Meeting of the
Pharmacy and Therapeutics Committee
October 15, 2003
Minutes
Final

Members Present:
Randy Axelrod, M.D., Chair
Gill Abernathy, M.S., R.Ph.
Arthur Garson, Jr, M.D.
Mariann Johnson, M.D.
Mark Oley, R.Ph.
Mark Szalwinski, Pharm.D.Vice Chair
Christine Tully, M.D.
Renita Warren, PharmD
(via phone) Roy Beveridge, M.D

Absent:
Sue Cantrell, M.D.
Avtar Dhillon, M.D.
James Reinhard, M.D.

A quorum was present

Guests:
Jane Woods, Secretary of Health and Human Resources
44 representatives from pharmaceutical companies, providers, advocates, associations, etc.
Manikoth Kurup, MD, Member, Board of Medical Assistance Services

DMAS Staff:
Patrick Finnerty, Agency Director
Cynthia Jones, Chief Deputy Director
Cheryl Roberts, Deputy Director of Programs and Operations
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:
Cathy England, Director of Clinical Operations
David Adams, Pharm.D., Rebate Support
Carol Perkins, Pharm.D., Clinical Manager
Douglas Lipton, Esq.

WELCOME AND INTRODUCTIONS

Chairman Axelrod called the meeting to order. Eight P&T Committee members were in attendance. Dr. Beveridge participated via phone in the open meeting. The chairman welcomed those in attendance.

COMMENTS FROM PATRICK FINNERTY, DMAS DIRECTOR

Mr. Finnerty noted the sound system would not be operational during the first half of the meeting but would be set up and be operational for the voting and clinical discussions after the confidential meeting concluded.

Dr. Axelrod introduced Virginia's Secretary of Health and Human Resources, the Honorable Jane Woods.

COMMENTS FROM THE SECRETARY OF HEALTH AND HUMAN RESOURCES

The Honorable Jane Woods, Secretary of Health and Human Resources thanked all participants for their help and input during the first stage of this process. She thanked the P&T Committee for their expertise in numerous areas and for accepting the primary charge of contributing to quality and cost-efficient healthcare for Medicaid enrollees. Secretary Woods reiterated from the previous meeting that this endeavor was a Virginia specific program, designed to have the best outcomes for Virginians. She discussed the compressed time frame required to maintain the implementation schedule and the importance of the next deadline – the deadline for contracts from the manufacturers involving the thirteen classes.

Virginia has benefited from the experiences of other plans and the PDL will be implemented in stages. These 13 classes are just the initial stage. Other classes will be phased in over time to prevent overwhelming the community, including the prescribers and providers.

She also thanked the members of the PDL Implementation Advisory Group for their suggestions on communication to and education of the providers and the community.

ACCEPTANCE OF MINUTES FROM SEPTEMBER 3RD MEETING

Dr. Axelrod noted two requests to add information to the minutes of the previous meeting. JoAnn Trainer (from the cardiovascular division of Pfizer) submitted additional information/clarifications regarding her presentation on Norvasc. Dr. Axelrod suggested adding the statement involving outcomes from ALLHAT, "The product was accepted for use in decreasing BP in newly diagnosed DM II patients with cardio problems; it decreased BP across all types of diabetics." However he suggested striking the information regarding specific details of the study because it was not feasible to include such details of all studies presented to the P&T Committee in the minutes and to strike the comment regarding pharmacoeconomic conclusions.

The Chair also noted receipt of letters from nine physicians in support of Celebrex use in African-Americans with osteoarthritis was also submitted.

Upon request of the Chairman, the Committee voted on a motion and second to approve the minutes of the September 3rd meeting with the stated additions. The Committee voted unanimously to approve the minutes as amended.

COMMENTS FROM THE CHAIRPERSON

Dr. Axelrod noted it was now time in the process for the P&T Committee to consider pricing information. The vast majority of the necessary clinical discussion had occurred during the previous meetings as each drug class was presented for consideration.

Dr. Axelrod introduced Paige Fitzgerald, Counsel to the Board, Office of the Attorney General.

COMMENTS FROM PAIGE FITZGERALD, OFFICE OF THE ATTORNEY GENERAL

Paige Fitzgerald stated that under the Virginia Freedom of Information Act, specifically Virginia Code section 2.2-3711, a public body such as the P&T Committee, may go into a closed session for any of the 31 reasons listed in that statute. However, discussion of manufacturer and wholesaler prices is not one of the 31 reasons listed.

