

**Pharmacy and Therapeutics Committee
Michigan Department of Community Health
Meeting of June 7, 2005, 6PM
Kellogg Center, East Lansing MI
Minutes**

I. Introductions, and Approval of April 5, 2005 Meeting Minutes:

Chairman Richard Slaughter convened the meeting at 6PM. Committee members present were Dean Van Loo, Robert Coffey, Paul Dake, Jonathon Arend, Ronald Bradley, Giovannino Perri, Khan Nedd, Max Robins. Committee members not in attendance were Jay Fiechtner. State staff present were Don Quillan, Annette Paul, Jacqueline Coleman, Mary Sandusky.

The Minutes of the April 5, 2005 meeting were approved as currently posted on the web site *www.Michigan.fhsc.com* by voice vote.

II. Public Comment

The following persons made public comment, having previously asked to do so per Committee procedures.

M. Safwan Badr, MD, WSU, Spiriva®

Sue Martin, PharmD., Novartis, Enablex®

Dr. Shelley Raebel, Purdue Pharma, Palladone®

Dr. James Sondheimer, WSU, Fosrenol®

Linda Neuman, MD, Peg Intron®

Allan Goldberg, MD, Merck, Singulair®

Chris Farnum, MD, Levaquin®

Neil Hyuck, PharmD, Astellas, Dr. David Berks, HFHS, Vesicare®

Todd Edwards, PharmD, GSK, Flonase®, Requip®

Greg Navarro, Michael Tindal, PhD, Sepracor, Xopenex®

John Valenti, Dr. B. Matthews, Sanofi-Aventis, Ketek®

Mark Faber, MD, HFHS, Nancy Mason, PharmD, Genzyme, Renagel®

Renu Govindaiah, MD, allergist, Zyrtec®

Iris Zink, NP, Martin Job, PharmD, , Abbott, Humira®, Omnicef®, Biaxin®

Peter Gulick, DO, Pegasys®

III. New Drugs for Review

Annette Paul, RPh. presented a synopsis of each of the following drug products. The Committee then discussed, and voted to add to the Michigan Pharmaceutical Product List as described below:

Vesicare® Following discussion, the Committee voted to recommend adding to the PDL category of Urinary Tract Antispasmodics with prior authorization; the Department will review the National Medicaid Pooling Initiative for products in this class, and report back to the Committee as to suggestions for any changes to the class list.

Fosrenol® Discussion was deferred to a discussion of the class of Electrolyte Depleters under Agenda item VI. (At that time, Fosrenol® was recommended to be added to the PDL new category, without prior authorization.

Ventavis® This drug received a priority rating by the FDA for treatment of pulmonary arterial hypertension. The Committee voted to recommend adding to the MPPL with clinical prior authorization, identical to the existing products for treatment of this disease, Flolan® and Remodulin®.

Palladone® Extensive discussion occurred because this drug has a high abuse potential and significant, lethal side effects with inappropriate use. The Committee voted to recommend the Department add Palladone® to the PDL category of Narcotics-Long Acting Analgesics, but require prior authorization, and enhance the criteria for prior authorization to include prescriber screening for ethanol and other substance use, such as requiring results of CAGE screening, and strict quantity limits and monitoring as is done with oxycodone, extended release.

Enablex® As with Vesicare®, the Committee recommended the Department add this to the PDL in the Urinary Tract Antispasmodics class, with prior authorization, and that the Department review the results of the National Medicaid Pooling Initiative and report back to the Committee for any recommended changes to this class.

Baraclude® The Committee voted to recommend the department add this drug to the MPPL without prior authorization. Discussion than took place about the prior authorization requirement placed on Hepsera®. Dr. Van Loo will review this matter and report back to the group.

IV. Line Extensions

The Committee voted to recommend the Department review these products, based on the current MPPL and/or PDL status of the related drug entity. For example, Niravam® is a form of alprazolam, which is available generically; any brand name, such as Niravam® would require prior authorization.

Niravam®

Zanaflex® capsules

Aricept ODT®

Razadyne® This is renamed from Reminyl®; the PDL will be changed to reflect the name change.

Depo-SubQ®

Cyclosporine 50mg caps

Vanos®cream Existing forms of fluocinonide creams available generically are 0.05%; this is a 0.1% strength

Fosamax Plus® For example, Fosamax® is currently listed as available without prior authorization on the PDL. FosamaxPlus® would be similarly categorized.

[Based on this discussion, the Department will code these products as follows:

Niravam® - requires prior authorization

Zanaflex caps® - requires prior authorization

Aricept ODT® - available on the PDL without prior authorization

Razadyne® - available on the PDL without prior authorization

Depo -SubQ – available on the MPPL without prior authorization

Cyclosporine 50 mg caps – available on the MPPL without prior authorization

Vanos 0.1% cream® – requires prior authorization

Fosamax Plus® - available on the PDL without prior authorization]

V. Current PDL Classes to be Reviewed

Dean Van Loo, PharmD., presented the workgroup recommendations for the **Antibiotics-Anti-infectives** classes of drugs. Discussion occurred about each class, with particular focus on the issue of antibiotic resistance, and how the PDL listing may be used to counter inappropriate prescribing, if possible. Following discussion of each class, the Committee voted to recommend to the Department the following:

Antifungals-onychomycosis, Move Griseofulvin to the antifungals-onychomycosis category, with continued availability without prior authorization; continue clinical PA on Lamisil®

Antifungals-oral, No other changes recommended from the current PDL listing

Antivirals-herpes, No changes recommended

Antivirals-influenza, Place Relenza® and Tamiflu® to requiring prior authorization. At the September meeting, re-evaluate if there is a need to change this status, based on public health authority assessment of availability of flu vaccine supplies.

