



STATE MEDICAID DUR BOARD MEETING
THURSDAY, November 13, 2008
7:00 a.m. to 8:30 a.m.
Cannon Health Building
Room 125



MINUTES

Board Members Present:

Mark Balk, PharmD.
Derek Christensen, R.Ph.
Dominic DeRose, R.Ph.
M.D.
Joseph Miner, M.D.

Neal Catalano, R.Ph.
Tony Dalpiaz, PharmD.
Wilhelm Lehmann,

Joseph Yau, M.D.

Board Members Excused:

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

Peter Knudson, D.D.S.
Colin VanOrman, M.D.

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

Jennifer Zeleny
Lisa Hulbert
Carol Runia
Rick Sorensen

Tim Morley
Duane Parke
Merelynn Berrett
Debbie Harrington

Other Individuals Present:

Jen Todd, Amylin
Alan Bailey, Pfizer
Ann Gustafson, GSK
Barbara Boner, Novartis
AstraZeneca

Jesse Hory, Amylin
Marianne Paul, U of U
Robert F. Miller
Trish McDaid-O'Neill,

Meeting conducted by: Derek Christensen, R.Ph.

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1. Minutes for October 16, 2008, were reviewed. A motion to accept the minutes was made by Mark Balk. Dr. Miner seconded the motion. The motion passed unanimously with votes by Mark Balk, Derek Christensen, Dominic DeRose, Dr. Miner, Neal Catalano, Tony Dalpiaz, Dr. Lehmann, and Dr. Yau.
 2. Usage Data Overview: Tim Morley addressed the Board. Due to the budget constraints that Medicaid is working with, Medicaid was asked to expand the use of MAC pricing within the last month. The Pharmacy Team evaluated over 22,000 different NDC's for potential MAC pricing effective on November 1. Since then, some errors have been discovered, and Medicaid will provide communication when they are fixed. This will allow pharmacies to reprocess claims where appropriate. Duane Parke added that the pharmacy

providers need to provide Medicaid with the latest invoice, so that the Medicaid can investigate the level of reimbursement.

The Board asked when some information would be sent out. Medicaid is anticipating having some problems fixed by next week. Communication will go out around that time.

The usage data overview, agenda items 2 and 5 have some overlap. Graphs were included in the DUR Board handouts. This is an informational piece for the benefit of the DUR Board having to do with PAs that were put in place on certain drugs and classes. The graphs show the date that a PA was enacted and the date that a PA was removed, and the results of the actions. The Overactive Bladder medications also show some impact from Medicare D, since many of the patients receiving those drugs were elderly.

A sheet showing the usage data for Cymbalta was also included. About two years ago the DUR Board considered requiring an ICD.9 code on anticonvulsants, as it does for Cymbalta, to get a handle on the types of conditions that the anticonvulsants are used for. At that time, the Board decided to do a trial with Cymbalta and evaluate the information received to justify such an approach. With Cymbalta, there was not a list of ICD-9's like there was with the antipsychotics. Rather, the pharmacy was asked to categorize the prescription into one of two codes: one for depression, and one for neuralgias. Pharmacies can put in up to 6 to 7 ICD.9 codes per claim, so some of the prescriptions for Cymbalta are coming in with extra information.

Dr. Miller asked where the pharmacy is getting the ICD.9 code from. The pharmacists on the Board stated that they typically call, but he is sure that some pharmacies just enter a code to get it through the system if they are busy. Many times the office staff doesn't even know the diagnosis code.

Tim stated that in the case of Cymbalta, Medicaid provides one of two billable diagnosis codes and it is up to the pharmacist to categorize the prescription. In the case of the antipsychotics, it is up to the pharmacy to call and get the diagnosis code.

