Meeting of the
Pharmacy and Therapeutics Committee
November 11, 2003
Minutes

Members Present:
Randy Axelrod, M.D., Chair
Gill Abernathy, M.S., R.Ph.

Avtar Dhillon, M.D.
Mariann Johnson, M.D.
Mark Oley, R.Ph.
James Reinhard, M.D.
Christine Tully, M.D.
Renita Warren, Pharm.D.

(via phone) Roy Beveridge, M.D
(via phone) Arthur Garson, Jr., M.D.

Absent:
Sue Cantrell, M.D.
Mark Szalwinski, Pharm.D.Vice Chair

A quorum was present

Guests:

49 representatives from pharmaceutical companies, providers, advocates, associations, etc.
Manikoth Kurup, MD, Member, Board of Medical Assistance Services
Dave Campana (via phone), P&T Committee Chair - Alaska

DMAS Staff:
Patrick Finnerty, Agency Director
Cynthia Jones, Chief Deputy Director
Cheryl Roberts, Deputy Director of Programs and Operations
Manju Ganeriwala, Deputy Director of Finance and Administration
Paige Fitzgerald, Counsel to the Board, Office of the Attorney General
Bryan Tomlinson, Director, Division Health Care Services
Adrienne Fegans, Program Operations Administrator
Javier Menendez, Pharmacy Manager

First Health Staff:
Carol Perkins, Pharm.D. Clinical Manager
Ken Kolb, Pharm.D. Director of Clinical Development

WELCOME AND INTRODUCTIONS

Patrick Finnerty called the meeting to order. Six P&T Committee members were in attendance at this time (Dr. Axelrod was in route and participated via phone for the initial part of the meeting. No votes were taken by the Committee until Dr. Axelrod was present on site.) Dr. Beveridge and Dr. Garson participated via phone. Dave Campana, Chair of the Alaska P&T Committee was also on the phone, participating as an observer.

COMMENTS FROM PATRICK FINNERTY, DMAS DIRECTOR

Mr. Finnerty welcomed those in attendance. He stated the supplemental rebate contracts for the first 13 drug classes had been received from the pharmaceutical manufacturers and thanked the manufacturers and First Health for their work in accomplishing this and meeting the established timeline.

He further noted that the meeting today would include a discussion of the prior authorization criteria for the first 13 drug classes. Since there were no issues to discuss involving the contracts, a confidential meeting (included on the agenda) would not be necessary.

Since Dr. Axelrod was in route, the meeting would begin with presentations on the drug classes to be considered for the second phase of the PDL (April implementation). Presenters would be limited to three minutes for their presentations. The same process utilized in Phase I (January 2004) for the submission of information, bids, and contracts will be used for this second phase (April 2004).

COMMENTS FROM RANDY AXELROD, COMMITTEE CHAIR (via phone)

Dr. Axelrod stated that until the process of obtaining clinical expertise from an ophthalmologist was complete, the Committee would not review the four related drug classes (Carbonic Anhydrase Inhibitors – Ophth, Alpha 2 Adrenergics – Ophth, Beta-blockers – Ophth, Prostaglandin Inhibitors – Ophth) at today's meeting. These classes will be scheduled for review at the January 6th P&T Committee meeting.

DRUG CLASS DISCUSSIONS

Oral Hypoglycemics

Joe Ogden, Diabetes Scientific Manager, Aventis Pharmaceuticals
Discussed safety profile of Amaryl®, issue of ischemic reconditioning, and efficacy of Amaryl® (improvement in first and second phase insulin release, decreases in HgA1c and fasting blood glucose). Provided packet including hard copies of slides and several studies.

Charlie Kelly, Pharm.D., CDE, Regional Scientific Manager, Takeda Pharmaceuticals North America
Discussed positive class properties of the "glitazone" class * improvement in insulin resistance and beta cell dysfunction. Specific to Actos® - positive lipid effects, daily dosing and lack of any clinically relevant drug interactions. Mentioned recent reports of a drug interaction between gemfibrozil and Avandia®. A handout was provided to the Committee.

Kerry L. Cunningham, Pharm.D. Sr. Regional Medical Scientist, CV/ Metabolic Clinical Development & Medical Affairs-North America (CDMA), GlaxoSmithKline
Also discussed positive class properties. Cited UKPDS study and importance of glycemic control, and studies showing long-term (36 months) efficacy of Avandia®, positive effects on lipids, lack of metabolism by 3A4 system (Actos® does undergo metabolism by this pathway). Avandia® is also available in combination with metformin (Avandamet®). Provided packet including hard copies of slides.

Mark A. McClanahan, MD, F.A.C.E., Diabetes and Thyroid Associates, PC
Practicing endocrinologist from Fredericksburg – declared no formal affiliation with any manufacturer. Also discussed UKPDS showing the importance of glucose control, reduction in beta cell function over time in Type 2 diabetics and improvement in beta cell function over time with use of a "glitazone." Provided packet including hard copies of slides and several studies.

