

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 – FIRST 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 (removed after PDL contract expired)</b> Nifedipine ER tablets Verapamil SR tablets	At least 1 product from each of the three sub-classes of calcium channel blockers should be available, no significant difference in outcomes with equipotent dosing.	Dosage strengths of extended release diltiazem
Beta Blockers	Atenolol Metoprolol tartrate Propranolol IR Bisoprolol (only for CHF) <b>Toprol XL (only for CHF)</b>	3 agents superior for treatment of congestive heart failure, few advantages for one agent over another for all other uses.	Diagnosis of symptomatic 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
Serotonin 5-HT <sub>1</sub> Receptor Agonists (triptans)	<b>Maxalt</b> <b>Maxalt MLT</b>	No significant difference among 5 of the 7 agents that any one agent is clinically superior to another agent.	Nasal spray and injectable formulations
Angiotensin II Receptor Blockers	<b>Cozaar, Hyzaar</b> <b>Diovan, Diovan HCT</b>	No significant advantage or disadvantage among the agents.	Congestive Heart Failure

<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>
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>	No significant differences among the agents.	None
Targeted Immune Modulators	<b>Enbrel</b> <b>Humira</b>	No differences found, but generally lacking comparative data for analysis.	Subject to previous DUR clinical edits
Inhaled Corticosteroids	<b>Asmanex</b> <b>Azmacort</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
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-thiazolidinediones	<b>Actos 30mg, 45mg</b> <b>Actosplus Met</b> <b>Avandamet</b> <b>Avandaryl</b> <b>Avandia</b>		
Nasal Corticosteroids	<b>Nasacort AQ</b> <b>Nasonex</b>		

# 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**

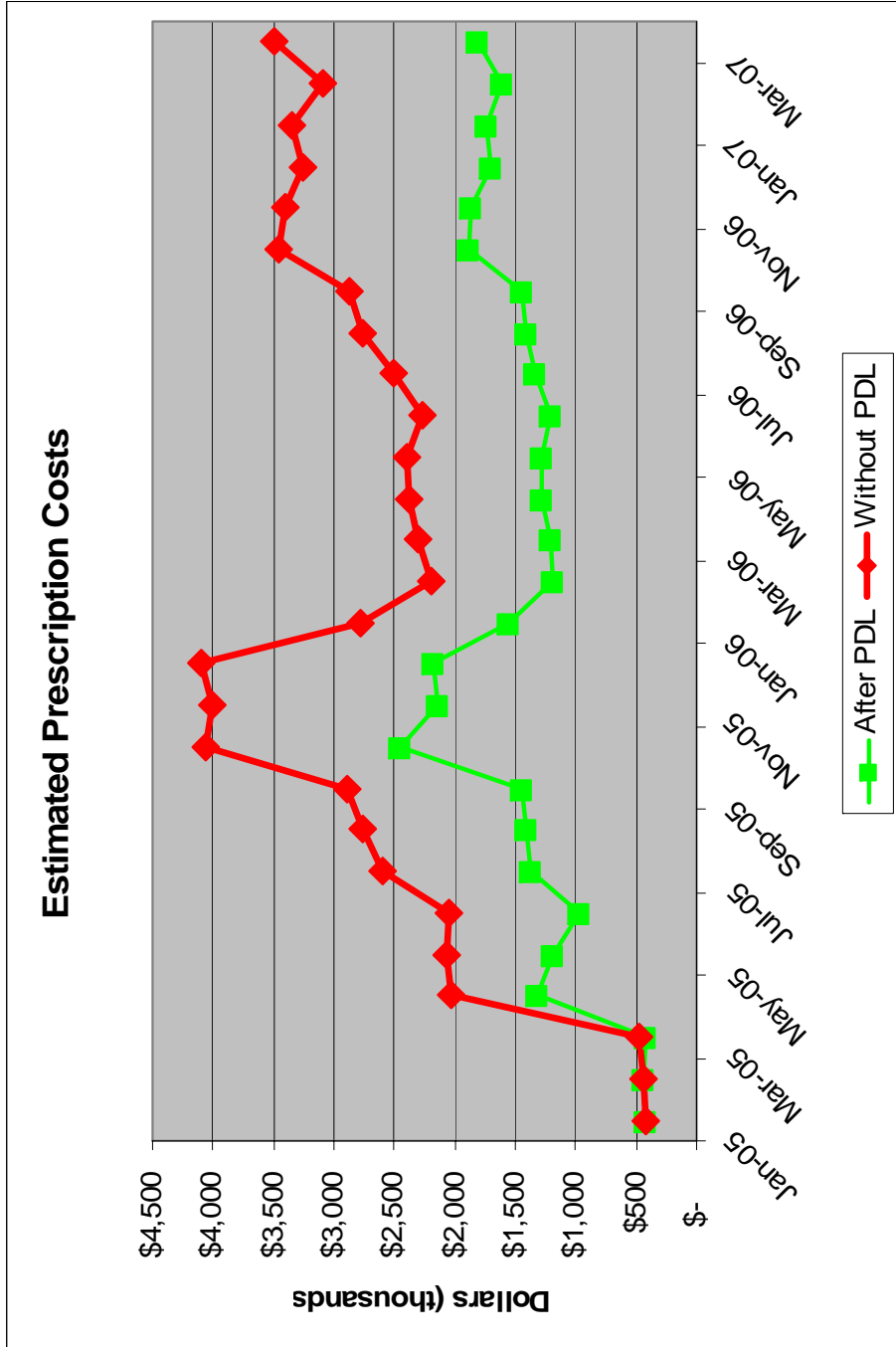
Products placed on the Preferred Drug List (PDL) represent therapies with proven advantages over other alternatives, or cost-effective selections in categories where no important differences between products can be found. Even though the foundation of the PDL is clinical, it has impacted the net medication 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.

