Division of Medicaid

Office of the Governor

State of Mississippi

DUR Board Meeting

May 17, 2007

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

Harold B. Blakely, R.Ph.
Delta Area Hospice Care
5357 Cliff Gookin Boulevard
Tupelo, MS 38801
Term Expires: June 30, 2008

Billy R. Brown, Pharm. D
Sonny Montgomery Veteren's Hospital
2825 Glenn Derry Street
Jackson, MS 39212
Term Expires: June 30 2007

Randy Calvert, R.Ph.
Brent's Drugs; 655 Duling Ave.
Jackson, MS 39216
Term Expires: June 30, 2007

Laura Gray, M.D.
905 Garfield Street
Tupelo, MS 38801
Term Expires: June 30, 2008

Troy Griffin
Advanced Healthcare Management
402 5th Avenue SW
Magee, MS 39111
Term Expires: June 30, 2008

Frank Marascalco, R.Ph
Sav-Mor Drugs
1967 Commerce Street
Grenada, MS 38901
Term Expires: June 30, 2008

Lee Montgomery, M.D.
Magnolia Family Medical
P.O. Box 1124
McComb, MS 39649
Term Expires: June 30, 2007

Andrea Phillips, M.D.
Phillips Medical Services
P.O. Box 21214
Jackson, MS 39289-1214
Term Expires: June 30, 2007

Wallace Strickland
Rush Foundation Hospital
8219 Sycamore Creek Drive
Meridian, MS 39305
Term Expires: June 30, 2008

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

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

Upcoming Mississippi Medicaid DUR Board Meeting Dates

August 16, 2007
November 15, 2007
February 21, 2008
May 15, 2008

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

May 17, 2007

Welcome — **Frank Marascalco, RPh**

Old Business

- **Approval of Meeting Minutes**
- **Updates** — **Dennis Smith, RPh**
  - **Cost Management Analysis**
  - **DUR Activity Report**

Pharmacy Program Update — **Judith Clark, RPh**

New Business — **Dennis Smith, RPh**

- **Bacterial Conjunctivitis – Appropriate Use of Ophthalmic Antibiotics**
- **HIV Therapy – Criteria Based on NIH Treatment Guidelines**
- **Other Criteria Recommendations**
- **Boxed Warning Update**

Next Meeting Information — **Frank Marascalco, RPh**

Mississippi Division of Medicaid
Drug Utilization Review (DUR) Board
Minutes of the February 15, 2007 Meeting

Members Attending: Roy Arnold, R.Ph.; Billy Brown, Pharm.D.; Randy Calvert, R.Ph.; Laura Gray, M.D.; Frank Marascalco, R.Ph.; Lee Montgomery, M.D.; Andrea Phillips, M.D.; Wallace Strickland; Lee Voulters, M.D.

Members Absent: Harold Blakely, R.Ph.; Troy Griffin; John Wallace, M.D.

Also Present:
DOM Staff: Judith Clark, R.Ph., Director of the Medicaid Pharmacy Bureau; Terri Kirby, R.Ph.; Paige Clayton, Pharm.D.; Phyllis Williams, Interim Deputy Administrator of Health Services

HID Staff: Dennis Smith, R.Ph.; Samuel Warman, R.Ph.; Kathleen Burns, R.N.

Call to Order
Randy Calvert, R.Ph., acting chair, called the meeting to order at 2:07 p.m.

Ms. Clark introduced several new DUR Board members. New members include Roy Arnold, R.Ph.; Laura Gray, M.D.; Lee Voulters, M.D.; and John Wallace, M.D. Ms. Clark also introduced the new Interim Deputy Administrator of Health Services, Phyllis Williams.

Approval of Minutes
Dr. Montgomery made a motion to accept the minutes for the May 16, 2006 and November 16, 2006 meetings as submitted. Dr. Voulters seconded the motion. All voted in favor of approval.

Election of Officers
Ms. Clark asked the Board to nominate new officers before continuing the meeting. Mr. Strickland nominated Mr. Marascalco as Chair and Dr. Gray as Co-Chair. This was seconded by Dr. Montgomery. All voted in favor of this motion.

Updates
Cost Management Analysis
Mr. Smith presented a report on point of sale pharmacy costs for the months of October 2006 and December 2006. He began the report with an analysis of the top 15 therapeutic classes by total cost of claims. The top therapeutic class was antipsychotic agents, followed by anticonvulsants. Next, the top 25 drugs based on total number of claims were presented. Leading the list was azithromycin. Mr. Smith continued with the top 25 drugs based on total claims cost. The top drug in this analysis was Synagis.

DUR Activity Report
Mr. Smith explained to the new members the focus of retrospective DUR activities and defined the terminology used to describe these activities. This explanation summarized the process by

which pharmacy claims are filtered through the various DUR criteria to obtain the needed data and the role of the DUR Board in setting the criteria.

Pharmacy Program Update

Ms. Clark began her update with the statement that approximately 600,000 beneficiaries rely on pharmacy benefits thru Medicaid. The average cost per claim to Medicaid last month for generic medications was approximately 26 dollars, compared to over 156 dollars for brand name medications. Ms. Clark also stated that Medicaid processed approximately 420,000 claims in January 2007.

New Business

Mr. Smith presented several suggested RDUR intervention modules which were originally presented at the November 2006 meeting. These were presented again because of a lack of quorum at the November meeting.

Restasis®

Mr. Smith presented the results of a review conducted to identify concurrent use of Restasis® and medications with anticholinergic properties. Information was presented to reflect the incidence of this concurrent use at approximately 30 percent. Based on these findings, a criterion was recommended to identify patients who may benefit from a change in therapy allowing discontinuation of Restasis®. A motion was made by Dr. Phillips to accept the criterion, and the motion was seconded by Dr. Gray. All voted in favor of the motion.

Triptans and Antidepressants

The next intervention discussed was the concurrent use of triptans with SSRI or SNRI antidepressants. This review resulted from recent FDA action regarding the risk of serotonin syndrome in patients taking these medications concurrently. Approximately 14 percent of patients who were treated with a triptan also received one or more prescriptions for an SNRI or SSRI during the report period. A criterion was recommended to identify patients who may be at risk for serotonin syndrome due to the concurrent use of members of these drug classes. Mr. Strickland made a motion to approve this criterion, and Dr. Brown seconded the motion. All voted in favor of the motion.

Exubera®

The new inhaled insulin product, Exubera®, was then discussed. Mr. Smith summarized possible concerns around this agent, including potential waste associated with the recommended dosing regimen. After much discussion, the board was presented a motion by Dr. Voulters to table this vote and have HID report back to the board in three to six months on the activity on this medication. This was seconded by Dr. Phillips. All voted in favor.

Additional Criteria Recommendations

Mr. Smith presented the following additional retrospective DUR criteria recommendations:

- Combunox: Duration of Therapy – Combunox (oxycodone/ibuprofen) may be over-utilized. This medication is indicated for short-term (no more than seven days) management of acute moderate to severe pain.

- Combunox: High Dose – Combunox (oxycodone/ibuprofen) may be over-utilized. The

manufacturer's recommended maximum dosage is four tablets in a 24-hour period, with use not to exceed seven days

- Duloxetine: Hepatic Insufficiency – It is recommended that Cymbalta (duloxetine) not be administered to patients with any hepatic insufficiency. These patients experience decreased duloxetine metabolism and elimination. After a single 20mg dose of duloxetine, cirrhotic patients with moderate liver impairment had a mean plasma clearance about 15 percent that of age and gender matched healthy subjects, a five-fold increase in AUC, and a half-life approximately three times longer.

- Duloxetine: End Stage Renal Disease – Cymbalta (duloxetine) is not recommended in patients with end stage renal disease. A single 60mg dose of duloxetine resulted in Cmax and AUC values approximately 100 percent greater in patients with end stage renal disease receiving intermittent hemodialysis than in patients with normal renal function.

- Duloxetine: MAO Inhibitors – The concurrent use of Cymbalta (duloxetine) and monoamine oxidase inhibitors is contraindicated due to the risk for developing serotonin syndrome, which may include hyperthermia, tremor, myoclonus, and irritability. It is recommended that duloxetine not be used within 14 days of discontinuing treatment with an MAOI, and at least five days should be allowed after discontinuing duloxetine before starting an MAOI.

- Duloxetine: Thioridazine – Cymbalta (duloxetine) and thioridazine should not be co-administered. Duloxetine is a moderate inhibitor of CYP 2D6, and concurrent use with thioridazine, a CYP 2D6 substrate, may increase the risk of serious ventricular arrhythmias and sudden death associated with elevated plasma levels of thioridazine.

- Duloxetine: Narrow-Angle Glaucoma – Cymbalta (duloxetine) should be used with caution in patients with controlled narrow-angle glaucoma and is contraindicated in patients with uncontrolled narrow-angle glaucoma. In clinical trials, duloxetine has been shown to increase the risk of mydriasis.

- Duloxetine: Fluoxetine – Cymbalta (duloxetine) should be used with caution in patients receiving Luvox (fluvoxamine), a potent CYP 1A2 inhibitor. Elimination of duloxetine is mainly through hepatic metabolism involving P450 isozymes, CYP 2D6 and CYP 1A2. Concurrent use of these agents resulted in an approximate six-fold increase in the AUC and a 2.5-fold increase in the Cmax of duloxetine.

- Duloxetine: Potent 2D6 Inhibitors – Cymbalta (duloxetine) should be used with caution in patients receiving potent CYP 2D6 inhibitors (paroxetine, fluoxetine, and quinidine). The concurrent use of these agents may result in elevated concentrations of duloxetine.

- Duloxetine: Certain Tricyclic Antidepressants – Cymbalta (duloxetine) should be used with caution in patients receiving certain tricyclic antidepressants (desipramine, amitriptyline, nortriptyline, and imipramine). Duloxetine is a moderate inhibitor of CYP 2D6, and concurrent use with these agents may result in elevated TCA plasma concentrations. TCA plasma levels may need to be monitored, and TCA dose reduction may be necessary.

- Duloxetine: CYP 2D6 Metabolized Drugs – Cymbalta (duloxetine) should be used with caution in patients receiving drugs that are extensively metabolized by the CYP 2D6 isozyme and which have a narrow therapeutic index (Type 1C antiarrhythmics and phenothiazines). Duloxetine is a moderate inhibitor of CYP 2D6, and concurrent use with these agents may result in elevated plasma concentrations of the CYP 2D6 substrate.

- Duloxetine: High Dose – Cymbalta (duloxetine) may be over-utilized. The recommended dosing range is 40mg to 60mg per day. There is no evidence that doses greater than 60mg per day confer any additional benefit.

- Duloxetine: Underuse – After reviewing your patients' refill frequency for Cymbalta (duloxetine), we are concerned that they may be non-adherent to the prescribed dosing regimen, which may lead to sub-therapeutic effects.

- Proton Pump Inhibitors and Warfarin – There have been reports of increases in INR and prothrombin time in patients receiving proton pump inhibitors and warfarin concurrently. Monitor PT/INR when a proton pump inhibitor is added to, changed during, or discontinued from concomitant treatment with warfarin. Adjustment of the warfarin dose may be necessary in order to maintain the desired level of anticoagulation.

A motion was offered by Dr. Montgomery to approve all of the above criteria and seconded by Dr. Gray. All voted in favor of the motion.

Carisoprodol

Mr. Smith then presented a review of carisoprodol (Soma®). The Pharmacy and Therapeutics (P&T) Committee discussed this agent during the January 9, 2007 P&T Committee meeting. The issues of dependence, abuse, and drug-seeking behavior associated with carisoprodol were of major concern to the P&T committee. A one page Prescribing Information Update (One-pager) was presented by Mr. Smith and described to the Board. This document summarizes the basic prescribing recommendations for and risks associated with carisoprodol. The One-pager is intended for distribution to prescribers. After much discussion, the DUR Board recommended that the One-pager be distributed to prescribers by the academic detailing staff, along with a suggested tapering schedule for discontinuing carisoprodol. A motion was made by Dr. Phillips and seconded by Dr. Montgomery to also include the One-pager and tapering schedule in the April Bulletin. Dr. Phillips added that the DUR Board should revisit carisoprodol prescribing trends periodically and consider recommending action by the P&T Committee if favorable results are not seen.

Cough and Cold Products in Young Children

Mr. Smith presented a report on utilization of cough and cold medications in young children. In January, the Centers for Disease Control and Prevention (CDC) issued a Morbidity and Mortality Weekly Report (MMWR) article describing three deaths in infants less than 12 months of age that were associated with cough and cold medications. This report showed that during the fourth quarter of 2006, over 15,000 prescriptions were filled for these agents among beneficiaries under two years of age. A copy of the CDC report was provided to the Board members. Ms. Clark

offered that a pediatrician from University Medical Center would be invited to the next DUR Board meeting to discuss this issue further.

Boxed Warnings Update

Mr. Smith presented black box warnings, other warnings, and labeling changes issued by the FDA concerning the following:

Coumadin (warfarin sodium)

[Posted 10/06/2006] The FDA and Bristol-Myers Squibb notified pharmacists and physicians of revisions to the labeling for Coumadin to include a new patient Medication Guide, as well as a reorganization and highlighting of the current safety information to better inform providers and patients.

Isotretinoin - Accutane and generic isotretinoin

[Posted 10/06/2006] The FDA and the iPLEDGE program notified healthcare professionals and patients of an update to iPLEDGE, a risk management program to reduce the risk of fetal exposure to isotretinoin, which will eliminate one element of the program, the 23 day lock-out period for males and females of non-child bearing potential. This change does not affect female patients of child-bearing potential.

Lamictal (lamotrigine)

[Posted 09/29/2006] The FDA notified healthcare professionals and patients of new preliminary information from the North American Antiepileptic Drug Pregnancy Registry that suggests that babies exposed to Lamictal, indicated to treat seizures and bipolar disorder, during the first three months of pregnancy may have a higher chance of being born with a cleft lip or cleft palate. More research is needed to be sure about the possibility of the increased chance of cleft lip or cleft palate developing in babies of pregnant women who take Lamictal. Women who take Lamictal and are pregnant or are thinking of becoming pregnant should talk with their doctor. Patients should not start or stop using Lamictal without talking to their doctor.

Ortho Evra (norelgestromin/ethinyl estradiol)

[Posted 09/20/2006] Ortho-McNeil and the FDA notified healthcare professionals and patients about revisions to the prescribing information to inform them of the results of two separate epidemiology studies that evaluated the risk of developing a serious blood clot in women using Ortho Evra compared to women using a different oral contraceptive. The first study found that the risk of non-fatal venous thromboembolism (VTE) associated with the use of Ortho Evra contraceptive patch is similar to the risk associated with the use of oral contraceptive pills containing 35 micrograms of ethinyl estradiol and norgestimate. The second study found an approximate two-fold increase in the risk of medically verified VTE events in users of Ortho Evra compared to users of norgestimate-containing oral contraceptives containing 35 micrograms of estrogen. Although the results of the two studies differ, the results of the second study support FDA's concerns regarding the potential for Ortho Evra use to increase the risk of blood clots in some women. Prescribing information for Ortho Evra continues to recommend that women with concerns or risk factors for thromboemboli disease talk with their healthcare professionals about using Ortho Evra versus other contraceptive options.

Ibuprofen and Aspirin Taken Together

[Posted 09/08/2006] The FDA notified consumers and healthcare professionals that taking Ibuprofen for pain relief and aspirin at the same time may interfere with the benefits of aspirin taken for the heart. Ibuprofen can interfere with the anti-platelet effect of low dose aspirin (81mg per day), that may render aspirin less effective when used for cardioprotection and stroke prevention. Although it is safe to use Ibuprofen and aspirin together, the FDA recommends that consumers contact their healthcare professional for more information on the timing of taking these two medicines together, so that both medicines can be optimally effective.

Dexedrine (dextroamphetamine sulfate)
[Posted 08/21/2006] The FDA and GlaxoSmithKline notified healthcare professionals of changes to the BOXED WARNING, WARNINGS, and PRECAUTIONS sections of the prescribing information for Dexedrine (dextroamphetamine sulfate), approved for the treatment of Attention-Deficit Hyperactivity Disorder and narcolepsy. The warnings describe reports of sudden death in association with CNS stimulant treatment at usual doses in children and adolescents with structural cardiac abnormalities or other serious heart problems.

Aptivus (tipranavir)
[Posted 06/30/2006] Boehringer Ingelheim and the FDA informed healthcare professionals of important new safety information for Aptivus (tipranavir) capsules co-administered with ritonavir (500mg/200mg) which includes an addition to the drug's Black Box Warning regarding reports of both fatal and non-fatal intracranial hemorrhage (ICH). Boehringer Ingelheim identified 14 reports of intracranial hemorrhage events, including eight fatalities, in 6,840 HIV-1 infected individuals receiving Aptivus capsules in combination antiretroviral therapy in clinical trials. Many of the patients experiencing ICH in the Aptivus clinical development program had other medical conditions (CNS lesions, head trauma, recent neurosurgery, coagulopathy, hypertension, or alcohol abuse) or were receiving concomitant medications, including anticoagulants and antiplatelet agents, that may have caused or contributed to these events. No pattern of abnormal coagulation parameters were observed in patients receiving Aptivus in general, or preceding the development of ICH. Routine measurement of coagulation parameters is not currently indicated in the management of patients on Aptivus. An increased risk of ICH was previously observed in patients with advanced HIV-1 disease/AIDS. Further investigations are ongoing to assess the role of Aptivus in ICH.

Ketek (telithromycin)
[Posted 06/29/2006] The FDA notified healthcare professionals and patients that it completed its safety assessment of Ketek (telithromycin), indicated for the treatment of acute exacerbation of chronic bronchitis, acute bacterial sinusitis, and community acquired pneumonia of mild to moderate severity, including pneumonia caused by resistant strep infections. The drug has been associated with rare cases of serious liver injury and liver failure, with four reported deaths and one liver transplant after the administration of the drug. The FDA determined that additional warnings are required and the manufacturer is revising the drug labeling to address this safety concern. The FDA is advising patients taking Ketek and their doctors to be on the alert for signs and symptoms of liver problems. Patients experiencing such signs or symptoms should discontinue Ketek and seek medical evaluation, which may include tests for liver function.

Paxil (paroxetine hydrochloride) Tablets and Oral Suspension
Paxil CR (paroxetine hydrochloride) Controlled-Release Tablets
[Posted 05/12/2006] GlaxoSmithKline (GSK) and the FDA notified healthcare professionals of changes to the Clinical Worsening and Suicide Risk subsection of the WARNINGS section in the prescribing Information for Paxil and Paxil CR. These labeling changes relate to adult patients, particularly those who are younger adults. A recent meta-analysis conducted of suicidal behavior and ideation in placebo-controlled clinical trials of paroxetine in adult patients with psychiatric disorders including Major Depressive Disorder (MDD), other depression, and non-depression disorders. Results of this analysis showed a higher frequency of suicidal behavior in young adults treated with paroxetine compared with placebo. Further, in the analysis of adults with MDD (all ages), the frequency of suicidal behavior was higher in patients treated with paroxetine compared with placebo. This difference was statistically significant. As the absolute number and incidence of events are small, however, these data should be interpreted with caution. All of the reported events of suicidal behavior in the adult patients with MDD were non-fatal suicide attempts, and the majority of these attempts (eight of 11) were in younger adults aged 18-30. These MDD data suggest that the higher frequency observed in the younger adult population across psychiatric disorders may extend beyond the age of 24. It is important that all patients, especially young adults and those who are improving, receive careful monitoring during paroxetine therapy regardless of the condition being treated.

Next Meeting Information:
Ms. Clark reminded the Board of the next scheduled meeting on May 17, 2007.
Randy Calvert adjourned the meeting at 3:40 p.m.

