Meeting of the
Pharmacy and Therapeutics Committee
January 6, 2004
Minutes
Final

Members Present:
Randy Axelrod, M.D., Chair
Gill Abernathy, M.S., R.Ph.
Roy Beveridge, M.D
Sue Cantrell, M.D.
Tim Garson, M.D.
Mariann Johnson, M.D.
James Reinhard, M.D.
Mark Szalwinski, Pharm.D. - Vice Chair
Christine Tully, M.D.
Renita Warren, Pharm.D.

Absent:
Avtar Dhillon, M.D.
Mark Oley, R.Ph.

A quorum was present

Guests:
Jane Woods, Secretary of Health and Human Resources
27 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
Adrienne Fegans, Program Operations Administrator
Javier Menendez, Pharmacy Manager

First Health Staff:
David Adams, Pharm.D., Rebate Support
Douglas Lipton, Esq.
Carol Perkins, Pharm.D., Clinical Manager
Debbie Stephens, R.Ph., Implementation Project Manager

WELCOME AND INTRODUCTIONS

Dr. Axelrod called the meeting to order. Nine P&T Committee members were in attendance at this time.

COMMENTS FROM PATRICK FINNERTY, DMAS DIRECTOR

Mr. Finnerty welcomed those in attendance. He stated the PDL program "went live" yesterday with the implementation of "soft edits" for the first thirteen classes of medications. He informed those in attendance that copies of the phase in schedule for hard edits were available by the door. He thanked those pharmacies that participated in the beta site testing. He noted the criteria and the PDL Quick List were available on the DMAS and First Health web sites and as information is finalized it will be included on these sites (www.dmas.virginia.gov and virginia.fhsc.com). Regional training for pharmacy providers has been scheduled for this week and sessions for various groups are ongoing through February.

He thanked the P&T Committee members for their clinical expertise and time as well as First Health, the pharmaceutical manufacturers, providers, and advocacy groups for their work and input – truly making this a collaborative effort.

ACCEPTANCE OF MINUTES FROM NOVEMBER 11, 2003 MEETING

Dr. Axelrod asked if there were any corrections, additions or deletions to the minutes from the November 11th meeting. None were noted and upon request of the Chairman, the Committee voted on a motion and second to approve the minutes of the November 11th meeting as written. The Committee voted unanimously to approve the minutes as drafted.

COMMENTS FROM RANDY AXELROD, COMMITTEE CHAIR

Dr. Axelrod thanked those interested parties for returning to discuss the ophthalmic classes. These products had been slated for discussion at the last meeting; however this discussion had been postponed pending additional clinical input from ophthalmologists.

DRUG CLASS DISCUSSIONS

Joel Fain, Ph.D., Senior Manager, Regional Medical and Research Specialist for Pfizer, Inc.
Xalatan® is indicated for the treatment of increased intraocular pressure resulting from glaucoma or ocular hypertension. Xalatan®, Travatan® and Lumigan® have similar efficacy, on average lowering IOP by 6-8 mm Hg. He noted Xalatan® is administered once daily and per published prescribing information the incidence of hyperemia was lower with Xalatan®. He also discussed issues of compliance and patient persistence. Copies of the slides were provided in each Committee member's packet.

Mark Szalwinski, Vice-Chair, provided an oral summary of the four ophthalmic classes included in the clinical information prepared for the Committee. Dr. Tully arrived – ten members in attendance.

Carbonic Anhydrase Inhibitors – topical agents

There are two agents available, Azopt® and Trusopt®. Both have similar efficacy, however Trusopt has a slightly lower pH leading to a slightly higher incidence of irritability to the eye. This class of agents is less potent than the other classes reviewed in its ability to lower IOP. One combination product of a carbonic anhydrase inhibitor and a beta-blocker is available, Cosopt®. Based on input from ophthalmologists, this would not be a first line option. Rather than using a less potent agent in a combination product, a more potent agent would be preferred first line.

Alpha-2 Agonists

There are three available agents, Iodipine®, Alphagan® (available generically) and Alphagan P®. Alphagan P® is a reformulated version of Alphagan®, with a better tolerability profile and comparable efficacy.

Beta-blockers

There are four non-selective beta-blockers – timolol, carteolol, levobunolol, and mitipranolol. All four products are available generically. Timoptic XE is available as a gel, which results in greater contact time and greater therapeutic action. Since they are non-selective, these agents may be contraindicated in some patients (ex. some cardiac or asthma patients). Betaxolol is a beta-1 selective agent that is available as a generic (0.5%) and Betopic S® (0.25% and brand only). One of the ophthalmologists consulted felt if a patient had a contraindication to a non-selective beta-blocker, they would also avoid the use of a beta-1 selective agent. They did not see a large need for this agent when there are multiple other effective agents available.

