

**MEDICAID PHARMACY PRIOR AUTHORIZATION
ADVISORY COMMITTEE
Meeting Summary
March 29, 2006**

Opening Remarks/Introductions

The Medicaid Pharmacy Prior Authorization (PA) Advisory Committee met on March 29, 2006, to review the Atypical Antipsychotics for inclusion on the Wisconsin Medicaid preferred drug list (PDL).

Mr. Moody, Administrator of the Division of Health Care Financing (DHCF), opened the meeting by reviewing the agenda and:

- Introduced Rosanne Barber as a new PA Advisory Committee member.
- Collected Nondisclosure and Conflict of Interest Statement forms from each of the Committee members present. Committee members will be asked to complete the form and disclose any possible conflicts of interest for all future meetings.
- Presented the Presenter/Witness Disclosure form. Anyone speaking or testifying during public comment must complete the form and provide to DHCF staff at the registration table prior to testifying.

Dr. Mergener summarized the recommendations and the Secretary's decisions from the February 8, 2006, meeting.

Review/Approval of February 8, 2006 Meeting Summary

Mr. Moody stated the meeting summary was distributed to Committee members, confirmed that the members had the opportunity to review, and requested modifications. Hearing no requests for modification Mr. Moody approved the minutes.

Public Testimony

Mr. Moody reviewed the testimony guidelines for the meeting. He also announced that speakers are welcome to remain for the 'open' Committee deliberation as committee members may question speakers who gave testimony earlier. He also reviewed the order of speakers, and encouraged additional speakers to testify.

The table below lists each speaker and the topic of their testimony:

SUMMARY OF PUBLIC TESTIMONY

Time	Name	Company	Product/Class	Notes
1:45	Carol Mixdorf		Atypical Antipsychotics	Ms. Mixdorf is a parent of a consumer. She provided a brief history of her family member's disorder and benefits of the wide variety of medications used to treat the disorder. Spoke in support of not restricting physician prescribing options. The ability to get a variety of drugs has allowed her

Time	Name	Company	Product/Class	Notes
				family member to keep employment and have less frequent hospitalization.
1:55	Jennifer Lowenberg	National Alliance on Mental Illness (NAMI)	Atypical Antipsychotics	Ms. Lowenberg is an advocate for NAMI and speaking on behalf of a number of consumers not able to attend the meeting. Spoke in support of not restricting physician prescribing options for the atypical antipsychotic class. Encouraged the Committee to consider all costs of restricting access to the medications. Also asked Committee to consider scientific, clinical and evidence based prescribing when making their recommendation. If any of the drugs are made non-preferred, Ms. Lowenberg requested the prior authorization process be made as clear and transparent as possible and allow for emergency dispensing of the drugs.
2:03	Dr Luis Vazquez		Atypical Antipsychotics	Spoke in support of not restricting prescribing options. If patients are not able to gain access to the medications to best treat their illness, emergency room and other physician related costs will increase.
2:08	Gary Yeast	Wisconsin Coalition for Advocacy	Atypical Antipsychotics	Spoke in support of not restricting physician prescribing options for the atypical antipsychotic class. Spoke to the benefits of drugs available in the class and national trends to not restrict access to drugs in this class.
2:13	Brenda McLaughlin	Alamo Pharmaceuticals	Fazaclo (clozapine) / Atypical Antipsychotics	Testified to include Fazaclo on the PDL. Presented efficacy, patient preference, and compliance advantages. Also presented the unique suicide prevention indication of clozapine.
2:19	Dr. Quynh Tran	Otsuka Pharmaceuticals	Abilify (aripiprazole) / Atypical Antipsychotics	Testified to include Abilify on the PDL. Presented unique pharmacology, mechanism of action, once daily dosing, and reduced risk of relapse, compliance, and lack of weight gain advantages.
2:26	Beth Winans, PharmD, BCPP	Johnson & Johnson	Risperdal (risperidone) / Atypical Antipsychotics	Testified to include Risperdal on the PDL.
2:31	Robert Sanchez, RPh, CEC	Pfizer	Geodon (ziprasidone) / Atypical Antipsychotics	Testified to include Geodon on the PDL. Presented the superior metabolic and side effect profile advantages, mechanism of action, once daily dosing, reduced risk of relapse, compliance, and lack of weight gain.
2:35	Dr Jamie Street	AstraZeneca	Seroquel (quetiapine) / Atypical Antipsychotics	Testified to include Seroquel on the PDL. Presented unique indications, mechanism of action, efficacy, and patient preference
2:40	Oladapo A. Tomori, MD	Eli Lilly	Zyprexa (olanzapine)	Testified to include Zyprexa on the PDL. Presented indications, prevention of relapse, efficacy, and duration of treatment advantages.
2:47	Dr. Burr Eichelman	UW Hospital	Atypical Antipsychotics	Spoke in support of not restricting prescribing options for atypical antipsychotics and the unique effectiveness, efficacy and side effects of drugs in the class.
2:53	Dr. Diamond	University of Wisconsin Hospitals		Assumes the recommendation will include grandfathering of all non-

Time	Name	Company and Clinics	Product/Class	Notes
				preferred products. The PDL requires a prescriber to try the preferred drugs first, but does not restrict access to non-preferred drugs. Non-preferred drugs are accessible via the STAT-PA system. Spoke about process to determine which drugs should be preferred based on efficacy, side effects, mechanism of actions, and price. Once a variety of drugs are available as first line products, price should be considered.
2:58	Dr Joseph Bugarino	Aurora Behavioral Health	Atypical Antipsychotics	Spoke in support of not restricting prescribing options for the second generation atypical antipsychotics.
3:04	Jerry Halverson	WI Psychiatric Association	Atypical Antipsychotics	Spoke in support of not restricting physician prescribing options for the atypical antipsychotic class. Spoke about the unique side effects and metabolic profiles of drugs in the class.

