

UNIVERSITY OF ARKANSAS
FOR MEDICAL SCIENCES
COLLEGE OF PHARMACY

ARKANSAS MEDICAID EVIDENCE-BASED PRESCRIPTION DRUG PROGRAM (EBR_x)

QUARTERLY REPORT – FOURTH QUARTER 2008



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INTRODUCTION

OVERVIEW OF THE EVIDENCE-BASED PRESCRIPTION DRUG PROGRAM

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

PDL CATEGORIES, SELECTIONS, RATIONALE, AND SPECIAL CONSIDERATIONS

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	omeprazole capsules Nexium capsules *Prevacid Solutabs Prevacid capsules (removed after re-review effective 4/1/08)	No difference in outcomes with equipotent dosing	*Patients under age 7 years, Patients with feeding tubes
HMG-CoA Reductase Inhibitors (statins)	Zocor (generic now available) pravastatin	Two of the three agents that have both primary and secondary outcome data should be available	Need for more potent agent
Calcium Channel Blockers	diltiazem ER capsules (equiv to Dilacor XR) Dynacirc CR Norvasc 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) Toprol XL (only for CHF) (generic now available) 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 Opana ER	No clinical advantage for one agent over another for treatment of chronic pain.	Terminal cancer diagnosis, Patients with long-term care eligibility, Patients unable to swallow pills
Angiotensin-Converting Enzyme (ACE) Inhibitors	Altace (generic now available) benazepril lisinopril captopril benazepril/amlodipine	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

Medication Class	Medicaid Preferred Agents (Brand Name Agents in Bold)	Drug Review Committee Recommendation Summary	Special Considerations
Serotonin 5-HT1 Receptor Agonists (triptans)	Maxalt Maxalt MLT Imitrex tablets, nasal spray, injection Trexima	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	Cozaar, Hyzaar Diovan, Diovan HCT Benicar, Benicar HCT Azor Exforge	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
Hormone Replacement	estradiol 0.5mg,1mg,2mg estropipate	No difference in the products at equipotent doses.	Dosage forms, combination products
Non-Benzodiazepine Sedative Hypnotics	Ambien CR Rozerem Sonata zolpidem	No significant differences among the agents.	None
Targeted Immune Modulators	Enbrel Humira Raptiva	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 DUR clinical edits
Inhaled Corticosteroids	Asmanex Azmacort (removed after contract terminated) Flovent (only to age 12)	No significant differences among the products at equipotent doses	Patients under age of 12 years
Anticholinergics for Overactive Bladder	Detrol LA oxybutinin syrup,5mg tablet Vesicare	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	Nasacort AQ Nasonex	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	Starlix	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	Actos 30mg, 45mg Actosplus Met Avandamet Avandaryl Avandia		
Antidepressants	bupropion regular release citalopram fluoxetine 10mg,20mg caps, 20mg/5ml solution Lexapro 10mg,20mg mirtazapine 15mg,30mg,45mg paroxetine Pexeva sertraline venlafaxine regular release Wellbutrin XL (generic now available)	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 ₂ Agonists	Short Acting albuterol 90mcg inhaler albuterol 5mg/ml soln albuterol 0.83mg/ml soln Maxair Autohaler Proair HFA Ventolin HFA Long Acting Serevent Diskus	No significant differences among the agents in regards to efficacy or safety.	Long acting agents still subject to 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 strengths 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 Adderall XR Focalin Focalin XR Concerta Daytrana 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.
Neuropathic Pain Agents	amitriptyline nortriptyline carbamazepine IR and chew tablets gabapentin 600mg, 800mg tablets and all capsules Lyrica venlafaxine IR tabs	At least 2 antiepileptics, 1 SNRI, 2 TCAD and 1 topical lidocaine preparations should be available.	Patients taking these medications for uses other than neuropathic pain.

