Alabama Medicaid DUR Board Meeting Minutes
January 23, 2013

Members Present: Denyse Thornley-Brown , Paula Thompson, Kelli Littlejohn, Robert Moon, Rhonda Harden, David Harwood, Wendy Gomez, Bernie Olin

Also Present: Clemice Hurst, Tiffany Minnifield, Heather Vega, Lori Thomas, Jonathon Sun

Present via Conference Call: Chris Barwick, Kristian Testerman, Amanda Sparkman, Holley Rice

Members Absent: Dan McConaghy, Donald Marks, Jimmy Jackson

Call to Order: The DUR meeting was called to order by D. Thornley-Brown at approximately 1:00p.m.

Review and Adoption of Minutes: The minutes of the July 25, 2012 meeting were presented and reviewed. D. Harwood made a motion to approve the minutes as presented and R. Moon seconded the motion. The motion was approved unanimously.

Prior Authorization and Overrides Update: L.Thomas began the Prior Authorization and Overrides Update with the Monthly Manual Prior Authorizations and Overrides Report for the month of August 2012. She reported 10,176 total requests. She then reported 29,827 electronic requests for the same time frame. From the Prior Authorization and Override Response Time Ratio report for August 2012, L.Thomas reported that approximately 81% of all manual PAs were responded to in less than two hours, about 96% in less than four hours and 99% in less than eight hours. For the month of September 2012, L.Thomas reported 9,396 manual PA requests and 24,576 electronic PA requests. She reported that about 72% of PAs and 67% of overrides were responded to in less than two hours and, approximately 95% in less than four hours and 99% in less than eight hours. For the month of October 2012, L.Thomas reported 11,126 manual PA requests and 29,196 electronic PA requests for the same time frame. For October, L.Thomas reported 80-81% of the manual PAs and overrides were approved in less than two hours, approximately 94% in less than four hours and 96-97% approved in less than eight hours.

Program Summary Review: L.Thomas briefly reviewed the Alabama Medicaid Program Summary. She reported 4,306,241 total prescriptions, 228,611 average recipients per month and an average paid per prescription of $57.44 for the months of April 2012 through September 2012.

Cost Management Analysis: L.Thomas reported an average cost per claim of $54.18 for September 2012. L. Thomas mentioned that the cost per claim has decreased since September 2011. R. Harden pointed out that there was almost a $5 difference between claims in August 2012 and September 2012. From the 1st Quarter 2012 Drug Analysis, L.Thomas reported 78.3% generic utilization, 9.2% brand single-source, 4.98% brand multi-source (those requests which required a DAW override) and 7.6% OTC and "other". From the Top 25 Drugs Based on Number of Claims from 07/01/2012 – 09/30/2012, L.Thomas reported the top five drugs: hydrocodone-acetaminophen, amoxicillin, omeprazole, alprazolam and ProAir® HFA. She also mentioned that Singulair® was no longer in the top five because a generic became available in August 2012. She then reported the top five drugs from the Top 25 Drugs Based on Claims Cost from 07/01/2012 – 09/30/2012: Abilify®, Vyvanse®, Singulair®, Focalin XR®, and Invega Sustenna®. L. Thomas reminded the Board that Singulair® has topped this list for several years. From the Top 15 Therapeutic Classes by Total Cost of Claims for the same time frame, L.Thomas reported the top five classes: Antipsychotic Agents, Hemostatics, Amphetamines, Corticosteroids (Respiratory Tract), and Anorexigenic Agents and Respiratory and Cerebral Stimulants. L. Thomas informed the Board that the Amphetamine AHFS Class includes medications such as Adderall® and Vyvanse® and that the Anorexigenic and Respiratory and Cerebral Stimulant AHFS Class includes Concerta®, Daytrana®, Focalin®, etc.

UPDATES

Hydrocodone Utilization: L. Thomas presented a version of the letter for the top 100 prescribers of hydrocodone. At the October 2012 DUR Board meeting, numerous suggestions were recommended by Board members and L. Thomas pointed out the addition of those suggestions to the letter. K. Littlejohn and D. Harwood made further recommendations to the letter. R. Harden made a motion to amend the letter and P. Thompson seconded the motion. The letter will be amended and sent to the Agency for final approval. L. Thomas also gave an overview of the query results for the top 100 prescribers of hydrodocone for 2012.

Proposed Criteria: L.Thomas presented the proposed set of 51 criteria to the Board. Results from the criteria vote returned 51 approved.

Medicaid Update: T. Minnifield reminded the Board members that all Medicaid information discussed is available online and that the Agency now has WiFi access. She advised the Board that effective January 1, 2013, all Ordering, Prescribing, and Referring Physician should be enrolled as an Alabama Medicaid provider. T. Minnifield reminded the Board of the next DUR meeting to be held on April 24, 2013. K. Littlejohn discussed the Medicaid Commission delegated by Governor Bentley to look at options for the future of Alabama Medicaid and encouraged interested parties to view the information on the Medicaid website

P & T Committee Update: C.Hurst began the P&T Update by informing the Board that the last meeting was held on November 14, 2012, but did not have a quorum and therefore the drug class reviews were tabled until the upcoming February 13, 2013 meeting. The next meeting will include re-reviews of several AHFS Classes.

New Business: There being no new business, D.Thornley-Brown moved to adjourn the meeting. P. Thompson made a motion to adjourn the meeting. The motion was seconded by D. Harwood. The meeting was adjourned at 2:00 p.m.

Next Meeting Date: The next DUR Board meeting will be held on April 24, 2013.

Respectfully submitted,

Lori Thomas, PharmD

Lori Thomas, PharmD

ALABAMA MEDICAID
RETROSPECTIVE DRUG UTILIZATION REVIEW
CRITERIA RECOMMENDATIONS

Criteria Recommendations	*Accepted*	*Approved As Amended*	*Rejected*

1. Mirabegron / High Dose ____√___ _____ _____

Alert Message: The manufacturer's maximum recommended daily dose of Myrbetriq (mirabegron) is 50 mg once daily.

Conflict Code: ER - Overutilization
Drugs/Diseases

Util A	Util B	Util C **(Negating)**
Mirabegron		Severe Renal Impairment
		Hepatic Impairment

Max dose: 50mg/day

References:
Myrbetriq Prescribing Information, June 2012, Astellas Pharma US, Inc.

