Division of Medicaid

Office of the Governor

State of Mississippi

DUR Board Meeting

February 19, 2009

2:00 p.m.

Woolfolk Building, Room 117

Jackson, MS

Drug Utilization Review Board

Roy L. Arnold, Jr., R.Ph.
Clayton Drug Store
216 Main Street
Collins, MS 39428-0787
Term Expires: June 30, 2009

Laura Gray, M.D.
905 Garfield Street
Tupelo, MS 38801
Term Expires: June 30, 2009

John M. Wallace, M.D.
Jefferson Medical Clinic
1203 Jefferson Street
Laurel, MS 39440
Term Expires: June 30, 2009

Lee Voulters, M.D.
1340 Broad Ave Suite 440
Gulfport, MS 39501
Term Expires: June 30, 2009

Edgar Donahoe, M.D.
Indianola Family Medical Group
122 Baker Street
Indianola, MS 38751
Term expires: June 30, 2010

Mark Reed, M.D.
University of Mississippi Medical Center
2500 North State Street, Trailer 16
Jackson, MS 39216
Term expires: June 30, 2010

Lee Merritt, R.Ph.
Medfusion
2211 5th Street North
Columbus, MS 39705
Term expires: June 30, 2010

Vickie Veasey, R.Ph.
MS State Hospital at Whitfield
Building #50
Whitfield, MS 39193
Term Expires: June 30, 2010

Frank Wade, M.D.
Family Medical Clinic
376A Simpson Highway 149
Magee, MS 39111
Term Expires: June 30, 2011

Jason Strong, Pharm.D.
Canton Discount
726 East Peace Street
Canton, MS 39046
Term Expires: June 30, 2011

Alvin Dixon, R.Ph.
182 Cherry Street
Clarksdale, MS 38614
Term expires: June 30, 2011

William Bastian, M.D.
Bastian Center of Pediatric
Endocrinology
1860 Chadwick Drive, Suite 206
Jackson, MS 39204
Term Expires: June 30, 2011

Upcoming Mississippi DUR Board Meeting Dates

May 21, 2009
August 20, 2009
November 19, 2009
February 18, 2010

DIVISION OF MEDICAID
OFFICE OF THE GOVERNOR
DRUG UTILIZATION REVIEW BOARD
AGENDA

February 19, 2009

Welcome	**Laura Gray, M.D.**
Old Business	**Laura Gray, M.D.**
Approval of Meeting Minutes	
Cost Management Analysis	**Ashleigh Holeman, Pharm.D.**
Pharmacy Program Update	**Paige Clayton, Pharm.D.**
New Business	**Ashleigh Holeman, Pharm.D.**

Potentially Inappropriate Medications in the Elderly
Guest Speaker - Jennifer D. Gholson, M.D., IQH Chief Medical Officer

Vitamin D Utilization in Mississippi Medicaid

Over-the-Counter Minimally Sedating Antihistamines in Children Under 2

Other Criteria Recommendations

FDA Updates

Next Meeting Information **Laura Gray, M.D.**

Mississippi Division of Medicaid
Drug Utilization Review (DUR) Board
Minutes of the November 20, 2008 Meeting

Members Attending: William Bastian, M.D.; Alvin Dixon, R.Ph.; Edgar Donahoe, M.D.; Laura Gray, M.D.; Lee Merritt, R.Ph.; Mark Reed, M.D.; Jason Strong, Pharm D.; Vickie Veazey, R.Ph.; John Wallace, M.D.
Members Absent: Roy Arnold, R.Ph.; Lee Voulters, M.D.; Frank Wade, M.D.

Also Present:
DOM Staff: Judith Clark, R.Ph., DOM Pharmacy Bureau Director; Paige Clayton, Pharm D., DOM DUR Coordinator
HID Staff: Ashleigh Holeman, Pharm D., Project Manager; Leslie Leon, Pharm. D., Clinical Pharmacist; Kathleen Burns, R.N., Call Center Manager

Awaiting the last members to arrive, Ms. Clark started the meeting by asking the newest members to introduce themselves to the Board. The minutes were reviewed and a motion was made by Dr. Donahoe to accept the minutes as written, seconded by Dr. Reed. All voted in favor of this motion by a yes. Ms. Clark again voiced the appreciation from the Division of Medicaid for the Board members to serve the State in this capacity.

Call To Order:
Laura Gray, Chairperson of the Board, called the meeting to order at 2:10 p.m.

Cost Management Analysis:
Dr. Holeman presented reports reflecting the last 2 months of data, indicating that since the last meeting was so close, the data was a more condensed version. She continued with the antipsychotic agents remaining in the lead for the top 15 therapeutic classes by total cost for the two months reported, July and August 2008. Once again, the top drug based on the number of claims for these two months was hydrocodone-acetaminophen. This was noted to be #1 in the national rank of based on number of claims. The top 25 drugs based on total claims cost for the two months reported was led by Prevacid® followed by Singulair®. Both of these drugs are listed on the Medicaid Preferred Drug List.

New Business:

FDA Updates:

Tumor necrosis factor-alpha blockers (TNF blockers), Cimzia (certolizumab pegol), Enbrel (etanercept), Humira (adalimumab), and Remicade (infliximab)
FDA notified healthcare professionals that pulmonary and disseminated histoplasmosis, coccidioidomycosis, blastomycosis and other opportunistic infections are not consistently recognized in patients taking tumor necrosis factor-α blockers (TNF blockers). This has resulted in delays in appropriate treatment, sometimes resulting in death. For patients taking TNF blockers who present with signs and symptoms of possible systemic fungal

infection, such as fever, malaise, weight loss, sweats, cough, dypsnea, and/or pulmonary infiltrates, or other serious systemic illness with or without concomitant shock, healthcare professionals should ascertain if patients live in or have traveled to areas of endemic mycoses. For patients at risk of histoplasmosis and other invasive fungal infections, clinicians should consider empiric antifungal treatment until the pathogen(s) are identified.

Rituxan (rituximab) Injection
Genentech informed healthcare professionals of revisions to prescribing information for Rituxan regarding a case of progressive multifocal leukoencephalopathy (PML) leading to death in a patient with rheumatoid arthritis who received Rituxan in a long-term safety extension clinical study. The patient developed a JC virus infection with resultant PML and death 18 months after taking the last dose of Rituxan. Healthcare professionals treating patients with Rituxan should consider PML in any patient presenting with new onset neurologic manifestations. Additionally, consultation with a neurologist, brain MRI and lumbar puncture should be considered as clinically indicated.

Tarceva (erlotinib) Tablets
OSI and Genentech notified healthcare professionals that cases of hepatic failure and hepatorenal syndrome, including fatalities, have been reported during use of Tarceva, particularly in patients with baseline hepatic impairment. Patients with hepatic impairment receiving Tarceva should be closely monitored during therapy and the product should be used with extra caution in patients with total bilirubin >3x ULN. Dosing should be interrupted or discontinued if changes in liver function are severe, such as doubling of total bilirubin and/or tripling of transaminases in the setting of pretreatment values outside the normal range. New information from a pharmacokinetic study in patients with moderate hepatic impairment associated with significant liver tumor burden has been provided in the revised prescribing information, and other recommendations are included in the WARNINGS and DOSAGE AND ADMINISTRATION sections.

Statin drugs and amyotrophic lateral sclerosis (ALS)
An FDA analysis provides new evidence that the use of statins does not increase incidence of amyotrophic lateral sclerosis (ALS), a neurodegenerative disease often referred to as "Lou Gehrig's Disease." The FDA analysis, undertaken after the agency received a higher than expected number of reports of ALS in patients on statins, is based on data from 41 long-term controlled clinical trials. The results showed no increased incidence of the disease in patients treated with a statin compared with placebo.
The FDA is anticipating the completion of a case-control or epidemiological study of ALS and statin use. Results from this study should be available within 6-9 months. FDA is also examining the feasibility of conducting additional epidemiologic studies to examine the incidence and clinical course of ALS in patients taking statins.
Based on currently available information, health care professionals should not change their prescribing practices for statins and patients should not change their use of statins.

Atypical Antipsychotic Utilization in Children:
Dr. Holeman reminded the Board that at the September 25, 2008 meeting, the Board had responded to the HID presentation with several concerns regarding the use of these medications in children. One concern was: What was the breakdown of pediatric beneficiaries receiving atypical antipsychotics regarding their diagnosis? More specifically, how many of these beneficiaries have an ADHD diagnosis and how many have an ODD diagnosis? The chart presented by HID revealed that 75% of all patients 18 years old or younger who received an atypical antipsychotic had a diagnosis of ADHD, while 55% had a diagnosis of ODD. 46% were found to have both diagnoses of ADHD and ODD. The second request from the Board was for the utilization data for pediatric beneficiaries with an ADHD and/or ODD diagnosis who had received an atypical antipsychotic concurrently with stimulants or Strattera®. HID reported that of the 4287 beneficiaries under the age of 19 on atypical antipsychotic treatment for these diagnoses, 59% also received treatment with a stimulant or Strattera®. This indicated that although the use of the atypical antipsychotics in pediatric patients for these diagnoses is off-label, the majority of providers treating these patients have attempted trials of conventional treatment modalities for these diagnoses and for whatever reason have had to continue on to other options. A final observation made at the September meeting was the increased risk of metabolic adverse effects when being treated with atypical antipsychotics. An analysis was done on the pediatric beneficiaries who received atypical antipsychotics to determine how many also had a diagnosis of Type 2 Diabetes, one of the more common and frightening risks associated with these medications. Only 2% of the pediatric beneficiaries receiving an atypical antipsychotic also had a diagnosis of Type II Diabetes Mellitus. However, the potential risk for metabolic side effects with these medications must not be disregarded based on these results. Dr. Donahoe posed a request that HID report at the next meeting what specialty is prescribing the atypical antipsychotics to these children. He suggested that with this report the Board might require that a psychiatric consult be required before a pediatrician/family medicine physician could prescribe these medications for Mississippi Medicaid pediatric beneficiaries. Dr. Bastian asked if the Board might obtain a number of pediatric psychiatrists in the State treating Medicaid patients. He was concerned that these patients might not have access to these physicians in all areas of the State. The Board continued with discussions that these general practitioners might have a phone consultation with a psychiatrist before prescribing this class of medications in geographic areas where accessibility is limited. Dr. Bastian continued that in the pediatric population with Type II diabetes , use of the atypical antipsychotics is commonly associated with weight gain. This also poses additional problems in this population. He requested reports from HID on these two diagnoses and the use of atypicals as a further study for the Board to review.

Cost Savings Potential- Preventative Treatment of Migraine Headaches:
Dr. Holeman began the report indicating that triptans and narcotic analgesics are considered rescue medications for migraine headaches. However, there are some treatment options available that help prevent the occurrence of migraines. These include amitriptyline, propranolol, Topamax® and Depakote®. HID conducted claims analyses to determine how many beneficiaries receiving rescue treatment with a triptan for

migraines also received a deterrent medication. Utilization data for this report was gathered over a 6-month interval from 3/27/2008 to 9/26/2008. These searches were then intersected to determine the number of beneficiaries who received both types of treatment versus those who received rescue medication only. Triptan only use was identified in 1236 or 27% of the beneficiaries. Triptan and maintenance medications were noted in 350 or 73% of these identified beneficiaries.

Recommendations:

HID recommends in an effort to increase the number of beneficiaries who may benefit from the use of a preventive medication, a consistent review be made of a current RDUR criterion identifying those patients with a diagnosis of migraine and claims history of an acute migraine treatment, but no claims history of one of the preventive medications. Dr. Wallace asked what type of interaction would be made to the provider. Dr. Holeman answered that an educational letter would be generated when the system identified the beneficiary and physician with this criterion. Dr. Donahoe asked if HID might report internally at the next meeting on the trend of these Migraine patients and their narcotic/triptan use. All agreed on this recommendation by show of hands.

Duplicate Therapy with Sedative/Hypnotics:

Dr. Holeman continued with the sedative/hypnotic agents and their treatment for insomnia. There is some concern that these agents are potentially being abused. Through HID reporting it was discovered that some beneficiaries were receiving multiple prescriptions for different agents within this class. Based on the total claims count for the months of July and August 2008, there was widespread duplication therapy on the agents targeted.

