

UNIVERSITY OF ARKANSAS  
FOR MEDICAL SCIENCES  
COLLEGE OF PHARMACY

# ARKANSAS MEDICAID EVIDENCE-BASED PRESCRIPTION DRUG PROGRAM (EBR<sub>x</sub>)

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QUARTERLY REPORT – FOURTH QUARTER 2007



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# INTRODUCTION

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## OVERVIEW OF THE EVIDENCE-BASED PRESCRIPTION DRUG PROGRAM

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The Evidence-Based Prescription Drug Program (EBRx) came into existence in November 2004. The program is a collaboration between the University of Arkansas for Medical Sciences (UAMS) College of Pharmacy and the Arkansas Department of Health and Human Services (DHHS) Medicaid Program, with the support and input of the Arkansas Medical Society and the Arkansas Pharmacist's Association. The primary role of EBRx for DHHS is to facilitate development of an Evidence-based Preferred Drug List and provide related Prior Authorization review services for Medicaid and ARKids recipients.

Medicaid is an entitlement program for individuals and families with low-income or disabilities. Prior to January 1, 2006, the Medicaid program provided prescription benefits for qualifying elderly patients whose primary insurance was through the Federal Medicare program. With the availability of Medicare Part D prescription drug coverage, the Arkansas Medicaid enrollee population is now predominantly children. In fact Arkansas' Medicaid and ARKids programs are estimated to provide healthcare coverage to approximately half of all Arkansas children.

In the years before development of the Evidence-based Preferred Drug List, medication cost growth was a major contributor to increased costs of the Arkansas Medicaid program. In the nine years before EBRx began, Medicaid prescription drug spending grew at a compound annual growth rate exceeding 16 percent. This growth was due to increases in the costs of medications as well as increases in the numbers of enrollees. The largest contributor to the increase in total medication expenditures was increases in average medication costs. The rate of medication cost growth far exceeds state revenue growth, and jeopardizes continuation of the optional Medicaid drug benefit, or other benefits at current levels.

The goals of the EBRx program are to: identify differences between medication options; recommend inclusion on the PDL of superior medications, if they exist; enhance predictability and reduce costs of medications whenever possible; and to provide access to medications not on the PDL through Prior Authorization Call Center activities. These efforts are hoped to ensure the continued ability of the state to provide appropriate medical coverage for Arkansas' Medicaid and ARKids recipients.

# Preferred Drug List Summary

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## PDL CATEGORIES, SELECTIONS, RATIONALE, AND SPECIAL CONSIDERATIONS

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Medication Class	Medicaid Preferred Agents (Brand Name Agents in Bold)	Drug Review Committee Recommendation Summary	Special Considerations
Less Sedating Antihistamines	Loratadine	No difference in patient total symptom scores	Patients under age 2 years
Proton Pump Inhibitors	<b>Prevacid capsules</b> <b>Nexium capsules</b> <b>Prevacid Solutabs</b>	No difference in outcomes with equipotent dosing	Patients under age 7 years, Patients with feeding tubes
HMG-CoA Reductase Inhibitors (statins)	<b>Zocor (generic products are now also available)</b>	Three agents superior to others based on prevention of heart attacks	Need for more potent agent
Calcium Channel Blockers	Diltiazem ER capsules (equiv to Dilacor XR) <b>Dynacirc CR</b> <b>Norvasc</b> Nifedipine ER tablets Verapamil SR tablets	Diltiazem, verapamil, amlodipine and at least one other dihydropyridine should be available.	Dosage strengths of extended release diltiazem not available as Dilacor XR
Beta Blockers	Atenolol Metoprolol tartrate Propranolol IR Bisoprolol (only for CHF) <b>Toprol XL (only for CHF)</b> Carvedilol (only for CHF)	No significant differences among the agents for most indications although there are differences in approved indications and data supporting use of specific products in specific conditions. 3 agents superior for treatment of congestive heart failure.	Diagnosis of Congestive Heart Failure
Long-Acting Opioids	Methadone Morphine sulfate ER tablets	No clinical advantage for one agent over another for treatment of chronic pain.	Terminal cancer diagnosis. Patients with long-term care coverage Patients unable to swallow
Angiotensin-Converting Enzyme (ACE) Inhibitors	<b>Altace</b> Captopril	No significant differences among the agents for most indications although there are differences in approved indications and data supporting use of specific products in specific conditions.	Patients under age 18 years

