

UNIVERSITY OF ARKANSAS
FOR MEDICAL SCIENCES
COLLEGE OF PHARMACY

ARKANSAS MEDICAID EVIDENCE-BASED PRESCRIPTION DRUG PROGRAM (EBR_x)

QUARTERLY REPORT - FIRST QUARTER 2005



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INTRODUCTION

OVERVIEW OF THE EVIDENCE-BASED PRESCRIPTION DRUG PROGRAM

Providing access to prescription medications is an integral part of ensuring the health and well being of Arkansas Medicaid enrollees. Medications help Medicaid recipients treat infections, ease pain, and slow or even halt the progression of chronic diseases. While it is clear that medications benefit the health of Medicaid recipients, it is also clear that rising costs and utilization have led to Medicaid prescription spending which will exceed half a billion dollars in the next state fiscal year.

The State of Arkansas can not ensure continued access to medications for the Medicaid population if costs continue to rise at their current annual rate. Consequently, the Department of Human Services (DHS) Division of Medical Services and the University of Arkansas for Medical Sciences (UAMS) College of Pharmacy created the Arkansas Medicaid Evidence-based Prescription Drug Program. The major goal of this program is to create an evidence-based Preferred Drug List, and to manage its implementation through a Prior Authorization (P.A.) Call Center operated by the College of Pharmacy.

After many months of planning, the program was approved by the state legislature, and authorized by the Governor. A contract between DHS and the College of Pharmacy was executed, and the program began November 1, 2004. This report details the progress of the program from inception through March 31, 2005.

INFRASTRUCTURE DEVELOPMENT

ASSEMBLING THE PROGRAM

The initial phase of the EBRx related to developing the required program infrastructure.

There are three basic infrastructure components:

- Staffing
- Development of Committees
- Construction of the P.A. Call Center

STAFFING

The EBRx budget provided for 20.85 FTE's. As of March 31, 2005, 9.0 FTE's have been employed. These positions include key employees required at the beginning of the program. The remaining employees will be added over the next several months as warranted by the needs of the program. Where appropriate, employees have signed a statement acknowledging no conflicts of interest. Each person currently hired under the contract and his/her title is listed below:

- Henry F. Simmons, Jr., M.D., Ph.D. – Call Center Medical Director
- Mark E. Helm, M.D., MBA – Call Center Medical Director
- Howell Foster, Pharm.D. – Prior Authorization Call Center Director
- Scott Pace, Pharm.D. – Drug Utilization & Cost Committee Coordinator
- Brady Crisp, Pharm.D. – Clinical Pharmacist
- Penny Davis, Pharm.D. – Clinical Pharmacist
- Marilyn McCauley, P.D. – Clinical Pharmacist
- Clay Patrick, Pharm.D. – Clinical Pharmacist
- Justin Harper, Pharm.D. – Clinical Pharmacist (part time)
- Keith McCain, Pharm.D. – Clinical Pharmacist (part time)
- Todd Nolte, Pharm.D. – Clinical Pharmacist (part time)
- Mickey Oates, Pharm.D. – Clinical Pharmacist (part time)
- Pamala Rossi, Pharm.D. – Clinical Pharmacist (part time)

- Heather Brewer – Administrative Assistant

Since the contract was executed, Dean Gardner has devoted considerable time towards the launch of the program and assembling the executive staff. In early January, the EBRx contracted with a consultant with expertise in Medicaid and pharmacy benefit management. Charlie Callihan was brought onsite in early January to critique the EBRx design and processes, including the first meeting of the Drug Review Committee.

There remain a number of critical areas to be staffed. Additional staff may be required to assist with monitoring and evaluation of the program and these positions will be added as appropriate. The Clinical Pharmacist staffing in the call center will require review and additional pharmacists may be added to the staff as the Preferred Drug List grows, and as call volume increases. Additional administrative assistant staff may also be added as the program moves forward. Two graduate students providing data analysis services relating to the contract are expected to begin in August. Other staff will continue to be added as we build to anticipate the future needs of the program.