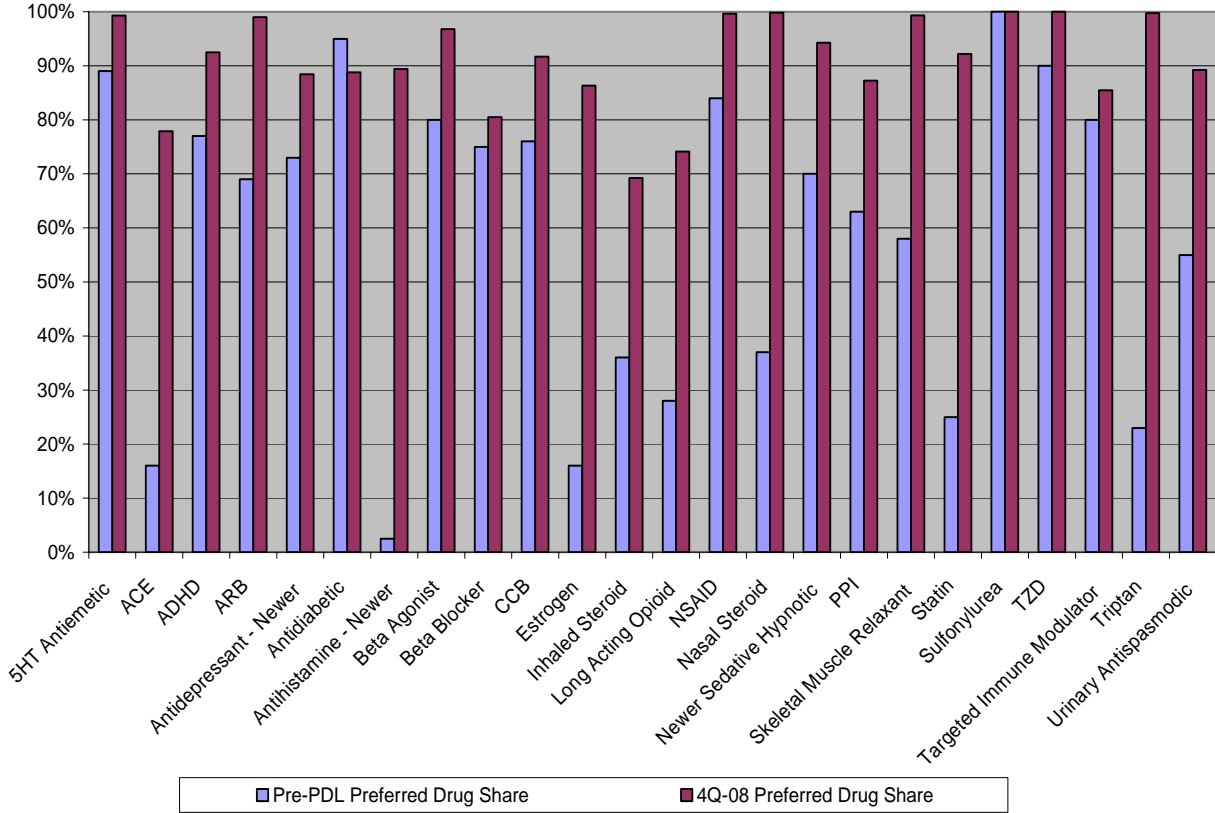
MARKET SHARE IMPACT OF PDL RECOMMENDATIONS

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

	Q107	Q207	Q307	Q407	Q108	Q208	Q308	Q408
Less Sedating Antihistamines	84	83	83	83	86	83	89	89
Proton Pump Inhibitors	100	99	99	100	99	89	88	87
Statins	98	98	98	98	99	98	94	92
Calcium Channel Blockers	83	87	88	94	94	94	91	92
Beta Blockers	91	91	91	91	83	81	80	80
Long-acting Opioids	79	75	76	75	75	74	73	74
ACE Inhibitors	77	76	75	75	79	79	79	78
Triptans	92	93	93	99	99	100	100	100
ARBs	99	99	99	99	99	99	100	100
Skeletal Muscle Relaxers	99	99	99	100	100	99	99	99
Estrogens	90	88	88	87	89	87	83	86
Newer Sleep Aids	99	99	99	100	100	100	94	94
Targeted Immune Modulators	66	63	57	81	81	82	83	85
Inhaled Corticosteroids	66	67	68	68	68	68	68	69
Overactive Bladder Agents	89	90	89	90	89	90	90	89
Newer Antiemetics	96	97	97	98	99	98	97	99
Oral Diabetes Agents	98	97	96	95	94	94	93	93
Nasal Steroids	100	100	100	100	100	100	100	100
Antidepressants	-	83	86	87	88	88	88	88
Beta₂ Agonists	-	87	97	96	96	97	97	97
NSAIDs	-	-	99	99	100	100	100	100
ADD/ADHD	-	-	85	88	90	91	91	92
Neuropathic pain	-	-	-	-	-	-	N/A	N/A

Share of Prescriptions Dispensed



Prior Authorization Call Center Statistics

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

“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 most recent quarter and the totals for CY 2008.

PA Call Center Statistics	1Q 2008	2Q 2008	3Q 2008	4Q2008	CY 2008 Totals
Incoming Calls from Healthcare Professionals	6297	6742	6443	6415	25,897
Number of SmartPA Tickets Created	4915	4865	4846	4543	19,169
Total Number of P.A. Requests at the Call Center	3439	3404	3468	3054	13,365
Total Number of P.A. Requests Approved at the Call Center	2429	2268	2555	2139	9,391
Call Center P.A. Approval Percentage	71%	67%	74%	70%	70%
Point of Sale SmartPA Requests	172,815	173,862	206,554	199,211	752,442
Point of Sale SmartPA Approvals	144,884	144,104	170,170	172,956	632,114
Point of Sale SmartPA Approval Percentage	84%	83%	82%	87%	84%
Average Call Duration	2 min 26 sec	2 min 38 sec	2 min 43 sec	2 min 36 sec	2 min 36 sec

Budget Update

A GENERAL OVERVIEW OF THE PROGRAM BUDGET

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.