She stated the Attorney General strongly supports the principles of open government embodied by the FOIA and believes in the opportunity of the Commonwealth's citizens to witness the operation of government to the fullest extent.

Federal Law 42.U.S.C. section 1396r-8 requires such pricing information to be kept confidential. On this point federal law supercedes the Virginia FOIA. Since this pricing information must be discussed by the P&T Committee as part of its duties as charged by the General Assembly, a confidential meeting must occur pursuant to Federal Law. She cautioned only this confidential information should be discussed.

Vice-Chairman, Mark Szwalinski, made a motion for the P&T Committee to resume the meeting in another room to discuss this confidential information regarding prices charged by the manufacturers and wholesalers of the drugs previously certified in today's and previous meetings. This confidential meeting is authorized by Federal Law that requires this information to be kept confidential. This motion was seconded and unanimously approved by the Committee.
The meeting adjourned to an executive session.

P&T COMMITTEE DISCUSSION

The Committee reconvened and a motion was made that only such matters as were identified in the motion by which the confidential session was convened were heard or discussed in the confidential meeting of the P&T Committee. The motion was seconded and unanimously approved by the Committee.

Dr. Axelrod stated that after clinical efficacy and financial considerations the Committee was going to entertain motions or discussions for each of the therapeutic classes. Dr Beveridge rejoined the meeting via phone.

Dr. Garson gave opening remarks and stated that as a pediatrician, he thought that special consideration should be granted to children under six.

Proton Pump Inhibitors

Dr. Tully requested that clinical allowances be made for pediatric patients and tube-fed patients. Dr. Garson stated that as a pediatrician, he requested general considerations for pediatric patients as the additional classes were discussed. Mark Szwalinski moved that Protonix® be added to the DMAS PDL with appropriate allowances for pediatric and tube-fed patients that may need alternate therapy. This motion was seconded and unanimously approved by the Committee.

HMG-CoA Reductase Inhibitors (Statins)

Mark Oley stated he thought a high potency Statin should be available. Dr. Tully asked for this issue, the differential between a high potency and a low potency and the importance of this, to be reviewed at a future meeting. Mark Szwalinski moved that Advicor®, Altocor®, Lescol®, Lescol XL®, lovastatin, Pravachol®, and Zocor® be added to the DMAS PDL and that the entire class be re-reviewed in the future to evaluate high potency versus low potency and the necessity of a high potency agent. This motion was seconded and unanimously approved by the Committee.

Low Sedating Antihistamines

Dr. Axelrod noted the necessity for the availability of a syrup for pediatric patients. Mark Szwalinski moved that loratadine® and Alavert® be added to the DMAS PDL with appropriate allowances for pediatric and tube-fed patients that may need the syrup. This motion was seconded and unanimously approved by the Committee.

Low Sedating Antihistamines/Decongestants

Mark Szwalinski moved that Claritin-D® (OTC) be added to the DMAS PDL with appropriate allowances for pediatric patients. This motion was seconded and unanimously approved by the Committee.

Inhaled Corticosteroids

Following no additional clinical discussion or issues, Mark Szwalinski moved that Aerobid, Advair Diskus®, Aerobid-M, Azmacort®, Flovent®, QVAR® 80 mcg, QVAR® 40 mcg be added to the DMAS PDL. This motion was seconded and unanimously approved by the Committee.

Sedative Hypnotics

Following no additional clinical discussion or issues, Mark Szwalinski moved that estazolam, flurazepam, temazepam, and triazolam be added to the DMAS PDL. This motion was seconded and unanimously approved by the Committee.

COX II Inhibitors

Dr. Axelrod noted that many issues were discussed during the previous clinical evaluation and presentation of this class, including the potential for drifting on some of the original indications. It was recommended that the entire class be reviewed for prior authorization clinical edits at a future meeting. Mark Szwalinski moved that Vioxx® be added to the DMAS PDL at this time with review at a future meeting to determine if the entire class should be subject to prior authorization. This motion was seconded and unanimously approved by the Committee.