Respectfully Submitted:
Health Information Designs

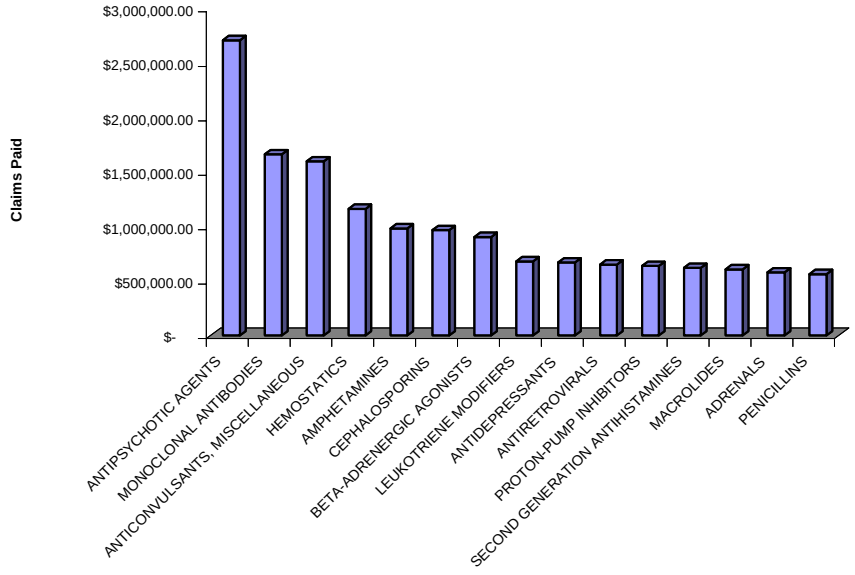
MISSISSIPPI MEDICAID
Cost Management Analysis

TOP 15 THERAPEUTIC CLASSES BY TOTAL COST OF CLAIMS FROM 02/01/07-02/28/07

AHFS Therapeutic Class	Rx	Paid	Paid/Rx	% Total Claims
ANTIPSYCHOTIC AGENTS	9,457	$ 2,710,338.50	$ 286.60	2.44%
MONOCLONAL ANTIBODIES	1,290	$ 1,663,332.99	$ 1,289.41	0.33%
ANTICONVULSANTS, MISCELLANEOUS	9,573	$ 1,598,178.23	$ 166.95	2.47%
HEMOSTATICS	31	$ 1,162,428.19	$37,497.68	0.01%
AMPHETAMINES	8,746	$ 982,822.55	$ 112.37	2.26%
CEPHALOSPORINS	15,401	$ 966,588.27	$ 62.76	3.97%
BETA-ADRENERGIC AGONISTS	12,705	$ 904,247.02	$ 71.17	3.28%
LEUKOTRIENE MODIFIERS	6,726	$ 681,105.00	$ 101.26	1.74%
ANTIDEPRESSANTS	13,147	$ 669,460.03	$ 50.92	3.39%
ANTIRETROVIRALS	1,015	$ 650,205.11	$ 640.60	0.26%
PROTON-PUMP INHIBITORS	4,533	$ 637,686.16	$ 140.68	1.17%
SECOND GENERATION ANTIHISTAMINES	12,603	$ 619,528.05	$ 49.16	3.25%
MACROLIDES	15,856	$ 606,912.26	$ 38.28	4.09%
ADRENALS	9,406	$ 579,479.51	$ 61.61	2.43%
PENICILLINS	23,693	$ 562,084.46	$ 23.72	6.11%
TOTAL TOP 15	144,182	$ 14,994,396.33	$ 104.00	37.21%

Total Rx Claims	387,512
From 02/01/07-02/28/07	

Top 15 Therapeutic Classes
Based on Total Cost of Claims



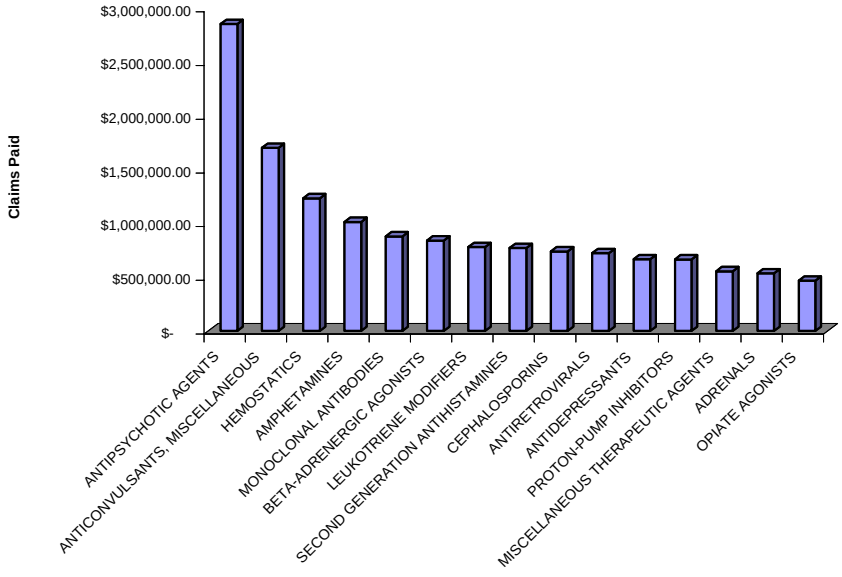
MISSISSIPPI MEDICAID
Cost Management Analysis

TOP 15 THERAPEUTIC CLASSES BY TOTAL COST OF CLAIMS FROM 03/01/07-03/31/07

AHFS Therapeutic Class	Rx	Paid	Paid/Rx	% Total Claims
ANTIPSYCHOTIC AGENTS	10,010	$ 2,858,255.10	$ 285.54	2.67%
ANTICONVULSANTS, MISCELLANEOUS	10,212	$ 1,704,566.58	$ 166.92	2.73%
HEMOSTATICS	50	$ 1,235,138.79	$24,702.78	0.01%
AMPHETAMINES	9,084	$ 1,013,728.43	$ 111.59	2.42%
MONOCLONAL ANTIBODIES	702	$ 880,298.89	$ 1,253.99	0.19%
BETA-ADRENERGIC AGONISTS	11,842	$ 841,458.48	$ 71.06	3.16%
LEUKOTRIENE MODIFIERS	7,621	$ 781,117.85	$ 102.50	2.03%
SECOND GENERATION ANTIHISTAMINES	15,252	$ 771,557.89	$ 50.59	4.07%
CEPHALOSPORINS	12,399	$ 740,515.60	$ 59.72	3.31%
ANTIRETROVIRALS	1,111	$ 723,719.88	$ 651.41	0.30%
ANTIDEPRESSANTS	13,739	$ 666,812.44	$ 48.53	3.67%
PROTON-PUMP INHIBITORS	4,749	$ 666,006.71	$ 140.24	1.27%
MISCELLANEOUS THERAPEUTIC AGENTS	2,168	$ 555,684.49	$ 256.31	0.58%
ADRENALS	8,586	$ 535,742.72	$ 62.40	2.29%
OPIATE AGONISTS	23,946	$ 466,618.71	$ 19.49	6.39%
TOTAL TOP 15	131,471	$ 14,441,222.56	$ 109.84	35.09%

Total Rx Claims	374,676
From 03/01/07-03/31/07	

Top 15 Therapeutic Classes
Based on Total Cost of Claims



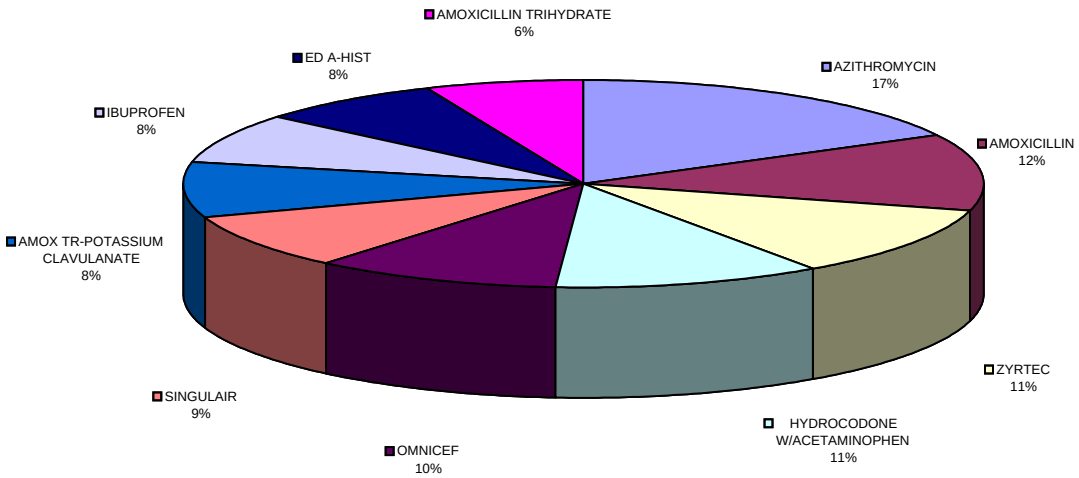
MISSISSIPPI MEDICAID
Cost Management Analysis

TOP 25 DRUGS BASED ON NUMBER OF CLAIMS FROM 02/01/07-02/28/07

Drug	AHFS Therapeutic Class	Rx	Paid	Paid/Rx
AZITHROMYCIN	MACROLIDES	13,353	$ 490,166.34	$ 36.71
AMOXICILLIN	PENICILLINS	9,263	$ 78,211.37	$ 8.44
ZYRTEC	SECOND GENERATION ANTIHISTAMINES	8,572	$ 452,902.88	$ 52.84
HYDROCODONE W/ACETAMINOPHEN	OPIATE AGONISTS	8,457	$ 87,555.53	$ 10.35
OMNICEF	CEPHALOSPORINS	7,888	$ 714,250.07	$ 90.55
SINGULAIR	LEUKOTRIENE MODIFIERS	6,722	$ 680,815.37	$ 101.28
AMOX TR-POTASSIUM CLAVULANATE	PENICILLINS	6,595	$ 354,902.68	$ 53.81
IBUPROFEN	NONSTEROIDAL ANTI-INFLAMMATORY AGENTS	6,061	$ 51,185.20	$ 8.45
ED A-HIST	PROPYLAMINE DERIVATIVES	5,865	$ 55,393.65	$ 9.44
AMOXICILLIN TRIHYDRATE	PENICILLINS	4,903	$ 60,160.84	$ 12.27
ALBUTEROL SULFATE	BETA-ADRENERGIC AGONISTS	4,440	$ 105,089.39	$ 23.67
PROMETHAZINE HCL	PHENOTHIAZINE DERIVATIVES	4,411	$ 49,333.17	$ 11.18
TAMIFLU	NEURAMINIDASE INHIBITORS	4,258	$ 302,334.71	$ 71.00
CEPHALEXIN	CEPHALOSPORINS	4,093	$ 67,082.97	$ 16.39
PREVACID	PROTON-PUMP INHIBITORS	4,016	$ 570,511.13	$ 142.06
SULFAMETHOXAZOLE/TRIMETHOPRIM	SULFONAMIDES (SYSTEMIC)	3,885	$ 47,304.65	$ 12.18
ALPRAZOLAM	BENZODIAZEPINES (ANXIOLYTIC,SEDATIV/HYP)	3,845	$ 31,575.21	$ 8.21
ACETAMINOPHEN W/CODEINE	OPIATE AGONISTS	3,307	$ 28,038.11	$ 8.48
ADDERALL XR	AMPHETAMINES	3,026	$ 381,491.06	$ 126.07
CLONAZEPAM	BENZODIAZEPINES (ANTICONVULSANTS)	2,973	$ 55,098.22	$ 18.53
ALBUTEROL	BETA-ADRENERGIC AGONISTS	2,914	$ 67,707.93	$ 23.24
RISPERDAL	ANTIPSYCHOTIC AGENTS	2,653	$ 695,639.83	$ 262.21
CONCERTA	AMPHETAMINES	2,545	$ 322,564.27	$ 126.74
LORAZEPAM	BENZODIAZEPINES (ANXIOLYTIC,SEDATIV/HYP)	2,482	$ 67,479.41	$ 27.19
FERROUS SULFATE	IRON PREPARATIONS	2,413	$ 9,252.39	$ 3.83
TOTAL TOP 25		128,940	$ 5,826,046.38	$ 45.18

Total Rx Claims	387,512
From 02/01/07-02/28/07	

Top 10 Drugs
Based on Number of Claims



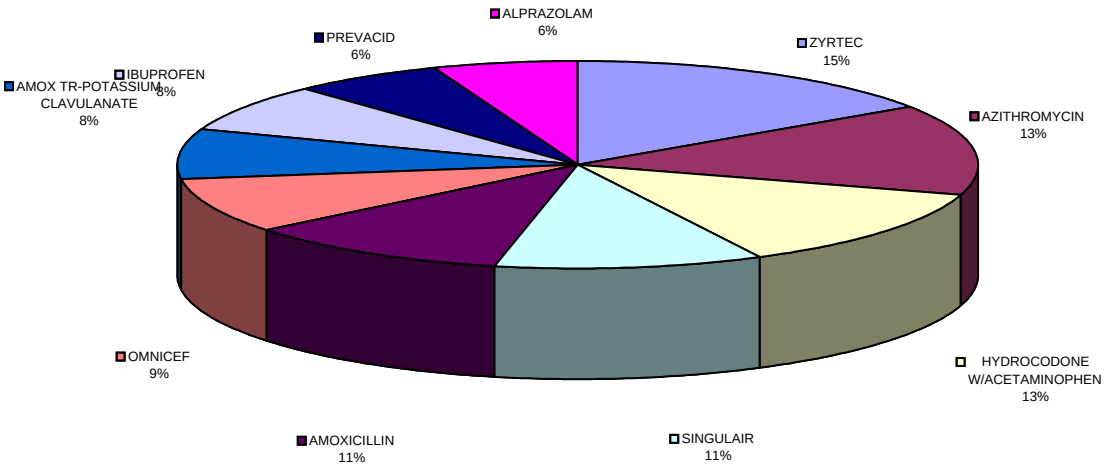
MISSISSIPPI MEDICAID
Cost Management Analysis

TOP 25 DRUGS BASED ON NUMBER OF CLAIMS FROM 03/01/07-03/31/07

Drug	AHFS Therapeutic Class	Rx	Paid	Paid/Rx
ZYRTEC	SECOND GENERATION ANTIHISTAMINES	10,733	$ 575,850.20	$ 53.65
AZITHROMYCIN	MACROLIDES	9,768	$ 356,449.21	$ 36.49
HYDROCODONE W/ACETAMINOPHEN	OPIATE AGONISTS	8,790	$ 91,219.83	$ 10.38
SINGULAIR	LEUKOTRIENE MODIFIERS	7,616	$ 780,533.30	$ 102.49
AMOXICILLIN	PENICILLINS	7,323	$ 60,884.63	$ 8.31
OMNICEF	CEPHALOSPORINS	5,948	$ 527,923.45	$ 88.76
AMOX TR-POTASSIUM CLAVULANATE	PENICILLINS	5,358	$ 282,295.09	$ 52.69
IBUPROFEN	NONSTEROIDAL ANTI-INFLAMMATORY AGENTS	5,185	$ 41,795.13	$ 8.06
PREVACID	PROTON-PUMP INHIBITORS	4,214	$ 596,406.33	$ 141.53
ALPRAZOLAM	BENZODIAZEPINES (ANXIOLYTIC,SEDATIV/HYP)	4,108	$ 33,863.37	$ 8.24
ED A-HIST	PROPYLAMINE DERIVATIVES	4,077	$ 38,632.35	$ 9.48
AMOXICILLIN TRIHYDRATE	PENICILLINS	3,887	$ 45,898.45	$ 11.81
PROMETHAZINE HCL	PHENOTHIAZINE DERIVATIVES	3,834	$ 44,157.21	$ 11.52
CEPHALEXIN	CEPHALOSPORINS	3,777	$ 62,240.60	$ 16.48
ALBUTEROL SULFATE	BETA-ADRENERGIC AGONISTS	3,697	$ 90,685.98	$ 24.53
SULFAMETHOXAZOLE/TRIMETHOPRIM	SULFONAMIDES (SYSTEMIC)	3,680	$ 42,695.44	$ 11.60
ACETAMINOPHEN W/CODEINE	OPIATE AGONISTS	3,419	$ 28,943.72	$ 8.47
CLONAZEPAM	BENZODIAZEPINES (ANTICONVULSANTS)	3,084	$ 58,317.75	$ 18.91
ADDERALL XR	AMPHETAMINES	3,082	$ 386,985.95	$ 125.56
ALBUTEROL	BETA-ADRENERGIC AGONISTS	2,988	$ 70,903.87	$ 23.73
RISPERDAL	ANTIPSYCHOTIC AGENTS	2,940	$ 769,580.95	$ 261.76
LORAZEPAM	BENZODIAZEPINES (ANXIOLYTIC,SEDATIV/HYP)	2,765	$ 74,436.12	$ 26.92
CONCERTA	AMPHETAMINES	2,607	$ 330,666.10	$ 126.84
FERROUS SULFATE	IRON PREPARATIONS	2,522	$ 9,601.18	$ 3.81
NYSTATIN	POLYENES	2,479	$ 33,924.55	$ 13.68
TOTAL TOP 25		117,881	$ 5,434,890.76	$ 46.10

Total Rx Claims From 03/01/07-03/31/07	374,676

Top 10 Drugs
Based on Number of Claims



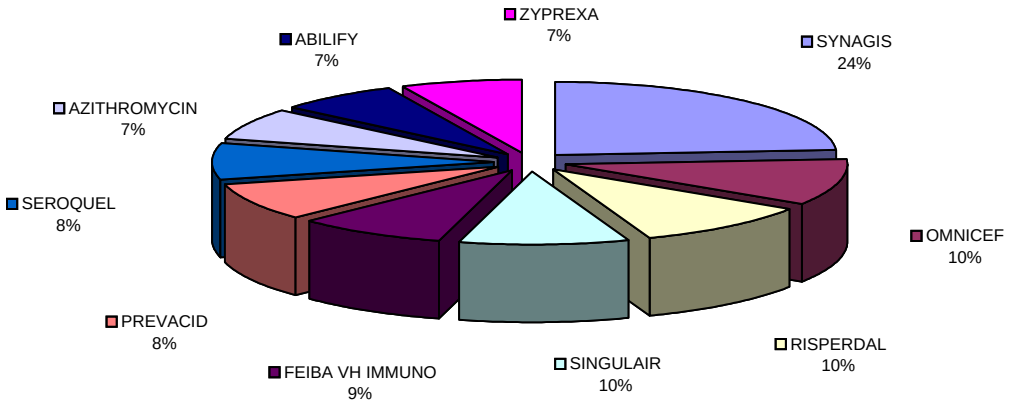
MISSISSIPPI MEDICAID
Cost Management Analysis

TOP 25 DRUGS BASED ON TOTAL CLAIMS COST FROM 02/01/07-02/28/07

Drug	AHFS Therapeutic Class	Rx	Paid	Paid/Rx
SYNAGIS	MONOCLONAL ANTIBODIES	1,290	$ 1,663,332.99	$ 1,289.41
OMNICEF	CEPHALOSPORINS	7,888	$ 714,250.07	$ 90.55
RISPERDAL	ANTIPSYCHOTIC AGENTS	2,653	$ 695,639.83	$ 262.21
SINGULAIR	LEUKOTRIENE MODIFIERS	6,722	$ 680,815.37	$ 101.28
FEIBA VH IMMUNO	HEMOSTATICS	7	$ 602,924.30	$ 86,132.04
PREVACID	PROTON-PUMP INHIBITORS	4,016	$ 570,511.13	$ 142.06
SEROQUEL	ANTIPSYCHOTIC AGENTS	1,871	$ 553,404.97	$ 295.78
AZITHROMYCIN	MACROLIDES	13,353	$ 490,166.34	$ 36.71
ABILIFY	ANTIPSYCHOTIC AGENTS	1,094	$ 483,386.44	$ 441.85
ZYPREXA	ANTIPSYCHOTIC AGENTS	1,032	$ 477,705.12	$ 462.89
ZYRTEC	SECOND GENERATION ANTIHISTAMINES	8,572	$ 452,902.88	$ 52.84
PULMICORT	ADRENALS	1,890	$ 440,971.05	$ 233.32
ADDERALL XR	AMPHETAMINES	3,026	$ 381,491.06	$ 126.07
AMOX TR-POTASSIUM CL	PENICILLINS	6,595	$ 354,902.68	$ 53.81
XOPENEX	BETA-ADRENERGIC AGONISTS	2,258	$ 335,744.36	$ 148.69
CONCERTA	AMPHETAMINES	2,545	$ 322,564.27	$ 126.74
TOPAMAX	ANTICONVULSANTS, MISCELLANEOUS	1,154	$ 321,301.75	$ 278.42
TAMIFLU	NEURAMINIDASE INHIBITORS	4,258	$ 302,334.71	$ 71.00
ADVAIR DISKUS	BETA-ADRENERGIC AGONISTS	1,572	$ 277,447.70	$ 176.49
ADVATE	HEMOSTATICS	6	$ 221,532.95	$ 36,922.16
GEODON	ANTIPSYCHOTIC AGENTS	717	$ 213,546.86	$ 297.83
TRILEPTAL	ANTICONVULSANTS, MISCELLANEOUS	1,088	$ 210,355.54	$ 193.34
LAMICTAL	ANTICONVULSANTS, MISCELLANEOUS	684	$ 203,739.90	$ 297.87
STRATTERA	CENTRAL NERVOUS SYSTEM AGENTS, MISC.	1,354	$ 195,749.14	$ 144.57
GABAPENTIN	ANTICONVULSANTS, MISCELLANEOUS	1,670	$ 192,490.99	$ 115.26
TOTAL TOP 25		77,315	$ 11,359,212.40	$ 146.92

