Nevada Medicaid
Pharmacy & Therapeutics Committee Meeting

Location of Meeting
401 South Carson Street, Room 2135, Carson City, NV

Teleconference
555 E. Washington, Room 4406 Las Vegas, NV

MINUTES OF
February 26th, 2004
1:00 p.m.

Committee Members Present:
Reno
Steven Phillips, MD, Chairman
Diana Bond, RPh
Judy Britt, PharmD
Linda Flynn, RPh
Alan Greenberg, MD
Carl Heard, MD
Robert Horne, MD
Susan Pintar, MD
Thomas Wiser, PharmD

Committee Members Absent:
Larry Pinson, PharmD

Others Present:
Chuck Duarte, Administrator, DHFCP
Darrell Faircloth, AGO
Laurie Buck, AGO
Coleen Lawrence, DHFCP
John Liveratti, DHCFP
Chris Apple, DHCFP
Nancy Davis, DHCFP
Ritz Owen, DHCFP
Anita Sheard, DHCFP
Jeff Monaghan, FHSC
Rita Marcoux, FHSC
Kenneth Kolb, FHSC
Dawn Daly, FHSC
Jamie Wyels, FHSC
Joseph Tyler, Advisory Committee
Paul Gowin, Advisory Committee
Terrie Livingston, Novartis
Jim Morgan, Novartis
Joann Phillips
Alan Sloan, Purdue
K. Hollingsworth, Takeda
Mary Staples, NACDS
Tracy Davies, Eli Lilly
Elizabeth MacMenamin, RAN
Ellen McCormick, Astra Zenecca
Jeanette Belz, Astra Zenecca, Nevada Psychiatric Assn.
Charlie S., Novartis
Eric Byrnes, Alcon
Bert Jones, GSK
Tom Wood, Wyeth
Steve Schaerrer, Astra Zenecca
Carl Usry, Astra Zenecca
Kevin Mills, Astra Zenecca
Karen Campbell, P&G
Laurie Buck, AGO
Craig Jermon, Wyeth
Angela Horn, Sankyo Pharma
Virginia Bose, Sepraeov
Jake Mater, Aventis
Kara Smith, Boehringer Ingleheim

Others Present (continued):

Las Vegas Attendees

Coleen Fong, BMS
Todd Pinkney, BMS
Serge Brunet, Merck
Gus Boesch, Biovail
Paul Pereiaa, Tap
Dennis Ryan, Pfizer
Robert Popevian, Pfizer
Edgar Gonzalez
Nancy Moredock, Merck
Trisha Geonetta, Resource
Harry Riceberg, Resource
Sedrick Spencer, Roche
Debbie Kapsar, Merck
June Oliver, Nevada Care
Carla Sloan, AARP
Barbara Tagge, CCSS

I. CALL TO ORDER AND ROLL CALL

Steven Phillips, Chairman introduced himself and called the meeting to order. He welcomed everyone to the meeting. He then introduced Charles Duarte, Administrator, DHCFP.

II. & III. WELCOME AND INTRODUCTIONS

Chuck Duarte welcomed everyone and introduced his staff. In an attempt to address the rapid rise in Medicaid drug expenditures, AB 384 was passed in the 2003 legislature. AB 384 requires the formation of a Preferred Drug List (PDL) along with criteria for management of the PDL. AB 384 requires this task to be done through the formation of a Pharmacy & Therapeutics Committee (P&T) along with an Advisory Committee. The P&T committee's task is to determine therapeutically equivalent drugs within certain drug classes without considering cost. AB384 also states that specific drug classes are exempt from this process.

At this time introduction of the P&T and Advisory committee members was done.

Jeff Monaghan, Account/Clinical Manager, explained First Health Services Corporation's (FHSC) role as the fiscal agent for the state. In addition to being the fiscal agent, FHSC has a contract with the state for Prescription Drug Management services. FHSC will assist the committee and the state in the implementation of the PDL, provider education, prior authorization, clinical edits and supplemental rebates. He stated the goal of FHSC is to assist the state in managing prescriptions expenses while providing positive clinical outcomes. He then introduced the FHSC staff.

