Division of Medicaid

Office of the Governor

State of Mississippi

DUR Board Meeting

February 18, 2010

2:00 p.m.

Woolfolk Building, Room 117

Jackson, MS

Drug Utilization Review Board

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

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

Vickie Veazey, 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

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

Jason Strong, Pharm.D.
Canton Discount
726 East Peace Street
Canton, MS 39046
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

Laura Gray, M.D.
905 Garfield Street
Tupelo, MS 38801
Term Expires: June 30, 2012

Gera Bynum, R.Ph.
Scott Regional Hospital
371 Highway 13S
Morton, MS 39117
Term Expires: June 30, 2012

Paul Read, Pharm.D.
CVS Pharmacy #5744
3910 Hardy Street
Hattiesburg, MS 36402
Term Expires: June 30, 2012

Jason Dees, D.O.
New Albany Medical Group
620 West Longview Drive
New Albany, MS 38652
Term Expires: June 30, 2012

Upcoming Mississippi DUR Board Meeting Dates

May 20, 2010
November 18, 2010

August 19, 2010
February 17, 2011

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

February 18, 2010

Welcome	**Mark Reed, M.D.**
Old Business	**Mark Reed, 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.**
Tamiflu® Utilization Update	
Atypical Antipsychotics: Issues within the Mississippi Medicaid Population	
ADHD Agents: Issues within the Mississippi Medicaid Population	
Mississippi Medicaid Coverage of Topical Acne Agents	
Other Criteria Recommendations	
FDA Updates	
Next Meeting Information	**Mark Reed, M.D.**

Mississippi Division of Medicaid
Drug Utilization Review (DUR) Board
Minutes of the November 19, 2009 Meeting

Members Attending: William Bastian, M.D.; Gera Bynum, RPh.; Alvin Dixon, RPh.; Edgar Donahoe, M.D.; Lee Merritt, RPh.; Mark Reed, M.D.; Paul Read, Pharm.D; Jason Strong, Pharm.D; Vickie Veazey, RPh.;
Members Absent: Jason Dees, D.O.; Laura Gray, M.D.; Frank Wade, M.D.

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

Call to Order: Dr. Mark Reed, Interim Chairman of the Board, called the meeting to order at 2:04 p.m. Dr. Reed asked for a motion to accept the minutes from the meeting of August 20, 2009. Dr. Donahoe made the motion to accept the recommendation with a second from Ms. Veazey. All voted in favor of the motion. Dr. Reed then asked for the Board to introduce themselves as there were new Board members present.

Dr. Reed continued the meeting by moving into the new business under the direction of Dr. Holeman.

Cost Management Analysis:
Dr. Holeman began with the presentation of the Top 15 Therapeutic classes by the total cost of claims dating June 01, 2009 thru August 31, 2009. The Top Therapeutic class remains Antipsychotic Agents. The Top 25 Drugs based on the number of claims for these same dates continues to be led by hydrocodone-acetaminophen agents. The Top 25 Drugs based on total claims cost was led by Abilify® and Prevacid® , with Singulair® leading the month of August.

Pharmacy Program Update:
Dr. Clayton reviewed several changes DOM implemented in order to facilitate the immediate claims transactions of Tamiflu® for Medicaid beneficiaries with the re-emergence of the H1N1 virus. These changes were implemented September 1, 2009. Tamiflu does not count towards the monthly service limits for children only, and compounding issues were addressed to allow for the timely treatment of the H1N1 virus. There were quantity limits placed on the medication to assure proper dosing and conservation of the product. Ms. Clark stated that Medicaid would pay for the dispensing fee of the H1N1 vaccine for adults only through the Pharmacy Program. Children will be required to obtain their H1N1 vaccine through their primary care physicians, as is the case with all vaccines. H1N1 vaccinations for long term care facilities will be handled through their normal processes for vaccinations and not the pharmacy program.

DUR Overview Review:
Dr. Holeman began by noting that with newly appointed Board members it would be beneficial to review the purpose of the DUR program. Dr. Holeman reviewed requirements that were outlined by OBRA 90 for states' DUR programs, as well as the roles and responsibilities of the DUR Board and the state Medicaid agencies in regard to drug utilization review. Dr. Holeman stated many proactive changes to the Pharmacy Program have been implemented by this Board.

Prior Authorization Status of Immunosupressants:
HID gathered utilization data for the fiscal year 2009 (7/1/08- 6/30/09) for the immunosuppressant class. This data was analyzed to determine if these agents were being used appropriately based on diagnoses. Dr. Holeman presented this data, concluding that these agents were being appropriately used. DOM requested the DUR Board's counsel regarding whether the prior authorization requirement should be lifted for the immunosuppressant class. Dr. Donahoe motioned that this prior authorization requirement be lifted but monitored the next year by HID for appropriate utilization. Dr. Strong seconded the motion. All voted in favor of the motion.

Appropriate Place in Therapy for Isentress®:
Recently, the AIDS Healthcare Foundation sent letters to all state AIDS Drug Assistance Programs (ADAP) and Medicaid directors requesting that Isentress® be placed on prior authorization in order to control costs while still ensuring access to the agent for those patients whom it was medically necessary. Based on the letter from AHF, DOM asked HID to conduct claims analyses of Isentress® Utilization. Utilization for three time periods (7/1/08 thru 9/25/09) were reported to the Board. It was noted that there was a steady increase in the average number of claims per month of approximately 18% even after the expanded indication for first-line therapy in July 2009. Based on the information obtained, DOM requested counsel of the DUR Board members regarding prospective prior authorization of Isentress®. After some discussion among the Board, it was recommended by Dr. Donahoe that this class be reviewed by the P&T Committee for PDL placement, rather than focusing on a single agent for prior authorization. Dr. Donahoe continued that consultation with Infectious Disease specialists would be helpful as it would be out of most DUR Board members' field of expertise. Ms. Veazey seconded the motion. All voted in favor of the motion.

Alzheimer's Agents:
At the October 2009 Mississippi Medicaid Pharmacy and Therapeutics Committee Meeting, it was noted by committee members that utilization of the Alzheimer's agents was rather high, considering that most of the beneficiaries who require these medications should be Medicare eligible. The P&T committee asked that the DUR Board analyze this utilization further to determine what Medicaid beneficiaries are receiving these medications. There were many concern's recognized by DOM through these reports. While utilization in beneficiaries over the age of 60 appeared to be appropriate, the number of beneficiaries under the age of 50 receiving these medications was noted to be concerning. Only 3 beneficiaries had an appropriate diagnosis of Alzheimer's disease. DOM requested the DUR Board's counsel whether age limits should be implemented for

this class at the point of sale. Dr.Donohaoe recommended, after much Board discussion, to start with the development of a RDUR criterion identifying those beneficiaries under age 50 receiving an Alzheimer's agent with no appropriate diagnosis. He also asked for a review of activity surrounding this criterion in six months to one year. This motion was seconded by Dr. Strong. All voted in favor of the motion.

Other Criteria Recommendations:
Dr. Reed asked for the Board to accept these recommendations as a block vote. All voted in favor of the motion.

FDA Updates:
Dr. Holeman asked if there were any questions in regard to the submitted updates. No questions were raised.

Before the conclusion of the meeting, Dr. Reed asked if there was any other business to be discussed.

Dr. Clayton interjected that she had a few items that she would like to present. She noted that the ADHD medications were some of the only controlled substances that did not have quantity limits for Mississippi Medicaid beneficiaries. After much concern and discussion, Dr. Donahoe motioned that an age limit of 21 and below be placed on the whole class. Also, he recommended that a cumulative limit of 31 units per month be placed on the extended-release ADHD medications. This was seconded by Dr. Paul Read as he had witnessed definite abuse of these medications from the retail pharmacy level. All voted in favor of this motion. The discussion of the short-acting ADHD agents was ended by Ms. Clark asking HID to run some analyses on these medication and report back to the Board at the next meeting. She stated that with this report, the Board might need to look at limiting these formulations also. Dr. Clayton continued by stating that the web submission of a prior authorization through the Mississippi Medicaid web portal is set to go live in a few weeks, easing some of the paperwork burden on physicians and clinics.

Dr. Mark Reed noted that the last order of business for the Board is to elect a Chairperson. Dr. Donahoe began by nominating Dr. Mark Reed to continue as Chairman of the Board. All voted in favor of the motion. Vickie Veazey nominated Dr. Donahoe to serve as Vice Chair of the Board. All voted in favor of the motion.

Dr. Mark Reed called for the meeting to be adjourned at 3:00 p.m. The next meeting will be held at 2:00 p.m. on February 18, 2010.

Respectfully Submitted
Health Information Designs, Inc.

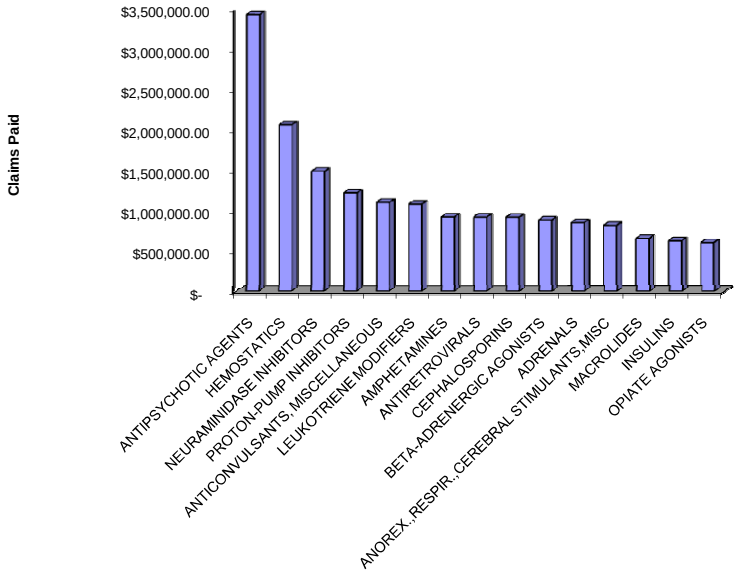
MISSISSIPPI MEDICAID
Cost Management Analysis

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

AHFS Therapeutic Class	Rx	Paid	Paid/Rx	% Total Claims
ANTIPSYCHOTIC AGENTS	11,339	$ 3,420,644.91	$ 301.67	2.36%
HEMOSTATICS	65	$ 2,061,703.13	$31,718.51	0.01%
NEURAMINIDASE INHIBITORS	17,597	$ 1,487,855.72	$ 84.55	3.66%
PROTON-PUMP INHIBITORS	8,148	$ 1,222,969.78	$ 150.09	1.70%
ANTICONVULSANTS, MISCELLANEOUS	12,573	$ 1,103,082.59	$ 87.73	2.62%
LEUKOTRIENE MODIFIERS	8,980	$ 1,081,884.98	$ 120.48	1.87%
AMPHETAMINES	6,419	$ 923,062.31	$ 143.80	1.34%
ANTIRETROVIRALS	1,117	$ 921,829.93	$ 825.27	0.23%
CEPHALOSPORINS	15,909	$ 920,473.74	$ 57.86	3.31%
BETA-ADRENERGIC AGONISTS	14,930	$ 886,198.54	$ 59.36	3.11%
ADRENALS	12,971	$ 854,454.21	$ 65.87	2.70%
ANOREX.,RESPIR.,CEREBRAL STIMULANTS,MISC	6,158	$ 819,256.06	$ 133.04	1.28%
MACROLIDES	21,281	$ 658,707.76	$ 30.95	4.43%
INSULINS	3,838	$ 629,542.20	$ 164.03	0.80%
OPIATE AGONISTS	30,381	$ 607,567.38	$ 20.00	6.33%
TOTAL TOP 15	171,706	$ 17,599,233.24	$ 102.50	35.76%