Recommendation:

Based on the potential for addiction associated with this therapeutic class, coupled with the high costs of some of the agents, a duplicate therapy edit at the point of sale was recommended by HID. This would prevent beneficiaries from receiving multiple prescriptions of differing agents within this class and require the physician to submit a prior authorization explaining the need for the additional medication. Dr. Donahoe made a motion to allow the first agent to go through at a 31-day supply and then deny the second agent by requiring a PA with explanation of medical justification from the physician. Dr. Reed seconded the motion. All voted in favor of the motion by show of hands.

Appropriate Use of Benzodiazepines:

Benzodiazepines are agents used in the treatment of symptoms associated with anxiety disorders. Dr. Holeman reviewed the most recent treatment guidelines that recommend these medications for short-term use only and that the maintenance of these anxiety disorders should be managed with either a selective serotonin reuptake inhibitor or a serotonin and norepinephrine reuptake inhibitor. HID gathered utilization for the months of July and August 2008 for each of the benzodiazepines. Based on the results, it was clear that there is some degree of duplication of therapy in the Medicaid population. The rate varied from 10- 15 % depending on the agent. The rate was noted much higher (30%) in the long-acting benzodiazepine category. It was recently bought to the attention of the HID staff by a Mental Health Provider that Medicaid had no limits on these agents

and that they had had repeated requests for high doses of these agents. The conclusion of this report was that even though there is an appropriate role in the treatment of anxiety disorders for these agents, this role should be limited and restricted to two to four weeks based on the treatment guidelines.

Recommendations:

HID recommended that edits be placed at the point of sale to curb the trend of duplicate therapy for benzodiazepines. HID also recommends that quantity limits be set in hopes to discourage this potential abuse. Dr. Donahoe made a motion to limit this class to 62 tablets per month with a limit of one prescription per 31 days of these agents. Ms. Veazey seconded the motion. Votes were approved by show of hands with the exception of Dr. Wallace who had left the room at the time of the voting.

Suboxone/Subutex Prior Authorization Process:

Dr. Holeman noted at present that these two medications require prior authorization for Mississippi Medicaid beneficiaries. A review of utilization for these agents confirms a significant increase of volume in the last few months. When compared to the same time period for 2006-2007, utilization has increased more than threefold and the cost to the Division of Medicaid increased by over 400%. While some of this growth can be attributed to increased marketing of the agents, such a jump is troublesome.

The purpose of this presentation to the DUR Board was to gather insight from the members to determine if the current criteria being used for prior authorization are appropriate. Currently, these agents have DOM-implemented quantity limits of 62 tablets per 31 days. This is consistent with the recommended dosing according to the prescribing information. It is the goal of the Division to ensure that the beneficiaries who truly need these products for treatment of their abuse condition are able to receive them. DOM maintains the stance that they are to be used appropriately and prescribed appropriately. Discussion was opened to the Board on these agents.

Recommendation:

After extensive discussion by the Board, there was acknowledgement of the urgency to implement policies immediately that would benefit the pharmacy program of Mississippi Medicaid without neglecting the needed treatment for the diagnosis of opioid dependency. The Board voted on the first of ongoing requirements that must be met by the prescribing provider and the beneficiary. The Board will also revisit these options at the February meeting should additional requirements be identified. Dr. Donahoe motioned that the Suboxone/Subutex PA be limited to a two month approval only without additional treatment. He continued that these medications should be limited to 62 pills per month according to the dosing guidelines in the prescribing information by the manufacturer. Dr. Reed suggested that, in this motion, a letter be sent to every prescriber of these agents defining the new guidelines mandated by the Board which would be delivered with the new Suboxone/Subutex prior authorization form by HID's Academic Detailers. Dr. Donahoe noted this addition and continued with there must be a signed statement by the patient on the prior authorization form that he/she is narcotic free at the time of the prescription, and additional information must be noted by the physician that a drug screen for the beneficiary was negative to opioids and positive to Suboxone/Subutex on the second request. Any deviation would be a denial of treatment. A positive pregnancy test with date of test must be noted on every request for Subutex. Dr Gray

suggested that this would only be a start to the prior authorization criteria and that in February there would be a need to modify the criteria for this medication. Dr. Gray then seconded the motion and all voted in favor of implementing, as soon as possible, the suggested prior authorization criteria for Suboxone/Subutex by a show of hands. Dr. Donahoe asked DOM how soon this policy could be implemented as this was of an urgent need due to the potential danger of abuse. He continued by noting that in his area there had been a "code" due to the beneficiary misusing this medication with other drugs of abuse. Dr. Gray supported this urgent need stating that this medication poses a danger to the Mississippi Medicaid Population when misused and inappropriately prescribed.

Criteria Recommendations for 4th Quarter 2008:
Dr. Holeman reviewed the criteria submitted by HID and all voted in favor by show of hands to adopt the submitted criteria without any additions or changes. HID asked the Board for a set quantity limit for the PPI's. The Board voted for the limit to be set at 62 units per 31 days. HID then recommended that a quantity limit of 31 units per 31 days be set on Singulair®. All voted for this recommendation. Next, the Board was asked to consider a vote on an educational letter to the prescribing physician for HIV patients who are noncompliant with their treatment. This letter would be in response to RDUR criteria that identify the beneficiaries who do not fill their medications on a month by month basis for either one or all or HIV medications. All voted to accept this recommendation.
Dr. Gray reminded the Board of the next meeting on February 19, 2009 and requested a motion for the meeting to be adjourned at 3:45pm. Motioned: Dr. Reed; Seconded: Dr. Strong

Respectfully Submitted:
Health Information Designs, Inc.

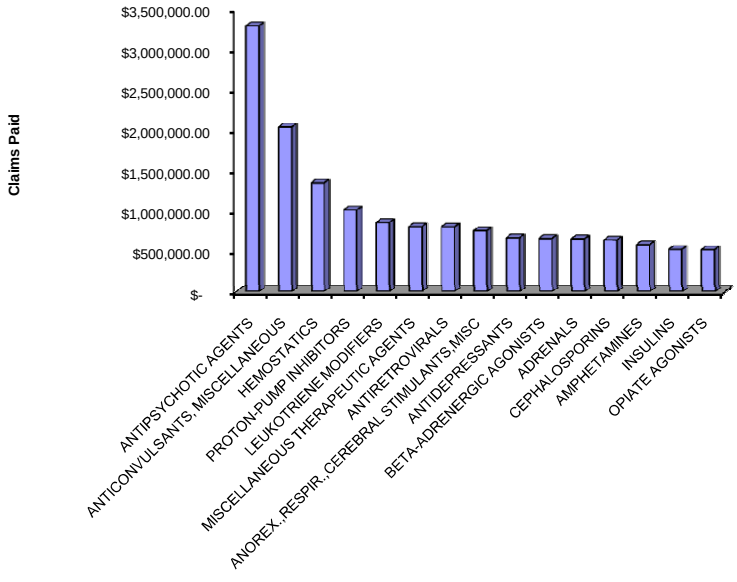
MISSISSIPPI MEDICAID
Cost Management Analysis

TOP 15 THERAPEUTIC CLASSES BY TOTAL COST OF CLAIMS FROM 09/01/08-09/30/08

AHFS Therapeutic Class	Rx	Paid	Paid/Rx	% Total Claims
ANTIPSYCHOTIC AGENTS	10,188	$ 3,294,468.86	$ 323.37	2.65%
ANTICONVULSANTS, MISCELLANEOUS	11,286	$ 2,038,960.60	$ 180.66	2.93%
HEMOSTATICS	43	$ 1,344,286.85	$31,262.48	0.01%
PROTON-PUMP INHIBITORS	6,635	$ 1,008,427.89	$ 151.99	1.73%
LEUKOTRIENE MODIFIERS	7,883	$ 853,563.63	$ 108.28	2.05%
MISCELLANEOUS THERAPEUTIC AGENTS	2,292	$ 799,859.11	$ 348.98	0.60%
ANTIRETROVIRALS	1,090	$ 797,039.07	$ 731.23	0.28%
ANOREX.,RESPIR.,CEREBRAL STIMULANTS,MISC	5,945	$ 752,879.31	$ 126.64	1.55%
ANTIDEPRESSANTS	13,588	$ 660,965.31	$ 48.64	3.53%
BETA-ADRENERGIC AGONISTS	11,685	$ 652,898.92	$ 55.87	3.04%
ADRENALS	9,399	$ 649,760.46	$ 69.13	2.44%
CEPHALOSPORINS	11,772	$ 635,015.53	$ 53.94	3.06%
AMPHETAMINES	4,519	$ 575,053.24	$ 127.25	1.18%
INSULINS	3,502	$ 520,107.37	$ 148.52	0.91%
OPIATE AGONISTS	27,639	$ 516,749.31	$ 18.70	7.19%
TOTAL TOP 15	127,466	$ 15,100,035.46	$ 118.46	33.15%

Total Rx Claims	384,554
From 09/01/08-09/30/08	

Top 15 Therapeutic Classes
Based on Total Cost of Claims



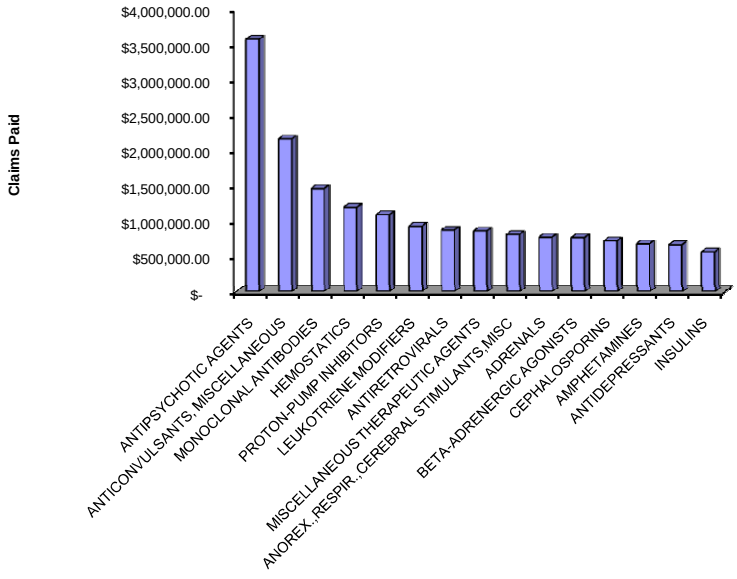
MISSISSIPPI MEDICAID
Cost Management Analysis

TOP 15 THERAPEUTIC CLASSES BY TOTAL COST OF CLAIMS FROM 10/01/08-10/31/08

AHFS Therapeutic Class	Rx	Paid	Paid/Rx	% Total Claims
ANTIPSYCHOTIC AGENTS	10,969	$ 3,576,275.31	$ 326.03	2.65%
ANTICONVULSANTS, MISCELLANEOUS	11,985	$ 2,161,206.43	$ 180.33	2.90%
MONOCLONAL ANTIBODIES	898	$ 1,454,751.88	$ 1,619.99	0.22%
HEMOSTATICS	52	$ 1,188,922.15	$22,863.89	0.01%
PROTON-PUMP INHIBITORS	7,201	$ 1,085,452.99	$ 150.74	1.74%
LEUKOTRIENE MODIFIERS	8,496	$ 920,134.89	$ 108.30	2.06%
ANTIRETROVIRALS	1,158	$ 866,713.58	$ 748.46	0.28%
MISCELLANEOUS THERAPEUTIC AGENTS	2,488	$ 855,863.49	$ 344.00	0.60%
ANOREX.,RESPIR.,CEREBRAL STIMULANTS,MISC	6,375	$ 804,734.52	$ 126.23	1.54%
ADRENALS	10,777	$ 763,771.28	$ 70.87	2.61%
BETA-ADRENERGIC AGONISTS	13,536	$ 760,455.54	$ 56.18	3.28%
CEPHALOSPORINS	12,774	$ 714,515.87	$ 55.94	3.09%
AMPHETAMINES	4,941	$ 672,567.62	$ 136.12	1.20%
ANTIDEPRESSANTS	14,581	$ 659,563.06	$ 45.23	3.53%
INSULINS	3,716	$ 558,395.40	$ 150.27	0.90%
TOTAL TOP 15	109,947	$ 17,043,324.01	$ 155.01	26.61%

