Alabama Medicaid DUR Board Meeting Minutes
April 24, 2013

Members Present: Denyse Thornley-Brown, Paula Thompson, Kelli Littlejohn, Bernie Olin, Wendy Gomez, David Harwood, Dan McConaghy, Jimmy Jackson, Frank Pettyjohn, Robert Moon

Also Present: Tiffany Minnifield, Clemice Hurst, Lori Thomas, Gary Frazier

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

Members Absent: Rhonda Harden, Donald Marks

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 January 23, 2013 meeting were presented and reviewed. Robert Moon made a motion to approve the minutes as presented and Paula Thompson 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 November 2012. She reported 9,197 total PA and override requests. She then reported 25,382 electronic PA requests for the same time frame. From the Prior Authorization and Override Response Time Ratio report for February 2012, L.Thomas reported that approximately 74% of all manual PAs and overrides were responded to in less than two hours, about 96-97% in less than four hours and 99% in less than eight hours. L. Thomas reminded the Board Members that 75% of PAs and overrides must be completed in less than 8 hours to meet contractual requirements. For the month of December 2012, L.Thomas reported 7,675 manual requests and 21,334 electronic PA requests. She reported that 80-81% of PAs and overrides were responded to in less than two hours, approximately 99% in less than four hours and 99% in less than eight hours. For the month of January 2013, L.Thomas reported 9,371 manual requests and 23,272 electronic PA requests for the same time frame. For January, L.Thomas reported that 71% of PAs and 69% of overrides were approved in less than two hours, approximately 94% in less than four hours and 99% approved in less than eight hours.

Program Summary Review: L.Thomas briefly reviewed the Alabama Medicaid Program Summary. She reported 4,494,970 total prescriptions, 239,277 average recipients per month and an average paid per prescription of $57.53 for the third and fourth quarter of 2012.

Cost Management Analysis: L.Thomas reported an average cost per claim of $58.26 for December 2012. From the 4th Quarter 2012 Drug Analysis, L.Thomas reported 76.8% generic utilization, 10.1% brand single-source, 4.3% brand multi-source (those requests which required a DAW override) and 8.9% OTC and "other". From the Top 25 Drugs Based on Number of Claims from 10/01/2012 – 12/31/2012, L.Thomas reported the top five drugs: hydrocodone-acetaminophen, amoxicillin, azithromycin, montelukast sodium, and omeprazole. L. Thomas reminded the Board that Singulair® became generic in August and therefore no claims were seen in the top 25 claims. She then reported the top five drugs from the Top 25 Drugs Based on Claims Cost from 10/01/2012 – 12/31/2012: Abilify®, Synagis®, Vyvanse®, Tamiflu®, and Focalin XR®. L. Thomas pointed out that Abilify remained at the top and that Synagis season ended on March 31, 2013. D. Thornley-Brown pointed out the utilization of Tamiflu. K. Littlejohn reminded the Board that Tamiflu was a preferred agent and that the reported timeframe was during the influenza season. 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,Corticosteroids (Respiratory Tract), Amphetamines, Hemostatics, and Respiratory and CNS Stimulants. K. Littlejohn reminded the Board that all antipsychotics require prior authorization. L. Thomas referred to Abilify's status as the top drug for claims cost and reminded the Board that Abilify is not available in a generic form.

UPDATES

Hydrocodone Utilization: L. Thomas presented a summary of prescriber responses received from the top 100 prescribers of hydrocodone focused intervention letter distributed by the Academic Detailers. L. Thomas mentioned that actually 99 prescribers were being targeted as one prescriber had passed away. L. Thomas stated that 92 letters had been delivered as of April 9, 2013, and 54 responses had been returned, which resulted in a 59% response return rate. P. Thompson mentioned targeting the same prescribers in six months to see if their hydrocodone prescribing patterns have changed. Board members supported this idea. K. Littlejohn explained several ways that the Agency is working to combat prescription drug abuse: modifying existing legislation to grant Medicaid access to Prescription Drug Monitoring Program (PDMP) data and expanding the pharmacy lock-in program. W. Gomez expressed some concern about the current PDMP database. K. Littlejohn asked that any concerns be sent to her so that she could pass along the information to the Alabama Department of Public Health.

Proposed Criteria: L.Thomas presented the proposed set of 81 criteria to the Board. T.Minnifield instructed the Board members to mark their ballots. Of the 81 criteria, results from the criteria vote returned 71 approved, 8 approved as amended, and 2 rejected.

Medicaid Update: T. Minnifield began the Medicaid Update by reminding the Board members that all Medicaid information discussed is available online, as well as any new Medicaid ALERTs. T. Minnifield discussed the new DEA edit that will begin on May 13, 2013. Several questions were posed by Board members regarding the future of the Agency. K. Littlejohn explained that nothing has been finalized as the Legislature is still in session. R. Moon gave a brief overview of the Regional Care Organizations (RCOs).

P & T Committee Update: C. Hurst began the P & T Update by informing the Board that the last meeting was held on February 13, 2013, and covered the pharmacotherapy class re-reviews from the November 2012 meeting and the February 2013 class re-reviews. The double meeting was held due to a lack of quorum at the November 2012 P & T meeting. The next P & T meeting is scheduled for May 15, 2013, at 9am and will cover several cardiovascular drug classes.

New Business: T. Minnifield notified the Board that the next DUR meeting will be held on July 24, 2013, and that a vote will be taken for vice chair. D.Thornley-Brown made a motion to adjourn the meeting. The motion was seconded by P. Thompson. A voice vote to adjourn was unanimous. The meeting was adjourned at 2:30p.m.

Next Meeting Date: The next DUR Board meeting will be held on July 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. Omega-3-Acid Ethyl Esters / Therapeutic Appropriateness	_____	___√___	_____

Alert Message: The safety/effectiveness of Lovaza (omega-3-acid ethyl esters) has not been established in patients less than 18 years of age.

Conflict Code: TA – Therapeutic Appropriateness
Drugs/Diseases

Util A	Util B	Util C
Omega-3-acid ethyl esters		

Age Range: 0 – 17 yoa

References:
Lovaza Prescribing Information, August 2012, GlaxoSmithKline.
Clinical Pharmacology, 2012 Elsevier / Gold Standard.

2. Omega-3-Acid Ethyl Esters / Overuse	___√___	_____	_____

Alert Message: Lovaza (omega-3-acid ethyl esters) may be over-utilized. The manufacturer's maximum recommended dose is 4 grams per day, taken as a single 4 gram dose or 2 grams twice daily.

Conflict Code: ER - Overutilization
Drugs/Diseases

Util A	Util B	Util C
Omega-3-acid ethyl esters		

Max Dose: 4 grams daily

References:
Lovaza Prescribing Information, August 2012, GlaxoSmithKline.
Clinical Pharmacology, 2012 Elsevier / Gold Standard.