Total Rx Claims From 09/01/09-09/30/09	480,211

Top 15 Therapeutic Classes
Based on Total Cost of Claims



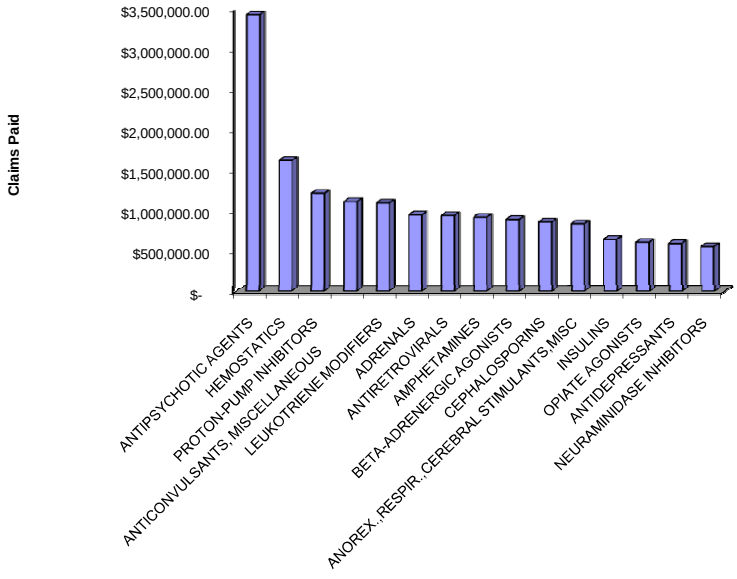
MISSISSIPPI MEDICAID
Cost Management Analysis

TOP 15 THERAPEUTIC CLASSES BY TOTAL COST OF CLAIMS FROM 10/01/09-10/31/09

AHFS Therapeutic Class	Rx	Paid	Paid/Rx	% Total Claims
ANTIPSYCHOTIC AGENTS	11,542	$ 3,420,125.09	$ 296.32	2.52%
HEMOSTATICS	58	$ 1,622,058.94	$27,966.53	0.01%
PROTON-PUMP INHIBITORS	8,556	$ 1,217,915.60	$ 142.35	1.87%
ANTICONVULSANTS, MISCELLANEOUS	12,859	$ 1,113,276.23	$ 86.58	2.81%
LEUKOTRIENE MODIFIERS	9,320	$ 1,096,277.08	$ 117.63	2.04%
ADRENALS	13,130	$ 950,624.34	$ 72.40	2.87%
ANTIRETROVIRALS	1,186	$ 941,913.01	$ 794.19	0.26%
AMPHETAMINES	6,569	$ 920,929.95	$ 140.19	1.44%
BETA-ADRENERGIC AGONISTS	15,847	$ 894,677.18	$ 56.46	3.47%
CEPHALOSPORINS	14,901	$ 862,414.07	$ 57.88	3.26%
ANOREX.,RESPIR.,CEREBRAL STIMULANTS,MISC	6,333	$ 839,950.52	$ 132.63	1.38%
INSULINS	4,025	$ 647,623.98	$ 160.90	0.88%
OPIATE AGONISTS	30,564	$ 612,941.77	$ 20.05	6.68%
ANTIDEPRESSANTS	15,267	$ 596,246.78	$ 39.05	3.34%
NEURAMINIDASE INHIBITORS	7,228	$ 558,473.83	$ 77.27	1.58%
TOTAL TOP 15	157,385	$ 16,295,448.37	$ 103.54	34.41%

Total Rx Claims	457,343
From 10/01/09-10/31/09	

Top 15 Therapeutic Classes
Based on Total Cost of Claims



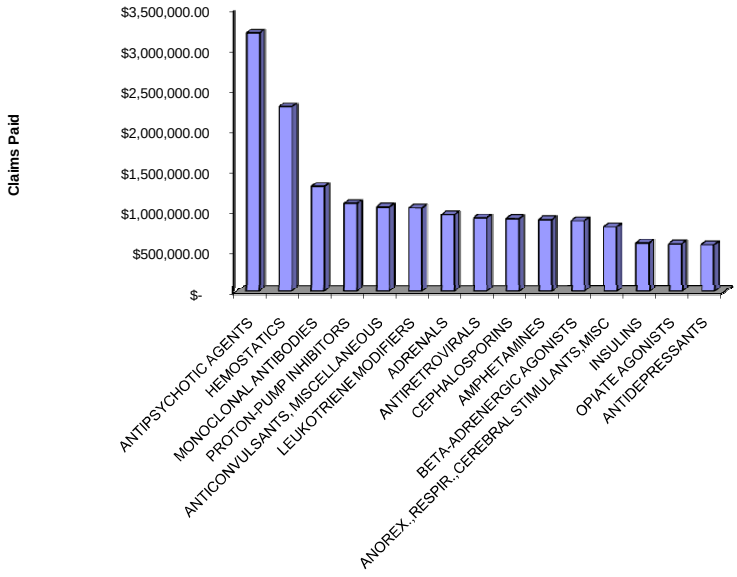
MISSISSIPPI MEDICAID
Cost Management Analysis

TOP 15 THERAPEUTIC CLASSES BY TOTAL COST OF CLAIMS FROM 11/01/09-11/30/09

AHFS Therapeutic Class	Rx	Paid	Paid/Rx	% Total Claims
ANTIPSYCHOTIC AGENTS	10,839	$ 3,195,179.80	$ 294.79	2.50%
HEMOSTATICS	51	$ 2,285,706.46	$44,817.77	0.01%
MONOCLONAL ANTIBODIES	812	$ 1,301,723.46	$ 1,603.11	0.19%
PROTON-PUMP INHIBITORS	8,030	$ 1,091,364.39	$ 135.91	1.85%
ANTICONVULSANTS, MISCELLANEOUS	12,358	$ 1,047,731.60	$ 84.78	2.85%
LEUKOTRIENE MODIFIERS	8,819	$ 1,035,837.52	$ 117.46	2.03%
ADRENALS	13,653	$ 952,562.49	$ 69.77	3.15%
ANTIRETROVIRALS	1,153	$ 912,788.11	$ 791.66	0.27%
CEPHALOSPORINS	15,226	$ 903,988.30	$ 59.37	3.51%
AMPHETAMINES	6,387	$ 891,610.34	$ 139.60	1.47%
BETA-ADRENERGIC AGONISTS	15,927	$ 877,434.86	$ 55.09	3.67%
ANOREX.,RESPIR.,CEREBRAL STIMULANTS,MISC	5,947	$ 802,917.36	$ 135.01	1.37%
INSULINS	3,743	$ 603,897.80	$ 161.34	0.86%
OPIATE AGONISTS	28,648	$ 591,547.07	$ 20.65	6.60%
ANTIDEPRESSANTS	14,545	$ 581,497.96	$ 39.98	3.35%
TOTAL TOP 15	146,138	$ 17,075,787.52	$ 116.85	33.69%

Total Rx Claims	433,771
From 11/01/09-11/30/09	

Top 15 Therapeutic Classes
Based on Total Cost of Claims
1/19/2010



Health Information Designs, Inc.
1/19/2010

MISSISSIPPI MEDICAID
Cost Management Analysis

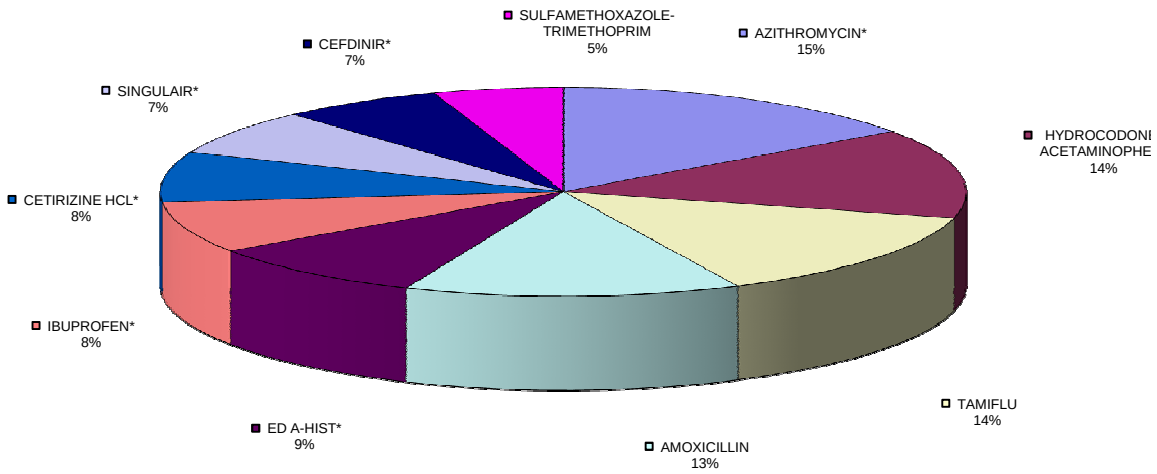
TOP 25 DRUGS BASED ON NUMBER OF CLAIMS FROM 09/01/09-09/30/09

Drug	AHFS Therapeutic Class	Rx	Paid	Top 200 Rank
AZITHROMYCIN*	MACROLIDES	19,146	$ 568,104.09	6
HYDROCODONE-ACETAMINOPHEN*	OPIATE AGONISTS	17,479	$ 244,149.32	1
TAMIFLU	NEURAMINIDASE INHIBITORS	17,473	$ 1,480,191.72	80
AMOXICILLIN	PENICILLINS	16,956	$ 161,395.84	5
ED A-HIST*	PROPYLAMINE DERIVATIVES	11,411	$ 94,047.16	~
IBUPROFEN*	NONSTEROIDAL ANTI-INFLAMMATORY AGENTS	10,059	$ 87,559.19	18
CETIRIZINE HCL*	SECOND GENERATION ANTIHISTAMINES	9,826	$ 196,796.20	~
SINGULAIR*	LEUKOTRIENE MODIFIERS	8,971	$ 1,081,001.33	4
CEFDINIR*	CEPHALOSPORINS	8,199	$ 618,165.62	68
SULFAMETHOXAZOLE-TRIMETHOPRIM	SULFONAMIDES (SYSTEMIC)	6,556	$ 82,207.49	39
AMOX TR-POTASSIUM CLAVULANATE*	PENICILLINS	6,529	$ 356,128.98	32
ALBUTEROL SULFATE*	BETA-ADRENERGIC AGONISTS	6,416	$ 198,817.02	67
PREVACID*	PROTON-PUMP INHIBITORS	5,177	$ 927,571.70	7
PROMETHAZINE HCL	PHENOTHIAZINE DERIVATIVES	4,720	$ 52,334.95	59
ALPRAZOLAM	BENZODIAZEPINES (ANXIOLYTIC,SEDATIV/HYP)	4,571	$ 31,729.29	8
CLONAZEPAM	BENZODIAZEPINES (ANTICONVULSANTS)	4,129	$ 31,624.06	24
PROAIR HFA*	BETA-ADRENERGIC AGONISTS	4,073	$ 175,271.54	14
CEPHALEXIN*	CEPHALOSPORINS	4,000	$ 63,399.66	22
ACETAMINOPHEN-CODEINE*	OPIATE AGONISTS	3,710	$ 30,728.28	43
CHERATUSSIN AC	ANTITUSSIVES	3,671	$ 19,128.13	105
RISPERIDONE*	ANTIPSYCHOTIC AGENTS	3,588	$ 349,799.24	140
NYSTATIN*	POLYENES	2,830	$ 35,357.21	142
MUPIROCIN	ANTIBACTERIALS (SKIN & MUCOUS MEMBRANE)	2,799	$ 105,838.13	107
AMLODIPINE BESYLATE*	DIHYDROPYRIDINES	2,775	$ 19,076.95	~
CONCERTA*	ANOREX.,RESPIR.,CEREBRAL STIMULANTS,MISC	2,754	$ 413,800.57	34
TOTAL TOP 25		187,818	$ 7,424,223.67	