2. Mirabegron / Severe Renal Impairment or Mod. Hepatic Impairment ____√____ _____ _____

Alert Message: The daily dose of Myrbetriq (mirabegron) should not exceed 25 mg in patients with severe renal impairment (CrCL 15-29mL/min) or moderate hepatic impairment (Child-Pugh Class B). Mirabegron use is not recommended in patients with end-stage renal disease (ESRD) or patients with severe hepatic impairment.

Conflict Code: ER - Overutilization
Drugs/Diseases

Util A	Util B	Util C **(Include)**
Mirabegron		Severe Renal Impairment
		Hepatic Impairment

Max Dose: 25 mg/day
References:
Myrbetriq Prescribing Information, June 2012, Astellas Pharma US, Inc.

3. Mirabegron / Hypertension & Antihypertensive Medications ____√____ _____ _____

Alert Message: Myrbetriq (mirabegron) can increase blood pressure and periodic blood pressure determinations are recommended especially in hypertensive patients. Mirabegron is not recommended for use in severe uncontrolled hypertensive patients.

Conflict Code: DB – Drug Disease and/or Drug Inferred Disease Precaution
Drugs/Diseases

Util A	Util B	Util C
Mirabegron	Hypertension ICD-9s	
	Antihypertensive Meds	

References:
Myrbetriq Prescribing Information, June 2012, Astellas Pharma US, Inc.

Criteria Recommendations	*Accepted*	*Approved As Amended*	*Rejected*

4. Mirabegron / Bladder Outlet Obstruction ___√___ _____ _____

Alert Message: Myrbetriq (mirabegron) should be administered with caution to patients with clinically significant bladder outlet obstruction (BOO). Urinary retention in patients with BOO has been reported in postmarketing experience in patients taking mirabegron.

Conflict Code: MC – Drug/Disease Precaution
Drugs/Diseases

Util A	Util B	Util C
Mirabegron	Bladder Obstruction	

References:
Myrbetriq Prescribing Information, June 2012, Astellas Pharma US, Inc.

5. Mirabegron / Antimuscarinic Medications ___√___ _____ _____

Alert Message: Myrbetriq (mirabegron) should be administered with caution to patients taking antimuscarinic medications for the treatment of overactive bladder (OAB). Urinary retention in patients taking antimuscarinic medications for the treatment of OAB has been reported in postmarketing experience in patients taking mirabegron.

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

Util A	Util B	Util C
Mirabegron	Darifenacin	
	Fesoterodine	
	Oxybutynin	
	Solifenacin	
	Tolterodine	
	Trospium	

References:
Myrbetriq Prescribing Information, June 2012, Astellas Pharma US, Inc.

6. Mirabegron / Digoxin ___√___ _____ _____

Alert Message: For patients who are initiating a combination of Myrbetriq (mirabegron) and digoxin, the lowest dose for digoxin should initially be considered. The concurrent use of mirabegron and digoxin has been shown to increase the Cmax and AUC of digoxin, 29% and 27%, respectively. Serum digoxin concentrations should be monitored and used for titration of the digoxin dose to obtain the desired clinical effect.

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

Util A	Util B	Util C
Mirabegron	Digoxin	

References:
Myrbetriq Prescribing Information, June 2012, Astellas Pharma US, Inc.

Criteria Recommendations	*Accepted*	*Approved As Amended*	*Rejected*

7. Mirabegron / Pediatric Patients ___√___ _____ _____

Alert Message: The safety and effectiveness of Myrbetriq (mirabegron) in pediatric patients have not been established.

Conflict Code: TA – Therapeutic Effectiveness

Drugs/Diseases

Util A	Util B	Util C
Mirabegron		

Age Range: 0-18 yoa

References:

Myrbetriq Prescribing Information, June 2012, Astellas Pharma US, Inc.

8. Mirabegron / Drugs Metabolized by CYP2D6 ___√___ _____ _____

Alert Message: Myrbetriq (mirabegron) is a moderate CYP2D6 inhibitor and co-administration with a drug that is a CYP2D6 substrate may result in increased systemic exposure to the substrate. Appropriate monitoring and dose adjustment may be necessary, especially with narrow therapeutic index drugs metabolized by CYP2D6.

Conflict Code: DD – Drug/Drug Interaction

Drugs/Diseases

Util A	Util B				Util C
Mirabegron	Thioridazine*	Codeine	Morphine	Clomipramine	
	Flecainide*	Cyclobenzaprine	Nortriptyline	Imipramine	
	Propafenone*	Darifenacin	Olanzapine	Protriptyline	
	Atomoxetine*	Delavirdine	Ondansetron	Trimipramine	
	Desipramine*	Dextromethorphan	Oxycodone	Venlafaxine	
	Dextroamphetamine*	Dolasetron	Paroxetine	Ziprasidone	
	Metoprolol*	Donepezil	Penbutolol	Zolpidem	
	Nebivolol*	Doxepin	Pentazocine	Clonidine	
	Perphenazine*	Flecainide	Propranolol	Fluvoxamine	
	Almotriptan	Fluoxetine	Perphenazine	Metoclopramide	
	Amphetamine	Fluphenazine	Propafenone	Nebivolol	
	Arformoterol	Haloperidol	Risperidone	Pimozide	
	Aripiprazole	Hydrocodone	Ritonavir		
	Asenapine	Iloperidone	Selegiline		
	Atomoxetine	Labetalol	Sertraline		
	Carvedilol	Maprotiline	Tamoxifen		
	Chlorpheniramine	Methamphetamine	Timolol		
	Cinacalcet	Metoprolol	Tolterodine		
	Citalopram	Mexiletine	Tramadol		
	Clozapine	Mirtazapine	Amitriptyline		

References:

Myrbetriq Prescribing Information, June 2012, Astellas Pharma US, Inc.
Hartshorn EA, Tatro DS. Principles of Drug Interactions Facts & Comparisons, 2012 Wolters Kluwer Health, Inc.
FDA: Drug Development and Drug Interactions: Tables of Substrates, Inhibitors and Inducers. [08/28/2012]. Available at:
http://www.fda.gov/Drugs/DevelopmentApprovalProcess/DevelopmentResources/DrugInteractionsLabeling/ucm093664.htm

*CYP2D6 Sensitive substrate and/or narrow therapeutic index CYP2D6 substrate

Criteria Recommendations	*Accepted*	*Approved As Amended*	*Rejected*

9. Stribild / Other Antiretroviral Therapy ___√___ _____ _____

Alert Message: The patient appears to be receiving other antiretroviral therapy in addition to Stribild (elvitegravir/cobicistat/emtricitabine/tenofovir). Stribild is a complete regimen for the treatment of HIV-1 infections and should not be administered with other antiretroviral medications.