Total Rx Claims	387,512
From 02/01/07-02/28/07	

Top 10 Drugs
Based on Total Claims Cost



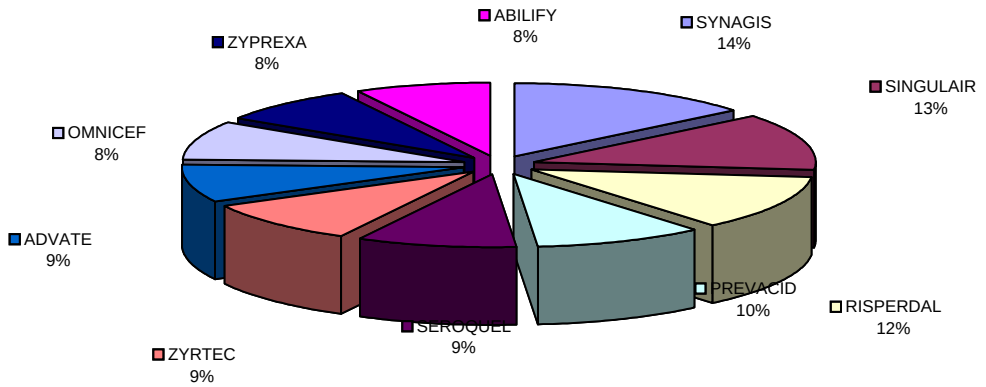
MISSISSIPPI MEDICAID
Cost Management Analysis

TOP 25 DRUGS BASED ON TOTAL CLAIMS COST FROM 03/01/07-03/31/07

Drug	AHFS Therapeutic Class	Rx	Paid	Paid/Rx
SYNAGIS	MONOCLONAL ANTIBODIES	702	$ 880,298.89	$ 1,253.99
SINGULAIR	LEUKOTRIENE MODIFIERS	7,616	$ 780,533.30	$ 102.49
RISPERDAL	ANTIPSYCHOTIC AGENTS	2,940	$ 769,580.95	$ 261.76
PREVACID	PROTON-PUMP INHIBITORS	4,214	$ 596,406.33	$ 141.53
SEROQUEL	ANTIPSYCHOTIC AGENTS	1,937	$ 577,533.51	$ 298.16
ZYRTEC	SECOND GENERATION ANTIHISTAMINES	10,733	$ 575,850.20	$ 53.65
ADVATE	HEMOSTATICS	15	$ 532,437.53	$ 35,495.84
OMNICEF	CEPHALOSPORINS	5,948	$ 527,923.45	$ 88.76
ZYPREXA	ANTIPSYCHOTIC AGENTS	1,066	$ 503,374.72	$ 472.21
ABILIFY	ANTIPSYCHOTIC AGENTS	1,121	$ 485,985.03	$ 433.53
PULMICORT	ADRENALS	1,770	$ 408,805.64	$ 230.96
ADDERALL XR	AMPHETAMINES	3,082	$ 386,985.95	$ 125.56
AZITHROMYCIN	MACROLIDES	9,768	$ 356,449.21	$ 36.49
TOPAMAX	ANTICONVULSANTS, MISCELLANEOUS	1,241	$ 338,783.63	$ 272.99
CONCERTA	AMPHETAMINES	2,607	$ 330,666.10	$ 126.84
FEIBA VH IMMUNO	HEMOSTATICS	5	$ 293,143.50	$ 58,628.70
XOPENEX	BETA-ADRENERGIC AGONISTS	1,878	$ 282,652.62	$ 150.51
AMOX TR-POTASSIUM CL	PENICILLINS	5,358	$ 282,295.09	$ 52.69
ADVAIR DISKUS	BETA-ADRENERGIC AGONISTS	1,577	$ 277,307.11	$ 175.84
TRILEPTAL	ANTICONVULSANTS, MISCELLANEOUS	1,182	$ 223,069.24	$ 188.72
LAMICTAL	ANTICONVULSANTS, MISCELLANEOUS	737	$ 220,306.87	$ 298.92
GEODON	ANTIPSYCHOTIC AGENTS	734	$ 218,031.59	$ 297.05
GABAPENTIN	ANTICONVULSANTS, MISCELLANEOUS	1,766	$ 210,012.39	$ 118.92
STRATTERA	CENTRAL NERVOUS SYSTEM AGENTS, MISC.	1,365	$ 200,421.22	$ 146.83
LIPITOR	HMG-COA REDUCTASE INHIBITORS	1,885	$ 191,274.07	$ 101.47
TOTAL TOP 25		71,247	$ 10,450,128.14	$ 146.67

Total Rx Claims From 03/01/07-03/31/07	374,676

Top 10 Drugs
Based on Total Claims Cost



Bacterial Conjunctivitis
Treatment with Ophthalmic Antibiotics

Introduction
Conjunctivitis is a very common disorder that is particularly prevalent among young children. The treatment of conjunctivitis of various etiologies is a common occurrence for physicians and nurse practitioners practicing in primary care settings.

Ophthalmic Antibiotics
There are many topical ophthalmic antibiotics on the market and most are available generically at relatively low cost. There are, however, branded products available with much higher costs. In order to make informed prescribing decisions about agents in this category, it is important for prescribers to be aware of the significant cost discrepancy between these agents.

The following chart lists many of the available agents.

Agent ***Generic (Brand Example)***	***Generically Available***	***Agent*** ***Generic (Brand Example)***	***Generically Available***
Bacitracin (AK-tracin®)	Yes	Levofloxacin (Quixin®)	No
Bacitracin/polymyxin B (Polysporin®)	Yes	Moxifloxacin (Vigamox®)	No
Chloramphenicol (Chloromycetin®)	Yes	Neomycin/polymyxin B/ bacitracin (Neosporin®)	Yes
Ciprofloxacin (Ciloxan®)	Yes	Ofloxacin (Ocuflox®)	Yes
Erythromycin (Ilotycin®)	Yes	Sulfacetamide (AK-sulf®, Bleph-10®)	Yes
Gatifloxacin (Zymar®)	No	Tobramycin (Tobrex®)	Yes
Gentamicin (Garamycin®)	Yes	Trimethoprim/polymyxin B (Polytrim®)	Yes

Market Trends
The appropriate use of these agents has become a concern of many managed care organizations, including Medicaid agencies and private sector groups. As a result, many health insurers have limited access to these agents through prior authorization step-therapy requirements. In fact, the Mississippi Medicaid Pharmacy and Therapeutics Committee will review these agents in July for inclusion on the Preferred Drug List (PDL).

Mississippi Medicaid Utilization

Ophthalmic Antibiotics
3/1/2006 - 2/28/2007

Label Name	Rx Num	Qty Dispensed	Total Reimbursed Amount	Average Cost per Claim
AK-POLY-BAC EYE OINTMENT	14	49	$280.41	$20.03
AKTOB 0.3% EYE DROPS	24	120	$179.12	$7.46
CILOXAN 0.3% OINTMENT	206	721	$12,754.60	$61.92
CIPROFLOXACIN 0.3% EYE DROP	1,641	8,563	66820.33	$40.72
ERYTHROMYCIN EYE OINTMENT	2,958	10,412	$23,859.67	$8.07
GENTAK 3 MG/GM EYE OINTMENT	584	2,058	$11,235.47	$19.24
GENTAK 3 MG/ML EYE DROPS	1	5	$3.76	$3.76
GENTAMICIN 3 MG/GM EYE OINT	270	945	$4,741.66	$17.56
GENTAMICIN 3 MG/ML EYE DROPS	6,368	36,012	$48,776.15	$7.66
NEO/BACIT/POLY EYE OINTMENT	171	599	$2,642.73	$15.45
NEOMYCI/POLY/GRAM OPHTH SOL	8	80	$188.24	$23.53
NEOMYCIN/POLY/GRAM EYE DROP	958	9,659	$23,639.09	$24.68
OFLOXACIN 0.3% EYE DROPS	797	4,743	$32,750.51	$41.09
POLYMYXIN B/TMP EYE DROPS	5,140	51,294	$83,196.53	$16.19
QUIXIN 0.5% EYE DROPS	329	1,647	$17,630.89	$53.59
SULFACETAMIDE 10% EYE DROPS	2,277	34,086	$15,461.52	$6.79
SULFACETAMIDE 10% EYE OINT	79	277	$708.76	$8.97
SULFAMIDE 10% EYE DROPS	58	870	$397.75	$6.86
TOBRAMYCIN 0.3% EYE DROPS	1,472	7,609	$11,436.58	$7.77
TOBREX 0.3% EYE OINTMENT	153	536	$8,716.14	$56.97
VIGAMOX 0.5% EYE DROPS	5,779	17,482	$329,112.79	$56.95
ZYMAR 0.3% EYE DROPS	383	1,935	$20,574.52	$53.72

Recommendations

1. In an effort to increase provider understanding of the available ophthalmic antibiotics, a Medicaid Prescribing Update, or “one-pager” has been developed for this drug category. This document is included on the following page. HID recommends distribution of this document to prescribers by the Academic Detailing Staff, as well as availability by link from the Division of Medicaid Website.

2. Retrospective DUR criteria are also recommended for these agents. These criteria focus on appropriate length of therapy and appropriate age and are included in this packet for review.

Prescribing Information Update

BACTERIAL CONJUNCTIVITIS

Mississippi Division of Medicaid

- *Conjunctivitis can be brought on by several different causes including allergies, viruses, and bacteria.*
- *The majority of cases of conjunctivitis in children are caused be adenoviruses, rather than bacteria.*
- *Conjunctivitis is generally self-limiting. Treatment should center around increasing patient comfort, reducing duration and preventing transmission.*
- *Generically-available ophthalmic antibiotics are sufficient for many cases of bacterial conjunctivitis and provide a more cost-effective alternative to more expensive brand agents.*

Commonly referred to as "pink eye", conjunctivitis is characterized by itching, tearing, discharge, irritation, or foreign body sensation. There are several types of conjunctivitis, based on etiology, including allergic, mechanical (irritative), viral, and bacterial.

Bacterial versus Viral

The majority of cases of conjunctivitis are caused by viruses, most commonly adenoviruses. Viral conjunctivitis is self-limiting and requires no therapy other than careful hand washing to minimize spread of the virus to others. According to The American Academy of Ophthalmology, bacterial conjunctivitis may also be self-limiting and not require antibiotic therapy, although this practice is not approved for children.

Management

The treatment of conjunctivitis centers around increasing patient comfort, reducing the duration of symptoms, and preventing transmission of infection to other patients. The following table is adapted from guidelines from the American Optometric Association.

Type	***Management Guidelines***
Allergic	Non-preserved lubricants, cold compresses, systemic antihistamines, topical pharmaceuticals
Bacterial	Identify organism if possible Topical ophthalmic antibiotics
Viral	Cold compresses, lubricants, ocular decongestants

Treatment Choices

There are many ophthalmic antibiotics available for the treatment of bacterial conjunctivitis. The chart below lists several available agents. Although the newer fluoroquinolones may have better *in vitro* activity against common pathogens, ophthalmic formulations of antibacterial drugs achieve high concentrations in the eye that may be effective clinically even when the organisms are reported to be resistant *in vitro*.

Agent	***Generic***	*Price*	***Agent***	***Generic***	*Price*
Bacitracin/poly B (Polysporin®)	Yes	$$	Moxifloxacin (Vigamox®)	No	$$$$
Chloramphenicol (Chloromycetin®)	Yes	$$	Neomycin/poly B/bacitracin (Neosporin®)	Yes	$$
Ciprofloxacin (Ciloxan®)	Yes	$$$	Ofloxacin (Ocuflox®)	Yes	$$$
Erythromycin (Ilotycin®)	Yes	$	Sulfacetamide (AK-sulf®, Bleph-10®)	Yes	$
Gatifloxacin (Zymar®)	No	$$$$	Tobramycin (Tobrex®)	Yes	$
Gentamicin (Garamycin®)	Yes	$	Trimethoprim/polymyxin B (Polytrim®)	Yes	$$
Bacitracin (AK-tracin®)	Yes	$	Levofloxacin (Quixin®)	No	$$$$

Price Indicators reflect average cost per claim based on Mississippi Medicaid Utilization.

References:

- Drugs for Some Common Eye Disorders. Treatment Guidelines from the Medical Letter. Vol. 5 (Issue 53). January 2007.
- Care of the Patient with Conjunctivitis Quick Reference Guide. Optometric Clinical Practice Guideline on Care of the Patient with Conjunctivitis. American Optometric Association. St. Louis, MO.
- American Academy of Ophthalmology Corneal/External Disease Panel. Preferred Practice Patter: Conjunctivitis. San Francisco, CA: AAO; 2003.

MISSISSIPPI MEDICAID
RETROSPECTIVE DRUG UTILIZATION REVIEW
CRITERIA RECOMMENDATIONS
OPHTHALMIC ANTIBIOTICS
MAY 2007

Criteria Recommendations	*Approved*	*Rejected*

1. Gatifloxacin Ophthalmic / Over-utilization _____ _____

Alert Message: Zymar (gatifloxacin ophthalmic) may be over-utilized. Gatifloxacin ophthalmic solution is recommended for a duration of 7 days. As with other anti-infectives, prolonged use may result in overgrowth of non-susceptible organisms, including fungi.
Conflict Code: ER - Overuse
Drugs/Disease:

Util A	Util B	Util C
Gatifloxacin Ophthalmic		

Day Supply: > 7 days
References:
Facts & Comparisons, 2007 Updates.
Zymar Prescribing Information, Aug. 2004, Allergan, Inc.

2. Moxifloxacin Ophthalmic / Over-utilization _____ _____

Alert Message: Vigamox (moxifloxacin ophthalmic) may be over-utilized. Moxifloxacin ophthalmic solution is recommended for a duration of 7 days. As with other anti-infectives, prolonged use may result in overgrowth of non-susceptible organisms, including fungi.
Conflict Code: ER - Overuse
Drugs/Disease:

Util A	Util B	Util C
Moxifloxacin Ophthalmic		

Day Supply: > 7 days
References:
Facts & Comparisons, 2007 Updates.
Vigamox Prescribing Information, Aug. 2004, Alcon Canada Inc.

3. Gatifloxacin Ophthalmic /Therapeutic Appropriateness _____ _____

Alert Message: The safety and effectiveness of Zymar (gatifloxacin ophthalmic) in infants below 1 year old have not been established.
Conflict Code: TA – Therapeutic Appropriateness
Drugs/Disease:

Util A	Util B	Util C
Gatifloxacin Ophthalmic		

Age Range: 0 -1 year of age
References:
Facts & Comparisons, 2007 Updates.
Zymar Prescribing Information, Aug. 2004, Allergan, Inc.

Criteria Recommendations	*Approved*	*Rejected*

4. Moxifloxacin Ophthalmic /Therapeutic Appropriateness _____ _____

Alert Message: The safety and effectiveness of Vigamox (moxifloxacin ophthalmic) in infants below 1 year old have not been established.
Conflict Code: TA – Therapeutic Appropriateness

~~Drugs~~/Disease:		
Util A	Util B	Util C
Moxifloxacin Ophthalmic		

Age Range: 0-1 years of age
References:
Facts & Comparisons, 2007 Updates.
Vigamox Prescribing Information, Aug. 2004, Allergan, Inc.
AHFS Drug Information, 2007.

HIV-Related Therapy

As you know, the treatment of HIV/AIDS has seen dramatic improvement in recent years. The availability of more effective medications combined with a better understanding of combination drug therapy strategies have resulted in much more positive prognoses for many patients with HIV.

Guidance for the treatment of HIV is updated regularly to assist treating physicians in keeping up with the most current developments. The most recent update of these guidelines occurred in October of 2006. Due to the rapid evolution of HIV management, the AIDSinfo website is maintained at http://AIDS*info*.nih.gov.

Due to the importance of appropriate use of these medications, retrospective DUR criteria can be used effectively to assist physicians in providing effective treatment to their patients. These criteria focus on several primary categories: noncompliance, appropriate monotherapy, and appropriate multi-drug therapy.

A listing of antiretroviral drugs is included below for reference.

Antiretroviral Drugs		
Sub-classification	***Generic Name***	***Brand Name***
Protease Inhibitors		
	saquinavir	Invirase®
	indinavir	Crixivan®
	tipranavir	Aptivus®
	darunavir	Prezista®
	nelfinavir	Viracept®
	fosamprenavir	Lexiva®
	amprenavir	Agenerase®
	atazanavir	Reyataz®
	ritonavir	Norvir®
Protease Inhibitor Combination		
	lopinavir/ritonavir	Kaletra®
Nucleotide Analog Reverse Transcriptase Inhibitor		
	tenofovir	Viread®
Nucleoside Reverse Transcriptase Inhibitors		
	didanosine (DDI)	Videx®, Videx EC®
	telbivudine	Tyzeka®
	lamivudine (3TC)	Epivir®, Epivir-HBV®
	stavudine (D4T)	Zerit®
	zidovudine (AZT)	Retrovir®
	abacavir	Ziagen®
	emtricitabine	Emtriva®
Nucleotide Analog Reverse Transcriptase Inhibitor Combinations		
	lamivudine/zidovudine	Combivir®

Sub-classification	***Generic Name***	***Brand Name***
	lamivudine/zidovudine/abacavir	Trizivir®
	emtricitabine/tenofovir	Truvada®
	abacavir/lamivudine	Epzicom®
Non-nucleoside Reverse Transcriptase Inhibitors		
	nevirapine	Viramune®
	delavirdine	Rescriptor®
	efavirenz	Sustiva®
Non-nucleoside Reverse Transcriptase Inhibitor/Nucleotide Analog Reverse Transcriptase Inhibitor Combination		
	efavirenz/emtricitabine/tenofovir	Atripla®
Fusion Inhibitor		
	enfuvirtide	Fuzeon®

The following excerpt summarizes changes that were made to the NIH treatment guidelines at the last update.

October 10, 2006

What's New in the Document?

The following changes have been made to the May 4, 2006 version of the guidelines:

What to Start Recommendations

- The Panel confirms that the regimens with the most experience in demonstrating virologic and immunologic efficacy are those composed of 1 NNRTI + 2 NRTI or of a PI (with or without ritonavir boosting) + 2 NRTI. The Panel also confirms that selection of an antiretroviral regimen should be individualized based on patient- and drug-specific factors.
- The Panel revised its recommendations for preferred and alternative antiretroviral components based on reported results from several randomized trials in treatment-naïve patients and on safety data that have emerged since the last revision. Specific recommendations can be found in Tables 6a and 6b. Rationale for the recommendations is outlined in the text.
- The revised recommendations for antiretroviral-naïve patients are summarized below. Clinicians are recommended to construct a regimen by choosing one component from Column A + one component from Column B.

	Column A		Column B
	NNRTI	PI	2-NRTI
Preferred (alphabetical order)	Efavirenz **(AII)**	Atazanavir + ritonavir **(AIII)** Fosamprenavir + ritonavir BID **(AII)** Lopinavir/ritonavir BID **(AII)**	Tenofovir/emtricitabine **(AII)** Zidovudine/lamivudine **(AII)**
Alternative (alphabetical order)	Nevirapine **(BII)**	Atazanavir (unboosted) **(BII)** Fosamprenavir (unboosted) **(BII)** Fosamprenavir + ritonavir once daily **(BII)** Lopinavir/ritonavir once daily **(BII)**	Abacavir/lamivudine **(BII)** Didanosine + lamivudine **(BII)**

- Several options are considered acceptable as initial components but, in the view of the Panel, are inferior to the preferred or alternative components; however, they may be preferred in selected settings. These options include nelfinavir, ritonavir-boosted saquinavir, stavudine + lamivudine, and a triple-NRTI regimen containing abacavir + zidovudine + lamivudine.

The following tables have been updated:

- Table 6 has been revised and divided into Tables 6a and 6b to reflect the above revisions.
- Tables 7 and 9 have been updated to reflect changes in the recommendations.
- Table 10 has been updated with results from several recently published clinical trials.
- Tables 11-13, 15, and 17-19 have been updated to include information regarding darunavir and the fixed-dose combination of efavirenz/emtricitabine/ tenofovir (Atripla™) and new safety information and black box warnings regarding rare cases of intracranial hemorrhages occurring in patients receiving tipranavir.
- Tables 20-22b have been updated to include darunavir drug-drug interactions.
- Tables 28 and 29 have been revised according to updates in the Perinatal Guidelines to incorporate preclinical and clinical data relevant to the use of darunavir during pregnancy and new recommendations on antiretroviral use during pregnancy.
- Table 30 has been updated to include information on expanded access programs for two investigational agents, TMC125 and MK-0518.