Total Rx Claims From 09/01/09-09/30/09	480,211

** Indicates preferred products on Preferred Drug List*

Top 10 Drugs
Based on Number of Claims



MISSISSIPPI MEDICAID
Cost Management Analysis

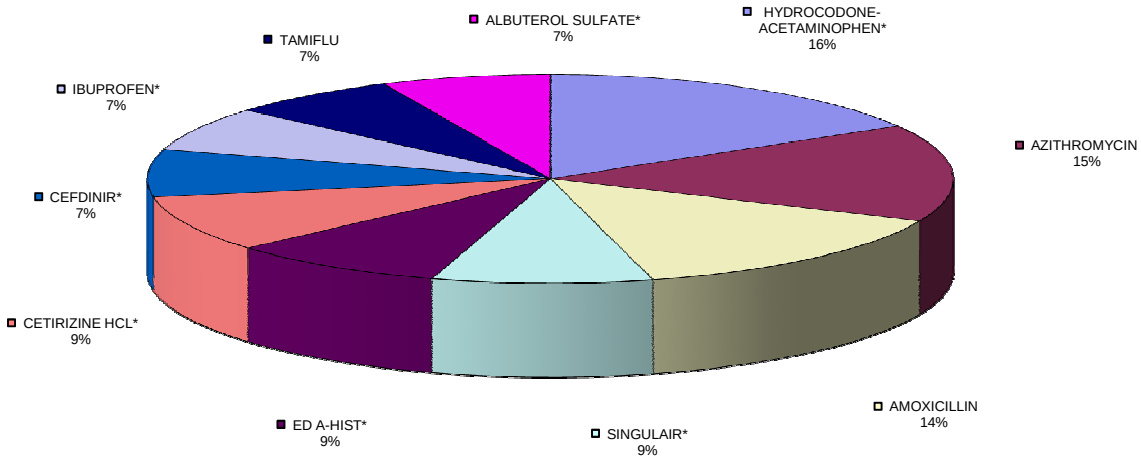
TOP 25 DRUGS BASED ON NUMBER OF CLAIMS FROM 10/01/09-10/31/09

Drug	AHFS Therapeutic Class	Rx	Paid	Top 200 Rank
HYDROCODONE-ACETAMINOPHEN*	OPIATE AGONISTS	17,497	$ 247,975.00	1
AZITHROMYCIN*	MACROLIDES	15,940	$ 473,619.78	6
AMOXICILLIN	PENICILLINS	15,096	$ 142,169.79	5
SINGULAIR*	LEUKOTRIENE MODIFIERS	9,313	$ 1,095,336.88	4
ED A-HIST*	PROPYLAMINE DERIVATIVES	9,227	$ 74,581.40	~
CETIRIZINE HCL*	SECOND GENERATION ANTIHISTAMINES	9,177	$ 184,652.96	~
CEFDINIR*	CEPHALOSPORINS	7,799	$ 579,643.26	68
IBUPROFEN*	NONSTEROIDAL ANTI-INFLAMMATORY AGENTS	7,284	$ 59,933.34	18
TAMIFLU	NEURAMINIDASE INHIBITORS	7,198	$ 556,642.03	80
ALBUTEROL SULFATE*	BETA-ADRENERGIC AGONISTS	7,164	$ 199,000.55	67
AMOX TR-POTASSIUM CLAVULANATE*	PENICILLINS	6,429	$ 325,754.71	32
SULFAMETHOXAZOLE-TRIMETHOPRIM	SULFONAMIDES (SYSTEMIC)	6,342	$ 79,831.44	39
PREVACID*	PROTON-PUMP INHIBITORS	5,300	$ 928,777.82	7
ALPRAZOLAM	BENZODIAZEPINES (ANXIOLYTIC,SEDATIV/HYP)	4,710	$ 32,581.02	8
CLONAZEPAM	BENZODIAZEPINES (ANTICONVULSANTS)	4,263	$ 32,994.35	24
PROAIR HFA*	BETA-ADRENERGIC AGONISTS	4,060	$ 171,223.12	14
CEPHALEXIN*	CEPHALOSPORINS	3,798	$ 59,949.88	22
PROMETHAZINE HCL	PHENOTHIAZINE DERIVATIVES	3,797	$ 43,530.48	59
RISPERIDONE*	ANTIPSYCHOTIC AGENTS	3,601	$ 349,126.30	140
ACETAMINOPHEN-CODEINE*	OPIATE AGONISTS	3,590	$ 29,712.93	43
NYSTATIN*	ANTIFUNGALS (SKIN & MUCOUS MEMBRANE)	2,893	$ 35,932.47	142
AMLODIPINE BESYLATE*	DIHYDROPYRIDINES	2,882	$ 19,865.76	~
CONCERTA*	ANOREX.,RESPIR.,CEREBRAL STIMULANTS,MISC	2,822	$ 428,842.91	34
LISINOPRIL*	ANGIOTENSIN-CONVERTING ENZYME INHIBITORS	2,773	$ 13,035.88	2
CHERATUSSIN AC	ANTITUSSIVES	2,770	$ 14,046.33	105
TOTAL TOP 25		165,725	$ 6,178,760.39	

Total Rx Claims From 10/01/09-10/31/09	457,343

** Indicates preferred products on Preferred Drug List*

Top 10 Drugs
Based on Number of Claims



MISSISSIPPI MEDICAID
Cost Management Analysis

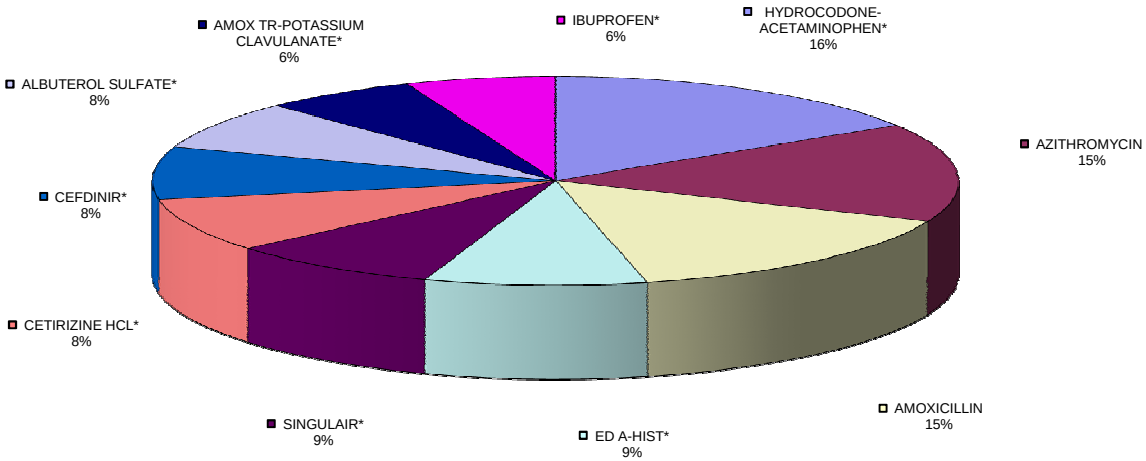
TOP 25 DRUGS BASED ON NUMBER OF CLAIMS FROM 11/01/09-11/30/09

Drug	AHFS Therapeutic Class	Rx	Paid	Top 200 Rank
HYDROCODONE-ACETAMINOPHEN*	OPIATE AGONISTS	16,565	$ 235,794.00	1
AZITHROMYCIN*	MACROLIDES	15,784	$ 475,613.52	6
AMOXICILLIN	PENICILLINS	15,456	$ 143,827.86	5
ED A-HIST*	PROPYLAMINE DERIVATIVES	9,151	$ 73,989.86	~
SINGULAIR*	LEUKOTRIENE MODIFIERS	8,812	$ 1,034,669.42	4
CETIRIZINE HCL*	SECOND GENERATION ANTIHISTAMINES	8,537	$ 171,300.92	~
CEFDINIR*	CEPHALOSPORINS	8,467	$ 625,795.83	68
ALBUTEROL SULFATE*	BETA-ADRENERGIC AGONISTS	7,776	$ 220,757.88	67
AMOX TR-POTASSIUM CLAVULANATE*	PENICILLINS	6,391	$ 321,445.67	32
IBUPROFEN*	NONSTEROIDAL ANTI-INFLAMMATORY AGENTS	6,182	$ 50,099.03	18
SULFAMETHOXAZOLE-TRIMETHOPRIM	SULFONAMIDES (SYSTEMIC)	5,524	$ 67,803.14	39
ALPRAZOLAM	BENZODIAZEPINES (ANXIOLYTIC,SEDATIV/HYP)	4,546	$ 31,713.46	8
PREVACID*	PROTON-PUMP INHIBITORS	4,468	$ 781,798.18	7
CLONAZEPAM	BENZODIAZEPINES (ANTICONVULSANTS)	4,166	$ 31,913.17	24
PROAIR HFA*	BETA-ADRENERGIC AGONISTS	3,672	$ 153,802.64	14
PROMETHAZINE HCL	PHENOTHIAZINE DERIVATIVES	3,653	$ 42,617.16	59
ACETAMINOPHEN-CODEINE*	OPIATE AGONISTS	3,442	$ 28,465.85	43
TAMIFLU	NEURAMINIDASE INHIBITORS	3,440	$ 260,378.07	80
RISPERIDONE*	ANTIPSYCHOTIC AGENTS	3,408	$ 323,644.15	140
CEPHALEXIN*	CEPHALOSPORINS	3,405	$ 49,872.76	22
CHERATUSSIN AC	ANTITUSSIVES	2,797	$ 14,233.82	105
PREDNISOLONE	ADRENALS	2,743	$ 34,590.35	143
NYSTATIN*	ANTIFUNGALS (SKIN & MUCOUS MEMBRANE)	2,663	$ 32,614.54	142
CONCERTA*	ANOREX.,RESPIR.,CEREBRAL STIMULANTS,MISC	2,661	$ 417,604.45	34
AMLODIPINE BESYLATE*	DIHYDROPYRIDINES	2,660	$ 18,212.07	~
TOTAL TOP 25		156,369	$ 5,642,557.80	

