Meeting of the
Pharmacy and Therapeutics Committee
February 9, 2004
Minutes
Final

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

Sue Cantrell, M.D.
Avtar Dhillon, M.D.
Mariann Johnson, M.D.
Mark Oley, R.Ph.
James Reinhard, M.D.
Mark Szalwinski, Pharm.D. - Vice Chair
Christine Tully, M.D.
Renita Warren, Pharm.D.

Via phone:
Roy Beveridge, M.D

Absent:
Tim Garson, M.D.

A quorum was present

Guests:
Jane Woods, Secretary of Health and Human Resources
58 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
Bryan Tomlinson, Director Division of Health Care Services
Katina Goodwyn

First Health Staff:
Carol Perkins, Pharm.D., Clinical Manager

WELCOME AND INTRODUCTIONS

Dr. Axelrod called the meeting to order. Ten P&T Committee members were in attendance, Dr. Beveridge participated via conference call.

COMMENTS FROM PATRICK FINNERTY, DMAS DIRECTOR

Mr. Finnerty welcomed those in attendance. He stated soft edits had started with the first thirteen classes on January 5th and hard edits were being added a few classes each week. The implementation is going very smoothly thanks to the work of the P&T Committee and the staffs of DMAS and First Health. He also recognized the contributions of Becky Snead and the Virginia Pharmacists Association, Dr. Christine Tully, John Pezzoli and Hill Hopper for their active involvement in the PDL training sessions to providers. Thanks also to Jill Hanken for her work on recipient information He thanked the P&T Committee members for their continued efforts.

COMMENTS FROM THE SECRETARY OF HEALTH AND HUMAN RESOURCES

Secretary Woods thanked the Committee for their expertise and their willingness to share their knowledge and experience. This has reaffirmed that at every step of the process clinical efficacy came first and price is always the last consideration. The clinical decision will always override the price. We are open to clinical discussion as illustrated today with over 23 speakers and numerous written submissions from the manufacturers and the physician community.

The P&T Committee had recommended a phased in roll out. This had concerned some of the people at the State due to the potential impact on early savings. It is important to note that the state held to the recommendation of the Committee and their clinical expertise. Clinical efficacy has been and will continue to be the guiding principle as each class of medications is examined and either included or not included on the PDL.

The Committee members also have contributed the experience of their practices as they have daily involvement with Virginians in their practices. Dr. Beveridge is a member of the National Patient Advocacy Program and has brought this piece to the discussion as well.

Secretary Woods also thanked the PDL Implementation Advisory Group in developing materials and facilitating input from manufacturers, pharmacists, physicians and advocates. Their recommendations have been included in the implementation of the program. This has allowed us to be at this point today. The first thirteen classes have been implemented in a way that could ensure that people's needs were being met both on the provider side and the patient side, as well as still meeting the mandate of the General Assembly.

ACCEPTANCE OF MINUTES FROM JANUARY 6, 2004 MEETING

Dr. Axelrod asked if there were any corrections, additions or deletions to the minutes from the January 6th meeting. None were noted and upon request of the Chairman, the Committee voted on a motion and a second to approve the minutes of the January 6th meeting as written. The Committee voted unanimously to approve the minutes as drafted.

COMMENTS FROM RANDY AXELROD, COMMITTEE CHAIR

Dr. Axelrod stated the COX2 inhibitors and the criteria would be included in today's meeting. This class, the differences within the class and potential complications, warranted more time and discussion. Dr. Axelrod called for a confidential meeting to discuss pricing related to the COX 2 drugs.

COX2 INHIBITOR CLINICAL DISCUSSION

Daniel Paulson, M.D., Chief, Group Practice A; Medical Director, Group Practice Research, VAMC, Richmond, Virginia

Dr. Paulson stated he was a paid consultant for Novartis, Aventis and Pfizer and over the past three years he has been involved with research examining the COX2 inhibitors and cardiovascular side effects. He provided a handout to the Committee. He acknowledged similar efficacy in pain control with the COX2 inhibitors and a more favorable GI side effect profile when compared to traditional NSAIDS. He discussed the CLASS, VIGOR, SUCCESS-6, SUCCESS-7, and CRESCENT trials. He believes the compounds are different in their pharmacologic properties. The sulfonamide COX2 inhibitors (valdecoxib and celecoxib) have weak carbonic anhydrase inhibition that would produce a mild diuretic effect. It is his belief that this is the reason for any observed differences in cardiovascular risk profiles for the agents.