Total Rx Claims	413,248
From 10/01/08-10/31/08	

Top 15 Therapeutic Classes
Based on Total Cost of Claims



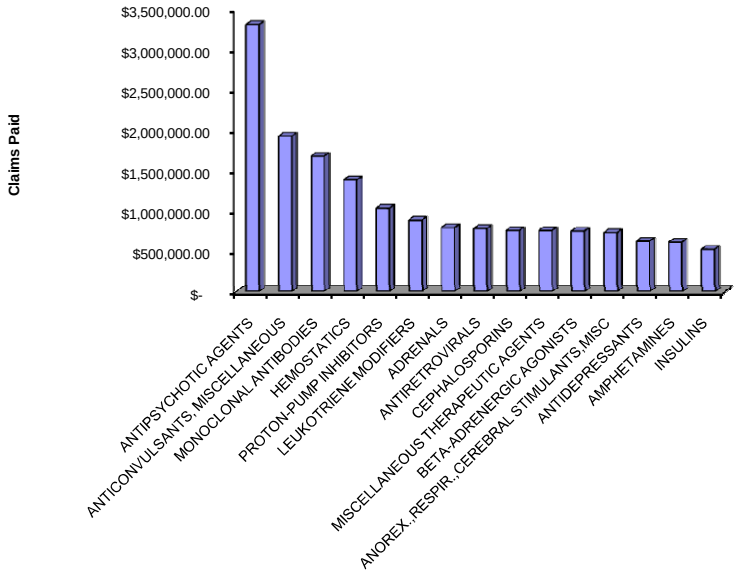
MISSISSIPPI MEDICAID
Cost Management Analysis

TOP 15 THERAPEUTIC CLASSES BY TOTAL COST OF CLAIMS FROM 11/01/08-11/30/08

AHFS Therapeutic Class	Rx	Paid	Paid/Rx	% Total Claims
ANTIPSYCHOTIC AGENTS	9,990	$ 3,310,552.90	$ 331.39	2.57%
ANTICONVULSANTS, MISCELLANEOUS	11,241	$ 1,924,428.14	$ 171.20	2.89%
MONOCLONAL ANTIBODIES	1,075	$ 1,675,489.20	$ 1,558.59	0.28%
HEMOSTATICS	40	$ 1,383,199.25	$34,579.98	0.01%
PROTON-PUMP INHIBITORS	6,878	$ 1,031,233.25	$ 149.93	1.77%
LEUKOTRIENE MODIFIERS	7,837	$ 881,296.04	$ 112.45	2.02%
ADRENALS	10,886	$ 787,171.19	$ 72.31	2.80%
ANTIRETROVIRALS	1,031	$ 778,541.19	$ 755.13	0.27%
CEPHALOSPORINS	13,151	$ 754,198.55	$ 57.35	3.38%
MISCELLANEOUS THERAPEUTIC AGENTS	2,273	$ 752,528.50	$ 331.07	0.58%
BETA-ADRENERGIC AGONISTS	13,542	$ 747,022.04	$ 55.16	3.48%
ANOREX.,RESPIR.,CEREBRAL STIMULANTS,MISC	5,731	$ 726,385.59	$ 126.75	1.47%
ANTIDEPRESSANTS	13,397	$ 618,987.01	$ 46.20	3.44%
AMPHETAMINES	4,431	$ 608,105.18	$ 137.24	1.14%
INSULINS	3,519	$ 520,792.22	$ 147.99	0.90%
TOTAL TOP 15	105,022	$ 16,499,930.25	$ 157.11	27.01%

Total Rx Claims	388,887
From 11/01/08-11/30/08	

Top 15 Therapeutic Classes
Based on Total Cost of Claims



MISSISSIPPI MEDICAID
Cost Management Analysis

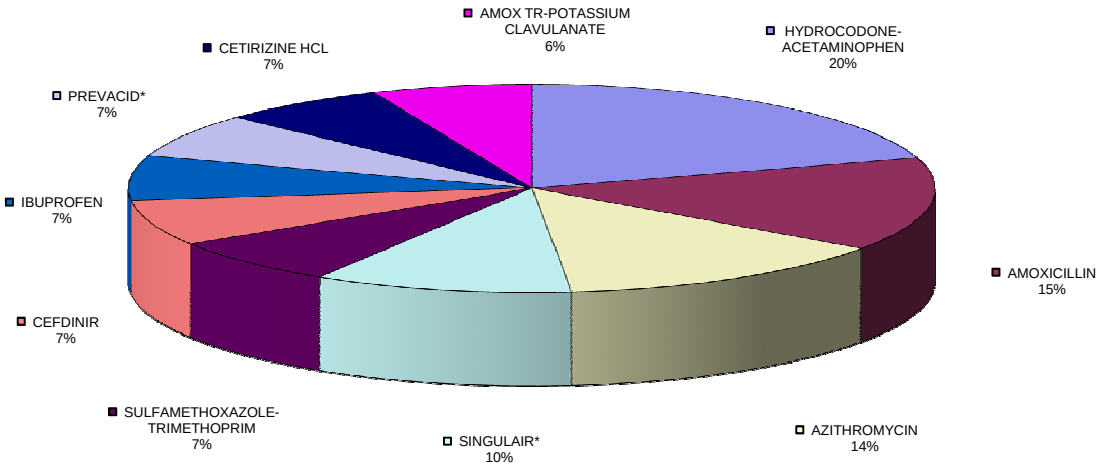
TOP 25 DRUGS BASED ON NUMBER OF CLAIMS FROM 09/01/08-09/30/08

Drug	AHFS Therapeutic Class	Rx	Paid	Top 200 Rank
HYDROCODONE-ACETAMINOPHEN	OPIATE AGONISTS	15,458	$ 160,766.57	1
AMOXICILLIN	PENICILLINS	11,075	$ 104,429.09	3
AZITHROMYCIN	MACROLIDES	10,333	$ 365,132.63	6
SINGULAIR*	LEUKOTRIENE MODIFIERS	7,878	$ 852,683.62	2
SULFAMETHOXAZOLE-TRIMETHOPRIM	SULFONAMIDES (SYSTEMIC)	5,504	$ 65,024.26	62
CEFDINIR	CEPHALOSPORINS	5,414	$ 400,262.18	105
IBUPROFEN	NONSTEROIDAL ANTI-INFLAMMATORY AGENTS	5,261	$ 40,934.58	14
PREVACID*	PROTON-PUMP INHIBITORS	5,244	$ 838,724.46	8
CETIRIZINE HCL	SECOND GENERATION ANTIHISTAMINES	5,098	$ 84,912.86	~
AMOX TR-POTASSIUM CLAVULANATE	PENICILLINS	4,867	$ 258,054.92	26
ALPRAZOLAM	BENZODIAZEPINES (ANXIOLYTIC,SEDATIV/HYP)	4,712	$ 39,001.17	9
ED A-HIST	PROPYLAMINE DERIVATIVES	4,663	$ 40,721.93	~
ALBUTEROL SULFATE	BETA-ADRENERGIC AGONISTS	4,645	$ 138,623.84	67
CLONAZEPAM	BENZODIAZEPINES (ANTICONVULSANTS)	3,630	$ 68,444.93	25
PROMETHAZINE HCL	PHENOTHIAZINE DERIVATIVES	3,509	$ 40,446.25	55
CEPHALEXIN	CEPHALOSPORINS	3,487	$ 53,479.65	18
ACETAMINOPHEN-CODEINE	OPIATE AGONISTS	3,407	$ 26,943.79	41
ADDERALL XR*	AMPHETAMINES	3,210	$ 478,009.77	36
FERROUS SULFATE	IRON PREPARATIONS	3,006	$ 10,951.24	113
MUPIROCIN	ANTIBACTERIALS (SKIN & MUCOUS MEMBRANE)	2,890	$ 109,528.12	108
RISPERIDONE	ANTIPSYCHOTIC AGENTS	2,799	$ 728,328.03	~
LORAZEPAM	BENZODIAZEPINES (ANXIOLYTIC,SEDATIV/HYP)	2,777	$ 72,736.43	23
ALBUTEROL	BETA-ADRENERGIC AGONISTS	2,752	$ 51,051.54	27
RANITIDINE HCL	HISTAMINE H2-ANTAGONISTS	2,601	$ 75,243.67	47
CONCERTA*	ANOREX.,RESPIR.,CEREBRAL STIMULANTS,MISC	2,592	$ 359,635.06	44
TOTAL TOP 25		126,812	$ 5,464,070.59	

Total Rx Claims From 09/01/08-09/30/08	384,554

** Indicates preferred products on Preferred Drug List*

Top 10 Drugs
Based on Number of Claims



MISSISSIPPI MEDICAID
Cost Management Analysis

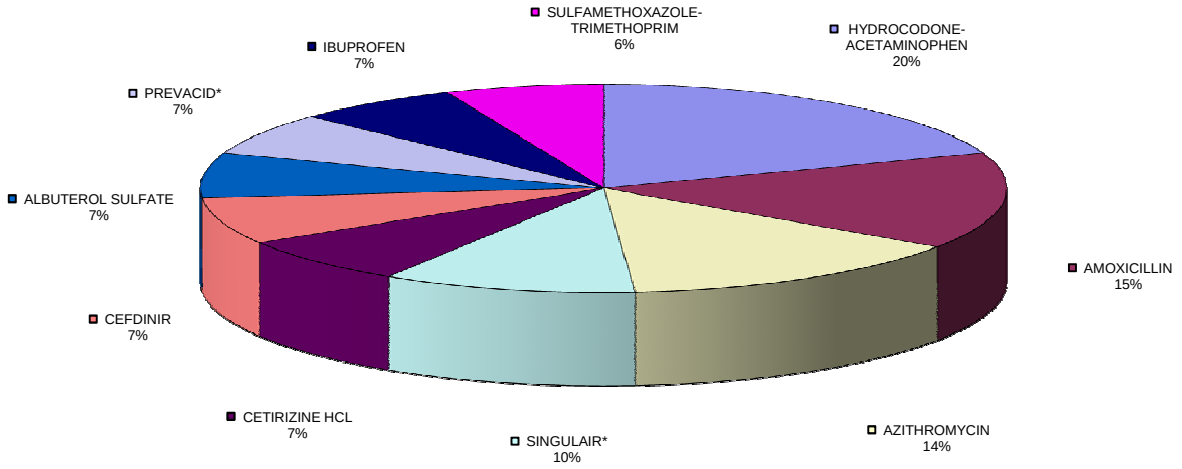
TOP 25 DRUGS BASED ON NUMBER OF CLAIMS FROM 10/01/08-10/31/08