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

Util A	Util B	Util C
Stribild	All Other Antiretroviral	

References:
Stribild Prescribing Information, August 2012, Gilead Sciences, Inc.

10. Fosamprenavir / Delavirdine ___√___ _____ _____

Alert Message: The concurrent use of Lexiva (fosamprenavir) and delavirdine is contraindicated. Co-administration of these agents may lead to loss of virologic response and possible resistance to delavirdine.

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

Util A	Util B	Util C
Fosamprenavir	Delavirdine	

References:
Facts & Comparisons, 2012 Updates.
Clinical Pharmacology, 2012 Elsevier/Gold Standard.

11. Revatio / Children 0-17 years of Age ___√___ _____ _____

Alert Message: Revatio (sildenafil) should not be prescribed to children (ages 1 through 17) for pulmonary arterial hypertension (PAH). This recommendation is based on a recent long-term clinical pediatric trial showing that: (1) children taking a high dose of Revatio had a higher risk of death than children taking a low dose and (2) the low doses of Revatio are not effective in improving exercise ability. Revatio is not FDA approved for the treatment of PAH in children.

Conflict Code: TA – Therapeutic Appropriateness
Drugs/Diseases

Util A	Util B	Util C
Revatio		

Age Range: 1-17 yoa

References:
MedWatch The FDA Safety Information and Adverse Event Reporting Program Safety Information. Revatio (sildenafil): Drug Safety Communication - Recommendation Against Use in Children [Posted 08/30/2012].

Criteria Recommendations	*Accepted*	*Approved As Amended*	*Rejected*

12. Didanosine / Ribavirin ___/___ _____ _____

Alert Message: The concurrent use of didanosine (Videx/Videx EC) with a ribavirin-containing agent is contraindicated. Co-administration of these agents may cause significant increases in blood concentrations of didanosine and its active metabolite, resulting in increased risk of didanosine-related toxicities including fatal hepatic failure, peripheral neuropathy, pancreatitis and symptomatic hyperlactatemia/lactic acidosis.

Conflict Code: DD – Drug/Drug Interactions

Util A	Util B	Util C
Didanosine	Ribavirin	

References:
Videx EC Prescribing Information, Nov. 2011, Bristol-Myers Squibb.
Clinical Pharmacology, 2012 Elsevier/Gold Standard.
Facts & Comparisons, 2012 Updates.

13. Rilpivirine / Prolongation Agents ___/___ _____ _____

Alert Message: Edurant (rilpivirine) has been shown to prolong the QTc interval and the concurrent use of other agents that prolong the QTc interval may result in additive effects increasing the risk of potentially life-threatening cardiac arrhythmias, including torsades de pointes.

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

Util A	Util B					Util C
Rilpivirine	Albuterol	Disopyramide	Imipramine	Pazopanib	Thioridazine	
	Alfuzosin	Dofetilide	Indapamide	Pentamidine	Tizanidine	
	Amantadine	Dolasetron	Isradipine	Pimozide	Tolterodine	
	Amiodarone	Doxepin	Itraconazole	Posaconazole	Trazodone	
	Amitriptyline	Dronedarone	Ketoconazole	Procainamide	Trimipramine	
	Amphetamine	Droperidol	Lapatinib	Propafenone	Vandetanib	
	Arsenic Trioxide	Ephedrine	Levalbuterol	Protriptyline	Vardenafil	
	Asenapine	Epinephrine	Levofloxacin	Quetiapine	Venlafaxine	
	Atazanavir	Erythromycin	Lithium	Quinidine	Ziprasidone	
	Atomoxetine	Escitalopram	Metaproterenol	Ranolazine	Zolmitriptan	
	Azithromycin	Felbamate	Methadone	Risperidone	Ezogabine	
	Chloral Hydrate	Flecainide	Moexipril/HCTZ	Rasagiline	Indacaterol	
	Chloroquine	Fluconazole	Moxifloxacin	Salmeterol		
	Chlorpromazine	Fluoxetine	Nicardipine	Saquinavir		
	Ciprofloxacin	Foscarnet	Nilotinib	Sertraline		
	Citalopram	Fosphenytoin	Norfloxacin	Solifenacin		
	Clarithromycin	Galantamine	Nortriptyline	Sotalol		
	Clomipramine	Gemifloxacin	Octreotide	Sunitinib		
	Clozapine	Granisetron	Ofloxacin	Tacrolimus		
	Dasatinib	Haloperidol	Ondansetron	Tamoxifen		
	Desipramine	Ibutilide	Paliperidone	Telithromycin		
	Diphenhydramine	Iloperidone	Paroxetine	Terbutaline		

References:
Edurant Prescribing Information, August 2012, Tibotec Therapeutics.
Clinical Pharmacology, 2012 Elsevier/Gold Standard.
Facts & Comparisons, 2012 Updates.

Criteria Recommendations	*Accepted*	*Approved As Amended*	*Rejected*

14. Cyclosporine / RA / Renal Imp & Uncontrolled HTN & Malignancies ___√___ _____ _____

Alert Message: The use of cyclosporine (i.e., Neoral & Gengraf) is contraindicated in rheumatoid arthritis patients with abnormal renal function, uncontrolled hypertension, or malignancies.

Conflict Code: MC – Drug/Disease Precaution/Warning

Drugs/Diseases

Util A	Util B	Util C (Include)
Neoral	Rheumatoid Arthritis	Abnormal Renal Function
Gengraf		Hypertension
		Malignancies

References;
Facts & Comparisons, 2012 Updates.
Neoral Prescribing Information, August 2012, Novartis Pharmaceuticals Corp.
Gengraf Prescribing information, 2010, Abbott Laboratories.