DEVELOPMENT OF COMMITTEES

The EBRx contract requires creation and maintenance of two review committees, the Drug Review Committee (DRC) and the Drug Utilization and Cost Committee (DUCC). Creation of these committees was completed in December 2004.

Three physicians and three pharmacists serve on the DRC. The DRC is charged with evaluating the available clinical evidence and making a determination about the superiority or homogeneity of products in a specific therapeutic class. The DRC meets monthly and considers a new medication class each month. Membership in the DRC was selected by Drs. Mark Helm, Henry Simmons, and Dean Gardner in conjunction with the Arkansas Medical Society and the Arkansas Pharmacists Association.

The DRC members held two organizational meetings in December for training on Drug Class Reviews, and to develop rules and policies for the DRC. Dr. Santa from the Oregon Evidence-based Practice Center (EPC) was in attendance to provide a tutorial to the DRC members about the Drug Class Reviews. At the second meeting, the committee elected Dr. Henry F. Simmons, Medical Director of the program and ex-officio member of the DRC, to be the committee chair. The terms of the committee members will be six months with initial terms being staggered to ensure continuity of the committee. The members of the DRC are:

- Henry F. Simmons, Jr., M.D., Ph.D. – ex-officio member, Chair
- Jill Johnson, Pharm.D. – Pharmacist, UAMS College of Pharmacy
- C.A. Kuykendall, P.D. – Pharmacist in Private Practice, Ozark, AR
- Ted Lancaster, M.D. – Physician in Private Practice, Walnut Ridge, AR
- Roberta Monson, M.D. – Physician, UAMS College of Medicine
- Kathryn Neill, Pharm.D. – Pharmacist, UAMS College of Pharmacy

- Joshua O'Neill, Pharm.D. – Physician in Private Practice, Little Rock

Since inception, the DRC has met five times. The Committee has completed review and deliberations on Non-sedating Antihistamines, Proton Pump Inhibitors, and Cholesterol Lowering HMG-Coenzyme-A Reductase Inhibitors (Statin) products. The DRC has also received public input on Calcium Channel Blocking agents. DRC members receive a monthly stipend for their participation in the committee process, which is a fixed hourly rate. The EBRx originally budgeted this as eight hours per month per committee member, however, because of the large volume of literature that the committee is expected to review, the stipend was increased to 12 hours per month.

The Drug Utilization and Cost Committee is responsible for analyzing Arkansas Medicaid expenditures in the medication classes reviewed by the DRC. This committee consists of two physicians and two pharmacists. One pharmacist and one physician are appointed by the EBRx staff, and one pharmacist and one physician are appointed by DHS. Members of this committee use DRC recommendations, utilization and cost data, and manufacturer supplemental rebate bids to recommend which product(s) should be added to the Preferred Drug List. Members of the DUCC include:

- Pamela Ford, P.D., MBA – DHS representative
- Mark E. Helm, M.D., MBA – Program Medical Director
- Scott Pace, Pharm.D. – Program DUCC Coordinator
- Jan Sullivan, M.D. – DHS representative

All members of the Drug Review Committee and the Drug Utilization and Cost Committee provided Conflict of Interest disclosures. In addition, the DRC members are required to sign a therapeutic class specific conflict of interest statement each month prior to their deliberation and voting. Ultimately, the names of each of the committee members were submitted to DHS who gave the final authorization for their participation in the committee process.

CONSTRUCTION OF THE P.A. CALL CENTER

In late January, construction began on the P.A. Call Center at the UAMS College of Pharmacy. The P.A. Call Center Director, Howell Foster coordinated this work. Construction required relocation and removal of walls, doors, and entire offices. New carpet, paint, electrical and telecommunications systems have been installed. Furniture and Computer systems were in place in the Call Center and all Call Center offices by the end of March 2005.