IV. Discussion of Open Meeting Law

Darrell Faircloth, DAG, explained the Nevada open meeting law. He stated this law applies to the P&T Committee. Any action items must be indicated as such on the agenda for action to be taken. If a closed session is deemed necessary by the chair, he requested advance notice in order to determine the necessity of the closed session.

V. Discussion of Confidentiality and Conflict of Interest Statement

Laurie Buck, DAG, explained the confidentiality and conflict of interest statement. She also explained that any proprietary information supplied by FHSC is to remain confidential and to be given back to FHSC at the end of the meeting. She had no questions from the committee.

VI. Discussion of Regulatory Authority

John Liveratti, Chief of Compliance, DHCFP, addressed regulatory issues which pertain to the P&T Committee. P&T committee operational regulations can be found in Medicaid chapter 200. AB 384 is now found in NRS 422.401 to 422.406.

Chapter 200 discusses all committees and boards within DHCFP. Committees will be taking individual action to adopt their respective bylaws. Once approved, bylaws can be changed by the committee through the process outlined in the regulations.

VII. Approval of Bylaws

No discussion.

Motion to approve.
Seconded.
Ayes: Unanimous

VIII. Operational Overview of process to Create the Preferred Drug List (PDL)

Jeff Monaghan, FHSC, presented an overview of the PDL process. The committee must first approve the individual drug classes for review. Next the committee will be reviewing the drugs within those categories looking at safety and efficacy. AB 384 does not allow the committee to consider cost. The public will be allowed to comment on the drug classes and FHSC will give a high level drug review summary. Ultimately, the committee will apply their clinical skills, experience, and judgement in making their decisions. After review and discussion, the drugs being considered will most likely fall into 3 categories: 1) Must have 2) Not necessary, or 3) therapeutically equivalent or interchangeable. It is likely most of the drugs will fall into this latter category. The committee will then formally act to determine equivalency. The state will then take this decision and assess the choices to determine which choices would provide the most cost savings to the state. The state will then recommend to the committee which drugs they would like to see included on the PDL. The committee will then take action on the recommendation. Once again, the committee is the decision- making body. Drugs not given preferred status will still be available. This will occur through a prior authorization process. Sample PDL exception criteria were referred to (available in members' binders and also to the public).

IX. Approval of monthly schedule of the Drug Classes to be reviewed.

It was decided to go through each class month by month. Schedule available on FHSC website http://nevada.fhsc.com (Pharmacy tab)

February 26, 2004 classes
Motion to approve
Motion seconded.
Ayes: Unanimous

March 25th, 2004 Classes
Motion to approve
Motion seconded
Ayes: Unanimous

April 22nd, 2004 Classes
Motion to approve
Motion seconded
Ayes: Unanimous

May 27th 2004 Classes
Motion to approve
Motion seconded
Ayes: Unanimous

June 24th classes to June 17th, 2004
Motioned to approve
Motion seconded.
Ayes: Unanimous

Dr. Carl Heard asked how the classes were determined.

Jeff Monaghan. FHSC, responded- Based to a large degree on dollars being spent, drug classes with a fairly large pool of interchangeable drugs, and a proven track record of applicable clinical edits.

X. Public Comment on Drug Classes to be Reviewed in February 2004

Dr Phillips stated they will take public comment in order. First class for comment Angiotensin Converting Enzyme Inhibitors (ACEI's) and combinations.

Edgar Gonzalez, PharmD, FASCP, FASHP from Las Vegas. Read a letter and referred to Hope trial and ramipril.

Terry Livingston, Regional Scientific Director, Novartis Pharmaceuticals.
Provided clinical overview of Lotrel.

Tom Wood, Wyeth Pharmaceuticals. He reminded the committee of AB384 and it's exclusion of antidiabetic medications. He asked the committee, after hearing Dr. Gonzalez's testimony, to consider ramipril an antidiabetic agent..