Based on the two diagnosis codes that are payable for Cymbalta, it is apparent the vast majority of Cymbalta use is for depression. If something like this were done with the anticonvulsants, Medicaid could categorize what they are being used for. This has been a big issue for Medicaid agencies, since there is an expectation that off-label use is to be minimized to off-label indications for which there is evidence. Since a large portion of the budget is spent on anticonvulsants, antidepressants, and other drugs of those categories, perhaps Medicaid will want to bring back another proposal for the anticonvulsants. Medicaid would also welcome a proposal from the DUR Board.

Dr. Yau said that he has taken the handout and highlighted the uses of Cymbalta that are unrelated to mental health. It appears that this usage has gone down over time. Now it seems like people have learned how to use the ICD.9 capture tool.

Tim stated that Medicaid could come up with a concise list of diagnoses to allow pharmacies to categorize usages of anticonvulsants. No one currently knows what they are being used for, but this could be a first step towards identifying it.

The Board suggested that perhaps only two diagnoses could be rolled out to begin with, one for seizures and one for mood stabilizers. Tim stated that Medicaid had initially proposed 4 categories, but was told to do a trial with Cymbalta first. The original categories proposed were for epilepsy, depression, mood disorder, and neuralgias.

Duane stated that this is similar to the roll-out of the atypicals. When those were first rolled out, they had a list as long as the table. The psychiatrists in the state and on the committee were supportive in helping Medicaid develop a list of diagnosis codes, which reflected what was happening in the prescribing habits.

Tim stated that Medicaid will return with a proposal.

3. Symlin PA Review: Alisa Hughes, PharmD. Candidate from the University of Utah addressed the Board. Symlin is a synthetic analog of human Amylin. Human Amylin is produced by pancreatic beta cells and secreted along with insulin in response to rising blood glucose after a meal. Its physiological effect is to slow the rate of gastric emptying. It also suppresses glucagon secretion by the liver, and it regulates food intake by modulating the appetite in the brain so it induces satiety. The drug Symlin is injected prior to a meal, separate from insulin, in patients. When a patient starts on Symlin, the insulin dose needs to be decreased by 50%, because the patient risks developing significant hypoglycemia. After the Symlin dose has been titrated from the initial dose up, the insulin is then titrated back up again to optimize the postprandial glucose level. The reason that it is started low is because when Symlin is first started it can cause a significant amount of nausea and possibly vomiting. The patient needs time to develop tolerance to these effects. Symlin is approved for use in patients with both Type I and Type II diabetes who are using mealtime insulin. It is indicated for patients who have failed to achieve blood glucose goals despite optimal insulin therapy. It is contraindicated in patients who have gastroparesis, for obvious reasons, because it further slows gut motility. It is also contraindicated in patients who have hypoglycemia unawareness. They would be unable to recognize the symptoms of hypoglycemia if they should develop it, and they probably would not be good candidates because Symlin can cause even worse hypoglycemia. Symlin use is contraindicated in the following patients: those who have poor compliance with their current insulin regimen, those who have poor compliance with their glucose self-monitoring regimen, who have recurrent hypoglycemia requiring assistance within the last 6 months, presence of hypoglycemia unawareness, a confirmed diagnosis of gastroparesis, or who require drugs that stimulate gastrointestinal motility. It has not been approved for use in pediatric patients. One of the biggest proposed changes is that there is no current upper limit on the A1C

requirements. It is not appropriate for patients with an A1C over 9%, just as it is not appropriate for patients with an A1C below 7%. The range of 7%-9% is based on the ADVANCE and ACCORD studies, which were released in the New England Journal of Medicine. Neither of them show an increased benefit, and ACCORD actually showed an increased risk of death with an A1C below 7%. The ACCORD study also showed increased episodes of hypoglycemia if the A1C is pushed below 7%, though the target goal in that study was 6.5%. In the American Diabetes Association's 2007 standards of diabetes care, it does not advise either for the use or against the use of Symlin, and their target is 7%.