Cephalosporin, 1st, 2nd Generation, No changes to current listing

Cephalosporins-3rd Generation, Remove the prior authorization requirement for Suprax® suspension.

Hepatitis C, No changes to the current listing. Discussion ensued on the weight-based dosing of Peg-Intron®, and the availability of data comparing and contrasting with Pegasys®, especially for selected patients, such as African American men.

Ketolides, Extensive discussion on the role of Ketek® as an alternative to quinolone antibiotics, and the concern of emerging resistance to quinolones, especially in serious infections. The Committee voted to recommend the Department remove prior authorization from Ketek®. The Committee asked for a report on activities ongoing to deal with the issue of antibiotic prescribing, such as a drug utilization report. A brief discussion ensued on the Department working with Blue Cross Blue Shield of Michigan on a Michigan Antibiotic Resistance project. The Committee asked for a report, hopefully by the December meeting, of any results from that project.

Macrolides, No changes to the current listing

Quinolones, Place prior authorization requirement on Neggram® and Noroxin®

Max Robins, DO presented the workgroup findings and recommendation for the **Asthma-Allergy** classes included in this category. Following class by class discussion, the Committee voted to recommend the following to the Department:

Inhaled Anticholinergics, No changes to the current listing, after discussion of utilization patterns of Spiriva®

Antihistamines-2nd Generation, Allow Zyrtec® to be available without prior authorization for beneficiaries 6months to 2 years of age; other products as currently listed

Beta Adrenergic-Short Acting, Long Acting, for Nebulizers, No changes to these classes from the current listing

Beta Adrenergic/ Corticosteroid Inhaler Combination, No changes to current listing

Inhaled Systemic Glucocorticoids, No changes to the current listing

Leukotriene Inhibitors, No changes to the current listing

Nasal Steroids, No changes to the current listing.

VI. Additional (New) Classes to be Reviewed

Because Dr. Fiechtner was not able to attend this meeting, the category

Immunomodulators, systemic (Humira®, Enbrel®, Kineret®) will be reviewed at the September meeting.

The Committee briefly discussed the implications of adding new categories to the PDL, after presentations by Annette Paul, RPh and Giovannino Perri, MD. At this time, the Department had recommended these new categories be added, with the identified products available without prior authorization. The Committee voted to recommend these classes be added to the PDL.

Electrolyte Depleters (Fosrenol®, Phoslo®, Renagel®)

Multiple Sclerosis Agents (Avonex®, Betaseron®, Copaxone®, Rebif®)

Non-ergot Dopamine Receptor Agonists (Mirapex®, Requip®)

Alpha Blockers for BPH (Flomax®, Uroxatrol®)

VII. Key Questions for PDL Classes for September Review

Chairman Slaughter handed out a new worksheet for workgroup assignments. For the categories listed below, there are pertinent drug product reviews on the Oregon Drug Effectiveness Review web site www.ohsu.edu/drugeffectiveness

Diabetes

Gastrointestinal

PDL Working Groups: 2005

PDL Class	Primary Reviewer	Secondary Reviewer	Secondary Reviewer	First Health	Oregon Class Review (report dates)	P&T Meeting Date
Analgesics	Fiechtner	Perri	Robbins	Paul	NSAIDS (3/05) Opioids, long acting (5/05)	December
Antibiotics/Anti-infectives	Van Loo	Perri	Robbins	Paul		June
Asthma/Allergy	Robbins	Van Loo	Coffey	Paul	Antihistamines (11/05)	June
Cardiac 1	Dake	Slaughter	Eggleston	Paul	ACEI (7/05) ARA (9/04,9/05) CCB (5/05)	February
Cardiac 2 (includes Caduet)	Nedd	Slaughter	Fiechtner	Paul	Statins (6/05) BB(5/05)	April
CNS	Bradley	Perri	Arends	Paul	Alzheimers (4/05) ADHD (6/05)	December
Diabetes	Coffey	Nedd	Slaughter	Paul	Oral hypoglycemics (6/05)	September
Gastrointestinal	Arend	Perri	Van Loo	Paul	PPIs (5/05)	September
Miscellaneous	Perri	Fiechtner	Bradley	Paul	Triptans (11/05) Urinary incontinence (2/05)	April
Therapeutic Controversies	Nedd	Slaughter	Dake	Paul		February

VIII. Next Meeting

The next meeting will be Tuesday, September 13, 2005 at 6PM at the Kellogg Center