Public comment completed

XI. Presentation of ACEI's-First Health Services

Ken Kolb, PharmD. He gave a high level summary for all reviews. Ten ACEI'S are available, all with indications for hypertension. Seven are FDA approved for heart failure. Studies show there is not a statistical difference in terms of effect among the ACEI's. Data shows that a decrease in morbidity of patients with heart failure is a class effect. ACEI's in the treatment of diabetic nephropathy is a class effect as stated by the American Diabetic Association (ADA). In January 2004 ADA specified 2 benefits of ACEI's: 1) Hypertensive Type 1 diabetic patient with albuminuria, ACEI's delayed the progression of kidney damage., 2) Hypertensive patients with Type 2 diabetes with microalbuminuria, ACEI's delayed the progression of kidney damage. The HOPE trial showed ACEI's reduced MI, stroke and death from CV accidents, but only ramipril was studied. All ACEI's may be dosed once a day with the exception of captopril. Contraindications are similar for the entire class.

Committee member asked Dr. Kolb to repeat the drugs to be used in kidney failure and renal failure. Dr. Kolb responded lisinopril is the drug of choice in hepatic disease and fosinopril is the drug of choice in kidney failure since it has a dual route of elimination.

No further questions.

Dr. Kolb moved on to the ACE combinations. Fixed combinations are not usually indicated in the initial treatment, since they are fixed combinations. All of these agents have the same indications and effects as their individual agents.

No further questions.

Jeff Monaghan distributed a letter to the committee from Dr. Lardinois.

XII. Dr. Phillips opened up the committee discussion with a letter from Larry Pinson, committee member. The letter stated he felt there was interchangeability among the class with the exception of ramipril due to the HOPE trial. Paul Gowin asked the chairman if the use of ACEI's was the major use of this type of drug in diabetics. Chairman responded no. Judy Britt asked at what point would we set exclusion criteria if they deemed this class as interchangeable. Dr. Kolb stated this would be done after the preferred drugs were determined. Dr. Phillips stated the drugs would be grouped as interchangeable and that action would be acted upon. Next the committee could then set the criteria for the prior authorization. He suggested the HOPE trial criteria could be used as the PA criteria for ramipril. Judy Britt asked if they decided the class was interchangeable did that include the combinations. Ken Kolb responded yes. Dr. Heard asked about the management of the volume of information regarding the classes. The chair responded that the committee can and should consider new information or new drugs within a class. Dr. Heard also questioned if the committee was limited to labeled indications or if unlabeled uses could it be considered. Ken Kolb responded that labeled indications or indications supported by peer reviewed literature could be considered. Dr. Phillips suggested two motions on this class. First a motion on equivalency or interchangeability.

Jeff Monaghan responded to the issue of labeled indications for diabetic nephropathy. Although the only drug with an FDA labeled indication for this is captopril, the ADA Guidelines, January 2004, do not recommend a specific ACEI and consider this a class effect.

Dr. Greenberg motioned the ACEI class be considered equivalent in the treatment of hypertension, heart failure and slowing the progression diabetic nephropathy.
Seconded: Dr. Heard
Ayes: Unanimous

Dr. Greenberg wanted to remove the age recommendation from the HOPE trial for the prior authorization criteria. Dr. Phillips responded that would be fine but can be done when actually choosing the preferred drugs and setting up the criteria.

Dr. Greenberg motioned to consider ramipril for certain diabetic patients with preexisting vascular disease that meet the criteria of the HOPE study, with the exception of the age limitation.
Seconded: Dr. Pintar
Ayes: Unanimous

Darrell Faircloth interjected that he wanted to make sure the committee's intentions were clear to the Medicaid agency.

Coleen Lawrence stated she was clear. She also clarified the question regarding experimental use of drugs. The agency is required under the Social Security Act to use drugs for approved indications, compendia or peer review. She also clarified the procedure once the state makes its recommendations back to the committee. At that point the committee can accept or not accept and make your clinical criteria at that point. Also noted the Medicaid regulations state if you do exclude a drug from the PDL it is not excluded from drug coverage. Chapter 1200 states specifically drugs which are excluded. Other than the excluded drugs in Chapter 1200, drugs would be offered through a prior authorization program.

