MENTAL HEALTH DRUG ADVISORS GROUP
Meeting Summary
August 13, 2008

Welcome / Introductions

Jason Helgerson, Medicaid Director, and John Easterday, Administrator of the Division of Mental Health and Substance Abuse Services, opened the meeting by welcoming the group and beginning introductions. Dr. Easterday reported that Secretary Karen Timberlake wanted to attend but it was necessary for her to accompany the Governor on his Northern Capitol tour for the week. She is very interested and will review the minutes carefully.

Members present: Ken Casimir, Clarence Chou, Molly Cisco, Ted Collins, Hugh Davis, Ronald Diamond, Shel Gross, Catherine Kunze, David Larson, Allen Liegel, Jenny Lowenberg, Mary Neubauer, Kenneth Robbins, Suzanne Seeger, Michael Witkovsky

Staff Present: Joyce Allen, Kay Cram, John Easterday, Carrie Gray, Rita Hallet, Jason Helgerson, Michael Mergener, Lynn Radmer, John Easterday, James Vavra

The meeting summary from March 4, 2008 was approved without changes.

Prior Authorization Committee's Recommendations Regarding Alzheimer's Agents; Antidepressants, Other; Antidepressants, SSRIs; Antiparkinson's Agents; Antipsychotics, Atypical; and Stimulants and Related Agents

Jim Vavra summarized the recommendations from the August 6, 2008 Medicaid Pharmacy Prior Authorization Advisory Committee (MA PA) meeting.
Alzheimer's Agents: There was one change from the current Preferred Drug List (PDL) with Exelon being recommended as non-preferred by staff and approved by the MA PA committee. This class includes grandfathering.
Antidepressants, Other: The new drug in this class is Pristiq. The staff recommendation, approved by the MA PA committee, was to make it non-preferred. There are no other changes from current PDL.
Antidepressants, SSRIs: There were no changes recommended except to make the new product Luvox CR non-preferred.
Antiparkinson's Agents: There are two changes in this class. One is to put ropinirole, the generic of Requip, as non-preferred. Brand requires PA. Bromocriptine is new to the list. It hasn't been on because it has limited use. For some states in TOPS it has to be in the review so it was added.
Antipsychoctics, Atypical: The staff recommended no changes from previous PDL. Motions and discussions were summarized. Shel Gross made a motion to accept the recommendations as presented, but modify to add Abilify. Dr. Izard seconded the motion. The vote failed. A second motion was made by Pat Towers to refer this issue to the Mental Health Drug Advisors due to a rush for time. This motion was passed.
Stimulants: There were no changes recommended to current PDL except to add the new drug, Vyvanse, to the PDL.

Kenneth Casimir asked why the MHDA doesn't meet prior to the MA PA meeting. Mr. Helgerson responded that the meeting was designed so the Secretary could hear final input from the expert committee prior to her final decision. Michael Mergener added that originally the MHDA wanted to review the recommendation and respond to those. Shel Gross added that the mental health advocates wanted input. He also wanted to highlight that the MA PA committee deferred to this group because

they didn't feel they had the expertise. Mr. Gross agrees that this committee may want to meet first if the MA PA committee wants input. Molly Cisco states that it makes sense to meet prior to the MA PA committee since they don't have a lot of mental health experts. Mr. Helgerson agreed to take that recommendation to the Secretary. Mr. Gross suggested that the MA PA committee have input on the process. Jenny Lowenberg is concerned that the decision about the Atypicals was made under the gun when it is such an important decision. Shel Gross has the perception that the discussion wasn't complete. Michael Witkovsky states that the psychotropic medications generate a lot of discussion and questioned why they are always put last. Mr. Helgerson thought it was an excellent suggestion said they could be moved first. They reported that staff had already recognized that they should be moved first. They talked about having the presentations on the mental health classes last and the discussion first.

Discussion regarding recommendations

Antipsychotics, Atypical
Michael Mergener described the antipsychotic prescriber charts. He indicates that there is an improvement from these numbers a few years ago with more psychiatrists prescribing Antipsychotics, Atypical than previously.

