MENTAL HEALTH DRUG ADVISORS GROUP
MEETING SUMMARY

Wednesday, August 5, 2009

Members and Staff Present: Joyce Allen, Clarence Chou, Molly Cisco, Ted Collins, Kay Cram, Hugh Davis, John Easterday, Carrie Gray, Shel Gross, Rita Hallett, Jason Helgerson, Hugh Johnston, Richard Kilmer, Catherine Kunze, David L Larson, Allen Liegel, Jenny Lowenberg, Jonathan Moody, Lynn Radmer, Susanne Seeger, James Vavra

Members not Present: Joanne Berman, Virginia Bryan, Ken Casimir, Ron Diamond, Harold Harsch, Kate Nesheim, Mary Neubauer, Linda D. Oakley, Pam Pauloski, DeeAnne L Peterson , Ken Robbins, Michelle M. Thoma, Michael Witkovsky

Guests Present: Jagdish Shasti – Eli Lilly; Dean Groth and Lori Greene – Pfizer; Amy Mackey, Grant Cale, and LaGenia Bailey – BMS; Robert Vlk – Azus; Mike Mergener – APS Healthcare

Welcome / Introductions

John Easterday, Administrator of the Division of Mental Health and Substance Abuse Services, led the welcome and introductions.

Approval of Meeting Summary from February 25, 2009

Hugh Davis noted he was not identified on the meeting summary. Meeting summary was approved with this change.

Medicaid Rate Reform Project

Jason Helgerson, Administrator of the Division of Health Care Access and Accountability, indicated that this project is an effort to identify ideas to meet budget needs. The Department received over 500 ideas. The DHCAA staff analyzed and put together 71 rate reform ideas. They re-engaged the work groups to re-evaluate the items. For pharmacy, consideration was given to the Texas Medication Algorithm Project (TMAP). The team decided not to pursue that item as it did not generate savings and major systems changes were involved TMAP was the only mental health drug related item. The rate reform ideas have been prioritized. One rate reform idea includes modifying the current dispensing fees for pharmacies. There are no reductions in reimbursement to mental health providers. The budget remains a challenge.

Presentation of Recommendations Regarding: Antipsychotics; and Stimulants and Related Agents; Antidepressants, Other; Antidepressants, SSRIs; Alzheimer's Agents; and Antiparkinson's Agents.

Jason indicated that they are requesting that the recommendations sheet distributed to the MHDA be returned at the end of the meeting due to it being highly confidential. Jim Vavra gave an overview of the list of preliminary recommendations.

The recommendations for Antipsychotics remained the same as current PDL with the addition of first generation antipsychotics. Dr. Larson noted that there is a new medication coming out.

Jenny Lowenberg asked what the policy is for new drugs. Jim indicated new drugs, in classes that have been reviewed and are included on the PDL are added as non-preferred until the PA Committee has had a chance to review the drug and make a recommendation.

The recommendations for Antidepressants, Others, are that MAOIs have been added to the class. Venlafaxine ER is not a generic equivalent to Effexor XR. Staff is suggesting that it remain non-preferred.

There are no recommended changes for Antidepressants, SSRIs. Generics are preferred.

Jim indicated that for Stimulants and Related Agents there is preliminary consideration to require PA for all ages for Strattera. Previously there was not a PA for members 18 and older. This change is being recommended due to potential cost savings of up to $200,000 annually. Daytrana is being recommended as being added as a preferred agent due to an increase in rebates. There is a generic equivalent for Adderall XR, but it is recommended as non-preferred because Adderall XR is less costly to the State than the generic.

No changes are recommended for Antiparkinson's Agents.

The recommendation in the Alzheimer's Agents is to add Exelon transdermal to PDL and make Exelon solution a non-preferred agent.

Discussion and Comments from Group Members on Preliminary Recommendations

<u>Antipsychotics</u> –

Hugh Johnston – Would like to see Abilify added as a preferred agent for a number of reasons. The Antipsychotics fall into 3 groups: 1) clozapine, 2) aripiprazole, 3) everything else. Abilify has unique qualities including quality and an advantage for tolerability; not limited to the side effect profile. Don't have the cost information but on a clinical and molecular biology basis it stands out. The data shows the benefits of aripiprazole especially if you look at the metabolic side effects. Zyprexa doesn't add quality due to the metabolic side effects. It can be dangerous if patients taking Zyprexa are not monitored closely. If you look at long term costs of metabolic side effects they are huge.

Molly Cisco – For Abilify, from a consumer standpoint, it is important that it doesn't cause weight gain. It is an easy drug to be on. It is an expensive drug, but at some point isn't it worth it? The state should consider the clinical advantage over the cost. The counties are where you are seeing the savings when members have more access to effective drugs.

