

ODJFS P&T Committee Meeting Minutes

January 12, 2011
77 S. High St., Room 1932

Committee members present: Robert Hunter, DO (chair); Karen Jacobs, DO; Margaret Scott, RPh; Michael Wascovich, RPh; Mary Jo Welker, MD.

Approximately 40 stakeholders were present, most representing pharmaceutical manufacturers and advocacy associations.

The meeting was called to order at 10:42 AM.

1. Conflict of interest statements
Ms. Scott reviewed the conflict of interest policy (attached) and asked the Committee members present to sign a copy.
2. Interested party presentations
 - a. Holly L. Pendell, Public Policy Specialist, National Multiple Sclerosis Society, Ohio Chapters. National MS Society Ohio Chapters Advocacy reports no relationship with the manufacturer.
3. New Business: Drugs under consideration
 - a. Pradaxa (dabigatran etexilate) capsules, Boehringer-Ingelheim
A representative from Boehringer-Ingelheim presented information about the drug.
Committee discussion:
Dr. Jacobs asked if therapy could be added to prevent gastrointestinal symptoms and bleeding. The representative responded that the increased gastrointestinal effects were unexpected, so the trial designs did not include prophylactic therapy. However, some patients in the trials were taking proton pump inhibitors, and there is no contraindication for concomitant therapy.
Dr. Jacobs asked about cost of the drug. The representative said it is priced at \$6.75 per day of therapy. Ms. Scott added that warfarin is pennies per day, but Pradaxa does not require international normalized ratio (INR) testing, so there may be some cost offset. In addition, Boehringer-Ingelheim has provided a cost model that showed decreased overall medical cost due to potential improved outcomes.
Mr. Wascovich asked if there are additional uses other than atrial fibrillation. The representative responded that the drug is approved in other countries for deep vein thrombosis, and studies are underway for Food and Drug Administration (FDA) approval.
Dr. Hunter asked why the 110mg dose used in the trials was not available. The representative responded that the FDA did not approve the 110mg dose.
Ms. Scott said that after discussion with the managed care plans and ACS, the recommendation is prior authorization (PA) required, with a diagnosis of non-valvular atrial fibrillation. This recommendation is based both on the cost and concerns that the anticoagulation effects are not reversible.
The Committee voted unanimously to accept the recommendation of PA required with a diagnosis of non-valvular atrial fibrillation. The Committee also asked that the department study utilization and outcomes with this drug and report back to the Committee in one year or when appropriate based on data.

- b. Antipsychotics, Second Generation: Latuda (lurasidone HCl) tablets, Sunovion
A representative of Sunovion and Columbus psychiatrist Kevin Ware, MD, presented information about the drug.

Committee discussion:

Dr. Jacobs noted a potential conflict of interest that she has had speaking engagements on behalf of Pfizer (manufacturer of Geodon). Dr. Jacobs asked if adverse effects decreased with continued therapy. The representative replied that the effects did diminish over time, and Sunovion is looking at this more formally. Dr. Jacobs then asked what the effects are if the patient does not take the drug with the recommended 350 calories. The representative responded that the clinical effects are unknown because trial participants all ate the recommended amounts, but blood levels are two to three times lower without food. The representative also noted that since the drug is dosed once per day the patient can be instructed to take the drug with a meal. Dr. Jacobs asked about the receptor profile, noting that Dr. Ware referred to the 5-HT₇ receptor that may enhance cognition. The representative answered that the company is examining this further and has no data now, but there appears to be effect at the 5-HT_{1A} receptor that affects mood and anxiety, and little to no affinity for the M₁ and H₁ receptors that are often the cause of side effects.

Mr. Wascovich asked about length of therapy, since the FDA approval was based on a 6-week trial. Dr. Ware said that his goal is to get the patient under control with symptoms managed, then over time try to decrease the dose to the lowest effective to minimize side effects. The representative from Sunovion mentioned that prescribers tend to keep the patients on the drug long-term, and maintenance trials are being conducted.