Clinical pharmacists and staff were trained on telecommunication systems and SmartPA software in the month of March. SmartPA software training was provided by an account manager from ACS-Heritage along with EDS staff on March 10th and 11th. Software training on the EDS Medicaid Decision Support System (DSS) was provided to the EBRx management staff. The Project Coordinator and Call Center Directors received training on the telecommunication system tracking and reporting software.

The Call Center may be reached at 501.526.4200 or 866.250.2518 (toll free) or 501.526.4188 (fax).

The Call Center's hours of operation are:

- Monday through Friday – 9AM – 5PM
- Saturday and Sunday – 12PM – 2PM

The EBRx management will continue to monitor the hours of the Call Center and will make any necessary adjustment to the hours as deemed appropriate by the Department of Human Services.

COMMITTEE PROGRESS

DRC & DUCC MEETING UPDATES

DRUG REVIEW COMMITTEE UPDATE

The DRC has held three public meetings where the committee made recommendations to DHS. The minutes to each of those meetings are attached at the end of this report (Appendices A, B, and C) and represent the procedures that the committee operates under as well as the progress of the committee.

DRUG UTILIZATION AND COST COMMITTEE UPDATE

The DUCC held their first meeting on Wednesday, January 19th at the DHS offices in Little Rock. It was determined that none of the DUCC meetings will be open to the public because of the confidential Centers for Medicare and Medicaid Services (CMS) rebates that are reviewed, as well as any supplemental rebate information that may be provided by the manufacturers. Each of the DUCC members also signed a Confidentiality Agreement that states that they will keep all manufacturer rebate information confidential.

The committee began by reviewing the recommendations of the DRC. Once these recommendations were read, then the sealed supplemental rebate information for the second generation antihistamines were opened. The committee reviewed the costs and calculated the net-net cost (i.e. final cost to Medicaid) per unit per drug. Once these calculations were done, the committee then voted to recommend to DHS that loratadine be placed on the preferred drug list (PDL). The recommendation for the second generation antihistamines was then forwarded to DHS.

The DUCC held its meetings to discuss the proton pump inhibitors on Wednesday, February 23rd and March 4th. The committee reviewed the proton pump inhibitor recommendations from the DRC. After the DRC recommendation was read the committee opened the sealed supplemental rebate bids from the manufacturers of the proton pump inhibitors. Once all of the bids were opened the net-net cost of all the products were reviewed. After reviewing the utilization and cost data, it was determined that it was most economical to select two preferred products for the proton pump inhibitors, esomeprazole capsules and lansoprazole capsules. The committee also preferred lansoprazole solutabs for children under the age of seven and for patients for whom solid oral dosages are unacceptable. The recommendations from the DUCC were then forwarded to DHS.

The third DUCC meeting was held on Monday, March 21st. The committee reviewed the recommendations from the DRC and evaluated the sealed supplemental rebate envelopes. It was decided that only the envelopes containing products that the DRC recommended should be opened initially. Once the net-net costs were determined, the committee made a determination that simvastatin met the recommendations from the DRC and presented the most economical option to the state. A motion was made to prefer simvastatin and it was passed unanimously. The recommendation from the DUCC was then forwarded to DHS.

The DUCC will continue to meet within five business days of receiving the recommendations from the DRC.

ESTIMATED FINANCIAL IMPACT OF COMMITTEE'S DECISIONS

PROJECTED COST SAVINGS TO THE STATE BECAUSE OF THE PDL

SECOND GENERATION ANTIHISTAMINES

Using 3rd quarter 2004 data for second generation antihistamines, potential cost savings of the Medicaid PDL were projected.

These estimates are made using only one quarter of data and do not take into consideration any seasonal increase or decrease in utilization. Additionally, the savings projections are made for the 12 month period post implementation, but DO NOT factor in the Medicaid/Medicare dual-eligibles that may be dropped from the Medicaid rolls on January 1, 2006.