Total Rx Claims From 11/01/09-11/30/09	433,771

** Indicates preferred products on Preferred Drug List*

Top 10 Drugs
Based on Number of Claims



MISSISSIPPI MEDICAID
Cost Management Analysis

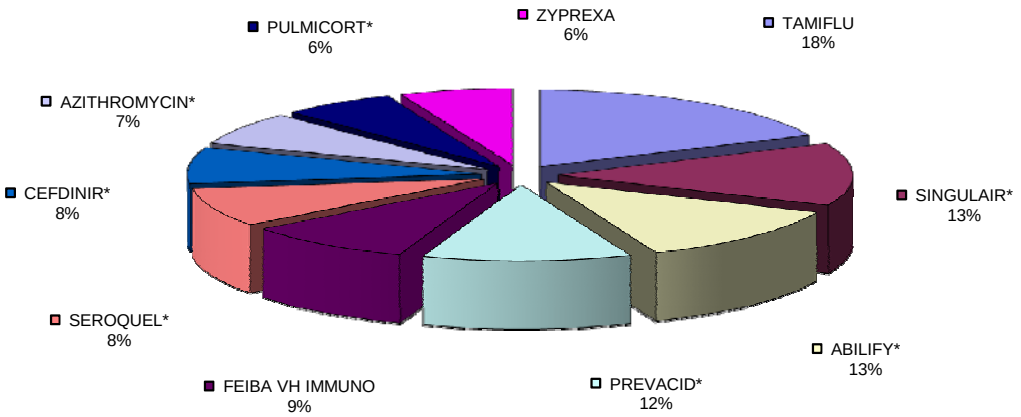
TOP 25 DRUGS BASED ON TOTAL CLAIMS COST FROM 09/01/09-09/30/09

Drug	AHFS Therapeutic Class	Rx	Paid	Top 200 Rank
TAMIFLU	NEURAMINIDASE INHIBITORS	17,473	$ 1,480,191.72	122
SINGULAIR*	LEUKOTRIENE MODIFIERS	8,971	$ 1,081,001.33	7
ABILIFY*	ANTIPSYCHOTIC AGENTS	1,961	$ 1,002,694.17	12
PREVACID*	PROTON-PUMP INHIBITORS	5,177	$ 927,571.70	5
FEIBA VH IMMUNO	HEMOSTATICS	9	$ 747,039.65	~
SEROQUEL*	ANTIPSYCHOTIC AGENTS	1,754	$ 677,350.49	6
CEFDINIR*	CEPHALOSPORINS	8,199	$ 618,165.62	17
AZITHROMYCIN*	MACROLIDES	19,146	$ 568,104.09	3
PULMICORT*	ADRENALS	1,557	$ 505,482.03	55
ZYPREXA	ANTIPSYCHOTIC AGENTS	783	$ 500,258.61	15
CONCERTA*	ANOREX.,RESPIR.,CEREBRAL STIMULANTS,MIS	2,754	$ 413,800.57	33
NOVOSEVEN RT	HEMOSTATICS	12	$ 364,782.78	~
AMOX TR-POTASSIUM CLAV*	PENICILLINS	6,529	$ 356,128.98	10
DEXTROAMPHETAMINE-AMPH	AMPHETAMINES	2,002	$ 354,694.04	~
RISPERIDONE*	ANTIPSYCHOTIC AGENTS	3,588	$ 349,799.24	24
ADVAIR DISKUS*	BETA-ADRENERGIC AGONISTS	1,596	$ 323,272.14	4
GEODON*	ANTIPSYCHOTIC AGENTS	743	$ 321,514.89	45
VYVANSE*	AMPHETAMINES	2,362	$ 309,061.35	96
ADVATE SH	HEMOSTATICS	7	$ 258,299.64	~
FOCALIN XR*	ANOREX.,RESPIR.,CEREBRAL STIMULANTS,MIS	1,788	$ 244,429.83	113
HYDROCODONE-ACETAMIN*	OPIATE AGONISTS	17,479	$ 244,149.32	1
ATRIPLA	ANTIRETROVIRALS	159	$ 240,704.28	39
PLAVIX*	PLATELET-AGGREGATION INHIBITORS	1,550	$ 238,797.00	3
EXJADE	HEAVY METAL ANTAGONISTS	47	$ 224,954.64	~
NASONEX*	CORTICOSTEROIDS (EENT)	2,218	$ 223,084.26	42
TOTAL TOP 25		107,864	$ 12,575,332.37	

Total Rx Claims From 09/01/09-09/30/09	480,211

** Indicates preferred products on Preferred Drug List*

Top 10 Drugs
Based on Total Claims Cost



MISSISSIPPI MEDICAID
Cost Management Analysis

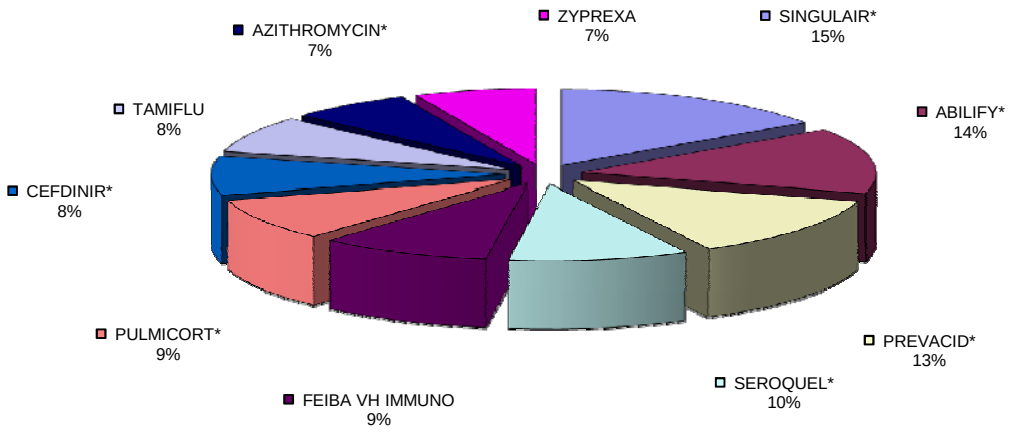
TOP 25 DRUGS BASED ON TOTAL CLAIMS COST FROM 10/01/09-10/31/09

Drug	AHFS Therapeutic Class	Rx	Paid	Top 200 Rank
SINGULAIR*	LEUKOTRIENE MODIFIERS	9,313	$ 1,095,336.88	7
ABILIFY*	ANTIPSYCHOTIC AGENTS	1,958	$ 986,383.96	12
PREVACID*	PROTON-PUMP INHIBITORS	5,300	$ 928,777.82	5
SEROQUEL*	ANTIPSYCHOTIC AGENTS	1,812	$ 698,417.74	6
FEIBA VH IMMUNO	HEMOSTATICS	10	$ 668,685.86	~
PULMICORT*	ADRENALS	2,036	$ 634,115.13	55
CEFDINIR*	CEPHALOSPORINS	7,799	$ 579,643.26	17
TAMIFLU	NEURAMINIDASE INHIBITORS	7,198	$ 556,642.03	122
AZITHROMYCIN*	MACROLIDES	15,940	$ 473,619.78	3
ZYPREXA	ANTIPSYCHOTIC AGENTS	785	$ 473,507.06	15
CONCERTA*	ANOREX.,RESPIR.,CEREBRAL STIMULANTS,MIS	2,822	$ 428,842.91	33
DEXTROAMPHETAMINE-AMPH	AMPHETAMINES	1,982	$ 352,028.35	~
RISPERIDONE*	ANTIPSYCHOTIC AGENTS	3,601	$ 349,126.30	24
ADVAIR DISKUS*	BETA-ADRENERGIC AGONISTS	1,682	$ 332,501.72	4
GEODON*	ANTIPSYCHOTIC AGENTS	769	$ 328,080.70	45
AMOX TR-POTASSIUM CLAV*	PENICILLINS	6,429	$ 325,754.71	10
VYVANSE*	AMPHETAMINES	2,489	$ 316,788.48	96
HYDROCODONE-ACETAMIN*	OPIATE AGONISTS	17,497	$ 247,975.00	1
FOCALIN XR*	ANOREX.,RESPIR.,CEREBRAL STIMULANTS,MIS	1,826	$ 245,478.00	113
PLAVIX*	PLATELET-AGGREGATION INHIBITORS	1,564	$ 236,589.39	3
ATRIPLA	ANTIRETROVIRALS	156	$ 232,481.79	39
STRATTERA*	CENTRAL NERVOUS SYSTEM AGENTS, MISC.	1,213	$ 212,719.99	78
EXJADE	HEAVY METAL ANTAGONISTS	46	$ 210,908.20	~
ALBUTEROL SULFATE*	BETA-ADRENERGIC AGONISTS	7,164	$ 199,000.55	63
LIPITOR*	HMG-COA REDUCTASE INHIBITORS	1,758	$ 197,554.14	1
TOTAL TOP 25		103,149	$ 11,310,959.75	

Total Rx Claims From 10/01/09-10/31/09	457,343

** Indicates preferred products on Preferred Drug List*

Top 10 Drugs
Based on Total Claims Cost



MISSISSIPPI MEDICAID
Cost Management Analysis

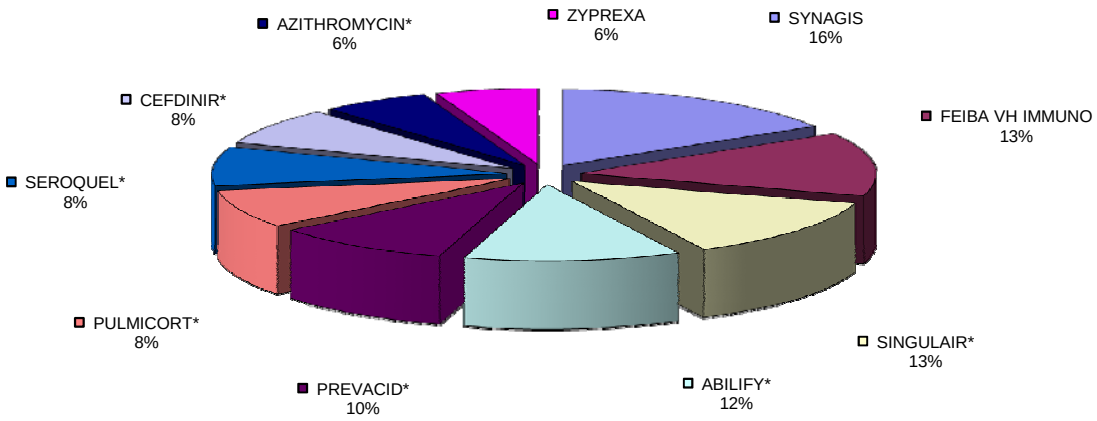
TOP 25 DRUGS BASED ON TOTAL CLAIMS COST FROM 11/01/09-11/30/09