<b>Medication Class</b>	<b>Medicaid Preferred Agents (Brand Name Agents in Bold)</b>	<b>Drug Review Committee Recommendation Summary</b>	<b>Special Considerations</b>
Serotonin 5-HT1 Receptor Agonists (triptans)	<b>Maxalt</b> <b>Maxalt MLT</b> <b>Imitrex tablets, nasal spray, injection</b>	No significant difference among the agents that any one agent is clinically superior to another, different dosage forms should be available	Criteria in place for injectable formulation
Angiotensin II Receptor Blockers	<b>Cozaar, Hyzaar</b> <b>Diovan, Diovan HCT</b>	No significant advantage or disadvantage among the agents.	Congestive Heart Failure
Skeletal Muscle Relaxants	Chlorzoxazone Cyclobenzaprine 10mg Methocarbamol Baclofen (spasticity only) Tizanidine (spasticity only)	Muscle spasms and spasticity disorders have different preferred agents, no advantage of one product over another.	None
Systemic Estrogens	Estradiol 0.5mg,1mg,2mg Estropipate	No difference in the products at equipotent doses. At least one oral and one topical product should be available	None
Non-Benzodiazepine Sedative Hypnotics	<b>Ambien CR</b> <b>Rozerem</b> <b>Sonata</b> zolpidem	No significant differences among the agents.	None
Targeted Immune Modulators	<b>Enbrel</b> <b>Humira</b> <b>Raptiva</b>	No significant differences among the agents for most indications although there are differences in approved indications and data supporting use of specific products in specific conditions.	Subject to previous DUR clinical edits
Inhaled Corticosteroids	<b>Asmanex</b> <b>Azmacort (removed after contract terminated)</b> <b>Flovent (only to age 12)</b>	No significant differences among the products at equipotent doses	Patients under age of 12 years
Anticholinergics for Overactive Bladder	<b>Detrol LA</b> Oxybutinin syrup,5mg tablet <b>Vesicare</b>	No significant differences among the products at equipotent doses. None particularly effective	Patients under age of 18 years with spina bifida diagnosis
Antiemetics 5-HT3 and NK1 Receptor Antagonists	ondansetron	No significant differences among the products at equipotent doses.	None
Nasal Corticosteroids	<b>Nasacort AQ</b> <b>Nasonex</b>	No significant differences among the agents.	None

Medication Class	Medicaid Preferred Agents (Brand Name Agents in Bold)	Drug Review Committee Recommendation Summary	Special Considerations
Antidiabetics-meglitinides	<b>Starlix</b>	At least one agent from each of the sub-classes of antidiabetics should be included. No significant differences in efficacy among the agents.	None
Antidiabetics-First Generation Sulfonylureas	Chlorpropamide Tolazamide		
Antidiabetics-Second Generation Sulfonylureas	Glimepiride Glipizide Glyburide Glyburide micronized Metformin Metformin/glipizide Metformin/glyburide		
Antidiabetics-Thiazoladinediones	<b>Actos 30mg, 45mg</b> <b>Actosplus Met</b> <b>Avandamet</b> <b>Avandaryl</b> <b>Avandia</b>		
Antidepressants	Bupropion regular release Citalopram Fluoxetine 10mg,20mg caps, 20mg/5ml solution <b>Lexapro</b> 10mg,20mg Mirtazapine 15mg,30mg,45mg Paroxetine <b>Pexeva</b> Sertraline Venlafaxine regular release <b>Wellbutrin XL</b>	No significant differences in efficacy among the agents but at least 3 should be available due to high initial failure rates. Fluoxetine should be available to those<18yo	Patients stable and compliant on non-preferred agents.
Beta <sub>2</sub> Agonists	<b>Short Acting</b> Albuterol 90mcg inhaler Albuterol 5mg/ml solution Albuterol 0.83mg/ml solution <b>Maxair Autohaler</b> <b>Proair HFA</b> <b>Ventolin HFA</b>  <b>Long Acting</b> <b>Serevent Diskus</b>	No significant differences among the agents in regards to efficacy or safety.	Long acting agents still subject to previous DUR clinical criteria edits.