<u>Estimated Annual Spend Prior to PDL</u>	<u>Estimated Annual Spend with 100% PDL Uptake</u>
\$ 4,502,000	\$ 2,519,000

Estimated Annual Total Potential Savings to the State - \$ 1,983,000

PROTON PUMP INHIBITORS

Using 3rd quarter 2004 data for proton pump inhibitors, potential cost savings of the Medicaid PDL were projected. It is worth noting that because supplemental rebates will be utilized, the state will experience a significant cost savings even without change in utilization.

These estimates are made using only one quarter of data and do not take into consideration any seasonal increase or decrease in utilization. Additionally, the savings projections are made for the 12 month period post implementation, but DO NOT factor in the Medicaid/Medicare dual-eligibles that may be dropped from the Medicaid rolls on January 1, 2006.

<u>Estimated Annual Spend Prior to PDL</u>	<u>Estimated Annual Spend with 100% PDL Uptake</u>
\$ 7,481,000	\$ 2,074,000

Estimated Potential Savings to the State with PDL and NO Change in Utilization or Product Selection - \$3,592,000

Estimated Annual Total Potential Savings to the State - \$5,407,000

HMG COENZYME-A REDUCTASE INHIBITORS (THE STATINS)

Using 3rd quarter 2004 data for statins, potential cost savings of the Medicaid PDL were projected. It is worth noting that because supplemental rebates will be utilized, the state will experience a significant cost savings even without change in utilization.

These estimates are made using only one quarter of data and do not take into consideration any seasonal increase or decrease in utilization. Additionally, the savings projections are made for the 12 month period post implementation, but DO NOT factor in the Medicaid/Medicare dual-eligibles that may be dropped from the Medicaid rolls on January 1, 2006.

Estimated Annual Spend Prior to PDL **Estimated Annual Spend with 100% PDL Uptake**

\$7,386,000

\$5,164,000

Estimated Annual Total Potential Savings to the State - \$2,222,000

Prior Authorization Call Center Statistics

P.A. CALL CENTER OPERATIONS AS A RESULT OF THE PDL

When the first class of PDL medications went live on Friday, March 25th, the P.A. Call Center opened to begin providing prescribers with a mechanism for obtaining a prior authorization. The statistics below represent the Call Center's activity for the first quarter 2005, which includes March 25th – 31st.

PA Call Center Statistics	March 25 – 31, 2005
Incoming Calls from Healthcare Professionals	218
Informational Outbound Calls to Prescribers	336
Number of SmartPA Tickets Created	219
Total Number of P.A. Request at the Call Center	143
Total Number of P.A. Requests Approved at the Call Center	43
Call Center P.A. Approval Percentage	30.1%
Point of Sale SmartPA Requests	1015
Point of Sale SmartPA Approvals	136
Point of Sale SmartPA Approval Percentage	13.4%

Budget Update

A GENERAL OVERVIEW OF THE PROGRAM BUDGET AS OF MARCH 31, 2005

The information below is representative of the current budget for the Arkansas Medicaid Evidence-based Prescription Drug Program for the State Fiscal Year 2005 (SFY05). The numbers for SFY05 represent a nine month period, from October 2004 through June 2005. There are currently a number of personnel positions that have yet to be filled; however, as demand arises the program will work within its budget to ensure that it can meet the demand. Additionally, the startup equipment expenses have been scaled back to meet our current employment level. The program will continue to work within the personnel and equipment budget, but request that the budgeted amounts unspent for SFY05 be allowed to be carried over to SFY06.

	FY05 Budget	Expenditures To Date	Projected Expenditures FY05
Personnel – (Salary and Fringes, includes DRC stipends)	\$1,563,656	\$275,175	\$548,657
Miscellaneous – (Supplies, Travel, etc)	\$132,488	\$6,920	\$62,420
Equipment – (computers, phones, furniture, renovation)	\$382,6000	\$147,435	\$365,385
Indirect Costs	\$915,918	\$152,331	\$329,981
TOTAL	\$2,994,662	\$581,861	\$1,306,442

Appendix A

Arkansas Medicaid Prior Authorization Program Drug Review Committee Minutes for January 14, 2005 ED II G137

Members Present: Jill Johnson, Pharm. D.; C.A. Kuykendall, PD; Ted Lancaster, MD; Roberta Monson, MD; Kathryn Neill, Pharm. D.; Josh O'Neill, MD; Henry Simmons, Jr., MD, Ph.D.]

