



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



MINUTES

Board Members Present:

Neal Catalano, R.Ph
Tony Dalpiaz, Pharm D.
Don Hawley, DDS
Colin VanOrman, M.D.

Derek Christensen, R.Ph.
Dominic DeRose, R.Ph.
Joseph Miner, M.D.
Joseph Yau, M.D.

Board Members Excused:

Mark Balk, Pharm D.
Wilhelm Lehmann, M.D.

Bradford Hare, M.D.
Bradley Pace, PA-C

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

Rae Dell Ashley, R.Ph.
Tim Morley, R.Ph.
Jennifer K. Zeleny, CPhT.
Duane Parke, R.Ph.

Suzanne Allgaier, R.N.
Merelynn Berrett, R.N.
Rick Sorenson, R.N.
Lisa Hulbert, R.Ph.

Other Individuals Present:

Jim Goddard, Shire
James Gaustad, Purdue
Slater Sparks, Sciele
Kara Anderson, MHAU
Marianne Paul, DRRC
Trish McDaid-O'Neill, AstraZeneca

Robb Host, Cephalon
Linda Craig, AstraZeneca
Cap Ferry, LEC
Kevin Craig, Lilly
Rich Heddens, Medimmune

Ann Glasser, Pfizer
Lori Howarth, Bayer
Kevin Carson, Alpharma
Reed Murdock, Wyeth
Tony Molchan, Abbott

Meeting conducted by: Dr. Colin VanOrman

1. Minutes for October 2007 were reviewed, corrected, and approved.
2. Business Items: Dr. VanOrman addressed the Board. He drew attention to the 30-day notice language at the top of the DUR Board agenda for the benefit of Board members and the public.
3. P&T Committee Update: Duane Parke addressed the Board. Last month, the P&T Committee considered oral hypoglycemics. They found that the TZD's are equally safe and efficacious. Next Friday, the Committee will be considering long-acting narcotic pain

medications. The Division appreciates the assistance of the pharmaceutical industry and the University of Utah Drug Information Center for providing evidence for the P&T Committee to consider.

4. Business Carried Forward:

- a. NPI: Tim Morley addressed the Board. The NPI is the National Provider Identification number. The NPI is now required on all claims that come from a provider, such as a pharmacy or physician. Beginning January 1, 2008, the NPI will be required in the prescriber field on claims that come from a pharmacy. This is a federal requirement that Medicaid must comply with.

The Board asked if the prescriber NPI must be written on the prescription. If the pharmacy already has the prescriber NPI this will not be necessary.

- b. The Deficit Reduction Act and New AMP Based FULs: Tim Morley addressed the Board. Beginning January 1, 2008, the Average Manufacturer Price (AMP) will have to come into the pricing methodology. The AMP is the price at which drug companies sell products to wholesalers, it is not the price that retailers pay to the wholesalers. The new FULs will be based on the AMPs that the manufacturers provide to CMS. The federal government is still re-examining these numbers. There is a measure that has passed the House that is going to the Senate where they will redo the definition of AMP and move the FUL even higher. The Board was provided with four Power Point sheets that give a cursory review of the Division's analysis of AMP and what it means. Providers are encouraged to share their opinions and findings as the program rolls out.

The Board asked if Medicaid is mandated to implement on January 1. Medicaid does intend to comply on this date. Medicaid will continue to use the pricing structures that are currently in place, add the new AMP-based FULs, and have the system pay the lowest of all the available pricing methodologies.

5. Vyvanse: Dr. VanOrman addressed the Board. Vyvanse is a prodrug of dextroamphetamine, and is rapidly absorbed in the GI tract and converted into dextroamphetamine. The Board needs to consider Prior Approval criteria. The drug is currently approved for ages 6-12. Last month, the Board considered age restrictions and the Board may wish to discuss the use of this drug in teenagers.

Dr. Yau wanted to discuss the use of this drug in teenagers. This drug may be particularly valuable for teenagers because has a lower potential for abuse. The lower potential for abuse should be taken advantage of in this particular age group. The rest of the proposed Prior Authorization criteria are reasonable.

Tim Morley addressed the Board. Medicaid put the age range on the Prior Authorization criteria because it is the age for which the medication is approved. Outside of this range, Medicaid may need to bring the requests to the Board. The Board also needs to consider how to handle requests for children who were started on the drug prior to the age of 12, and who need the Prior Authorization renewed.

Dr. Brent Petersen provided email comment. Vyvanse is only approved for age 6 to 12 years old, but the aspect of potentially less abuse risk makes it attractive for older youth and adults.

Its predictability of Tmax, GI motility, and PH do not effect it much, make it much more predictable for effect size than Adderall XR. It is priced within \$4-5 of Adderall XR.

The Board felt that once a patient is stabilized on the medication between the ages of 6 to 12, the Prior Authorization should be re-authorized outside of the age limits. The age requirement could be re-stated to require initiation of therapy prior to age 12.