3. Omega-3-Acid Ethyl Esters / Therapeutic Duplication	___√___	_____	_____

Alert Message: Therapeutic duplication of omega-3 acids may be occurring. The safety/efficacy of coadministration of these agents has not been studied and, therefore, is not recommended.

Conflict Code: TD – Therapeutic Duplication
Drugs/Diseases

Util A	Util B	Util C
Omega-3-acid ethyl esters	Icosapent ethyl	

References:
Vascepa Prescribing Information, July 2012, Amarin Pharma Inc.
Lovaza Prescribing Information, August 2012, GlaxoSmithKline.
Clinical Pharmacology, 2012 Elsevier / Gold Standard.

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

4. Omega-3-Acid Ethyl Esters / Anticoagulants _____ ___√___ _____

Alert Message: Some studies have demonstrated prolongation of bleeding time when anticoagulants and omega-3 fatty acids are used concurrently. Patients receiving treatment with Lovaza (omega-3-acid ethyl esters) and drugs affecting coagulation should be monitored periodically.

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

Util A	Util B		Util C
Omega-3-acid ethyl esters	Aspirin	Dalteparin	Prasugrel
	NSAIDs	Enoxaparin	Ticagrelor
	Warfarin	Dabigatran	Ticlopidine
	Heparin	Anagrelide	SSRIs
	Fondaparinux	Dipyridamole	SNRIs
	Rivaroxaban	Cilostazol	Clopidogrel

References:
Lovaza Prescribing Information, August 2012, GlaxoSmithKline.
Clinical Pharmacology, 2012 Elsevier / Gold Standard.

5. Omega-3-Acid Ethyl Esters / Pregnancy / Pregnancy Negating ___√___ _____ _____

Alert Message: Lovaza (omega-3-acid ethyl esters) is FDA pregnancy category C. There are no adequate and well-controlled studies in pregnant women and it is unknown if omega-3-acid ethyl esters can cause fetal harm. Omega-3-acid ethyl esters should be used during pregnancy only if the potential benefit to the patient justifies the potential risk to the fetus.

Conflict Code: MC – Drug/Diagnosis Precaution/Warning/Contraindication
Drugs/Diseases

Util A	Util B	Util C **(Negating)**
Omega-3-Acid Ethyl Esters	Pregnancy ICD-9s	Delivery
		Miscarriage
		Abortion

References:
Lovaza Prescribing Information, August 2012, GlaxoSmithKline.
Clinical Pharmacology, 2012 Elsevier / Gold Standard.

6. Omega-3-Acid Ethyl Esters / Hepatic Impairment ___√___ _____ _____

Alert Message: Patients taking Lovaza (omega-3-acid ethyl esters) that have hepatic impairment should have ALT and AST levels monitored periodically.

Conflict Code: TA – Therapeutic Appropriateness
Drugs/Diseases

Util A	Util B	Util C (Include)
Omega-3-acid ethyl esters		Chronic Liver Disease
		Cirrhosis

References:
Lovaza Prescribing Information, August 2012, GlaxoSmithKline.
Clinical Pharmacology, 2012 Elsevier / Gold Standard.

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

7. Omega-3-Acid Ethyl Esters / Atrial Fibrillation or Flutter ____√____ _____ _____

Alert Message: In clinical trials with Lovaza (omega-3-acid ethyl esters), recurrent atrial fibrillation (AF) or persistent AF was seen in some patients with symptomatic paroxysmal AF or persistent AF. The clinical significance of these results is uncertain, but there may be an association between omega-3-acid ethyl esters and more frequent recurrences of symptomatic AF or flutter in these patients.

Conflict Code: TA – Therapeutic Appropriateness
Drugs/Diseases

Util A	Util B	Util C (Include)
Omega-3-acid ethyl esters		Atrial Fibrillation
		Atrial Flutter

References:
Lovaza Prescribing Information, August 2012, GlaxoSmithKline.
Clinical Pharmacology, 2012 Elsevier / Gold Standard.

8. Omega-3-Acid Ethyl Esters / Non-adherence ____√____ _____ _____

Alert Message: Based on refill history, your patients may be under-utilizing Lovaza (omega-3-acid ethyl esters). Non-adherence to the prescribed dosing regimen may result in sub-therapeutic effects which may lead to decreased patient outcomes and additional healthcare costs.

Conflict Code: LR – Nonadherence
Drugs/Diseases

Util A	Util B	Util C
Omega-3-acid ethyl esters		

References:
Schedlbauer A, Davis P, Fahey T. Interventions to Improve Adherence to Lipid Lowering Medication (Review). Cochrane Database System Rev. 2010 Mar 17;(3):CD004371.
Bersot T, Haffner S, Harris WS, et al., Hypertriglyceridemia: Management of Atherogenic Dyslipidemia. Jrnl of Fam Pract. 2006 Jul;55(7):S1-S8.
Osterberg L and Blaschke T. Adherence to Medication. N Engl J Med 2005;353:487-497.

9. Dronedarone / Therapeutic Appropriateness ____√____ _____ _____

Alert Message: The safety/effectiveness of Multaq (dronedarone) has not been established in patients less than 18 years of age.

Conflict Code: TA – Therapeutic Appropriateness
Drugs/Diseases

Util A	Util B	Util C
Dronedarone		

Age Range: 0 – 17 yoa

References:
Multaq Prescribing Information, September 2012, Sanofi-Aventis U.S.
Clinical Pharmacology, 2012 Elsevier / Gold Standard.

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

10. Dronedarone / Pulmonary Toxicity ____√____ _____ _____

Alert Message: Cases of interstitial lung disease (including pneumonitis and pulmonary fibrosis) have been reported in patients treated with Multaq (dronedarone). Onset of dyspnea or non-productive cough may be related to pulmonary toxicity and patients should be carefully evaluated. In the event that pulmonary toxicity is confirmed, dronedarone should be discontinued.

Conflict Code: DB – Drug-Drug Marker and/or Diagnosis

Drugs/Diseases

Util A	Util B	Util C
Dronedarone	Pneumonitis	
	Pulmonary Fibrosis	
	Dyspnea	

References:
Multaq Prescribing Information, September 2012, Sanofi-Aventis U.S.
Clinical Pharmacology, 2012 Elsevier / Gold Standard.

11. Forfivo XL / Overutilization ____√____ _____ _____

Alert Message: Forfivo XL (extended-release bupropion) may be over-utilized. The manufacturer's maximum recommended dose is 450 mg once daily. Exceeding the recommended dose increases the risk of dose-related seizures.

Drugs/Diseases

Util A	Util B	Util C
Forfivo XL		

References:
Forfivo XL Prescribing Information, Nov. 2011, Intelgenx Corp.
Facts & Comparisons, 2012 Updates Wolters Kluwer Health.