Drug	AHFS Therapeutic Class	Rx	Paid	Top 200 Rank
SYNAGIS	MONOCLONAL ANTIBODIES	812	$ 1,301,723.46	~
FEIBA VH IMMUNO	HEMOSTATICS	13	$ 1,063,957.82	~
SINGULAIR*	LEUKOTRIENE MODIFIERS	8,812	$ 1,034,669.42	7
ABILIFY*	ANTIPSYCHOTIC AGENTS	1,891	$ 943,308.99	12
PREVACID*	PROTON-PUMP INHIBITORS	4,468	$ 781,798.18	5
PULMICORT*	ADRENALS	2,101	$ 649,948.58	55
SEROQUEL*	ANTIPSYCHOTIC AGENTS	1,738	$ 641,993.07	6
CEFDINIR*	CEPHALOSPORINS	8,467	$ 625,795.83	17
AZITHROMYCIN*	MACROLIDES	15,784	$ 475,613.52	3
ZYPREXA	ANTIPSYCHOTIC AGENTS	736	$ 445,626.57	15
CONCERTA*	ANOREX.,RESPIR.,CEREBRAL STIMULANTS,MIS	2,661	$ 417,604.45	33
DEXTROAMPHETAMINE-AMPH	AMPHETAMINES	1,926	$ 341,699.54	~
NOVOSEVEN RT	HEMOSTATICS	8	$ 326,097.68	~
RISPERIDONE*	ANTIPSYCHOTIC AGENTS	3,408	$ 323,644.15	24
AMOX TR-POTASSIUM CLAV*	PENICILLINS	6,391	$ 321,445.67	10
ADVAIR DISKUS*	BETA-ADRENERGIC AGONISTS	1,616	$ 317,776.40	4
VYVANSE*	AMPHETAMINES	2,464	$ 315,407.87	96
HUMATE-P	HEMOSTATICS	4	$ 299,411.66	~
GEODON*	ANTIPSYCHOTIC AGENTS	708	$ 298,038.20	45
TAMIFLU	NEURAMINIDASE INHIBITORS	3,440	$ 260,378.07	122
HYDROCODONE-ACETAMIN*	OPIATE AGONISTS	16,565	$ 235,794.00	1
FOCALIN XR*	ANOREX.,RESPIR.,CEREBRAL STIMULANTS,MIS	1,726	$ 234,178.83	113
PLAVIX*	PLATELET-AGGREGATION INHIBITORS	1,528	$ 230,399.73	3
ATRIPLA	ANTIRETROVIRALS	152	$ 225,968.03	39
ALBUTEROL SULFATE*	BETA-ADRENERGIC AGONISTS	7,776	$ 220,757.88	63
TOTAL TOP 25		95,195	$ 12,333,037.60	

Total Rx Claims From 11/01/09-11/30/09	433,771

** Indicates preferred products on Preferred Drug List*

Top 10 Drugs
Based on Total Claims Cost



Tamiflu® Utilization Update

Novel H1N1 virus is a new flu virus that first caused illness in Mexico and the United States in March and April 2009. By mid-June 2009, all 50 states in the U.S, the District of Columbia, Puerto Rico, and the U.S. Virgin Islands had reported infections with novel H1N1 virus. The CDC recommends the use of Tamiflu® or Relenza® for the treatment and prevention of infection with novel H1N1 virus. These medications prevent flu viruses from reproducing in the body, and can reduce illness and recovery time in infected persons. They may also prevent serious flu complications.

In August 2009, a widespread outbreak of H1N1 influenza occurred in Mississippi. DOM, attempting to be proactive in discouraging stockpiling of medication and preventing potential antiviral resistance problems with the H1N1 virus, presented the DUR Board with a motion to limit antiviral medications to two (2) prescriptions per calendar year through the Mississippi Medicaid pharmacy benefit. The Board approved this motion unanimously.

Recently, DOM asked HID to gather claims data for the antiviral medications (and the syrup required for compounding) in order to analyze the impact that the H1N1 virus had on utilization of these medications. HID gathered data from 8/1 through 12/26 for 2008 and 2009 and compared the results. The table below summarizes the findings.

Label Name	2008 Rx Count	2009 Rx Count
TAMIFLU 75 MG GELCAP	223	18972
TAMIFLU 12 MG/ML SUSPENSION	374	14,685
TAMIFLU 30 MG GELCAP	1	996
TAMIFLU 45 MG GELCAP	1	973
CHERRY SYRUP	0	706
ORA-SWEET-SF SYRUP	6	378
ORA-SWEET ORAL SYRUP	35	260
CHERRY SYRUP	0	67
SIMPLE SYRUP	0	3
CHERRY SYRUP	0	1
ORA SWEET ORAL SYRUP	0	3
CHERRY SYRUP	0	1
RELENZA 5MG DISKHALER	0	236
Total Claims	**640**	**37,281**

Total Beneficiaries	**608**	**34,853**

It is evident that the arrival of H1N1 in Mississippi had a substantial impact on the utilization of antiviral medications in the Mississippi Medicaid population. The claims count for antiviral medications and the number of beneficiaries receiving an antiviral medication in 2009 were nearly **60 times** higher than during the same time period in the previous year. If DOM, in conjunction with the DUR Board, had not

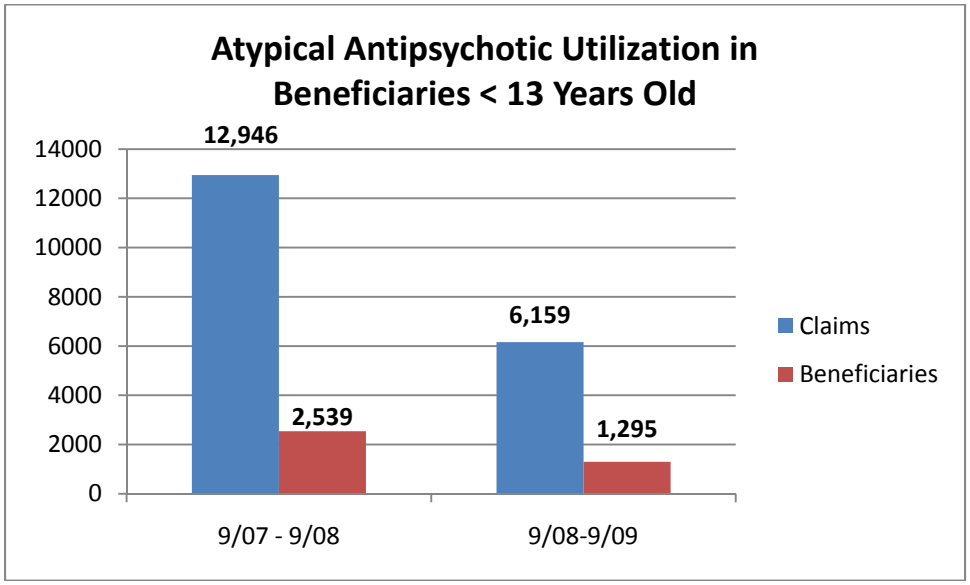
recognized the potential for abuse of these medications at the beginning of the outbreak in August, the2009 utilization numbers would have irrefutably been even higher.

Atypical Antipsychotics: Issues within the Mississippi Medicaid Population

Atypical antipsychotic utilization continues to be a hot topic across the country, for both private and public payors. News headlines are constantly populated with stories of multi-million dollar lawsuits for alleged inappropriate promotion of atypical antipsychotics in pediatric populations or adverse events associated with their use. A review of the cost analyses for Mississippi Medicaid for any given month will find these agents at or near the top of the list of most costly medications covered by the Division. As a result, their prominence in the budget and media require constant review and oversight by DOM to ensure that state dollars are being used appropriately for these medications. HID looked at two separate issues related to the atypical antipsychotics for this meeting: the impact of the age edits implemented for the class in September 2009, and possible duplication of therapy with multiple atypical antipsychotics.

Atypical Antipsychotic Age Edits

On September 11, 2008, the Division of Medicaid implemented age edits for the atypical antipsychotic class based on the FDA-approved age for each agent, respectively. This proactive measure was the result of nationwide scrutiny regarding the growing use of this therapeutic class in pediatric beneficiaries. The edits cause claims to deny at the point of sale if the beneficiary is younger than the FDA-approved age for the medication being submitted on the claim. Providers may submit a prior authorization request, providing HID and DOM with medical justification for the outlier use of the medication in a pediatric beneficiary as well as documented acceptance of responsibility for the risks of using the medication in such situations. HID gathered claims data for the year prior to and the year after the implementation of the age edits for beneficiaries less than 13 years old to see what the impact of these edits was for this population.



In the year following the implementation of the age edits for atypical antipsychotic class, the claims count for these medications decreased by **53%**, and the number of beneficiaries less than 13 years old receiving an atypical antipsychotic decreased by **49%**. Clearly, these edits were successful in encouraging responsible and informed prescribing of atypical antipsychotics in the Mississippi Medicaid pediatric population.

Duplicate therapy

DOM also asked HID to analyze utilization data for the atypical antipsychotics specifically related to possible duplicate therapy within the class. With the high cost associated with treatment with a single agent within the atypical antipsychotic class, duplicate therapy with two or more agents is a concern. Additionally, although there are no contraindications or prohibitions against duplicate therapy within the class, it stands to reason that the risk of adverse events commonly associated with atypical antipsychotic use would be higher in beneficiaries being treated with more than one agent. HID gathered utilization data for the atypical antipsychotics for the six-month period from 6/27/09 to 12/26/09. The results of the analysis are provided below.

Number of Days of Duplicate Therapy	Beneficiaries Receiving ≥2 Atypical Antipsychotics	Beneficiaries Receiving ≥ 3 Atypical Antipsychotics
30	332	12
60	252	7
90	201	4

From the data gathered, it appears that there is a significant amount of duplicate therapy occurring within the atypical antipsychotic class. Nearly 800 beneficiaries received two or more atypical antipsychotics within the six-month period analyzed. The incidence of duplicate therapy does appear to sharply decrease at three or more atypical antipsychotics per beneficiary, however, with only 23 beneficiaries receiving three or more atypical antipsychotics within the six months reviewed.

Conclusion

Atypical antipsychotics have garnered significant attention within the past few years, whether it is due to media coverage of pending litigation or publication of data related to adverse events associated with their use. Because of the intense scrutiny of this therapeutic class, DOM must continually monitor utilization of these agents to ensure appropriate utilization within its population. From the data presented in this report, it is evident that minimum age edits implemented for the class in September 2008 were successful in encouraging appropriate utilization of atypical antipsychotics in children covered by Mississippi Medicaid. Additional data provided in this report indicates that duplicate therapy within the atypical antipsychotic class may be a problem in Mississippi Medicaid beneficiaries. While there are no contraindications to duplicate atypical antipsychotic therapy, this practice causes concern due to the adverse events and high cost associated with single-agent use.

Recommendation

HID does not recommend any action regarding the atypical antipsychotic class at this time. Minimum age edits currently in place appear to be effective in ensuring appropriate pediatric utilization. Regarding duplicate therapy within the class, there is an RDUR criterion previously approved and implemented by the DUR Board that identifies beneficiaries receiving multiple atypical antipsychotics. The prescribers of these medications are then flagged, and education letters are mailed to them explaining the concerns of multiple atypical antipsychotic use. HID will continue to monitor the activity of this criterion and intervene when necessary.