Drug	AHFS Therapeutic Class	Rx	Paid	Top 200 Rank
HYDROCODONE-ACETAMINOPHEN	OPIATE AGONISTS	16,324	$ 171,765.95	1
AMOXICILLIN	PENICILLINS	12,545	$ 118,039.47	3
AZITHROMYCIN	MACROLIDES	11,860	$ 419,552.68	6
SINGULAIR*	LEUKOTRIENE MODIFIERS	8,491	$ 919,458.44	2
CETIRIZINE HCL	SECOND GENERATION ANTIHISTAMINES	6,104	$ 98,320.29	~
CEFDINIR	CEPHALOSPORINS	6,094	$ 453,065.53	105
ALBUTEROL SULFATE	BETA-ADRENERGIC AGONISTS	5,786	$ 172,163.17	67
PREVACID*	PROTON-PUMP INHIBITORS	5,538	$ 887,757.50	8
IBUPROFEN	NONSTEROIDAL ANTI-INFLAMMATORY AGENTS	5,512	$ 44,011.15	14
SULFAMETHOXAZOLE-TRIMETHOPRIM	SULFONAMIDES (SYSTEMIC)	5,295	$ 62,480.89	62
AMOX TR-POTASSIUM CLAVULANATE	PENICILLINS	5,260	$ 283,818.51	26
ED A-HIST	PROPYLAMINE DERIVATIVES	5,126	$ 44,828.27	~
ALPRAZOLAM	BENZODIAZEPINES (ANXIOLYTIC,SEDATIV/HYP)	4,904	$ 40,811.72	9
PROMETHAZINE HCL	PHENOTHIAZINE DERIVATIVES	3,840	$ 43,762.19	55
CLONAZEPAM	BENZODIAZEPINES (ANTICONVULSANTS)	3,829	$ 71,567.60	25
ACETAMINOPHEN-CODEINE	OPIATE AGONISTS	3,594	$ 28,567.42	41
CEPHALEXIN	CEPHALOSPORINS	3,430	$ 52,196.93	18
ADDERALL XR*	AMPHETAMINES	3,413	$ 560,360.57	36
RISPERIDONE	ANTIPSYCHOTIC AGENTS	3,202	$ 804,943.33	~
FERROUS SULFATE	IRON PREPARATIONS	3,101	$ 12,063.45	113
LORAZEPAM	BENZODIAZEPINES (ANXIOLYTIC,SEDATIV/HYP)	2,924	$ 78,058.78	23
RANITIDINE HCL	HISTAMINE H2-ANTAGONISTS	2,745	$ 69,649.73	47
CONCERTA*	ANOREX.,RESPIR.,CEREBRAL STIMULANTS,MISC	2,735	$ 379,897.42	44
VAZOBID	PROPYLAMINE DERIVATIVES	2,698	$ 126,243.03	~
AMLODIPINE BESYLATE	DIHYDROPYRIDINES	2,674	$ 118,379.98	15
TOTAL TOP 25		137,024	$ 6,061,764.00	

Total Rx Claims From 10/01/08-10/31/08	413,248

** Indicates preferred products on Preferred Drug List*

Top 10 Drugs
Based on Number of Claims



MISSISSIPPI MEDICAID
Cost Management Analysis

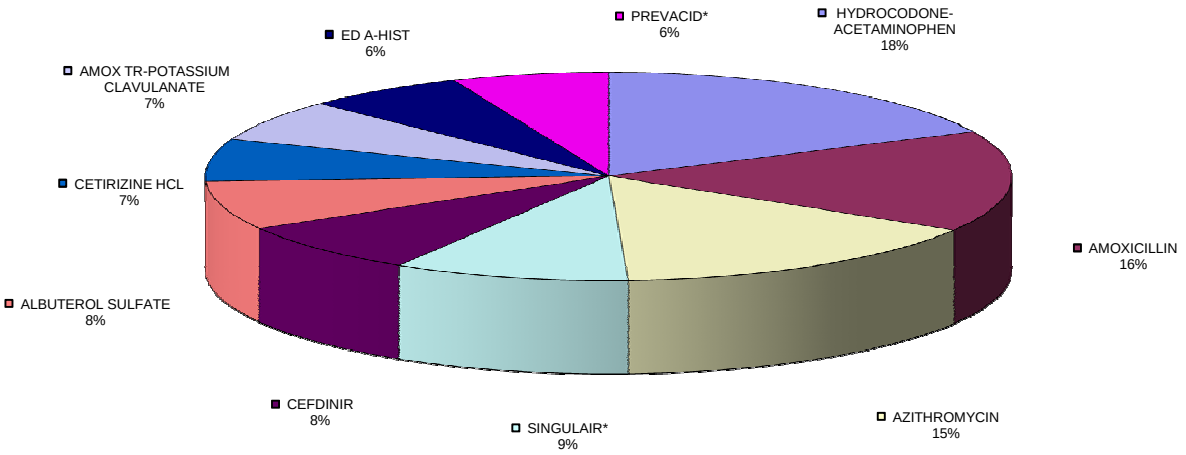
TOP 25 DRUGS BASED ON NUMBER OF CLAIMS FROM 11/01/08-11/30/08

Drug	AHFS Therapeutic Class	Rx	Paid	Top 200 Rank
HYDROCODONE-ACETAMINOPHEN	OPIATE AGONISTS	14,893	$ 161,174.08	1
AMOXICILLIN	PENICILLINS	13,003	$ 123,628.80	3
AZITHROMYCIN	MACROLIDES	12,867	$ 391,991.83	6
SINGULAIR*	LEUKOTRIENE MODIFIERS	7,833	$ 880,714.24	2
CEFDINIR	CEPHALOSPORINS	6,589	$ 495,142.14	105
ALBUTEROL SULFATE	BETA-ADRENERGIC AGONISTS	6,261	$ 186,402.37	67
CETIRIZINE HCL	SECOND GENERATION ANTIHISTAMINES	5,442	$ 86,566.02	~
AMOX TR-POTASSIUM CLAVULANATE	PENICILLINS	5,419	$ 286,698.11	26
ED A-HIST	PROPYLAMINE DERIVATIVES	5,330	$ 46,723.26	~
PREVACID*	PROTON-PUMP INHIBITORS	5,200	$ 835,396.81	8
IBUPROFEN	NONSTEROIDAL ANTI-INFLAMMATORY AGENTS	5,149	$ 41,322.00	14
ALPRAZOLAM	BENZODIAZEPINES (ANXIOLYTIC,SEDATIV/HYP)	4,574	$ 38,108.67	9
SULFAMETHOXAZOLE-TRIMETHOPRIM	SULFONAMIDES (SYSTEMIC)	4,284	$ 49,503.74	62
PROMETHAZINE HCL	PHENOTHIAZINE DERIVATIVES	3,789	$ 42,568.83	55
CLONAZEPAM	BENZODIAZEPINES (ANTICONVULSANTS)	3,595	$ 67,286.92	25
CEPHALEXIN	CEPHALOSPORINS	3,206	$ 49,309.71	18
VAZOBID	PROPYLAMINE DERIVATIVES	3,184	$ 160,217.41	~
ACETAMINOPHEN-CODEINE	OPIATE AGONISTS	3,140	$ 24,961.55	41
ADDERALL XR*	AMPHETAMINES	3,079	$ 508,890.41	36
RISPERIDONE	ANTIPSYCHOTIC AGENTS	3,021	$ 742,888.04	~
FERROUS SULFATE	IRON PREPARATIONS	2,683	$ 10,675.51	113
LORAZEPAM	BENZODIAZEPINES (ANXIOLYTIC,SEDATIV/HYP)	2,658	$ 66,528.52	23
CONCERTA*	ANOREX.,RESPIR.,CEREBRAL STIMULANTS,MISC	2,558	$ 357,741.55	44
RANITIDINE HCL	HISTAMINE H2-ANTAGONISTS	2,483	$ 62,984.26	47
PREDNISOLONE SODIUM PHOSPHATE	ADRENALS	2,438	$ 33,071.26	136
TOTAL TOP 25		132,678	$ 5,750,496.04	

Total Rx Claims From 11/01/08-11/30/08	388,887

** Indicates preferred products on Preferred Drug List*

Top 10 Drugs
Based on Number of Claims



MISSISSIPPI MEDICAID
Cost Management Analysis

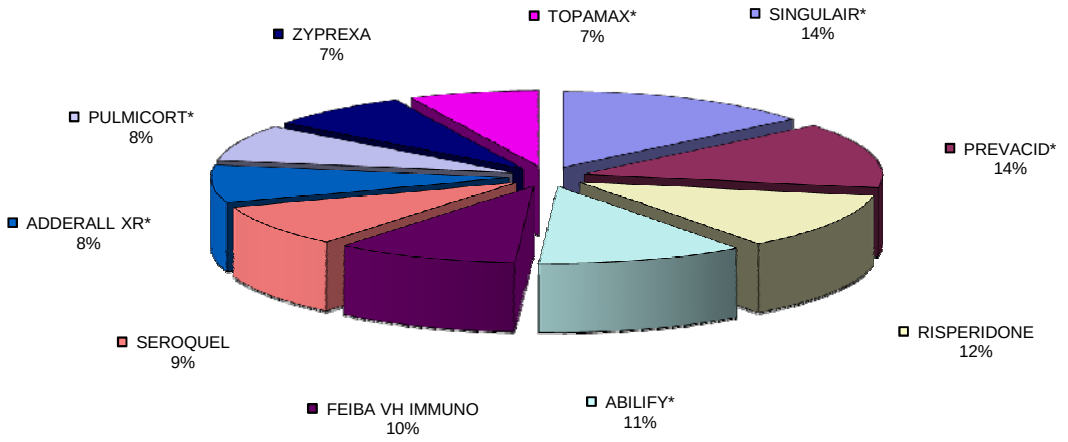
TOP 25 DRUGS BASED ON TOTAL CLAIMS COST FROM 09/01/08-09/30/08

Drug	AHFS Therapeutic Class	Rx	Paid	Top 200 Rank
SINGULAIR*	LEUKOTRIENE MODIFIERS	7,878	$ 852,683.62	6
PREVACID*	PROTON-PUMP INHIBITORS	5,244	$ 838,724.46	4
RISPERIDONE	ANTIPSYCHOTIC AGENTS	2,799	$ 728,328.03	~
ABILIFY*	ANTIPSYCHOTIC AGENTS	1,463	$ 680,617.75	15
FEIBA VH IMMUNO	HEMOSTATICS	9	$ 601,986.78	~
SEROQUEL	ANTIPSYCHOTIC AGENTS	1,497	$ 532,405.54	7
ADDERALL XR*	AMPHETAMINES	3,210	$ 478,009.77	27
PULMICORT*	ADRENALS	1,661	$ 470,392.13	64
ZYPREXA	ANTIPSYCHOTIC AGENTS	834	$ 466,759.16	18
TOPAMAX*	ANTICONVULSANTS, MISCELLANEOUS	1,283	$ 427,220.03	13
CEFDINIR	CEPHALOSPORINS	5,414	$ 400,262.18	31
AZITHROMYCIN	MACROLIDES	10,333	$ 365,132.63	2
CONCERTA*	ANOREX.,RESPIR.,CEREBRAL STIMULANTS,MISC	2,592	$ 359,635.06	34
ADVAIR DISKUS*	BETA-ADRENERGIC AGONISTS	1,512	$ 290,546.93	3
ACTHAR H.P.	ADRENOCORTICAL INSUFFICIENCY	5	$ 279,014.86	~
KEPPRA*	ANTICONVULSANTS, MISCELLANEOUS	964	$ 269,504.47	57
ADVATE UH	HEMOSTATICS	4	$ 265,520.01	~
GEODON*	ANTIPSYCHOTIC AGENTS	740	$ 265,076.68	58
AMOX TR-POTASSIUM CL	PENICILLINS	4,867	$ 258,054.92	9
GABAPENTIN	ANTICONVULSANTS, MISCELLANEOUS	1,979	$ 216,103.71	11
FOCALIN XR*	ANOREX.,RESPIR.,CEREBRAL STIMULANTS,MISC	1,617	$ 206,757.75	133
LAMOTRIGINE	ANTICONVULSANTS, MISCELLANEOUS	704	$ 202,558.96	181
STRATTERA*	CENTRAL NERVOUS SYSTEM AGENTS, MISC.	1,269	$ 199,276.44	73
PLAVIX*	PLATELET-AGGREGATION INHIBITORS	1,377	$ 191,957.36	5
EFFEXOR XR*	ANTIDEPRESSANTS	1,131	$ 186,905.45	8
TOTAL TOP 25		60,386	$ 10,033,434.68	