Mark Oley, P&T Committee Member, provided an oral summary of the classes of oral hypoglycemics included in the clinical information prepared for the Committee. He recommend all of the classes of oral hypoglycemcis be considered for inclusion on the PDL – excluding the first generation sulfonylureas which are not used as commonly and are all available as generic products.

Dr. Axelrod provided a brief overall summary of oral hypoglycemics. There are several classes and combinations products available and each class has its own unique properties. The P&T Committee should consider how to best represent these classes, considering duplication within each class and potential for overlap between the classes.

Dr. Tully asked about the prevalence of use for the alpha-glucosidase inhibitors, to assist in determining the necessity of the inclusion of all of the classes/medications. Market share information will be made available for all selected classes before the next meeting. A motion was made to consider all of the classes of oral hypoglycemics (excluding first generation sulfonylureas) as eligible for inclusion on the PDL. This motion was seconded and unanimously approved by the Committee.

ACCEPTANCE OF MINUTES FROM OCTOBER 15TH MEETING

Dr. Axelrod asked if there were any corrections, additions or deletions to the minutes from the October 15th meeting. None were noted and upon request of the Chairman, the Committee voted on a motion and second to approve the minutes of the October 15th meeting as written. The Committee voted unanimously to approve the minutes.

DISCUSSION OF DRAFT PDL CRITERIA FOR THE FIRST 13 CLASSES

Dr. Axelrod noted the general format of the criteria was length of authorization, additional information to aid in the final decision, and any clinical notes. Specific issues discussed:

- Combination products may still require PA even if the individual components do not.
- For patients over age 65, a trial of trazodone (or a contraindication to a trial) will be required for prior authorization of Ambien®.
- Requests for Ambien® for pregnant patients will be allowed - approve the request for the duration of the pregnancy or the duration of the prescription - prior authorization request will be necessary.
- One of the preferred steroid nasal sprays only has an indication down to age 4. Nasonex® is indicated to age 2. Nasonex® is non-preferred, but will not require prior authorization for children under age 4.
- Allowance of alternate PPIs for pediatric patients and patients unable to swallow Protonix® (the preferred PPI). Allowances will be made for these patients (omeprazole for oral or "tubed" patients and Prevacid susp. for oral use).
- Allowance of alternate dosing forms for pediatric patients for the second generation antihistamines. Zyrtec® has indication down to age 6 months and Claritin® for age 2 and older. Zyrtec® will not require prior authorization for children under age 2. Claritin® syrup will not require prior authorization for children under 6 (until a generic syrup is readily available).

A motion was made to accept the criteria with the noted changes. This motion was seconded and unanimously approved by the Committee.

DISCUSSION OF CLINICAL CRITERIA FOR COXII EDIT

Dr. Axelrod noted there have been some recent clinical developments with this class (particularly relating to cardiovascular risk) and requested that the criteria be accepted as presented, with additional consideration, including any new information, to occur at the January meeting. This motion was seconded and unanimously approved by the Committee.

DRUG CLASS DISCUSSIONS (continued)

Leukotriene Modifiers

Allan I. Goldberg, M.D. Executive Medical Director for Merck, Mid-Atlantic Region

Discussed overview of asthma – prevalence, impact on the community, importance of daily controller therapy and access to quick relief therapy. NIH has stated inhaled steroids as the preferred controller therapy; however leukotriene modifiers are listed as an alternative for use as controller therapy. Discussed available dosing formulations and potential uses for Singulair® in asthma therapy.

Mark Oley, P&T Committee Member, provided an oral summary of the leukotriene modifiers included in the clinical information prepared for the Committee. He asked Dr. Goldberg about the use of leukotriene modifiers in allergic rhinitis. Dr. Goldberg stated they had shown statistically and clinically meaningful differences in studies versus placebo in treatment of allergic rhinitis. Dr. Axelrod acknowledged the importance of leukotriene modifiers in the treatment of asthma; however, they do not play as significant a role in the treatment of allergic rhinitis. The Committee will consider this. There was a motion and a second to consider the leukotriene modifiers as PDL eligible. The motion was unanimously approved by the Committee.

Bisphosphonates
Lisa Goetz, Pharm. D. Procter & Gamble Medical Communications was scheduled to present, but was unable to attend. Bruce Freeman presented in her place, and she will forward her slides to the Committee. He discussed reduction in vertebral fractures with Actonel®, speed of action, and GI tolerability (GI tolerability similar to placebo).