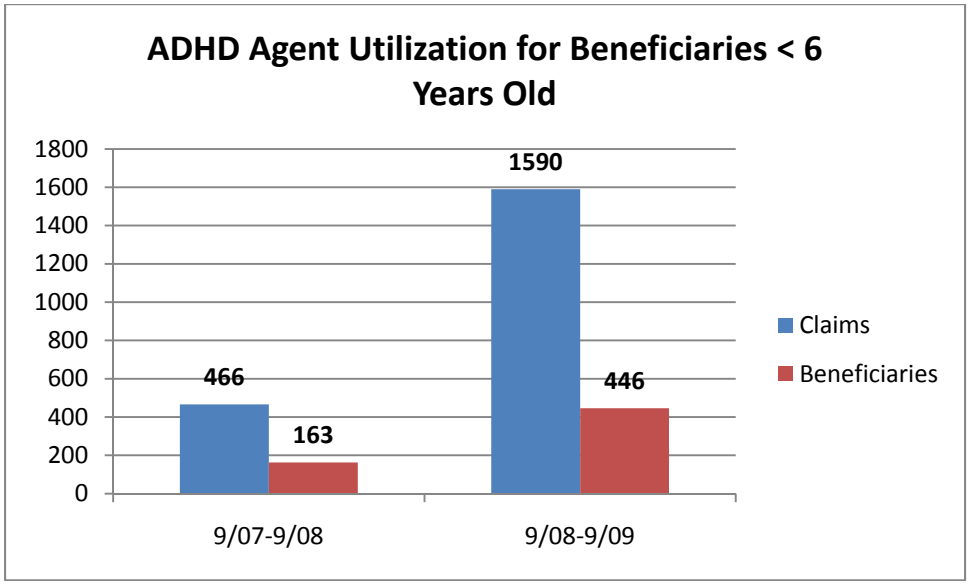
ADHD Agents: Issues within the Mississippi Medicaid Population

ADHD agents continue to be one of the most utilized therapeutic classes within the Mississippi Medicaid population, with agents within this class consistently appearing in the cost analyses presented to the DUR Board. Scrutiny also exists regarding the potential overprescribing of ADHD agents, particularly in young children. Because of the high utilization and attention associated with this class, DOM monitors the ADHD agents continuously, looking for trends of inappropriate utilization and abuse. For this meeting, HID gathered utilization data for the ADHD agents based on three different issues:

- the impact of age edits implemented for the class in September 2009
- use of ADHD agents in beneficiaries 21 years of age and older
- use of multiple daily doses of short-acting ADHD agents

ADHD Agent Age Edits

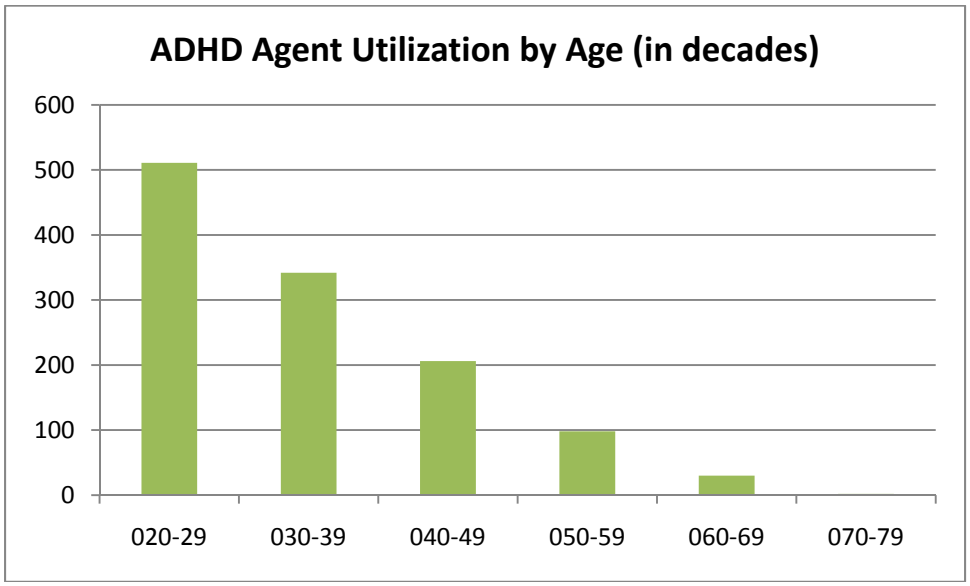
On September 11, 2008, the Division of Medicaid implemented age edits for the ADHD agents based on the FDA-approved age for each agent, respectively. The edits cause claims to deny at the point of sale if the beneficiary is younger than the FDA-approved age for the medication being submitted on the claim. Providers may submit a prior authorization request, providing HID and DOM with medical justification for the outlier use of the medication in an underage beneficiary as well as documented acceptance of responsibility for the risks of using the medication in such situations. HID gathered claims data for the year prior to and the year after the implementation of the age edits for beneficiaries less than 6 years old to see what the impact of these edits was for this population.



As the chart above illustrates, there was a dramatic increase in both the claims count and beneficiary count for ADHD agents in beneficiaries under the age of 6 years in the year following the implementation of the age edits for this class. There was a **341%** increase in ADHD agent claims for this age group, and a **274%** increase in the number of beneficiaries under the age of 6 receiving an ADHD agent. DOM expected to see some increase in the utilization of ADHD agents in this age group, due to similar age edits implemented on the atypical antipsychotics discussed earlier. However, the degree of increased utilization seen in this age group for this class was not expected.

Utilization in Adults

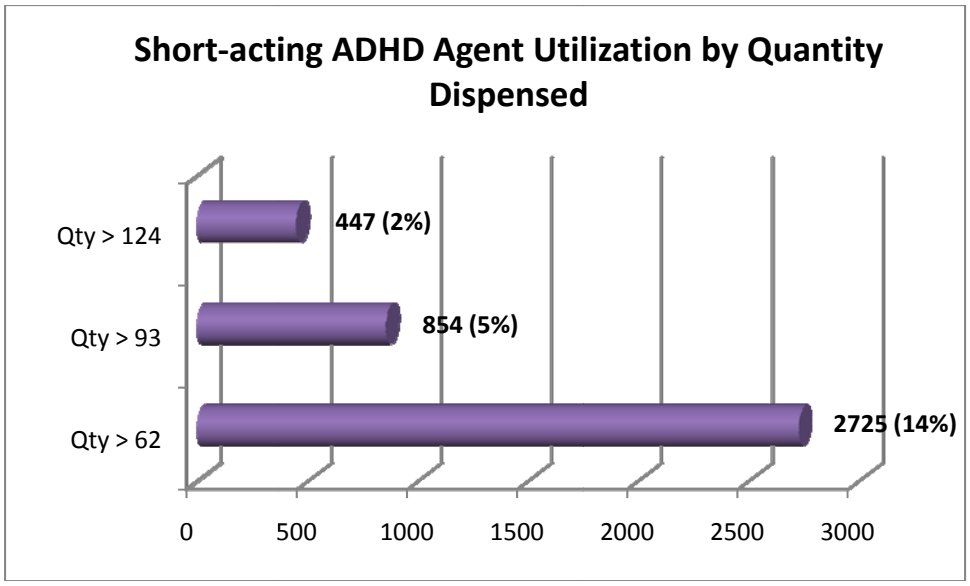
At the last DUR Board meeting, members were asked to vote on the implementation of maximum age edits of 21 years for the ADHD agent class. This measure was approved, but members asked for some data depicting exactly how much utilization of these agents occurs in adult beneficiaries. HID gathered ADHD agent claims data for FY2009 (7/1/08 – 6/30/09) or all beneficiaries 21 years and older and analyzed these claims to determine the distribution of utilization by age (in decades).



A total of 1189 beneficiaries ≥21 years old received an ADHD agent in FY2009. Of these, 43% were 20-29 years old, with the beneficiary count steadily declining with each decade.

Multiple Daily Doses of Short-Acting ADHD Agents

Another area that DUR Board members requested further reporting for was the use of multiple daily doses of short-acting ADHD agents. At the November 2009 DUR Board meeting, members were asked about a possible quantity limit for long-acting ADHD agents of 1 unit/day. Board members agreed that this would be an acceptable limit, with the option of submitting a prior authorization request if more units were necessary. As a result of this conversation, the possibility of quantity limits for the short-acting agents was discussed, and HID was asked to provide utilization data for these agents. HID analyzed claims data for FY 2009 for the short-acting ADHD agents, specifically looking at the quantities dispensed.



In FY2009 there were a total of 19,097 claims for short-acting ADHD agents. Of these claims, 14% were for more than 62 tablets, which indicates dosing more frequent than twice daily. 5% of these claims were for more than 93 tablets, indicating dosing more frequent than three times daily. 2% of the short-acting ADHD claims for FY2009 were for more than 124 tablets. From this data, it appears that a quantity limit may be necessary to curb the potential for abuse with short-acting agents and increase patient compliance by encouraging the use of long-acting agents that allow for once-daily dosing.

Conclusion

The ADHD agent class is one of the most utilized in the Mississippi Medicaid population, with agents in the class routinely appearing in the cost analyses provided to the DUR Board quarterly. This fact, coupled with the increasing concern of potential overuse of these agents in children, requires continuous monitoring of ADHD agents by DOM to ensure appropriate utilization within its population. Age edits implemented for the class in September 2008 do not appear to have decreased utilization in beneficiaries less than 6 years old; in fact, utilization for the ADHD agents in this age group has increased significantly. An increase was expected due to similar age edits implemented for the atypical antipsychotics, shifting utilization to the ADHD class instead. When looking at ADHD agent utilization in adults, the greatest amount of use appears to be in 20-29 year olds, with utilization decreasing with each decade following. Finally, approximately 14% of short-acting ADHD agent utilization is for more than 62 tablets per month, indicating a potential need for quantity limits on these agents.

Recommendation

HID recommends a cumulative quantity limit of 62 tablets per every 31 days on the short-acting ADHD agents. This limit would be in line with the quantity limits present on most all other narcotics through the pharmacy benefit for Mississippi Medicaid. A limit on the short-acting agents would, in theory, increase compliance by encouraging the use of a long-acting ADHD agent in beneficiaries requiring multiple dosing with a short-acting agent.

Mississippi Medicaid Coverage of Topical Acne Agents

Acne is the most common skin condition in the United States. It is estimated that 40 million to 50 million Americans have acne, with most of these victims being teenagers or young adults. Each year, 85% of U.S. teenagers will have acne. While acne can leave permanent physical scars, the psychological effects of acne can be devastating as well, with poor self-image, depression and anxiety being common peripheral issues associated with acne.

A common misconception in the retail pharmacy world is that DOM does not cover topical acne agents. DOM does in fact cover these agents; however, this class is addressed by the preferred drug list (PDL). Those products that are non-preferred require trial and failure of two preferred products in order to obtain prior authorization approval. Mississippi Medicaid beneficiaries sometimes are not provided the necessary medications for acne based on this misunderstanding in retail pharmacies across the state.

DOM asked HID to develop a Medicaid Prescribing Update merging information from the most recent treatment guidelines for acne and the Preferred Drug List, in an effort to educate providers about the proper treatment of acne as well as the availability of coverage of topical acne agents by Mississippi Medicaid. This Medicaid Prescribing Update will be distributed to prescribers by the HID Academic Detailers; they will also be available, along with others on additional topics, by a link from the Division of Medicaid website.

Prescribing Information Update

Acne

Mississippi Division of Medicaid

- *Mississippi Medicaid covers topical acne agents for beneficiaries under the age of 21.*
- *Acne is the most common skin condition in the United States.*
- *The four fundamental components of acne development are excess oil, clogged pores, bacteria and inflammation.*
- *According to the AAD, topical therapy is the standard of care in acne treatment.*

Acne is the most common skin condition in the United States. It is estimated that 40 million to 50 million Americans have acne, with most of these victims being teenagers or young adults. Each year, 85% of U.S. teenagers will have acne. While acne can leave permanent physical scars, the psychological effects of acne can be devastating as well, with poor self-image, depression and anxiety being common peripheral issues associated with acne.

Mississippi Medicaid

Recognizing the psychological and emotional impact of acne in children and adolescents, DOM covers topical acne agents at the point of sale for beneficiaries under the age of 21. This class is addressed by the preferred drug list (PDL); those products that are non-preferred require trial and failure of two preferred products in order to obtain prior authorization approval.