# Graph 1



## OVERALL RESULTS

The first PDL selection became effective March 25, 2005. By the end of March, 2007 preferred drugs had been selected and implemented in eighteen drug classes. Since the first PDL selection, EBRx estimates that the PDL process has yielded potential savings/excess costs avoided of at least \$32 million. Table 1 shows implementation dates, and costs avoided or incurred for each category reviewed.

TABLE 1 – Summary of Estimated Prescription Costs Avoided to Date by Category

Drug Category	PDL Effective Date	Costs Avoided/Potential Savings or Costs Incurred Estimates		
		State Fiscal Year 05	State Fiscal Year 06	State Fiscal Year 07 (to date)
Less Sedating Antihistamines	3/25/05	\$ 810,000	\$ 2,340,000	\$ 1,750,000
Proton Pump Inhibitors	5/18/05	\$ 1,680,000	\$ 8,540,000	\$ 4,870,000
“Statin” Cholesterol Agents	6/8/05	\$ 240,000	\$ 1,940,000	\$ 1,990,000
Calcium Channel Blockers	7/12/05	\$ -	\$ 580,000	\$ 210,000
Beta Blockers	10/5/05	\$ -	\$ 650,000	\$ 380,000
Long-Acting Opioids	10/26/05	\$ -	\$ 1,240,000	\$ 1,100,000
ACE Inhibitors	11/16/05	\$ -	\$ 290,000	\$ 180,000
“Triptan” Antimigraine Agents	2/7/06	\$ -	\$ 120,000	\$ 210,000
Angiotensin Receptor Blockers	2/21/06	\$ -	\$ 140,000	\$ 230,000
Skeletal Muscle Relaxers	3/20/06	\$ -	\$ 100,000	\$ 290,000
Estrogens	4/17/06	\$ -	\$ 20,000	\$ 80,000
Sedative Hypnotics (Sleep Aids)	5/9/06	\$ -	\$ 100,000	\$ 410,000
Targeted Immune Modulators	6/13/06	\$ -	\$ (20,000)	\$ 20,000
Inhaled Corticosteroids	7/11/06	\$ -	\$ -	\$ 830,000
Overactive Bladder Agents	8/15/06	\$ -	\$ -	\$ 130,000
Newer Antiemetics	10/10/06	\$ -	\$ -	\$ (60,000)
Oral Diabetes Agents	11/28/06	\$ -	\$ -	\$ 240,000
Nasal Steroids	11/28/06	\$ -	\$ -	\$ 550,000
<b>Grand Total</b>		<b>\$ 2,730,000</b>	<b>\$ 16,030,000</b>	<b>\$ 13,400,000</b>

# MARKET SHARE IMPACT OF PDL RECOMMENDATIONS

The success of the PDL depends in large part on participation by prescribers with the recommendations of the Drug Review and Drug Utilization and Cost Committees. Prescribing compliance with the Preferred Drug List is monitored by EBRx. The following table presents data on the percentage of prescriptions that were filled for preferred product(s) in each of the therapeutic categories reviewed and implemented to date. This percentage is commonly called market share in the pharmaceutical industry. Outcomes and cost savings are maximized as market share approaches 100 percent compliance with the Preferred Drug List recommendations. However, it should be noted that complete compliance with the Preferred Drug List is unlikely as there remains individual variation in response to any medicine.