[TODAY]

[adrs1]
[adrs2]
[adrs3]
[adrs4]

DEAR [tadrs1]:

In compliance with the OBRA '90 federal legislation, state Medicaid agencies are mandated to institute Retrospective Drug Utilization Review Programs (RDUR). The program's goal is to ensure that Medicaid patients receive optimal drug therapy at the lowest reasonable cost. One way to achieve this goal is to identify potential drug therapy problems that may place patients at risk, particularly if multiple providers are identified. This RDUR program is informational in nature and allows you to incorporate the information provided into your continuing assessment of the patient's drug therapy requirements.

During a recent review of the enclosed drug history profile, *it was noted that your patient,* **[t1d0-recip-fst-nm] [t1d0-recip-lst-nm]**, *is receiving* **([drug_a_name]).** [alert_msg] In presenting this information to you, we recognize that management of each patient's drug therapy depends upon an assessment of the patient's entire clinical situation about which we are not fully aware.

The success of the DUR program is enhanced by effective two-way exchange of information. Therefore, at your convenience, we would appreciate learning of your assessment of this information and of any action taken in response to this notice. Although your participation in this program is voluntary, we find your feedback helpful in adjusting our program to address clinically important problems. Please use the enclosed response to note your comments and return it in the enclosed envelope or fax it to the number below.

At the bottom of this letter are the specific prescriptions attributed to you by the dispensing pharmacy. In addition, if multiple prescribers are involved in the therapy identified above, each will receive this information. Thank you for your professional consideration.

RX #(s): [rx_no_a]

Sincerely,

W. Murray Yarbrough M.D.

W. Murray Yarbrough, M.D.
Medical Director

Case#: [case_no]
Enclosures

PRESCRIBER RESPONSE

All information used to generate the enclosed letter, including Prescriber identification, was obtained from Pharmacy Claims Data. If there appears to be an error in the information provided, please note the discrepancy. Thank you for your cooperation.

1. This patient **is** under my care:

_____ I have reviewed the information and will continue without change.
_____ however, I did not prescribe the following medication(s)_____.
_____ and has an appointment to discuss drug therapy.
_____ however, has not seen me recently.
_____ however, I was not aware of other prescribers.
_____ I have reviewed the information and modified drug therapy.
_____ I have not modified drug therapy because benefits outweigh the risks.
_____ I have tried to modify therapy, however the patient refuses to change.
_____ I have tried to modify therapy, however symptoms reoccurred.

2. This patient **is not** under my care:

_____ however, I did prescribe medication while covering for other MD or in the ER.
_____ but has previously been a patient of mine.
_____ because the patient recently expired.
_____ and has never been under my care.

3. I have reviewed the enclosed information and found it:
_____ very useful_____ useful_____ neutral_____ somewhat useful_____ not useful.

4. Please check here if you wish to receive reference information on the identified problem___.(Please provide a fax number if available_____-_____-_____.)

Comments:
_____
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[adrs1] Case# [case_no]
Letter Type [letter_type]
[alert_msg]
[criteria]

MISSISSIPPI MEDICAID
RETROSPECTIVE DRUG UTILIZATION REVIEW
HIV CRITERIA RECOMMENDATIONS
MAY 2007

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

1. Saquinavir / Noncompliance **2833** _____ _____

Alert Message: A review of the patient's prescription refill history suggests that the patient may not be taking the drug in the manner it was prescribed. Nonadherence to antiretroviral therapy may result in insufficient plasma drug levels and partial suppression of viral load leading to the development of resistance, HIV progression, and increased mortality.
Conflict Code: LR – Underuse
Severity: Major
Drugs/Disease:
Util A Util B Util C
Saquinavir

References:
Hoffman C, Mulcahy F, Goals and Principles of Therapy, Eradication, Cost, Prevention and Adherence. In: Hoffman C, Rockstroh J, Kamps BS, eds. HIV Medicine, Flying Publishers-Paris, Cagliari, Wuppertal, Sevilla, 2005:167-173.
Cheever LW, Chapter V: Adherence to HIV Therapies. In: A guide to the Clinical Care of Women with HIV/AIDS, 2005 Edition, HIV/ADIS Bureau, US Department of Health and Human Services.
http://hab.hrsa.gov/publications/womencare05/WG05chap5.htm

2. Indinavir / Noncompliance **2834** _____ _____

Alert Message: A review of the patient's prescription refill history suggests that the patient may not be taking the drug in the manner it was prescribed. Nonadherence to antiretroviral therapy may result in insufficient plasma drug levels and partial suppression of viral load leading to the development of resistance, HIV progression and increased mortality.
Conflict Code: LR – Underuse
Severity: Major
Drugs/Disease:
Util A Util B Util C
Indinavir

References:
Hoffman C, Mulcahy F, Goals and Principles of Therapy, Eradication, Cost, Prevention and Adherence. In: Hoffman C, Rockstroh J, Kamps BS, eds. HIV Medicine, Flying Publishers-Paris, Cagliari, Wuppertal, Sevilla, 2005:167-173.
Cheever LW, Chapter V: Adherence to HIV Therapies. In: A guide to the Clinical Care of Women with HIV/AIDS, 2005 Edition, HIV/ADIS Bureau, US Department of Health and Human Services.
http://hab.hrsa.gov/publications/womencare05/WG05chap5.htm

3. Tipranavir / Noncompliance **2860** _____ _____

Alert Message: A review of the patient's prescription refill history suggests that the patient may not be taking the drug in the manner it was prescribed. Nonadherence to antiretroviral therapy may result in insufficient plasma drug levels and partial suppression of viral load leading to the development of resistance, HIV progression and increased mortality.
Conflict Code: LR – Underuse
Severity: Major
Drugs/Disease:
Util A Util B Util C
Tipranavir

References:
Hoffman C, Mulcahy F, Goals and Principles of Therapy, Eradication, Cost, Prevention and Adherence. In: Hoffman C, Rockstroh J, Kamps BS, eds. HIV Medicine, Flying Publishers-Paris, Cagliari, Wuppertal, Sevilla, 2005:167-173.
Cheever LW, Chapter V: Adherence to HIV Therapies. In: A guide to the Clinical Care of Women with HIV/AIDS, 2005 Edition, HIV/ADIS Bureau, US Department of Health and Human Services.
http://hab.hrsa.gov/publications/womencare05/WG05chap5.htm

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

4. Nelfinavir / Noncompliance **2835** _____ _____

Alert Message: A review of the patient's prescription refill history suggests that the patient may not be taking the drug in the manner it was prescribed. Nonadherence to antiretroviral therapy may result in insufficient plasma drug levels and partial suppression of viral load leading to the development of resistance, HIV progression and increased mortality.
Conflict Code: LR – Underuse
Severity: Major
Drugs/Disease:

Util A	Util B	Util C
Nelfinavir		

References:
Hoffman C, Mulcahy F, Goals and Principles of Therapy, Eradication, Cost, Prevention and Adherence. In: Hoffman C, Rockstroh J, Kamps BS, eds. HIV Medicine, Flying Publishers-Paris, Cagliari, Wuppertal, Sevilla, 2005:167-173.
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http://hab.hrsa.gov/publications/womencare05/WG05chap5.htm

5. Fosamprenavir / Noncompliance **2836** _____ _____

Alert Message: A review of the patient's prescription refill history suggests that the patient may not be taking the drug in the manner it was prescribed. Nonadherence to antiretroviral therapy may result in insufficient plasma drug levels and partial suppression of viral load leading to the development of resistance, HIV progression and increased mortality.
Conflict Code: LR – Underuse
Severity: Major
Drugs/Disease:

Util A	Util B	Util C
Fosamprenavir		

References:
Hoffman C, Mulcahy F, Goals and Principles of Therapy, Eradication, Cost, Prevention and Adherence. In: Hoffman C, Rockstroh J, Kamps BS, eds. HIV Medicine, Flying Publishers-Paris, Cagliari, Wuppertal, Sevilla, 2005:167-173.
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http://hab.hrsa.gov/publications/womencare05/WG05chap5.htm

6. Amprenavir / Noncompliance **2837** _____ _____

Alert Message: A review of the patient's prescription refill history suggests that the patient may not be taking the drug in the manner it was prescribed. Nonadherence to antiretroviral therapy may result in insufficient plasma drug levels and partial suppression of viral load leading to the development of resistance, HIV progression and increased mortality.
Conflict Code: LR – Underuse
Severity: Major
Drugs/Disease:

Util A	Util B	Util C
Amprenavir		

References:
Hoffman C, Mulcahy F, Goals and Principles of Therapy, Eradication, Cost, Prevention and Adherence. In: Hoffman C, Rockstroh J, Kamps BS, eds. HIV Medicine, Flying Publishers-Paris, Cagliari, Wuppertal, Sevilla, 2005:167-173.
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http://hab.hrsa.gov/publications/womencare05/WG05chap5.htm

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

7. Atazanavir / Noncompliance **2838** _____ _____

Alert Message: A review of the patient's prescription refill history suggests that the patient may not be taking the drug in the manner it was prescribed. Nonadherence to antiretroviral therapy may result in insufficient plasma drug levels and partial suppression of viral load leading to the development of resistance, HIV progression and increased mortality.
Conflict Code: LR – Underuse
Severity: Major
Drugs/Disease:

Util A	Util B	Util C
Atazanavir		

References:
Hoffman C, Mulcahy F, Goals and Principles of Therapy, Eradication, Cost, Prevention and Adherence. In: Hoffman C, Rockstroh J, Kamps BS, eds. HIV Medicine, Flying Publishers-Paris, Cagliari, Wuppertal, Sevilla, 2005:167-173.
Cheever LW, Chapter V: Adherence to HIV Therapies. In: A guide to the Clinical Care of Women with HIV/AIDS, 2005 Edition, HIV/ADIS Bureau, US Department of Health and Human Services.
http://hab.hrsa.gov/publications/womencare05/WG05chap5.htm

8. Ritonavir / Noncompliance **2839** _____ _____

Alert Message: A review of the patient's prescription refill history suggests that the patient may not be taking the drug in the manner it was prescribed. Nonadherence to antiretroviral therapy may result in insufficient plasma drug levels and partial suppression of viral load leading to the development of resistance, HIV progression and increased mortality.
Conflict Code: LR – Underuse
Severity: Major
Drugs/Disease:

Util A	Util B	Util C
Ritonavir		

References:
Hoffman C, Mulcahy F, Goals and Principles of Therapy, Eradication, Cost, Prevention and Adherence. In: Hoffman C, Rockstroh J, Kamps BS, eds. HIV Medicine, Flying Publishers-Paris, Cagliari, Wuppertal, Sevilla, 2005:167-173.
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http://hab.hrsa.gov/publications/womencare05/WG05chap5.htm

9. Tenofovir / Noncompliance **2841** _____ _____

Alert Message: A review of the patient's prescription refill history suggests that the patient may not be taking the drug in the manner it was prescribed. Nonadherence o antiretroviral therapy may result in insufficient plasma drug levels and partial suppression of viral load leading to the development of resistance, HIV progression and increased mortality.
Conflict Code: LR – Underuse
Severity: Major
Drugs/Disease:

Util A	Util B	Util C
Tenofovir		

References:
Hoffman C, Mulcahy F, Goals and Principles of Therapy, Eradication, Cost, Prevention and Adherence. In: Hoffman C, Rockstroh J, Kamps BS, eds. HIV Medicine, Flying Publishers-Paris, Cagliari, Wuppertal, Sevilla, 2005:167-173.
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http://hab.hrsa.gov/publications/womencare05/WG05chap5.htm

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

10. Didanosine / Noncompliance **2842** _____ _____

Alert Message: A review of the patient's prescription refill history suggests that the patient may not be taking the drug in the manner it was prescribed. Nonadherence to antiretroviral therapy may result in insufficient plasma drug levels and partial suppression of viral load leading to the development of resistance, HIV progression and increased mortality.
Conflict Code: LR – Underuse
Severity: Major
Drugs/Disease:

Util A	Util B	Util C
Didanosine		

References:
Hoffman C, Mulcahy F, Goals and Principles of Therapy, Eradication, Cost, Prevention and Adherence. In: Hoffman C, Rockstroh J, Kamps BS, eds. HIV Medicine, Flying Publishers-Paris, Cagliari, Wuppertal, Sevilla, 2005:167-173.
Cheever LW, Chapter V: Adherence to HIV Therapies. In: A guide to the Clinical Care of Women with HIV/AIDS, 2005 Edition, HIV/ADIS Bureau, US Department of Health and Human Services.
http://hab.hrsa.gov/publications/womencare05/WG05chap5.htm

11. Lamivudine / Noncompliance **2843** _____ _____

Alert Message: A review of the patient's prescription refill history suggests that the patient may not be taking the drug in the manner it was prescribed. Nonadherence to antiretroviral therapy may result in insufficient plasma drug levels and partial suppression of viral load leading to the development of resistance, HIV progression and increased mortality.
Conflict Code: LR – Underuse
Severity: Major
Drugs/Disease:

Util A	Util B	Util C
Lamivudine		

References:
Hoffman C, Mulcahy F, Goals and Principles of Therapy, Eradication, Cost, Prevention and Adherence. In: Hoffman C, Rockstroh J, Kamps BS, eds. HIV Medicine, Flying Publishers-Paris, Cagliari, Wuppertal, Sevilla, 2005:167-173.
Cheever LW, Chapter V: Adherence to HIV Therapies. In: A guide to the Clinical Care of Women with HIV/AIDS, 2005 Edition, HIV/ADIS Bureau, US Department of Health and Human Services.
http://hab.hrsa.gov/publications/womencare05/WG05chap5.htm

12. Stavudine / Noncompliance **2844** _____ _____

Alert Message: A review of the patient's prescription refill history suggests that the patient may not be taking the drug in the manner it was prescribed. Nonadherence to antiretroviral therapy may result in insufficient plasma drug levels and partial suppression of viral load leading to the development of resistance, HIV progression and increased mortality.
Conflict Code: LR – Underuse
Severity: Major
Drugs/Disease:

Util A	Util B	Util C
Stavudine		

References:
Hoffman C, Mulcahy F, Goals and Principles of Therapy, Eradication, Cost, Prevention and Adherence. In: Hoffman C, Rockstroh J, Kamps BS, eds. HIV Medicine, Flying Publishers-Paris, Cagliari, Wuppertal, Sevilla, 2005:167-173.
Cheever LW, Chapter V: Adherence to HIV Therapies. In: A guide to the Clinical Care of Women with HIV/AIDS, 2005 Edition, HIV/ADIS Bureau, US Department of Health and Human Services.
http://hab.hrsa.gov/publications/womencare05/WG05chap5.htm

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

13. Zalcitabine / Noncompliance **2857** _____ _____

Alert Message: A review of the patient's prescription refill history suggests that the patient may not be taking the drug in the manner it was prescribed. Nonadherence to antiretroviral therapy may result in insufficient plasma drug levels and partial suppression of viral load leading to the development of resistance, HIV progression and increased mortality.
Conflict Code: LR – Underuse
Severity: Major
Drugs/Disease:

Util A	Util B	Util C
Zalcitabine		

References:
Hoffman C, Mulcahy F, Goals and Principles of Therapy, Eradication, Cost, Prevention and Adherence. In: Hoffman C, Rockstroh J, Kamps BS, eds. HIV Medicine, Flying Publishers-Paris, Cagliari, Wuppertal, Sevilla, 2005:167-173.
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http://hab.hrsa.gov/publications/womencare05/WG05chap5.htm

14. Zidovudine / Noncompliance **2858** _____ _____

Alert Message: A review of the patient's prescription refill history suggests that the patient may not be taking the drug in the manner it was prescribed. Nonadherence to antiretroviral therapy may result in insufficient plasma drug levels and partial suppression of viral load leading to the development of resistance, HIV progression and increased mortality.
Conflict Code: LR – Underuse
Severity: Major
Drugs/Disease:

Util A	Util B	Util C
Zidovudine		

References:
Hoffman C, Mulcahy F, Goals and Principles of Therapy, Eradication, Cost, Prevention and Adherence. In: Hoffman C, Rockstroh J, Kamps BS, eds. HIV Medicine, Flying Publishers-Paris, Cagliari, Wuppertal, Sevilla, 2005:167-173.
Cheever LW, Chapter V: Adherence to HIV Therapies. In: A guide to the Clinical Care of Women with HIV/AIDS, 2005 Edition, HIV/ADIS Bureau, US Department of Health and Human Services.

15. Abacavir / Noncompliance **2859** _____ _____

Alert Message: A review of the patient's prescription refill history suggests that the patient may not be taking the drug in the manner it was prescribed. Nonadherence to antiretroviral therapy may result in insufficient plasma drug levels and partial suppression of viral load leading to the development of resistance, HIV progression and increased mortality.
Conflict Code: LR – Underuse
Severity: Major
Drugs/Disease:

Util A	Util B	Util C
Abacavir		

References:
Hoffman C, Mulcahy F, Goals and Principles of Therapy, Eradication, Cost, Prevention and Adherence. In: Hoffman C, Rockstroh J, Kamps BS, eds. HIV Medicine, Flying Publishers-Paris, Cagliari, Wuppertal, Sevilla, 2005:167-173.
Cheever LW, Chapter V: Adherence to HIV Therapies. In: A guide to the Clinical Care of Women with HIV/AIDS, 2005 Edition, HIV/ADIS Bureau, US Department of Health and Human Services.
http://hab.hrsa.gov/publications/womencare05/WG05chap5.htm

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

16. Emtricitabine / Noncompliance **2845** _____ _____

Alert Message: A review of the patient's prescription refill history suggests that the patient may not be taking the drug in the manner it was prescribed. Nonadherence to antiretroviral therapy may result in insufficient plasma drug levels and partial suppression of viral load leading to the development of resistance, HIV progression and increased mortality.
Conflict Code: LR – Underuse
Severity: Major
Drugs/Disease:

Util A	Util B	Util C
Emtricitabine		

References:
Hoffman C, Mulcahy F, Goals and Principles of Therapy, Eradication, Cost, Prevention and Adherence. In: Hoffman C, Rockstroh J, Kamps BS, eds. HIV Medicine, Flying Publishers-Paris, Cagliari, Wuppertal, Sevilla, 2005:167-173.
Cheever LW, Chapter V: Adherence to HIV Therapies. In: A guide to the Clinical Care of Women with HIV/AIDS, 2005 Edition, HIV/ADIS Bureau, US Department of Health and Human Services.
http://hab.hrsa.gov/publications/womencare05/WG05chap5.htm

17. Nevirapine / Noncompliance **2846** _____ _____

Alert Message: A review of the patient's prescription refill history suggests that the patient may not be taking the drug in the manner it was prescribed. Nonadherence to antiretroviral therapy may result in insufficient plasma drug levels and partial suppression of viral load leading to the development of resistance, HIV progression and increased mortality.
Conflict Code: LR – Underuse
Severity: Major
Drugs/Disease:

Util A	Util B	Util C
Nevirapine		

References:
Hoffman C, Mulcahy F, Goals and Principles of Therapy, Eradication, Cost, Prevention and Adherence. In: Hoffman C, Rockstroh J, Kamps BS, eds. HIV Medicine, Flying Publishers-Paris, Cagliari, Wuppertal, Sevilla, 2005:167-173.
Cheever LW, Chapter V: Adherence to HIV Therapies. In: A guide to the Clinical Care of Women with HIV/AIDS, 2005 Edition, HIV/ADIS Bureau, US Department of Health and Human Services.
http://hab.hrsa.gov/publications/womencare05/WG05chap5.htm

18. Delavirdine / Noncompliance **2847** _____ _____

Alert Message: A review of the patient's prescription refill history suggests that the patient may not be taking the drug in the manner it was prescribed. Nonadherence to antiretroviral therapy may result in insufficient plasma drug levels and partial suppression of viral load leading to the development of resistance, HIV progression and increased mortality.
Conflict Code: LR – Underuse
Severity: Major
Drugs/Disease:

Util A	Util B	Util C
Delavirdine		

References:
Hoffman C, Mulcahy F, Goals and Principles of Therapy, Eradication, Cost, Prevention and Adherence. In: Hoffman C, Rockstroh J, Kamps BS, eds. HIV Medicine, Flying Publishers-Paris, Cagliari, Wuppertal, Sevilla, 2005:167-173.
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http://hab.hrsa.gov/publications/womencare05/WG05chap5.htm

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

19. Efavirenz / Noncompliance **2848** _____ _____

Alert Message: A review of the patient's prescription refill history suggests that the patient may not be taking the drug in the manner it was prescribed. Nonadherence to antiretroviral therapy may result in insufficient plasma drug levels and partial suppression of viral load leading to the development of resistance, HIV progression and increased mortality.
Conflict Code: LR – Underuse
Severity: Major
Drugs/Disease:

Util A	Util B	Util C
Efavirenz		

References:
Hoffman C, Mulcahy F, Goals and Principles of Therapy, Eradication, Cost, Prevention and Adherence. In: Hoffman C, Rockstroh J, Kamps BS, eds. HIV Medicine, Flying Publishers-Paris, Cagliari, Wuppertal, Sevilla, 2005:167-173.
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http://hab.hrsa.gov/publications/womencare05/WG05chap5.htm

20. Enfuvirtide / Noncompliance **2849** _____ _____

Alert Message: A review of the patient's prescription refill history suggests that the patient may not be taking the drug in the manner it was prescribed. Nonadherence to antiretroviral therapy may result in insufficient plasma drug levels and partial suppression of viral load leading to the development of resistance, HIV progression and increased mortality.
Conflict Code: LR – Underuse
Severity: Major
Drugs/Disease:

Util A	Util B	Util C
Enfuvirtide		

References:
Hoffman C, Mulcahy F, Goals and Principles of Therapy, Eradication, Cost, Prevention and Adherence. In: Hoffman C, Rockstroh J, Kamps BS, eds. HIV Medicine, Flying Publishers-Paris, Cagliari, Wuppertal, Sevilla, 2005:167-173.
Cheever LW, Chapter V: Adherence to HIV Therapies. In: A guide to the Clinical Care of Women with HIV/AIDS, 2005 Edition, HIV/ADIS Bureau, US Department of Health and Human Services.
http://hab.hrsa.gov/publications/womencare05/WG05chap5.htm

21. Darunavir / Noncompliance **2850** _____ _____

Alert Message: A review of the patient's prescription refill history suggests that the patient may not be taking the drug in the manner it was prescribed. Nonadherence to antiretroviral therapy may result in insufficient plasma drug levels and partial suppression of viral load leading to the development of resistance, HIV progression and increased mortality.
Conflict Code: LR – Underuse
Severity: Major
Drugs/Disease:

Util A	Util B	Util C
Darunavir		

References:
Hoffman C, Mulcahy F, Goals and Principles of Therapy, Eradication, Cost, Prevention and Adherence. In: Hoffman C, Rockstroh J, Kamps BS, eds. HIV Medicine, Flying Publishers-Paris, Cagliari, Wuppertal, Sevilla, 2005:167-173.
Cheever LW, Chapter V: Adherence to HIV Therapies. In: A guide to the Clinical Care of Women with HIV/AIDS, 2005 Edition, HIV/ADIS Bureau, US Department of Health and Human Services.
http://hab.hrsa.gov/publications/womencare05/WG05chap5.htm

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

22. Combivir / Noncompliance **2851** _____ _____

Alert Message: A review of the patient's prescription refill history suggests that the patient may not be taking the drug in the manner it was prescribed. Nonadherence to antiretroviral therapy may result in insufficient plasma drug levels and partial suppression of viral load leading to the development of resistance, HIV progression and increased mortality.
Conflict Code: LR – Underuse
Severity: Major
Drugs/Disease:

Util A	Util B	Util C
Combivir		

References:
Hoffman C, Mulcahy F, Goals and Principles of Therapy, Eradication, Cost, Prevention and Adherence. In: Hoffman C, Rockstroh J, Kamps BS, eds. HIV Medicine, Flying Publishers-Paris, Cagliari, Wuppertal, Sevilla, 2005:167-173.
Cheever LW, Chapter V: Adherence to HIV Therapies. In: A guide to the Clinical Care of Women with HIV/AIDS, 2005 Edition, HIV/ADIS Bureau, US Department of Health and Human Services.
http://hab.hrsa.gov/publications/womencare05/WG05chap5.htm

23. Truvada / Noncompliance **2852** _____ _____

Alert Message: A review of the patient's prescription refill history suggests that the patient may not be taking the drug in the manner it was prescribed. Nonadherence to antiretroviral therapy may result in insufficient plasma drug levels and partial suppression of viral load leading to the development of resistance, HIV progression and increased mortality.
Conflict Code: LR – Underuse
Severity: Major
Drugs/Disease:

Util A	Util B	Util C
Truvada		

References:
Hoffman C, Mulcahy F, Goals and Principles of Therapy, Eradication, Cost, Prevention and Adherence. In: Hoffman C, Rockstroh J, Kamps BS, eds. HIV Medicine, Flying Publishers-Paris, Cagliari, Wuppertal, Sevilla, 2005:167-173.
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http://hab.hrsa.gov/publications/womencare05/WG05chap5.htm

24. Trizivir / Noncompliance **2853** _____ _____

Alert Message: A review of the patient's prescription refill history suggests that the patient may not be taking the drug in the manner it was prescribed. Nonadherence to antiretroviral therapy may result in insufficient plasma drug levels and partial suppression of viral load leading to the development of resistance, HIV progression and increased mortality.
Conflict Code: LR – Underuse
Severity: Major
Drugs/Disease:

Util A	Util B	Util C
Trizivir		

References:
Hoffman C, Mulcahy F, Goals and Principles of Therapy, Eradication, Cost, Prevention and Adherence. In: Hoffman C, Rockstroh J, Kamps BS, eds. HIV Medicine, Flying Publishers-Paris, Cagliari, Wuppertal, Sevilla, 2005:167-173.
Cheever LW, Chapter V: Adherence to HIV Therapies. In: A guide to the Clinical Care of Women with HIV/AIDS, 2005 Edition, HIV/ADIS Bureau, US Department of Health and Human Services.
http://hab.hrsa.gov/publications/womencare05/WG05chap5.htm

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

25. Epzicom / Noncompliance **2854** _____ _____

Alert Message: A review of the patient's prescription refill history suggests that the patient may not be taking the drug in the manner it was prescribed. Nonadherence to antiretroviral therapy may result in insufficient plasma drug levels and partial suppression of viral load leading to the development of resistance, HIV progression and increased mortality.
Conflict Code: LR – Underuse
Severity: Major
Drugs/Disease:

Util A	Util B	Util C
Trizivir		

References:
Hoffman C, Mulcahy F, Goals and Principles of Therapy, Eradication, Cost, Prevention and Adherence. In: Hoffman C, Rockstroh J, Kamps BS, eds. HIV Medicine, Flying Publishers-Paris, Cagliari, Wuppertal, Sevilla, 2005:167-173.
Cheever LW, Chapter V: Adherence to HIV Therapies. In: A guide to the Clinical Care of Women with HIV/AIDS, 2005 Edition, HIV/ADIS Bureau, US Department of Health and Human Services.
http://hab.hrsa.gov/publications/womencare05/WG05chap5.htm

26. Atripla / Noncompliance _____ _____

Alert Message: A review of the patient's prescription refill history suggests that the patient may not be taking the drug in the manner it was prescribed. Nonadherence to antiretroviral therapy may result in insufficient plasma drug levels and partial suppression of viral load leading to the development of resistance, HIV progression and increased mortality.
Conflict Code: LR – Underuse
Severity: Major
Drugs/Disease:

Util A	Util B	Util C
Atripla		

References:
Hoffman C, Mulcahy F, Goals and Principles of Therapy, Eradication, Cost, Prevention and Adherence. In: Hoffman C, Rockstroh J, Kamps BS, eds. HIV Medicine, Flying Publishers-Paris, Cagliari, Wuppertal, Sevilla, 2005:167-173.
Cheever LW, Chapter V: Adherence to HIV Therapies. In: A guide to the Clinical Care of Women with HIV/AIDS, 2005 Edition, HIV/ADIS Bureau, US Department of Health and Human Services.
http://hab.hrsa.gov/publications/womencare05/WG05chap5.htm

27. Saquinavir / Monotherapy **2902** _____ _____

Alert Message: Monotherapy with a protease inhibitor is not recommended in HIV-1 patients at any time. Monotherapy does not demonstrate potent and sustained antiretroviral activity when compared to combination therapy with three or more antiretrovirals. The rare exception, though controversial, is the use of zidovudine monotherapy to women who do not meet clinical immunologic, or virologic criteria for standard antiretroviral therapy.
Conflict Code: TA - Therapeutic Appropriateness
Drug/Disease:

Util A	Util B	Util C (Negating)
Saquinavir		All other Antiretrovirals

References:
Guidelines for the Use of Antiretroviral Agents in HIV-1-Infected Adults and Adolescents. Developed by the DHHS Panel on Antiretroviral Guidelines for Adults and Adolescents - A Working Group of the Office of AIDS Research Advisory Council (OARAC). May 4, 2006.

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

28. Indinavir / Monotherapy **2903** _____ _____

Alert Message: Monotherapy with a protease inhibitor is not recommended in HIV-1 patients at any time. Monotherapy does not demonstrate potent and sustained antiretroviral activity when compared to combination therapy with three or more antiretrovirals. The rare exception, though controversial, is the use of zidovudine monotherapy to women who do not meet clinical immunologic, or virologic criteria for standard antiretroviral therapy.
Conflict Code: TA -Therapeutic Appropriateness
Drug/Disease:

Util A	Util B	Util C (Negating)
Indinavir		All other Antiretrovirals

References:
Guidelines for the Use of Antiretroviral Agents in HIV-1-Infected Adults and Adolescents. Developed by the DHHS Panel on Antiretroviral Guidelines for Adults and Adolescents - A Working Group of the Office of AIDS Research Advisory Council (OARAC). May 4, 2006.

29. Tipranavir / Monotherapy **2911** _____ _____

Alert Message: Monotherapy with a protease inhibitor is not recommended in HIV-1 patients at any time. Monotherapy does not demonstrate potent and sustained antiretroviral activity when compared to combination therapy with three or more antiretrovirals. The rare exception, though controversial, is the use of zidovudine monotherapy to women who do not meet clinical immunologic, or virologic criteria for standard antiretroviral therapy.
Conflict Code: TA - Therapeutic Appropriateness
Drug/Disease:

Util A	Util B	Util C (Negating)
Tipranavir		All other Antiretrovirals

References:
Guidelines for the Use of Antiretroviral Agents in HIV-1-Infected Adults and Adolescents. Developed by the DHHS Panel on Antiretroviral Guidelines for Adults and Adolescents - A Working Group of the Office of AIDS Research Advisory Council (OARAC). May 4, 2006.

30. Darunavir / Monotherapy **2910** _____ _____

Alert Message: Monotherapy with a protease inhibitor is not recommended in HIV-1 patients at any time. Monotherapy does not demonstrate potent and sustained antiretroviral activity when compared to combination therapy with three or more antiretrovirals. The rare exception, though controversial, is the use of zidovudine monotherapy to women who do not meet clinical immunologic, or virologic criteria for standard antiretroviral therapy.
Conflict Code: TA - Therapeutic Appropriateness
Drug/Disease:

Util A	Util B	Util C (Negating)
Darunavir		All other Antiretrovirals

References:
Guidelines for the Use of Antiretroviral Agents in HIV-1-Infected Adults and Adolescents. Developed by the DHHS Panel on Antiretroviral Guidelines for Adults and Adolescents - A Working Group of the Office of AIDS Research Advisory Council (OARAC). May 4, 2006.

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

31. Nelfinavir / Monotherapy **2904** _____ _____

Alert Message: Monotherapy with a protease inhibitor is not recommended in HIV-1 patients at any time. Monotherapy does not demonstrate potent and sustained antiretroviral activity when compared to combination therapy with three or more antiretrovirals. The rare exception, though controversial, is the use of zidovudine monotherapy to women who do not meet clinical immunologic, or virologic criteria for standard antiretroviral therapy.
Conflict Code: TA - Therapeutic Appropriateness
Drug/Disease:

Util A	Util B	Util C (Negating)
Nelfinavir		All other Antiretrovirals

References:
Guidelines for the Use of Antiretroviral Agents in HIV-1-Infected Adults and Adolescents. Developed by the DHHS Panel on Antiretroviral Guidelines for Adults and Adolescents - A Working Group of the Office of AIDS Research Advisory Council (OARAC). May 4, 2006.

32. Fosamprenavir / Monotherapy **2905** _____ _____

Alert Message: Monotherapy with a protease inhibitor is not recommended in HIV-1 patients at any time. Monotherapy does not demonstrate potent and sustained antiretroviral activity when compared to combination therapy with three or more antiretrovirals. The rare exception, though controversial, is the use of zidovudine monotherapy to women who do not meet clinical immunologic, or virologic criteria for standard antiretroviral therapy.
Conflict Code: TA - Therapeutic Appropriateness
Drug/Disease:

Util A	Util B	Util C (Negating)
Fosamprenavir		All other Antiretrovirals

References:
Guidelines for the Use of Antiretroviral Agents in HIV-1-Infected Adults and Adolescents. Developed by the DHHS Panel on Antiretroviral Guidelines for Adults and Adolescents - A Working Group of the Office of AIDS Research Advisory Council (OARAC). May 4, 2006.

33. Amprenavir / Monotherapy **2906** _____ _____

Alert Message: Monotherapy with a protease inhibitor is not recommended in HIV-1 patients at any time. Monotherapy does not demonstrate potent and sustained antiretroviral activity when compared to combination therapy with three or more antiretrovirals. The rare exception, though controversial, is the use of zidovudine monotherapy to women who do not meet clinical immunologic, or virologic criteria for standard antiretroviral therapy.
Conflict Code: TA -Therapeutic Appropriateness
Drug/Disease:

Util A	Util B	Util C (Negating)
Amprenavir		All other Antiretrovirals

References:
Guidelines for the Use of Antiretroviral Agents in HIV-1-Infected Adults and Adolescents. Developed by the DHHS Panel on Antiretroviral Guidelines for Adults and Adolescents - A Working Group of the Office of AIDS Research Advisory Council (OARAC). May 4, 2006.

34. Atazanavir / Monotherapy **2907** _____ _____

Alert Message: Monotherapy with a protease inhibitor is not recommended in HIV-1 patients at any time. Monotherapy does not demonstrate potent and sustained antiretroviral activity when compared to combination therapy with three or more antiretrovirals. The rare exception, though controversial, is the use of zidovudine monotherapy to women who do not meet clinical immunologic, or virologic criteria for standard antiretroviral therapy.
Conflict Code: TA - Therapeutic Appropriateness
Drug/Disease:

Util A	Util B	Util C (Negating)
Atazanavir		All other Antiretrovirals

References:
Guidelines for the Use of Antiretroviral Agents in HIV-1-Infected Adults and Adolescents. Developed by the DHHS Panel on Antiretroviral Guidelines for Adults and Adolescents - A Working Group of the Office of AIDS Research Advisory Council (OARAC). May 4, 2006.

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

35. Ritonavir / Monotherapy **2908** _____ _____

Alert Message: Monotherapy with a protease inhibitor is not recommended in HIV-1 patients at any time. Monotherapy does not demonstrate potent and sustained antiretroviral activity when compared to combination therapy with three or more antiretrovirals. The rare exception, though controversial, is the use of zidovudine monotherapy to women who do not meet clinical immunologic, or virologic criteria for standard antiretroviral therapy.
Conflict Code: TA - Therapeutic Appropriateness
Drug/Disease:

Util A	Util B	Util C (Negating)
Ritonavir		All other Antiretrovirals

References:
Guidelines for the Use of Antiretroviral Agents in HIV-1-Infected Adults and Adolescents. Developed by the DHHS Panel on Antiretroviral Guidelines for Adults and Adolescents - A Working Group of the Office of AIDS Research Advisory Council (OARAC). May 4, 2006.

36. Kaletra / Monotherapy **2909** _____ _____

Alert Message: Kaletra (lopinavir/ritonavir) is FDA approved to be used in combination with other antiretroviral agents for the treatment of HIV infection. There is insufficient data to recommend dual protease only therapy.
Conflict Code: TA - Therapeutic Appropriateness
Drug/Disease:

Util A	Util B	Util C (Negating)
Lopinavir/ritonavir		All other Antiretrovirals

References:
Guidelines for the Use of Antiretroviral Agents in HIV-1-Infected Adults and Adolescents. Developed by the DHHS Panel on Antiretroviral Guidelines for Adults and Adolescents - A Working Group of the Office of AIDS Research Advisory Council (OARAC). May 4, 2006.
Facts & Comparisons, 2006 Updates.

37. Tenofovir / Monotherapy **2861** _____ _____

Alert Message: Monotherapy with a NRTI is not recommended in HIV-1 infected patients at any time. Monotherapy does not demonstrate potent and sustained antiviral activity when compared to combination therapy with three or more antiretrovirals. The rare exception, though controversial, is the use of zidovudine monotherapy to prevent perinatal HIV-1 transmission in women who do not meet clinical immunologic, or virologic criteria for standard antiretroviral therapy.
Conflict Code: TA - Therapeutic Appropriateness
Drug/Disease:

Util A	Util B	Util C (Negating)
Tenofovir		All other Antiretrovirals

References:
Guidelines for the Use of Antiretroviral Agents in HIV-1-Infected Adults and Adolescents. Developed by the DHHS Panel on Antiretroviral Guidelines for Adults and Adolescents - A Working Group of the Office of AIDS Research Advisory Council (OARAC). May 4, 2006.
Facts & Comparisons, 2006 Updates.

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

38. Didanosine / Monotherapy **2862** _____ _____

Alert Message: Monotherapy with a NRTI is not recommended in HIV-1 infected patients at any time. Monotherapy does not demonstrate potent and sustained antiviral activity when compared to combination therapy with three or more antiretrovirals. The rare exception, though controversial, is the use of zidovudine monotherapy to prevent perinatal HIV-1 transmission in women who do not meet clinical immunologic, or virologic criteria for standard antiretroviral therapy.
Conflict Code: TA - Therapeutic Appropriateness
Drug/Disease:

Util A	Util B	Util C (Negating)
Didanosine		All other Antiretrovirals

References:
Guidelines for the Use of Antiretroviral Agents in HIV-1-Infected Adults and Adolescents. Developed by the DHHS Panel on Antiretroviral Guidelines for Adults and Adolescents - A Working Group of the Office of AIDS Research Advisory Council (OARAC). May 4, 2006.

39. Lamivudine (Single Entity) / Monotherapy **2863** _____ _____

Alert Message: Monotherapy with a NRTI is not recommended in HIV-1 infected patients at any time. Monotherapy does not demonstrate potent and sustained antiviral activity when compared to combination therapy with three or more antiretrovirals. The rare exception, though controversial, is the use of zidovudine monotherapy to prevent perinatal HIV-1 transmission in women who do not meet clinical immunologic, or virologic criteria for standard antiretroviral therapy.
Conflict Code: TA - Therapeutic Appropriateness
Drug/Disease:

Util A	Util B	Util C (Negating)
Lamivudine		All other Antiretrovirals

References:
Guidelines for the Use of Antiretroviral Agents in HIV-1-Infected Adults and Adolescents. Developed by the DHHS Panel on Antiretroviral Guidelines for Adults and Adolescents - A Working Group of the Office of AIDS Research Advisory Council (OARAC). May 4, 2006.

40. Stavudine (Single Entity) / Monotherapy **2864** _____ _____

Alert Message: Monotherapy with a NRTI is not recommended in HIV-1 infected patients at any time. Monotherapy does not demonstrate potent and sustained antiviral activity when compared to combination therapy with three or more antiretrovirals. The rare exception, though controversial, is the use of zidovudine monotherapy to prevent perinatal HIV-1 transmission in women who do not meet clinical immunologic, or virologic criteria for standard antiretroviral therapy.
Conflict Code: TA - Therapeutic Appropriateness
Drug/Disease:

Util A	Util B	Util C (Negating)
Stavudine		All other Antiretrovirals

References:
Guidelines for the Use of Antiretroviral Agents in HIV-1-Infected Adults and Adolescents. Developed by the DHHS Panel on Antiretroviral Guidelines for Adults and Adolescents - A Working Group of the Office of AIDS Research Advisory Council (OARAC). May 4, 2006.

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

41. Zalcitabine / Monotherapy **2865** _____ _____

Alert Message: Monotherapy with a NRTI is not recommended in HIV-1 infected patients at any time. Monotherapy does not demonstrate potent and sustained antiviral activity when compared to combination therapy with three or more antiretrovirals. The rare exception, though controversial, is the use of zidovudine monotherapy to prevent perinatal HIV-1 transmission in women who do not meet clinical immunologic, or virologic criteria for standard antiretroviral therapy.
Conflict Code: TA - Therapeutic Appropriateness
Drug/Disease:

Util A	Util B	Util C (Negating)
Zalcitabine		All other Antiretrovirals

References:
Guidelines for the Use of Antiretroviral Agents in HIV-1-Infected Adults and Adolescents. Developed by the DHHS Panel on Antiretroviral Guidelines for Adults and Adolescents - A Working Group of the Office of AIDS Research Advisory Council (OARAC). May 4, 2006.