Treatment Guidelines

The American Academy of Dermatology (AAD) recommends the following for the treatment of acne vulgaris:

- Gently wash the face once or twice daily with a mild cleanser and lukewarm water.
- Although it may be tempting to squeeze acne lesions, this is not recommended by dermatologists because it tends to make acne worse and can result in scars.
- To avoid clogging pores, cosmetics, toiletries and sunscreens should be oil-free; oil-free products will be labeled 'non-comedogenic' or 'non-acnegenic'

According to treatment guidelines published by the AAD, topical therapy is the standard of care in acne treatment. A listing of preferred topical acne agents is provided in the table below:

Therapeutic class	Place in Treatment	Preferred Products
Topical Retinoids	Considered to be important in acne treatment; more effective when used in combination with topical clindamycin or erythromycin	Retin-A Micro®
Benzoyl Peroxide (Rx and OTC)	Bactericidal; prevents/eradicates the development of bacterial resistance	Inova®, Panoxyl®, Zaclir®, Clinac BPO®, benzoyl peroxide
Topical antibiotics	More effective when used in combination with topical retinoids	Clindamycin, Erythromycin
Combination Products	Enhanced efficacy in combination products with erythromycin or clindamycin and benzoyl peroxide due to the elimination of bacterial resistance	Benzaclin®
	Limited efficacy data for sulfur-containing products	Nuox®
Others	Reported to have limited efficacy compared to other agents, according to experts, but was shown to be effective in clinical trials	Azelex®
	Limited efficacy data	Sodium Sulfacetamide/Sulfur

The *AAD Guidelines of Care for Acne Vulgaris Management* can be found at http://www.aad.org/research/_doc/ClinicalResearch_Acne%20Vulgaris.pdf .

MISSISSIPPI MEDICAID
RETROSPECTIVE DRUG UTILIZATION REVIEW
CRITERIA RECOMMENDATIONS
1ST QUARTER 2010

Criteria Recommendations	*Approved*	*Rejected*

1. Saxagliptin / High Dose _____ _____

Alert Message: The recommended dose of Onglyza (saxagliptin) is 2.5 mg or 5.0 mg once daily.

Conflict Code: ER – Overutilization
Drug/Disease:

Util A	Util B	Util C (Negating)	
Saxagliptin		Renal Impairment	Nelfinavir
		Ketoconazole	Atazanavir
		Itraconazole	Nefazodone
		Clarithromycin	Saquinavir
		Telithromycin	Ritonavir
		Indinavir	

Maximum Dose: 5 mg/day

References:
Onglyza Prescribing Information, July 2009, Bristol-Myers Squibb/AstraZeneca.
Facts & Comparisons, 2009 Updates.

2. Saxagliptin / Renal Impairment _____ _____

Alert Message: The recommended dose of Onglyza (saxagliptin) is 2.5 mg once daily for patients with moderate or severe renal impairment, or with end-stage renal disease (ESRD) requiring hemodialysis. Assessment of renal function is recommended prior to initiation of saxagliptin therapy and periodically thereafter.

Conflict Code: ER - Overutilization
Drug/Disease:

Util A	Util B	Util C (Include)
Saxagliptin		Renal Impairment

Maximum Dose: 2.5 mg/day

References:
Onglyza Prescribing Information, July 2009, Bristol-Myers Squibb/AstraZeneca.
Facts & Comparisons, 2009 Updates.

3. Saxagliptin / Nonadherence _____ _____

Alert Message: Non-adherence to Onglyza (saxagliptin) therapy may result in loss of glycemic control and an increased risk of developing adverse diabetic-related complications.

Conflict Code: LR - Nonadherence
Drug/Disease:

Util A	Util B	Util C
Saxagliptin		

References:
Onglyza Prescribing Information, July 2009, Bristol-Myers Squibb/AstraZeneca.
Facts & Comparisons, 2009 Updates.

Criteria Recommendations ***Approved Rejected***

4. Saxagliptin / Strong 3A4/5 Inhibitors _____ _____

Alert Message: The dose of Onglyza (saxagliptin) should be limited to 2.5 mg daily when coadministered with strong CYP3A4/5 inhibitors (e.g., ketoconazole, atazanavir, clarithromycin, indinavir, itraconazole, nefazodone, ritonavir, saquinavir, and telithromycin). Concurrent use of saxagliptin with a strong 3A4/5 inhibitor may result in significantly elevated saxagliptin levels and risk of adverse events.

Conflict Code: ER – Overutilization
Drug/Disease:

Util A	Util B	Util C (Include)
Saxagliptin		Ketoconazole
		Itraconazole
		Clarithromycin
		Telithromycin
		Indinavir
		Ritonavir
		Saquinavir
		Nelfinavir
		Atazanavir
		Nefazodone

Maximum Dose: 2.5 mg/day

References:
Onglyza Prescribing Information, July 2009, Bristol-Myers Squibb/AstraZeneca.
Facts & Comparisons, 2009 Updates.

5. Saxagliptin / Sulfonylureas _____ _____

Alert Message: The concurrent use of Onglyza (saxagliptin) with a sulfonylurea may result in hypoglycemia. A dose reduction of the sulfonylurea may be necessary to reduce the risk of hypoglycemia.

Conflict Code: DD – Drug/Drug Interaction
Drug/Disease:

Util A	Util B	Util C
Saxagliptin	Chlorpropamide	
	Tolbutamide	
	Tolazamide	
	Glyburide	
	Glipizide	
	Glimepiride	

References:
Onglyza Prescribing Information, July 2009, Bristol-Myers Squibb/AstraZeneca.
Facts & Comparisons, 2009 Updates.

6. Saxagliptin / Sitagliptin _____ _____

Alert Message: Therapeutic duplication of dipeptidyl peptidase-4 inhibitor therapy may be occurring.

Conflict Code: DD – Therapeutic Duplication (Drug/Drug)
Drug/Disease:

Util A	Util B	Util C
Saxagliptin	Sitagliptin	

References:
Onglyza Prescribing Information, July 2009, Bristol-Myers Squibb/AstraZeneca.
Januvia Prescribing Information, July 2008, Merck & Co., Inc.
Facts & Comparisons, 2009 Updates.

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

7. Tapentadol / Overutilization _____ _____

Alert Message: Nucynta (tapentadol) may be over-utilized. The maximum recommended daily dose (after the first day) of tapentadol is 600 mg. Daily doses greater than 700 mg on the first day of therapy and 600mg on subsequent days have not been studied and are not recommended.

Conflict Code: ER - Overutilization

Util A	Util B	Util C
Tapentadol		

Max Dose: 600 mg/day

References:
Nucynta Prescribing Information, March 2009, Ortho-McNeil-Janssen Pharmaceuticals, Inc.
Facts & Comparisons, 2009 Updates.

8. Tapentadol / Impaired Pulmonary Function _____ _____

Alert Message: Nucynta (tapentadol) is contraindicated in patients with impaired pulmonary function (e.g. significant respiratory depression, acute or severe bronchial asthma or hypercapnia in unmonitored settings).

Conflict Code: MC – Drug (Actual) Disease Precaution

Util A	Util B	Util C
Tapentadol	Impaired Respiratory Function	
	Asthma	
	COPD	
	Emphysema	

References:
Nucynta Prescribing Information, March 2009, Ortho-McNeil-Janssen Pharmaceuticals, Inc.
Facts & Comparisons, 2009 Updates.

9. Tapentadol / Paralytic Ileus _____ _____

Alert Message: Nucynta (tapentadol) is contraindicated in patients who have paralytic ileus or are suspected of having paralytic ileus. Tapentadol is a mu-opioid agonist and these agents can cause or exacerbate this condition.

Conflict Code: MC – Drug (Actual) Disease Precaution

Util A	Util B	Util C
Tapentadol	Paralytic Ileus	

References:
Nucynta Prescribing Information, March 2009, Ortho-McNeil-Janssen Pharmaceuticals, Inc.
Facts & Comparisons, 2009 Updates.

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

10. Tapentadol / MAO Inhibitors _____ _____

Alert Message: Nucynta (tapentadol) is contraindicated in patients who are receiving a monoamine oxidase inhibitor (MAOI) or who have taken a MAOI within the last 14 days due to the potential for elevated norepinephrine (NE) levels which may result in adverse cardiovascular effects. Tapentadol is a mu-opioid agonist as well as a NE reuptake inhibitor.

Conflict Code: DD – Drug/Drug Interaction (Contraindication)

Util A	Util B	Util C
Tapentadol	Isocarboxazid	
	Tranylcypromine	
	Phenelzine	
	Selegiline	

References:
Nucynta Prescribing Information, March 2009, Ortho-McNeil-Janssen Pharmaceuticals, Inc.
Facts & Comparisons, 2009 Updates.

11. Tapentadol / Seizures _____ _____

Alert Message: Nucynta (tapentadol) should be prescribed with caution in patients with a history of seizure disorder or any condition that would put the patient at risk of seizures.

Conflict Code: DB – Drug/Disease and/or (Drug Inferred Disease) Precaution

Util A	Util B		Util C
Tapentadol	Epilepsy	Lacosamide	Tiagabine
	Seizures	Rufinamide	Valproic
	Convulsions	Oxcarbazepine	Zonisamide
	Carbamazepine	Methsuximide	Ethosuximide
	Phenytoin	Felbamate	Primidone
	Lamotrigine	Gabapentin	
	Topiramate	Levetiracetam	

References:
Nucynta Prescribing Information, March 2009, Ortho-McNeil-Janssen Pharmaceuticals, Inc.
Facts & Comparisons, 2009 Updates.

12. Tapentadol / CNS Depressants & Alcohol Dependence/Abuse _____ _____

Alert Message: Nucynta (tapentadol) should be prescribed with caution in patients receiving other CNS depressants (e.g. opioid analgesics, phenothiazines, and sedatives) including alcohol. The concurrent use of tapentadol with any of these agents may result in respiratory depression, hypotension, profound sedation, coma, or death. If combination therapy is necessary, a dose reduction of one or both agents should be considered.

Conflict Code: DB - Drug/Disease and/or (Drug Inferred Disease) Precaution

Util A	Util B	Util C
Tapentadol	Opioid Analgesics	
	Phenothiazines	
	Sedative/Hypnotics	
	Anxiolytics	
	Anticonvulsants	
	Antipsychotics	
	Sedating Antihistamines	
	Muscle Relaxants	
	Alcohol Dependence	

References:
Nucynta Prescribing Information, March 2009, Ortho-McNeil-Janssen Pharmaceuticals, Inc.
Facts & Comparisons, 2009 Updates.

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

13. Tapentadol / Serotonergic Drugs _____ _____

Alert Message: Nucynta (tapentadol) should be prescribed with caution in patients taking serotonergic drugs (e.g. SSRIs, SNRI, triptans and MAOIs) due to the risk of developing potentially life-threatening serotonin syndrome.

Conflict Code: DD – Drug/Drug Interaction

Util A	Util B			Util C
Tapentadol	Triptans	TCAs	Lithium	
	Tramadol	Mirtazapine	Fentanyl	
	SSRIs	Bupropion	Zyvox	
	SNRIs	Trazodone	Nefazodone	
	MAOIs	Meperidine		

References:
Nucynta Prescribing Information, March 2009, Ortho-McNeil-Janssen Pharmaceuticals, Inc.
Facts & Comparisons, 2009 Updates.

14. Tapentadol / Severe Renal Impairment _____ _____

Alert Message: The safety and effectiveness of Nucynta (tapentadol) have not been established in patients with severe renal impairment and its use is not recommended in this population.

Conflict Code: DB - Drug/Disease and/or (Drug Inferred Disease) Precaution

Util A	Util B	Util C
Tapentadol	Stage IV Kidney Disease	
	Stage V Kidney Disease	
	ESRD	
	PhosLo	
	Renagel	
	Zemplar	
	Hectorol	
	Fosrenol	

References:
Nucynta Prescribing Information, March 2009, Ortho-McNeil-Janssen Pharmaceuticals, Inc.
Facts & Comparisons, 2009 Updates.