**Percent Market Share of PDL Preferred Agents by Drug Class and Month**

	Apr 06	May 06	Jun 06	July 06	Aug 06	Sept 06	Oct 06	Nov 06	Dec 06	Jan 07	Feb 07	March 07
<b>Less Sedating Antihistamines</b>	87	86	82	82	84	85	84	84	83	84	84	86
<b>Proton Pump Inhibitors</b>	100	100	100	99	100	100	100	100	100	100	100	100
<b>Statins</b>	99	99	99	99	98	98	98	98	99	98	98	98
<b>Calcium Channel Blockers</b>	96	97	97	96	95	95	96	96	96	95	95	95
<b>Beta Blockers</b>	91	92	91	91	92	91	91	91	92	91	91	91
<b>Long-acting Opioids</b>	81	83	82	83	80	81	83	83	81	82	83	80
<b>ACE Inhibitors</b>	77	78	79	79	78	78	78	78	79	77	78	76
<b>Triptans</b>	90	85	88	86	88	87	87	88	88	87	85	89
<b>ARBs</b>	100	100	100	100	100	100	100	100	100	100	100	100
<b>Skeletal Muscle Relaxers</b>	99	99	99	99	99	99	99	99	99	99	99	99
<b>Estrogens</b>	<b>32</b>	93	93	92	91	93	92	91	93	91	92	91
<b>Newer Sleep Aids</b>	27	<b>60</b>	100	99	100	100	99	100	100	99	100	99
<b>Targeted Immune Modulators</b>	91	84	<b>87</b>	85	81	86	82	77	88	82	76	76
<b>Inhaled Corticosteroids</b>	67	70	72	<b>80</b>	84	83	84	83	82	79	81	83
<b>Overactive Bladder Agents</b>	54	54	56	55	<b>71</b>	89	89	89	93	88	89	91
<b>Newer Antiemetics</b>	89	94	90	89	88	86	<b>93</b>	96	98	96	95	98
<b>Oral Diabetes Agents</b>	66	66	65	66	67	66	66	<b>67</b>	66	67	65	64
<b>Nasal Steroids</b>	39	40	36	36	37	38	46	<b>53</b>	100	100	100	100

Data in bold highlight the month PDL recommendations for the drug class became effective.

# 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 the FY 2007, which includes July 1<sup>st</sup> 2006 through March 31, 2007.

<b>PA Call Center Statistics</b>	<b>3Q 2006</b>	<b>4Q 2006</b>	<b>1Q 2007</b>	<b>FY To Date</b>
Incoming Calls from Healthcare Professionals	<b>2940</b>	<b>2939</b>	<b>3039</b>	<b>8918</b>
Number of SmartPA Tickets Created	<b>2928</b>	<b>2226</b>	<b>2346</b>	<b>7500</b>
Total Number of P.A. Request at the Call Center	<b>1649</b>	<b>1473</b>	<b>1691</b>	<b>4813</b>
Total Number of P.A. Requests Approved at the Call Center	<b>1153</b>	<b>1014</b>	<b>1222</b>	<b>3389</b>
Call Center P.A. Approval Percentage	<b>70%</b>	<b>68%</b>	<b>72%</b>	<b>70%</b>
Point of Sale SmartPA Requests	<b>36,736</b>	<b>40,527</b>	<b>42,935</b>	<b>120,198</b>
Point of Sale SmartPA Approvals	<b>23,389</b>	<b>27,393</b>	<b>26,268</b>	<b>77,050</b>
Point of Sale SmartPA Approval Percentage	<b>64%</b>	<b>68%</b>	<b>61%</b>	<b>64%</b>
Average Call Duration	<b>2 min 14 sec</b>	<b>1 min 57 sec</b>	<b>1min 57 sec</b>	<b>2 min 3 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 the third quarter of SFY 07, the program is approximately \$1,500,000 under budget from July 1, 2006 through March 31, 2007.

	<b>SFY07 Budget</b>	<b>SFY07 Expenditures To Date</b> <small>(through March. 31, 2007)</small>
<b>Personnel –(Salary and Fringes, includes DRC stipends)</b>	\$2,341,514	\$852, 312.64
<b>Miscellaneous – (Supplies, Travel, etc)</b>	\$160,750	\$24,720.44
<b>Equipment – (computers, phones, furniture, renovation)</b>	\$0	\$0
<b>Indirect Costs</b>	\$1,351,223	\$473,597.86
<b>TOTAL</b>	<b>\$3,856,487</b>	<b>\$1,350,630.90</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.

