



STATE MEDICAID DUR BOARD MEETING
 THURSDAY, October 11, 2007
 7:00 a.m. to 8:30 a.m.
 Cannon Health Building
 Room 125



MINUTES

Board Members Present:

Neal Catalano, R.Ph.
 Mark Balk, PharmD.
 Bradley Pace, PA-C
 Joseph Miner, M.D.
 Bradford D. Hare, M.D.

Dominic DeRose, R.Ph.
 Tony Dalpiaz, Pharm D.
 Wilhelm Lehmann, M.D.
 Colin VanOrman, M.D.
 Derek G. Christensen, R. Ph.
 Joseph Yau, M.D.

Board Members Excused:

Don Hawley, DDS

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

Rae Dell Ashley, R.Ph.
 Tim Morley, R.Ph.
 Jennifer K. Zeleny, CphT.

Suzanne Allgaier, R.N.
 Merelynn Berrett, R.N.
 Rick Sorenson, R.N.

Other Individuals Present:

Craig Boody, Eli Lilly
 Gary Okanu, Amgen
 Alan Bailey, Pfizer
 Barbara Boner, Novartis
 Rich Hertgen, UCB
 Erica Brumleve, GSK
 Steve Schaerrer, DSI
 Robb Host, Cephalon

John Stockton, Genentech
 Steve Farmer, Amgen
 Trish McDaid-O'Neill, AstraZeneca
 David Stallard, AG/MFCU
 Lori Howarth, Bayer
 Cap Ferry, LEC
 Bret Brewer, EMD Serono
 Sedrick Spencer, Roche

Sabrina Aery, BMS
 Linda Craig, AstraZeneca
 Lynda Oderda, U of Utah
 James Gaustad, Purdue
 Tony Molchan, Abbott
 Elizabeth Stoltz, J&J
 Michael C. Stevens, M.D.
 Kara Anderson, MHAU

Meeting conducted by: Dr. Colin VanOrman

1. Minutes for August 2007 were reviewed 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: Tim Morley addressed the Board. The P&T Committee is up and functioning. They generally meet on the third Friday of every month. They have already accomplished work with two drug categories: the proton pump inhibitors and the Statins.

The Division has begun implementation of those two categories for the Preferred Drug List beginning October 1. They will meet again on October 19th and take under consideration another category of drugs: oral hypoglycemics. They are taking information under consideration from manufacturers and other sources of input to make their decisions about what will be on the Preferred Drug List.

The Board asked if all of the high-potency Statins had preferred status. All of the high-potency Statins do have preferred status. In the PPI class, there are two preferred drugs: Prevacid products and Prilosec OTC. Generic omeprazole is also preferred.

Barbara Boner of PhRMA asked if the list is posted on the web. Medicaid will make sure that this is posted on the website.

4. Synagis: Dr. VanOrman addressed the Board. Board members should have received an informational packet about Synagis, including current Prior Authorization criteria. There is no action that needs to be taken; the Prior Authorization criteria need to be reviewed. The Synagis season starts on November 1, and provides 5 doses to be given over 6 months. Claims since 2004 have been included in the packet. Dr. VanOrman asked Tim Morley to explain the claims data that was provided.

Tim Morley addressed the Board. The claims data that was provided is laid out in the format of average claims per client. One would expect that there would be 5 claims per recipient, and that does not appear to be the case. There is a column included that indicates what the full expense would have been if all clients had received 5 doses. The bold numbers on the handout indicate the expenses that were actually realized.

Medicaid had a meeting with Medimmune, the manufacturer of Synagis several weeks ago. The reason that Synagis was brought the Board today was in anticipation of any amendments that need to be made to the Prior Authorization criteria. Medicaid will be having another meeting with Medimmune later this month, but does not anticipate any changes to the criteria at this time. Medicaid would welcome comment at this point.

5. Tamiflu and Relenza: Dr. VanOrman addressed the Board. The Prior Authorization criteria for both Tamiflu and Relenza have been provided for the DUR Board to review. The Board needs to review these criteria sets and make a motion to approve them if they are acceptable.

The DUR Board first looked at the Tamiflu criteria. It is authorized for patients one year or older with immunodeficiency states, HIV, radiation treatment, and other immunosuppressive agents. It is limited to 10 capsules per year for prophylaxis. This would be for any household contact with severe cardiopulmonary conditions, immunocompromised patients, or age > 65 with documented exposure to influenza, with treatment to be started within 72 hours of diagnosis.

