

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

April 10, 2013

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

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

Xerox staff present: Stephanie Levine, PharmD, Clinical Manager

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

Approximately 40 stakeholders were present, most representing pharmaceutical manufacturers.

The meeting was called to order at 10:10 AM by Dr. Hunter

Dr. Huffman signed the conflict of interest policy. All other members present signed the policy at the January meeting.

1. Interested party presentations
No interested parties submitted intent to present.
2. New Preferred Drug List (PDL) Drugs
 - a. Anti-Rheumatic Drugs: Xeljanz (tofacitinib citrate) tablets, Pfizer.
A representative from Pfizer presented information about the drug.
Mr. Wascovich asked about the severity of the drug interactions. The Pfizer representative said that they are manageable with the decreased doses recommended in the product labeling.
Mr. Wascovich asked whether Xeljanz is superior to any other products. The Pfizer representative said that no clinical trials have been done that were powered to compare the drugs. The biggest advantage is its oral dosage form.
Dr. Levine gave the recommendation from Xerox and the state for non-preferred status.
Dr. Welker clarified the existing prior authorization (PA) criteria, which includes prior non-biologic therapy, then trials on two preferred, injectable products, for a total of four drug trials before a non-preferred, oral, product would be approved.
Ms. Eastman said she saw no reason to not add Xeljanz to preferred status.
Ms. Scott suggested changing the PA criteria to a trial of one preferred drug (following appropriate non-biologic therapy) rather than two preferred drugs.
The committee unanimously approved Xeljanz as non-preferred with the PA criteria change.
 - b. Blood Agents, Oral Anticoagulants: Eliquis (apixiban) tablets, BMS/Pfizer
A representative from Pfizer presented information about Eliquis.

Mr. Wascovich asked how the action is reversed. The representative said that the company has no recommendation, but anecdotally prothrombin complex concentrate and factor 7 have been used. Mr. Wascovich asked about the advantages over warfarin. The representative said that the half-life is about 12 hours, so steady state is reached in about 36 hours as opposed to five or more days for warfarin. Dose titrations are not needed for Eliquis, while they are for warfarin.

Dr. Levine gave the recommendation from Xerox and the state for non-preferred status. Ms. Scott added that Xarelto has more indications than Eliquis and also once daily dosing while Eliquis is twice daily.

Dr. Hunter said he is in favor of using less warfarin and using products with less bleeding risk.

The committee unanimously approved Eliquis as non-preferred.

- c. CNS, ADHD Agents: Quillivant XR (methylphenidate) extended-release oral suspension CII, Pfizer

A representative from Pfizer presented information about Quillivant XR.

Dr. Jacobs clarified that the duration of action is 12 hours. The Pfizer representative confirmed that the patients' behavior in the clinical trials was back to baseline at 12 hours.

Ms. Eastman asked about any data on the impact of not shaking the suspension as instructed, since suspensions may settle and have different concentrations. The representative was not aware of any data.

Dr. Huffman said that there is a need for options for younger children, patients who can't swallow pills and patients with G-tubes.

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

The committee voted unanimously to approve Quillivant XR as non-preferred status but with PA approval for patients unable to swallow pills or using a G-tube.

- d. Endocrine, Diabetes – Oral Hypoglycemics: Invokana (canagliflozin) tablets, Janssen

A representative from Janssen presented information about Invokana.

Mr. Wascovich asked if there is any effect in patients with benign prostatic hyperplasia. The representative was not aware of any data.

Dr. Hunter asked if patients on dialysis could use Invokana. The representative said the drug is highly protein bound so there is no expectation that it is dialyzable.

Mr. Wascovich asked whether the drug should be decreased or discontinued if renal function is low. The representative said the dose should be decreased if there is moderate renal impairment and not initiated or stopped in patients with severe renal impairment.

Dr. Hauler asked about the potential for proteinuria and hyperkalemia. The representative responded that proteinuria is not significant and hyperkalemia is similar to the effects of angiotensin converting enzyme inhibitors and angiotensin receptor blockers.

Dr. Levine gave the recommendation from Xerox and the state for non-preferred status, third tier.

The committee voted unanimously to approve Invokana as non-preferred, third tier.

- e. Respiratory, COPD: Combivent Respimat (ipratropium bromide and albuterol) inhalation spray, Boehringer Ingelheim

A representative from Boehringer Ingelheim demonstrated the new Respimat device to the committee.

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

Dr. Welker asked what current Combivent patients would do when the older metered dose inhaler device is off the market. Ms. Scott said that there are superior products available with once-daily dosing and simpler devices, so the department would like patients to change therapy. About 200 patients are currently using Combivent.

Mr. Wascovich agreed that patients should change products.

The committee unanimously voted to grandfather current patients but communicate to patients and providers that other products are preferred.

- f. Topical, Anti-Parasitics: Sklice (ivermectin) lotion, Sanofi Pasteur

A representative from Sanofi Pasteur presented information about Sklice.