Total Rx Claims From 09/01/08-09/30/08	384,554

** Indicates preferred products on Preferred Drug List*

Top 10 Drugs
Based on Total Claims Cost



MISSISSIPPI MEDICAID
Cost Management Analysis

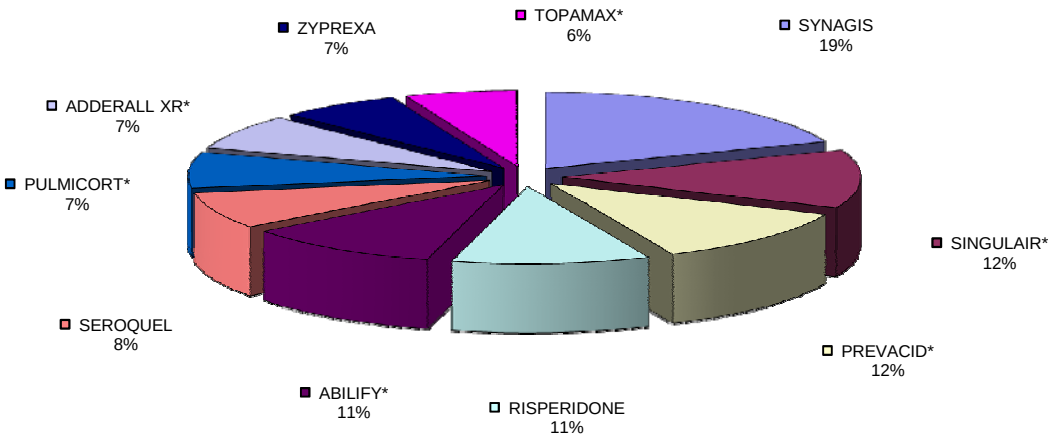
TOP 25 DRUGS BASED ON TOTAL CLAIMS COST FROM 10/01/08-10/31/08

Drug	AHFS Therapeutic Class	Rx	Paid	Top 200 Rank
SYNAGIS	MONOCLONAL ANTIBODIES	898	$ 1,454,751.88	~
SINGULAIR*	LEUKOTRIENE MODIFIERS	8,491	$ 919,458.44	6
PREVACID*	PROTON-PUMP INHIBITORS	5,538	$ 887,757.50	4
RISPERIDONE	ANTIPSYCHOTIC AGENTS	3,202	$ 804,943.33	~
ABILIFY*	ANTIPSYCHOTIC AGENTS	1,641	$ 804,277.25	15
SEROQUEL	ANTIPSYCHOTIC AGENTS	1,601	$ 577,110.88	7
PULMICORT*	ADRENALS	2,005	$ 564,024.38	64
ADDERALL XR*	AMPHETAMINES	3,413	$ 560,360.57	27
ZYPREXA	ANTIPSYCHOTIC AGENTS	864	$ 493,485.46	18
TOPAMAX*	ANTICONVULSANTS, MISCELLANEOUS	1,398	$ 455,486.32	13
CEFDINIR	CEPHALOSPORINS	6,094	$ 453,065.53	31
AZITHROMYCIN	MACROLIDES	11,860	$ 419,552.68	2
CONCERTA*	ANOREX.,RESPIR.,CEREBRAL STIMULANTS,MISC	2,735	$ 379,897.42	34
ADVAIR DISKUS*	BETA-ADRENERGIC AGONISTS	1,683	$ 328,106.93	3
FEIBA VH IMMUNO	HEMOSTATICS	5	$ 323,031.92	~
KEPPRA*	ANTICONVULSANTS, MISCELLANEOUS	1,016	$ 295,565.01	57
GEODON*	ANTIPSYCHOTIC AGENTS	773	$ 291,198.85	58
AMOX TR-POTASSIUM CL	PENICILLINS	5,260	$ 283,818.51	9
LAMOTRIGINE	ANTICONVULSANTS, MISCELLANEOUS	849	$ 234,891.13	181
FOCALIN XR*	ANOREX.,RESPIR.,CEREBRAL STIMULANTS,MISC	1,788	$ 224,895.81	133
GABAPENTIN	ANTICONVULSANTS, MISCELLANEOUS	2,048	$ 221,464.84	11
ADVATE H	HEMOSTATICS	5	$ 219,833.80	~
PLAVIX*	PLATELET-AGGREGATION INHIBITORS	1,504	$ 217,327.31	5
STRATTERA*	CENTRAL NERVOUS SYSTEM AGENTS, MISC.	1,322	$ 206,442.74	73
EFFEXOR XR*	ANTIDEPRESSANTS	1,200	$ 205,614.78	8
TOTAL TOP 25		67,193	$ 11,826,363.27	

Total Rx Claims From 10/01/08-10/31/08	413,248

** Indicates preferred products on Preferred Drug List*

Top 10 Drugs
Based on Total Claims Cost



MISSISSIPPI MEDICAID
Cost Management Analysis

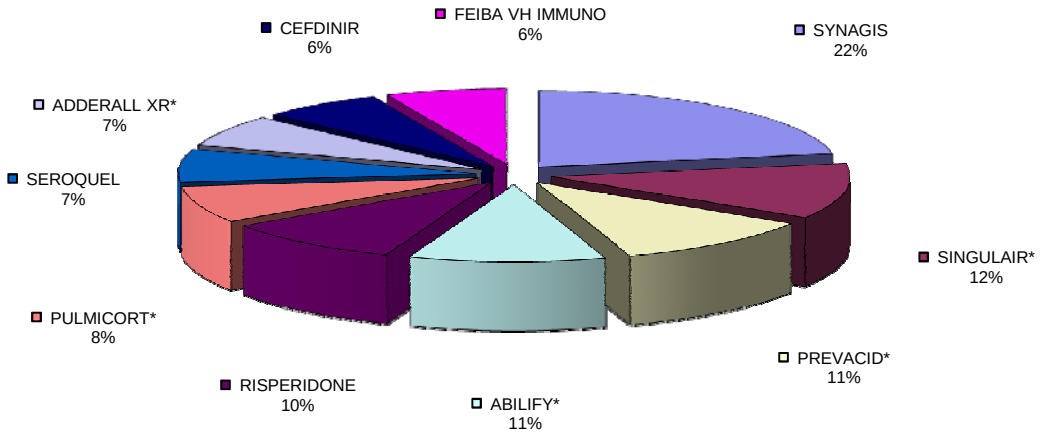
TOP 25 DRUGS BASED ON TOTAL CLAIMS COST FROM 11/01/08-11/30/08

Drug	AHFS Therapeutic Class	Rx	Paid	Top 200 Rank
SYNAGIS	MONOCLONAL ANTIBODIES	1,075	$ 1,675,489.20	~
SINGULAIR*	LEUKOTRIENE MODIFIERS	7,833	$ 880,714.24	6
PREVACID*	PROTON-PUMP INHIBITORS	5,200	$ 835,396.81	4
ABILIFY*	ANTIPSYCHOTIC AGENTS	1,580	$ 800,139.77	15
RISPERIDONE	ANTIPSYCHOTIC AGENTS	3,021	$ 742,888.04	~
PULMICORT*	ADRENALS	2,036	$ 579,989.40	64
SEROQUEL	ANTIPSYCHOTIC AGENTS	1,424	$ 520,518.66	7
ADDERALL XR*	AMPHETAMINES	3,079	$ 508,890.41	27
CEFDINIR	CEPHALOSPORINS	6,589	$ 495,142.14	31
FEIBA VH IMMUNO	HEMOSTATICS	10	$ 492,611.58	~
ZYPREXA	ANTIPSYCHOTIC AGENTS	782	$ 453,333.77	18
TOPAMAX*	ANTICONVULSANTS, MISCELLANEOUS	1,247	$ 413,229.92	13
AZITHROMYCIN	MACROLIDES	12,867	$ 391,991.83	2
CONCERTA*	ANOREX.,RESPIR.,CEREBRAL STIMULANTS,MISC	2,558	$ 357,741.55	34
ADVAIR DISKUS*	BETA-ADRENERGIC AGONISTS	1,529	$ 298,034.33	3
AMOX TR-POTASSIUM CL	PENICILLINS	5,419	$ 286,698.11	9
GEODON*	ANTIPSYCHOTIC AGENTS	699	$ 251,994.58	58
NOVOSEVEN RT	HEMOSTATICS	2	$ 238,929.82	~
KEPPRA*	ANTICONVULSANTS, MISCELLANEOUS	828	$ 236,065.57	57
LAMOTRIGINE	ANTICONVULSANTS, MISCELLANEOUS	790	$ 223,223.93	181
PLAVIX*	PLATELET-AGGREGATION INHIBITORS	1,436	$ 207,542.60	5
ACTHAR H.P.	ADRENOCORTICAL INSUFFICIENCY	5	$ 202,925.23	~
GABAPENTIN	ANTICONVULSANTS, MISCELLANEOUS	1,900	$ 200,087.45	11
EFFEXOR XR*	ANTIDEPRESSANTS	1,121	$ 197,066.45	8
FOCALIN XR*	ANOREX.,RESPIR.,CEREBRAL STIMULANTS,MISC	1,549	$ 196,546.13	133
TOTAL TOP 25		64,579	$ 11,687,191.52	

Total Rx Claims	388,887
From 11/01/08-11/30/08	

** Indicates preferred products on Preferred Drug List*

Top 10 Drugs
Based on Total Claims Cost



January 13, 2009

Judith Polk Clark, B.S. Ph. R.Ph.
Pharmacy Director
Division of Medicaid, State of Mississippi
Walter Sillers Building
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Jackson, MS 39201
phjpc@medicaid.state.ms.us

Dear Ms. Clark:

Pharmacists without question play a most vital role in the campaign to raise awareness about inappropriate medications for the elderly. The cooperation of the Division of Medicaid can serve as a most valuable asset in this educational effort that Information & Quality Healthcare (IQH), the state's Medicare quality improvement organization, has begun. A chart has been developed and is being distributed to serve as a tool in helping to reduce the number of inappropriate medications for our elderly patients.

The importance of the campaign as well as the sharing of the information is reflected in the shocking fact that Mississippi providers rank second in the nation in prescribing inappropriate medications to the elderly. And the chief potentially inappropriate medication prescribed in the state: Darvocet!

Thank you for any assistance in the educational effort to share this information that can result in taking Mississippi out of second place and ensuring more appropriate medication treatment for our elderly citizens.

Sincerely,

Jennifer Gholson, MD

Potentially Inappropriate Medications

Mississippi Providers Rank #2 in the Nation in Prescribing Potentially Inappropriate Medications to the Elderly

DRUG CLASS	GENERIC	BRAND	JUSTIFICATION	ALTERNATIVES
Analgesics	Propoxyphene HCL (and all product combination)	Darvon®, Darvon-N®, Darvocet®	High potential for dependence. Offers few analgesic advantages over acetaminophen.	Acetaminophen (Tylenol®)
Skeletal Muscle Relaxants	Cyclobenzaprine Carisoprodol	Flexeril® Soma® Skelaxin®	Most muscle relaxants are poorly tolerated by elderly patients due to anticholinergic adverse effects, sedation, and weakness. At doses tolerated by elderly patients, their effectiveness is questionable.	Tizanidine (Zanaflex®) – somnolence 50%. Use with caution.
Antihistamines/ Antiemetics	Promethazine, Transderm-Scopolomine, Trimethobenzamide Hydrochloride	Phenergan®, Transderm-Scop® Tigan®	Anticholinergic effects, sedation, and confusion.	Ondansetron (Zofran®)
Benzodiazepines (long acting)	Diazepam	Valium®	These drugs have a long half-life in elderly patients (often several days) and produce prolonged sedation and increased risk for falls and fractures.	Anxiety: Low dose short-acting benzodiazepine or SSRI; Sleep: short-acting benzodiazepine or low dose Ambien®, Sonata®, Lunesta® or Rozerem®

Prescribing in elderly patients is highly complex and should be conducted with the greatest care on a case-by case basis, considering the complete patient medical profile. The above information is intended only as a general guide. Prescribers are encouraged to refer to the most current and reputable medical evidence for more detailed guidance.

Sources: CMS, Physician Practice/Pharmacy: Part D Benefit Reports, Part D Medication Measures Rates by State; Fick, D., Cooper, J., et al. Updating the Beers Criteria for Potentially Inappropriate Medication Use in Older Patients. Arch Intern Med. 2003; 163:2716-2724

This material was prepared by Information & Quality Healthcare, the Medicare Quality Improvement Organization for Mississippi, under contract with the Centers for Medicare & Medicaid Services (CMS), an agency of the U.S. Department of Health and Human Services. The contents presented do not necessarily reflect CMS policy. Pub.No. 9SOW-MS-DS1290.