Dr. Welker asked if there are long-term data regarding metabolic effects. The representative said that current data are up to 52 weeks, and the company is continuing open label trials.

Dr. Wascovich asked if the drug would be considered for first-line use. Dr. Ware responded that he would consider it for first-line treatment.

Dr. Jacobs asked if Dr. Ware has experience with the drug. Dr. Ware responded the drug is not yet available so he does not yet have experience, but would start at 40mg daily and increase to 80mg if necessary. The Sunovion representative said that clinical trials started participants at all doses (40mg, 80mg, and 120mg) and there was no difference in the discontinuation rate due to adverse effects.

Dr. Welker asked if there is a difference in price between the available doses. The representative responded that the 40mg and 80mg doses are the only doses that will be available, and they are flat priced (same price for both strengths).

Ms. Scott said that after discussion with the managed care plans and ACS, the recommendation is non-preferred, primarily because Zyprexa will be available generically in 2011, and Geodon and Seroquel will be available generically in 2012. Psychiatrists would be exempt from PA requirements in the same way that other atypical antipsychotics are exempted.

The Committee voted four in favor with one abstention to accept the recommendation of non-preferred status with a psychiatrist exemption from PA.

- c. Multiple Sclerosis Agents: Gilenya (fingolimod) capsules, Novartis
A representative from Novartis presented information about the drug.

Committee discussion:

Dr. Welker asked if it was expected that patients would switch from other drugs such as Avonex to Gilenya, and whether there are particular subgroups of patients that are better candidates for the drug. The representative responded that there is no particular subset of patients and that Gilenya is a good option for all patients.

Dr. Jacobs said that she likes that the product is an oral medication, but asked about the recommendation to monitor the patient for the first six hours after the first dose. The representative said that the drug may cause bradycardia, a reduction in heart rate of six to 10 beats per minute within the first six hours, and over the next three to four weeks the heart rate should normalize. Only 0.4% of patients in the trials were symptomatic of bradycardia.

Dr. Hunter asked about the discontinuation rate for bradycardia, and the representative said that it was two to three percent.

Mr. Wascovich asked if the drug is contraindicated in heart failure or other type of patient, and Dr. Welker asked if patients taking drugs that may reduce heart rate such as beta blockers should not take Gilenya. The representative answered that there is no contraindication but that at-risk patients should have an electrocardiogram (EKG) before starting the drug. Dr. Welker asked if there is anything on the EKG that would predict bradycardia, and the representative said no. Dr. Welker asked about the marketing plan, whether the drug is being targeted to neurologists. A representative from Novartis confirmed that it is being marketed only to neurologists.

Ms. Scott said that after discussion with the managed care plans and ACS, the recommendation is non-preferred, primarily because of an increased risk of infection with Gilenya and because Novartis has priced the drug higher than the injectable competitors.

Dr. Hunter asked the representative about the infection rate. The representative responded that there was no statistical difference in the infection rate, but the mechanism of action of all disease-modifying multiple sclerosis drugs is to prevent the egress of lymphocytes so infections are a class effect.

Mr. Wascovich said that from the perspective of a newly-diagnosed patient, the patient would be more likely to want an oral drug, and symptoms may be reduced versus other drugs at one year.

Dr. Welker said that the drug should be unrestricted, agreed that the patient would want oral therapy, and the data show decreased recurrence. She also noted that the Committee had received the most stakeholder input on this drug.

The Committee voted four opposed and one in favor to accept the recommendation of non-preferred status. The recommendation of the committee is preferred status.

d. Benign Prostatic Hyperplasia: Jalyn (dutasteride and tamsulosin HCl) capsules, GlaxoSmithKline

A representative from GlaxoSmithKline presented information about the drug.