Discussion of Manufacturer-Specific Supplemental Rebate Amounts (Closed Session)

Mr. Moody indicated that the next agenda item, a discussion of manufacturer-specific supplemental rebate amounts, was intended for consideration in closed session pursuant to s.19.85(1)(e), Wis. Stats. He further indicated that, under federal and state law, the rebate amounts must remain confidential due to the competitive nature of the rebate agreements and federal drug price confidentiality requirements.

Mr. Moody called for a motion to adjourn into closed session. Motion made by Dr. Witkovsky and seconded by Dr. Walker. Voting results were:

- Tom Frazier – aye
- Nancy Phythyon – aye
- Michael Witkovsky – aye
- Steve Maike – aye
- Alicia Walker – aye
- Rosanne Barber – aye

There were no votes opposed and no abstentions.

Therapeutic Class Reviews, Committee Discussion, and Response to Proposal (Open Session)

Mr. Moody announced that Dr. Valerie Taylor from Provider Synergies would present the therapeutic class review and recommendations and Dr. Mergener from APS Healthcare would present summary conclusions from the Drug Effectiveness Review Project (DERP) report.

1) Atypical Antipsychotics

- a) Review – Atypical Antipsychotics act on serotonin 2A receptors as well as D2 receptors. The side effect profiles differ from conventional antipsychotics by producing low EPS and they also are effective in decreasing negative symptoms associated with schizophrenia.

In addition all of the atypicals have varying activities at a variety of other receptors, i.e., muscarinic, histaminic, GABA and benzodiazepine.

These products are indicated for schizophrenia and bipolar disorder with the exception of clozapine (only indicated for refractory schizophrenia). The combination product, Symbyax, is indicated for bipolar depression.

For treatment of schizophrenia, schizoaffective disorder and schizophreniform disorder -- clinical trials have shown relative similar efficacy across the agents. Differences are seen in side-effect profiles with olanzapine showing most consistency across trials in increasing weight, risperidone causing the most EPS. Side effects reported in clinical trials were dependent on dosing. Persistency on staying on the drug has been shown for olanzapine, but very high drop out rate shown for all medications.

Dosage of the agents is once or twice daily with titration recommended. Per many different guidelines, no one agent is recommended as first line therapy. Different patients may respond differently to different products.

Dr. Mergener reviewed the DERP report for Atypical Antipsychotics. The DERP report found that in head-to-head studies, different drugs in the class have different superiorities in efficacy depending on the study. Overall, no agent demonstrated consistent benefit over any other drug. There are a wide variety of differences in the side-effect profiles of the drugs. In summary, there are no clear cut first line agents in indications, efficacy or side-effect profiles.

b) Recommendation:

Brand Name	Current PDL Status	PDL Recommendation
clozapine	NR	Generic
Fazacllo	NR	Yes
Risperdal	NR	Yes
Geodon	NR	Yes
Seroquel	NR	Yes
Symbyax	NR	No
Zyprexa	NR	No
Abilify	NR	No

c) Discussion –

- Mr. Moody summarized the differences between the Wisconsin Medicaid PDL and formularies. All non-preferred drugs on the Wisconsin PDL are still available through prior authorization. The recommendation presented includes grandfathering all recipients currently taking any of the non-preferred products. Therefore, only patients that have not previously been taking a non-preferred drug are required to try a preferred product initially. Mr. Moody also provided information on the current real-time STAT-PA system. In general, the PA

procedures are quite easy and expeditious. Mr. Moody reviewed the emergency dispensing policy of a drug without needing a prior authorization.

- Mr. Maike requested DHCF perform an analysis after implementation of the recommendations for this class, including hospital and emergency room costs for patients trying preferred products versus those taking non-preferred products. Mr. Maike asked if the recommendations implemented could be changed before the end of the contract period due to patient safety concerns. Mr. Moody and Dr. Taylor confirmed it is possible to change the PDL for patient safety.
- Mr. Moody reminded the Committee that the recommendations approved at the meeting would be reviewed by a mental health advisory committee on April 12, 2006. After listening to the advice of the mental health committee the Secretary will make a final decision on the class.
- Mr. Frazier made a motion to accept the recommendation. Dr. Witkovsky seconded the motion. Ms. Phythyon amended the motion to add Abilify as a preferred drug because of the efficacy and unique metabolic profile. The amendment was seconded by Dr. Walker.
- Dr. Witkovsky stated that Geodon would offer the same metabolic profile and similar efficacy. Dr. Walker stated that the side-effect profile of Geodon was different and therefore, she would like Abilify to be preferred.

d) An amendment was made to the motion as stated in the discussion. Voting results to **accept the amendment** were:

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|---------------------------|------------------------|
| ▪ Tom Frazier – aye | ▪ Steve Maike – NAY |
| ▪ Nancy Phythyon – aye | ▪ Alicia Walker – aye |
| ▪ Michael Witkovsky – NAY | ▪ Rosanne Barber – aye |

Amendment passed--4 ayes to 2 nays. There were no abstentions.

Amended motion to accept amended recommendation.

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|---------------------------|------------------------|
| ▪ Tom Frazier – aye | ▪ Steve Maike – aye |
| ▪ Nancy Phythyon – aye | ▪ Alicia Walker – aye |
| ▪ Michael Witkovsky – aye | ▪ Rosanne Barber – aye |

There were no votes opposed and no abstentions.

Closing

The next meeting is August 16, 2006, Madison, 8:30 am – 4:30 pm.

Mr. Moody thanked the Committee for its service, participation and attentiveness throughout the day. Mr. Moody adjourned the meeting.