Members Absent: None

I. Dr. Simmons called the meeting to order at 0900.

II. There were no minutes from earlier meetings to review, approve, or change.

III. OLD BUSINESS/STANDING REPORTS

Submission of CVs and SSNs

IV. NEW BUSINESS

A. Item: Public presentations regarding proton pump inhibitors

The Committee heard from John Frey of Santarus regarding Zegerid, Daniel Halberg of Astra Zeneca regarding Nexium, and James King regarding Prevacid.

Presenters also answered questions from some of the Committee members and submitted other information in printed and/or electronic form.

B. Item: Public presentations regarding 2nd generation antihistamines

The Committee heard from Rick Learned regarding Zyrtec, Robert Cortes regarding Clarinex, and Aubrey Ziegler regarding multiple 2nd generation agents.

Presenters also answered questions from some of the Committee members and submitted other information in printed and/or electronic form. Dr. Helfand of the EPC attended these presentations telephonically.

C. Item: Conflicts of interest

Each Committee member reviewed and signed a general conflict of interest statement as well as one specific to the 2nd generation antihistamines.

D. Item: Dr Helfand of the EPC presented by telephone and Power Point a brief overview of his organization's impressions on the state of the literature regarding selected 2nd generation antihistamines.

E. The Committee considered a series of questions regarding the potential toxicity and therapeutic roles of cetirizine [Zyrtec], desloratadine [Clarinex], fexofenadine [Allegra], and loratadine [Claritin-OTC] in the treatment of seasonal allergic rhinitis [SAR], perennial allergic rhinitis [PAR] and chronic idiopathic urticaria [CIU]. Dr. Helfand of the EPC listened by telephone and responded to questions.

Item: Does the bulk of the available evidence suggest that any of the second generation

antihistamines pose sufficient risk of either toxicity or adverse interaction potential that they should

be stricken from consideration?

The voting members felt that none of the four drugs presents a special risk relative to the others based upon the bulk of the available evidence.
Dr. Lancaster made a formal motion to so notify DHS and the DUCC that was seconded by Dr. Johnson.
The motion passed unanimously.

Item: Does the bulk of the available evidence support a conclusion that differences exist in the ability to improve the total symptom score between the remaining drugs for treating SAR, PAR or CIU in adults?

The voting members concluded that based upon the bulk of the available evidence that cetirizine, loratadine and fexofenadine did not differ in their in their ability to improve total symptom scores in adults.
However, they felt that there was inadequate data to support inclusion of desloratadine in this group at this time. The Committee agreed to reconsider desloratadine in the future as additional evidence appears.
Dr. Johnson made a formal motion to so notify DHS and the DUCC that was seconded by Dr. Neill.
The motion passed unanimously.

Item: Does the bulk of the available evidence suggest that any of the remaining drugs are more effective in improving the total symptom score for any particular subgroup?

The voting members noted that there was insufficient pediatric data to prefer one or more drugs over the others in improving total symptoms scores. Accordingly, they were unable to exclude any of the drugs from consideration.

The voting members concluded that with the exception of the liquid dosing forms for cetirizine, desloratadine and loratadine that none of the four drugs posed a special benefit for children based upon the bulk of the available evidence.
Dr. Lancaster made a formal motion to so notify DHS and the DUCC that was seconded by Dr. Neill.
The motion passed unanimously.

Dr. Lancaster raised the issue that cetirizine posed a special benefit for symptom relief in asthmatics. The group noted, however that in the absence of head to head data, that those results were not necessarily specific to cetirizine. Furthermore, other members noted that the study under discussion did not document improvement in tests of pulmonary functions. No specific recommendation regarding cetirizine followed.