15. Teriflunomide / Overutilization ___√___ _____ _____

Alert Message: The manufacturer's maximum recommended daily dose of Aubagio (teriflunomide) is 14 mg.

Conflict Code: ER - Overutilization

Drugs/Diseases

Util A	Util B	Util C
Teriflunomide		

Max Dose: 14mg/day

References:
Aubagio Prescribing Information, Sept. 2012, Genzyme Corporation.

16. Teriflunomide / Hepatic Impairment (Black Box Warning) ___√___ _____ _____

Alert Message: Aubagio (teriflunomide) use is contraindicated in patients with severe hepatic impairment as it may increase the risk of hepatic injury. Teriflunomide is the principal active metabolite of leflunomide a drug that has been reported to cause severe liver injury. If drug induced liver injury is suspected, discontinue teriflunomide and start accelerated elimination procedure.

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

Drugs/Diseases

Util A	Util B	Util C
Teriflunomide	Hepatic Impairment	

References:
Aubagio Prescribing Information, Sept. 2012, Genzyme Corporation.

Criteria Recommendations	*Accepted*	*Approved As Amended*	*Rejected*

17. Teriflunomide / Pregnancy / Miscarriage, Delivery, Contraceptives ____√____ _____ _____

Alert Message: Aubagio (teriflunomide) is contraindicated in pregnant women or in women of childbearing potential who are not using reliable contraception. If the drug is required during pregnancy, or if the patient becomes pregnant while taking the drug, apprise the patient of the potential harm to the fetus. If pregnancy does occur during treatment discontinue drug immediately and initiate an accelerated elimination procedure. Also inform patient that there is an Aubagio pregnancy registry available.

Conflict Code: MC – Drug/Diagnosis Precaution/Warning (Black Box Warning)
Drugs/Diseases

Util A	Util B	Util C **(Negate)**
Teriflunomide	Pregnancy	Miscarriage
		Abortion
		Delivery
		Contraceptives

Age Range: 12-50 yoa

References:
Aubagio Prescribing Information, Sept. 2012, Genzyme Corporation.

18. Teriflunomide / Leflunomide ____√____ _____ _____

Alert Message: The concurrent administration of Aubagio (teriflunomide) and leflunomide is contraindicated. Teriflunomide is the principal active metabolite of leflunomide and coadministration of these agents would result in elevated plasma concentrations of teriflunomide.

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

Util A	Util B	Util C
Teriflunomide	Leflunomide	

References:
Aubagio Prescribing Information, Sept. 2012, Genzyme Corporation.

19. Teriflunomide / CYP2C8 Substrates ____√____ _____ _____

Alert Message: The concurrent administration of Aubagio (teriflunomide), a CYP2C8 inhibitor, with a CYP2C8 substrate (e.g., repaglinide, pioglitazone and rosiglitazone) may result in increased concentrations of the substrate. Therefore, monitoring patients for increased exposure to the substrate is recommended.

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

Util A	Util B	Util C
Teriflunomide	Repaglinide	
	Pioglitazone	
	Rosiglitazone	
	Sitagliptin	
	Treprostinil	
	Amiodarone	

References:
Aubagio Prescribing Information, Sept. 2012, Genzyme Corporation.
Clinical Pharmacology, 2012 Elsevier/Gold Standard.

Criteria Recommendations	*Accepted*	*Approved As Amended*	*Rejected*

20. Teriflunomide / Ethinyl Estradiol & Levonorgestrel ___√___ _____ _____

Alert Message: The concurrent administration of Aubagio (teriflunomide) and ethinyl estradiol-containing or levonorgestrel-containing oral contraceptives may result in increased concentrations of the oral contraceptive. Consideration should be given to the type or dose of oral contraceptives used in combination with teriflunomide.

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

Util A	Util B	Util C
Teriflunomide	Ethinyl Estradiol	
	Levonorgestrel	

References:
Aubagio Prescribing Information, Sept. 2012, Genzyme Corporation.

21. Teriflunomide / CYP1A2 Substrates ___√___ _____ _____

Alert Message: The concurrent administration of Aubagio (teriflunomide), a CYP1A2 inducer, with a CYP1A2 substrate (e.g., duloxetine, alosetron and tizanidine) may result in decreased concentrations of the substrate. Therefore, monitoring patients for reduced efficacy of the CYP1A2 substrate is recommended.

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

Util A	Util B		Util C
Teriflunomide	Duloxetine	Alosetron	Zileuton
	Fluvoxamine	Ondansetron	Almotriptan
	Amitriptyline	Mexiletine	Frovatriptan
	Clomipramine	Propafenone	Zolmitriptan
	Desipramine	Carvedilol	Rasagiline
	Imipramine	Propranolol	Selegiline
	Nortriptyline	Verapamil	Ropinirole
	Mirtazapine	Triamterene	Riluzole
	Asenapine	Pentoxifylline	Tamoxifen
	Clozapine	Cyclobenzaprine	Cinacalcet
	Olanzapine	Tizanidine	Erlotinib
	Thioridazine	Acetaminophen	Ramelteon
	Azelastine	Naproxen	Zolpidem
	Diphenhydramine	Theophylline	

References:
Aubagio Prescribing Information, Sept. 2012, Genzyme Corporation.
Zhou SF, Yang LP, Zhou ZW, et al., Insights into the Substrate Specificity, Inhibitors, Regulation, and Polymorphisms and the Clinical Impact of Human Cytochrome P450 1A2. AAPS Jrnl. 2009 Sep;11(3): 481-494.
Facts & Comparisons, 2012 Updates.

22. Teriflunomide / Warfarin ___√___ _____ _____

Alert Message: The concurrent administration of Aubagio (teriflunomide) and warfarin may result in a 25% decrease in the peak INR. When warfarin is co-administered with teriflunomide, close INR follow-up and monitoring is recommended.

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

Util A	Util B	Util C
Teriflunomide	Warfarin	

References:
Aubagio Prescribing Information, Sept. 2012, Genzyme Corporation.