Dr. Yau asked to clarify the definition of long-term steroid use. Would inhaled corticosteroids in asthmatics be included in this definition? Tim Morley stated that these products are only available during the flu season, and that asthmatics on long-term inhaled corticosteroid therapy would be eligible.

Cap Ferry, LEC, asked if Medicaid defined the flu season as a certain number of cases being reported by Primary Children's Medical Center. Tim Morley clarified that this is the criteria

that was used with Synagis. It used to be that when five cases per week were reported by Primary, the Synagis season would open. Now the season opens on November 1. This is not the case with Tamiflu. It is covered from November to March. RaeDell Ashley clarified that the season could be opened earlier than November 1, if Primary's reported an epidemic earlier.

The DUR Board is required to review Prior Authorization criteria on a somewhat regular basis. These criteria were brought to the DUR Board today to make sure that they were still adequate for Medicaid's needs.

The major difference between Tamiflu and Relenza were age. Relenza is approved for age 13 and over. Tamiflu is approved for age 1 and over.

The Division included some utilization data for Amantadine and Rimantadine. This was provided for informational purposes only. The ACIP does not recommend either of these drugs to be used for influenza at all, because there is a significant amount of resistance to these agents. Medicaid still spends a significant amount of money on these products, but cannot defer to those products based on cost due to ACIP regulations. The ACIP guidelines were included in the information provided to the DUR Board.

The Board asked if Medicaid had a way to tell whether Amantadine and Rimantadine were being prescribed to treat influenza or movement-related disorders due to psychotropic drugs. For the liquid formulations, that is probably used more for children, and that's where the bulk of the use is. There is no way to tell the diagnosis.

Mark Balk pointed out that the approved age for Relenza on the Prior Authorization criteria is age 13 and over. However, it looks like it is approved for age 7 and older. Tim Morley stated that age restrictions are usually put on Prior Authorization criteria due to FDA approved limits. If this has changed, the Division will address it. Mark Balk stated that children's dosing was available in the ACIP guidelines. This was confirmed by checking e-Pocrates. Tim Morley agreed to add this updated age guidelines to the Prior Authorization criteria. The 72 hour statement should also be on the Relenza criteria.

The Board pointed out that Tamiflu is the chemoprophylaxis drug of choice. However, it would be difficult for Medicaid to enforce any sort of step therapy on these drugs, particularly with a Prior Authorization on drugs that need to be started within 72 hours. It would best be left to the physician's discretion.

The Board also asked why the criteria restricted Tamiflu prophylactically to age 13 and older. It is now available in a liquid dosage form and indicated for age 1 and over. This was confirmed by consulting e-Pocrates.

Dr. Miner made a motion to accept the criteria for both drugs as corrected: Tamiflu age 1 and older for treatment and prophylaxis, Relenza for age 7 and older for treatment and prophylaxis, and a 72 hour statement added to the Relenza criteria. Mark Balk seconded the motion. It passed unanimously.

6. Age Limit Restrictions - FDA Limits.
 - a. PPIs: Tim Morley addressed the Board. When the P&T Committee considered the Proton Pump Inhibitors, they were especially concerned that dosages for children be

available. Part of the difficulty with that is that children's doses are not part of the Preferred Drug List. The question arises if limits need to be set to ensure that these dosage forms are used only in that particular arena. Prevacid does have children's dosage forms available in the form of powder packets and rapidly dissolving tablets. Prevacid is enteric coated granules in all dosage forms - even the orally disintegrating tablets. For Prilosec OTC, that would be an identical consideration. Do we need to put an age restriction on these products so that going beyond a limit of, for example, age 12, an adult dosage form would need to be used. There is also a question of utility with J-tubes and nasogastric tubes, and if they would clog using opened capsules. However, the children's dosage forms have the same enteric coated granules as the open capsules, so unless the manufacturing community has information to the contrary, it would seem that the opened capsules could be used in these tubes. PPIs are extensively used in children, newborns, and premature infants. However, there is an age limit on the FDA approval. Rather than hold hard and fast to these restrictions, it would be preferable to have a discussion with the DUR Board to provide a safety net due to the extensive use in these ages, although there are no studies available for children under 2.

Derek Christensen stated that a sizable body of data on the use of PPI's in newborns does exist. Anecdotally, he stated that working on the NICU at Primary's for seven years it is widely used and effective in this population. He is in support of approving its use in that populations.

Dr. Hare asked what the criteria are for putting these children on PPI's. Tim Morley stated that Medicaid was interested mainly in an age restriction rather than Prior Authorization criteria, since they are open for this age group now. Derek Christensen stated that he observes that mainly "colicky kids" who are symptomatic are prescribed PPI's. Dr. VanOrman stated that he doesn't personally treat colic, but he sees a lot of children with developmental disabilities that may be put on a PPI for a few months, and many are off it by one year of age. The DUR Board was provided with utilization data from birth to age 12.