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

Dr. Hunter asked if any preferred products are approved for age 6 months and older. Ms. Scott said the over-the-counter permethrins and pyrethrins are approved for ages 2 months and older.

Dr. Huffman said that lice infestation is a huge problem and there should be options.

Dr. Welker noted that the committee approved Natroba, which has a similar profile.

Ms. Baker added that this product is not toxic and asked if it would be possible to add as preferred for patients age 6 months to under 4 years, since Natroba is indicated for patients 4 years and older.

The committee unanimously voted to approve Sklice for patients 6 months to less than 4 years, non-preferred for ages 4 and older.

3. PDL information for June 12 meeting

- a. New drug classes

Ms. Scott reviewed the new drug classes that will be considered at the June meeting for the PDL. Draft criteria for each class except cardiovascular, antianginal agents are attached. Criteria for antianginal agents will be use of first-line calcium channel blockers and nitrates before ranolazine.

1. Cardiovascular, Antianginal Agents
2. CNS, Anticonvulsants
3. Infectious Disease, Antivirals for HIV
4. Respiratory, Self-Injected Epinephrine
5. Topical, Androgenic Agents

- b. Review of current drug classes with remaining questions from the committee
Ms. Scott gave an overview of the use of glyburide since Dr. Hrometz had pointed out last June that glyburide is no longer recommended.

Between September 2012 and February 2013, 728 patients received glyburide, ranging in age from 2 to 92 years. Approximately 20% of the patients were using glyburide as monotherapy for diabetes, with the rest using it in combination with other oral and injectable therapy. The children using glyburide were receiving it from specialists at children's hospitals, and the prescribers for all patients were scattered throughout the state. The Drug Utilization Review program plans to focus on diabetes and will include education about glyburide in interventions. Ms. Scott also discussed the use of single-ingredient, immediate-release, schedule II opiates. Last June, the committee voted to allow step therapy for these products, requiring a trial of an opiate combination or tramadol before these products would be approved. Upon review of utilization, there were over 1000 patients and a large number of prescribers. Without enough communication regarding the change, we risked patients going into withdrawal if therapy was stopped. The department is working on a communication and implementation plan and intends to implement this policy later in the year.

4. Atypical antipsychotic use in children and nursing facility residents

Antipsychotic use in children: Mr. Howcroft provided an update on the progress of the drug utilization review letters to be sent to providers that meet thresholds of antipsychotic prescribing in children. The drug utilization review provider letter is being modified and should be completed the week of April 15, 2013 and is anticipated the letters will be mailed June 2013.

Antipsychotic use in nursing facility residents: Mr. Howcroft provided an update on the progress of the statewide collaborative to improve appropriate antipsychotic prescribing in long term nursing facility residents. A data collection tool is being designed and developed to be used by the nursing facility staff. The data will be analyzed and then circled back to the nursing homes with recommendations for a quality improvement.

Announcements:

Ms. Scott informed the committee that long-time member Ruth Purdy, DO, has passed away.

Ms. Scott also said that Dr. Welker has decided to resign from the committee after more than 15 years of service. The committee expressed thanks to Dr. Welker for her participation on the committee. The department is working with the Ohio State Medical Association to find a suitable replacement.

Dr. Hunter announced that the Ohio Osteopathic Association is sponsoring a symposium on diabetes in Columbus in May. Additional information is available on the OOA web page, www.ooanet.org.

The meeting was adjourned at 12:46 PM.

Notes from OMA after the meeting:

All recommendations of the committee will be implemented.

Central Nervous System (CNS) Agents: Anticonvulsants

LENGTH OF AUTHORIZATIONS: 1 year

GRANDFATHERING:

Patients who have a claim for a non-preferred drug in the previous 120 days will be automatically approved to continue the drug through the automated PA system. Patients who have taken the drug in the previous 120 days, but do not have claims history (new to Medicaid, samples, etc.), will be approved for PA after prescriber contact.

- 1.** For initial therapy, non-preferred anticonvulsants may be approved if there have been therapeutic failures on two preferred agents.
- 2.** Is there any reason the patient cannot use a medication not requiring prior approval? Acceptable reasons include:
 - Allergy to two medications not requiring prior approval
 - Contraindication to or potential drug interaction with two medications not requiring prior approval
 - History of unacceptable/toxic side effects to two medications not requiring prior approval

ADDITIONAL INFORMATION

In addition to PDL criteria, requests for Banzel[®] and Onfi[®] require a diagnosis of “Lennox-Gastaut syndrome”. Requests for Sabril[®] require a diagnosis of “infantile spasms”.