	SFY09 Budget	SFY09 Expenditures To Date
Personnel –(Salary and Fringes, includes DRC stipends)	\$2,610,805	\$594,196
Miscellaneous – (Supplies, Travel, etc)	\$150,750	\$13,981
Equipment – (computers, phones, furniture, renovation)	\$13,000	\$5,345
Indirect Costs	\$1,491,240	\$328,415
TOTAL	\$4,265,795	\$941,937

Cost Savings Estimates

In past quarters, this report provided estimates of the fiscal impact of PDL policies on net medication costs for the Medicaid program. These estimates provided an early indicator of the pharmacy budget implication of PDL policies. The estimates could not provide insights on other effects of the PDL policy, and were crudely derived using estimates of Medicaid Net Costs. At DHS' request the Net Cost estimates are no longer used, and therefore avoided cost estimates can no longer be calculated.

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. This project will focus on uses of antidepressants and the treatment of depression and anxiety in Arkansas children.

Provider education on current treatment guidelines and recent research on the most effective/appropriate anxiety and depression treatments for children will be delivered through three approaches. An hour-long educational presentation for health-care providers, complementary materials for academic detailing by AFMC, and a comprehensive set of web-based resources have been prepared. UAMS' Institutional Review Board (IRB) has reviewed the research protocol and approved the project. A waiver of informed consent has been granted by the IRB for this project meaning that the research meets all standards and requirements to protect the prescriber research subjects. In the view of the IRB adequate plans are in place to protect confidentiality of all data used in this research.

The project will use changes seen in initial treatment selection as the measure of the effectiveness of the educational campaign. Providers will be targeted based on the numbers of children and adolescents treated with newer antidepressant medications. Every effort will be made to ensure that these providers receive the educational intervention through at least one of the different media/approaches. Comparisons between the changes seen among the providers receiving the educational material and those who are not exposed are expected to provide some insight on the effectiveness of the components used to elicit some treatment behavior change. Specific effects which will indicate a positive impact of the educational intervention will be an increase in the use of counseling as a primary treatment and more frequent use of medications for which evidence of usefulness in children is present.

Drug Review Committee

Activities

Date: October 16, 2008

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 10/16/08 meeting, the Drug Review Committee considered the potential toxicity and therapeutic roles of selected anti-diabetic agents.

Non-insulin anti-diabetic agents under consideration

First generation oral sulfonylureas

Chlorpropamide

Tolazamide

Tolbutamide

Second generation oral sulfonylureas

Glimepiride

Glipizide

Glyburide

Glyburide-micronized

Non-sulfonylurea secretagogues (meglitinides)

Nateglinide (Starlix)

Repaglinide (Prandin)

Thiazoladinediones

Pioglitazone (Actos)

Rosiglitazone (Avandia)

Newer agents

Exenatide (Byetta)

Pramlintide (Symlin)

Sitagliptin (Januvia)

Indications under consideration in adults and children

Diabetes mellitus

Pre-diabetes or metabolic syndrome

Discussion

The Committee concluded the following based upon its perception of the bulk of the best available evidence utilizing comparable doses where appropriate:

1. None of the captioned agents is associated with clinically evident adverse events of sufficient severity or number to exclude it from further consideration.

2. At least one first generation sulfonylurea should be available.
3. At least one second generation sulfonylurea should be available, and if only one, then glyburide.
4. At least one meglitinide should be available.
5. At least one thiazoladinedione should be available, and if only one, then pioglitazone.
6. Relative to insulin, sulfonylureas, meglitinides, and thiazolidinediones there is relatively little data regarding the efficacy and toxicity of exenatide, pramlintide and sitagliptin. At this time, these three agents should not be considered as routine first or second line therapy and they should be used only after documented failure of optimal established treatments.

Henry F. Simmons, Jr.
October 16, 2008

Date: November 20, 2008

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 meeting today, the Drug Review Committee considered the potential toxicity and therapeutic roles of newer sedative hypnotic agents for adults and children with insomnia.

Newer sedative hypnotic agents under consideration include the following:

Eszopiclone [Lunesta]

Ramelteon [Rozarem]

Zaleplon [Sonata]

Zolpidem [Ambien and Ambien CR]

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

The agents do not differ in terms of either safety considerations or frequency of adverse events to the extent that one or more should be excluded from consideration.

At least two of the agents should be available.

With the exception of eszopiclone, which may be of special benefit relative to zolpidem and ramelteon for patients over 65 years of age, none of the agents otherwise appear to be associated with either special benefits or special risks on the basis of demographics.

Henry F. Simmons, Jr.

November 20, 2008