Cathy Kunze – agrees with Molly's comments. The newer drugs can make a difference and are superior. Looking at MH expenditures, there were over 11,000 prescriptions even though it is non-preferred. It has the third highest market share even though it is non-preferred. Whatever is decided, please keep the forms simple for prior authorization (PA). It is important to keep the personal account of the experience, which isn't tied into the statistics. At what cost do you save the pharmacy budget? There are savings in other services.

Richard Kilmer – Sees Abilify as a really good drug for patients. The PA process is easier than it used to be.

David Larson – Would favor unrestricted access for this class. One drug is not equivalent to another. Favors the addition of Abilify and Zyprexa as preferred agents on the PDL. Stated that the pharmacy cost data and volume data are not helpful by themselves, but rather the total cost of care is more important. Pharmacy costs are not the only cost of total care. If you have a hospitalization due to an ineffective drug, any savings in pharmacy will be gone. Abilify has very high utilization despite being non-preferred. That is a referendum. It is an indication that it is needed and preferred. Abilify has a number of indications. There are benefits for augmentation of treatment with Abilify. There is better tolerance for many patients. Fazaclo is beneficial in some situations. Zyprexa has benefits despite the metabolic side effects. The metabolic side effects need to be closely monitored.

Hugh Davis – Agrees with Dr. Larson that cost and efficacy are very important. The individual experience of drug is also an important factor. Abilify and Zyprexa both have large market shares despite being non-preferred He thinks there should be a psychiatric exemption. In rural communities there are such long waiting lists for psychiatric services. If psychiatrists spent less time on PA they might be able to see more patients. Consumer experience should be a strong factor in decisions.

Jenny Lowenberg – Agrees with much of what has been said. Abilify and Zyprexa use has stayed relatively the same despite being non-preferred on the PDL. Abilify should be preferred. If you look at the cost, both financially and as a result of death due to metabolic side effects, it is well worth the pharmacy cost to add this agent as preferred.

Shel Gross – Has consistently been in support of adding Abilify for the reasons already mentioned. Has spent some time looking at the DERP reports and thinks the balancing act is pretty complicated. There is a good argument for open access for all of these drugs. There is potential value of allowing a PDL by-pass when a psychiatrist is prescribing these agents.

Clarence Chou – We need variety. There are a number of prescriptions for Abilify despite PA. The total cost of care is important. Who are the prescribers? The tricky cases are treated by psychiatrists. People coming from systems with restricted formularies don't do as well as those with open access.

Ted Collins – Takes the market share of Abilify and Zyprexa as reflecting the ease of PA. Doesn't think that there is evidence that aripiprazole has any advantage. Can't predict what is going to work so why make it preferred.

Allen Liegel – Questioned the process of preferring brand over generic. Jason and Jim explained the reasoning behind it and that they watch it carefully. It appears that the PA process has allowed people to get the drugs that are needed. Risperdone is now generic and is not being promoted. Concerned about adding to costs. If we could quantify the savings of Abilify by looking outside of pharmacy then it would be worth it.

Summary Regarding Antipsychotics

The majority are recommending Abilify be added as a preferred agent on the PDL due to personal experiences regarding tolerability, effectiveness, and cost savings in total cost of care. Abilify has unique clinical and molecular biology qualities as well as benefits regarding metabolic side effects. This position has remained the same for the past three reviews.

Antidepressants, Other –

Ted Collins – Effexor ER brand is going generic next year.

Suzanne Seeger – Cymbalta is used for other indications. There are no alternatives for Cymbalta for treatment of Fibromyalgia in this class. Lyrica and gabapentin are available for the treatment of fibromyalgia. One pill may treat multiple conditions rather than needing more than one drug which would be a savings. There are fewer side effects than with some of the alternatives for Fibromyalgia.

Hugh Johnston – Agrees with Dr. Seeger's comments.

Cathy Kunze – Cymbalta has been incredible for her personally for the combination of depression and pain. It is better to be on that than narcotics or ibuprofen. Please don't limit quantity. Keep in mind that sometimes time release drugs are not the same for everyone

Richard Kilmer – Patients who are on Cymbalta have tried and failed a lot of different combinations.

David Larson – Argues for unrestricted access especially for consumers with severe and persistent mental illness or prescribers working with them. Agrees with arguments for Cymbalta. Lexapro is well tolerated and simple to use.

Clarence Chou – If you can use one medication for as many indications as possible it is ideal. Dose at a therapeutic level is an important issue for all medications.

Summary Regarding Antidepressants
Most of the group agrees that there are advantages of Cymbalta for other indications such as Fibromyalgia and pain. The use of one medication for multiple indications is ideal.

Stimulants and Related Agents –

Ted Collins – Vyvanse doesn't merit preferred status.

Allen Liegel – Concerned that brand Adderall XR is on PDL and generic is non-preferred.

Suzanne Seeger – Would like to see how many of the drugs are prescribed to children and adults.