12. Forfivo XL / Therapeutic Appropriateness (0-18 yoa) _____ ____√____ _____

Alert Message: Safety/effectiveness of Forfivo XL (extended-release bupropion) in pediatric patients has not been established. Anyone considering the use of bupropion in a child or adolescent must balance the potential risks with the clinical need.

Drugs/Diseases

Util A	Util B	Util C
Forfivo XL		

Age Range: 0-18 yoa
References:
Forfivo XL Prescribing Information, Nov. 2011, Intelgenx Corp.
Facts & Comparisons, 2012 Updates Wolters Kluwer Health.

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

13. Bupropion / Ticlopidine & Clopidogrel ___√___ _____ _____

Alert Message: Concurrent use of a bupropion-containing agent with clopidogrel or ticlopidine (CYP2B6 Inhibitors) is not recommended. Co-administration of these agents may result in elevated bupropion (CYP2B6 substrate) plasma concentrations and risk of bupropion-related adverse effects (e.g., seizures, nausea, tremor and insomnia).

Drugs/Diseases

Util A	Util B	Util C
Bupropion-All	Ticlopidine	
	Clopidogrel	

References:

Forfivo XL Prescribing Information, Nov. 2011, Intelgenx Corp.
Facts & Comparisons, 2012 Updates Wolters Kluwer Health.
Clinical Pharmacology, 2012 Elsevier/Gold Standard.

14. Carbamazepine / Nonadherence ___√___ _____ _____

Alert Message: Based on refill history, your patient may be under-utilizing carbamazepine. Non-adherence to the prescribed dosing regimen may result in sub-therapeutic effects which may lead to decreased patient outcomes and additional healthcare costs.

Conflict Code: LR - Nonadherence

Drugs/Diseases

Util A	Util B	Util C
Carbamazepine		

References:

Faught E, Duh MS, Weiner JR, et al. Nonadherence to Antiepileptic Drugs and Increased Mortality, Findings from the RANSOM Study. Neurology 2008;71(20): 1572-1578.
Faught ER, Weiner JR, Guerin A, et al. Impact of Nonadherence to Antiepileptic Drugs on Health Care Utilization and Costs: Findings from the RANSOM Study. Epilepsia 2009;50(3):501-509.
Sajatovic M, Valenstein M, Blow F, et al. Treatment Adherence with Lithium Anticonvulsant medications Among Patients with Bipolar Disorder. Psychiatr Serv. 2007 Jun;58(6):855-63.
Scott J and Pope M. Self-Reported Adherence to Treatment with Mood Stabilizers, Plasma Levels and Psychiatric Hospitalization. Am J Psychiatry 2002; 159:1927-1929.
Osterberg L, Blaschke T. Adherence to Medication. N Engl J Med 2005; 353:487- 497.

15. Gabapentin / Nonadherence ___√___ _____ _____

Alert Message: Based on refill history, your patient may be under-utilizing gabapentin. Non-adherence to the prescribed dosing regimen may result in sub-therapeutic effects which may lead to decreased patient outcomes and additional healthcare costs.

Conflict Code: LR - Nonadherence

Drugs/Diseases

Util A	Util B	Util C
Gabapentin		

References:

Faught E, Duh MS, Weiner JR, et al. Nonadherence to Antiepileptic Drugs and Increased Mortality, Findings from the RANSOM Study. Neurology 2008;71(20): 1572-1578.
Faught ER, Weiner JR, Guerin A, et al. Impact of Nonadherence to Antiepileptic Drugs on Health Care Utilization and Costs: Findings from the RANSOM Study. Epilepsia 2009;50(3):501-509.
Sajatovic M, Valenstein M, Blow F, et al. Treatment Adherence with Lithium Anticonvulsant medications Among Patients with Bipolar Disorder. Psychiatr Serv. 2007 Jun;58(6):855-63.
Scott J and Pope M. Self-Reported Adherence to Treatment with Mood Stabilizers, Plasma Levels and Psychiatric Hospitalization. Am J Psychiatry 2002; 159:1927-1929.
Osterberg L, Blaschke T. Adherence to Medication. N Engl J Med 2005; 353:487- 497.

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

16. Lamotrigine / Nonadherence ____√____ _____ _____

Alert Message: Based on refill history, your patient may be under-utilizing lamotrigine. Non-adherence to the prescribed dosing regimen may result in sub-therapeutic effects which may lead to decreased patient outcomes and additional healthcare costs.

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

References:
Faught E, Duh MS, Weiner JR, et al. Nonadherence to Antiepileptic Drugs and Increased Mortality, Findings from the RANSOM Study. Neurology 2008;71(20): 1572-1578.
Faught ER, Weiner JR, Guerin A, et al. Impact of Nonadherence to Antiepileptic Drugs on Health Care Utilization and Costs: Findings from the RANSOM Study. Epilepsia 2009;50(3):501-509.
Sajatovic M, Valenstein M, Blow F, et al. Treatment Adherence with Lithium Ant Anticonvulsant medications Among Patients with Bipolar Disorder. Psychiatr Serv. 2007 Jun;58(6):855-63.
Scott J and Pope M. Self-Reported Adherence to Treatment with Mood Stabilizers, Plasma Levels and Psychiatric Hospitalization. Am J Psychiatry 2002; 159:1927-1929.
Osterberg L, Blaschke T. Adherence to Medication. N Engl J Med 2005; 353:487- 497.

17. Lacosamide / Nonadherence ____√____ _____ _____

Alert Message: Based on refill history, your patient may be under-utilizing Vimpat (lacosamide). Non-adherence to the prescribed dosing regimen may result in sub-therapeutic effects which may lead to decreased patient outcomes and additional healthcare costs.

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

References:
Faught E, Duh MS, Weiner JR, et al. Nonadherence to Antiepileptic Drugs and Increased Mortality, Findings from the RANSOM Study. Neurology 2008;71(20): 1572-1578.
Faught ER, Weiner JR, Guerin A, et al. Impact of Nonadherence to Antiepileptic Drugs on Health Care Utilization and Costs: Findings from the RANSOM Study. Epilepsia 2009;50(3):501-509.
Sajatovic M, Valenstein M, Blow F, et al. Treatment Adherence with Lithium Ant Anticonvulsant medications Among Patients with Bipolar Disorder. Psychiatr Serv. 2007 Jun;58(6):855-63.
Scott J and Pope M. Self-Reported Adherence to Treatment with Mood Stabilizers, Plasma Levels and Psychiatric Hospitalization. Am J Psychiatry 2002; 159:1927-1929.
Osterberg L, Blaschke T. Adherence to Medication. N Engl J Med 2005; 353:487- 497.

18. Levetiracetam / Nonadherence ____√____ _____ _____

Alert Message: Based on refill history, your patient may be under-utilizing levetiracetam. Non-adherence to the prescribed dosing regimen may result in sub-therapeutic effects which may lead to decreased patient outcomes and additional healthcare costs.