The PEP division has produced analyses of the impact of four PDL category decisions to estimate the prescription cost impact of the policies of the affected drugs and potential substitute drugs. The categories that have been evaluated are Less Sedating Antihistamines for allergy, Proton Pump Inhibitors for acid reflux, "Statin" cholesterol medicines and Calcium Channel Blocker blood pressure medications. Currently the PEP division is investigating the impact of the PDL on statin adherence/persistence and the impact of the ACE inhibitor PDL on prescription costs. The next analysis will be to assess the impact of the long acting opioid PDL. The analyses describing the impact of the less sedating antihistamine and statin PDLs were presented at the Academy of Managed Care Pharmacy Annual Meeting as poster presentations in April 2007. The abstracts describing a summary of the methods and result highlights appear below. A more detailed description of the methods and study findings are available upon request. The analyses of the impact of the calcium channel blocker and proton pump inhibitors have been accepted for presentation at the International Society for Pharmacoeconomics and Outcomes Research annual meeting in May

#### **Costs Reductions Attained from an Evidence Based Preferred Drug List Policy on Less Sedating Antihistamines in a Medicaid Population**

Martin BC, Karve S, Helm M, Division of Pharmaceutical Evaluation and Policy, University of Arkansas for Medical Sciences, 4301 W. Markham Street, slot#522, Little Rock, AR, 72205, bmartin@uams.edu, 501.603.1992

**Introduction:** On March 25, 2005, the Arkansas Medicaid program implemented a prior approval policy whereby all less sedating antihistamines (LSA), except loratidine, required prior approval to be reimbursed. **Purpose:** The objective of this study was to estimate the impact of this policy on LSA costs and utilization as well as utilization of possible substitute drugs; leukotriene inhibitors, nasal steroids and other antihistamines. **Methods:** This study utilized a time series panel design to evaluate the impact of the policy using Arkansas Medicaid administrative claims data obtained from January 2003 through May 2006. Auto-Regressive Integrated Moving Average (ARIMA) time series models were specified using monthly prescription expenditures and utilization in the pre-policy period (January 2003 – February 2005) to forecast expenditures and utilization in the post-policy period. Differences between post-policy forecasts and actual expenditures were calculated to estimate cost reductions. The Medicaid payer perspective was used and all prescription costs were calculated based on the amount paid for each claim adjusted for product specific CMS rebates. **Results:** Annual LSA forecast expenditures for April 2005 – March 2006 were \$6,650,590 and observed expenditures were \$1,954,280 indicating that the prior approval policy was associated with a 71% reduction in LSA expenditures or \$4,696,310 (95%CI: \$3,546,819 – 5,845,801) in annual savings. The policy was associated with a 29% (95%CI: 14%-45%) reduction in total LSA utilization. The proportion of non-preferred LSA utilization was reduced from 98% to 18% after the policy. There were no significant changes observed for leukotriene inhibitors, other antihistamines, and nasal steroid utilization through December

2005. Conclusions: The prior approval policy for LSA resulted in substantial cost reductions to AR Medicaid of approximately \$400,000 per month without increasing the utilization of leukotriene inhibitors, other antihistamines, or nasal steroids.

### **Cost Reductions Attained from an Evidence Based Preferred Drug List Policy on HMG-CoA Reductase Inhibitors in a Medicaid Population**

Martin BC, Pathak P, Helm M, Division of Pharmaceutical Evaluation and Policy, University of Arkansas for Medical Sciences, 4301 W. Markham Street, slot#522, Little Rock, AR, 72205, bmartin@uams.edu, 501.603.1992

