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

October 10, 2012
77 S. High St., Room 1960

Committee members present: Suzanne Eastman, RPh; Jennifer Hauler, DO; Karen Jacobs, DO; Margaret Scott, RPh; Michael Wascovich, RPh (acting chair); 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 10:11 AM.

1. Membership and Conflict of Interest Policy
   Ms. Scott introduced new member Jennifer Hauler, DO, who specializes in emergency medicine and family practice. She was recommended by the Ohio Osteopathic Association to replace Dr. Giatis.
   Ms. Scott also reviewed the conflict of interest policy that all members have signed. A copy of the policy is attached to these minutes.

2. Interested party presentations
   No interested parties submitted intent to present.

3. New Business
   a. New PDL Drugs
      1. CNS: Parkinson's Disease (PD) and Restless Legs Syndrome (RLS) – Neupro (rotigotine transdermal system)
         A representative from UCB Pharma presented clinical information on the drug.
         Dr. Welker asked if there are particular symptoms of PD that this drug is better for. The UCB representative said that upon retrospective review of the data, the drug did not seem to have better effect on any particular motor features. Dr. Welker also asked if Neupro is being marketed as first-line therapy. The representative stated that the recommendation is to delay starting levodopa in PD patients for as long as possible so other dopamine receptor agonists are recommended first-line. In addition, it is marketed as first line therapy for RLS. Mr. Wascovich asked if there are data showing advantages over current therapy, and whether titration packs are available for new patients. The representative responded that starter packs are available for both indications, and samples are being provided to prescribers. Head-to-head studies have been completed against pramipexole and ropinirole. A non-

inferiority study done for the European Medicines Agency found that rotigotine was non-inferior to pramipexole. A study in 2002 comparing 6mg rotigotine to 24mg ropinirole found that rotigotine was not non-inferior, but current research suggests that 6mg rotigotine equivalent to a lower dose of ropinirole than used in the study.
Dr. Levine said that the recommendation from Xerox and the state is for Neupro to be placed in a non-preferred position in both PDL classes because there are viable generic options in both classes. With no discussion, the committee vote was unanimous to accept the recommendation.

2. Respiratory: chronic obstructive pulmonary disease (COPD) – Arcapta Neohaler (indacaterol inhalation powder)
A representative from Novartis presented clinical information on the drug. Mr. Wascovich asked if there are instructions on the box regarding use of the capsules in the inhaler, to ensure that patients are inhaling rather than swallowing the drug. The representative said that the box is clearly labeled. Ms. Scott asked if there are head-to-head studies against other therapies. The representative said that the studies that exist used higher doses of indacaterol so may not be accurate for the dose that was approved in the United States. Mr. Wascovich asked if there is evidence of decreased emergency department utilization or other cost avoidance. The representative said that there are no studies specific to this drug but that other studies have shown that once-daily inhalers as compared to more daily doses have shows a decrease in hospitalizations.
Dr. Levine said that the recommendation from Xerox and the state is for Arcapta to be placed in a non-preferred position on the PDL. Dr. Welker asked if the same step therapy criteria in place for other long-acting beta agonists will be used since Arcapta is not indicated for asthma. Ms. Scott said that the criteria would be specific to COPD. The committee vote was unanimous to accept the recommendation.

b. Atypical antipsychotic use in pediatrics and in patients with dementia
Ms. Scott said that this topic is being added as a standing agenda item on both the P&T Committee and Drug Utilization Review (DUR) Board meeting agendas. Mr. Howcroft discussed some of the initiatives that OMA is involved with to improve appropriate use of atypical antipsychotics in specific populations. The Best Evidence for Advancing Childhealth in Ohio Now (BEACON) Collaborative is leading an effort to ensure that atypical antipsychotics are being used appropriately in children. The federal Centers for Medicare and Medicaid Services (CMS) and child welfare agencies have directed states to ensure that utilization of these drugs in foster children is decreased, since data show that foster children are more likely to be prescribed atypical antipsychotics than other children. The federal goal is to reduce prescribing in foster children. Ohio has chosen to expand this work to all children, with an aim to reduce the use of antipsychotic medications in children less than 6 years of age and reduce the combined use of antipsychotic medications in children for over 2 months duration in youth under 18 years of age by 25% by June 30, 2014. Key stakeholders in this

collaborative are the Ohio Department of Mental Health, the Department of Job and Family Services Office of Children and Families, provider groups including the Ohio Psychiatric Physicians Association (OPPA), the Ohio chapter of the National Alliance on Mental Illness, and many other groups.
A partnership between CMS, federal and state partners, nursing facilities and other providers, advocacy groups and caregivers has set a national goal of reducing use of antipsychotic drugs in nursing home residents by 15% by the end of 2012. The Ohio Department of Aging is leading a steering committee to form a project plan by December 2012. Mr. Wascovich asked who has been chosen as experts for these initiatives. Dr. Jacobs said OPPA has been asked to provide specialists in child and geriatric psychiatry to assist with both of these initiatives.

4. Old Business – Growth Hormone Criteria
   Mr. Howcroft presented an updated version of the growth hormone clinical criteria that were presented at the June P&T Committee meeting. Questions had been raised at that meeting by Dr. Huffman that required additional research. Changes from the previous version include removing an age limit for children with chronic renal insufficiency, changing the specialists that can request prior authorization, extending the approval length for short bowel syndrome to 6 months, and adding age limits of 2 to 4 years for diagnosis of small for gestational age. In addition, diagnosis of short stature homeobox gene deficiency (SHOX) was added to the criteria.
   With no discussion, the committee vote was unanimous to accept the recommended criteria.