Committee discussion:

Dr. Jacobs asked if the dosing of the combination product is the same as the commercially available components. The representative responded that it is the same, 0.5mg of dutasteride and 0.4mg of tamsulosin. Dr. Jacobs also asked about cost. Ms. Scott responded that the cost is higher for the combination product than for the separate components, because tamsulosin is available generically. From a copay standpoint for the consumer, if Jalyn were non-preferred the copay would be \$3 with the separate components Avodart having a \$2 copay and tamsulosin having a zero

copy. If Jalyn were preferred it would have a \$2 copay and there would be a cost to the state.

Ms. Scott said that after discussion with the managed care plans and ACS, the recommendation is non-preferred, primarily because of increased cost over the component products.

The Committee voted unanimously to accept the recommendation of non-preferred status.

e. Sedative-Hypnotics: Silenor (doxepin) tablets, Somaxon

A representative from Somaxon presented information about the drug.

Committee discussion:

Dr. Jacobs asked what the lowest commercially-available dose of generic doxepin is (10mg). The representative had noted that anticholinergic side effects with doxepin start at 25mg, so Dr. Jacobs asked about side effects at 10mg. The representative said that there were no data available to compare the Silenor doses of 3mg or 6mg to the 10mg doxepin dose.

Dr. Welker asked why it wouldn't be preferable to give ½ of a 10mg dose. The representative said that doxepin is a capsule, and if opened the powder acts as an anesthetic so the mouth would be numb.

Dr. Jacobs asked about safety from overdose. The representative answered that a 30 days supply of Silenor is not enough for an overdose.

Mr. Wascovich asked about cost. Ms. Scott responded that the cost is about \$5 per day compared with a few cents for zolpidem or the other options.

Dr. Jacobs said that she would like to have a nonscheduled option. Ms. Scott suggested that PA criteria for this class could be changed to allow for approval of Rozerem or Silenor if the patient has a history of addiction.

Dr. Welker said that the anticholinergic effects of the 10mg dose are not significant, and that 10mg is considered a homeopathic dose.

Ms. Scott said that after discussion with the managed care plans and ACS, the recommendation is non-preferred, primarily because of increased cost over the alternatives.

The Committee voted unanimously to accept the recommendation of non-preferred status, with a change in PA criteria for the class to allow for approval of a non-scheduled product if the patient has a history of addiction.

Announcements:

Ms. Scott noted that the FDA has withdrawn propoxyphene products from the market, so preferred drug list documents are being updated to remove references to propoxyphene.

Dr. Hunter reminded the audience about the next meeting on April 13, and about the policy for interested party submissions.

The meeting was adjourned at 12:04 PM.

Following the meeting, ODJFS accepted the recommendations of the committee for Pradaxa, Latuda, Jalyn, and Silenor. The recommendation for Gilenya is under review.

**Ohio Department of Job and Family Services
Office of Ohio Health Plans**

**Pharmacy and Therapeutics Committee
Conflict of Interest Policy**

Purpose: To require members of the ODJFS Pharmacy and Therapeutics Committee to abide by this policy so that scientific and economic data serves as the primary basis in rendering objective decisions about drugs being considered for coverage by Ohio Health Plans.

Definition: A potential “conflict of interest” may exist when a committee member has a relationship with a manufacturer of the medication or class of medications being considered that could inappropriately influence his/her judgment, or the judgment of other members. This may include a relationship with a manufacturer of a drug which competes with the drug under consideration. A relationship with a manufacturer may include any of the following:

- Acceptance of honoraria
- Participation in speaker’s bureau
- Acceptance of support for travel for professional or education activities
- Acceptance of research support
- Relationship valued at \$500 or more with one company
- Consultant arrangement

Policy Statements

1. A member shall not participate in the discussion of an issue that is before the committee unless he/she has first disclosed any potentially relevant conflict of interest.
2. The committee will determine if a specific activity or relationship represents a potential conflict of interest and whether the member disclosing a potentially relevant conflict should continue to participate in the discussion.

Procedure: Committee members must sign this agreement once each year.

Signature _____ Date _____

Printed Name _____