Hugh Johnston – Agrees with issues regarding Vyvanse. There is good theoretical evidence that it doesn't work as well as generic in a relative sense. Prescription drug abuse with this class is pretty small. Focalin XR is not any better than long-acting methylphenidate. Focalin XR metabolizes to methylphenidate.

Molly Cisco –From a drug and alcohol addiction side it is good to have the option of Strattera as the only non-addicting drug for ADHD. It should be a preferred agent because there are a lot of people with addictions who don't want to take an addicting drug.

Cathy Kunze – Agrees with Molly on the addiction comments. Potentially, the generic of a time release drug may not work as well as the brand drug. Ritalin works and there is no desire to take more than necessary or to lend it out.

David Larson – ADHD in adulthood is emerging and increasing with 40% to 50% of the population having chemical dependency issues. There is concern with diversion in some communities as well.

Hugh Davis – There should be a psychiatric exemption for this class. The class should be open to psychiatrists. Strattera may be first choice for some people.

Jenny Lowenberg – There are idiosyncrasies with these medications so she would like to see open access.

Clarence Chou – There is little variation of medications in this class compared to other classes. You have to go by how the patient responds. Vyvanse works well for some. Untreated ADHD has significant impact on quality of life. On medications people are very successful. These people aren't abusing the drugs. Prescribers have to do the appropriate evaluation to diagnose and prescribe these agents. There can be some placebo effect. Have to look at long standing history. There is a difference between prescribing to adults and kids because adults can provide informed consent.

<u>Summary Regarding Stimulants</u>

There were some concerns expressed that Strattera should be preferred for those with chemical dependency issues. Vyvanse and Focalin XR have no clinical advantage or reason to be preferred agents.

<u>Antiparkinson's Agents –</u>

Suzanne Seeger – Need to have a group of neurologists review this class.

Jenny Lowenberg – Is this the right group to look at this class?

Shel Gross – Use with Restless Leg Syndrome was reviewed.

<u>Alzheimer's Agents –</u>

Suzanne Seeger – Another reason to use a non-oral agent such as an Exelon patch is the difficulty some patients have swallowing.

Richard Kilmer – This class of drugs is expensive and not real effective.

Clarence Chou – This class might be used for autism at some point.

Discussion Regarding Co-pays for SSI Members

Jonathan Moody provided information for SSI members regarding whether the carve out impacted access to medications due to the copay. The co-pays in BadgerCare Plus Standard Plan and Medicaid are $3 for brand and $1 for generic with a maximum out of pocket of $12 per member, per provider, per month. The drug must be dispensed if the member is unable to pay the copay. Initial report suggests there has not been a negative impact. The same 10,000 members were reviewed pre and post carve out and utilization was compared. There was a slight increase in utilization over the year. They will be looking at member level regarding individual prescriptions and differences between classes. Richard Kilmer indicated that it is putting a hardship on pharmacies because they aren't collecting the co-pay from people refusing to pay it. Jason clarified that the policy is specific to the Standard plan. Jonathan will continue to report on results.

Core Plan Formulary

Shel Gross asked for clarification on which formularies are impacted by the group's decisions. Jason Helgerson provided information on the Core plan. CACHET advises on the Core waiver. They have sufficient budgetary authority to cover 50,000 people for the Core plan. The benefit is limited. There are trade offs based on the number of people covered vs. the benefits provided. Currently there are 13,000 people on the program. Since June, there have been 35,000 applications received. They can't exceed the pot of money available. Cathy Kunze suggested that it will be important to talk to potential members about losing patient assistance to receive medications through pharmaceutical companies if they go on the Core plan. The discount for members using a discount card varies by medication. The Core plan is not an entitlement program. They are taking a comprehensive look at the population. May have to change the benefit based on what is found regarding the population. It covers very few mental health services and does not cover inpatient or outpatient mental health services. Trying to look at the overall healthcare cost is the goal of this group. PDL applies to the Standard Plan and Senior Care. It may influence Core plan.

Next Steps and Adjourn

Today's discussion will be shared with the PA committee and the Secretary. The PA committee meeting is August 19, 2009

Ted Collins would like to suggest that some one from DERP come to present to the group. Ted suggests that we look at patterns of drug use.

Jason Helgerson suggested that we look at the Antipsychotics class regarding prescribing patterns. We should look at non-therapeutic doses. Jim Vavra suggested incorporating it into the DUR targeted interventions.

Shel Gross wants to have more discussions about opening up prescribing of mental health drugs on the PDL to psychiatrists.

The next Mental Health Drug Advisors meeting will be in February 2010. The group will have more opportunity for discussion. The group will talk about the Gold Card idea. DHCAA staff will look into the possibility of a DERP presentation. They will also have data regarding prescribing practices by prescriber and drug class.