Dr. Axelrod observed that these studies had six to twelve week end points and wondered if the observations would be consistent over a longer period of time. Dr. Paulson discussed a therapeutic interchange at the VAMC involving a switch from celecoxib to rofecoxib. This followed patients over a one-year period and he received the first set of data three weeks ago. Mark Szalwinski asked about the use of a COX2 agent versus a traditional NSAID plus a cytoprotective agent. Dr. Paulson stated he did not think the cardiovascular issues were a class effect – that the agents differed in their cardiovascular risks. He acknowledged the need for long-term safety outcome trials; currently the data available are from short-term trials looking at surrogate markers (ex. hypertension, edema).

Mark Szalwinski, Vice-Chair, provided a brief oral summary. He highlighted that there are no differences in efficacy among the COX2 inhibitors or between the COX2 inhibitors and traditional

NSAIDs. There are two large trials demonstrating a beneficial GI profile for valdecoxib and celecoxib – VIGOR (valdecoxib) and CLASS (celecoxib). In the VIGOR trial the comparator agent was Naprosyn. The comparator agents for CLASS were ibuprofen and diclofenac and patients were allowed to use aspirin in this trial. There is a need for data from long-term trials to establish a definitive answer for the cardiovascular risk profiles of the COX2 inhibitors.

Dr. Axelrod explained there would be vote to reaffirm that the COX2 class remain PDL eligible and this class will continue to be followed closely until the clinical issues involving cardiac risk are resolved. The issue of a clinical edit or step therapy was discussed. This would require treatment failure(s) or a clinical contraindication to the NSAID class before a COX2 is used. Dr. Tully felt that cost savings would have to be significant enough to warrant the potential disruption to the community. Dr. Axelrod relayed that in his experience this was a worthwhile edit – but allowed that his experience was with a large commercial company, not a Medicaid population.

A motion was made for the COX2 class to remain PDL eligible and be subject to a clinical edit/step therapy. This motion was seconded and unanimously approved by the Committee. The COX2 PDL edit will still be implemented as planned on February 23rd. Dr. Axelrod asked staff of DMAS and FHSC to work on the process to operationalize the edit/step therapy.

DISCUSSION OF DRAFT PDL CRITEIRA FOR SECOND PHASE (APRIL) IMPLEMENTATION

Dr. Axelrod briefly reviewed the criteria for the NSAIDs, oral antifungals for onychomycosis, bisphosphonates for osteoporosis, the "triptans," leukotriene receptor modifiers, and the oral hypoglycemics. A motion was made to approve the criteria for all of the classes included as presented. This motion was seconded and unanimously approved by the Committee.

DRUG CLASS DISCUSSIONS

Long-acting Narcotics

Hassan Sabbah, Pharm. D., Manager, Regional Medical Services, Janssen Pharmaceuticals

He discussed Duragesic® and its unique transdermal delivery system with up to a 72 hour dosing interval. It has a slower onset that avoids the "rush" effect that can contribute to increase potential for abuse. The transdermal route of delivery can minimize some of the GI side effects (including constipation) observed with other long-acting opiods. Dr. Axelrod asked about other uses and it was clarified that this medication is recommended for use in chronic pain, not post-operative pain.

Leo Sullivan, D.Ph., Organon Pharmaceuticals (Former Pharmacy Director of Tennessee Medicaid – Tenncare)

He discussed his experience with long-acting narcotics as Director of the Tennessee Medicaid program (slides provided in packet). Avinza® was the preferred agent in the Tenncare program. He discussed their process for reaching this conclusion and potential for savings. Dr. Axelrod also clarified Avinza® was recommended for chronic (not acute) use – he felt this was an important issue to discuss with all agents in this class.

Matthew Gainey, Pharm.D., Medical Liaison,Purdue Pharma L.P.