Potentially Inappropriate Medications in the Elderly

In 2003, an expert panel reviewed and updated the Beers criteria, a listing of medications that should be avoided in patients 65 years of age and older. The original criteria were composed in 1991 by Dr. M.H. Beers, and have been repeatedly revised and updated. This most recent update in 2003 identified 48 medications or classes of medications, sometimes referred to as 'Beer's list medications', that should be avoided in older adults due to the increased rate of adverse events in this population. A recent report issued by Information & Quality Healthcare (IQH), the state's Medicare quality improvement organization, shows that Mississippi providers rank ***#2 in the nation*** in prescribing these potentially inappropriate medications to elderly patients.

Although pharmacy benefits for Mississippi Medicaid beneficiaries over the age of 65 are generally paid for through Medicare Part D, there are some medications that fall through to Medicaid for coverage because they are not covered by Part D plans. Benzodiazepines are one of these exceptions. Also, there are some Medicaid beneficiaries who, for one reason or another, have not paid enough in Medicare taxes to be eligible for Medicare. As such, their pharmacy coverage falls through to Medicaid.

Since the report mentioned above was not Medicaid-specific, HID was asked to conduct claims analyses to determine the rate of use of these medications in the elderly Mississippi Medicaid population. Utilization data was gathered through RxExplorer®, which searches through paid claims data submitted to HID by the fiscal agent. These searches were conducted for the 6-month time period from 5/1/08 to 10/31/08. The results of the analyses of those specific medications mentioned in the IQH report are provided below.

Generic Name	Rx Count	Beneficiary Count
TEMAZEPAM [a]	2437	703
DIAZEPAM [a]	1479	436
PROPOXYPHENE Products	378	222
CYCLOBENZAPRINE HCL	205	122
PROMETHAZINE HCL	109	73
CARISOPRODOL Products [b]	45	27
SCOPOLAMINE HYDROBROMIDE	2	2
TRIMETHOBENZAMIDE HCL [c]	0	0
TOTAL	**4655**	**1585**

[a] *This medication is not covered by Medicare Part D plans and therefore falls through to Medicaid for pharmacy coverage for a dual eligible beneficiary.*

b Beginning July 1, 2008, all carisoprodol products require prior authorization for coverage.

[c] *This medication is considered a DESI drug and therefore is not covered under Mississippi Medicaid pharmacy benefits.*

The results above show that the utilization of these potentially inappropriate medications in the elderly Medicaid population in MS is significant, with 4655 prescriptions for 1585 beneficiaries within the studied time frame.

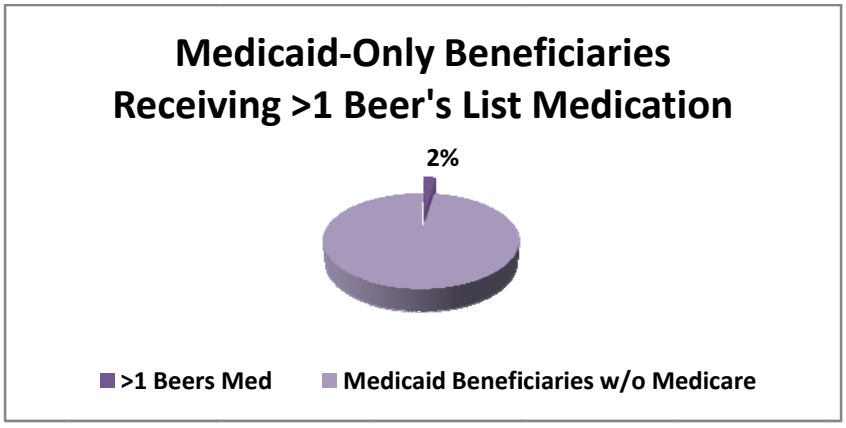
Although the medications in the chart below were not included on the IQH report, HID conducted claims analyses on alprazolam and lorazepam as well since they routinely show up in the Cost Analysis each quarter. They are also included on the Beer's list (higher doses only).

Generic Name	Rx Count	Beneficiary Count
ALPRAZOLAM [a]	5889	1579
LORAZEPAM [a]	8687	2509
TOTAL	**14576**	**4088**

[a] *This medication is not covered by Medicare Part D plans and therefore falls through to Medicaid for pharmacy coverage for a dual eligible beneficiary.*

The utilization of these 2 medications in beneficiaries 65 and older is significantly higher than any of the others provided in the first chart. A total of 14,576 claims for 4,088 beneficiaries were found for alprazolam and lorazepam, indicating a considerable risk to these elderly beneficiaries.

Because benzodiazepines are the only Beer's list medication covered by Medicaid for dual eligibles (beneficiaries with Medicaid and Medicare), those beneficiaries who received more than one of these medications would fall into the category of beneficiaries with no Medicare coverage. During the time analyzed, there were approximately 3441 Medicaid beneficiaries who did not have Medicare coverage.



81 beneficiaries (2%) actually received more than one of the Beer's list medications that were reviewed in this analysis, putting them at even higher risk for an adverse event. While this is a small number, the costs associated with injuries, emergency room visits, and hospitalizations

from adverse events associated with the use of these medications in elderly patients is significant.

Recommendation

In an effort to reduce or prevent the incidence of adverse events, emergency room visits, and hospitalizations that may result from their use in this population, HID is providing 2 recommendations for the DUR Board to consider.

1) HID recommends the development of a RDUR criterion identifying elderly patients (≥65) who are receiving one or more of these potentially inappropriate medications to educate prescribers about the risks associated with their use in this population.

2) HID recommends an edit at the point of sale that would require prior authorization for these medications for any beneficiary 65 years of age or older.

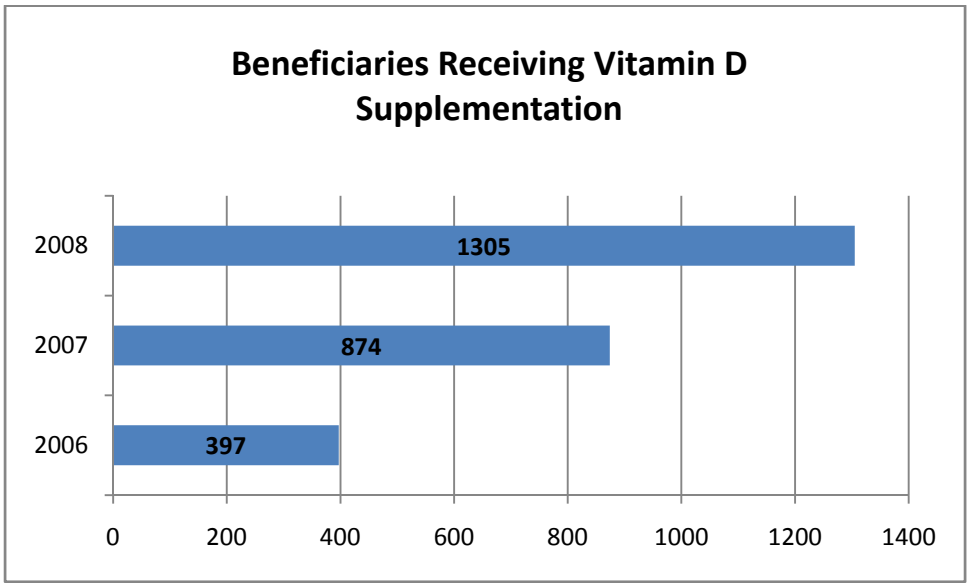
Vitamin D Utilization in Mississippi Medicaid

Vitamin D is a fat-soluble vitamin derived from natural sources (fish liver oils) or from conversion of the provitamins 7-dehydrocholesterol or ergosterol. In humans, natural supplies of vitamin D depend on ultraviolet light for conversion of 7-dehydrocholesterol to vitamin D_3 or ergosterol to vitamin D_2. Following exposure to UV light, vitamin D_3 must then be converted to the active form of vitamin D, calcitriol, by the liver and kidneys. A growing number of studies have linked vitamin D deficiency with an increased risk of cardiovascular disease, hypertension, obesity, diabetes, and some types of cancer. Based on a request from one of the DUR Board Members, HID conducted a claims analysis to determine the utilization of vitamin D in the Mississippi Medicaid population.

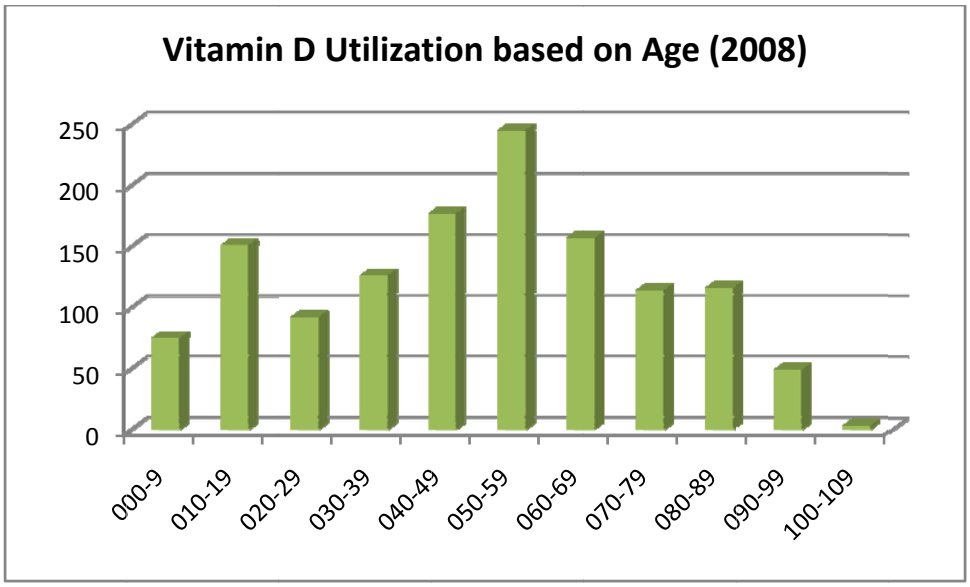
Method

Utilization data was gathered through RxExplorer®, which searches through paid claims data submitted to HID by the fiscal agent. Three searches were conducted covering the last 3 calendar years up to 11/21/08, the most recent date claims data was available.

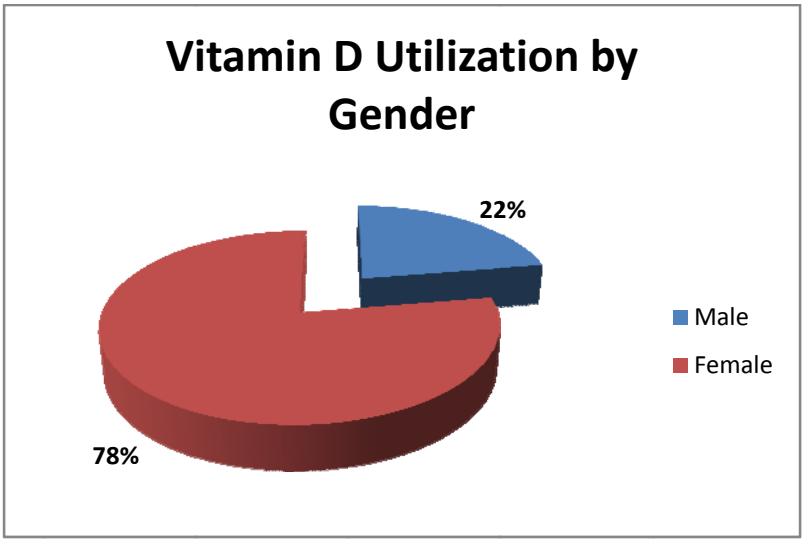
Results



Since 2006, there has been a 328% increase in the number of beneficiaries receiving vitamin D supplementation through the pharmacy program of Mississippi Medicaid. This dramatic increase may be a result of increased awareness of the importance of this vitamin in the prevention of many disease states.



