the category that is being deliberated. It is important for the P&T Committee process that individuals considered for nomination not demonstrate direct connection to the pharmaceutical manufacturing industry.

Decisions made by the P&T Committee will be made by majority vote when a majority quorum is present. A quorum must consist of at least one physician and one pharmacist member. Meeting schedule and times will be decided by the Committee. Meetings shall occur no less than quarterly. They will be open to the public, except for when in executive session. Open testimony will not be accepted at the meetings, but they will be open to public attendance. The Committee will review drug classes and make recommendations to the division and to the DUR Board for implementation of a PDL. They will review new drugs and new drug classes and make recommendations to the DUR Board, and they will also review drugs and drug classes as assigned or requested by the division or the DUR Board. Public comment and participation is encouraged at DUR meetings where Prior Authorization criteria for non-preferred members of drug classes is being considered.

The Division was asked if manufacturers will be able to provide written testimony for P&T Committee meetings. Drug manufacturers will be able to submit written testimony. Notice of drug classes being considered in P&T Committee meetings and meeting times will be available 30 days beforehand.

The Division was asked what role, if any, a PBM will have in the process. Medicaid will not have a PBM. Utah has traditionally operated as its own PBM, and that will continue.

Dr. Michael Measom had requested time to address the Board with regard to the PDL. Dr. Measom wanted to comment on a PDL, in general, and how much it increases health care costs. Dr. Measom has reviewed pertinent literature, and has included his comments to the Board in letter form.

5. PDL Prior Authorization Criteria for PPI's: Tim Morley addressed the Board. The Board has been provided with a Spec Sheet for PPI's, and evidence-based review for both PPI's and Statins. The differences between the agents in this class of drugs is not great. The cost information that the Division currently has is the cost information as it now exists for the Medicaid Program. Medicaid anticipates participating in a purchasing pool. Until Medicaid joins the purchasing pool, cost information will not be available. Today, agents will be only considered based on their clinical status. Due to the homogeneity of these classes, Medicaid anticipates that the Prior Authorization criteria for all agents in the classes considered today will look the same for all non-preferred agents in the classes.

The Board asked the Division to comment on the purchasing pool. Medicaid will be joining a purchasing pool with four other states. The volume done in Utah will be combined with each of the four other states, and the pool then negotiates with drug manufacturers for secondary rebate pricing considerations. "Purchasing pool" is a misnomer - Medicaid does not purchase the drugs from this group; this is a group of states where prescription volume is combined and used to leverage secondary rebates. Secondary rebates come to Medicaid

after the fact. Medicaid will continue to reimburse pharmacies at the current levels. The four other states are not in the same geographical area. Utah anticipates joining Maine, Vermont, and Iowa in the Sovereign States Drug Consortium. This group will allow Utah to remain autonomous, continue to act as our own PBM, and negotiate outside the group for secondary rebates if desired. The other states in the group have PDL's, but Utah does not have to adopt the same PDL's.

Prior Authorization for non-preferred PPI's was considered. The DUR Board is not going to choose a preferred agent, the DUR Board is only considering Prior Authorization criteria for non-preferred PPI's. There is not much difference in the agents in the PPI class. Medicaid anticipates that the only differences that will be seen in the agents in the PPI class will be due to allergy or adverse effects. In those cases, non-preferred drugs will have to be given. The criteria that Medicaid is recommending includes some of the criteria that are currently being used on PPI's, but also includes documented failure of a preferred agent at appropriate doses. Many times, PPI's fail because they are not taken correctly or dosed at appropriate levels. The guiding factor in the criteria is "when taken as directed by the manufacturers labeled instructions".

The Board asked if there were time limits in place for the duration of a trial of preferred agents. It was suggested that Medicaid include such time limits on a trial. A time limit of 30 days was suggested. It was also suggested that Medicaid require a failure on all preferred agents in a class if multiple agents were included as preferred.

Medicaid was asked if a preferred agents will be subject to the 30 units/30 days dose limitations. Preferred agents will not be subject to these requirements.

Medicaid was asked how higher BID doses will be handled for non-preferred agents. Medicaid was also asked if the criteria are allowing physicians to request non-preferred agents initially if a patient presents with one of the conditions listed in the criteria. Medicaid was also asked what documentation would be required for a Prior Authorization for a non-preferred agent (such as EGD). Medicaid anticipates that there are two types of PA - one is that a patient cannot take a preferred agent due to allergy, and the other is that a patient requires a PA because they need an elevated dose. Medicaid was asked to simplify the logistics of the PA process. The Board was asked to cut out pieces of the criteria that were confusing or unwieldy.

Medicaid will not treat preferred agents as open-label drugs and not monitor the usage. If a non-preferred agent needs to be used, a physician should have to demonstrate to the state that there is a good reason that a preferred agent should not be used. If the Prior Authorization criteria should be handled so simply, the physicians should only have to demonstrate to Medicaid that the preferred agents either will not work or cause an allergic reaction or unacceptable adverse event. In that case, the criteria should be documented failure of preferred agent at appropriate dosing, allergic reaction, or adverse side effect of a preferred agent. If these criteria are met, a non-preferred agent, and Medicaid will not necessarily monitor how long it is used or if BID dosing is used.

A motion was made to accept criteria that a preferred agent must be tried at appropriate dosage levels, taken correctly as directed by the manufacturers dosing instructions, or that a preferred agent has caused allergy or an adverse event. The Board asked if any limitations were going to be in place to monitor appropriate usage of non-preferred agents. It was

suggested that current Prior Authorization criteria be applied for non-preferred agents. Another suggestion was made that non-preferred agents only be approved for up to BID dosing to stay within acceptable usage guidelines. Medicaid suggested that criteria be changed to reflect that clinical judgement of the prescriber will be respected for daily versus BID dosing once a non-preferred drug is requested. Prior authorization will be granted for non-preferred agents without a time limit, and may be granted for the highest dose if the prescriber feels that it is necessary. The motion was modified to make one criterion for documented failure of a preferred agent at appropriate or elevated dosage levels when taken as directed by manufacturers label instructions, and one criterion for documented allergic reaction or adverse reaction to preferred agent. The motion was passed.

6. PDL Prior Authorization Criteria for Statins: Dr. VanOrman had suggested that the criteria proposed by Medicaid be compressed into two requirements, and that allergy and/or adverse reaction to a preferred agent comprise the same requirement. It was also suggested that no re-authorization be required for non-preferred agents. The Prior Authorization Team stated that it was not possible to issue an open-ended Prior Authorization in the system. However, prescriptions presented at the pharmacy and telephone calls from pharmacies are treated as acceptable requests for Prior Authorization. The PA staff could, conceivably, issue a Prior Authorization with a dummy long-term date and dummy long-term quantity. However, at some point a re-authorization would be required in the current computer system. It was pointed out that a long-term date on the Prior Authorization, such as 5 years, could reduce the workload of the PA staff. Rick Sorenson said that he would examine the capabilities of the current system, and whether or not these were viable options.

A motion was made to accept the revised criteria with the re-authorization requirement stricken. The intent of the Board is that the PA Staff look into making open-ended Prior Authorizations possible. The motion was passed.

Next meeting set for May 10, 2007

Meeting adjourned.

The DUR Board Prior approval sub-committee convened and considered 2 petitions. Drug Histories were for 12 months unless otherwise noted.