Prevacid is approved down to age 1. The majority of medications for this age group is used without FDA approval. Medicaid would like to make these drugs available to children, but would like to restrict the dosage forms made for children to children. This means that Medicaid would need to go before the Board to seek to use it outside of FDA approved uses.

Dr. Miner made a motion to have children's dosage forms available for children from birth to age 12. Mark Balk seconded the motion. The motion passed unanimously.

b. ADHD Medications: Dr. Stevens addressed the Board. The FDA has had a long and checkered history since it first started requiring efficacy data in addition to safety data since 1962. There is a brand new medication that has come on the market that has been approved for ages 6-12 when ADHD is most often diagnosed. Clearly, the scientific literature indicates that it is frequently diagnosed between the ages of 12-18, in adults, and also down to age 4. There are no qualitative differences being found in these medications in the scientific literature. The FDA regulations have become more assertive about an indication being appropriate for reimbursement, particularly in the public sector. When the ability to use medication off label is lost,

particularly in pediatric psychopharmacology, and ADHD is probably the most non-controversial area, an enormous tool to treat effectively the Medicaid population is lost when reimbursement is lost. With ADHD medicines, when there is a categorical position that these medicines will be reimbursed based on FDA indications in this age range, and it is not opened up somehow, a problem is created where physicians can be asked to practice unethically in the sense that they are not practicing evidence-based medicine - rather regulatory-based medicine in terms of reimbursement controlling real-world access. This should be reconsidered in a categorical way. If there is a group of medications where this could be done rationally, it is ADHD medicines.

Dr. VanOrman wanted to clarify the background of this discussion. Many of the stimulants are approved for age 6 and above. Some of them are approved down to age 3. Dr. VanOrman asked Dr. Stevens if he was requesting all of them to be covered for age 3 and above. Dr. Stevens stated that this is what he is requesting. For example, when Vyvanse enters the bloodstream it is dextroamphetamine. Dextroamphetamine is reimbursed by Medicaid, Vyvanse is not. Yet when Vyvanse enters the bloodstream it is the same molecule as dextroamphetamine in tablet form. Much of the progress in the treatment of ADHD is improvement in the ability to deliver the psychotropics that are used to treat ADHD in a much more even way across the course of the day. This particular methodology of delivering dextroamphetamine is very smooth. In this case, Medicaid is potentially cutting off a superior way to deliver the same molecule.

Tim Morley addressed the Board. This whole issue puts the science of kinetics on trial. For example, amphetamine salts are approved down to age 3. Yet in an extended-release form they are only approved for age 6 and above. Dr. Stevens highlighted the issue of Vyvanse, which is dextroamphetamine when cleaved in the body. The question being asked is how does the prodrug, approved for ages 6-12, differ for ages outside of this range for which it is FDA approved, versus dextroamphetamine which is approved for ages 3 and above. What is the approval range for the kinetics involved with the medication? Clinically, dextroamphetamine is dextroamphetamine. Why not pay for a lower cost alternative?

Dr. Stevens stated that he agrees with that. There are other treatments for ADHD for which he has never submitted a PA request, because he has not seen a clinical difference from a lower cost of generic. He would not make an argument unless there were a clinical difference. There are numerous factors in the real world including patient choice - what patients will take, won't take, what they have read on the internet, much of which has been misleading. It becomes a medical/legal issue when patients are denied access to a medicine when the clinician writes a prescription and the patient cannot pay for it. For prescribers, it is an ethical bind if they cannot provide a standard of care. He agrees that treatment needs to be cost-effective.

Dr. Yao stated that he agrees with many of the points, including that delivery of medications throughout the day needs to be smooth, particularly with medications for ADHD. Short-acting medications given three times per day create three peaks and valleys. This can even create confusion with the diagnosis. Whether there are really distinct differences within this class of medications, it is hard to say. Human bodies are individuals, as well. Therefore, treating clinicians need to have a choice in the

medications they can use. The approvals of medications is based on the age range of the people being studied - this does not necessarily mean that medications do not work outside of the age range. Therefore, there are restrictive criteria for many indications. The issue about diagnosis for ADHD under the age of 5 sometimes creates a challenge - there can be many conditions that resemble this with ups and downs and a child being irritated. In the hands of experienced clinicians, the symptomatology can be quite telling and it can be quite practical in trying to get these children to improve with the medications that are available.