Medication Class	Medicaid Preferred Agents (Brand Name Agents in Bold)	Drug Review Committee Recommendation Summary	Special Considerations
NSAIDs	Ibuprofen suspension and doses above 200mg Indomethacin 25mg Ketoprofen 50mg,75mg Ketorolac Meloxicam 7.5,15mg Naproxen 250mg,375mg,500mg Naproxen sodium 275mg,550mg Naproxen 375mg, 550mg enteric coated tablets Piroxicam Salsalate	No significant differences exist among the agents in regards to safety or efficacy. At least 3 agents should be available.	None.
ADD/ADHD	Amphetamine salts <b>Adderall XR</b> <b>Focalin</b> <b>Focalin XR</b> <b>Concerta</b> <b>Daytrana</b> Methylphenidate tablets	At least 1 IR and SR methylphenidate and amphetamine preparation should be available. Absent some co-morbidities, methylphenidate and amphetamines are more likely to be appropriate initial choices than atomoxetine.	Patients compliant on non-preferred agents.

# FINANCIAL IMPACT OF PDL SELECTIONS

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## COST SAVINGS TO THE STATE RESULTING FROM THE PDL

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### **METHOD OF ESTIMATING COSTS AVOIDED/SAVINGS**

Products placed on the Preferred Drug List (PDL) represent therapies with proven advantages over other alternatives, or cost-effective selections in categories where no important differences between products can be found. Even though the foundation of the PDL is clinical, it has impacted the net medication costs for Arkansas Medicaid. Estimates of the cost impact of PDL selections are presented in this section. The costs for a medication category could be either increased or decreased as a consequence of the PDL.

Several factors make it likely that medication costs in a drug category will decrease after preferred agents are selected. First, manufacturers of patent-protected, single source products offer supplemental rebates to Arkansas Medicaid in consideration of inclusion on the Preferred Drug List. Selection as a preferred agent has significant impact on product sales and market share, and manufacturers often generate higher sales from Arkansas Medicaid if their products are selected as preferred agents. These supplemental rebate offers ensure Arkansas Medicaid lower net costs than without the PDL. Second, there are situations where no important clinical differences exist among the medications in a category. In many cases there are less expensive, equally effective generic medications available at lower costs than single source agents in a drug category. Where there is the opportunity to gain all important clinical benefits offered by a group of drugs, while using a lower cost agent, these agents are selected for the PDL.

These estimates of medication costs avoided are calculated with estimates of the Medicaid net cost per prescription. Two estimates of net costs are made. One value is based on the weighted average net cost per prescription in a drug category immediately prior to the preferred drug selection. This average net cost per prescription represents the expected Medicaid net cost which would have been incurred without the PDL. It is important to remember that the estimated expected Medicaid net cost is not adjusted for price increases imposed after the PDL effective date for the category. Multiplying the expected net cost per prescription by the total number of prescriptions dispensed in the current period yields the Estimated Expected Costs. The second estimate is based on current Medicaid net costs for preferred agents. These costs are multiplied by the prescription volumes for each preferred drug. The total net costs estimated for each of the non-preferred drugs currently used is added to this result. This estimate is called the Post-PDL Net Cost Estimate. The difference between the Estimated Expected Costs and the Post-PDL Net Cost Estimate is our estimate of costs avoided (or incurred) as a consequence of the PDL.

The reported savings or costs avoided do not consider the impact of PDL decisions on total care costs. There may be either increases or decreases in others categories of Medicaid spending as a result of the PDL. There may also be shifts to or from particular drug categories as a consequence of the PDL recommendations. Along with the EBRx staff, UAMS' College of Pharmacy, Pharmaceutical Evaluation and Policy Division conducts ongoing analyses and reviews of the impact of the PDL on total Medicaid costs.

## **OVERALL RESULTS**

Due to difficulty with data extraction, financial information is not available at this time. An addendum to the quarterly report containing the financial information will be released as soon as it becomes available. There were no significant changes in the most recent quarter, and financial results are expected to be similar to those reported in the prior Quarterly Report.

# Prior Authorization Call Center Statistics

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

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“Non-preferred” medications continue to be available to Medicaid recipients, but require prior authorization. Two processes are in place to provide prior authorization. The first is a computer-based system called Smart-PA. If the patient meets predetermined authorization guidelines, Smart-PA can grant an instantaneous prior authorization at the pharmacy counter with no additional effort by the provider or pharmacist. This occurs as a prescription claim is processed at the pharmacy

The second prior authorization process is the PDL Call Center. This center approves or denies prior authorization requests from physicians for products that have been placed in non-preferred status. The approval, denial, and appeal of denials are handled by the clinical pharmacists and medical directors of the EBRx Program. The statistics below represent the Call Center’s activity for calendar year 2007 and the most recent quarter, 4Q 2007, which includes October 1, 2007 through December 31, 2007.