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

References:
Faught E, Duh MS, Weiner JR, et al. Nonadherence to Antiepileptic Drugs and Increased Mortality, Findings from the RANSOM Study. Neurology 2008;71(20): 1572-1578.
Faught ER, Weiner JR, Guerin A, et al. Impact of Nonadherence to Antiepileptic Drugs on Health Care Utilization and Costs: Findings from the RANSOM Study. Epilepsia 2009;50(3):501-509.

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

19. Pregabalin / Nonadherence ___√___ _____ _____

Alert Message: Based on refill history, your patient may be under-utilizing Lyrica (pregabalin). Non-adherence to the prescribed dosing regimen may result in sub-therapeutic effects which may lead to decreased patient outcomes and additional healthcare costs.

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

References:
Faught E, Duh MS, Weiner JR, et al. Nonadherence to Antiepileptic Drugs and Increased Mortality, Findings from the RANSOM Study. Neurology 2008;71(20): 1572-1578.
Faught ER, Weiner JR, Guerin A, et al. Impact of Nonadherence to Antiepileptic Drugs on Health Care Utilization and Costs: Findings from the RANSOM Study. Epilepsia 2009;50(3):501-509.

20. Primidone / Nonadherence ___√___ _____ _____

Alert Message: Based on refill history, your patient may be under-utilizing primidone. Non-adherence to the prescribed dosing regimen may result in sub-therapeutic effects which may lead to decreased patient outcomes and additional healthcare costs.

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

References:
Faught E, Duh MS, Weiner JR, et al. Nonadherence to Antiepileptic Drugs and Increased Mortality, Findings from the RANSOM Study. Neurology 2008;71(20): 1572-1578.
Faught ER, Weiner JR, Guerin A, et al. Impact of Nonadherence to Antiepileptic Drugs on Health Care Utilization and Costs: Findings from the RANSOM Study. Epilepsia 2009;50(3):501-509.

21. Tiagabine / Nonadherence ___√___ _____ _____

Alert Message: Based on refill history, your patient may be under-utilizing tiagabine. Non-adherence to the prescribed dosing regimen may result in sub-therapeutic effects which may lead to decreased patient outcomes and additional healthcare costs.

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

References:
Faught E, Duh MS, Weiner JR, et al. Nonadherence to Antiepileptic Drugs and Increased Mortality, Findings from the RANSOM Study. Neurology 2008;71(20): 1572-1578.
Faught ER, Weiner JR, Guerin A, et al. Impact of Nonadherence to Antiepileptic Drugs on Health Care Utilization and Costs: Findings from the RANSOM Study. Epilepsia 2009;50(3):501-509.

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

22. Topiramate / Nonadherence ___√___ _____ _____

Alert Message: Based on refill history, your patient may be under-utilizing topiramate. Non-adherence to the prescribed dosing regimen may result in sub-therapeutic effects which may lead to decreased patient outcomes and additional healthcare costs.

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

References:
Faught E, Duh MS, Weiner JR, et al. Nonadherence to Antiepileptic Drugs and Increased Mortality, Findings from the RANSOM Study. Neurology 2008;71(20): 1572-1578.
Faught ER, Weiner JR, Guerin A, et al. Impact of Nonadherence to Antiepileptic Drugs on Health Care Utilization and Costs: Findings from the RANSOM Study. Epilepsia 2009;50(3):501-509.

23. Valproic Acid / Nonadherence ___√___ _____ _____

Alert Message: Based on refill history, your patient may be under-utilizing valproic acid. Non-adherence to the prescribed dosing regimen may result in sub-therapeutic effects which may lead to decreased patient outcomes and additional healthcare costs.

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

References:
Faught E, Duh MS, Weiner JR, et al. Nonadherence to Antiepileptic Drugs and Increased Mortality, Findings from the RANSOM Study. Neurology 2008;71(20): 1572-1578.
Faught ER, Weiner JR, Guerin A, et al. Impact of Nonadherence to Antiepileptic Drugs on Health Care Utilization and Costs: Findings from the RANSOM Study. Epilepsia 2009;50(3):501-509.
Sajatovic M, Valenstein M, Blow F, et al. Treatment Adherence with Lithium Ant Anticonvulsant medications Among Patients with Bipolar Disorder. Psychiatr Serv. 2007 Jun;58(6):855-63.
Scott J and Pope M. Self-Reported Adherence to Treatment with Mood Stabilizers, Plasma Levels and Psychiatric Hospitalization. Am J Psychiatry 2002; 159:1927-1929.
Osterberg L, Blaschke T. Adherence to Medication. N Engl J Med 2005; 353:487- 497.

24. Vigabatrin / Nonadherence ___√___ _____ _____

Alert Message: Based on refill history, your patient may be under-utilizing Sabril (vigabatrin). Non-adherence to the prescribed dosing regimen may result in sub-therapeutic effects which may lead to decreased patient outcomes and additional healthcare costs.

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

References:
Faught E, Duh MS, Weiner JR, et al. Nonadherence to Antiepileptic Drugs and Increased Mortality, Findings from the RANSOM Study. Neurology 2008;71(20): 1572-1578.
Faught ER, Weiner JR, Guerin A, et al. Impact of Nonadherence to Antiepileptic Drugs on Health Care Utilization and Costs: Findings from the RANSOM Study. Epilepsia 2009;50(3):501-509.

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

25. Zonisamide / Nonadherence ____√____ _____ _____

Alert Message: Based on refill history, your patient may be under-utilizing zonisamide. Non-adherence to the prescribed dosing regimen may result in sub-therapeutic effects which may lead to decreased patient outcomes and additional healthcare costs.

Conflict Code: LR - Nonadherence
Drugs/Diseases

Util A	Util B	Util C
Zonisamide		

References:
Faught E, Duh MS, Weiner JR, et al. Nonadherence to Antiepileptic Drugs and Increased Mortality, Findings from the RANSOM Study. Neurology 2008;71(20): 1572-1578.
Faught ER, Weiner JR, Guerin A, et al. Impact of Nonadherence to Antiepileptic Drugs on Health Care Utilization and Costs: Findings from the RANSOM Study. Epilepsia 2009;50(3):501-509.

26. Ethosuximide / Nonadherence ____√____ _____ _____

Alert Message: Based on refill history, your patient may be under-utilizing ethosuximide. Non-adherence to the prescribed dosing regimen may result in sub-therapeutic effects which may lead to decreased patient outcomes and additional healthcare costs.