Beta-blockers

Following no additional clinical discussion or issues, Mark Szwalinski moved that acebutolol HCl, atenolol, bisoprolol fumerate, Coreg®, labetalol HCl, metoprolol tartrate, propranolol, timolol maleate, atenolol with chlorthalidone, bisoprolol fumerate/HCTZ, betaxolol HCl be added to the DMAS PDL. This motion was seconded and unanimously approved by the Committee.

Nasal Steroids

Following no additional clinical discussion or issues, Mark Szwalinski moved that Flonase®, Nasarel®, Nasalide®, and flunisolide be added to the DMAS PDL. This motion was seconded and unanimously approved by the Committee.

Angiotensin Receptor Blockers (ARBs)

The issue of doses per day was discussed. Mark Szwalinski noted that all of the medications in this class were once a day, but some are used more than once a day. Mark Szwalinski moved that Benicar®, Diovan®, and Micardis® be added to the DMAS PDL. This motion was seconded and unanimously approved by the Committee.

Angiotensin Receptor Blockers/Diuretics

The issue of doses per day was again discussed. Mark Szwalinski moved that Benicar HCT®, Diovan HCT®, and Micardis HCT® be added to the DMAS PDL. This motion was seconded and unanimously approved by the Committee.

Histamine-2 Receptor Antagonists

Mark Szwalinski moved that ranitidine be added to the DMAS PDL with the syrup available as an alternative for pediatric and tube-fed patients. This motion was seconded and unanimously approved by the Committee.

Beta-Adrenergic Agents - nebs

Following no additional clinical discussion or issues, Mark Szwalinski moved that albuterol sulfate, Accuneb®, Duoneb®, Xopenex® and metaproterenol sulfate be added to the DMAS PDL. This motion was seconded and unanimously approved by the Committee.

Short-Acting Beta-Adrenergics
Following no additional clinical discussion or issues, Mark Szwalinski moved that albuterol, Alupent®, Combivent®, Maxair®, Maxair Autohaler®, Proventil HFA®, and Ventolin HFA® be added to the DMAS PDL. This motion was seconded and unanimously approved by the Committee.

Long-Acting Beta-Adrenergics
Following no additional clinical discussion or issues, Mark Szwalinski moved that Foradil® and Serevent Diskus® be added to the DMAS PDL. This motion was seconded and unanimously approved by the Committee.

Non-Dihydropyridine Calcium Channel Blockers
Following no additional clinical discussion or issues, Mark Szwalinski moved that diltiazem and verapamil be added to the DMAS PDL. This motion was seconded and unanimously approved by the Committee.

ACE Inhibitors
Following no additional clinical discussion or issues, Mark Szwalinski moved that captopril, enalapril, and lisinopril be added to the DMAS PDL. This motion was seconded and unanimously approved by the Committee.

ACE Inhibitors/Diuretics
Following no additional clinical discussion or issues, Mark Szwalinski moved that captopril/HCTZ, enalapril/HCTZ, and lisinopril/HCTZ be added to the DMAS PDL. This motion was seconded and unanimously approved by the Committee.

ACE Inhibitor/Calcium Channel Blocker Combinations
Following no additional clinical discussion or issues, Mark Szwalinski moved that Lotrel® be added to the DMAS PDL. This motion was seconded and unanimously approved by the Committee.

Dihydropyridine Calcium Channel Blockers
Following no additional clinical discussion or issues, Mark Szwalinski moved that Dynacirc®, Dynacirc CR, ® nicardipine HCl, Nifedical XL®, nifedipine ER, nifedipine I.R., nifedipine tablet SA, Norvasc®, Plendil, ® and Sular® be added to the DMAS PDL with a re-review in three months after further consideration of the pricing profile. This motion was seconded and unanimously approved by the Committee.

OPEN ISSUES

Dr. Garson had to leave the meeting at this time.

Dr. Axelrod asked if there were any open issues. He thanked the Committee members on behalf of Secretary Woods and DMAS.

The next meeting is scheduled for November 11th at 1:30 PM in the DMAS Board Room. The objectives of the meeting will be consideration of additional drug classes for inclusion in the PDL, determination of the clinical criteria for the classes in the first phase of the PDL, and consider the option of clinical edits and the potential applications to the drug classes that have been selected.

There will not be a meeting in December.

Chairman Axelrod adjourned the meeting.