Introduction: On June 8, 2005, the Arkansas Medicaid program implemented a prior approval policy whereby all HMG-CoA reductase inhibitors (statins), except simvastatin, required prior approval to be reimbursed. Purpose: The objective of this study was to estimate the impact of this policy on statin costs and utilization as well as utilization of non-statin antihyperlipidemic drugs. Methods: This study utilized a time series panel design to evaluate the impact of the policy using Arkansas Medicaid administrative claims data obtained from January 2003 through May 2006. Auto-Regressive Integrated Moving Average (ARIMA) time series models were specified using monthly prescription expenditures and utilization in the pre-policy period (January 2003 – May 2005) to forecast expenditures and utilization in the post-policy period. Differences between post-policy forecasts and actual expenditures were calculated to estimate cost reductions. The Medicaid payer perspective was used and all prescription costs were calculated based on the amount paid for each claim adjusted for product specific CMS rebates. Results: Annual statin forecast expenditures for June 2005 – May 2006 were \$6,939,193 and observed expenditures were \$4,437,322 indicating that the prior approval policy was associated with a 36% reduction in statin expenditures or \$2,501,872 (95%CI: \$2,235,607-\$2,768,136) in annual cost reductions. Smaller monthly cost reductions occurred after the Medicare Part-D implementation. The policy was associated with a 6% (95%CI: 3%-10%) reduction in total statin utilization. Prescription utilization of non-statin antihyperlipidemics increased 10% (95%CI: 5%-15%) over trend forecasts translating to annual increase in costs of \$157,674 (95%CI: \$105,095-\$210,252). The non-statin increased utilization consisted mostly of ezetimibe, however, the increase in non-statin antihyperlipidemics did not fully offset the decrease in statin utilization. Conclusions: The statin prior approval policy resulted in substantial antihyperlipidemic cost reductions to AR Medicaid of approximately \$195,000 per month. Further study is necessary to determine if the policy affected persistence and adherence with antihyperlipidemic therapy.

### **Other EBRx Activities**

At the end of 2006, both programmers for the EBRx program found other employment, closer to their families. Recruitment for new programmers occupied part of the first quarter, these new staff members are now working to overcome the backlog of work accumulated in the first quarter.

Research activities arising from the EBRx project were highlighted at two conferences in the first quarter. At the Southern Society for Pediatric Research, two projects were presented. Information on the prevalence of use of atypical antipsychotic in the pediatric population was presented. Additionally, an analysis of the consequences of selecting loratadine as the preferred less-sedating antihistamine on patients with allergic rhinitis was presented. The findings of this analysis were consistent with previous analyses which showed no

significant impact on patient care, and considerable cost savings. Both projects are being developed as manuscripts for submission to scientific journals.

A poster of the analysis of Advair use in the Arkansas Medicaid program was presented at the American Academy of Allergy, Asthma and Immunology convention. The information and the poster were well received. This poster was also shared with some individuals at the Association of Managed Care Pharmacy. The individuals at this convention encouraged development of these data into a manuscript for potential publication.

In preparation for the Beta Agonist review, EBRx staff recognized an opportunity to examine the frequency of use of Short Acting Beta Agonist (SABA) rescue medications. This examination was completed in April and presented at the Drug Utilization Review board. The DUR board has elected to use a DHHS contractor to provide notification to providers when their asthma patients refill their SABA medications too frequently. To frequent use of an SABA is one indicator of poor asthma control.

# Drug Review Committee

## Activities

- January 11, 2007 – DRC Meeting  
Meeting was for Public Comment only for Beta 2 Agonists
- February 16, 2007 – DRC Meeting

Subject: DRC Recommendations to DCC and DHS

To: DHHS, DCC, Dean's Office

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

At its 02/15/07 meeting, the Drug Review Committee considered the potential toxicity and therapeutic roles of selected inhaled beta 2 agonists.

### **Long acting inhaled beta2 agonists [LABAs]**

Formoterol (Foradil Aerolizer)

Salmeterol (Servent Diskus)

### **Short- acting Inhaled beta2 agonists [SABAs]**

Albuterol (Ventolin, Proventil)

Levalbuterol (Xopenex)

Pirbuterol (Exirel, Maxair)

Metaproterenol (Alupent)

### **Indications**

Asthma, exercise-induced asthma, exercise induced asthma prophylaxis, and chronic obstructive pulmonary disease in adults in outpatient settings

Asthma, exercise induced asthma, and exercise induced asthma prophylaxis in children in outpatient settings

### **Discussion**

The Committee reached the following conclusions unanimously based upon its perception of the bulk of the best available evidence:

### **Safety Adverse Events**

1. Neither of the LABAs listed above is associated with a greater risk of either adverse events or lesser safety when used to treat adults in the outpatient setting with the captioned indications.

2. None of the SABAs listed above are associated with a greater risk of either adverse events or lesser safety when used to treat adults in the outpatient setting with the captioned indications?

3. Neither of the LABAs listed above is associated with a greater risk of either adverse events or lesser safety when used to treat children in the outpatient setting with the captioned indications.