Conflict Code: LR - Nonadherence
Drugs/Diseases

Util A	Util B	Util C
Ethosuximide		

References:
Faught E, Duh MS, Weiner JR, et al. Nonadherence to Antiepileptic Drugs and Increased Mortality, Findings from the RANSOM Study. Neurology 2008;71(20): 1572-1578.
Faught ER, Weiner JR, Guerin A, et al. Impact of Nonadherence to Antiepileptic Drugs on Health Care Utilization and Costs: Findings from the RANSOM Study. Epilepsia 2009;50(3):501-509.

27. Felbamate / Nonadherence ____√____ _____ _____

Alert Message: Based on refill history, your patient may be under-utilizing felbamate. Non-adherence to the prescribed dosing regimen may result in sub-therapeutic effects which may lead to decreased patient outcomes and additional healthcare costs.

Conflict Code: LR - Nonadherence
Drugs/Diseases

Util A	Util B	Util C
Felbamate		

References:
Faught E, Duh MS, Weiner JR, et al. Nonadherence to Antiepileptic Drugs and Increased Mortality, Findings from the RANSOM Study. Neurology 2008;71(20): 1572-1578.
Faught ER, Weiner JR, Guerin A, et al. Impact of Nonadherence to Antiepileptic Drugs on Health Care Utilization and Costs: Findings from the RANSOM Study. Epilepsia 2009;50(3):501-509.

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

28. Methsuximide / Nonadherence ____√____ _____ _____

Alert Message: Based on refill history, your patient may be under-utilizing methsuximide. Non-adherence to the prescribed dosing regimen may result in sub-therapeutic effects which may lead to decreased patient outcomes and additional healthcare costs.

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

References:
Faught E, Duh MS, Weiner JR, et al. Nonadherence to Antiepileptic Drugs and Increased Mortality, Findings from the RANSOM Study. Neurology 2008;71(20): 1572-1578.
Faught ER, Weiner JR, Guerin A, et al. Impact of Nonadherence to Antiepileptic Drugs on Health Care Utilization and Costs: Findings from the RANSOM Study. Epilepsia 2009;50(3):501-509.

29. Phenytoin / Nonadherence ____√____ _____ _____

Alert Message: Based on refill history, your patient may be under-utilizing phenytoin. Non-adherence to the prescribed dosing regimen may result in sub-therapeutic effects which may lead to decreased patient outcomes and additional healthcare costs.

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

References:
Faught E, Duh MS, Weiner JR, et al. Nonadherence to Antiepileptic Drugs and Increased Mortality, Findings from the RANSOM Study. Neurology 2008;71(20): 1572-1578.
Faught ER, Weiner JR, Guerin A, et al. Impact of Nonadherence to Antiepileptic Drugs on Health Care Utilization and Costs: Findings from the RANSOM Study. Epilepsia 2009;50(3):501-509.

30. Rufinamide / Nonadherence ____√____ _____ _____

Alert Message: Based on refill history, your patient may be under-utilizing rufinamide. Non-adherence to the prescribed dosing regimen may result in sub-therapeutic effects which may lead to decreased patient outcomes and additional healthcare costs.

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

References:
Faught E, Duh MS, Weiner JR, et al. Nonadherence to Antiepileptic Drugs and Increased Mortality, Findings from the RANSOM Study. Neurology 2008;71(20): 1572-1578.
Faught ER, Weiner JR, Guerin A, et al. Impact of Nonadherence to Antiepileptic Drugs on Health Care Utilization and Costs: Findings from the RANSOM Study. Epilepsia 2009;50(3):501-509.

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

31. Oxcarbazepine / Nonadherence ____√____ _____ _____

Alert Message: Based on refill history, your patient may be under-utilizing oxcarbazepine. Non-adherence to the prescribed dosing regimen may result in sub-therapeutic effects which may lead to decreased patient outcomes and additional healthcare costs.

Conflict Code: LR - Nonadherence
Drugs/Diseases

Util A	Util B	Util C
Oxcarbazepine		

References:
Faught E, Duh MS, Weiner JR, et al. Nonadherence to Antiepileptic Drugs and Increased Mortality, Findings from the RANSOM Study. Neurology 2008;71(20): 1572-1578.
Faught ER, Weiner JR, Guerin A, et al. Impact of Nonadherence to Antiepileptic Drugs on Health Care Utilization and Costs: Findings from the RANSOM Study. Epilepsia 2009;50(3):501-509.
Sajatovic M, Valenstein M, Blow F, et al. Treatment Adherence with Lithium Ant Anticonvulsant medications Among Patients with Bipolar Disorder. Psychiatr Serv. 2007 Jun;58(6):855-63.
Scott J and Pope M. Self-Reported Adherence to Treatment with Mood Stabilizers, Plasma Levels and Psychiatric Hospitalization. Am J Psychiatry 2002; 159:1927-1929.
Osterberg L, Blaschke T. Adherence to Medication. N Engl J Med 2005; 353:487- 497.

32. Divalproex Sodium / Nonadherence ____√____ _____ _____

Alert Message: Based on refill history, your patient may be under-utilizing divalproex sodium. Non-adherence to the prescribed dosing regimen may result in sub-therapeutic effects which may lead to decreased patient outcomes and additional healthcare costs.

Conflict Code: LR - Nonadherence
Drugs/Diseases

Util A	Util B	Util C
Divalproex Sodium		

References:
Faught E, Duh MS, Weiner JR, et al. Nonadherence to Antiepileptic Drugs and Increased Mortality, Findings from the RANSOM Study. Neurology 2008;71(20): 1572-1578.
Faught ER, Weiner JR, Guerin A, et al. Impact of Nonadherence to Antiepileptic Drugs on Health Care Utilization and Costs: Findings from the RANSOM Study. Epilepsia 2009;50(3):501-509.
Sajatovic M, Valenstein M, Blow F, et al. Treatment Adherence with Lithium Ant Anticonvulsant medications Among Patients with Bipolar Disorder. Psychiatr Serv. 2007 Jun;58(6):855-63.
Scott J and Pope M. Self-Reported Adherence to Treatment with Mood Stabilizers, Plasma Levels and Psychiatric Hospitalization. Am J Psychiatry 2002; 159:1927-1929.
Osterberg L, Blaschke T. Adherence to Medication. N Engl J Med 2005; 353:487- 497.

33. Tenofovir / Abacavir / Lamivudine & Emtricitabine ____√____ _____ _____

Alert Message: The triple-NRTI regimen tenofovir/abacavir/lamivudine or emtricitabine is not recommended for treatment of HIV infection in children. This combination has demonstrated a high rate of viral failure when used as initial therapy in treatment–naïve adults.