The Board asked if the FDA had a reason to restrict the age from 6 to 12. The FDA was provided with safety and efficacy information for that particular cohort, so that is the cohort that the drug was approved for. The active metabolite, dextroamphetamine, is approved for the older age group.

Neal Catalano made a motion to accept the revised criteria, which was changed to require initiation of therapy between age 6-12. All other requirements were kept the same. Derek Christensen seconded the motion. The motion passed with a unanimous vote by Neal Catalano, Derek Christensen, Tony Dalpiaz, Dominic DeRose, Don Hawley, Joseph Miner, Colin VanOrman, and Joseph Yau.

6. Selzentry: Dr. VanOrman addressed the Board. This is an antiretroviral. The drug requires a tropism assay test as part of the proposed Prior Authorization criteria. The problem is that the tropism assay test costs approximately \$1600 and is not carried by the local labs.

Tim Morley addressed the Board. This medication is only effective for patients who carry an HIV virus that has a particular resistance marker that is carried on the surface of the viral shell. The medication is not effective for anyone who has not had this resistance conversion in their viral load. Therefore, there is a tropism test to determine whether or not the particular virus will respond to this medication. The problem is that the test is extremely expensive, and the major labs in the area have determined that they will not carry it. Patients don't have that lab test available to them. Nevertheless, the Division proposes that this medication should not be used without this test. There is a national lab that carries the test and will do it, but they do not have any agreements with Utah Medicaid. For patients who are on an antiretroviral cocktail and their therapy begins to fail, this medication can be very useful, but the marker needs to be determined to not waste money on the therapy.

The Board asked if Medicaid could provide reimbursement for the tropism test if the national lab were to become a provider. RaeDell Ashley stated that the OBRA 90 law states that Medicaid does not need to pay for a drug that requires a specialty service to be purchased as a condition of prescribing the drug. Ann Glasser of Pfizer responded that Pfizer does not manufacture the tropism assay test. The test is provided by National Biosciences Lab, and is the only validated assay at this time, although there are more companies developing it. The blood can be drawn here, sent to the National Biosciences Lab that provides the tropism assay test, and returned to the doctor within approximately two weeks. This lab will bill whoever the payer is. Lack of local availability of the test is an inconvenience, but not insurmountable. The labeling of the drug says that the test "should" be performed prior to initiating therapy, but not that it "must" be performed. The Prior Authorization criteria that is proposed by Utah Medicaid is consistent with what has been passed in other states. Other states have also had the requirement of optimized background therapy before Selzentry is initiated.

The Board asked if the tropism test would be covered by the pharmacy program, or if it

would be paid by the medical program. The best that the Board can do is require that the test be done before the drug is covered. The Board cannot administer how the test is obtained.

The Board asked about the OBRA 90 law. The law states that Medicaid does not cover a drug if it requires a sole-source test, or something to that effect. That needs to be more closely examined to determine whether or not Medicaid can cover it under these circumstances. There are about 165 HIV clients for FY 2007.

Dr. VanOrman asked if Medicaid can more closely research the issue of the OBRA 90 statute. Don Hawley moved that the discussion of Selzentry be tabled until the OBRA 90 laws are researched. Neal Catalano seconded the motion. The motion passed with a unanimous vote by Neal Catalano, Derek Christensen, Tony Dalpiaz, Dominic DeRose, Don Hawley, Joseph Miner, Colin VanOrman, and Joseph Yau.

7. Wakefulness Promoting Agents (Provigil, Nuvigil), PA Review: Dr. VanOrman addressed the Board. The Board needs to review Prior Authorization criteria for Provigil and look at a new agent in the class, Nuvigil. The Board frequently receives requests for off-label uses of Provigil. In looking at the two sets of proposed criteria, the only difference is that Provigil can be used to offset the sedation related to treatment for multiple sclerosis. The Board may consider adding that as one of the uses of Nuvigil on the Prior Authorization criteria. Otherwise, both agents are used for clients older than 17 years of age, for narcolepsy, for daytime somnolence for patients being treated for obstructive sleep apnea, and for shift work sleep disorder.

Tim Morley addressed the Board. Yesterday afternoon, the Division was told that Nuvigil will not be marketed until 2011. A generic version of Provigil is also not imminent. At the time that the Prior Authorization criteria were drafted, the Division did not have this information.

Yesterday, Medicaid met with a representative from Provigil and a sleep specialist from one of the local sleep centers. The sleep specialist felt that Medicaid should not require a trial and failure of stimulants before approving Provigil for narcolepsy; however, he did say that stimulants are effective. Medicaid asked for the Board to consider this when reviewing the current Prior Authorization criteria.

Dr. Miner stated that he understands the concerns with using a controlled substance prior to using Provigil, but that stimulants are effective and should be tried prior to Provigil.