4. None of the SABAs listed above is associated with a greater risk of either adverse events or lesser safety when used to treat children in the outpatient setting with the captioned indications.

### **Efficacy/Effectiveness**

5. Neither of the LABAs listed above is superior to the other in either efficacy or effectiveness for treating adults in the outpatient setting with the captioned indications.

6. None of the SABAs listed above is superior to the others in either efficacy or effectiveness for treating adults in the outpatient setting with the captioned indications.

7. Neither of the LABAs listed above is superior to the others in either efficacy or effectiveness for treating children in the outpatient setting with the captioned indications.

8. None of the SABAs listed above are superior to the others in either efficacy or effectiveness for treating children in the outpatient setting with the captioned indications.

### **Demographics**

9. Neither of the LABAs listed above when used to treat the captioned indications is likely to be more efficacious, more effective, or associated with fewer adverse events on the basis of a patient's age, race, gender, concomitant medications, comorbidities or pregnancy status than the other.

10. None of the SABAs listed above when used to treat the captioned indications are likely to be more efficacious, more effective, or associated with fewer adverse events on the basis of a patient's age, race, gender, concomitant medications, comorbidities or pregnancy status than the others. However, if pirbuterol is the only SABA chosen, then an alternative should be available for children less than 12 years of age.

➤ Date: March 22, 2007

Subject: DRC Recommendations to DCC and DHS

To: DHHS, DCC, Dean's Office

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

At its 03/22/07 meeting, the Drug Review Committee considered the potential toxicity and therapeutic roles of selected NSAIDs.

**NSAIDs under consideration**

- Celcoxib (Celebrex)
- Diclofenac sodium (Voltaren, Voltaren-XR)
- Diclofenac potassium (Cataflam)
- Diflunisal (Dolobid)
- Etodolac (Lodine, Lodine XL)
- Fenoprofen (Nalfon)
- Flurbiprofen (Ansaid)
- Ibuprofen (Motrin)
- Indomethacin (Indocin, Indocin SR)
- Ketoprofen
- Ketoprofen XR (Oruvail)
- Ketorolac (Toradol)
- Meclofenamate
- Mefanamic acid
- Meloxicam (Mobic)
- Nabumetone (Relafen)
- Naproxen
- Naproxen delayed release
- Naproxen sodium (Anaprox, Anaprox DS, Naprelan)
- Oxaprozin (Daypro)
- Piroxicam (Feldene)
- Salsalate (Disalcid)
- Sulindac (Clinoril)
- Tolmetin (Tolectin)

**Indications under consideration in adults and children**

Acute pain of diverse etiology and chronic pain from osteoarthritis, rheumatoid arthritis, soft tissues, or the back including ankylosing spondylitis.

## Discussion

The Committee reached the following conclusions unanimously based upon its perception of the bulk of the best available evidence:

1. Based upon the bulk of the available data, for patients in the captioned groups with chronic pain the available coxibs, other NSAIDs, or NSAIDs plus an antiulcer medication with the exception of ketorolac do not differ in **long term** safety or adverse events to the degree that one or more should be stricken from further consideration.

Therapy with ketorolac should not exceed five days.

2. Based upon the bulk of the available data, for patients in the captioned groups with chronic pain the available coxibs, other NSAIDs, or NSAIDs plus an antiulcer medication do not differ in **short term** safety or adverse events to the degree that one or more should be stricken from further consideration.

3. Based upon the bulk of the available data, for patients in the captioned groups with chronic pain there are no clinically significant differences in effectiveness between the available coxibs and other NSAIDs.

However, at least three different agents should be available.

4. Based upon the bulk of the available data, for patients in the captioned groups with chronic pain are there subgroups based upon demographics, other medications (e.g. aspirin), or comorbidities for which one medication is more effective or associated with fewer adverse effects?

5. Upon consideration of issues related to demographics, comorbidities, pregnancy and other medications the Committee offers the following advice to DCC and DHS in lieu of formal recommendations.

Ibuprofen liquid should be available for the pediatric population.

If a pregnant patient requires an NSAID, naproxen or flurbiprofen should be available.

NSAIDs pose significant risks in the third trimester.

Naproxen should be available if an NSAID is required for a patient with increased cardiac risk factors.

Patients with hepatic disease who require an NSAID should have an alternative to both sulindac and diclofenac.

There are multiple ways to treat patients with a perceived increased risk of adverse GI effects.

All of the agents pose additional risk when administered with anticoagulant medications or aspirin.