Criteria Recommendations	*Accepted*	*Approved As Amended*	*Rejected*

23. Teriflunomide / Peripheral Neuropathy ___√___ _____ _____

Alert Message: Peripheral neuropathy has been reported in patients receiving Aubagio (teriflunomide). If a patient taking teriflunomide develops symptoms consistent with peripheral neuropathy, such as bilateral numbness or tingling of hands or feet, consider discontinuing teriflunomide therapy and performing an accelerated elimination procedure.

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

Util A	Util B	Util C
Teriflunomide	Peripheral Neuropathy	
	Paresthesia	

References:
Aubagio Prescribing Information, Sept. 2012, Genzyme Corporation.

24. Teriflunomide / Acute Renal Failure & Hyperkalemia ___√___ _____ _____

Alert Message: Patients receiving Aubagio (teriflunomide) with symptoms of renal failure or hyperkalemia should have renal function and potassium levels monitored. In clinical trials, transient acute renal failure and hyperkalemia (1.2% and 1%, respectively) were reported in subjects receiving teriflunomide.

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

Util A	Util B	Util C
Teriflunomide	Acute Renal Failure	
	Hyperkalemia	

References:
Aubagio Prescribing Information, Sept. 2012, Genzyme Corporation.

25. Teriflunomide / Hypertension / Antihypertensive Meds (Negate) ___√___ _____ _____

Alert Message: Aubagio (teriflunomide) can increase blood pressure therefore blood pressure should be checked before initiating teriflunomide treatment and periodically thereafter. Elevated blood pressure should be appropriately managed during teriflunomide therapy.

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

Util A	Util B	Util C **(Negate)**
Teriflunomide	Hypertension	Antihypertensive Medications

References:
Aubagio Prescribing Information, Sept. 2012, Genzyme Corporation.

Criteria Recommendations	*Accepted*	*Approved As Amended*	*Rejected*

26. Teriflunomide / Hepatotoxic Drugs ___/___ _____ _____

Alert Message: Aubagio (teriflunomide) is the principal active metabolite of leflunomide a drug that has been reported to cause severe liver injury. Concomitant use of teriflunomide with other potentially hepatotoxic drugs may increase the risk of severe liver injury. If drug induced liver injury is suspected, discontinue teriflunomide and start accelerated elimination procedure.

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

Util A	Util B				
Teriflunomide	Amoxicillin/Clavulanate	Abacavir	Fluoxetine	Sertraline	Cyclosporine
	Erythromycin	Allopurinol	Hydralazine	Stavudine	Sirolimus
	Cotrimoxazole	Amiloride	HCTZ	Sulfasalazine	Tacrolimus
	Isoniazid	Amiodarone	Hydrocodone	Tamoxifen	Atomoxetine
	Disulfiram	Aspirin	Itraconazole	Venlafaxine	Balsalazide
	Flutamide	Atenolol	Ketoconazole	Zafirlukast	Protease Inh.
	Carbamazepine	Bleomycin	Labetalol	Niacin	Delavirdine
	Nitrofurantoin	Bromfenac	Lamivudine	Naltrexone	Efavirenz
	Acetaminophen	Bupropion	Levofloxacin	Sunitinib	Nevirapine
	Ticlopidine	Butorphanol	Lisinopril	Lapatinib	NSAIDs
	Rifampin	Captopril	Melphalan	Pazopanib	Statins
	Valproic Acid	Cefadroxil	Methyldopa	Methotrexate	
	Ciprofloxacin	Cefepime	Nefazodone	Procainamide	
	Ranitidine	Chlorpromazine	Nelfinavir	Azathioprine	
	Levofloxacin	Clarithromycin	Norfloxacin	Bosentan	
	Phenytoin	Cyclophosphamide	Omeprazole	Fluconazole	
	Enalapril	Dapsone	Orlistat	Posaconazole	
	Chlorpromazine	Dicloxacillin	Paroxetine	Voriconazole	
	Azithromycin	Didanosine	Pemoline	Felbamate	
	Mercaptopurine	Doxycycline	Propylthiouracil	Chlorzoxazone	
	Telithromycin	Ezetimibe	Pyrazinamide	Dantrolene	
	Duloxetine	Felodipine	Quetiapine	Rifapentine	
	Ethinyl Estradiol-Levonorgestrel		Ranitidine	Oxandrolone	

References:
Aubagio Prescribing Information, Sept. 2012, Genzyme Corporation.
Chang CY & Schiano TD. Review Article; Drug Hepatotoxicity. Aliment Pharmacol Ther. May 15;25(10):1135-1151
Suzuki A, Andrade RJ, Bjornsson E, et al., Drugs Associated with Hepatotoxicity and Their Reporting Frequency of Liver Adverse Events in VigiBase: Unified List Based on International Collaborative Work. Drug Saf. 2010 Jun1;33(6):503-522.

27. Stribild / Contraindicated Drugs ___/___ _____ _____

Alert Message: Coadministration of Stribild (elvitegravir/cobicistat/emtricitabine/tenofovir) is contraindicated with drugs that are highly dependent on CYP3A4 for clearance and for which elevated plasma concentrations are associated with serious and/or life-threatening adverse events.

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

Util A	Util B	Util C
Stribild	Alfuzosin	
	Ergot Derivatives	
	Lovastatin	
	Simvastatin	
	Pimozide	
	Revatio	
	Triazolam	
	Midazolam - Oral	

References:
Stribild Prescribing Information, August 2012, Gilead Sciences, Inc.
Clinical Pharmacology, 2012 Elsevier/Gold Standard.

Criteria Recommendations	*Accepted*	*Approved As Amended*	*Rejected*

28. Stribild / Rifampin ___√___ _____ _____

Alert Message: Coadministration of Stribild (elvitegravir/cobicistat/emtricitabine/tenofovir) is contraindicated with the potent CYP3A4 inducer rifampin. Concurrent use of these agents may result in significant decreases in the plasma concentrations of cobicistat and elvitegravir (CYP3A4 substrates), leading to loss of virologic response and possible resistance.

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

Util A	Util B	Util C
Stribild	Rifampin	

References:
Stribild Prescribing Information, August 2012, Gilead Sciences, Inc.
Clinical Pharmacology, 2012 Elsevier/Gold Standard.

