

Office of Medical Assistance (OMA) P&T Committee Meeting Minutes

January 9, 2013

Lazarus Building, 50 W. Town St., Columbus, OH 43215

Committee members present: Susan Baker, CNS; Suzanne Eastman, RPh; Jennifer Hauler, DO; Robert Hunter, DO (Chair); Karen Jacobs, DO; Margaret Scott, RPh; Michael Wascovich, RPh; Mary Jo Welker, MD

Xerox staff present: Stephanie Levine, RPh, Clinical Manager

ODJFS staff present: Michael Howcroft, RPh; Jill Griffith, PharmD

Approximately 35 stakeholders were present, most representing pharmaceutical manufacturers.

The meeting was called to order at 10:05 AM.

1. Membership and Conflict of Interest Policy

Dr. Hunter asked all members to sign the conflict of interest policy. A copy of the policy is attached to the minutes.

2. Interested party presentations

No interested parties submitted intent to present.

3. New Business

a. New PDL Drugs

1. CNS – Multiple Sclerosis: Aubagio (teriflunomide tablets), Sanofi

A representative from Genzyme, a Sanofi company, presented clinical information about the drug.

Dr. Jacobs asked the differences between Gilenya and Aubagio. The representative said that while both drugs are once-daily oral dosage forms, the mechanism of action is different.

Mr. Wascovich asked if the indication for the 7mg strength is different than 14mg. The representative said that there is no recommendation for dosage adjustment in any population.

Dr. Hunter asked about the cost compared to Gilenya. At the retail level, Gilenya is slightly higher.

Dr. Levine gave the recommendation from Xerox and the state as non-preferred status.

Mr. Wascovich asked if there is any reason to start a patient on Aubagio rather than Gilenya. Ms. Eastman pointed out the unique mechanism of action and said that she has seen patients changed from Gilenya to Aubagio.

The committee vote was tied, with Dr. Hauler, Dr. Hunter, Mr. Wascovich and Ms. Scott voting for non-preferred status and Ms. Baker, Ms. Eastman, Dr. Jacobs and Dr. Welker voting for preferred status.

2. Gastrointestinal

a. Pancreatic Enzymes: Pertzye (pancrelipase delayed-release capsules), Digestive Care

A representative from Digestive Care presented clinical information about the drug.

Dr. Welker noted that Pertzye does not require concomitant use of an H2 blocker or proton pump inhibitor (PPI) and asked how many patients on the other pancreatic enzymes are using this therapy. Ms. Scott said this has not been researched, but the cost of H2 or PPI therapy is negligible compared to the cost of the pancreatic enzymes.

The committee and speaker discussed the FDA's requirement that pancreatic enzymes go through the approval process, which has caused this class of drugs to become more expensive over the last several years. Dr. Levine gave the recommendation from Xerox and the state as non-preferred status.

The committee vote was unanimous for non-preferred status.

b. Chronic Constipation: Linzess (linaclotide capsules), Forest

A representative from Forest presented clinical information about the drug.

Mr. Wascovich asked how long a patient can remain on Linzess. The representative said that studies have been completed for efficacy at 26 weeks and longer-term for safety.

Dr. Jacobs asked if diarrhea was dose dependent. The representative said that it is not, and that in one trial the incidence was higher with the lower dose.

Dr. Levine gave the recommendation from Xerox and the state as non-preferred status. Ms. Scott added that this would be at parity with Amitiza.

Mr. Wascovich noted that Linzess has a different mechanism of action and that we may be treating gastrointestinal pain with drugs that cause constipation. He recommended that the Drug Utilization Review program monitor utilization of drugs in this class.

The committee vote was 6 for non-preferred status and 2 for preferred status (Dr. Hunter and Mr. Wascovich).

The committee noted that the class name is chronic constipation rather than irritable bowel syndrome. Ms. Scott said that the department is likely to recommend changing the class name to include IBS.