Dr. Phillips clarified that today's task was to determine the therapeutic equivalency of the drugs within the classes. The next task will be to determine what drugs will be on the list once the state comes back with their recommendations. It was brought up that there could be several drugs on the PDL within a specific drug class.

Judy Britt asked if they would consider step therapy. Dr. Phillips responded that it would be up to the Drug Utilization Review Board (DUR) to evaluate step therapy.

Recess

Dr. Phillips clarified that the previous vote was on **ACEI's and diuretic combinations**.
Motioned by Dr. Greenberg
Seconded: Judy Britt
Ayes: Unanimous

Ken Kolb recommended that the committee come to a consensus on how to handle combination drugs.

Dr. Phillips suggested tabling the ACEI's and calcium channel blocker combinations. Diana Bond suggested considering these agents after they review the calcium channel blockers. Dr. Phillips asked for a motion to table until after the calcium channel blockers are reviewed.
Motioned: Diana Bond
Seconded: Carl Heard

XIII. Angiotensin II Receptor Blockers and Combinations (ARB's)

Public Comment

Terry Livingston, Novartis, presented a clinical overview of Diovan. Attached. Dr. Wiser asked about the effects on uric acid. She replied it actually can increase uric acid and stated it wasn't clinically significant.

Colleen Fong, BMS, gave a clinical overview of AVAPRO.

Dr. Wiser stated they are getting the good qualities but wanted a discussion about the safety issues of the drugs. Diana Bond asked FHSC if the new format will address that. Dr. Wiser requested a table that addresses the safety issues. Ken Kolb stated we could do that if it makes sense and would look into it for the future. Dr. Phillips suggested FHSC highlight the safety issues when giving the drug class overview.

Susan True, Astra Zeneca Pharmaceutical, gave an overview of Atacand.

Nancy Moredock, Merck, gave overview of Cozaar.

Angel Horn, Sankyo, gave an overview of Benicar.

Public comment completed.

Ken Kolb, FHSC. Seven ARB's available. All seven are available as a combination product with the thiazide diuretics. All seven ARB's are labeled for the indication of hypertension. It is considered controversial to prescribe both an ACEI and an ARB. It is considered a class effect for the treatment of diabetic nephropathy, but Avapro and Cozaar have FDA labeled indications for this treatment. ADA 1/2004 position statement states that in hypertensive type 2 diabetic patients with microalbuminuria, ARB's have been shown to delay the progression to macroalbuminuria. No specific agents were cited. Diovan has the only indication for the treatment of heart failure; some of the others are being studied in the Valiant and CHARM trials. There is a small uircosuric effect with Cozaar. Hyperuricemia has been seen with Atacand. Using the Veteran's Administration (VA) as a national benchmark there are no ARB's on the VA formulary. They are only used for patients who are intolerant of ACEI's.

Dr. Wiser asked how the committee should approach companies or products that appear to have a larger volume of studies to support efficacy versus the competition? Ken Kolb stated one usually looks for consensus statements from groups or organizations that have credibility or

expertise in the specialty area. He also stated the volume of literature can also be skewed, depending on the amount of money the company wants to spend and the therapeutic niche being sought. For most drug classes, there are very few head-to-head studies.

Dr. Heard motioned that all ARB's presented be considered therapeutically equivalent as a class.
Seconded.
Ayes: Unanimous

Diana Bond made a motion to deem ARB/thiazide combinations therapeutically equivalent as a class.
Seconded
Ayes: Unanimous

XIV. Proton Pump Inhibitors (PPI's)

Public Comment

Paul Pereira, Tap Pharmaceuticals, speaking on behalf of a pediatrician in Las Vegas who could not attend. He suggested a carve out for pediatric patients in the PPI class. Letters have been submitted.

Kevin Mills, Astra Zeneca, presented an overview of Nexium.

Harvey Riceberg, LTC pharmacist. Consider OTC omeprazole as an option for LTC patients. Coleen Lawrence pointed out to the committee that written comments regarding the PPI's had been distributed to the committee.