<b>PA Call Center Statistics</b>	<b>1Q 2007</b>	<b>2Q 2007</b>	<b>3Q 2007</b>	<b>4Q 2007</b>	<b>2007 Total</b>
Incoming Calls from Healthcare Professionals	<b>3039</b>	<b>5423</b>	<b>8441</b>	<b>7029</b>	<b>23,932</b>
Number of SmartPA Tickets Created	<b>2346</b>	<b>4527</b>	<b>5766</b>	<b>4382</b>	<b>17,021</b>
Total Number of P.A. Requests at the Call Center	<b>1691</b>	<b>2973</b>	<b>5362</b>	<b>4017</b>	<b>14,043</b>
Total Number of P.A. Requests Approved at the Call Center	<b>1222</b>	<b>1993</b>	<b>3888</b>	<b>2944</b>	<b>10,047</b>
Call Center P.A. Approval Percentage	<b>72%</b>	<b>67%</b>	<b>73%</b>	<b>73%</b>	<b>72%</b>
Point of Sale SmartPA Requests	<b>42,935</b>	<b>99,637</b>	<b>161,037</b>	<b>170,859</b>	<b>474,468</b>
Point of Sale SmartPA Approvals	<b>26,268</b>	<b>68,858</b>	<b>126,153</b>	<b>140,288</b>	<b>361,567</b>
Point of Sale SmartPA Approval Percentage	<b>61%</b>	<b>69%</b>	<b>78%</b>	<b>82%</b>	<b>76%</b>
Average Call Duration	<b>1 min 57 sec</b>	<b>2 min 29 sec</b>	<b>2 min 35 sec</b>	<b>2 min 16 sec</b>	<b>2 min 19 sec</b>

# Budget Update

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## A GENERAL OVERVIEW OF THE PROGRAM BUDGET

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The Arkansas Medicaid Evidence-based Prescription Drug Program budget and expenditures to date are presented below. There remain a number of personnel positions initially budgeted but not filled. If needs for additional program personnel arise, the program will work within the existing budget to ensure that service obligations are met. At the end of 4Q 07, the program was approximately \$3,163,366 under budget for the current fiscal year.

	<b>SFY08 Budget</b>	<b>SFY08 Expenditures To Date</b> (through December 31, 2007)
<b>Personnel –(Salary and Fringes, includes DRC stipends)</b>	2,496,381	587,353
<b>Miscellaneous – (Supplies, Travel, etc)</b>	150,750	14,086
<b>Equipment – (computers, phones, furniture, renovation)</b>	13,000	0
<b>Indirect Costs</b>	1,429,451	324,777
<b>TOTAL</b>	<b>4,089,582</b>	<b>926,216</b>

# Data Evaluation

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## TRACKING OUTCOMES OF THE PDL DECISIONS

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### **PEP Division Activities**

One of the most important aspects of the EBRx program is the evaluation of Medicaid data to determine what the long term ramifications of the PDL decisions are. Through the College of Pharmacy's Pharmaceutical Evaluation and Policy (PEP) Division, the Medicaid claims database is analyzed to determine impacts to the Medicaid program, beyond potential changes in medication costs.

There have been no new analyses generated in the PEP division relating to the Evidence-based Prescription Drug Program. A new set of graduate students have started with the program. As the year progresses, more PEP division analyses should be forthcoming.

### **Other EBRx Activities**

Work continues on the grant project funded by the Attorney General Consumer and Prescriber Grant Program. This program was funded from the settlement paid by Pfizer/Pharmacia relating to illegal promotion of Neurontin (gabapentin) for uses not approved by the FDA. UAMS College of Pharmacy was awarded \$370,000 over two years to study approaches to influence prescribers of medications for uses which are not approved by the Food and Drug Administration.

The project will focus on uses of antidepressants in Arkansas children. An outline of the educational curriculum has been prepared, and in coming months will be further developed with the assistance of the Arkansas Foundation for Medical Care. The Quality Improvement Organization will also assist in delivering the educational curriculum to Arkansas providers, as a subcontractor to the grant program.