The voting members felt that based upon the available evidence that none of the drugs offered a special benefit to other subgroups in improving total symptom scores.
Dr. O'Neill made a formal motion to so notify DHS and the DUCC that was seconded by Dr. Kuykendall.
The motion passed unanimously.

V. The Chairman adjourned the meeting with the agreement of the Committee.

VI. The next meeting is scheduled for 02/18/05 at 1000 in the same location.

Respectfully submitted,

Charlotte Robertson
Recorder

Henry F. Simmons, Jr., MD., Ph.D
Chairman

Appendix B

Arkansas Medicaid Prior Authorization Program Drug Review Committee Minutes for February 18, 2005

Members Present: Jill Johnson, Pharm. D.; C.A. Kuykendall, PD; Ted Lancaster, MD; Roberta Monson, MD; Kathryn Neill, Pharm. D.; Josh O'Neill, MD; Henry Simmons, Jr., MD, Ph.D. Marian McDonough, Pharm. D. of EPC and Bruce Johnson MD of Gastroenterology Associates of Little Rock also attended.

Members Absent: None

I. Dr. Simmons called the meeting to order at 1000.

II. OLD BUSINESS/STANDING REPORTS

The Committee reviewed the minutes of the January 14 meeting and voted to accept them after receipt of a motion and second.

III. NEW BUSINESS

A. Item: Public presentations about the HMG CO-A reductase inhibitors (statins)

The Committee along with Dr. McDonough of EPC heard from Drs. James Kendall, Maurice Rozek and Rick Learned of Pfizer for Lipitor; Dr. Karmen Johnson of Bristol Myers Squibb regarding for Pravachol; Dr. Daniel Teat of Astra Zeneca for Crestor; Dr. Robert Calder of Merck for Zocor; and David Abrahamson of Merck Schering Plough for Vytorin.

Presenters also answered questions from Committee members and submitted other information in either printed or electronic form.

B. Item: Conflicts of interest

Each Committee member reviewed and signed a conflict of interest statement specific to the proton pump inhibitors.

C. Item: Dr McDonough of the EPC presented an overview of her organization's impressions on the state of the literature regarding the PPIs.

E. Item: The Committee considered a series of questions regarding the potential toxicity and therapeutic roles of omeprazole, lansoprazole, pantoprazole, rabeprazole and esomeprazole as used to manage common conditions in adults.

1. Does the bulk of the available evidence suggest that the aforementioned PPIs differ in either the incidence or nature of clinically significant complications in adults treated for symptoms of GERD, peptic ulcer and NSAID-induced ulcer to the degree that precludes further consideration?

The voting members felt that none of the five drugs presents a special risk relative to the others based upon the bulk of the available evidence.

A voting member made a formal motion to so notify DHS and the DUCC that was seconded by Dr. Neill.

The motion passed unanimously.

2. Does the bulk of the available evidence support the conclusion that no clinically significant differences exist among the remaining drugs for management of symptoms of GERD in adults?

The voting members concluded that based upon the bulk of the available evidence that the five agents do not differ in their in their ability to manage symptoms of GERD in adults when equivalent doses are employed.

Dr. Lancaster made a formal motion to so notify DHS and the DUCC that was seconded by Dr. O'Neill.

The motion passed unanimously.

Dr. Monson noted that under some circumstances it is difficult to for patients to receive doses of omeprazole exceeding 20 mg per day. The Committee felt that DHS might consider advising physicians that recipients are eligible to receive 20 mg BID under current guidelines.

3. Does the bulk of the available evidence suggest that any of the remaining drugs are more effective from a clinical standpoint in adult patients with peptic ulcers?

The voting members concluded that based upon the bulk of the available evidence that the five agents do not differ in their in their ability to manage peptic ulcers in adults when equivalent doses are employed.