Discussed OxyContin® (an extended release form of oxycodone), indicated in moderate to severe pain when continuous relief is needed for an extended period of time. He provided a handout to the Committee. It is not recommended for "as needed" dosing. He stated onset of relief is usually within one hour and usually dosing is once every twelve hours. Dr. Axelrod asked about the warning for the 80 mg tablets – that they should only be used in opiod-tolerant patients. Dr. Gainey explained there are studies evaluating the 10 mg dose in opiod naïve patients, but the higher strengths (as for the other agents) should be used after dose titration.

Patrick J. Coyne, MSN, APRN, BC-PCM, Clinical Director, Thomas Palliative Care Unit and the Massey Cancer Pain Center
Declared he was speaking on behalf of the Virginia Cancer Pain initiative, to request none of the agents be restricted by prior authorization. He discussed there are multiple barriers to effective pain management, the variability of patient response to a particular opiod and acknowledged the issue of preventing abuse. He did not want a new barrier to be placed before the patients with chronic pain.

Dr. Beveridge stated he, as well as other members of the Committee, were committed to ensure that all patients are under good pain control and want to implement this initiative correctly.

Mark Oley, P&T Committee member, provided an oral summary of the clinical information prepared for the Committee on the long-acting narcotics. He highlighted the differences in dosage forms, routes of administration and dosing intervals. There was a general discussion about issues surrounding limiting access to these medications. Dr. Tully discussed her experience at the VAMC with a restricted formulary. She reminded everyone that if the preferred medication is not effective for a patient, the other medications are available via a PA request. Dr. Beveridge also discussed the need for a diverse selection and that the Committee should also consider that many physicians become comfortable with a certain set of medications and become familiar with the therapeutic index of those medications.

A motion was made to consider the long-acting narcotics as eligible for inclusion in the PDL. This motion was seconded and unanimously approved by the Committee.

ADD/ADHD Medications/CNS Stimulants
Shilpa Ekbote, PharmD, Outcomes Liaison, US Medical Division, Eli Lilly and Company
Discussed Stratterra® – it is not a stimulant, not a controlled substance and no evidence of abuse potential. It is selective for norepinephrine and can be used in some patients that have conditions that would contraindicate the use of a stimulant (including anxiety and tics). Unlike stimulants, somnolence can occur as an adverse effect.

Martin Buxton, M.D., FAPA, FAACP, VCU/MCV Clinical Professor of Psychiatry, Medical Director of Child and Adolescent Psychiatry for Tuckers Pavilion and Poplar Springs Hospital's Daybreak Program, President of Insight Physicians, P.C.
He discussed Strattera® and that this medication is longer acting, so it avoids the stigma associated with mid-day dosing at school. He recommends dosing seven days a week, not giving "drug holidays" on the weekends that some parents do with stimulants. During the drug holidays the ADHD behaviors recur and can result in frequent redirection that can negatively affect the child's self-esteem. If somnolence is a problem he recommends dosing at night. Monitoring of growth is recommended for children on Strattera® (also recommended with the stimulants).

John Pellock, M.D., Chair, VCU/MCV Division of Child Neurology
Discussed Strattera® – focusing on lack of addiction potential, mechanism of action allowing use in children with motor abnormalities (specifically tics) and the ability to include refills on prescriptions.

Scott Chappell, Pharm.D., Neuro-Science Scientific Operations, Novartis
He discussed Ritalin LA® and Focalin® – focusing on Ritalin LA®. Focalin® is the more active enantiomer of methylphenidate. Ritalin LA® is a controlled release form of methylphenidate (the medication with the most experience treating ADHD). The capsule can be swallowed whole or opened and administered on applesauce and still administered once daily.

Cheryl Almateen, VCU Child and Adolescent Psychology. Discussed efficacy of medication management of ADHD and the superiority to behavioral management. Practice guidelines recommend stimulants as first line therapy for ADHD. Focused on Concerta® and benefit of once daily dosing. Concerta® avoids mid-day dosing and all of the issues associated with this and avoids the peak to trough fluctuations (and the accompanying rebound of systems) seen with three times a day dosing of the regular release. Concerta® has a portion of the dose that is released as an immediate release with the remainder as controlled release.