29. Stribild / Non-adherence ___√___ _____ _____

Alert Message: Nonadherence to antiretroviral therapy may result in insufficient drug plasma levels and partial suppression of viral load leading to the development of resistance, HIV progression, and increased mortality.

Conflict Code: LR - Nonadherence
Drugs/Diseases

Util A	Util B	Util C
Stribild		

References:
Stribild Prescribing Information, August 2012, Gilead Sciences, Inc.
Panel on Antiretroviral Guidelines for Adults and Adolescents. Guidelines for the Use of Antiretroviral Agents in HIV-1 Infected Adults and Adolescents. Department of Health and Human Services. March 27, 2012;1-167.
Available at: http://www.aidsinfo.nih.gov/ContentFiles/AdultandAdolescentGL.pdf.
Beer L, Heffelfinger J, Frazier E. et al. Use of and Adherence to Antiretroviral Therapy in a Large U.S. Sample of HIV-Infected Adults in Care, 2007-2008. Open AIDS J. 2012;6:213-223.

30. Stribild / Renal Impairment ___√___ _____ _____

Alert Message: Stribild (elvitegravir/cobicistat/emtricitabine/tenofovir) should not be initiated in patients with estimated creatinine clearance below 70 ml/min. Because Stribild is a fixed-dose combination tablet it should be discontinued if estimated creatinine clearance declines below 50 mL/min during treatment as dose interval adjustment required for emtricitabine and tenofovir cannot be achieved.

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

Util A	Util B	Util C
Stribild	Renal Impairment	

References:
Stribild Prescribing Information, August 2012, Gilead Sciences, Inc.
Clinical Pharmacology, 2012 Elsevier/Gold Standard.

Criteria Recommendations	*Accepted*	*Approved As Amended*	*Rejected*

31. Stribild / Hepatic Impairment ___√___ _____ _____

Alert Message: Stribild (elvitegravir/cobicistat/emtricitabine/tenofovir) use has not been evaluated in patients with severe hepatic impairment (Child-Pugh Class C) and therefore its use is not recommended in this population. No dose adjustment of Stribild is required in patients with mild (Child-Pugh Class A) or moderate (Child-Pugh Class B) hepatic impairment.

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

Util A	Util B	Util C
Stribild	Hepatic Impairment	

References:
Stribild Prescribing Information, August 2012, Gilead Sciences, Inc.
Clinical Pharmacology, 2012 Elsevier/Gold Standard.

32. Stribild / CYP3A4 Inducers ___√___ _____ _____

Alert Message: Coadministration of Stribild (elvitegravir/cobicistat/emtricitabine/tenofovir) with the CYP3A4 inducers rifabutin or rifapentine is not recommended. Concurrent use with either inducer may result in significant decreases in the plasma concentrations of cobicistat and elvitegravir (CYP3A4 substrates), leading to loss of virologic response and possible resistance.

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

Util A	Util B	Util C
Stribild	Rifabutin	
	Rifapentine	

References:
Stribild Prescribing Information, August 2012, Gilead Sciences, Inc.
Clinical Pharmacology, 2012 Elsevier/Gold Standard.

33. Stribild / Anticonvulsants ___√___ _____ _____

Alert Message: Coadministration of Stribild (elvitegravir/cobicistat/emtricitabine/tenofovir) with the CYP3A4 inducers carbamazepine, oxcarbazepine, phenytoin or phenobarbital may significantly decrease plasma concentrations of elvitegravir and cobicistat (CYP3A4 substrates), which may result in loss of therapeutic effect and development of resistance. Alternative anticonvulsants should be considered.

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

Util A	Util B	Util C
Stribild	Carbamazepine	
	Oxcarbazepine	
	Phenytoin	
	Phenobarbital	

References:
Stribild Prescribing Information, August 2012, Gilead Sciences, Inc.

Criteria Recommendations	*Accepted*	*Approved As Amended*	*Rejected*

34. Stribild / Clarithromycin ___√___ _____ _____

Alert Message: Coadministration of Stribild (elvitegravir/cobicistat/emtricitabine/tenofovir) with clarithromycin may increase plasma concentrations of both clarithromycin and cobicistat. Patients with a CrCl between 50mL/min and 60mL/min should have the clarithromycin dose reduced by 50%. No dose adjustment is required for CrCl of 60mL/min or greater.

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

Util A	Util B	Util C
Stribild	Clarithromycin	

References:
Stribild Prescribing Information, August 2012, Gilead Sciences, Inc.

35. Stribild / Telithromycin ___√___ _____ _____

Alert Message: Coadministration of Stribild (elvitegravir/cobicistat/emtricitabine/tenofovir) with telithromycin may increase plasma concentrations of both telithromycin and cobicistat. Monitor patient for adverse effects of either agent.

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

Util A	Util B	Util C
Stribild	Telithromycin	

References:
Stribild Prescribing Information, August 2012, Gilead Sciences, Inc.

36. Stribild / Neuroleptics ___√___ _____ _____

Alert Message: Coadministration of Stribild (elvitegravir/cobicistat/emtricitabine/tenofovir) with a neuroleptic agent may increase plasma concentrations of the neuroleptic. A decrease in the dose of the neuroleptic may be needed when co-administered with Stribild.

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

Util A	Util B	Util C
Stribild	Antipsychotics 1st & 2nd Generation	

References:
Stribild Prescribing Information, August 2012, Gilead Sciences, Inc.

37. Stribild / Ketoconazole and Itraconazole ___√___ _____ _____

Alert Message: Coadministration of Stribild (elvitegravir/cobicistat/emtricitabine/tenofovir) with ketoconazole or itraconazole may increase plasma concentrations of the antifungal due to inhibition by cobicistat of CYP3A4-mediated antifungal metabolism. The maximum daily dose of ketoconazole or itraconazole should not exceed 200mg per day.

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

Util A	Util B	Util C (Include)
Ketoconazole		Stribild
Itraconazole		

Max Dose: 200mg/day

References:
Stribild Prescribing Information, August 2012, Gilead Sciences, Inc.