42. Zidovudine (Single Entity) / Monotherapy **2866** _____ _____

Alert Message: Monotherapy with a NRTI is not recommended in HIV-1 infected patients at any time. Monotherapy does not demonstrate potent and sustained antiviral activity when compared to combination therapy with three or more antiretrovirals. The rare exception, though controversial, is the use of zidovudine monotherapy to prevent perinatal HIV-1 transmission in women who do not meet clinical immunologic, or virologic criteria for standard antiretroviral therapy.
Conflict Code: TA - Therapeutic Appropriateness
Drug/Disease:

Util A	Util B	Util C (Negating)
Zidovudine		All other Antiretrovirals

References:
Guidelines for the Use of Antiretroviral Agents in HIV-1-Infected Adults and Adolescents. Developed by the DHHS Panel on Antiretroviral Guidelines for Adults and Adolescents - A Working Group of the Office of AIDS Research Advisory Council (OARAC). May 4, 2006.

43. Abacavir (Single Entity) / Monotherapy **2867** _____ _____

Alert Message: Monotherapy with a NRTI is not recommended in HIV-1 infected patients at any time. Monotherapy does not demonstrate potent and sustained antiviral activity when compared to combination therapy with three or more antiretrovirals. The rare exception, though controversial, is the use of zidovudine monotherapy to prevent perinatal HIV-1 transmission in women who do not meet clinical immunologic, or virologic criteria for standard antiretroviral therapy.
Conflict Code: TA - Therapeutic Appropriateness
Drug/Disease:

Util A	Util B	Util C (Negating)
Abacavir		All other Antiretrovirals

References:
Guidelines for the Use of Antiretroviral Agents in HIV-1-Infected Adults and Adolescents. Developed by the DHHS Panel on Antiretroviral Guidelines for Adults and Adolescents - A Working Group of the Office of AIDS Research Advisory Council (OARAC). May 4, 2006.

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

44. Emtricitabine (Single Entity)/ Monotherapy **2868** _____ _____

Alert Message: Monotherapy with a NRTI is not recommended in HIV-1 infected patients at any time. Monotherapy does not demonstrate potent and sustained antiviral activity when compared to combination therapy with three or more antiretrovirals. The rare exception, though controversial, is the use of zidovudine monotherapy to prevent perinatal HIV-1 transmission in women who do not meet clinical immunologic, or virologic criteria for standard antiretroviral therapy.
Conflict Code: TA - Therapeutic Appropriateness
Drug/Disease:

Util A	Util B	Util C (Negating)
Emtricitabine		All other Antiretrovirals

References:
Guidelines for the Use of Antiretroviral Agents in HIV-1-Infected Adults and Adolescents. Developed by the DHHS Panel on Antiretroviral Guidelines for Adults and Adolescents - A Working Group of the Office of AIDS Research Advisory Council (OARAC). May 4, 2006.

45. Nevirapine / Monotherapy **2871** _____ _____

Alert Message: Monotherapy with a NNRTI is not recommended in HIV-1-infected patients at any time. Monotherapy does not demonstrate potent and sustained antiviral activity when compared to combination therapy with three or more antiretrovirals. The rare exception, though controversial, is the use of zidovudine monotherapy to prevent perinatal HIV-1 transmission in women who do not meet immunologic or virologic criteria for standard antiretroviral therapy.
Conflict Code: TA - Therapeutic Appropriateness
Drug/Disease:

Util A	Util B	Util C (Negating)
Nevirapine		All other Antiretrovirals

References:
Guidelines for the Use of Antiretroviral Agents in HIV-1-Infected Adults and Adolescents. Developed by the DHHS Panel on Antiretroviral Guidelines for Adults and Adolescents - A Working Group of the Office of AIDS Research Advisory Council (OARAC). May 4, 2006.

46. Delavirdine / Monotherapy **2869** _____ _____

Alert Message: Monotherapy with a NNRTI is not recommended in HIV-1-infected patients at any time. Monotherapy does not demonstrate potent and sustained antiviral activity when compared to combination therapy with three or more antiretrovirals. The rare exception, though controversial, is the use of zidovudine monotherapy to prevent perinatal HIV-1 transmission in women who do not meet immunologic or virologic criteria for standard antiretroviral therapy.
Conflict Code: TA - Therapeutic Appropriateness
Drug/Disease:

Util A	Util B	Util C (Negating)
Delavirdine		All other Antiretrovirals

References:
Guidelines for the Use of Antiretroviral Agents in HIV-1-Infected Adults and Adolescents. Developed by the DHHS Panel on Antiretroviral Guidelines for Adults and Adolescents - A Working Group of the Office of AIDS Research Advisory Council (OARAC). May 4, 2006.

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

47. Efavirenz / Monotherapy **2870** _____ _____

Alert Message: Monotherapy with a NNRTI is not recommended in HIV-1-infected patients at any time. Monotherapy does not demonstrate potent and sustained antiviral activity when compared to combination therapy with three or more antiretrovirals. The rare exception, though controversial, is the use of zidovudine monotherapy to prevent perinatal HIV-1 transmission in women who do not meet immunologic or virologic criteria for standard antiretroviral therapy.
Conflict Code: TA - Therapeutic Appropriateness
Drug/Disease:

Util A	Util B	Util C (Negating)
Efavirenz		All other Antiretrovirals

References:
Guidelines for the Use of Antiretroviral Agents in HIV-1-Infected Adults and Adolescents. Developed by the DHHS Panel on Antiretroviral Guidelines for Adults and Adolescents - A Working Group of the Office of AIDS Research Advisory Council (OARAC). May 4, 2006.

48. Enfuvirtide / Monotherapy **2901** _____ _____

Alert Message: Single agent antiretroviral therapy is not recommended in HIV-1-infected patients at any time. Monotherapy does not demonstrate potent and sustained antiretroviral activity when compared to combination therapy with three or more antiretrovirals. The rare exception, though controversial, is the use of zidovudine monotherapy to prevent perinatal HIV-1 transmission in women who do not meet clinical immunologic, or virologic criteria for standard antiretroviral therapy.
Conflict Code: TA - Therapeutic Appropriateness
Drug/Disease:

Util A	Util B	Util C (Negating)
Enfuvirtide		All other Antiretrovirals

References:
Guidelines for the Use of Antiretroviral Agents in HIV-1-Infected Adults and Adolescents. Developed by the DHHS Panel on Antiretroviral Guidelines for Adults and Adolescents - A Working Group of the Office of AIDS Research Advisory Council (OARAC). May 4, 2006.

49. Lamivudine + Zidovudine / Therapeutic Appropriateness **2872** _____ _____

Alert Message: Dual nucleoside reverse transcriptase inhibitor (NRTI) regimens are not recommended as antiretroviral therapy for HIV-1 patients because they have not demonstrated potent and sustained antiretroviral activity as compared to three-drug combination regimens.
Conflict Code: TA - Therapeutic Appropriateness
Drug/Disease:

Util A	Util B	Util C (Negating)
Lamivudine/Zidovudine		All other Antiretrovirals

References:
Guidelines for the Use of Antiretroviral Agents in HIV-1-Infected Adults and Adolescents. Developed by the DHHS Panel on Antiretroviral Guidelines for Adults and Adolescents - A Working Group of the Office of AIDS Research Advisory Council (OARAC). May 4, 2006.

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

50. Abacavir + Lamivudine / Therapeutic Appropriateness 2873 _____ _____

Alert Message: Dual nucleoside reverse transcriptase inhibitor (NRTI) regimens are not recommended as antiretroviral therapy for HIV-1 patients because they have not demonstrated potent and sustained antiretroviral activity as compared to three-drug combination regimens.
Conflict Code: TA - Therapeutic Appropriateness
Drug/Disease:

Util A	Util B	Util C (Negating)
Abacavir/Lamivudine		All other Antiretrovirals

References:
Guidelines for the Use of Antiretroviral Agents in HIV-1-Infected Adults and Adolescents. Developed by the DHHS Panel on Antiretroviral Guidelines for Adults and Adolescents - A Working Group of the Office of AIDS Research Advisory Council (OARAC). May 4, 2006.

51. Emtricitabine + Tenofovir /Therapeutic Appropriateness 2874 _____ _____

Alert Message: Dual nucleoside reverse transcriptase inhibitor (NRTI) regimens are not recommended as antiretroviral therapy for HIV-1 patients because they have not demonstrated potent and sustained antiretroviral activity as compared to three-drug combination regimens.
Conflict Code: TA - Therapeutic Appropriateness
Drug/Disease:

Util A	Util B	Util C (Negating)
Emtricitabine/Tenofovir		All other Antiretrovirals

References:
Guidelines for the Use of Antiretroviral Agents in HIV-1-Infected Adults and Adolescents. Developed by the DHHS Panel on Antiretroviral Guidelines for Adults and Adolescents - A Working Group of the Office of AIDS Research Advisory Council (OARAC). May 4, 2006.

52. Saquinavir Mesylate / / Ritonavir (Negating) 2875 _____ _____

Alert Message: Saquinavir mesylate (Invirase) should only be used in combination with ritonavir, which significantly inhibits saquinavir's metabolism to provide acceptable saquinavir plasma levels.
Conflict Code: TA - Therapeutic Appropriateness
Drugs/Disease:

Util A	Util B	Util C (Negating)
Saquinavir Mesylate		Ritonavir

References:
Facts & Comparisons, 2006 Updates.
Invirase Prescribing Information, Sept 2005, Roche Laboratories, Inc.

53. Tipranavir / / Ritonavir (Negating) 2876 _____ _____

Alert message: Aptivus (tipranavir) must be coadministered with ritonavir 200 mg to exert its therapeutic effect. Failure to co-administer tipranavir with ritonavir will result in insufficient plasma levels of tipranavir to achieve the desired antiviral effect and will alter some drug interactions (effect of tipranavir and ritonavir on other drugs).
Conflict Code: TA - Therapeutic Appropriateness
Drugs/Disease:

Util A	Util B	Util C (Negating)
Tipranavir		Ritonavir

References:
Facts & Comparisons, 2006 Updates.
Aptivus Prescribing Information, June 2006, Boehringer Ingelheim Pharmaceuticals, Inc.

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

54. Trizivir // Antiretrovirals except Trizivir (Negating) **2877** _____ _____

Alert Message: Trizivir (abacavir/lamivudine/zidovudine) should not but the sole antiretroviral product used in the treatment of HIV-1 patients unless the preferred or an alternative NNRTI-based or PI-based regimen cannot be used because of concerns of toxicities, drug interactions or regimen complexity.
Conflict Code: TA - Therapeutic Appropriateness
Drugs/Disease:

Util A	Util B	Util C (Negating)
Trizivir		All Other antiretrovirals

References:
Guidelines for the Use of Antiretroviral Agents in HIV-1-Infected Adults and Adolescents. Developed by the DHHS Panel on Antiretroviral Guidelines for Adults and Adolescents - A Working Group of the Office of AIDS Research Advisory Council (OARAC). May 4, 2006.

55. Triple NRTI Therapy / Therapeutic Appropriateness **2912** _____ _____

Alert Message: The use of triple-NRTI therapy (except for abacavir/zidovudine/lamivudine or possible zidovudine/lamivudine + tenofovir) should not be used at any time. A high rate of early virologic non-response has been seen with triple-NRTI combinations involving abacavir/tenofovir/lamivudine or tenofovir/didanosine/lamivudine as initial therapy in treatment-naive patients. Other 3-NRTI regimens have not been evaluated.
Conflict Code: TD – Therapeutic Duplication
Drugs/Disease:

Util A	Util B	Util C (Negating)
Abacavir		All other antiretrovirals
Lamivudine		
Emtricitabine		
Stavudine		
Zalcitabine		
Didanosine		
Zidovudine		

Number of gcns required: 3
Letter Type: **New letter at end of document (must code 3 agents). The [drug a name] will accumulate all drugs and insert them in the letter. AR does have letters that will do this (multiple name insertion) but there is other language in the letter that is not appropriate with this criterion.**

References:
Guidelines for the Use of Antiretroviral Agents in HIV-1-Infected Adults and Adolescents. Developed by the DHHS Panel on Antiretroviral Guidelines for Adults and Adolescents - A Working Group of the Office of AIDS Research Advisory Council (OARAC). May 4, 2006.

****System will be set to identify any patient receiving 3 or more NRTIs (3 different gcns). But if a patient is receiving the combo NRTI and on other NRTI then this will only be 2 gcns and the criterion will not hit. Therefore, another criteria has to be created that will look for patients who are receiving the combo product and another NRTI (see below).***

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

56. Epzicom / Certain NRTIs (Triple Therapy) **2913** _____ _____

Alert Message: The use of triple-NRTI therapy (except for abacavir/zidovudine/lamivudine or possible zidovudine/lamivudine + tenofovir) should not be used at any time. A high rate of early virologic non-response has been seen with triple-NRTI combinations involving abacavir/tenofovir/lamivudine or tenofovir/didanosine/lamivudine as initial therapy in treatment-naive patients. Other 3-NRTI regimens have not been evaluated.
Conflict Code: DD – Drug/Drug Interaction
Drugs/Disease:

Util A	Util B	Util C (Negating)
Abacavir/Lamivudine	Tenofovir	All other antiretrovirals
	Emtricitabine	
	Didanosine	
	Zalcitabine	
	Stavudine	

References:
Guidelines for the Use of Antiretroviral Agents in HIV-1-Infected Adults and Adolescents. Developed by the DHHS Panel on Antiretroviral Guidelines for Adults and Adolescents - A Working Group of the Office of AIDS Research Advisory Council (OARAC). May 4, 2006.

57. Truvada /Lamivudine or Abacavir (Triple Therapy) **2914** _____ _____

Alert Message: The use of triple-NRTI therapy (except for abacavir/zidovudine/lamivudine or possible zidovudine/lamivudine + tenofovir) should not be used at any time. A high rate of early virologic non-response has been seen with triple-NRTI combinations involving abacavir/tenofovir/lamivudine or tenofovir/didanosine/lamivudine as initial therapy in treatment-naive patients. Other 3-NRTI regimens have not been evaluated.
Conflict Code: DD – Drug/Drug Interaction
Drugs/Disease:

Util A	Util B	Util C (Negating)
Emtricitabine/Tenofovir	Lamivudine	All other antiretrovirals
	Abacavir	
	Stavudine	
	Zalcitabine	
	Didanosine	
	Zidovudine	

References:
Guidelines for the Use of Antiretroviral Agents in HIV-1-Infected Adults and Adolescents. Developed by the DHHS Panel on Antiretroviral Guidelines for Adults and Adolescents - A Working Group of the Office of AIDS Research Advisory Council (OARAC). May 4, 2006.

58. Amprenavir / Fosamprenavir **2878** _____ _____

Alert Message: The combined use of amprenavir and fosamprenavir is not recommended at any time. Amprenavir is the active metabolite of fosamprenavir and combined use of these agents offers no benefits and may increase toxicities.
Conflict Code: DD – Drug/Drug Interaction
Drugs/Disease:

Util A	Util B	Util C
Amprenavir	Fosamprenavir	

References:
Guidelines for the Use of Antiretroviral Agents in HIV-1-Infected Adults and Adolescents. Developed by the DHHS Panel on Antiretroviral Guidelines for Adults and Adolescents - A Working Group of the Office of AIDS Research Advisory Council (OARAC). May 4, 2006.

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

59. Dual Nucleoside Regimen / Therapeutic Appropriateness 2879 _____ _____

Alert Message: Dual nucleoside reverse transcriptase inhibitor (NRTI) regimens are not recommended as antiretroviral therapy for HIV-1 patients because they have not demonstrated potent and sustained antiretroviral activity as compared to three-drug combination regimens.
Conflict Code: (DD) – TA – Therapeutic Appropriateness
Drugs/Disease:

Util A	Util B	Util C (Negating)
Didanosine	Lamivudine	Protease Inhibitors
	Stavudine	Non-Nucleoside Reverse Transcriptase Inhibitors
	Zalcitabine	Fusion Inhibitors
	Zidovudine	
	Abacavir	
	Emtricitabine	
	Tenofovir	

References:
Guidelines for the Use of Antiretroviral Agents in HIV-1-Infected Adults and Adolescents. Developed by the DHHS Panel on Antiretroviral Guidelines for Adults and Adolescents - A Working Group of the Office of AIDS Research Advisory Council (OARAC). May 4, 2006.

60. Dual Nucleoside Regimen / Therapeutic Appropriateness 2880 _____ _____

Alert Message: Dual nucleoside reverse transcriptase inhibitor (NRTI) regimens are not recommended as antiretroviral therapy for HIV-1 patients because they have not demonstrated potent and sustained antiretroviral activity as compared to three-drug combination regimens.
Conflict Code: DD – Drug/Drug Interaction
Drugs/Disease:

Util A	Util B	Util C (Negating)
Lamivudine	Stavudine	Protease Inhibitors
	Tenofovir	Non-Nucleoside Reverse Transcriptase Inhibitors
	Zalcitabine	Fusion Inhibitors
	Zidovudine	
	Abacavir	
	Emtricitabine	

References:
Guidelines for the Use of Antiretroviral Agents in HIV-1-Infected Adults and Adolescents. Developed by the DHHS Panel on Antiretroviral Guidelines for Adults and Adolescents - A Working Group of the Office of AIDS Research Advisory Council (OARAC). May 4, 2006.

61. Dual Nucleoside Regimen / Therapeutic Appropriateness 2881 _____ _____

Alert Message: Dual nucleoside reverse transcriptase inhibitor (NRTI) regimens are not recommended as antiretroviral therapy for HIV-1 patients because they have not demonstrated potent and sustained antiretroviral activity as compared to three-drug combination regimens.
Conflict Code: DD – Drug/Drug Interaction
Drugs/Disease:

Util A	Util B	Util C (Negating)
Stavudine	Zalcitabine	Protease Inhibitors
	Tenofovir	Non-Nucleoside Reverse Transcriptase Inhibitors
	Zidovudine	Fusion Inhibitors
	Abacavir	
	Emtricitabine	

References:
Guidelines for the Use of Antiretroviral Agents in HIV-1-Infected Adults and Adolescents. Developed by the DHHS Panel on Antiretroviral Guidelines for Adults and Adolescents - A Working Group of the Office of AIDS Research Advisory Council (OARAC). May 4, 2006.

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

62. Dual Nucleoside Regimen / Therapeutic Appropriateness 2882 _____ _____

Alert Message: Dual nucleoside reverse transcriptase inhibitor (NRTI) regimens are not recommended as antiretroviral therapy for HIV-1 patients because they have not demonstrated potent and sustained antiretroviral activity as compared to three-drug combination regimens.
Conflict Code: DD – Drug/Drug Interaction
Drugs/Disease:

Util A	Util B	Util C (Negating)
Zalcitabine	Zidovudine	Protease Inhibitors
	Abacavir	Non-Nucleoside Reverse Transcriptase Inhibitors
	Emtricitabine	Fusion Inhibitors
	Tenofovir	

References:
Guidelines for the Use of Antiretroviral Agents in HIV-1-Infected Adults and Adolescents. Developed by the DHHS Panel on Antiretroviral Guidelines for Adults and Adolescents - A Working Group of the Office of AIDS Research Advisory Council (OARAC). May 4, 2006.

63. Dual Nucleoside Regimen / Therapeutic Appropriateness 2883 _____ _____

Alert Message: Dual nucleoside reverse transcriptase inhibitor (NRTI) regimens are not recommended as antiretroviral therapy for HIV-1 patients because they have not demonstrated potent and sustained antiretroviral activity as compared to three-drug combination regimens.
Conflict Code: DD – Drug/Drug Interaction
Drugs/Disease:

Util A	Util B	Util C (Negating)
Zidovudine	Abacavir	Protease Inhibitors
	Emtricitabine	Non-Nucleoside Reverse Transcriptase Inhibitors
	Tenofovir	Fusion Inhibitors

References:
Guidelines for the Use of Antiretroviral Agents in HIV-1-Infected Adults and Adolescents. Developed by the DHHS Panel on Antiretroviral Guidelines for Adults and Adolescents - A Working Group of the Office of AIDS Research Advisory Council (OARAC). May 4, 2006.

64. Dual Nucleoside Regimen / Therapeutic Appropriateness 2884 _____ _____

Alert Message: Dual nucleoside reverse transcriptase inhibitor (NRTI) regimens are not recommended as antiretroviral therapy for HIV-1 patients because they have not demonstrated potent and sustained antiretroviral activity as compared to three-drug combination regimens.
Conflict Code: (DD) TA – Therapeutic Appropriateness
Drugs/Disease:

Util A	Util B	Util C (Negating)
Abacavir	Emtricitabine	Protease Inhibitors
	Tenofovir	Non-Nucleoside Reverse Transcriptase Inhibitors
		Fusion Inhibitors

References:
Guidelines for the Use of Antiretroviral Agents in HIV-1-Infected Adults and Adolescents. Developed by the DHHS Panel on Antiretroviral Guidelines for Adults and Adolescents - A Working Group of the Office of AIDS Research Advisory Council (OARAC). May 4, 2006.