Public comment completed

Ken Kolb, FHSC. Five PPI agents are available. Most studies suggest minimal difference. AGA Consensus statement stated there is no clinical evidence to support differences between available PPI's for the treatment of endoscopy- negative GERD. For erosive esophagitis, esomeprazole has been inconsistently found to have higher espohagitis healing rates than omeprazole and lansoprazole; the clinical significance of this is not substantiated. Standard doses of PPI's resulted in comparable rates of healing and remission in erosive esophagitis. The class has an excellent safety profile. VA formulary conclusion states the PPI's can be considered therapeutically interchangeable.

Dr. Britt asked about legal issues regarding the long term use of the OTC PPI's since it is not recommended for long term use. Dr. Horne asked if OTC drugs were covered by Medicaid. Coleen Lawrence responded yes, however there are policy limitations. Diana Bond wanted to know about the pediatric population and how will the committee approach this population with regard to the PDL.

Jeff Monaghan stated that the FHSC claims system can edit for patient age and therefore override the PA requirement based on patient age.

Diana Bond made a motion that Proton Pump Inhibitors be considered therapeutically equivalent with a pediatric exception.
Seconded.
Ayes: Unanimous

XV. Histamine-Two Receptor Antagonists (H2RAs)

Public Comment-None

Ken Kolb, FHSC. All H2RAs have been shown to be efficacious in the treatment of GERD. They are most effective for mild to moderate esophagitis. Efficacy improves at higher and more frequent doses for esophagitis; however, more potent acid supressors such as proton pump inhibitors may be needed for severe cases of GERD. All H2RAs are therapeutically equivalent in treating duodenal and gastric ulcers when used in appropriate doses. Few differences have been seen. The major differences in this class are their side effect profile. Cimetidine has a higher incidence of drug interactions and side effects than other agents.

Judy Britt made a motion to exclude cimetidine.
Seconded.

Dr. Wiser made a motion that histamine-two receptor antagonists be considered therapeutically equivalent with the exclusion of cimetidine.
Seconded.
Ayes; Unanimous

Bisphophonates
Public Comment

Karen Campbell- P&G Pharmaceuticals, gave an overview of Actonel.

Serge Bruent, Merck, gave an overview of Fosamax.

Public comment completed.

Ken Kolb, FHSC. No head to head clinical studies. American Association of Clinical Endocrinologists 2001 Medical Guidelines for the Prevention and Management of Postmenopausal Osteoporosis stated level 1 evidence of efficacy in reducing the risk of vertebral fractures is available for Bisphosphonates. Only Bisphosphonates have been shown to reduce the risk of hip and other non-vertebral fractures in prospective trials. VA formulary considers these agents to be therapeutically equivalent.

Dr. Wiser asked, based on drug administration issues, would one agent be considered better than the other? Ken Kolb stated there is no clear cut data to support one over the other in this regard.

Dr. Horne made a motion that the biphosphonates be considered therapeutically equivalent.
Seconded: Judy Britt
Ayes: unanimous

XVIII. DHCFP's Recommendation to the Committee on PDL Inclusions- Deferred

XIX. Committee Action on DHCFP Recommendations – Deferred

XX. Future Meeting Schedule

Dr. Pintar raised the question of changing the weekday of the meetings to Monday or Friday. After discussion the committee decided to revisit this at another time.

Dr. Horne asked if they could entertain the idea of some of the meetings being held in Las Vegas.

Chuck Duarte stated the division and FHSC could make arrangements to have meetings in Las Vegas.

Dr. Horne motioned to have the next meeting on March 25, 2004 with teleconferencing in Las Vegas.
Seconded.
Ayes: Unanimous

XXI. Public Comment

Tom Wood, Wyeth, stated many companies bring scientists to the meeting and they might be able to better answer questions if FHSC would make their presentation prior to the industry comment.

Darrell Faircloth, DAG, asked when the DHCFP's recommendations to the committee will occur.

Coleen Lawrence responded that this item will be rescheduled for an upcoming meeting.

The committee adjourned at 4:15pm

For additional details, an electronic recording of this meeting is available