Conflict Code: TA – Therapeutic Appropriateness
Drugs/Diseases

Util A	Util B	Util C (Include)
Tenofovir	Abacavir	Lamivudine Emtricitabine

Age Range: 0-12 yoa

References:
Panel on Antiretroviral Therapy and Medical Management of HIV-Infected Children. Guidelines for the Use of Antiretroviral Agents in Pediatric HIV Infection. November 5, 2012;pp1-333.
Available at: http://aidsinfo.nih.gov/contentfiles/lvguidelines/pediatricguidelines.pdf

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

34. Tenofovir / Didanosine / Lamivudine & Emtricitabine ____√____ _____ _____

Alert Message: The triple-NRTI regimen tenofovir/didanosine/lamivudine or emtricitabine is not recommended for treatment of HIV infection in children. This combination has demonstrated a high rate of viral failure when used as initial therapy in treatment–naïve adults.

Conflict Code: TA – Therapeutic Appropriateness
Drugs/Diseases

Util A	Util B	Util C (Include)
Tenofovir	Didanosine	Lamivudine
		Emtricitabine

Age Range: 0-12 yoa

References:
Panel on Antiretroviral Therapy and Medical Management of HIV-Infected Children. Guidelines for the Use of Antiretroviral Agents in Pediatric HIV Infection. November 5, 2012;pp1-333.
Available at: http://aidsinfo.nih.gov/contentfiles/lvguidelines/pediatricguidelines.pdf

35. Xyrem / CNS Depressants ____√____ _____ _____

Alert Message: Concurrent use of Xyrem (sodium oxybate) with central nervous system (CNS) depressant drugs may lead to loss of consciousness, coma and death. If the use of CNS depressants in combination with Xyrem is required, dose reduction or discontinuation of one or more CNS depressants (including Xyrem) should be considered. The use of sodium oxybate is contraindicated with sedative hypnotic agents and alcohol.

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

Util A	Util B	Util C
Xyrem	Sedative/Hypnotics (Benzos, Non-Benzos, & Barbiturates)	
	Opioids	
	Skeletal Muscle Relaxants	
	Sedating H-1 Blockers	
	Trimethobenzamide	
	Dronabinol	
	Nabilone	

References:
Facts & Comparisons, 2012 Updates, Wolters Kluwer Health.
MedWatch The FDA Safety Information and Adverse Event Reporting Program. Xyrem (sodium oxybate): Drug Safety Communication – Warning Against Use with Alcohol or Drugs Causing Respiratory Depression. [Posted 12/17/2012].
Available at:
http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm332430.htm?source=govdelivery
Clinical Pharmacology, 2012 Elsevier/Gold Standard.

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

36. Horizant / Overutilization-Restless Leg Syndrome ____√____ _____ _____

Alert Message: The manufacturer's recommended dosage of Horizant (gabapentin enacarbil extended-release) in patients with restless leg syndrome is 600 mg once daily taken at about 5 PM. Clinical trial experience revealed that a dose of 1,200 mg once daily provided no additional benefit compared to the 600 mg dose, but caused an increase in adverse reactions (e.g., somnolence/sedation, dizziness and headache).

Conflict Code: ER - Overutilization
Drugs/Diseases

Util A	Util B	Util C (Include)
Horizant		Restless Leg Syndrome

Max Dose: 600mg/day

References:
Horizant Prescribing Information, Dec. 2012, GlaxoSmithKline.
Facts & Comparisons, 2013 Updates, Wolters Kluwer Health.

37. Horizant / Overutilization – Postherpetic Neuralgia ____√____ _____ _____

Alert Message: The manufacturer's recommended daily dosage of Horizant (gabapentin enacarbil extended-release) in patients with postherpetic neuralgia (PHN) is 1200 mg (600 mg twice daily). The clinical efficacy study revealed no additional benefit of using doses greater 1,200 mg a day, but did show an increase in adverse reactions (e.g., somnolence, dizziness and headache).

Conflict Code: ER - Overutilization
Drugs/Diseases

Util A	Util B	Util C (Include)
Horizant		Postherpetic Neuralgia

Max Dose: 1200mg/day

References:
Horizant Prescribing Information, Dec. 2012, GlaxoSmithKline.
Facts & Comparisons, 2013 Updates, Wolters Kluwer Health.

38. Gralise / Overutilization ____√____ _____ _____

Alert Message: The manufacturer's recommended maintenance dose of Gralise (gabapentin) is 1800 mg once daily taken with the evening meal.

Conflict Code: ER - Overutilization
Drugs/Diseases

Util A	Util B	Util C
Gralise		

Max Dose: 1800mg/day

References:
Gralise Prescribing Information, Sept. 2012, Depomed, Inc.
Facts & Comparisons, 2013 Updates, Wolters Kluwer Health.

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

39. Apixaban / Overutilization _____ _____ ___√___

Alert Message: The manufacturer's recommended daily dose of Eliquis (apixaban) is 10 mg (5 mg twice daily). A reduced daily dose of 5 mg (2.5 mg twice daily) is recommended for patients with at least 2 of the following characteristics: age 80 years or older, body weight of 60 kg or less, or serum creatinine greater than or equal to 1.5 mg/dL.

Conflict Code: ER – Overutilization
Drugs/Diseases

Util A	Util B	Util C (Negate)
Apixaban		CKD Stage III
		CKD Stage IV
		ESRD
		Dialysis

Max Dose: 10mg/day

References:
Eliquis Prescribing Information, Dec. 2012, Bristol-Myers Squibb.

40. Apixaban / Overutilization (≥80 yoa & Renal Impairment) _____ ___√___ _____

Alert Message: The manufacturer's recommended daily dose of Eliquis (apixaban) in patients with at least 2 of the following characteristics: age 80 years or older, body weight of 60 kg or less, or serum creatinine greater than or equal to 1.5mg/dL, is 5 mg (2.5mg twice daily).

Conflict Code: ER – Overutilization
Drugs/Diseases

Util A	Util B	Util C (Include)
Apixaban		Stage I, II & III CKD

Max Dose: 5mg/day
Age Range: ≥80 yoa

References:
Eliquis Prescribing Information, Dec. 2012, Bristol-Myers Squibb.

*Do not receive weight data – cannot create criteria to hit on this.

41. Apixaban / Strong Dual CYP3A4 & P-gp Inhibitors _____ ___√___ _____

Alert Message: The dose of Eliquis (apixaban) should not exceed 2.5 mg twice daily when it is co-administered with drugs that are strong dual inhibitors of CYP3A4 and P-gp (e.g., ketoconazole, itraconazole, ritonavir and clarithromycin). Concurrent use with a dual strong inhibitor may result in increased exposure to apixaban (CYP3A4 & P-gp substrate) and an increased risk of bleeding.

Conflict Code: ER – Overutilization
Drugs/Diseases

Util A	Util B	Util C (Include)
Apixaban		Ketoconazole
		Itraconazole
		Ritonavir
		Clarithromycin

Max Dose: 5mg/day

References:
Eliquis Prescribing Information, Dec. 2012, Bristol-Myers Squibb.
Clinical Pharmacology, 2013 Elsevier/Gold Standard.