The Board asked how hypoglycemia unawareness is defined. Alisa stated that there are many definitions in the literature, but it really is the patient's inability to recognize hypoglycemia symptoms as they come on. There are usually physiological changes that include shaking, sweating, nervousness, confusion, and many patients who have had repeated episodes of hypoglycemia may not recognize this, since their body does not give them such signals. Dr. Lehmann asked how it would present in clinical practice. Alisa stated that a patient who didn't feel that his blood sugar was down to 40 would have hypoglycemia unawareness. Patients should have some signal that their blood sugar is that low. Some patients may be on medications that mask the effects of hypoglycemia, such as beta blockers; but sweating doesn't usually go away as a symptom.

Mark Balk asked if there were any recommendations on how many times per day to dose Symlin. The package states that it can be injected up to 3 times per day, for Type II diabetes, with meals. It can be used up to 4 times per day with Type I diabetes, again only with meals. It is injected along with insulin, but at a different site.

Mark Balk stated that it may be beneficial to add to the criteria that patients may not have received drugs for GI motility. Many of the criteria in the suggested PA requirements are difficult to measure objectively, but excluding patients who have received these drugs would be easy to identify.

Dr. Yau asked how recurrent hypoglycemia would be defined? Would it be defined as a certain number of episodes per 6 months? He also asked how severity would be measured. Alisa stated that severe hypoglycemia requiring assistance would be defined as an episode in which the patient receives glucagon or requires another person to administer glucose to them. The literature did not provide a definition of recurrence. Tim Morley stated that if a person has been diabetic for a long amount of time and still requires assistance with hypoglycemia that is probably an indication that they are missing out on something that they need to be doing in their therapy. These patients should probably not be exposed to the danger of taking this drug.

Tim Morley stated that the only differences in the proposed new criteria was the addition of an upper limit on the A1C, the addition of the new indication of Type II diabetes, and the exclusion of patients with hypoglycemia unawareness.

Mark Balk suggested that the PA criteria be cleaned up. He suggested removing redundant language requiring documentation to be faxed. Rick Sorensen stated that many times the PA nurses do not receive necessary documentation, so the redundancy doesn't hurt. However, there were a few points that could be consolidated or removed altogether.

The Board suggested requiring that a patient's blood glucose testing record be required with the PA. This may help show that the patient is testing properly and injecting in a compliant manner. The PA nurses felt that it would be an excessive requirement, since it is the provider's responsibility to monitor compliance rather than the PA nurses. The Board members felt that this would be easy, since the meters generally record a history and print it out or sync it into the patients chart. This could allow Medicaid to consolidate several points on the PA, including the failed glucose control despite optimal therapy, insulin injections, and regular monitoring.

Mark Balk suggested that a hard age requirement be added to the PA, since it is not approved for pediatric use. In the studies, it was studied in age 15-84 years. Tim stated that the age should probably only be kept as a note rather than a requirement, since there could be a legitimate use for this product in a 16 or 17 year old.

Mark Balk moved to accept the changes as stated. Neal Catalano seconded the motion. The motion was approved with unanimous votes from Mark Balk, Derek Christensen, Dominic DeRose, Dr. Miner, Neal Catalano, Tony Dalpiaz, Dr. Lehmann, and Dr. Yau.

The manufacturer's representative from Amylin wanted to address the Board. Jesse Hong, clinical pharmacist, addressed the Board. Because of hypoglycemia, when Symlin was approved, they had received a Boxed Warning on Type I diabetics, for patients to reduce their insulin by about half. In Amylin's clinical experience, that has almost eliminated the incidence of hypoglycemia. If a non-diabetes patient were to take Symlin, they would not experience any hypoglycemia, because Symlin by itself does not induce insulin production. The concern is hypoglycemia is intended for people who are already on insulin. Because Symlin is such a potent medication, it may cause the patient's insulin need to be reduced. This can cause hypoglycemia, which occurs most often in patients with Type I diabetes. The previous speaker mentioned not using Symlin in patients with an A1C of less than 7%, citing the ACCORD and ADVANCE studies. These studies evaluated cardiovascular risk, and did not include the use of Symlin. In these studies, the risk of death was actually related to intensified treatment in insulin or TZD groups. Because of that, it was recommended that patients should consider how fast they bring down an A1C level, rather than a random number. Whether a patient is greater or less than 7% really had no bearing. The primary benefit of Symlin is that it reduces the daily glucose fluctuation and reduces postprandial hyperglycemia. These things happen regardless of the A1C level. The Board is asked to reconsider the Symlin PA criteria.