Dr. Kuykendall made a formal motion to so notify DHS and the DUCC that was seconded by Dr. Neill.

The motion passed unanimously.

4. Does the bulk of the available evidence suggest that any of the remaining drugs are more effective from a clinical standpoint in adult patients with NSAID-induced ulcers?

The voting members concluded that based upon the bulk of the available evidence that the five agents do not differ in their in their ability to manage NSAID-induced ulcers in adults when equivalent doses are employed.

Dr. Monson made a formal motion to so notify DHS and the DUCC that was seconded by Dr. O'Neill.

The motion passed unanimously.

5. Does the bulk of the available evidence suggest that there are subgroups of patients based upon demographics, other medications, or co-morbidities for which one medication is more effective or associated with fewer adverse effects?

After comments by multiple members, the Committee decided that it had insufficient information to recommend that DHS either prefer or disallow any of the five medications for individuals under 18 years of age. When asked about the EPC position on prescribing these drugs for children, Dr. McDonough noted that although the organization had access to some data, they had not formally reviewed it.

Dr. O'Neill noted that it is rare for children to need proton pump inhibitors who cannot swallow solid dosing forms. He also stated that babies are typically maintained on H2 blockers and that they are often followed by gastroenterologists. The use of a PPI in a small child or baby would ordinarily follow evaluation by a specialist.

Dr. Lancaster commented that pediatric gastroenterologists are not routinely available in rural areas and that PCPs must occasionally write such prescriptions for pediatric patients after they have been referred.

The Committee believes that a liquid PPI of some kind should be available for use by children too small to swallow solid preparations.

The voting members concluded that based upon the bulk of the available evidence that the five agents do not differ among adult subgroups based upon demographics, other medications or co-morbidities.

Dr. Lancaster made a formal motion to so notify DHS and the DUCC that was seconded by Dr. O'Neill.

The motion passed unanimously.

IV. Following a motion to adjourn by Dr. Lancaster and a second by Dr. Johnson, the meeting ended.

V. The next meeting is scheduled for 03/18/05 at 1000 in the same location.

Respectfully submitted,

Heather Brewer
Recorder

Henry F. Simmons, Jr., MD., Ph.D.
Chairman

Appendix C

DRAFT DOCUMENT – AWAITING DRC APPROVAL ON APRIL 14, 2005

Arkansas Medicaid Prior Authorization Program Drug Review Committee Minutes for March 18, 2005

Members Present: Jill Johnson, Pharm. D.; Ted Lancaster, MD; Roberta Monson, MD; Kathryn Neill, Pharm. D.; Henry Simmons, Jr., MD, Ph.D.

Members Absent: C.A. Kuykendall, PD and Josh O'Neill, MD.

I. Dr. Simmons called the meeting to order at 10:00.

II. OLD BUSINESS/OUTSTANDING REPORTS

The Committee reviewed the minutes of the February 18 meeting and voted to accept them after receipt of a motion and second.

III. NEW BUSINESS

A. Item: Public presentations about the calcium channel blockers

The Committee heard from Drs. Maurice Rozek and Rick Learned of Pfizer for Caduet; Dr. Glen Lepard of First Horizon for Sular; and Dr. Harold Betton of the Betton Clinic who had been sponsored by Biovail for Cardizem LA

Presenters also answered questions from Committee members and submitted other information in either printed or electronic form.

B. Item: Conflicts of interest

Each Committee member reviewed and signed a conflict of interest statement specific to the statins.

C. Item: Dr McDonough of the EPC telephonically presented an overview of her organization's impressions on the state of the literature regarding the statins, audited the Committee's deliberations and answered questions.

E. Item: The Committee considered a series of questions regarding the potential toxicity and therapeutic roles of atorvastatin, fluvastatin, lovastatin, pravastatin, rosuvastatin and simvastatin as used to manage common conditions in adults. Their conclusions and the results of votes taken on various motions follow.

