

ODJFS P&T Committee Meeting Minutes

April 21, 2010
30 E. Broad St., Room 2529

Committee members present: Susan Baker, APN; Suzanne Eastman, RPh; Ioanna Giatis, DO; Karen Jacobs, DO; Margaret Scott, RPh (acting chair); Michael Wascovich, RPh; Mary Jo Welker, MD

ACS staff present: Stephanie Levine, PharmD, Clinical Manager

Approximately 65 stakeholders were present, most representing pharmaceutical manufacturers and advocacy associations.

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

1. Interested party presentations
 - Jim Mauro, Executive Director, National Alliance on Mental Illness of Ohio
2. Old Business
 - a. Conflict of interest statement. Dr. Giatis signed the conflict of interest statement. She was the only member present who had not previously signed the statement.
 - b. Discussion about policy regarding interested party presentations. Ms. Scott has consulted with the ODJFS Office of Legal and Acquisition Services, and several changes were suggested. The statute requires that the interested party may request either to make an oral presentation, or to submit written materials to the committee. ODJFS Legal's interpretation of the statute is that the request shall be granted in the form requested. Since there is no decision about which interested parties would be able to make a presentation, the deadline for presentation requests will be the Friday prior to the meeting. Some stakeholders have raised concerns that five minutes is not enough time for an interested party to convey their message. ODJFS Legal suggested that the chair may either extend or limit a speaker's time depending on the circumstances. Ms. Scott suggested that Medicaid consumers and family members may be given more leeway than health or advocacy professionals. The guidelines were also changed to reflect that written submissions provided less than two business days prior to the meeting may not be considered at the meeting, and that written information provided at the meeting will not be considered during the meeting. The committee unanimously voted to accept the revised guidelines.
 - c. Discussion about procedure for July 7, 2010, meeting and preferred drug list (PDL) updates. Several pharmaceutical manufacturers have expressed concern that in past years the clinical presentations have been scheduled for the day prior to the committee meeting, and that most committee members have been unable to attend. In the last few years, presentations have taken about four hours, with presentations limited to ten minutes each. The manufacturers have expressed a willingness to shorten the presentations if they are the same day as the meeting. The committee discussed the timing of the presentations and length of the meeting if presentations are given the same day. The committee decided to schedule the clinical presentations for July 7th prior to the meeting, beginning at 9 AM.

- d. Outstanding issues from previous committee meetings
 1. Ophthalmic and otic quinolones. At a previous meeting, concern was expressed by committee members that ophthalmic quinolones are over-prescribed, and that other antibiotics are effective and more appropriate. Ms. Scott took this concern to the Drug Utilization Review (DUR) Board, who also suggested that otic quinolones may be over-prescribed. The DUR program addressed this situation through letters to high prescribers of these products.

For ophthalmic quinolones, prescribers who had medical claims for five or more cases of conjunctivitis were identified. Letters were sent to prescribers if at least 25% of the prescriptions resulting from those claims were for an ophthalmic quinolone. The letter states that the September 2008 Conjunctivitis Preferred Practice Pattern Guideline published by the American Academy of Ophthalmology recommends that the most convenient or least expensive antibacterial therapy can be selected. The letter also included the cost per bottle of each of the ophthalmic quinolones.

For otic quinolones, prescribers who had medical claims for five or more cases of otitis media were identified. Letters were sent to prescribers if at least 25% of the prescriptions resulting from those claims were for an otic quinolone. The letter states that the American Academy of Pediatrics Clinical Practice Guideline for Diagnosis and Management of Acute Otitis Media recommends oral amoxicillin as the treatment of choice. The guideline does not recommend routine use of otic quinolone preparations. Cost information about the otic quinolones as compared to generic Cortisporin Otic was included.
 2. Attention Deficit Hyperactivity Disorder (ADHD) drug prior authorization (PA) criteria. At the meeting on January 27, 2010, the committee voted to exempt psychiatrists from prior authorization requirements for ADHD drugs. After researching the utilization of ADHD drugs by psychiatrists, pediatricians, and neurologists as compared to physicians in other specialties, ODJFS has decided not to exempt psychiatrists. Very few ADHD drugs are listed as non-preferred on the PDL. Over 97% of all claims are for preferred drugs, and this percentage is stable across all specialties. Ms. Scott also said that the SmartPA program will automatically approve a patient to continue to receive a non-preferred drug if the patient had a claim for the same drug in the previous 60 days, regardless of prescriber. If the PDL becomes more limited in the future, this decision can be revisited.
3. Drugs under consideration
 - a. Voltaren gel (diclofenac sodium topical gel), Endo. This drug has been available with prior authorization, but had never been presented to the committee. This review is at the manufacturer's request. A speaker from Endo presented clinical information. Dr. Levine from ACS presented the recommendation of ACS, ODJFS, and the managed care plans. The recommendation is that PA be retained. The committee discussed cost. Ms. Scott reported that reimbursement to the pharmacy for the highest dose of Voltaren gel is about \$9 per day, while oral therapy with diclofenac is about \$0.80 per day. Therapy with other generic