As the chart above shows, the utilization of vitamin D was highest among those beneficiaries ages 50-59, with the next highest utilization being in those beneficiaries 40-49. Pediatric beneficiaries ages 10-19, as well as beneficiaries ages 60-69, were also significant utilizers of vitamin D in the Mississippi Medicaid pharmacy program in 2008.



In 2008, 78% of vitamin D utilization was in women and 22% was in men. This information, coupled with the age information above, indicates that the majority of vitamin D utilization is in postmenopausal women who are most likely receiving calcium supplementation as well for osteoporosis.

Of the 226 beneficiaries ≤ 19 years old, a significant number had an endocrine or metabolic disorder of some type. Specific disorders and the beneficiary count associated with that disorder are listed below.

Diagnosis	Beneficiary Count	% of total beneficiaries
Metabolic disorders	79	35%
Obesity	76	34%
Diabetes Mellitus	46	20%
Hypertension	44	19%
Parathyroid disorders	20	9%
Menstrual disorders	18	8%
Adrenal gland disorder	4	2%
Endocrine disorder	2	<1%

The numbers in the chart above indicate that trends seen in national literature and research regarding vitamin D deficiency are also evident in the Mississippi Medicaid pediatric population.

Conclusion

As awareness of the potential risks associated with vitamin D deficiencies has become more prevalent, the utilization of vitamin D supplementation has increased as well. While the largest groups to utilize the supplementation are in the 40-69 age range, presumably in postmenopausal women, there is significant use of vitamin D in pediatric patients ages 10-19. This age group may see the most benefit of vitamin D supplementation, with provision of this important vitamin early in life possibly preventing chronic diseases such as diabetes, hypertension, and cardiovascular disease in later years.

Over-The-Counter Minimally Sedating Antihistamines in Children under the Age of 2

In January 2007, the CDC warned caregivers and healthcare providers of the risk for serious injury or fatal overdose from the administration of cough and cold products to children and infants less than 2 years of age. This warning followed an investigation of the deaths of three (3) infants less than 6 months of age that were attributed to the accidental inappropriate use of these products. The CDC report estimated that 1519 children under the age of 2 were treated in emergency rooms during 2004—2005 for adverse events related to cough and cold medications.

In October 2007, the FDA Nonprescription Drug Advisory Committee and the Pediatric Advisory Committee recommended that nonprescription cough and cold products not be used in children less than 6 years of age. In January 2008, the FDA issued a Public Health Advisory recommending that OTC cough and cold products, including decongestants, expectorants, antihistamines, and antitussives, not be used in infants and children under 2 years. This recommendation did not address the use of these products in children over the age of 2, as their review of data in this age group is continuing. As soon as this review is complete, the FDA plans to issue its recommendations regarding the use of these products in children ages 2-11.

Mississippi Medicaid

Recently, DOM closed coverage of the over-the-counter cough and cold products for beneficiaries under the age of 2 based on the recommendations of the FDA. Legend, or prescription, products are still available as a treatment option for cough and cold symptoms in pediatric patients with point-of-sale edits based on the FDA-approved age for each product. This means that if a certain legend product is FDA-approved for children over the age of 6, claims for this product for beneficiaries under that age will deny at the point of sale and require prior authorization. Based on pushback from the provider community, loratadine and cetirizine, both of which are OTC, were left open with no age limits in place as the only treatment option for cough and cold symptoms for these beneficiaries. Currently, neither loratadine or cetirizine are FDA-approved for use in children under the age of 2. There is, however, primary literature that supports the safe and effective use of these medications in children over the age of 6 months.

HID conducted claim analyses to determine the utilization of over-the-counter second generation antihistamines in Mississippi Medicaid beneficiaries under the age of 2. These searches were conducted for the six month time frame from 6/1/08 to 11/30/08. The results are shown in the table below.

Generic Name	Rx Count	Total DOM Cost
CETIRIZINE HCL	3071	$29,540.73
LORATADINE	215	$1,846.70
TOTAL	3286	$31,387.43

From June 2008 through November 2008, there were a total of 3286 claims for the OTC minimally sedating antihistamines for 2626 beneficiaries under 2. This represented only 9% of the total claim volume for cetirizine and loratadine, for all ages, during the referenced 6 month time frame.

Conclusion

Based on the FDA recommendations, the Division of Medicaid has taken a strong stand on the OTC cough and cold products by closing coverageof these products for beneficiaries under the age of 2. An outpouring of protests from the provider community led DOM to leave OTC loratadine and cetirizine open for coverage for this particular population. DOM seeks the DUR Board's counsel regarding whether OTC loratadine and cetirizine should be left open for coverage for beneficiaries under 2.

MISSISSIPPI MEDICAID
RETROSPECTIVE DRUG UTILIZATION REVIEW
CRITERIA RECOMMENDATIONS
1st QUARTER 2009

Criteria Recommendations ***Approved*** ***Rejected***

1. Rufinamide / Over-utilization _____ _____

Alert Message: The maximum recommended dose of rufinamide (Banzel) is 3200 mg per day administered in 2 equally divided doses.

Conflict Code: ER - Overutilization
Drugs/Diseases

Util A	Util B	Util C
Rufinamide		

Max Dose: 3200 mg/day

References:
Facts & Comparisons, 2008 Updates.
Banzel Prescribing Information, November 2008, Novartis Pharma AG

2. Rufinamide / Nonadherence _____ _____

Alert Message: Non-adherence to the prescribed dosing regimen for Banzel (rufinamide) may result in sub-therapeutic effects and loss of seizure control.

Conflict Code: LR – Non-adherence
Drugs/Diseases

Util A	Util B	Util C
Rufinamide		

Less than 75 days in 90 day review.

References:
Facts & Comparisons, 2008 Updates.
Banzel Prescribing Information, November 2008, Novartis Pharma AG.

3. Rufinamide / Triazolam _____ _____

Alert Message: The concurrent use of Banzel (rufinamide) with triazolam may result in decreased exposure to triazolam due to the induction, by rufinamide, of CYP3A4-mediated triazolam metabolism. Based on in-vivo studies the co-administration and pre-treatment with rufinamide (400 mg bid) resulted in a 37% decrease in AUC and 23% decrease in Cmax of triazolam.

Conflict Code: DD- Drug/Drug Interaction
Drugs/Diseases

Util A	Util B	Util C
Rufinamide	Triazolam	

References:
Facts & Comparisons, 2008 Updates.
Banzel Prescribing Information, November 2008, Novartis Pharma AG.

Criteria Recommendations ***Approved*** ***Rejected***

4. Rufinamide / Oral Contraceptives _____ _____

Alert Message: The concurrent use of Banzel (rufinamide) with oral contraceptives (OC) may result in decreased exposure to the OC due to the induction, by rufinamide, of CYP3A4-mediated hormone metabolism. Patients of childbearing age should be warned that the coadministration of these agents may render the OC less effective. Additional non-hormonal forms of contraception are recommended during rufinamide therapy.

Conflict Code: DD- Drug/Drug Interaction
Drugs/Diseases

Util A	Util B	Util C
Rufinamide	Oral Contraceptives	

References:
Facts & Comparisons, 2008 Updates.
Banzel Prescribing Information, November 2008, Novartis Pharma AG.

5. Rufinamide / Carbamazepine _____ _____

Alert Message: Concurrent use of Banzel (rufinamide) with carbamazepine may result in decreased plasma levels of both rufinamide (19% to 26%) and carbamazepine (7% to 13%) with the effects being more marked in the pediatric population.

Conflict Code: DD - Drug/Drug Interaction
Drugs/Diseases

Util A	Util B	Util C
Rufinamide	Carbamazepine	

References:
Facts & Comparisons, 2008 Updates.
Banzel Prescribing Information, November 2008, Novartis Pharma AG.

6. Rufinamide / Phenobarbital _____ _____

Alert Message: Concurrent use of Banzel (rufinamide) with phenobarbital may result in a 25% to 46% decrease in rufinamide plasma concentrations and increased phenobarbital concentrations of 8% - 13%. The effect is usually more marked in the pediatric population.

Conflict Code: DD - Drug/Drug Interaction
Drugs/Diseases

Util A	Util B	Util C
Rufinamide	Phenobarbital	

References:
Facts & Comparisons, 2008 Updates.
Banzel Prescribing Information, November 2008, Novartis Pharma AG.

Criteria Recommendations ***Approved*** ***Rejected***

7. Rufinamide / Phenytoin _____ _____

Alert Message: Concurrent use of Banzel (rufinamide) with phenytoin may result in a 25% to 46% decrease in the rufinamide plasma concentrations. Phenytoin plasma levels may increase by 7% to21% due to phenytoin's non-linear pharmacokinetics. The effect is usually more marked in the pediatric population.

Conflict Code: DD - Drug/Drug Interaction
Drugs/Diseases

Util A	Util B	Util C
Rufinamide	Phenytoin	

References:
Facts & Comparisons, 2008 Updates.
Banzel Prescribing Information, November 2008, Novartis Pharma AG.

8. Rufinamide / Primidone _____ _____

Alert Message: Concurrent use of Banzel (rufinamide) with primidone may result in a 25% to 46% decrease in rufinamide concentrations independent of dose or concentration of primidone. The effect is usually more marked in the pediatric population.

Conflict Code: DD - Drug/Drug Interaction
Drugs/Diseases

Util A	Util B	Util C
Rufinamide	Primidone	

References:
Facts & Comparisons, 2008 Updates.
Banzel Prescribing Information, November 2008, Novartis Pharma AG.

9. Rufinamide / Valproate _____ _____

Alert Message: Concurrent use of Banzel (rufinamide) with valporate may result in a 16% to 70% increase in rufinamide concentrations with the more marked effect in the pediatric population. Patients stabilized on rufinamide before being prescribed valproate should begin valproate therapy at a low dose, and titrate to a clinically effective dose. Patients on valporate who have rufinamide added to the regimen should begin with a rufinamide dose lower than 400mg.

Conflict Code: DD - Drug/Drug Interaction
Drugs/Diseases

Util A	Util B	Util C
Rufinamide	Valporate	

References:
Facts & Comparisons, 2008 Updates.
Banzel Prescribing Information, November 2008, Novartis Pharma AG.

Criteria Recommendations ***Approved*** ***Rejected***

10. Rufinamide / Lamotrigine _____ _____

Alert Message: Concurrent use of Banzel (rufinamide) and lamotrigine may result in a 7% to 13% decrease in lamotrigine concentrations in a concentration-dependent manner. The effect is usually more marked in the pediatric population.

Conflict Code: DD - Drug/Drug Interaction
Drugs/Diseases

Util A	Util B	Util C
Rufinamide	Lamotrigine	

References:
Facts & Comparisons, 2008 Updates.
Banzel Prescribing Information, November 2008, Novartis Pharma AG.

11. Rufinamide /Short QT Syndrome Inducing Drugs _____ _____

Alert Message: Banzel (rufinamide) is contraindicated in patients with familial short QT syndrome. Formal cardiac ECG studies demonstrated shortening of the QT interval up to 20 msec with rufinamide treatment. Caution should also be used when administering rufinamide with other drugs that shorten the QT interval.

Conflict Code: DC – Inferred Drug Disease Warning
Drugs/Diseases

Util A	Util B		Util C
Rufinamide	Short QT Interval		
	Digoxin	Propafenone	
	Lamotrigine	Moricizine	
	Ranolazine	Lidocaine	
	Magnesium	Carbamazepine	
	Mexiletine	Amitriptyline	
	Procainamide	Imipramine	
	Disopyramide	Haloperidol	
	Phenytoin	Metoclopramide	
	Flecainide		

References:
Facts & Comparisons, 2008 Updates.
Banzel Prescribing Information, November 2008, Novartis Pharma AG.

FDA Updates

The following information is provided to the DUR Board to assist in identifying drug products with potential for concern surrounding safety and appropriate utilization. Most of the safety alert information provided is derived from recent FDA safety alerts. While many of the alerts included are not Black Box Warning additions or updates, they are labeling changes or updates with relevance worthy of action by FDA.