Michael Witkovsky: States that he would agree with Shel Gross' recommendation to add Abilify to the PDL if Seroquel is taken off. He indicates that they had heard at the MA PA meeting about a number of new indications for Abilify and heard from Primary care about calls in the night for number of emergencies and thinks that if it is on the PDL it would be simple to fill a prescription. Seroquel has a history of being used in excess for a number of needs. When medications have open access they aren't always used with judiciousness. If one is put on the PDL then one should be taken off. Wants to use this process to insert thoughtfulness into physician behavior because he feels that not every time a dose is given it is to treat a serious psychiatric illness
Ronald Diamond: Shares Dr. Witkovsky's concerns about primary care doctors prescribing more but not sure if this is the role of this committee.
Ted Collins: For 20 years he has been looking at nursing home populations. Dr. Collins states that 25 years ago there was an overuse of traditional antipsychotics in nursing homes. They were able to dramatically decrease utilization with regulations. What came of that was the introduction of Atypicals with this population which is no less problematic. Dr. Collins is struck by 15% of the market share being on Abilify so thinks PA hasn't had an impact. He presumes that it is off PDL due to the costs and questions that since the MA PA committee deferred to the MHDA, if cost is something they should know. Mr. Helgerson states that the costs are confidential but general costs are provided. Dr. Diamond thinks that if the mandate of this committee isn't to include cost they will have different recommendations than the PA committee which is considering cost. John Easterday indicates that the Secretary is looking for efficacy issues from this committee.
Allen Liegel: Requested more information on what Shel presented at the earlier meeting. Questioned why Abilify was the only one requested to be added. Mr. Gross responded that the points of adding Abilify and not Zyprexa were because of the side effect profile. That is important because this committee has considered safety issues. When Zyprexa was originally not on it was because of the safety. For certain indications like bipolar they are the only two with indications and one should be on. The cost issue is the third issue – the market share has stayed the same so we actually loose money not having it on the PDL. It is going to get prescribed anyway we might as well get the rebate. Dr. Liegel also asked the psychiatrists if they prescribe Abilify. Dr. Diamond thinks Abilify is a very good drug for efficacy and side effects. He states that if cost is not an issue then it should be on but if cost is an issue it has to be part of the decision. He states that it is a very tolerable drug. Dr. Liegel points out that here the cost of the drug is only being considered but notes the drug side effects costs due to metabolic disorders and other issues are very high. Dr. Robbins states that he would go further and say that if cost wasn't an issue then there is an argument that any one of the Atypicals should be on the PDL. Dr.

Robbins states that assuming that cost is an issue he doesn't think Abilfiy is unique and if you ignore cost you shouldn't restrict the formulary. There is good clinical rational for each of them. There are situations where he would clearly prescribe Zyprexa first but doesn't because it isn't on the PDL. Hugh Davis questioned whether there was any discussion regarding the merits of Shel's motion. Jason Helgerson responded that there was a lot of discussion. Mr. Davis questioned that not putting it on PDL may lead to changes in physician behavior where they would use Abilify first it were on PDL because it is the best medication for a patient but won't if it is off PDL because they don't want to go through the PA process despite the best interest of the patient. Speaking as a family member he thinks if there is a compelling clinical reason to use it then cost shouldn't be prioritized. Dr. Diamond reported that if you use Geodon according to label restrictions then it is useless. Dr. Casimir stated that if you stay in clinical guidelines for the drug then it is putting the consumer at risk. Dr. Robbins stated that Abilify is a better choice if some one is psychotic and has depressive symptoms. Dr. Diamond stated that STAT PA will be approved with clinical reason but the problem is that a lot of doctors don't realize this.
Molly Cisco: Would like to look at the discussion regarding prescribing MH drugs in nursing homes at some point. It was noted that people in nursing homes are mostly covered by Medicare, Part D rather than Medicaid. Ms. Cisco knows first hand the consequences of non-psychiatrists prescribing mental health drugs. If the PA process is something that we need to educate doctors about then the staff should be getting the word out. After listening to Mr. Gross' argument regarding Abilify then her first thought is to do no harm. If Abilify has the least side effects we should be using it first. We have a medication that is a good medication which no one disagrees with and it seems that the decision is being based purely on cost. Dr. Casimir states that there is no debate that it is a unique molecule.
Jenny Lowenberg: The prescriber charts are pretty telling. A number of medications are being prescribed by non-psychiatrists which may be telling us that there are not enough psychiatrists. An easier decision is to not do PA. Time limits are going to lead people to make decisions that aren't in the best interest of the consumer. You can look at cost and consider the cost of the metabolic side effects. Concerned that if the only Atypical that doesn't cause weight gain that is on PDL is Geodon, which isn't being used therapeutically, then this has a negative effect on the consumer. Dr. Diamond confirmed that if used by guidelines then Geodon is not effective. Having an arsenal to easy prescribe is important. Given the PA process then a lot of it has to fall to consumers to say what they need and to take responsibility and if they are in a bad way then they don't have the ability to do that.
Mary Neubauer: Depending on a person's state of mind they won't be able to direct their care effectively.
Shel Gross: Noted that the current discussion is a good discussion that the MA PA committee may not have been able to have. He reports that the summary from the MA PA committee didn't include Dr. Witkovsky's comment that he would love to have Abilify on and the turn in the discussion. He has concerns that the prescribing by primary care reflects that there is limited access to psychiatrists. Questions if diagnosis edits are done. Staff responded yes for certain classes but there are limits. He wonders if the PA process distorts the prescribing practices but notes that if Abilify has stayed the same or even increased then maybe it hasn't or whether it must make a difference if we are going through all this trouble. Jim Vavra said they could check of the market share of the products in states where it is on PDL.
David Larson: In the real world the PA process does influence prescribing. Some sites are more willing or able to do the process. Questions if it is necessary to have only one PDL. States that the indications for this class are relatively precise. Suggests you could have one PDL for those with mental illness or psychiatrists or something similar. Mr. Vavra responded that their movement has been towards simplification. Dr. Larson states that when you look at this list, around 1990 clozapine was added then every 2 to 3 years another added. States that when each of these were introduced they were heralded with strong promises but also with strong concerns about side effects. There were restrictions when first introduced then the restrictions got lost along the way. With the passage of time we learn more about them. He was impressed with aripiprazole's unique make up. One can make an argument for all the drugs on this list to have unfettered access. Dr. Casimir agreed that it makes sense to make the hardship