Analysis of PA call center activities for ADHD medications was conducted by EBRx personnel in December. This information was sent earlier to DHS and other interested parties. A copy of this analysis is included as an appendix.

# Drug Review Committee

## Activities

Date: October 18, 2007

Subject: DRC Recommendations to DCC and DHS

To: DHS, DCC, Dean's Office

From: Henry F. Simmons, Jr., MD, Ph.D.  
Chairman DRC

At its 10/18/07 meeting, the Drug Review Committee considered the potential toxicity and therapeutic roles of the angiotensin converting enzyme inhibitor [ACEIs] class in the management of adult patients with hypertension, recent myocardial infarction, heart failure, diabetic nephropathy, non-diabetic nephropathy, and high cardiovascular risk. [For the purposes of the discussion, high cardiovascular risk was defined as CHD/CVD or a combination of other risk factors for CHD/CVD, such as diabetes, smoking, hyperlipidemia, or hypertension.]

The medications discussed included the following:

- Benazepril (Lotensin)
- Captopril (Capoten)
- Enalapril (Vasotec)
- Fosinopril (Monopril)
- Lisinopril (Prinivil, Zestril)
- Moexepiril (Univasc)
- Perindopril (Aceon)
- Quinapril (Accupril)
- Ramipril (Altace)
- Trandolapril (Mavik)

Based upon the bulk of the best available evidence pertaining to the aforementioned drugs the Committee concluded the following:

There is insufficient evidence to conclude in general that one agent is safer or has fewer adverse effects than another.

There is sufficient evidence to conclude that all of the listed ACEIs are efficacious for the treatment of hypertension. However, since captopril, enalapril and lisinopril have outcome data, at least one of these three should be available for this indication.

There is sufficient evidence to conclude that captopril, ramipril, trandolapril, lisinopril, and perindopril are efficacious for treatment of patients with recent myocardial infarction. However, since the first three have mortality outcome data, at least one of them should be available for this indication.

There is sufficient evidence to conclude that captopril, enalapril, fosinopril, ramipril and trandolapril are efficacious for the treatment of heart failure outside the setting of recent myocardial infarction. Accordingly, at least one of the five should be available for this indication.

There is sufficient evidence to conclude that captopril is efficacious for the treatment of diabetic nephropathy in type I diabetics. It should be available for this indication.

There is sufficient evidence to conclude that benazepril, captopril, lisinopril, perindopril and ramipril are efficacious for the treatment of non-diabetic nephropathy. However, since the evidence is strongest for benazepril and ramipril, at least one of these two agents should be available.

There is sufficient evidence to conclude that enalapril, perindopril, quinapril and ramipril are efficacious for patients at high risk of cardiovascular disease as defined above. However, since the evidence is strongest for ramipril, it should be available for this indication.

There is insufficient evidence to conclude in general that one agent out of the group is either more efficacious or associated with more adverse effects based upon demographics, comorbidities or adverse drug interactions.

At least one ACEI with single daily dosing should be available for patients for whom multiple dosing poses special problems.

Date: November 15, 2007

Subject: DRC Recommendations to DCC and DHS

To: DHS, DCC, Dean's Office

From: Henry F. Simmons, Jr., MD, Ph.D.  
Chairman DRC

At its 11/15/07 meeting, the Drug Review Committee considered the potential toxicity and therapeutic roles of selected antihistamines in children and adults with seasonal allergic rhinitis [SAR], perennial allergic rhinitis [PAR] and chronic idiopathic urticaria [CIU].

The medications discussed included the following:

Cetirizine [Zyrtec]  
Desloratidine [Clarinex]  
Fexofenadine [Allegra]  
Loratidine [Claritin]

Based upon the bulk of the best available evidence pertaining to the aforementioned drugs the Committee concluded the following:

1. None of the four drugs presents a special risk relative to the others.
2. Cetirizine, desloratidine, loratidine and fexofenadine do not differ in efficacy for treatment of SAR, PAR and CIU in adults and children to the degree that one should be preferred over another.
3. Aside from pregnant patients for whom either cetirizine or loratidine should be available, none of the drugs offers a special benefit to other subgroups in either improving total symptom scores or reducing adverse effects.

Henry F. Simmons, Jr.  
Chairman, DRC