1. Does the bulk of the available evidence suggest that the aforementioned statins differ significantly in either the incidence or nature of clinically evident complications in patients of a particular sex, age or race?

None of the six drugs differ significantly in either the incidence or the nature of clinically evident complications in patients of a particular sex, age or race when appropriately dosed.

Dr. Neill made a formal motion to so notify DHS and the DUCC that was seconded by Dr. Monson. The motion passed unanimously.

2. Does the bulk of the available evidence suggest that one or more of the remaining statins are more efficacious for patients of a particular sex, age or race?

None of the six drugs have been proven more efficacious for patients of a particular sex, age or race.

Dr. Monson made a motion to so notify DHS and the DUCC that was seconded by Dr. Neill. The motion passed unanimously.

3. Does the bulk of the available evidence suggest that any of the remaining drugs are more effective in reducing the risk of nonfatal MI, angina, CAD mortality, all cause mortality, stroke, or the need for revascularization?

This question generated a lengthy discussion and gave rise to multiple conclusions and motions. Atorvastatin, simvastatin, pravastatin, fluvastatin and lovastatin all improve some health outcomes. However, lovastatin lacks data on secondary health outcomes, fluvastatin on primary and rosuvastatin on both primary and secondary.

Because of these gaps in the data base, the Committee excluded rosuvastatin, lovastatin and fluvastatin from further consideration.

Atorvastatin, pravastatin and simvastatin are effective in reducing both primary and secondary outcomes.

Dr. Johnson made a motion to strike rosuvastatin from further consideration that was seconded by Dr. Neill. With the exception of Dr. Lancaster, all voting Committee members voted for this motion. Due a tie in the two physician votes, Dr. Simmons cast a vote in favor of the motion that resulted in its passage.

Dr. Johnson made a motion to strike fluvastatin and lovastatin from further consideration that was seconded by Dr. Lancaster. The motion passed unanimously.

Dr. Monson made a motion to limit its recommendations to atorvastatin, pravastatin and simvastatin. After Dr. Johnson seconded the motion, it passed unanimously.

4. Does the bulk of the available evidence support the conclusion that the remaining drugs are effective in for the management of elevated LDL-c?

Atorvastatin, simvastatin and pravastatin are all three effective in reducing LDL cholesterol in patients with moderate elevations.

Atorvastatin or simvastatin should be available for patients who need more than 40% reduction in LDL cholesterol from the outset or who fail control with a less potent agent such as pravastatin. In particular a patient with a need for more than 40% reduction at the initiation of treatment should not have to fail control with pravastatin before being switched to atorvastatin or simvastatin. Therefore, a minimum of two drugs would have to be available if one of them were pravastatin.

5. Does the bulk of the available evidence suggest that any of the remaining drugs are more effective in their ability to increase HDL-c to a clinically significant degree?

Atorvastatin, simvastatin and pravastatin do not differ in the ability to increase HDL-c to a clinically significant degree.

Dr. Johnson made a motion to so notify DHS and the DUCC that was seconded by Dr. Neill. The motion passed unanimously.

After a discussion about potential problems that might arise in prescribing statins and Committee offers the following considerations:

It is not possible to make generic recommendations for individuals having certain co-morbidities, taking potentially interacting drugs or experiencing refractory hyperlipidemias. However, pravastatin was considered a good potential choice for patients taking cytochrome P450 inhibitors and atorvastatin a potential drug for those with refractory LDL-c elevations. Such cases will quite possibly need to be addressed in the prior authorization process.

Finally, the members briefly discussed a potential change in meeting day from Friday morning to Thursday afternoon in mid summer of 2005. It appeared that such a change would pose minimal problems.

IV. Following simultaneous motions to adjourn by Drs. Monson and Neill and a second by Dr. Johnson, the meeting ended.

V. The next meeting is scheduled for 04/14/05 at 10:00 in the same location.

Respectfully submitted,

Heather Brewer
Recorder

Henry F. Simmons, Jr., MD., Ph.D
Chairman