Included for reference, the following is the Code of Federal Regulations definition for Black Box Warnings. (Citation: Title 21 CFR 201.57 Section E)

(e) Warnings. Under this section heading, the labeling shall describe serious adverse reactions and potential safety hazards, limitations in use imposed by them, and steps that should be taken if they occur. The labeling shall be revised to include a warning as soon as there is reasonable evidence of an association of a serious hazard with a drug; a causal relationship need not have been proved. A specific warning relating to a use not provided for under the "Indications and Usage: section of labeling may be required by the Food and Drug Administration if the drug is commonly prescribed for a disease of condition, and there is lack of substantial evidence of effectiveness for that disease or condition, and such usage is associated with serious risk or hazard. Special problems, particularly those that may lead to death or serious risk or hazard. Special problems, particularly those that may lead to death or serious injury, may be required by the Food and Drug Administration to be placed in a prominently displayed box. The boxed warning ordinarily shall be based on clinical data, but serious animal toxicity may also be the basis of a boxed warning in the absence of clinical data. If a boxed warning is required, its location will be specified by the Food and Drug Administration. The frequency of these adverse reactions and, if known, the approximate mortality and morbidity rates for patients sustaining the reaction, which are important to safe and effective used of the drug, shall be expressed as provided under the "Adverse Reactions" section of the labeling.

ReliOn Insulin Syringes for use with U-100 Insulin (Tyco Healthcare - Covidien)

Covidien and FDA notified patients and healthcare professionals of a recall of ReliOn sterile, single-use, disposable, hypodermic syringes with permanently affixed hypodermic needles. The mislabeled syringe may result in patients receiving an overdose of as much as 2.5 times the intended dose, with serious health consequences, low blood sugar, and even death. These syringes are sold only by Wal-Mart or Sam's Club pharmacies under the ReliOn name. The recall applies only to lot number 813900. The product was distributed from Aug. 1, 2008 until Oct. 8, 2008, and includes 471,000 individual syringes in 4,710 boxes. FDA urges patients and health care professionals to check syringe packaging carefully for products with this lot number, not to use the product, and return the product to the pharmacy for replacement. The lot number can be found on the back panel of the 100 count syringe carton, or on the white paper backing of each individual syringe "peel-pack".

Propafenone HCl Tablets 150 mg, 225 mg, and 300 mg; Isosorbide Mononitrate Extended Release Tablets 30 mg and 60 mg; Morphine Sulfate Extended Release Tablets 15 mg; Morphine Sulfate Immediate Release Tablets 15 mg and 30 mg; Dextroamphetamine Sulfate Tablets 10 mg

Ethex Corp and FDA notified healthcare professionals of a voluntary recall of five generic products (Propafenone HCl Tablets, Isosorbide Mononitrate Extended Release Tablets, Morphine Sulfate Extended Release Tablets, Morphine Sulfate Immediate Release Tablets, and Dextroamphetamine Sulfate Tablets). The products were recalled because they may contain oversized tablets. Oversized tablets may contain more than the intended levels of the active drug ingredient that could result in patients receiving as much as twice the expected dosage of these drugs, which could cause serious or life-threatening consequences.

Overdoses can include arrhythmias and low blood pressure with Propafenone HCl; fainting and low blood pressure with Isosorbide Mononitrate; respiratory depression and low blood pressure with Morphine Sulfate; and rapid heart rate and high blood pressure with Dextroamphetamine Sulfate. Patients who experience any adverse reactions to these drugs should contact their healthcare professional immediately. See the manufacturer's recall notice for specific lot numbers of the products affected by this recall.

Bisphosphonates marketed as Alendronate (Fosamax, Fosamax Plus D), Etidronate (Didronel) Ibandronate (Boniva), Pamidronate (Aredia), Risedronate (Actonel, Actonel W/Calcium) Tiludronate (Skelid), Zoledronic acid (Reclast, Zometa)

FDA issued an update about the Agency's review of safety data regarding the potential increased risk of atrial fibrillation in patients treated with a bisphosphonate drug. Bisphosphonates are a class of drugs used primarily to increase bone mass and reduce the risk for fracture in patients with osteoporosis, slow bone turnover in patients with Paget’s disease of the bone, and to treat bone metastases and lower elevated levels of blood calcium in patients with cancer. FDA reviewed data on 19,687 bisphosphonate-treated patients and 18,358 placebo-treated patients who were followed for 6 months to 3 years. The occurrence of atrial fibrillation was rare within each study, with most studies containing 2 or fewer events. Across all studies, no clear association between overall bisphosphonate exposure and the rate of serious or non-serious atrial fibrillation was observed. Additionally, increasing dose or duration of bisphosphonate therapy was not associated with an increase rate of atrial fibrillation. Healthcare professionals should not alter their prescribing patterns for bisphosphonates and patients should not stop taking their bisphosphonate medication.

Infants' Mylicon Gas Relief Dye Free Drops (Simethicone-Antigas)

Johnson & Johnson- Merck Consumer Pharmaceuticals Company and FDA notified consumers and healthcare professionals of a voluntary recall of Infants' Mylicon Gas Relief Dye Free Drops (Lot No. SMF007 and SMF008) sold in 1 oz plastic bottles that were distributed after October 5, 2008, nationwide. The product was recalled because some bottles could include metal fragments that were generated during the manufacturing process. Parents who have given the product to their infant and are concerned should contact their healthcare professional.

Benzoyl Peroxide Acne Cream 10% marked as: DG Maximum Strength Acne Medicated Gel, Kroger Acne Gel 10% Benzoyl Peroxide Acne Medication, Equate: Medicated Acne Gel

CSI USA Inc. and FDA informed consumers and healthcare professionals of a nationwide recall of all lots of 1 ounce tubes of 10% Benzoyl Peroxide Acne Cream. The products were recalled because samples of the products were found to contain bacteria, Burkholderia Cepacia, formerly known as Pseudomonas Cepacia. There may be an increased health risk of infections for individuals with cuts, scrapes, rashes or other compromised skin conditions; or those with weakened or suppressed immune systems.

Consumers should discontinue using the product and should return it to the place of purchase. See the company's press release for photos of product packaging.

Phenytoin
FDA is investigating new preliminary data regarding a potential increased risk of serious skin reactions including Stevens Johnson syndrome (SJS) and toxic epidermal necrolysis (TEN) from phenytoin therapy in Asian patients positive for human leukocyte antigen (HLA) allele, HLA-B*1502. This allele occurs almost exclusively in patients with ancestry across broad areas of Asia, including Han Chinese, Filipinos, Malaysians, South Asian Indians, and Thais. Until the FDA evaluation is completed, healthcare providers who are considering the use of phenytoin or fosphenytoin should be aware of the risks and benefits described in the current prescribing information for this drug. Healthcare providers should consider avoiding phenytoin and fosphenytoin as alternatives for carbamazepine in patients who test positive for HLA-B*1502. A summary of the data currently being analyzed by FDA, and information for patients and healthcare professionals to consider, can be found in the links provided in the MedWatch safety alert.

Starcaps Dietary Supplement Capsules
Balanced Health Products, Inc. announced a recall of STARCAPS due to the presence of an undeclared drug ingredient, Bumetanide. Bumetanide is a diuretic indicated for the treatment of edema associated with congestive heart failure, hepatic and renal disease including nephrotic syndrome. Potential risks associated with the use of Bumetanide include serious and significant fluid and electrolyte loss and an elevation in uric acid concentrations. Consumers should not take Bumetanide if they are allergic to sulfonamides. Significant drug interactions with Bumetanide, such as with digoxin and lithium, may lead to an increase risk of toxicity. Patients may also be at an increased risk of hypotension (low blood pressure), fainting (syncope) and resultant injury if they have normal blood pressure or are already taking an antihypertensive medication and take STARCAPS with undeclared Bumetanide. Consumers who have this product should immediately discontinue taking it and return the product to the manufacturer. See the company's press release for specific lot number information.

Zhen De Shou Fat Loss Capsules
Fashion Sanctuary announced a recall of Zhen De Shou Fat Loss Capsules because FDA analysis found the product to contain undeclared sibutramine, an FDA approved drug used as an appetite suppressant for weight loss. This poses a potential threat to consumers because sibutramine is known to substantially increase blood pressure and/or pulse rate in some patients and may present a significant risk for patients with a history of coronary artery disease, congestive heart failure, arrhythmias or stroke. The product was primarily distributed in the U.S and sold via the Internet and the recall affects all lot codes and use by dates. Consumers who may have purchased product from this company should immediately discontinue using the product.

Innohep (tinzaparin sodium injection)
FDA has received information about the clinical study: Innohep in Renal Insufficiency Study (IRIS) that was stopped in February, 2008 by the study's Data Safety Monitoring Committee because of an interim finding of an increase in all-cause mortality in patients who received Innohep. Information on the patients enrolled in the study, on the heparin used to manufacture Innohep, and on the heparin used in the study is still being collected and analyzed.

In July 2008, the company revised the prescribing information to restrict the use of Innohep in patients

90 years of age or older. FDA is concerned that the preliminary data from the IRIS study suggest that the increased risk of mortality is not limited only to patients 90 years of age or older. Therefore, FDA has requested that the company revise the labeling for Innohep to better describe the overall study results which suggest that, when compared to unfractionated heparin, Innohep increases the risk of death for elderly patients (i.e., 70 years of age and older) with renal insufficiency. Healthcare professionals should consider the use of alternative treatments to Innohep when treating elderly patients over 70 years of age with renal insufficiency and DVT, PE, or both. This communication is in keeping with FDA's commitment to inform the public about its ongoing safety reviews of drugs. FDA anticipates submission of the final IRIS study report in January, 2009 and plans to complete its review soon thereafter. FDA will communicate its conclusions and any resulting recommendations to the public at that time. FDA will consider additional regulatory actions as appropriate after thorough review of all applicable data from the manufacturer of Innohep.

Oral Sodium Phosphate Products

FDA has become aware of reports of acute phosphate nephropathy, a type of acute kidney injury, associated with the use of oral sodium phosphate products (OSP) for bowel cleansing prior to colonoscopy or other procedures. These products include the prescription products, Visicol and OsmoPrep, and OSPs available over-the-counter without a prescription as laxatives (e.g., Fleet Phospho-soda). In some cases when used for bowel cleansing, these serious adverse events have occurred in patients without identifiable factors that would put them at risk for developing acute kidney injury.

FDA is requiring the manufacturer of Visicol and OsmoPrep, the two OSPs available by prescription only, to add a Boxed Warning to the labeling for these products. FDA is also requiring that the manufacturer develop and implement a risk evaluation and mitigation strategy (REMS), which will include a Medication Guide, to ensure that the benefits of these products outweigh the risk of acute phosphate nephropathy, and to conduct a postmarketing clinical trial to further assess the risk of acute kidney injury with use of these products. FDA recommends, in light of the risk of acute phosphate nephropathy, over-the-counter laxative OSP products should not be used for bowel cleansing. Consumers should only use OSPs for bowel cleansing pursuant to a prescription from a healthcare professional.

Hydromorphone HCl 2 mg Tablets

ETHEX and FDA notified heathcare professionals of a nationwide recall of a single lot of Hydromorphone HCl 2 mg Tablets due to potential for oversized tablets. Hydromorphone is a drug used for pain management. If someone were to take a higher than expected dose of Hydromorphone, the risk of adverse effects known to be associated with the drug may be increased, including respiratory depression (difficulty or lack of breathing), low blood pressure, and sedation. The recalled tablets are a blue, round tablet with a script "E" on one side and a "2" on the other side.

The parent company of ETHEX Corporation, KV Pharmaceutical has advised FDA that it is voluntarily suspending shipments of all FDA-approved drug products in tablet form. This action is being taken as a precautionary measure, to allow KV to address manufacturing issues that have come to management's attention.

Innohep (tinzaparin sodium injection)
Celgene has issued a Dear Healthcare Professional letter describing a controlled clinical study suggesting that Innohep may increase the risk for death, compared to unfractionated heparin when used to treat elderly patients with renal insufficiency. It recommended consideration of alternatives to Innohep when treating these patients for deep vein thrombosis with or without pulmonary embolism.