Criteria Recommendations	*Accepted*	*Approved As Amended*	*Rejected*

38. Stribild / Voriconazole ____√____ _____ _____

Alert Message: An assessment of benefit/risk ratio is recommended to justify use of Stribild (elvitegravir/cobicistat/emtricitabine/tenofovir) with Vfend (voriconazole). Concurrent use of these agents may increase plasma concentrations of voriconazole due to inhibition by cobicistat of CYP3A4-mediated voriconazole metabolism.

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

Util A	Util B	Util C
Stribild	Voriconazole	

References:
Stribild Prescribing Information, August 2012, Gilead Sciences, Inc.

39. Stribild / Colchicine / Renal & Hepatic Impairment ____√____ _____ _____

Alert Message: Stribild (elvitegravir/cobicistat/emtricitabine/tenofovir) should not be administered with colchicine to patients with renal or hepatic impairment. Concurrent use of these agents in patients with these disease states may significantly increase the plasma concentrations of colchicine.

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

Util A	Util B	Util C (Include)
Stribild	Colchicine	Renal Impairment
		Hepatic Impairment

References:
Stribild Prescribing Information, August 2012, Gilead Sciences, Inc.

40. Colchicine / Stribild ____√____ _____ _____

Alert Message: Coadministration of Stribild (elvitegravir/cobicistat/emtricitabine/tenofovir) with colchicine may increase colchicine plasma concentrations and dosage adjustment of colchicine is required. If used to treat gout flares, administer a single 0.6mg dose of colchicine, followed by 0.3mg 1 hour later (repeat no sooner than 3 days). If used for gout prophylaxis and the original regimen was 0.6mg BID, reduce dose to 0.3mg QD, if regimen was 0.6mg QD, reduce to 0.3mg QOD. If used for familial Mediterranean fever the maximum daily dose is 0.6mg daily.

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

Util A	Util B	Util C (Include)
Colchicine		Stribild

Max Dose: 0.6mg/day
References:
Stribild Prescribing Information, August 2012, Gilead Sciences, Inc.

Criteria Recommendations	*Accepted*	*Approved As Amended*	*Rejected*

41. Stribild / Dexamethasone ___√___ _____ _____

Alert Message: Caution is advised when co-administering Stribild (elvitegravir/ cobicistat/emtricitabine/tenofovir) with the CYP3A4 inducer dexamethasone. Concurrent use may significantly decrease plasma concentrations of elvitegravir and cobicistat (CYP3A4 substrates) leading to loss of therapeutic effect and development of resistance.

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

Util A	Util B	Util C
Stribild	Dexamethasone	

References:
Stribild Prescribing Information, August 2012, Gilead Sciences, Inc.

42. Stribild / Fluticasone ___√___ _____ _____

Alert Message: Coadministration of Stribild (elvitegravir/cobicistat/emtricitabine/tenofovir) with an inhaled or nasal fluticasone product may increase plasma concentrations of fluticasone resulting in reduced serum cortisol concentrations. Alternative corticosteroids should be considered, particularly for long term use.

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

Util A	Util B	Util C
Stribild	Fluticasone Inhaled & Nasal	

References:
Stribild Prescribing Information, August 2012, Gilead Sciences, Inc.

43. Stribild / Salmeterol ___√___ _____ _____

Alert Message: Coadministration of Stribild (elvitegravir/cobicistat/emtricitabine/tenofovir) with salmeterol is not recommended. Concurrent use may result in increased risk of cardiovascular adverse events associated with salmeterol, including QT prolongation, palpitations, and sinus tachycardia.

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

Util A	Util B	Util C
Stribild	Salmeterol	

References:
Stribild Prescribing Information, August 2012, Gilead Sciences, Inc.

44. Stribild / Atorvastatin ___√___ _____ _____

Alert Message: Coadministration of Stribild (elvitegravir/cobicistat/emtricitabine/tenofovir) with an atorvastatin-containing product (Lipitor and Caduet) should be initiated at the lowest starting dose of atorvastatin and titrated carefully while monitoring for atorvastatin-related adverse effects. Concurrent use of these agents may result in increased atorvastatin plasma concentrations due to inhibition by cobicistat of CYP3A4-mediated atorvastatin metabolism.

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

Util A	Util B	Util C
Stribild	Atorvastatin	

References:
Stribild Prescribing Information, August 2012, Gilead Sciences, Inc.

Criteria Recommendations	*Accepted*	*Approved As Amended*	*Rejected*

45. Stribild / CYP3A4, 2D6, P-gp, BCRP, OATP1B1 or OATP1B3 Substrates & Agents undergoing Active Tubular Secretion ___J___ _____ _____

Alert Message: Caution is advised when co-administering Stribild (elvitegravir/ cobicistat/emtricitabine/tenofovir) with drugs that are primarily metabolized by CYP3A4 or CYP2D6, or are substrates of P-gp, BCRP, OATP1B1 or OATP1B3 as concurrent use may result in increased plasma concentrations of the substrate. Clinical and/or therapeutic drug concentration monitoring is advised during coadministration.

Conflict Code: DD – Drug/Drug Interaction

Drugs/Diseases

Util A	Util B*			Util C
Stribild	SSRIs	Pitavastatin	Salicylates	Saxagliptin
	TCAs	Rosuvastatin	Thiazides	Linagliptin
	Trazodone	Tamoxifen	Acyclovir	Clonazepam
	Bupropion	Valsartan	Cidofovir	Ethosuximide
	CCBs	Olmesartan	Ganciclovir	Cyclosporine
	Carvedilol	Telmisartan	Valacyclovir	Tacrolimus
	Metoprolol	Digoxin	Valganciclovir	Sirolimus
	Nebivolol	Warfarin	Ezetimibe	
	Propranolol	Metformin	Glyburide	
	Timolol	Morphine	Repaglinide	
	Antiarrhythmics	Vancomycin	Nateglinide	

References:

Stribild Prescribing Information, August 2012, Gilead Sciences, Inc.
FDA: Drug Development and Drug Interactions: Table of Substrates, Inhibitors and Inducers. [Accessed 10/17/2012] Available at: http://www.fda.gov/Drugs/DevelopmentApprovalProcess/DevelopmentResources/DrugInteractionsLabeling/ucm093664.htm#4

Drugs that are substrates but are contraindicated or have other more specific alerts are not included in this group.