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

42. Apixaban / Strong Dual CYP3A4 & P-gp Inducers ____√____ _____ _____

Alert Message: Concurrent use of Eliquis (apixaban) with a strong dual inducer of CYP3A4 and P-gp (e.g., carbamazepine, phenytoin and rifampin) should be avoided. Dual inducers of CYP3A4 and P-gp decrease exposure to apixaban (CYP3A4 & P-gp substrate) and increase the risk of stroke.

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

Util A	Util B	Util C
Apixaban	Carbamazepine	
	Phenytoin	
	Rifampin	

References:
Eliquis Prescribing Information, Dec. 2012, Bristol-Myers Squibb.
Clinical Pharmacology, 2013 Elsevier/Gold Standard.

43. Apixaban / Drugs that Increase Risk of Bleeding _____ ____√____ _____

Alert Message: Eliquis (apixaban) increases the risk of bleeding and can cause serious, potentially fatal, bleeding. Concomitant use of drugs affecting hemostasis (e.g., antiplatelet agents, fibrinolytics, chronic NSAIDs and SSRIs) can further increase the bleeding risk.

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

Util A	Util B			Util C
Apixaban	Aspirin	Dalteparin	Prasugrel	
	NSAIDs	Enoxaparin	Ticagrelor	
	Warfarin	Dabigatran	Ticlopidine	
	Heparin	Anagrelide	SSRIs	
	Fondaparinux	Dipyridamole	SNRIs	
	Rivaroxaban	Cilostazol	Clopidogrel	

References:
Eliquis Prescribing Information, Dec. 2012, Bristol-Myers Squibb.
Clinical Pharmacology, 2013 Elsevier/Gold Standard.

44. Apixaban / Nonadherence ____√____ _____ _____

Alert Message: Based on refill history, your patient may be under-utilizing Eliquis (apixaban). Non-adherence to the prescribed dosing regimen may result in sub-therapeutic effects (i.e., increasing risk of thrombotic events), which may lead to decreased patient outcomes and additional healthcare costs.

Conflict Code: LR – Nonadherence
Drugs/Diseases

Util A	Util B	Util C
Apixaban		

References:
Eliquis Prescribing Information, Dec. 2012, Bristol-Myers Squibb.
Clinical Pharmacology, 2013 Elsevier/Gold Standard

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

45. Apixaban / Therapeutic Appropriateness _____ ___√___ _____

Alert Message: Discontinuing Eliquis (apixaban) in patients without adequate continuous anticoagulation increases the risk of stroke. If apixaban must be discontinued for a reason other than pathological bleeding, consider coverage with another anticoagulant.

Conflict Code: TA – Therapeutic Appropriateness
Drugs/Diseases

Util A	Util B	Util C (Negate)		
Apixaban		Warfarin	Dalteparin	Ticlopidine
		Heparin	Enoxaparin	Clopidogrel
		Fondaparinux	Dabigatran	
		Rivaroxaban	Anagrelide	
		Dipyridamole	Prasugrel	
		Cilostazol	Ticagrelor	

References:
Eliquis Prescribing Information, Dec. 2012, Bristol-Myers Squibb.
Clinical Pharmacology, 2013 Elsevier/Gold Standard

46. Apixaban / Active Pathological Bleeds ___√___ _____ _____

Alert Message: Eliquis (apixaban) can cause serious, potentially fatal bleeding and is contraindicated in any patient with active pathological bleeding.

Conflict Code: TA – Therapeutic Appropriateness
Drugs/Diseases

Util A	Util B	Util C
Apixaban	Active Bleeds	

References:
Eliquis Prescribing Information, Dec. 2012, Bristol-Myers Squibb.
Clinical Pharmacology, 2013 Elsevier/Gold Standard.

47. Apixaban / Heart Valve Replacement ___√___ _____ _____

Alert Message: The safety and efficacy of Eliquis (apixaban) has not been studied in patients with prosthetic heart valves and its use is not recommended in these patients.

Conflict Code: TA – Therapeutic Appropriateness
Drugs/Diseases

Util A	Util B	Util C
Apixaban	Heart Valve Replaced (V43.3)	

References:
Eliquis Prescribing Information, Dec. 2012, Bristol-Myers Squibb.
Clinical Pharmacology, 2013 Elsevier/Gold Standard.

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

48. Bedaquiline /Therapeutic Appropriateness _____ ___√___ _____

Alert Message: Sirturo (bedaquiline) should only be used in combination with at least 3 other drugs to which the patient's pulmonary multidrug-resistant tuberculosis (MDR-TB) isolate has been shown to be susceptible in vitro or 4 other drugs suspected of being active against patient's MDR-TB.

Conflict Code: ER - Overutilization
Drugs/Diseases

Util A	Util B	Util C (Negate)
Bedaquiline		Isoniazid
		Aminosalicylic Acid
		Cycloserine
		Ethambutol
		Ethionamide
		Pyrazinamide
		Rifabutin
		Rifampin
		Rifapentine
		Streptomycin
		Capremoycin

References:
Sirturo Prescribing Information, December 2012, Janssen Products, LP.
Clinical Pharmacology, 2013 Elsevier/Gold Standard.

49. Bedaquiline / Nonadherence _____ ___√___ _____

Alert Message: Based on refill history, your patient may be under-utilizing Sirturo (bedaquiline). Compliance with the full course of therapy must be emphasized. Skipping doses or not completing the full course of therapy may decrease the effectiveness of the treatment and increase the likelihood that their mycobacterium may develop resistance and the disease will not be treatable by bedaquiline or other antibacterial drugs in the future.

Conflict Code: LR – Nonadherence
Drugs/Diseases

Util A	Util B	Util C
Bedaquiline		

References:
Sirturo Prescribing Information, December 2012, Janssen Products, LP.
Clinical Pharmacology, 2013 Elsevier/Gold Standard

50. Bedaquiline /Hepatic Impairment ___√___ _____ _____

Alert Message: Sirturo (bedaquiline) has not been studied in patients with severe hepatic impairment and should be used with caution in these patients only when the benefits outweigh the risks. Clinical monitoring of bedaquiline-related adverse reactions is recommended.

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

Util A	Util B	Util C
Bedaquiline	Hepatic Imp.	

References:
Sirturo Prescribing Information, December 2012, Janssen Products, LP.
Clinical Pharmacology, 2013 Elsevier/Gold Standard.

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

51. Bedaquiline /Renal Impairment ___√___ _____ _____

Alert Message: Sirturo (bedaquiline) should be used with caution in patients with severe renal impairment or end stage renal disease requiring hemodialysis or peritoneal dialysis. Clinical monitoring of bedaquiline-related adverse reactions is recommended as bedaquiline concentrations may be increased due to alteration of drug absorption, distribution and metabolism secondary to renal dysfunction.