NSAIDs is much less than diclofenac. The committee expressed support for the idea of having a topical option with few side effects, but said that the cost is high. Members said that their experience has been that Medicare Part D and commercial plans require prior authorization. Ms. Scott said that current prior authorization criteria is that the patient must try a therapeutic alternative, such as oral NSAID, before being approved for Voltaren Gel. The committee suggested updating the PA criteria to be specific about contraindications to oral therapy. The committee voted unanimously to recommend retaining PA but creating more specific criteria.

- b. Antipsychotics, Second Generation
 1. Saphris (asenapine) sublingual tablets, Merck. Peter Zafirides, MD, psychiatrist, spoke about his experience with Saphris. A representative from Merck also made a presentation. Dr. Levine said that ACS, ODJFS, and the managed care plans did not have a recommendation on this drug. The committee discussed side effects, drug interactions, cost, and efficacy. Ms. Scott also noted that the drug is only available in an orally disintegrating tablet formulation, which normally requires the patient to try the standard tablet first. In the case of this drug, which does not have a standard tablet, the requirement is not necessary. The committee unanimously recommended that Saphris be preferred.
 2. Fanapt (iloperidone) tablets, Novartis. A representative from Novartis gave a clinical presentation. Dr. Levine said that the recommendation of ACS, ODJFS, and the managed care plans is non-preferred. The committee discussed the titration schedule, the recommendation that titration be re-started after any break in therapy of more than three days, and side effects. The committee unanimously recommended that Fanapt be non-preferred.
- c. Diabetes – Incretin Mimetics: Victoza (liraglutide [rDNA origin]) injection, Novo Nordisk. A representative from Novo Nordisk made a clinical presentation. Dr. Levine said that ACS, ODJFS and the managed care plans do not have a recommendation on this drug. Committee members discussed the cost as compared to Byetta, possible improvement in compliance due to once daily dosing, efficacy, and effects on measures other than blood glucose. The committee unanimously recommended that Victoza be preferred.
- d. Multiple Sclerosis (MS) Agents: Ampyra (dalfampridine) extended release tablets, Acorda Therapeutics. A speaker from Acorda made a clinical presentation, Dr. Kottil Rammohan from the Ohio State University Medical Center MS Center shared his experience with the drug, and Holly Pendell with the National MS Society also shared information. The committee addressed many questions to Dr. Rammohan about his experience with Ampyra. He indicated that patients who will respond to the drug will most likely respond in the first month. He also stated that he has seen improvement in function other than walking that improves quality of life. Dr. Levine said that the recommendation of ACS, ODJFS, and the managed care plans is non-preferred, with PA criteria including diagnosis of MS and therapy on a disease-modifying drug. The committee discussed appropriate PA criteria, and unanimously recommended that the initial request must be made by a neurologist who has made a diagnosis of MS, the initial approval should be for 60 days, and that subsequent approvals may be granted if there has been an improvement in

function. Because disease-modifying drugs are not used in all forms of MS, they did not recommend this therapy as a requirement.

The next meeting is scheduled for Wednesday, July 7, 2010, at 9 AM in the Riffe Building, 77 S. High St., Room 1948.

Ms. Scott announced a technical problem with the letters that had been sent to managed care plan (MCP) members during the transition period. The letters were sent to MCP members who had a claim for a drug that requires PA on fee-for-service Medicaid, that was filled by the member between August 2009 and January 2010. The intention was that letters would only be sent if the claim could not be approved automatically through the SmartPA system, or if there is no prescriber-requested PA on file. During the week of April 12, it came to ODJFS' attention that transition period letters were sent to MCP members even if the member had a PA on file or the SmartPA system approved the claim and generated an automatic PA. The mistake has been corrected for the last 3 weeks of April. Correction letters are being sent to MCP members who received letters about antidepressants and second generation antipsychotics. Correction letters will not be sent to members receiving other drugs.

The meeting was adjourned at 12:03 PM.

Following the meeting, ODJFS followed the Committee's recommendations to keep Voltaren gel on PA, and will create more specific clinical criteria; to make Saphris and Victoza preferred; to make Fanapt non-preferred; and to implement the PA criteria recommended for Ampyra.