15. Tapentadol / Hepatic Impairment _____ _____

Alert Message: Nucynta (tapentadol) should be used with caution in patients with moderate hepatic impairment due to the potential for higher serum levels and risk for adverse effects. Treatment should be initiated at 50 mg with the interval between doses no less than every 8 hours (max 3 doses in 24 hrs). Tapentadol has not been studied in patients with severe hepatic impairment and its use is not recommended in this population.

Conflict Code: MC – Drug (Actual) Disease Warning/Precaution

Util A	Util B	Util C
Tapentadol	Hepatic Impairment	

References:
Nucynta Prescribing Information, March 2009, Ortho-McNeil-Janssen Pharmaceuticals, Inc.
Facts & Comparisons, 2009 Updates.

Criteria Recommendations ***Approved Rejected***

16. Tapentadol / Pancreatic & Biliary Tract Disease _____ _____

Alert Message: Nucynta (tapentadol) should be used with caution in patients with biliary tract disease, including acute pancreatitis. Tapentadol is a mu-opioid receptor (MOR) agonist and may cause spasms of the Sphincter of Oddi.

Conflict Code: MC – Drug (Actual) Disease Precaution
Drug/Disease:

Util A	Util B	Util C
Tapentadol	Acute Pancreatitis	
	Choledocholithiasis	
	Obstruction of Bile Duct	
	Spasm of Sphincter of Oddi	

References:
Nucynta Prescribing Information, March 2009, Ortho-McNeil-Janssen Pharmaceuticals, Inc.
Facts & Comparisons, 2009 Updates.

17. Donepezil / Therapeutic Appropriateness _____ _____

Alert Message: A review of the patient's diagnosis history does not reveal a FDA approved indication for the use of Aricept (donepezil). Donepezil is only approved for the treatment of dementia of the Alzheimer type. The drug has not been shown to be safe and effective as treatment in other disease states.

Conflict Code: TA – Therapeutic Appropriateness
Drug/Disease:

Util A	Util B	Util C (Negating)
Donepezil		All Dementias
		Memory Loss
		Alcohol Dementia
		Drug Induced Dementia
		All Cerebral Vascular Degeneration

References:
Facts & Comparisons, 2009 Updates.
Aricept Prescribing Information, Nov. 2006, Eisai/Pfizer.

18. Memantine / Therapeutic Appropriateness _____ _____

Alert Message: A review of the patient's diagnostic history does not reveal a FDA approved indication for the use of Namenda (memantine). Memantine is only approved for the treatment of moderate to severe dementia of the Alzheimer type. The drug has not been shown to be safe and effective as treatment in other disease states.

Conflict Code: TA – Therapeutic Appropriateness
Drug/Disease:

Util A	Util B	Util C (Negating)
Memantine		All Dementias
		Memory Loss
		Alcohol Dementia
		Drug Induced Dementia
		All Cerebral Vascular Degeneration

References:
Facts & Comparisons, 2009 Updates.
Namenda Prescribing information, April 2007, Forrest Laboratories, Inc.

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.

Peramivir IV

FDA notified healthcare professionals that, in response to a request from the U.S. Centers for Disease Control and Prevention, it has issued an emergency use authorization (EUA) for the investigational antiviral drug peramivir intravenous in certain adult and pediatric patients with confirmed or suspected 2009 H1N1 influenza infection who are admitted to a hospital. IV peramivir is authorized only for hospitalized adult and pediatric patients for whom therapy with an IV drug is clinically appropriate, based on one or more of the following: 1] the patient is not responding to either oral or inhaled antiviral therapy, 2] when drug delivery by a route other than an intravenous route is not expected to be dependable or feasible, or 3] for adults only, when the clinician judges IV therapy is appropriate due to other circumstances.

Given there are limited safety data on peramivir, mandatory reporting requirements are important to defining the safety profile of this unapproved drug. As part of the conditions of the EUA, health care providers (or designee) must report adverse events and all medication errors associated with peramivir to FDA's MedWatch program within 7 calendar days from the onset of the adverse event. Additionally, healthcare providers (or designee) must conduct follow-up requested by FDA or CDC related to peramivir adverse event or medication error reports submitted to FDA.

Accusure Insulin Syringes (Qualitest Pharmaceuticals)
Qualitest Pharmaceuticals and FDA notified healthcare professionals of a nationwide recall of Accusure Insulin Syringes. All syringes, regardless of lot number, are subject to this recall. These syringes were distributed between January 2002 and October 2009 to wholesale and retail pharmacies nationwide (including Puerto Rico). The syringes in these lots may have needles which detach from the syringe. If the needle becomes detached from the syringe during use, it can become stuck in the insulin vial, push back into to the syringe, or remain in the skin after injection. Consumers who have any Accusure insulin syringes should stop using them and contact Qualitest at 1-800-444-4011 for reimbursement.

Byetta (exenatide)
FDA notified healthcare professionals of revisions to the prescribing information for Byetta (exenatide) to include information on post-marketing reports of altered kidney function, including acute renal failure and insufficiency. Byetta, an incretin-mimetic, is approved as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus.
From April 2005 through October 2008, FDA received 78 cases of altered kidney function (62 cases of acute renal failure and 16 cases of renal insufficiency), in patients using Byetta. Some cases occurred in patients with pre-existing kidney disease or in patients with one or more risk factors for developing kidney problems. Labeling changes include:

- Information regarding post-market reports of acute renal failure and insufficiency, highlighting that Byetta should not be used in patients with severe renal impairment (creatinine clearance <30 ml/min) or end-stage renal disease.
- Recommendations to healthcare professionals that caution should be applied when initiating or increasing doses of Byetta from 5 mcg to 10 mcg in patients with moderate renal impairment (creatinine clearance 30 to 50 ml/min).
- Recommendations that healthcare professionals monitor patients carefully for the development of kidney dysfunction, and evaluate the continued need for Byetta if kidney dysfunction is suspected while using the product.
- Information about kidney dysfunction in the patient Medication Guide to help patients understand the benefits and potential risks associated with Byetta.

Norpramin (desipramine hydrochloride)
Sanofi-Aventis and FDA notified healthcare professionals of changes to the Warnings and Overdosage sections of the Prescribing Information for Norpramin (desipramine hydrochloride), indicated for the treatment of depression. The new safety information states that extreme caution should be used when this drug is given to patients who have a family history of sudden death, cardiac dysrhythmias, and cardiac conduction disturbances; and that seizures precede cardiac dysrhythmias and death in some patients.

Lexiva (fosamprenavir calcium)
GlaxoSmithKline and FDA notified healthcare professionals of a potential association between Lexiva and myocardial infarction and dyslipidemia in HIV infected adults. GSK has modified the existing Warnings and Precautions section of the Prescribing Information to note that increases in cholesterol have occurred with treatment, the importance of lipids management, and a recommendation that triglyceride and cholesterol testing be performed prior to initiating therapy with LEXIVA and at periodic intervals during therapy. The Dear Healthcare Professional letter also provides key messages, actions required by healthcare professionals and supporting information from a case-control study reported at a February 2009 international HIV conference.

Topical testosterone gel products
FDA has received postmarket reports of inappropriate development of early sex characteristics (i.e., enlargement of genitalia, advanced bone age, increased growth velocity, aggressive behavior) in children exposed to testosterone through contact with a person using these products. To mitigate this risk and increase awareness of this adverse event, FDA required a *Boxed Warning* on the product's prescribing information, as well as a Medication Guide.

Valproate Sodium and related products (valproic acid and divalproex sodium)
The FDA notified health care professionals and patients about the increased risk of neural tube defects and other major birth defects, such as craniofacial defects and cardiovascular malformations, in babies exposed to valproate sodium and related products (valproic acid and divalproex sodium) during pregnancy. Healthcare practitioners should inform women of childbearing potential about these risks, and consider alternative therapies, especially if using valproate to treat migraines or other conditions not usually considered life-threatening.
Women of childbearing potential should only use valproate if it is essential to manage their medical condition. Those who are not actively planning a pregnancy should use effective contraception, as birth defect risks are particularly high during the first trimester, before many women know they are pregnant. A valproate Medication Guide, provided with each outpatient prescription, will explain the benefits and risks of valproate and encourage patients to discuss options with their healthcare professional. Pregnant women using valproate or other AEDs should be encouraged to enroll in the North American Antiepileptic Drug (NAAED) Pregnancy Registry (1-888-233-2334; www.aedpregnancyregistry.org).

Voltaren Gel (diclofenac sodium topical gel) 1%
Endo, Novartis and FDA notified healthcare professionals of revisions to the Hepatic Effects section of the Prescribing Information to add new warnings and precautions about the potential for elevation in liver function tests during treatment with all products containing diclofenac sodium.
In postmarketing reports, cases of drug-induced hepatotoxicity have been reported in the first month but can occur at any time during treatment with diclofenac. Postmarketing surveillance has reported cases of severe hepatic reactions, including liver necrosis, jaundice, fulminant hepatitis with and without jaundice, and liver failure. Some of these reported cases resulted in fatalities or liver transplantation. Physicians should measure transaminases periodically in patients receiving long-term therapy with diclofenac. The optimum times for making the first and subsequent transaminase measurement are not known. Based on clinical trial data and postmarketing experiences, transaminases should be monitored within 4 to 8 weeks after initiating treatment with diclofenac.

Rapamune (sirolimus)
Wyeth notified healthcare professionals of changes to the Rapamune Prescribing Information regarding changes in the performance of an immunoassay used for therapeutic drug monitoring (TDM) of sirolimus. The TDM results reported from the assay are both assay and laboratory-dependent. In addition, the results may change over time. Therefore, adjustment to the targeted therapeutic range must be made with a detailed knowledge of the site-specific assay used.
Sirolimus whole blood concentrations can be measured by either chromatographic or immunoassay methodologies. These two methodologies are not directly interchangeable and the measured sirolimus whole blood concentrations depend on the type of assay used. As such, if different assays are used in monitoring a single patient, the dose of Rapamune might be adjusted improperly with potential consequences, such as allograft rejection if drug exposure is too low or toxic side effects if exposure is too high.

Wyeth has advised healthcare providers involved in the management of patients taking Rapamune to determine: 1) which assay is being used in their laboratory(ies); 2) if there is any change to the assay used; 3) if there is a change to the laboratory's reference range and/or a subsequent change to the institution's or referring center's recommended range for sirolimus. With this information, target levels can be appropriately adjusted in order to achieve optimal clinical results.
It is critical that the clinician caring for a patient on sirolimus maintain communication with their laboratory to determine whether the assay used for measuring sirolimus concentrations has been changed.

McNeil Consumer Healthcare Over-The-Counter Products: Recall
McNeil and FDA notified healthcare professionals of an expansion of the December 2009 recall. McNeil Consumer Healthcare has now applied broader criteria to identify and remove all product lots that it believes may have the potential to be affected, even if they have not been the subject of consumer complaints. Consumers who purchased product from the lots included in this recall should stop using the product and contact McNeil Consumer Healthcare for instructions on a refund or replacement. Affected products include Extra Strength Tylenol, Children's Motrin, and Benadryl, among others. The entire list of affected products can be found at http://www.fda.gov/downloads/Safety/Recalls/UCM197813.pdf . The affected product lot numbers for the recalled products can be found on the side of the bottle label. Any adverse reactions may also be reported to the FDA's MedWatch Program by fax at 1-800-FDA-0178, by mail at MedWatch, FDA, 5600 Fishers Lane, Rockville, MD 20852-9787, or on the MedWatch website at www.fda.gov/medwatch.