Kerry I. Edwards, M.D., F.A.C.P. Senior Medical Director US Medical & Scientific Affairs Merck & Co., Inc.
Fosamax® is indicated in the treatment and prevention of post-menopausal osteoporosis, reduces incidence of hip and spine fractures, and used in the treatment of steroid-induced osteoporosis. Discussed long-term data on fracture reduction (Fracture Intervention Trial with Fosamax®) and incidence of adverse effects similar to placebo (in Phase III trials).

Mark Oley, P&T Committee Member, provided oral summary of the clinical information prepared for the Committee on the bisphosphonates. A motion was made to consider the bisphosphonate class as eligible for inclusion on the PDL. This motion was seconded and unanimously approved by the Committee.

Dr. Axelrod stated he appreciated the interest the pharmaceutical industry has in communicating with the Committee; however, he asked that they do so in the proper format. Emails should not be sent to his business email address. He asked that emails be sent to DMAS or to First Health to his attention. *(DMAS has an email address established to handle issues related to the P&T Committee and the PDL implementation process. All emails should be directed there – pdl.input.dmas.va.state.us)*

NSAIDs
Helena Nunn, MSc, MPH, Regional Medical Scientist, Boehringer/Ingelheim
Mobic® is approved for the treatment of osteoarthritis. She discussed safety profile - no platelet inhibition, no dosage adjustment necessary with renal dysfunction, and lack of a drug interaction with furosemide, does not block platelet inhibition of aspirin. A handout was provided to the Committee.

Allan I. Goldberg, M.D. Executive Medical Director for Merck, Mid-Atlantic Region
He referred to his presentation at a previous meeting. He highlighted the place in therapy for Vioxx® – cited treatment guidelines recommending COXII therapy and discussed safety profile.

Mark Oley, P&T Committee Member, provided an oral summary of the clinical information prepared for the Committee on the NSAID class. He mentioned there were a large number of options available generically in this class. A motion was made to consider the NSAID class as eligible for inclusion on the PDL. This motion was seconded and unanimously approved by the Committee.

Serotonin Receptor Agonists (Triptans)
Thomas Barsanti, M.D., Director, Regional Medical and Research Specialist for Pfizer, Inc.
He discussed receptor binding, onset of action, efficacy, and recurrence rate of headaches with Relpax®. Several studies from peer-reviewed journals were discussed. A detailed handout was provided to the Committee.

Patricia E. Jacob, Pharm.D. Senior Regional Medical Scientist II (Neurology) Clinical Development and Medical Affairs North America GlaxoSmithKline
She discussed issues of pain relief and maintenance of pain relief. She stated Imitrex® tablets have been reformulated for more rapid dissolution and absorption into the blood stream. Tmax is reduced by 15 minutes – the reformulated tablets will be available in January (same patent expiration as current tablets). She discussed efficacy (focusing on the injection and oral). A handout was provided to the Committee.

Mark A. Flanzenbaum, M.D. Chairman and Medical Director Department of Emergency Medicine Bon Secours St. Mary's Hospital
He reported no support from or research funding from pharmaceutical manufacturers. Discussed utility of Imitrex® injection in the Emergency Department to provide rapid release and the flexibility of dosing form for Imitrex® (available as injection, tablet and nasal spray). In response to a question from the Committee, he stated he was not bound by a hospital formulary, he uses Imitrex® because of his experience with its efficacy and the variety of dosage forms available.

Kerry I. Edwards, M.D., F.A.C.P. Senior Medical Director US Medical & Scientific Affairs Merck & Co., Inc.
He discussed prevalence of migraine and recommendation of American Academy of Neurology for the use of migraine specific agents for all patients with moderate to severe symptoms and whose headaches are poorly responsive to other forms of therapy (including NSAIDs). Cited several studies showing efficacy and tolerability of Maxalt®, specifically a large meta-analysis involving all available Triptans (originally published in *Lancet* in 2001 and highlighted in the *NEJM* in 2002 – this reference will be provided to the Committee before the next meeting).

Mark Oley, P&T Committee Member, provided an oral summary of the clinical information prepared for the Committee on the Triptans. A motion was made to consider the class as eligible for inclusion on the PDL. This motion was seconded and unanimously approved by the Committee.

Oral Antifungals (Onychomycosis Agents Only)
No oral presenters for this class. Written comments were submitted and included in the Committee's packets.

Mark Oley, P&T Committee Member, provided an oral summary of the clinical information prepared for the Committee. A motion was made to consider the agents (Lamisil®, Sporanox® and griseofulvin) as eligible for inclusion on the PDL. This motion was seconded and unanimously approved by the Committee.

OPEN ISSUES

Dr. Axelrod asked if there were any open issues. He would like to contact Dr. Allen (MCV Department of Ophthalmology) for his input on the ophthalmology classes.

There will not be a meeting in December.

The next meeting is scheduled for January 6, 2004 at 1:00 PM in the DMAS Board Room.

Chairman Axelrod adjourned the meeting.