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

65. Dual Nucleoside Regimen / Therapeutic Appropriateness 2885 _____ _____

Alert Message: Dual nucleoside reverse transcriptase inhibitor (NRTI) regimens are not recommended as antiretroviral therapy for HIV-1 patients because they have not demonstrated potent and sustained antiretroviral activity as compared to three-drug combination regimens.
Conflict Code: DD – Drug/Drug Interaction
Drugs/Disease:

Util A	Util B	Util C (Negating)
Emtricitabine	Tenofovir	Protease Inhibitors
		Non-Nucleoside Reverse Transcriptase Inhibitors
		Fusion Inhibitors

References:
Guidelines for the Use of Antiretroviral Agents in HIV-1-Infected Adults and Adolescents. Developed by the DHHS Panel on Antiretroviral Guidelines for Adults and Adolescents - A Working Group of the Office of AIDS Research Advisory Council (OARAC). May 4, 2006.

66. Delavirdine/Preferred NRTIs/Negating Efavirenz, Nevirapine or Pregnancy 2886 _____ _____

Alert Message: The recommended NNRTI-based antiretroviral regimen for the treatment of HIV-1 in antiretroviral naive patients involves efavirenz plus two NRTIs, preferably zidovudine/lamivudine or tenofovir/emtricitabine (except during the first trimester of pregnancy or in women with high pregnancy potential). Delavirdine is not recommended as the initial NRTI therapy because of inferior virologic efficacy and inconvenient TID dosing.
Conflict Code: TA – Therapeutic Appropriateness
Drug Disease:

Util A	Util B	Util C (Negating)
Delavirdine	Lamivudine	Efavirenz
	Zidovudine	Pregnancy
	Tenofovir	Nevirapine

References:
Guidelines for the Use of Antiretroviral Agents in HIV-1-Infected Adults and Adolescents. Developed by the DHHS Panel on Antiretroviral Guidelines for Adults and Adolescents - A Working Group of the Office of AIDS Research Advisory Council (OARAC). May 4, 2006.

*****The system cannot determine if therapy is initial therapy or not. The reviewer will have to determine this. All patients on these drugs will hit this criterion – treatment naïve or not.***

67. PI-Based Regimen / Therapeutic Appropriateness 2887 _____ _____

Alert Message: The recommended PI-based antiretroviral therapy for the initial treatment of HIV-1 in treatment-naive patients involves 1 or 2 PIs + 2 NRTIs. The preferred regimen includes lopinavir/ritonavir or (atazanavir + ritonavir) or (fosamprenavir + ritonavir) with either zidovudine/lamivudine or tenofovir/emtricitabine as the NRTIs. PIs not recommended in initial treatment regimens include darunavir + ritonavir, indinavir (with or without ritonavir), ritonavir alone, saquinavir (without ritonavir) or tipranavir + ritonavir.
Conflict Code: TA –Therapeutic Appropriateness
Drugs/Disease:

Util A	Util B	Util C (Negating)
Indinavir	Lamivudine	Lopinavir/Ritonavir
Saquinavir	Emtricitabine	Ritonavir
Tipranavir	Zidovudine	
Darunavir	Stavudine	
	Tenofovir	
	Abacavir	
	Didanosine	
	Zalcitabine	

References:
Guidelines for the Use of Antiretroviral Agents in HIV-1-Infected Adults and Adolescents. Developed by the DHHS Panel on Antiretroviral Guidelines for Adults and Adolescents - A Working Group of the Office of AIDS Research Advisory Council (OARAC). May 4, 2006.
*****The system cannot determine if therapy is initial therapy or not. The reviewer will have to determine this. All patients on these drugs will hit this criterion.***

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

67. Didanosine/Tenofovir/NNRTI **2888** _____ _____

Alert message: The combination of didanosine and tenofovir is not recommended as initial therapy for the treatment of HIV-1. This drug combination has shown rapid selection of resistant mutations and potential for immunologic non-response.
Conflict Code: TA - Therapeutic Appropriateness
Drugs/Disease:

Util A	Util B	Util C
Didanosine	Tenofovir	

References:
Guidelines for the Use of Antiretroviral Agents in HIV-1-Infected Adults and Adolescents. Developed by the DHHS Panel on Antiretroviral Guidelines for Adults and Adolescents - A Working Group of the Office of AIDS Research Advisory Council (OARAC). May 4, 2006.

*****The system cannot determine if therapy is INITIAL therapy or not. The reviewer will have to determine this. All patients on these drugs will hit this criterion.***

69. Enfuvirtide / Therapeutic Appropriateness **2889** _____ _____

Alert Message: Fuzeon (enfuvirtide) is not recommended as initial antiretroviral therapy in treatment-naïve patients. There has been no clinical trial experience in this patient population and the drug requires twice daily subcutaneous injections.
Conflict Code: TA – Therapeutic Appropriateness
Drugs/Disease:

Util A	Util B	Util C
Enfuvirtide		

References:
Guidelines for the Use of Antiretroviral Agents in HIV-1-Infected Adults and Adolescents. Developed by the DHHS Panel on Antiretroviral Guidelines for Adults and Adolescents - A Working Group of the Office of AIDS Research Advisory Council (OARAC). May 4, 2006.

*****The system cannot determine if therapy is INITIAL therapy. The reviewer will have to determine this. All patients on these drugs will hit this criterion.***

70. Tipranavir / Therapeutic Appropriateness **2890** _____ _____

Alert Message: Aptivus (tipranavir) is not recommended as initial antiretroviral therapy in treatment-naïve patients. There is a lack of data in treatment-naïve patients to support the use of tipranavir (boosted with ritonavir) as initial PI therapy.
Conflict Code: TA - Therapeutic Appropriateness
Drugs/Disease

Util A	Util B	Util C
Tipranavir		

References:
Guidelines for the Use of Antiretroviral Agents in HIV-1-Infected Adults and Adolescents. Developed by the DHHS Panel on Antiretroviral Guidelines for Adults and Adolescents - A Working Group of the Office of AIDS Research Advisory Council (OARAC). May 4, 2006.

*****The system cannot determine if therapy is INITIAL therapy. The reviewer will have to determine this. All patients on these drugs will hit this criterion.***

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

71. Amprenavir Oral Solution / Contraindication 2787 _____ _____

Alert message: The use of amprenavir oral solution is contraindicated in infants and children below 4 years of age, pregnant women, patients with hepatic or renal failure, and patients treated with disulfiram or metronidazole. Oral liquid amprenavir contains a large amount of the excipient propylene glycol, which may be toxic in the these patient populations.
Conflict Code: TA - Therapeutic Appropriateness
Drugs/Disease

Util A	Util B	Util C
Amprenavir Oral Solution	Metronidazole	
	Disulfiram	
	Renal Impairment	
	Hepatic Impairment	
	Pregnancy	

References:
Guidelines for the Use of Antiretroviral Agents in HIV-1-Infected Adults and Adolescents. Developed by the DHHS Panel on Antiretroviral Guidelines for Adults and Adolescents - A Working Group of the Office of AIDS Research Advisory Council (OARAC). May 4, 2006.
Facts & Comparisons, 2006 Updates.

*****The drug is contraindicated in patients less than 4 years of age regardless of drugs or disease state so there has to be another criterion created to identify this population (without drugs or disease states). The above criterion requires that one a drug or disease state be present. A 4 year old could be taking the medication but would not hit on the above criterion because he/she did not have a required disease/drug.***

72. Amprenavir Oral Solution / Contraindication 2788 _____ _____

Alert message: The use of amprenavir oral solution is contraindicated in infants and children below 4 years of age, pregnant women, patients with hepatic or renal failure, and patients treated with disulfiram or metronidazole. Oral liquid amprenavir contains a large amount of the excipient propylene glycol, which may be toxic in the these patient populations.
Conflict Code: TA - Therapeutic Appropriateness
Drugs/Disease

Util A	Util B	Util C
Amprenavir Oral Solution		

Age Range: Less than 4 years of age

References:
Guidelines for the Use of Antiretroviral Agents in HIV-1-Infected Adults and Adolescents. Developed by the DHHS Panel on Antiretroviral Guidelines for Adults and Adolescents - A Working Group of the Office of AIDS Research Advisory Council (OARAC). May 4, 2006.
Facts & Comparisons, 2006 Updates.

73. Amprenavir Oral Solution / Ritonavir Oral Solution 2891 _____ _____

Alert Message: The combined use of amprenavir oral solution and ritonavir oral solution is not recommended. The large amount of propyl glycol used as a vehicle in amprenavir oral solution may compete with the ethanol, vehicle in oral ritonavir solution, for the same metabolic pathway for elimination. This may lead to accumulation of either of the vehicles.
Conflict Code: DD – Drug/Drug Interaction
Drug/Disease:

Util A	Util B	Util C
Amprenavir Oral Solution	Ritonavir Oral Solution	

References:
Guidelines for the Use of Antiretroviral Agents in HIV-1-Infected Adults and Adolescents. Developed by the DHHS Panel on Antiretroviral Guidelines for Adults and Adolescents - A Working Group of the Office of AIDS Research Advisory Council (OARAC). May 4, 2006.
Facts & Comparisons, 2006 Updates.

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

74. Atazanavir / Indinavir **2892** _____ _____

Alert Message: The combined use of atazanavir and indinavir is not recommended at any time. Both of these PIs can cause grade 3 to 4 hyperbilirubinemia and jaundice. Additive or worsening of these adverse effects may be possible when these agents are used concurrently.
Conflict Code: DD – Drug/Drug Interaction
Drug/Disease:

Util A	Util B	Util C
Atazanavir	Indinavir	

References:
Guidelines for the Use of Antiretroviral Agents in HIV-1-Infected Adults and Adolescents. Developed by the DHHS Panel on Antiretroviral Guidelines for Adults and Adolescents - A Working Group of the Office of AIDS Research Advisory Council (OARAC). May 4, 2006.

75. Didanosine / Stavudine / Pregnancy (Negating) **2893** _____ _____

Alert Message: The combined use of didanosine and stavudine as a 2-NRTI backbone can result in a high incidence of toxicities, particularly peripheral neuropathy, pancreatitis and lactic acidosis. In general, this a combination should be avoided unless 2-NRTI combinations have failed or have caused unacceptable toxicities, and where potential benefits outweigh the risks of toxicities.
Conflict Code: DD – Drug/Drug Interaction
Drug/Disease:

Util A	Util B	Util C (Negating)
Didanosine	Stavudine	Pregnancy

References:
Guidelines for the Use of Antiretroviral Agents in HIV-1-Infected Adults and Adolescents. Developed by the DHHS Panel on Antiretroviral Guidelines for Adults and Adolescents - A Working Group of the Office of AIDS Research Advisory Council (OARAC). May 4, 2006.

76. Didanosine / Stavudine / Pregnancy (inclusive) **2923** _____ _____

Alert Message: The dual NRTI backbone of didanosine plus stavudine should be used in pregnant women only if no other alternatives are available. Cases of lactic acidosis, some fatal, have been reported in pregnant women receiving this dual NRTI combination. The recommended dual NRTI backbone in this population is zidovudine plus lamivudine.
Conflict Code: DD – Drug/Drug Interaction
Drug/Disease:

Util A	Util B	Util C (Inclusive)
Didanosine	Stavudine	Pregnancy

References:
Public Health Service Task Force Recommendations for Use of Antiretroviral Drugs in Pregnant HIV-1-Infected Women for Maternal Health and Intervention to Reduce Perinatal HIV-1 Transmission in the United States. Developed by the Perinatal HIV Guidelines Working Group. Oct. 12, 2006.

77. Didanosine or Stavudine / Zalcitabine **2894** _____ _____

Alert Message: The combined use of zalcitabine with didanosine or stavudine is not recommended at any time. Concurrent use of these agents may increase the risk and severity of peripheral neuropathy.
Conflict Code: DD – Drug/Drug Interaction
Drug/Disease:

Util A	Util B	Util C
Didanosine	Zalcitabine	
Stavudine		

References:
Guidelines for the Use of Antiretroviral Agents in HIV-1-Infected Adults and Adolescents. Developed by the DHHS Panel on Antiretroviral Guidelines for Adults and Adolescents - A Working Group of the Office of AIDS Research Advisory Council (OARAC). May 4, 2006.
Facts & Comparisons, 2006 Updates.

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

78. Emtricitabine / Lamivudine **2895** _____ _____

Alert Message: The combined use of emtricitabine and lamivudine is not recommended at any time. These agents have similar resistance profiles and have minimal additive antiviral activity.
Conflict Code: DD – Drug/Drug Interaction
Drug/Disease:

Util A	Util B	Util C
Emtricitabine	Lamivudine	

References:
Guidelines for the Use of Antiretroviral Agents in HIV-1-Infected Adults and Adolescents. Developed by the DHHS Panel on Antiretroviral Guidelines for Adults and Adolescents - A Working Group of the Office of AIDS Research Advisory Council (OARAC). May 4, 2006.

79. Lamivudine / Zalcitabine **2896** _____ _____

Alert Message: The combined use of lamivudine and zalcitabine is not recommended at any time. In vitro data has shown that these two agents may inhibit intracellular phosphorylation of one another, resulting in decreased triphosphate concentration and antiretroviral activities.
Conflict Code: DD – Drug/Drug Interaction
Drug/Disease:

Util A	Util B	Util C
Lamivudine	Zalcitabine	

References:
Guidelines for the Use of Antiretroviral Agents in HIV-1-Infected Adults and Adolescents. Developed by the DHHS Panel on Antiretroviral Guidelines for Adults and Adolescents - A Working Group of the Office of AIDS Research Advisory Council (OARAC). May 4, 2006.

80. Efavirenz / Pregnancy / Pregnancy Negating **2897** _____ _____

Alert Message: Sustiva (efavirenz) is not recommended during pregnancy due to the possible risk of fetal abnormalities in humans. Efavirenz may cause fetal harm when administered during the first trimester to a pregnant woman. Efavirenz should be used only if the benefits outweigh the risks of harm to the fetus. Efavirenz is FDA pregnancy category D.
Conflict Code: DD – Drug/Drug Interaction
Drug/Disease:

Util A	Util B	Util C (Negating)
Efavirenz	Pregnancy	Miscarriage
		Delivery

References:
Guidelines for the Use of Antiretroviral Agents in HIV-1-Infected Adults and Adolescents. Developed by the DHHS Panel on Antiretroviral Guidelines for Adults and Adolescents - A Working Group of the Office of AIDS Research Advisory Council (OARAC). May 4, 2006.

81. Saquinavir / All Other Protease Inhibitors **2898** _____ _____

Alert Message: Saquinavir mesylate (Invirase) is contraindicated as a single protease inhibitor because of poor bioavailability that averages only 4% even with a concurrent high fat meal and inferior antiretroviral activity when compared to other protease inhibitors.
Conflict Code: DD – Drug/Drug Interaction
Drug/Disease:

Util A	Util B	Util C (Negating)	
Saquinavir Hard Gel		Atazanavir	Nelfinavir
		Fosamprenavir	Tipranavir
		Indinavir	Ritonavir
		Lopinavir/Ritonavir	Darunavir

References:
Guidelines for the Use of Antiretroviral Agents in HIV-1-Infected Adults and Adolescents. Developed by the DHHS Panel on Antiretroviral Guidelines for Adults and Adolescents - A Working Group of the Office of AIDS Research Advisory Council (OARAC). May 4, 2006.

82. Stavudine / Zidovudine **2899** _____ _____

Alert Message: Combination regimens containing the two NRTIs, stavudine and zidovudine should be avoided. Zidovudine competitively inhibits the intracellular phosphorylation of stavudine causing an antagonistic effect on HIV-1.
Conflict Code: DD – Drug/Drug Interaction
Drug/Disease:

Util A	Util B	Util C
Stavudine	Zidovudine	

References:
Guidelines for the Use of Antiretroviral Agents in HIV-1-Infected Adults and Adolescents. Developed by the DHHS Panel on Antiretroviral Guidelines for Adults and Adolescents - A Working Group of the Office of AIDS Research Advisory Council (OARAC). May 4, 2006.

83. NRTI / NNRTI / PI **2900** _____ _____

Alert Message: The triple class antiretroviral regimen involving a NRTI, a NNRTI, and a PI has not been shown to have any benefit over standard regimens and is not recommended as a strategy for treatment-naive patients. The 2006 guidelines for the use of antiretroviral agents in HIV-1-infected patients recommend a NNRTI-based regimen (1 NNRTI + 2 NRTIs) or a PI-based regimen (1 or 2 PIs + 2 NRTIs) for initial therapy.
Conflict Code: TA - Therapeutic Appropriateness
Drug/Disease:

Util A	Util B	Util C (Inclusive)
Delavirdine	Abacavir	Atazanavir
Efavirenz	Didanosine	Fosamprenavir
Nevirapine	Emtricitabine	Indinavir
	Lamivudine	Lopinavir/Ritonavir
	Stavudine	Nelfinavir
	Tenofovir	Ritonavir
	Zidovudine	Saquinavir
	Zalcitabine	Tipranavir
		Darunavir

References:
Guidelines for the Use of Antiretroviral Agents in HIV-1-Infected Adults and Adolescents. Developed by the DHHS Panel on Antiretroviral Guidelines for Adults and Adolescents - A Working Group of the Office of AIDS Research Advisory Council (OARAC). May 4, 2006.

*****The system cannot determine if therapy is INITIAL therapy. The reviewer will have to determine this. All patients on these drugs will hit this criterion.***

MISSISSIPPI MEDICAID
RETROSPECTIVE DRUG UTILIZATION REVIEW
CRITERIA RECOMMENDATIONS
MAY 2007

Criteria Recommendations	*Approved*	*Rejected*

1. Sitagliptin / High Dose _____ _____

Alert Message: Januvia (sitagliptin) may be over-utilized. The manufacturer's recommended maximum dose is 100 mg once daily as monotherapy or in combination with metformin or a thiazolidinedione.
Conflict Code: HD – High Dose
Drugs/Disease:

Util A	Util B	Util C
Sitagliptin		

Max Dose: 100mg/day
References:
Januvia Prescribing Information, October 2006, Merck & Co., Inc.

2. Sitagliptin / Moderate Renal Impairment _____ _____

Alert Message: The recommended dose of Januvia (sitagliptin) in patients with moderate renal impairment (CrCl ≥ 30 mL/min to <50 mL/min) is 50 mg once daily. Patients with more severe renal insufficiency (CrCl < 30 mL/min) or with end-stage renal disease on hemodialysis or peritoneal dialysis should be dosed at 25 mg once daily. Assessment of renal function is recommended prior to initiation of sitagliptin and periodically thereafter.
Conflict Code: ER– Overutilization
Drugs/Disease:

Util A	Util B	Util C
Sitagliptin		Renal Impairment – No ERSD or Stage IV or V

Max Dose: 50 mg/day
References:
Januvia Prescribing Information, October 2006, Merck & Co., Inc.

3. Sitagliptin / Severe Renal Impairment _____ _____

Alert Message: The recommended dose of Januvia (sitagliptin) in patients with severe renal insufficiency (CrCl < 30 mL/min) or with end-stage renal disease on hemodialysis or peritoneal dialysis is 25 mg once daily. In patients with moderate renal impairment (CrCl ≥ 30 mL/min to <50 mL/min) sitagliptin should be dosed at 50 mg once daily. Assessment of renal function is recommended prior to initiation of sitagliptin and periodically thereafter.
Conflict Code: ER– Overutilization
Drugs/Disease:

Util A	Util B	Util C	
Sitagliptin		ESRD	PhosLo
		CKD Stage IV (severe) GFR (15-29)	Renagel
		CKD Stage V GFR <15	Zemplar
		Fosrenol	

Max Dose: 25 mg/day
References:
Januvia Prescribing Information, October 2006, Merck & Co., Inc.

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

4. Sitagliptin / Type I Diabetes _____ _____
Alert Message: Januvia (sitagliptin) should not be used in patients with type 1 diabetes mellitus or for the treatment of diabetic ketoacidosis.
Conflict Code: MC – Drug (Actual) Disease Precaution
Drugs/Disease:

Util A	Util B	Util C
Sitagliptin	Type I Diabetes	
	Diabetic Ketoacidosis	

References:
Januvia Prescribing Information, October 2006, Merck & Co., Inc.

5. Sitagliptin / Digoxin _____ _____
Alert Message: The concurrent use of Januvia (sitagliptin) and digoxin has been reported to cause increases in the AUC and Cmax of digoxin 11% and 18%, respectively. While no dosage adjustment of either agent is necessary appropriate monitoring of digoxin is recommended.
Conflict Code: DD – Drug/Drug Interaction
Drugs/Disease:

Util A	Util B	Util C
Sitagliptin	Digoxin	

References:
Januvia Prescribing Information, October 2006, Merck & Co., Inc.