Criteria Recommendations	*Accepted*	*Approved As Amended*	*Rejected*

46. Stribild / Nephrotoxic Drugs ___√___ _____ _____

Alert Message: Avoid administering Stribild (elvitegravir/cobicistat/emtricitabine/tenofovir) with concurrent or recent use of nephrotoxic agents. Renal impairment, including cases of acute renal failure and Fanconi syndrome, has been reported with Stribild use.

Conflict Code: DD – Drug/Drug Interaction

Drugs/Diseases

Util A	Util B		Util C
Stribild	Acetaminophen	Adefovir	Zoledronate
	Aspirin	Cidofovir	Bea Lactams
	NSAIDs	Indinavir	Clopidogrel
	Amitriptyline	Benzodiazepines	Tetracycline
	Doxepin	Cyclosporine	Statins
	Fluoxetine	Tacrolimus	Gemfibrozil
	Lithium	ACEIs	Mesalamine
	Acyclovir	ARBs	
	Neomycin	Statins	
	Paromomycin	Carmustine	
	Foscarnet	Methotrexate	
	Ganciclovir	Loop Diuretics	
	Pentamidine	Triamterene	
	Quinolones	Proton Pump Inhibitors	
	Rifampin	Allopurinol	
	Sulfonamides	Haloperidol	
	Vancomycin	Pamidronate	
	Doxylamine	Phenytoin	
	Diphenhydramine	Ranitidine	

References:

Stribild Prescribing Information, August 2012, Gilead Sciences, Inc.
Naughton CA. Drug-Induced Nephrotoxicity. Am Fam Physician. 2008 Sep.15;78(6):743-750.

47. Stribild / CYP3A4 Sedative Hypnotics ___√___ _____ _____

Alert Message: Coadministration of Stribild (elvitegravir/cobicistat/emtricitabine/tenofovir) and a sedative/hypnotic agent that is a CYP3A4 substrate may result in elevated plasma concentrations of the sedative/hypnotic due to inhibition by cobicistat of CYP3A4-mediated metabolism. Dose reduction and clinical monitoring of the sedative/hypnotic agent is recommended when used currently with Stribild.

Conflict Code: DD – Drug/Drug Interaction

Drugs/Diseases

Util A	Util B	Util C
Stribild	Clorazepate	
	Diazepam	
	Estazolam	
	Flurazepam	
	Chlordiazepoxide	
	Alprazolam	
	Buspirone	
	Zolpidem	
	Clobazam	

References:

Stribild Prescribing Information, August 2012, Gilead Sciences, Inc.

Criteria Recommendations	*Accepted*	*Approved As Amended*	*Rejected*

48. Stribild / Ethinyl Estradiol-Norgestimate ___√___ _____ _____

Alert Message: Coadministration of Stribild (elvitegravir/cobicistat/emtricitabine/tenofovir) and an ethinyl estradiol/norgestimate contraceptive may result in elevated norgestimate and reduced ethinyl estradiol concentrations. Risk associated with these altered levels may include insulin resistance, dyslipidemia and venous thrombosis. Consider the risk/benefits associated with concurrent use, particularly in women who have risk factors for these events. Alternative (non-hormonal) methods of contraception can be considered.

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

Util A	Util B	Util C
Stribild	Ethinyl Estradiol/Norgestimate	

References:
Stribild Prescribing Information, August 2012, Gilead Sciences, Inc.

49. Atazanavir / PR Interval Prolongation ___√___ _____ _____

Alert Message: Reyataz (atazanavir) has been shown to prolong the PR interval in some patients. Atazanavir should be used with caution in patients with preexisting conduction system disease or when administered with other drugs that may prolong the PR interval.

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

Util A	Util B	Util C
Atazanavir	PR Prolongation	
	Conduction Disorder	

References:
Reyataz Prescribing Information, March 2012, Bristol-Myers Squibb.

50. Atazanavir / PR Interval Prolongation ___√___ _____ _____

Alert Message: Reyataz (atazanavir) has been shown to prolong the PR interval in some patients. Atazanavir should be used with caution in patients with preexisting conduction system disease or when administered with other drugs that may prolong the PR interval.

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

Util A	Util B		Util C
Atazanavir	Digoxin	Labetalol	
	Quinidine	Timolol	
	Procainamide	Pindolol	
	Disopyramide	Bisoprolol	
	Flecainide	Acebutolol	
	Amiodarone	Betaxolol	
	Propafenone	Penbutolol	
	Verapamil	Carteolol	
	Lacosamide	Sotalol	
	Propranolol	Nebivolol	
	Metoprolol	Ritonavir	
	Nadolol	Atazanavir	

References:
Reyataz Prescribing Information, March 2012, Bristol-Myers Squibb.

Criteria Recommendations	*Accepted*	*Approved As Amended*	*Rejected*

51. Complera / Non-adherence ___√___ _____ _____

Alert Message: Nonadherence to antiretroviral therapy may result in insufficient drug plasma levels and partial suppression of viral load leading to the development of resistance, HIV progression, and increased mortality.

Conflict Code: LR - Nonadherence
Drugs/Diseases
Util A Util B Util C
Complera

References:
Complera Prescribing Information, August 2012, Gilead Sciences, Inc.
Panel on Antiretroviral Guidelines for Adults and Adolescents. Guidelines for the Use of Antiretroviral Agents in HIV-1 Infected Adults and Adolescents. Department of Health and Human Services. March 27, 2012;1-167.
Available at: http://www.aidsinfo.nih.gov/ContentFiles/AdultandAdolescentGL.pdf.
Beer L, Heffelfinger J, Frazier E. et al. Use of and Adherence to Antiretroviral Therapy in a Large U.S. Sample of HIV-Infected Adults in Care, 2007-2008. Open AIDS J. 2012;6:213-223.

Stephanie McGee Azar, Commissioner (X) Approve ( ) Deny 3/8/13 Date

Robert Moon, M.D., Deputy Commissioner and Medical Director (X) Approve ( ) Deny 3-5-13 Date

Kathy Hall, Deputy Commissioner (✓) Approve ( ) Deny 3/5/13 Date