AGENTS UNDER REVIEW:

Tegretol[®], etc. (carbamazepine IR/ER)
Onfi[®] (clobazam)
Klonopin[®] (clonazepam)
Diastat[®], Valium[®] (diazepam)
Depakote[®] (divalproex Sodium IR/DR/ER)
Zarontin[®] (ethosuximide)
Peganone[®] (ethotoin)
Potiga[®] (ezogabine)
Felbatol[®] (felbamate)
Neurontin[®] (gabapentin)
Vimpat[®] (lacosamide)
Lamictal[®] (lamotrigine IR/ER)

Keppra[®] (levetiracetam IR/ER)
Celontin[®] (methsuximide)
Trileptal[®], etc. (oxcarbazepine IR/ER)
Dilantin[®] (phenytoin Sodium IR/ER)
Lyrica[®] (pregabalin)
Mysoline[®] (primidone)
Banzel[®] (rufinamide)
Gabitril[®] (tiagabine)
Topamax[®] (topiramate)
Depakene[®], Stavzor[®] (valproic acid IR/DR)
Sabril[®] (vigabatrin)
Zonegran[®] (zonisamide)

Infectious Disease Agents: Antivirals – HIV

LENGTH OF AUTHORIZATIONS: 1 year

GRANDFATHERING:

Patients who have a claim for a non-preferred drug in the previous 120 days will be automatically approved to continue the drug through the automated PA system. Patients who have taken the drug in the previous 120 days, but do not have claims history (new to Medicaid, samples, etc.), will be approved for PA after prescriber contact.

1. 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 all medications not requiring prior approval
 - History of unacceptable/toxic side effects to medications not requiring prior approval
2. Has the patient failed a therapeutic trial of at least one month with at least one medication not requiring prior approval?

AGENTS UNDER REVIEW:

Anti-virals – HIV Protease Inhibitors

Reyataz [®] (atazanavir sulfate)	Viracept [®] (nelfinavir mesylate)
Lexiva [®] (fosamprenavir calcium)	Norvir [®] (ritonavir)
Crixivan [®] (indinavir sulfate)	Invirase [®] (saquinavir mesylate)
Kaletra [®] (lopinavir/ritonavir)	

Anti-virals – HIV Non-Peptidic Protease Inhibitors

Prezista[®] (darunavir ethanolate)
Aptivus[®] (tipranavir; tipranavir/vitamin E)

Anti-virals – HIV Reverse Transcriptase Inhibitors, Nucleoside Analogs

Ziagen [®] (abacavir sulfate)	Emtriva [®] (emtricitabine)
Epzicom [®] (abacavir/lamivudine)	Epivir [®] (lamivudine)
Trizivir [®] (abacavir/lamivudine/zidovudine)	Zerit [®] (stavudine)
Videx [®] (didanosine)	Retrovir [®] (zidovudine)

Anti-virals – HIV Reverse Transcriptase Inhibitors, Non-Nucleoside Analogs

Rescriptor[®] (delavirdine mesylate)
Sustiva[®] (efavirenz)
Intelence[®] (etravirine)
Viramune[®] (nevirapine IR/ER)
Edurant[®] (rilpivirine)

Anti-virals – HIV Reverse Transcriptase Inhibitors, Nucleotide Analogs

Viread[®] (tenofovir disoproxil fumarate)

Anti-virals – HIV RTI, Nucleoside-Nucleotide Analogs

Truvada[®] (emtricitabine/tenofovir)

Anti-virals – HIV RTI, Nucleoside, Nucleotide, & Non-Nucleoside Analogs

Atripla[®] (emtricitabine/efavirenz/tenofovir)

Complera[®] (emtricitabine/rilpivirine/tenofovir)

Anti-virals – HIV Integrase Strand Transfer Inhibitors

Isentress[®] (raltegravir potassium)

Anti-virals – HIV Integrase Inhibitor & RTI Combination

Stribild[®] (elvitegravir/cobicistat/emtricitabine/tenofovir)

Anti-virals – HIV CCR5 Co-Receptor Antagonists

Selzentry[®] (maraviroc)

Anti-virals – HIV Fusion Inhibitors

Fuzeon[®] (enfuvirtide)

Respiratory Agents: Epinephrine Auto-Injectors

LENGTH OF AUTHORIZATIONS: 1 year

The requested medication may be approved if there has been therapeutic failure using the product(s) not requiring prior approval.

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

- Allergy to medication(s) not requiring prior approval
- Contraindication to or drug interaction with medication(s) not requiring prior approval
- History of unacceptable/toxic side effects to medication(s) not requiring prior approval

AGENTS UNDER REVIEW:

Auvi-Q™ (epinephrine)

Epipen® and Epipen Jr® (epinephrine)

Topical Agents: Androgens

LENGTH OF AUTHORIZATIONS: 1 year

The requested medication may be approved if there has been a therapeutic failure to no less than a three-month trial of all medications not requiring prior approval.

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

Acceptable reasons include:

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

ADDITIONAL INFORMATION

Limited to males \geq 18 years

AGENTS UNDER REVIEW:

Androderm[®] (testosterone)

AndroGel[®] (testosterone)

Axiron[®] (testosterone)

Fortesta[®] (testosterone)

Testim[®] (testosterone)