Prostaglandin Agonists

Four agents are available, Xalatan®, Lumigan®, Travatan® and Rescula®. Rescula® has not been shown to have comparable efficacy to the other three agents. The other agents have similar efficacy. Xalatan® was the first available agent and has the largest percent of the market share. There were initial reports of increased efficacy of Travatan® in the African-American population. This has not been reproduced in a large-scale trial. One of the ophthalmologists consulted felt there was some validity to this concern. One or two studies have shown Lumigan® to have greater

efficacy than Xalatan®. However, this is an emerging issue. It has been established that Lumigan® and Travatan® have a higher incidence of hyperemia, but the clinical significance of this unknown.

The oral agents for glaucoma and the older topical agents such as pilocarpine that are available generically will still be available. He recommended all of the ophthalmic classes presented be considered for inclusion on the PDL. A motion was made to consider these classes as eligible for inclusion on the PDL. This motion was seconded and unanimously approved by the Committee.

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 Szalwinski, 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 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 to expedite the meeting, he would read the class and the medications that will be preferred on the PDL. This will set the motion for each of the classes and the motion will be seconded and any additional clinical discussion can occur and then the Committee will vote on each of the classes.

Second Generation Sulfonylureas

Dr. Axelrod moved that glyburide, glipizide, glyburide micronized and glipizide ER be added to the DMAS PDL. This motion was seconded and unanimously approved by the Committee.

Alpha-glucosidase Inhibitors

Dr. Axelrod moved that Precose® and Glyset® be added to the DMAS PDL. This motion was seconded and unanimously approved by the Committee.

Analgesics – NSAIDS

Dr. Axelrod moved that ibuprofen, naproxen, nabumetone, Mobic®, diclofenac sodium, naproxen sodium, indomethacin, indomethacin SA, etodolac, sulindac, oxaprozin, ketorolac tromethamine, piroxicam, diclofenac potassium, diflunisal, ketoprofen, ketoprofen 24HR, flurbiprofen, tolmetin sodium, fenoprofen calcium and meclofenamate sodium be added to the DMAS PDL. This motion was seconded and unanimously approved by the Committee.

Biguanides

Dr. Axelrod moved that metformin and metformin ER be added to the DMAS PDL. This motion was seconded and unanimously approved by the Committee.

Biguanide Combinations

Dr. Axelrod moved that Avandamet®, Glucovance® and Metaglip® be added to the DMAS PDL. This motion was seconded and unanimously approved by the Committee.

Bone Ossification Suppression Agents

Dr. Axelrod moved that Actonel® be added to the DMAS PDL. This motion was seconded and unanimously approved by the Committee.

Leukotriene Modifiers

Dr. Axelrod moved that Accolate® and Singulair® be added to the DMAS PDL. This motion was seconded and unanimously approved by the Committee.

Meglitinides

Dr. Axelrod moved that Starlix® be added to the DMAS PDL. This motion was seconded and unanimously approved by the Committee.

Oral Antifungals (Onycomycosis Agents Only)

Dr. Axelrod moved that Lamisil ®be added to the DMAS PDL. This motion was seconded and unanimously approved by the Committee.

Serotonin Receptor Agonists (Triptans)

Dr. Axelrod moved that Imitrex® (all currently available formulations) and Maxalt® (all currently available formulations) be added to the DMAS PDL. This motion was seconded and unanimously approved by the Committee.

Thiazolidinediones

Dr. Axelrod moved that Actos® and Avandia® be added to the DMAS PDL. This motion was seconded and unanimously approved by the Committee.

OPEN ISSUES

The next meeting is scheduled for February 9th at 9:00 AM in the DMAS Board Room. The remaining medications for July implementation will be discussed at this meeting – Long-acting Narcotics, medications for ADD/ADHD, Macrolides, second and third generation quinolones, second and third generation cephalosporins.

There was a general discussion regarding how to handle reviews of new medications in classes included in the VA PDL. There will be a mechanism for "break through" products to have an expedited review. Other products will be evaluated at future P&T meetings on a scheduled basis. The Committee will review appropriate studies and publications as part of the decision process. In addition the Committee will be provided with information such as disease categories and demographics on the affected Medicaid population in order to assess the potential impact on the population. The Committee approved the process with the additional language. This process will be posted to the DMAS website.

Chairman Axelrod adjourned the meeting.