3. GU – Urinary Antispasmodics: Myrbetriq (mirabegron extended-release tablets), Astellas

A representative from Astellas presented clinical information about the drug.

Mr. Wascovich asked if the adverse events were seen more often in patients with asthma or pregnant women. The representative said that Myrbetriq is pregnancy category C so should not be used. The drug is not contraindicated in asthma even though it works on the β_3 receptors. There was some simulation of β_1 and β_2 receptors in animals at doses more than eight times recommended.

Dr. Levine gave the recommendation from Xerox and the state as non-preferred status, which is third tier (to be used after trials on preferred generic and/or brand drugs).

The committee vote was unanimous for non-preferred status.

4. Nasal Preparations:

a. Zetonna (ciclesonide nasal aerosol), Sunovion

A representative from Sunovion presented clinical information about the drug.

Dr. Levine gave the recommendation from Xerox and the state as non-preferred status, which is third tier (to be used after trials on preferred generic and/or brand drugs).

With no discussion, the committee vote was unanimous for non-preferred status.

b. Dymista (azelastine HCl and fluticasone propionate nasal spray), Meda

A representative from Meda presented clinical information about the drug.

Dr. Levine gave the recommendation from Xerox and the state as non-preferred status, which is third tier (to be used after trials on preferred generic and/or brand nasal steroids).

Dr. Jacobs asked about the comparison between the Dymista product and the separate fluticasone and Astelin products. Ms. Scott said that the cost of the separate products is lower than the cost of Dymista. Ms. Eastman pointed out that the spray volume for the combination product is much lower than for the separate products.

The committee vote was 6 for non-preferred status and 2 for preferred brand status (Ms. Eastman and Dr. Jacobs).

5. Respiratory – COPD: Tudorza Pressair (aclidinium bromide inhalation powder), Forest

A representative from Forest presented clinical information about the drug.

Dr. Hauler noted that the speaker had mentioned a decrease in rescue inhaler use (about 1 puff per day) and asked if any decrease in medical costs had been seen. The representative said that the trials were 12 to 24 weeks in duration, and while there were numeric differences in the number of exacerbations the FDA requires at least a year of comparison to be able to indicate fewer exacerbations. Those studies are underway.

Dr. Hunter asked if there are any geriatric studies. The representative said that there were many geriatric patients in the clinical trials, with 2/3 of the

participants over age 60. There was no significant difference seen between geriatric patients and younger patients. Patients age 70 and older reported more adverse effects, but the effects reported were similar to those reported by younger patients.

Dr. Hauler asked if the new device showed an improvement in patient compliance. The representative said there are no studies showing an improvement in compliance, but patient preference in clinical trials was 80% for the Pressair device vs. 10% for the Handihaler device. There were also fewer errors made in the steps to inhalation.

Dr. Levine gave the recommendation from Xerox and the state as non-preferred status.

Ms. Eastman said that the device has advantages over the Spiriva Handihaler device.

The committee vote was seven for preferred status and one for non-preferred status (Ms. Scott).

4. Old Business: Atypical antipsychotic use in pediatrics and patients with dementia
Mr. Howcroft presented the department's progress on these initiatives. The information is attached to the minutes.

The committee discussed moving the June meeting date to June 12. The committee members agreed. The remaining meeting dates for 2013 are Wednesdays, April 10, June 12, and October 9.

The meeting was adjourned at 11:43 AM.

Notes from OMA after the meeting:

Pertzye, Linzess, Myrbetriq, Zetonna and Dymista will be added to non-preferred status. The department will review the committee recommendations for Aubagio and Tudorza.

Ohio Office of Medical Assistance

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

Purpose: To require members of the Office of Medical Assistance 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 Medicaid.