6. Paliperidone / High Dose _____ _____
Alert Message: Invega (paliperidone) may be over-utilized. The manufacturer's maximum recommended dose is 12 mg once daily administered in the morning.
Conflict Code: HD – High Dose
Drugs/Disease:

Util A	Util B	Util C
Paliperidone		

Max Dose: 12 mg/day
References:
Invega Prescribing Information, December 2006, Janssen, L.P.

7. Paliperidone / Risperidone _____ _____
Alert Message: Invega (paliperidone) is the major active metabolite of Risperdal (risperidone) and concurrent use of these agents may result in additive paliperidone exposure and risk of adverse effects.
Conflict Code: DD – Drug/Drug Interaction
Drugs/Disease:

Util A	Util B	Util C
Paliperidone	Risperidone	

References:
Invega Prescribing Information, December 2006, Janssen, L.P.

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

8. Paliperidone / Moderate to Severe Renal Impairment _____ _____

Alert Message: The maximum recommended dose of Invega (paliperidone) in patients with moderate to severe renal impairment (CrCl 10 mL/min to < 50 mL/min) is 3 mg once daily. The maximum recommended dose of paliperidone in patients with mild renal impairment (CrCl >/= 50 mL/min to < 80 mL/min) is 6 mg once daily.
Conflict Code: ER – Overutilization
Drugs/Disease:

Util A	Util B	Util C (Inclusive)	
Paliperidone		ICD-9s & Drugs:	
		CKD Stage III (moderate) GFR (30-59)	PhosLo
		CKD Stage IIV (severe) GFR (15-29)	Renagel
		CKD Stage V GFR <15	Zemplar
		End Stage Renal Disease	Fosrenol

Max Dose: 3 mg/day
References:
Invega Prescribing Information, December 2006, Janssen, L.P.

9. Paliperidone / Mild Renal Impairment _____ _____

Alert Message: The maximum recommended dose of Invega (paliperidone) in patients with mild renal impairment (CrCl >/= 50 mL/min to < 80 mL/min) is 6 mg once daily. The maximum recommended dose of Invega (paliperidone) in patients with moderate to severe renal impairment (CrCl 10 mL/min to < 50 mL/min) is 3 mg once daily.
Conflict Code: ER – Overutilization
Drugs/Disease:

Util A	Util B	Util C
Paliperidone		CKD Stage I GFR >90
		CKD Stage II (mild) (GFR 60 - 89)
		Chronic Kidney Disease, Unspecified

Max Dose: 6 mg/day
References:
Invega Prescribing Information, December 2006, Janssen, L.P.

10. Paliperidone / Therapeutic Appropriateness _____ _____

Alert Message: The safety and efficacy of Invega (paliperidone) have not been established in patients less than 18 years of age.
Conflict Code: TA – Therapeutic Appropriateness
Drugs/Disease:

Util A	Util B	Util C
Paliperidone		

Age Range: 0 – 17 years of age
References:
Invega Prescribing Information, December 2006, Janssen, L.P.

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

11. Paliperidone / QT Prolongation _____ _____

Alert Message: Invega (paliperidone) has been shown to cause moderate increases in the corrected QT (QTc) interval. Paliperidone use should be avoided in patients with congenital long QT syndrome, a history of cardiac arrhythmias and in patients receiving any drug that prolongs the QTc interval (i.e., Class 1A & III antiarrhythmics, antipsychotics, macrolides and fluoroquinolones).
Conflict Code: DB - Drug/Drug and/or Disease Marker
Drugs/Disease:

Util A	Util B	Util C
Paliperidone	QT Prolongation	Levofloxacin
	Cardiac Arrhythmias	Flecainide
	Quinidine	Propafenone
	Procainamide	Dofetilide
	Disopyramide	Pimozide
	Amiodarone	Ziprasidone
	Sotalol	Erythromycin
	Chlorpromazine	Clarithromycin
	Thioridazine	Norfloxacin
	Gatifloxacin	
	Moxifloxacin	

References:
Invega Prescribing Information, December 2006, Janssen, L.P.

12. Paliperidone / Seizures _____ _____

Alert Message: Invega (paliperidone) should be used with caution in patients with a history of seizures or other conditions that potentially lower the seizure threshold.
Conflict Code: DB - Drug/Drug and/or Disease Marker
Drugs/Disease:

Util A	Util B	Util C
Paliperidone	Seizures	Gabapentin
	Epilepsy	Pregabalin
	Phenytoin	Lamotrigine
	Ethosuximide	Levetiracetam
	Methsuximide	Primidone
	Zonisamide	Tiagabine
	Oxcarbazepine	Topiramate
	Felbamate	Valproic Acid & Derivatives

References:
Invega Prescribing Information, December 2006, Janssen, L.P.

13. Paliperidone / Orthostatic Hypotension _____ _____

Alert Message: Invega (paliperidone) can produce hypotension and syncope due to its alpha-blocking activity. Paliperidone should be used with caution in patients with known cardiovascular disease, cerebrovascular disease, or conditions that predispose a patient to hypotension (e.g., dehydration, hypovolemia, and antihypertensive medications).
Conflict Code: DB - Drug/Drug and/or Disease Marker
Drugs/Disease:

Util A	Util B	Util C
Paliperidone	Heart Failure	CCBs
	Myocardial Infarction	ARBs
	Conduction Abnormalities	Diuretics
	Dehydration	Antiadrenergic Antihypertensives
	Hypovolemia	
	ACE Inhibitors	
	Beta Blockers	

References:
Invega Prescribing Information, December 2006, Janssen, L.P.

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

14. Paliperidone / Dopamine Agonists _____ _____

Alert Message: Invega (paliperidone) may antagonize the effects of levodopa and other dopamine agonists. Monitor patients for dopamine agonist efficacy.
Conflict Code: DD – Drug/Drug Interaction
Drugs/Disease:

Util A	Util B	Util C
Paliperidone	Levodopa	
	Pramipexole	
	Ropinirole	
	Apomorphine	
	Pergolide	

References:
Invega Prescribing Information, December 2006, Janssen, L.P.

15. Paliperidone / Gastrointestinal Narrowing _____ _____

Alert Message: Invega (paliperidone) ordinarily should not be used in patients with severe pathologic or iatrogenic gastrointestinal narrowing. The agent is a non-deformable controlled-release formulation and does not appreciably change shape in the gastrointestinal tract.
Conflict Code: MC – Drug Actual Disease Precaution
Drugs/Disease:

Util A	Util B	Util C
Paliperidone	Cystic Fibrosis	
	Meckel's Diverticulum	
	Peritonitis	
	Short Bowel Syndrome	
	Achalasia	

References:
Invega Prescribing Information, December 2006, Janssen, L.P.

16. Paliperidone / Hyperprolactinemia _____ _____

Alert Message: Invega (paliperidone) like other dopamine-2 antagonists elevates prolactin levels initially and during chronic administration. The prolactin elevating effect is similar to that seen with risperidone, a drug associated with higher levels of prolactin than other antipsychotics. Prolactin elevating agents may cause galactorrhea, amenorrhea, gynecomastia, impotence, and decreased bone density.
Conflict Code: MC – Drug Actual Disease Precaution
Drugs/Disease:

Util A	Util B	Util C
Paliperidone	Galactorrhea	
	Amenorrhea	
	Gynecomastia	
	Impotence	
	Osteoporosis	

References:
Invega Prescribing Information, December 2006, Janssen, L.P.

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

17. Lisdexamfetamine / High Dose _____ _____

Alert Message: Vyvanse (lisdexamfetamine) may be over-utilized. The manufacturer's recommended maximum dose for children is 70 mg daily. Doses greater than 70 mg have not been studied in children.
Conflict Code: HD – High Dose
Drugs/Disease:

Util A	Util B	Util C
Lisdexamfetamine		

Max Dose: 70 mg/day
Age Range 6 – 12 years of age
References:
Vyvanse Prescribing Information, February 2007, New River Pharmaceuticals Inc.

18. Lisdexamfetamine / Therapeutic Appropriateness _____ _____

Alert Message: Vyvanse (lisdexamfetamine) is indicated for the treatment of Attention-Deficit/Hyperactivity Disorder (ADHD) in patients 6 to 12 years of age. This agent has not been studied in children 3 to 5 years of age. Amphetamines are not recommended for children under 3 years of age.
Conflict Code: TA – Therapeutic Appropriateness
Drugs/Disease:

Util A	Util B	Util C
Lisdexamfetamine		

Age Range: 3 – 5 years of age
References:
Vyvanse Prescribing Information, February 2007, New River Pharmaceuticals Inc.

19. Aliskiren / Pregnancy / Pregnancy Negating _____ _____

Alert Message: When pregnancy is detected Tekturna (aliskiren) should be discontinued as soon as possible. Aliskiren is a direct renin inhibitor and drugs acting directly on the renin-angiotensin system can cause fetal and neonatal morbidity and death when administered to pregnant women. Aliskiren is FDA pregnancy category C during the first trimester and pregnancy category D during the second and third trimesters.
Conflict Code: MC – Drug (Actual) Disease Precaution (Black Box Warning)
Drugs/Disease:

Util A	Util B	Util C (Negating)
Aliskiren	Pregnancy	Miscarriage
		Delivery
		Abortion

References:
Tekturna Prescribing Information, March 2007, Novartis Pharmaceuticals Corporation.

20. Aliskiren / High Dose _____ _____

Alert Message: Tekturna (aliskiren) may be over-utilized. The usual recommended starting dose is 150 mg once daily but may be increased to 300 mg if blood pressure is not adequately controlled. Doses above 300 mg have not increased the blood pressure response but have increased the rate of diarrhea.
Conflict Code: HD – High Dose
Drugs/Disease:

Util A	Util B	Util C
Aliskiren		

Max Dose: 300 mg/day
References:
Tekturna Prescribing Information, March 2007, Novartis Pharmaceuticals Corporation.

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

21. Aliskiren / Severe Renal Impairment _____ _____

Alert Message: Tekturna (aliskiren) should be used with caution in patients with severe renal impairment (GFR < 30mL/min), a history of dialysis, nephrotic syndrome or renovascular hypertension. Drugs acting on the renin-angiotensin system have the potential to increase serum creatinine and blood urea nitrogen.
Conflict Code: MC – Drug/Drug or Drug/Disease Precaution
Drugs/Disease:

Util A	Util B	Util C
Aliskiren	Severe Renal Impairment	Nephrotic Syndrome
	Lanthanum	Renovascular Hypertension
	Sevelamer	Dialysis
	Paricalcitol	
	Doxercalciferol	
	Calcitriol	

References:
Tekturna Prescribing Information, March 2007, Novartis Pharmaceuticals Corporation.

22. Aliskiren / ACEIs / Diabetes _____ _____

Alert Message: The concurrent use of Tekturna (aliskiren) and an ACE inhibitor in patients with diabetes may result in increased serum potassium levels. Routine monitoring of electrolytes and renal function is indicated in this population.
Conflict Code: DD – Drug/Drug Interaction
Drugs/Disease:

Util A	Util B	Util C (Inclusive)	
Aliskiren	ACE Inhibitors	Diabetes	Dipeptidyl Peptidase-4 Inhibitor
		Insulin	Biguanide
		Sulfonylureas	Meglitinides
		Amylin Analog	Thiazolidinediones
		Incretin Mimetic	
		Alpha-Glucosidase Inhibitors	

References:
Tekturna Prescribing Information, March 2007, Novartis Pharmaceuticals Corporation.

23. Aliskiren / Furosemide _____ _____

Alert Message: The concurrent use of Tekturna (aliskiren) with furosemide has been shown to significantly reduce the blood concentrations of furosemide. Co-administration of these agents resulted in a decrease in the AUC and Cmax of furosemide by 30% and 50%, respectively. The effects of furosemide may be diminished after starting aliskiren.
Conflict Code: DD – Drug/Drug Interaction
Drugs/Disease:

Util A	Util B	Util C
Aliskiren	Furosemide	

Reference:
Tekturna Prescribing Information, March 2007, Novartis Pharmaceuticals Corporation.

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

24. Aliskiren / Ketoconazole _____ _____

Alert Message: The concurrent use of Tekturna (aliskiren) with ketoconazole may result in elevated aliskiren plasma levels due to inhibition of aliskiren CYP 3A4 mediated metabolism by ketoconazole. Co-administration of aliskiren with ketoconazole 200 mg twice daily has been shown to increase the plasma levels of aliskiren approximately 80%. A 400mg once-daily dose has not been studied but would be expected to increase aliskiren levels further.
Conflict Code: DD – Drug/Drug Interaction
Drugs/Disease:

Util A	Util B	Util C
Aliskiren	Ketoconazole	

Reference:
Tekturna Prescribing Information, March 2007, Novartis Pharmaceuticals Corporation.
The Medical Letter on Drugs & Therapeutics, Volume 49 (Issue 1258), April 2007.

25. Arformoterol /Hepatic Impairment _____ _____

Alert Message: Brovana (arformoterol) should be used cautiously in patients with hepatic impairment. Systemic exposure (Cmax & AUC) to arformoterol increased 1.3 to 2.4-fold in subjects with hepatic impairment as compared to matched healthy control subjects. While dosage adjustment is not required it is recommended that these patients be monitored closely.
Conflict Code: MC – Drug (Actual) Disease Precaution
Drugs/Disease:

Util A	Util B	Util C
Arformoterol	Hepatic Impairment	

References:
Facts & Comparisons, 2007 Updates.
Brovana Prescribing Information, Oct. 2006, Sepracor Inc.

26. Arformoterol / Other Inhaled Long-Acting Beta2-Agonists _____ _____

Alert Message: Brovana (arformoterol) should not be used in conjunction with other inhaled, long-acting beta-2 agonists due to the increased risk of adverse cardiovascular effects. When beginning treatment with arformoterol, instruct patients who have been taking inhaled, short-acting beta-2 agonists on a regular basis (e.g., 4 times a day) to discontinue the regular use of these drugs and use them only for symptomatic relief of acute respiratory symptoms.
Conflict Code: TD – Therapeutic Duplication (DD)
Drugs/Disease:

Util A	Util B	Util C
Arformoterol	Salmeterol	
	Formoterol	

References:
Facts & Comparisons, 2007 Updates.
Brovana Prescribing Information, Oct. 2006, Sepracor Inc.
Clinical Pharmacology, Gold Standard Inc, 2007.

27. Arformoterol / Therapeutic Appropriateness _____ _____

Alert Message: Brovana (arformoterol) should not be used in children as the safety and efficacy of arformoterol have not been established in pediatric patients.
Conflict Code: TA - Therapeutic Appropriateness
Drugs/Disease:

Util A	Util B	Util C
Arformoterol		

Age Range: 0 – 18 years of age
References:
Facts & Comparisons, 2007 Updates.
Brovana Prescribing Information, Oct. 2006, Sepracor Inc.

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

28. Arformoterol / MOAIs & TCAs & QT Prolongation _____ _____

Alert Message: Brovana (arformoterol), as well as other beta 2-agonists, should be administered with extreme caution to patients being treated with monoamine oxidase inhibitors, tricyclic antidepressants, or drugs known to prolong the QTc interval. Concurrent use of these agents may potentiate the adrenergic agonist action of arformoterol on the cardiovascular system.
Conflict Code: DD – Drug/Drug Interaction
Drugs/Disease:

Util A	Util B		Util C
Arformoterol	Isocarboxazid	Phenelzine	
	Tranylcypromine	Nortriptyline	
	Amitriptyline	Protriptyline	
	Imipramine	Trimipramine	
	Doxepin	Desipramine	
	Amoxapine	QT Prolongation Drugs	
	Clomipramine		

References:
Facts & Comparisons, 2007 Updates.
Brovana Prescribing Information, Oct. 2006, Sepracor Inc.

29. Arformoterol / Beta-Blockers _____ _____

Alert Message: The concurrent use of Brovana (arformoterol) and a beta-adrenergic receptor blocker may result in antagonism. The beta blocker may block the therapeutic effect of the beta-agonist as well as produce severe bronchospasms in COPD patients.
Conflict Code: DD – Drug/Drug Interaction
Drugs/Disease:

Util A	Util B		Util C
Arformoterol	Atenolol	Metoprolol	
	Betaxolol	Timolol	
	Penbutolol	Sotalol	
	Carteolol	Acebutolol	
	Bisoprolol	Propranolol	
	Pindolol	Timolol	

References:
Facts & Comparisons, 2007 Updates.
Brovana Prescribing Information, Oct. 2006, Sepracor Inc.

30. Arformoterol / Methylxanthines & Steroids & K+ Depleting Diuretics _____ _____

Alert Message: The concurrent use of Brovana (arformoterol) with methylxanthines (theophylline, aminophylline), steroids or potassium depleting diuretics may potentiate any hypokalemic effect of arformoterol. Monitor patients for development of hypokalemia.
Conflict Code: DD – Drug/Drug Interaction
Drugs/Disease:

Util A	Util B		Util C
Arformoterol	Theophylline	Budesonide	Chlorothiazide
	Aminophylline	Betamethasone	Hydrochlorothiazide
	Prednisone	Triamcinolone	Bendroflumethiazide
	Prednisolone	Furosemide	Methyclothiazide
	Hydrocortisone	Bumetanide	Indapamide
	Cortisone	Torsemide	Metolazone
	Dexamethasone	Ethacrynic Acid	Chlorthalidone
	Methylprednisolone		

References:
Facts & Comparisons, 2007 Updates.
Brovana Prescribing Information, Oct. 2006, Sepracor Inc.

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

31. Arformoterol / High Dose _____ _____

Alert Message: Brovana (arformoterol) may be over-utilized. The manufacturer's recommended maximum dose is 30 mcg per day (15 mcg twice daily). Fatalities have been reported in association with excessive use of inhaled sympathomimetic drugs. As with other inhaled beta-2 adrenergic drugs, do not use arformoterol more often, at higher doses than recommended or with other long-acting beta agonists.
Conflict Code: HD – High Dose
Drugs/Disease:

Util A	Util B	Util C
Arformoterol		

Max Dose: 30 mcg/day
References:
Facts & Comparisons, 2007 Updates.

Boxed Warning Update

Code of Federal Regulations definition for Black Box:

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.

Actiq (fentanyl citrate) Oral Transmucosal Lozenge:

WARNINGS: IMPORTANCE OF PROPER PATIENT SELECTION and POTENTIAL FOR ABUSE *See full prescribing information for complete boxed warning*.
• Must not be used in opioid non-tolerant patients.
• Contains fentanyl, a Schedule II controlled substance with abuse liability similar to other opioid analgesics.
• Life-threatening hypoventilation could occur at any dose in patients not taking chronic opiates.
• Contraindicated in management of acute or postoperative pain.
• Contains medicine in an amount that can be fatal to a child. Keep out of reach of children and discard opened units properly.
- Use with strong and moderate CYP450 3A4 inhibitors may result in potentially fatal respiratory depression.

Femring (estradiol acetate vaginal ring):

BOXED WARNING: Cardiovascular and Other Risks
.....The estrogen-alone substudy of the Women's Health Initiative (WHI) reported increased risks of stroke and deep vein thrombosis (DVT) in postmenopausal women (50 to 79 years of age) during 6.8 years and 7.1 years, respectively, of treatment with oral conjugated estrogens (CE 0.625 mg) per day relative to placebo.
The estrogen-plus-progestin substudy of WHI reported increased risks of myocardial infarction, stroke, invasive breast cancer, pulmonary emboli, and deep vein thrombosis in postmenopausal women (50 to 79 years of age) during 5.6 years of treatment with oral conjugated estrogens (CE 0.625 mg) combined with medroxyprogesterone acetate (MPA 2.5 mg) per day, relative to placebo.
The Women's Health Initiative Memory Study (WHIMS), a substudy of WHI, reported increased risk of developing probable dementia in postmenopausal women 65 years of age or older during 5.2 years of treatment with CE 0.625 mg alone and during 4 years of treatment
with CE 0.625 mg combined with MPA 2.5 mg, relative to placebo. It is unknown whether this finding applies to younger postmenopausal women.....

Humira (adalimumab) Solution for Subcutaneous Injection:

BOXED WARNING
.....Patients should be evaluated for tuberculosis risk factors and be tested for latent tuberculosis infection prior to initiating Humira and during therapy.....

Ketek (telithromycin) Tablets:

BOXED WARNING
Ketek is contraindicated in patients with myasthenia gravis. There have been reports of fatal and life-threatening respiratory failure in patients with myasthenia gravis associated with the use of Ketek.

Lotensin (benazepril hydrochloride) Tablets;
Lotensin HCT (benazepril hydrochloride and hydrochlorothiazide, USP) Combination Tablets;
Lotrel (amlodipine besylate and benazepril hydrochloride):

BOXED WARNING**: Use in Pregnancy**
When used in pregnancy, ACE inhibitors can cause injury and even death to the developing fetus. When pregnancy is detected, Lotensin should be discontinued as soon as possible.....