Dr. Miner stated that if the patient is above 7% A1C at the time of initiation and then goes below 7, the drug will not be discontinued. The 7 is the A1C requirement for the time of initiation.

Derek asked if the Board was still comfortable with the previous decision and asked for a motion to accept the PA requirement as previously discussed. Mark Balk made the motion, Neal Catalano seconded it. The motion was approved with unanimous votes from Mark Balk, Derek Christensen, Dominic DeRose, Dr. Miner, Neal Catalano, Tony Dalpiaz, Dr. Lehmann, and Dr. Yau.

4. Amitiza PA Review: Anne Schweighardt, PharmD. Candidate from the University of Utah addressed the Board. Amitiza is the brand name for lubiprostone. It currently carries two FDA indications. One is for chronic constipation in adults; the other is for irritable bowel syndrome with the constipation component. Amitiza is a chloride channel agonist, and it activates the chloride channel, which pulls chloride into the intestinal lumen. The sodium follows that, and pulls water in, creating an osmotic effect and hopefully stimulating a bowel movement. There have been some changes to the FDA approved indications since Amitiza was initially approved. The initial PA only included chronic constipation. Since that time, they have received the indication for IBS with constipation. The new proposed PA reflects those changes. The information on the chronic constipation is the same. What has been added is the IBS, which is only approved in females. It would require a documented diagnosis of IBS with constipation, documented failure within the last 12 months using a psyllium product or an osmotic laxative, and other causes of constipation to be ruled out. The recommendation is to approve it for a 3 month period. The reason for this is that the package insert talks about whether a patient is an overall responder. The way that this is defined is if a patient was a monthly responder, which is a patient who experiences significant relief for 2 weeks per month or moderate relief for 4 weeks per month. An overall responder is a monthly responder for 2 out of 3 months. Basically, this means that 2/3 of the time the patient is responding to the medication. When compared to placebo, about 13% of the population became an overall responder on the medication, as compared to a 7% effect on placebo. Because of the very low effect for overall responders group, it was determined that these patients needed to be re-examined after 3 months to ensure that the therapy is still appropriate.

The Board asked if it was appropriate to broaden the “psyllium” to any fiber laxative. Anne stated that there was no specific requirement in the data for psyllium. That came from the AGA guidelines and some of the European guidelines, but it seems reasonable to allow a trial of any fiber laxative. The Board felt that it was appropriate to allow any fiber laxative to be consistent between the IBS and chronic constipation guidelines.

The Board asked if the guidelines require that a patient fail a bulk forming and an osmotic laxative together or separately. The guidelines do not require the two laxatives to be tried together.

Rick Sorensen asked what the reauthorization policy would be. In the past, a patient would get two 3-month approvals within a lifetime. These PA criteria do not specify. Anne did not feel that it would be unreasonable to allow them to receive it indefinitely due to the nature of IBS.

The Board asked if it would still be required that a patient re-try a lower cost laxative before being reauthorized for a PA. Tim Morley felt that if there was a lower cost alternative that may work for the patient, they should have to try it to see if they could be managed on it.

Dominic DeRose moved to accept the PA criteria as amended. Mark Balk seconded the motion. The motion was approved with unanimous votes from Mark Balk, Derek Christensen, Dominic DeRose, Dr. Miner, Neal Catalano, Tony Dalpiaz, Dr. Lehmann, and Dr. Yau.

Next meeting set for January 15, 2009
Meeting adjourned.

The DUR Board Prior Approval Subcommittee considered 4 petitions this month.

Minutes prepared by Jennifer Zeleny