The meeting was adjourned with a reminder that the next meeting is Wednesday, January 9, 2013, at 10 AM.

Notes from OMA after the meeting:

Neupro and Arcapta will be added to coverage with prior authorization. The criteria for Arcapta will be specific to COPD.
The new criteria for growth hormone were shared with Dr. Huffman since she was unable to attend the meeting. She agreed with the changes so they will be implemented.

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 _____

Endocrine Agents: rH Growth Hormone

LENGTH OF AUTHORIZATIONS: varies as listed below.

- All products in this class require clinical prior authorization
- Must be treated and followed by a pediatric endocrinologist, pediatric nephrologist, clinical geneticist, endocrinologist or gastroenterologist (as appropriate for diagnosis)

PDL CRITERIA:

Is there any reason the patient cannot be changed to a medication not requiring prior approval?

Acceptable reasons include:

- Allergy to medications not requiring prior approval
- Contraindication to or drug interaction with medications not requiring prior approval
- History of unacceptable/toxic side effects to medications not requiring prior approval

The requested medication may be approved if the following is true:

- If there has been a therapeutic failure to no less than a three-month trial of at least one preferred medication

CLINICAL CRITERIA

Children - initial approval for the following diagnoses:

1. Growth Hormone Deficiency (GHD) – 6 month approval:
    a. Acquired GHD due to cranial irradiation, panhypopituitarism, central nervous system tumors, trauma, radiation, or pituitary damage; OR
    b. GHD with all the following:
        i. Must be evaluated, therapy prescribed and monitored by a pediatric endocrinologist; and
        ii. Must not have attained epiphyseal closure (documented by X-ray); and
        iii. Must have failed to respond to TWO standard GH stimulation tests (with insulin, levodopa, arginine, propranolol, clonidine, or glucagon; may be done in the same session) defined as a peak measure GH level of less than 10ng/ml after stimulation; and
        iv. Height at initiation of therapy must be > 2 standard deviations below population normal mean height for age and sex; and
        v. Bone age is ≥ 2 years behind chronological age

2. Genetic diagnosis – 1 year approval:
    a. Krause-Kivlin Syndrome; or
    b. Turner Syndrome; or
    c. Prader-Willi Syndrome; or
    d. Noonan Syndrome

3. Short stature associated with Chronic Renal Insufficiency PRIOR to kidney transplant – 6 month approval (AACE does not recommend GH for post-transplantation).

4. SHOX – Short Stature Homeobox Gene deficiency
    a. Diagnosis documented by chromosome analysis; and
    b. Must not have attained epiphyseal closure (documented by X-ray); and
    c. Height at initiation of therapy must be > 2 standard deviations below population normal mean height for age and sex; and
    d. Bone age is ≥ 2 years behind chronological age

5. Small for gestational age (intrauterine growth restriction) – 1 year approval:
    a. Birth weight or length is ≥ 2 SD below the mean for gestational age; and
    b. Child fails to manifest catch-up growth by age of 2 years, defined as a height ≥ 2 SD below the mean for age and sex; and
    c. Age is no less than 24 months and no more than 48 months

6. Reauthorization– 1 year approval:
    a. Acquired GHD or genetic syndrome diagnosis; or
    b. Growth Hormone Deficiency, Small for Gestational Age and SHOX
        i. Must not have attained epiphyseal closure (documented by X-ray)
        ii. Increase in growth double the annualized pre-treatment growth rate within first six months, then at least 3cm per year thereafter

Adults - initial approval for the following diagnoses:

1. AIDS-related wasting or cachexia – 6 month approval
    a. Diagnosis; and
    b. Involuntary weight loss of >10% from baseline or BMI < 20; and
    c. Patient has not responded to high-calorie diet; and
    d. Patient is being treated with antiretroviral drugs
2. Short bowel syndrome – 6 month approval
    a. Diagnosis by gastroenterologist; and
    b. Patient receiving intravenous nutritional support
3. Pituitary damage – 1 year approval
    a. Acquired GHD due to cranial irradiation, panhypopituitarism, central nervous system tumors, trauma, radiation, or pituitary damage; OR
    b. Must have failed to respond to TWO standard GH stimulation tests (with insulin, levodopa, arginine, propranolol, clonidine, or glucagon; may be done in the same session) defined as a peak measure GH level of less than 5 ng/ml after stimulation
4. Reauthorization: The patient health status has improved since last approval (weight gain, improved body composition)
    a. AIDS-related wasting or cachexia or short bowel syndrome – 6 months
    b. Pituitary damage or genetic syndrome – 1 year

GROWTH HORMONES

CLINICAL PA REQUIRED "PREFERRED"	PA REQUIRED
GENOTROPIN® cartridge, Miniquick (somatropin) NORDITROPIN® cartridge, FlexPro, NordiFlex, vial (somatropin) OMNITROPE® cartridge, vial (somatropin) TEV-TROPIN® vial (somatropin)	HUMATROPE® cartridge, vial (somatropin) NUTROPIN AQ® cartridge, Nuspin, vial (somatropin) NUTROPIN® vial (somatropin) SAIZEN® cartridge, vial (somatropin) SEROSTIM® vial (somatropin) ZORBTIVE® vial (somatropin)