Mark Oley, P&T Committee member, provided an oral summary of the clinical information prepared for the Committee on this class. He highlighted the differences in dosage forms, dosing intervals and unique adverse effects and indications. A motion was made to consider the class as eligible for inclusion in the PDL. This motion was seconded and unanimously approved by the Committee.

Macrolides

Dennis Pontani, M.S., Ph.D., Regional Medical Director ID/Pulmonary, Pfizer, Inc.
He discussed unique features of Azithromycin – indications, Category B for pregnancy and lack of cytochrome p450 interactions. Based on its pharmacokinetics it can be administered once daily and for shortened durations.

Arlene Price, Pharm.D., National Clinical Executive, Abbott Laboratories
She reviewed Biaxin® and Omnicef® (see below). She discussed indications, spectrum of activity and issues of bacterial resistance. Several practice guidelines recommend Biaxin® as a first line agent in treatment of outpatient community acquired pneumonia.

Daniel Bechard, MD, FCCP, McGuire VA Medical Center
He requested that issues of antibiotic resistance be considered in the selection of agents for inclusion on the PDL. He reviewed several clinical trials – handouts were provided to the Committee. Also brought up the cost of antibiotics and considering the other associated costs – time between exacerbations, monitoring for potential drug interactions, etc.

Quinolones

Randy Pryka, PharmD, Clinical Science Specialist, Bayer Pharmaceuticals
He discussed Avelox® and Cipro XR®. For Avelox, he focused on indications and efficacy, specifically community acquired pneumonia and acute exacerbations of chronic bronchitis. Cipro XR® is 500 mg indicated for treatment of acute uncomplicated cystitis and he cited growing resistance to Bactrim® formulations. Cipro XR® 1000 mg is indicated for treatment of complicated urinary tract infections and acute, uncomplicated polynephritis. Written information was provided in the packets. There have been drug interactions involving the cytochrome p450 system with ciprofloxacin, but not with Avelox®.

Patricia Colaizzi Cosler, Pharm.D., Anti-Infectives Scientific Liaison, Clinical Communications Department, Ortho-McNeil Pharmaceutical, Inc.
She discussed levofloxacin indications, efficacy, and safety record – new indication for short course, high dose treatment of community-acquired pneumonia. A handout was provided to the Committee. In response to a question from the Committee, she stated there were no increases in adverse reactions with the high dose-short course regimen.

Cephalosporins
Arlene Price, Pharm.D., National Clinical Executive, Abbott Laboratories
(Presented as part of Macrolide presentation).
Omnicef® recommended by several practice guidelines for the treatment of otitis media and sinusitis. Children prefer the taste to several other common antibiotic suspensions. Dosed once daily and can be used as a five day or a ten day regimen.

Matthew Gainey, Pharm.D., Medical Liaison,Purdue Pharma L.P.
He discussed Spectracef® tablets. Indicated in children over age 12 and adults for the treatment of acute exacerbations of chronic bronchitis, community acquired pneumonia, pharyngitis and uncomplicated skin and skin-structure infections. It is contraindicated in patients with milk-protein sensitivity. This medication was just release by Purdue Pharma in October 2003.

Gill Abernathy, P&T Committee member, provided an oral summary of the clinical information prepared for the Committee on the antibiotic classes reviewed. She highlighted the differences in indications, drug interactions, contraindications and adverse effects. She recommended pediatric considerations and considerations for unique indications be made where clinically indicated. The cephalosporins will be considered as a group, including both second and third generation agents. Motions were made to consider the classes as eligible for inclusion in the PDL. The motions were seconded and unanimously approved by the Committee.

Due to the length of the Committee meeting and the time, Dr. Axelrod cancelled the previously called for confidential meeting.

OPEN ISSUES
The next meeting is scheduled for April 21st at 1:00 PM in the DMAS Board Room. This will include discussions of the COX2 clinical criteria and the individual agents in the classes reviewed today will be determined preferred or non-preferred.

As an open issue, Dr. Axelrod discussed the antidepressants and said this will be considered by the General Assembly and further consideration on this class by the Committee will occur after the end of the legislative session.

Chairman Axelrod adjourned the meeting.