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 _____

***Ohio Partnership To Improve Dementia Care
in Nursing Home Residents and
BEACON (Best Evidence Advancing
Childhealth in Ohio Now) P&T Update***

January 9, 2012

***Ohio Partnership To Improve Dementia Care in Nursing
Home Residents***

- CMS goal to reduce the percentage of antipsychotics prescribed for dementia by 15% by December 31, 2012
- Ohio-the percentage of nursing home residents who received an antipsychotic medication for dementia from 4Q2011 through 2ndQ2012 is 25.2%. So Ohio needs to get that number down to 21.42%.
- Currently the percentage of residents who are on antipsychotics is reported (in addition to other quality measures) on a form called the Minimum Data Set but does not go far enough towards quality improvement
- The Challenge: 963 Nursing Homes in Ohio that partner with different pharmacies, different tracking reports, different frequency of reporting. Does not contain vital data such as diagnosis or recommendations
- December meeting organized with Office of Medical Assistance, Department of Aging, Department of Health, KePRO (Ohio Medicare Quality Improvement Organization) , Centers for Medicare and Medicaid Services, Omnicare, and Nursing Homes to talk about challenges and successes

Ohio Partnership To Improve Dementia Care in Nursing Home Residents

- December 2012 meeting organized with the help of the Long term Care Association Office of Medical Assistance, Department of Aging, Department of Health, KePRO (Ohio Medicare Quality Improvement Organization) , Centers for Medicare and Medicaid Services, Omnicare, and Nursing Homes to talk about challenges and successes
- Each Nursing Home can serve as a resource and the agencies such as Department of Aging and Clinical Advisory groups such as the P&T Committee can help be the bridge CONNECTING the CMS Quality Improvement Plan for dementia care in the senior population to the Nursing Homes.
- One of the first steps is to meet with the Long Term Association and others and collaborate on the measurements and the metrics (patient, drug, dose, frequency, diagnosis, recommendation)

Best Evidence For Advancing Childhealth In Ohio Now BEACON – P&T Update

- **Targets**
 - Target is a 25% reduction by June 30, 2014 in:
 - The use of Atypical Antipsychotics (AAP) in children < 6 years old
 - The use of ≥ 2 Atypical Antipsychotics in children for ≥ 2 month duration
 - The use of ≥ 4 psychotropic medications in children < 18 years old
- **Example Franklin County 2010:**
 - Number of children < 6 who received at least 1 AAP = 65
 - Number of children receiving 4 or more psychotropics = 268
 - Number of children receiving 2 or more AAP for 2 months duration = 9
 - 5224 children seen by providers for an outpatient mental health service
- **Strategies over a three year period**
 - Provide technical resources to support clinical standards
 - Promote adoption of best practice
 - Advance medication knowledge of caregivers, parents, youth, advocates
 - Communication
 - Transparency in data and outcome

**Best Evidence For Advancing Childhealth In Ohio Now
BEACON – P&T Update**

- Leadership Structure
 - BEACON Statewide Stakeholders
 - State Steering Committee (25 members)
 - Clinical Advisory Panel (13 members)
 - Pilot Community Chairs (3)
- Lots of work to do:
 - Stakeholder input
 - Define authority
 - Definition of medications
 - Medication Guidelines, titration guidelines
 - Consent
 - When to obtain medical consultation
 - Checklists

TIMELINE

ACTIVITIES	YEAR 1	YEAR 2	YEAR 3	DELIVERABLES
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LAUNCH PROJECT (Procure Clinical experts & QI vendor)	+++			Implementation plan, procurement, contract
DEVELOP TECHNICAL RESOURCES	+++++	+++++		Preliminary toolkits for clinicians: youth, families, workers & test/improve
IMPROVE CLINICIAN ADOPTION OF BEST PRACTICE	+++++	+++++	+++++	Monitoring, second opinion, outreach data, feedback, QI implementation
STATEWIDE SPREAD			+++++	Final toolkits, expansion targets
ADVANCE P/P PARTNERSHIP	+++++	+++++	+++++	Input, strategy, real-time feedback, community resource development
EVALUATION PLAN	+++++	+++++	+++++	Scope & evaluation strategy with progress reports & final report capturing key lessons & recs