Medicaid has recently received a number of requests for Provigil for patients with a history of drug abuse who would rather not take a stimulant prior to Provigil based on that history. To allow that on a regular basis would require more documentation from the patients and a change in the criteria. The Board asked what sort of drugs have been abused and in what degree. Dr. Yau stated that it is not unusual to find patients who abuse different drugs based on what is available to change their unwanted mood state.

The Board asked about what kind of doses were being requested. The available data does not support 400mg daily doses for any condition other than narcolepsy. The sleep specialist that met with Medicaid felt that the doses approved by Medicaid were appropriate. The Prior Authorization nurses stated that their volume would not change very much if the stimulant requirement was dropped for narcoleptics. The use of Provigil is higher in other categories

where stimulant use is not indicated. Medicaid also receives many requests for patients who are overly-sedated due to narcotic pain medications, but those are not approved. Medicaid approves use for patients with sleep apnea who are on BiPAP or VPAP, not just CPAP, since those machines are used for the same purpose.

Robb Host from Cephalon addressed the Board. Nobody is saying that Provigil is more effective than stimulants for treating narcolepsy. However, Provigil is a safer alternative because it is less abusive and not a sympathomimetic product. Thus far the Board has discussed efficacy, but not safety. Removing the step therapy requirement from the Prior Authorization criteria will not change the number of narcoleptics in Utah, and the Prior Authorization requests for narcoleptics are not very high. There are only 200,000 narcoleptics in the United States.

The Board asked if Medicaid could provide specific utilization data for narcolepsy medications to get an idea of the budget impact that removing the step therapy requirement would have. Tim Morley stated that it would be possible. Preliminarily, he stated that Provigil 100mg tablets are \$5.85, Provigil 200mg tablets are \$8.01, and generic methylphenidates are less than half of that cost. A trial of stimulants is only required for narcolepsy.

The Board suggested that Medicaid could revise the criteria to say that stimulants must be tried unless there is a contraindication. Administering that, however, could be burdensome. The Prior Authorization nurses stated that providers generally ask to waive the requirement if there is some contraindication, so leaving the criteria as is would not change that.

Neal Catalano made a motion to approve the Prior Authorization criteria as they are currently written, and removing references to generic modafanil. Dr. Yau seconded the motion. The motion passed with a unanimous vote by Neal Catalano, Derek Christensen, Tony Dalpiaz, Dominic DeRose, Don Hawley, Joseph Miner, Colin VanOrman, and Joseph Yau.

8. Tamper Resistant Prescription Pads: Tim Morley addressed the Board. This is a law that was passed in May. The federal government did not issue any guidance until August. On September 30, implementation was postponed by 6 months by President Bush. Medicaid and the Department of Health feel that there is a problem in extending this requirement to one segment of the prescription industry. Physicians note that the paper is expensive, may require the purchase of an additional printer, and exposes providers to liability in that they have to remember which of their clients need to have these special prescriptions. It applies only to prescriptions that are hand-carried to the pharmacy. When the OBRA 90 counseling laws came out, the Pharmacy Boards nationwide passed counseling requirement to require counseling for all patients and not just one segment of the population. Medicaid takes the position that if the Tamper Resistant Prescription Pad requirements are good for one segment of the population, they are good for all segments of the industry. The Board of Pharmacy debated this issue briefly and did not act on it. Medicaid is requesting that the DUR Board issue a position statement to the Board of Pharmacy urging that these prescription pad requirements be extended to all segments of the population. A draft of a position statement is presented to the DUR Board for approval of the statement and for approval to forward it to the Board of Pharmacy.

Dr. Miner made the motion to approve the position statement and forward the statement to the Board of Pharmacy. Derek Christensen seconded the motion. The motion passed with

a unanimous vote by Neal Catalano, Derek Christensen, Tony Dalpiaz, Dominic DeRose, Don Hawley, Joseph Miner, Colin VanOrman, and Joseph Yau.

Dominic DeRose stated that he is on the State Board of Pharmacy and he does not remember this being discussed at any of the meetings. Tim Morley stated that he called the Board of Pharmacy and was told that it was discussed in July, no action was taken, and it will not be discussed again. Dominic stated that he will bring this issue up at the next Board meeting.

Dr. Hawley asked if Medicaid has any idea of the cost associated with these tamper resistant prescription pads or printer paper. Dr. Dalpiaz stated that the cost at his institution, which uses full sheets of paper, is 5 times current cost.

The Board feels that this requirement will place an unreasonable burden on the pharmacists, since pharmacists will have to bear the cost if noncompliant prescriptions are discovered during audit. It also increases the pharmacist's workload to have to call and verify noncompliant prescriptions by phone.

Next meeting set for December 13, 2007

Meeting adjourned.

The DUR Board Prior Approval Subcommittee convened and considered 4 petitions.