not on the people with severe mental illness but on the others. Dr. Larson cautions to be careful of who you make these requirements for. If PA is automatic for clinical reasons why make them go through the PA process. You could have a Gold card by specialty. Jim Vavra noted that if we do that then we have to be more careful how we get our physician specialty. The letter from the WPA makes good points and should be looked at carefully. People with severe mental illness are unique including how they respond to medications. Seriously disappointed in recent studies including CATIE. The real question is which drug is used when for which patients. Psychiatrists have their own professional algorithm to make that decision. The STAR D for depression was more useful. The issue of cost of care needs to be considered. The cost of medications are irrelevant if you don't look at cost of care. Acknowledges that it comes out of some one else's budget. Dr. Witkovsky notes that one of the issues of this committee is safety and states that 1 in 5 using these medications gets metabolic syndrome yet there is no requirements for monitoring like there is for clozapine. Dr. Witkovsky questions if this committee should continue to support the medications without careful monitoring.

Clarence Chou: This whole issue of not looking at the entire cost issue is important. Need to look at cost of care and not just cost of medications. Supports open access for Abilify. Notes examples of not using good data and states you have to look at good data. In regard to the prescriber charts, he notes that when working with kids the psychiatrists found the right mediations and then the pediatricians do the follow-up prescribing. If we put things on PA then there is a potential of it being used in different ways. Just because psychiatrists are prescribing doesn't mean it is done perfectly. PA is not the way to go to address prescribing practices. If you really want to look at cost you should look at the 100 most expensive cases and look at their circumstances. Questions what we want to get from the data. Jason Helgerson responds that we still have to try to manage the overall Medicaid spend. Dr. Chou suggests a pilot program to try and help some the people who are frequently accessing resources.

Kenneth Casimir: Explains that the WPA/APA letter's primary purpose is to try and expand the scope of thinking. It would seem that to sit in a silo and think about small costs in a single budget doesn't make sense. We live in an era of Evidence-Based Practices which shows that when you restrict formularies then costs go up. Good example is that MMHI costs go up when admissions go up due to medication issues. In other states it shows in the data. Whatever way we are going to save money it shouldn't be on the backs of the most mentally ill patients. People who are having suicide attempts and psychotic breaks shouldn't be where we are trying to balance the budget. He gravitates toward the issue regarding Abilify and Zyprexa being 25% of market share which is 1 in 4 patients. This shows it has unique qualities if they are willing to go over this speed bump to get it. He notes that even a low speed bump can be a hardship for a vehicle low to the ground.

Suzanne Seeger: She notes that you can't really tell if the charts are indicating if the primary care physician is the original or only prescriber. Can read into it that there is a shortage of psychiatrists. When looking at PDL for Anti-seizure medications, pretty much everything is on the PDL. She supports that as important but questions why that is for that class and not Atypicals. Why look at Antipsychotics more than the Antiseizures. Are you more scared of seizures than psychotic breaks.