RaeDell Ashley asked Dr. Yao why he would want a particular formulation for a 3 year old if a drug is available in immediate release. Dr. Stevens stated that the older a child gets, the more slowly they metabolize a medicine. Therefore, the ups and downs that Dr. Yao refers to become even more dramatic in a 5 year old. Rebound is a clinical reality. When treating patients, the consequences of rebound will offset the benefit of treating ADHD. A parent may not tolerate this in their child, and the clinician must listen to the parent. This was a repeated problem with short acting medicines. There is also the added problem of noncompliance as dosing goes from one to two to three times per day. In the case of Vyvanse, when it remains in the GI tract as Vyvanse throughout the day, it has the slowest and most even release in the body throughout the day. This medicine is a good example because the molecule in the body is the same. The single largest improvement over the last 10-15 years has been the ability to deliver psychostimulants evenly throughout the day.

Dr. VanOrman pointed out the Vyvanse is on the agenda for the next month. The current question is if the DUR Board feels it is appropriate to continue to abide by FDA-approved indications. For example, Adderall is approved down to age 3, but Adderall XR is only approved to age 6.

Tim Morley added that there are substantial requests for use of these medications under the FDA-approved age limit. For children age 3 or 4 requesting methylphenidate, Medicaid will bring each request to the DUR Board. A study has been provided to the Board members stating that immediate-release methylphenidate on a TID basis does provide significant changes in ADHD symptoms. There is the issue of parental convenience versus lower-cost alternatives with different dosage forms. There is another study about the impact on growth that these agents have. These are all things that need to be considered.

Dr. Stevens is not arguing for an expansion of the number of cases of ADHD treated - rather availability of agents used to treat. The diagnosis should be made conservatively. The growth data are all extremely reassuring. Every study has shown that at 22 the children are where they should be on the growth curves. The issue of parental convenience shows that even in the schools as well, there is only about 50% adherence with noon dosing. There was a time where there was a nurse in every school - now there is a nurse in every district. Children under 6 may be in preschool, which do not have the same requirements as public schools. Also, because of the rapid metabolism of the younger children, the longer acting dosage forms which have traditionally been off the list of agents available to children under 6 need to be available for this age group.

Tim Morley stated that the action brought for consideration is that there may be some

modulation in the age restriction that Medicaid could do based on specialty prescribing, or that Medicaid could stay the course with limiting prescribing to FDA-indicated ages. There may be some position in between that Medicaid could take. Most of the requests do come from child and adolescent psychiatrists.

Dr. VanOrman asked if it is practical for all children between age 3-6 to see a child psychiatrist. Dr. Stevens stated that child psychiatrists typically see more referrals for this age group, because pediatricians are more hesitant to treat children under 5.

Mark Balk stated that it seems reasonable to drop the age to 3, but that seems more practical to try intermediate-release dosage forms for younger children because they are available in lower doses. Tim Morley stated that the Board has taken this position with individual petitions in the past. However, in the case of methylphenidate, the age restrictions are the same on all of the products. This seems to be where Medicaid is getting a bulk of the requests, since amphetamines appear to cause mood problems in younger children.

Dr. Stevens that this appears to be the case with children diagnosed with developmental disabilities. ADHD is subsumed under this diagnoses, which is also associated with anxiety. Amphetamines appear to aggravate this. The scientific literature supports trying a methylphenidate before an amphetamine in patients with anxiety.

Dr. Yao stated that he agrees with this interpretation. It is difficult to take a stand on this issue, because it is so complex. It is not a convenience issue - the longer acting dosage forms can really deliver medication very smoothly throughout the day.

RaeDell Ashley stated that she feels that it is best to be able to take individual petitions to the Board, rather than taking a stand that is diametrically opposed to FDA regulations.

Mark Balk stated that the policy statement talks about consideration of medications down to 5 years of age. Below 5 years of age, treatment in that age group should be consulted with someone with specialized training. The reality is that the specialist with advanced training will come before the Board and state what was tried. Most of the denials are based on a documentation issues. FDA rules can be used to a certain point. The DUR Board can make exceptions and often do. The Board can avoid taking a physician away from practice, which will cost the system money and cost patients in quality of life. He made a motion to allow specialists to prescribe down to the age of 3. Dr. Miner seconded the motion. The motion passed unanimously.

7. NPI: Discussion was postponed to next month.
8. Deficit Reduction Act and new AMP based FULs: Discussion was postponed to next month.

Next meeting set for November 8, 2007
Meeting adjourned.

The DUR Board Prior Approval Subcommittee convened and considered 9 petitions.