Catherine Kunze Is for an open formulary especially for antipsychotics and antidepressants. Highlights the last page of WPA letter. If there is always a problem with PA even as simple as it is we should consider new ideas such as the gold card. We have to keep in mind that there a lot of consumers out in the country away from choices of psychiatrists. There may be a way to tweak the ideas geographically. Dr. Chou agrees that there is an algorithm psychiatrists go through in their heads of what drug to choose. Dr. Casimir notes that EPS hasn't kept other agents off the PDL and reports that in regard to akathisia dose can manage this. When managing the children's unit he saw kids where the risk benefit showed Abilify to be a unique agent for this population working nicely. There is such a nuance there that a PDL makes it hard to capture. Import to have a specialist trying to way through this. Ms. Kunze notes that the written testimony is very compelling.

Kenneth Robbins: We are hearing significant disagreements regarding the use of these drugs. If you are looking at clinical rationale then it looks like we have randomly chosen the PDL. Most people will change their practice based on the process of PA. MA is wasting money because this is one class of

drugs that it is a major mistake to have any kind of speed bump. There is compelling arguments for any one of these medications.
Virginia Bryan Was not present at the meeting but provided an email that John Easterday read to the group.

Antiparkison's Agents
Michael Witkovsky questioned the Status of Mirapex for restless leg. The answer was that Mirapex is non-preferred. Participants were grandfathered for Parkinson's diagnosis and not restless leg. Ropinirole is on for restless leg. Suzanne Seeger questioned why Mirapex and Comtan off. Michael Mergener responded that there is a cost effective alternative.

Antidepressants SSRI
There was no discussion.

Antidepressants, Other
Catherine Kunze questioned why Cymbalta was non-preferred and highlighted the letter not agreeing with Cymbalta being non-preferred.
Dr. Larson stated that there are specific indications for Cymbalta for people with physical co-morbidities.

Alzheimer's
Jenny Lowenberg question if Exelon was moved from on to off because of cost. The response was yes.

Stimulants
Dr. Casimir asked why Vyvancse has come on PDL so quickly when it takes Atypicals so long. Dr. Mergener noted that the drugs are listed in increasing order of cost so Vyvanse isn't any more expensive than the generics. He indicates that there was also a lot of discussions regarding the clinical issues such as dosing and less potential for diversion.
Clarence Chou stated that there are some situations that you can't use stimulants for ADHD like hypertension so it would be nice to have as many options as possible.
Molly questioned the history with Strattera and PDL related to age. The response was that adults do not require PA. Hugh Davis states that as a parent it would be great to see a non-stimulant alternative without PA required.

Ken Casimir stated that one of the key issues for the meeting was regarding Abilify asked if there should be a vote. Mr. Helgerson responded that the MHDA don't vote.

The group agrees that Abilify should be on the PDL and not require PA.

Michael Witkovsky stated that we rely on data from others and don't get our own state specific data. He questions how we protect people. He asked if it would be a burden to ask the Secretary to spend some money to have the staff collect some data regarding health status of participants. Jason Helgerson noted that if we add additional requirements to the speed bump like requiring BMI then there are other issues to consider. He is all in favor of finding a way to collect the data without requiring more hardships. Dr. Diamond suggested setting up a work group to have a brainstorming session to address this issue. Childless adults will need a physical exam to be eligible. Clarence Chou suggested a psychiatric screening might be helpful also.
Risperdal to generic will be gradual. Dr. Larson stated that generic substitution works for some but not all. He questioned how the transition will be structured and asked if there is any information to guide prescribers to determine who will have difficulty. Jim Vavra noted that there will be PA needed for brand name.

Atypical Antipsychotic DUR 2nd Intervention

Michael Mergener indicated that he started the data for the 2nd intervention looking at the next group of prescribers. It looks like this group of patients are different from the first intervention group. He still has to crunch the data and will have more for next time. Catherine Kunze stated that she would like to see feedback from the consumers in this group. Allen Liegel is wondering about age data and whether it could be related to use in nursing homes. Dr. Mergener indicated that nursing home residents are not in this patient population.

Therapeutic Substitution

Current policy is that Pharmacists can't prescribe and have no power to change prescriptions. We do have brand medically necessary where a pharmacist may call the doctor regarding changes. We need a prescription from a physician. Hospitals settings and jails may have different policies.

Next Steps

John Easterday reported that we are looking for psychiatrist recommendations to fill an opening on the MHDA group. Issues suggested as possible topics for next meeting include: Prescribing practices and data regarding cost of care.