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

Util A	Util B	Util C
Bedaquiline	ESRD	
	CKD Stage IV	

References:
Sirturo Prescribing Information, December 2012, Janssen Products, LP.
Clinical Pharmacology, 2013 Elsevier/Gold Standard.

52. Bedaquiline /Drugs Causing QT Prolongation (Black Box Warning) ___√___ _____ _____

Alert Message: Sirturo (bedaquiline) prolongs the QT interval. The concurrent use of this agent with other drugs that prolong the QT interval may have an additive effect increasing the risk of life-threatening arrhythmias, including torsades de pointes. Monitor EKGs frequently and discontinue bedaquiline and all other QT prolonging drugs if the patient develops clinically significant ventricular arrhythmia or a QTcF interval of > 500ms.

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

Util A	Util B				Util C
Bedaquiline	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	Rilpivirine
	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:
Sirturo Prescribing Information, December 2012, Janssen Products, LP.
Clinical Pharmacology, 2013 Elsevier/Gold Standard.

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

53. Bedaquiline /QT Prolongation (Black Box Warning) ___√___ _____ _____

Alert Message: Sirturo (bedaquiline) prolongs the QT interval and should be used with caution in patients who have conditions which would increase the risk for QT prolongation (e.g., history of torsades de pointes, congenital QT syndrome, and bradyarrhythmias). Discontinue bedaquiline if significant ventricular arrhythmia or QTcF interval > 500ms develops.

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

Util A	Util B	Util C
Bedaquiline	Long QT Syndrome	
	Hypothyroidism	
	Bradyarrhythmias	
	Uncompensated Heart Failure	
	Hypomagnesemia	
	Hypokalemia	

References:
Sirturo Prescribing Information, December 2012, Janssen Products, LP.
Clinical Pharmacology, 2013 Elsevier/Gold Standard.

54. Bedaquiline /Strong CYP3A4 Inducers ___√___ _____ _____

Alert Message: The concurrent use of Sirturo (bedaquiline) with a strong CYP3A4 inducer should be avoided. Bedaquiline is a CYP3A4 substrate and it's systemic exposure and therapeutic effect may be reduced during co-administration with CYP3A4 inducers.

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

Util A	Util B	Util C
Bedaquiline	Carbamazepine	
	Phenytoin	
	Rifampin	
	Rifapentine	
	Rifabutin	

References:
Sirturo Prescribing Information, December 2012, Janssen Products, LP.

55. Bedaquiline /Strong CYP3A4 Inhibitors ___√___ _____ _____

Alert Message: The concurrent use of Sirturo (bedaquiline) with a strong CYP3A4 inhibitor for longer than 14 consecutive days should be avoided, unless the benefit of treatment with the drug combination outweighs the risk. Bedaquiline is a CYP3A4 substrate and co-administration with strong CYP3A4 inhibitors may increase its systemic exposure and risk of adverse reactions. Appropriate clinical monitoring for bedaquiline-related adverse reactions is recommended.

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

Util A	Util B		Util C
Bedaquiline	Ketoconazole	Indinavir	
	Itraconazole	Saquinavir	
	Clarithromycin	Nelfinavir	
	Telithromycin	Ritonavir	
	Nefazodone	Boceprevir	
	Posaconazole	Telaprevir	
	Voriconazole		

References:
Sirturo Prescribing Information, December 2012, Janssen Products, LP.

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

56. Venlafaxine / Metoprolol ___√___ _____ _____

Alert Message: Concurrent use of venlafaxine and metoprolol may reduce the blood pressure-lowering effect of metoprolol. Venlafaxine may also cause sustained hypertension. Regular monitoring of blood pressure is recommended.

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

Util A	Util B	Util C
Venlafaxine	Metoprolol	

References:
Clinical Pharmacology, 2013 Elsevier/Gold Standard.
Facts & Comparisons, 2013 Updates. Wolters Kluwer Health.

57. Duloxetine / Serotonergic Agents ___√___ _____ _____

Alert Message: Caution should be exercised when administering Cymbalta (duloxetine) with another serotonergic drug due to the potential for the accumulation of serotonin and increased risk of serotonin syndrome (e.g., agitation, hallucinations, tachycardia and seizures). Inform patients of risk of serotonin syndrome and counsel them concerning appropriate actions if syndrome occurs.

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

Util A	Util B	Util C
Duloxetine	Lithium	
	Triptans	
	Antipsychotics	
	TCAs	
	SSRIs	
	Buspirone	
	Cyclobenzaprine	
	Meperidine	
	Tramadol	
	Fentanyl	
	Linezolid	

References:
Clinical Pharmacology, 2013 Elsevier/Gold Standard.
Facts & Comparisons, 2013 Updates, Wolters Kluwer Health.

58. Benicar / Therapeutic Appropriateness ___√___ _____ _____

Alert Message: Benicar (olmesartan) has not been shown to be effective in children less than 6 years of age. Children less than 1 year of age should not receive olmesartan for hypertension. Olmesartan acts directly on the renin-angiotensin aldosterone system and can have effects on the development of immature kidneys.

Conflict Code: TA Therapeutic Appropriateness
Drugs/Diseases

Util A	Util B	Util C
Benicar		

Age Range: 0-5

References:
Clinical Pharmacology, 2013 Elsevier/Gold Standard.
Facts & Comparisons, 2013 Updates. Wolters Kluwer Health.
Benicar Prescribing Information, Nov. 2012, Daiichi Sankyo, Inc.

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

59. Benicar / Overutilization (6 to 16 yoa) ___√___ _____ _____

Alert Message: The manufacture's recommended maximum daily dose of Benicar (olmesartan) in pediatric patients 6 to 16 years of age, weighing 35 kg or more, is 40 mg. Pediatric patients weighing less than 35 kg should receive a maximum of 20mg once daily.

Conflict Code: TA Therapeutic Appropriateness
Drugs/Diseases

Util A	Util B	Util C
Benicar		

Max Dose: 40mg/day
Age Range: 6-16 yoa

References:
Clinical Pharmacology, 2013 Elsevier/Gold Standard.
Facts & Comparisons, 2013. Updates, Wolters Kluwer Health.
Benicar Prescribing Information, Nov. 2012, Daiichi Sankyo, Inc.

60. Pasireotide / Hypocortisolism ___√___ _____ _____

Alert Message: Signifor (pasireotide) treatment may lead to decreases in circulating cortisol levels and potentially hypocortisolism. If hypocortisolism occurs, consider temporary dose reduction or interruption of treatment and/or adding low-dose short-term glucocorticoid therapy.

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

Util A	Util B	Util C (Negate)
Pasireotide	Hypocortisolism	Glucocorticoids

References:
Signifor Prescribing Information, December 2012, Novartis Pharmaceuticals Corporation.

61. Pasireotide / Hyperglycemia ___√___ _____ _____

Alert Message: Signifor (pasireotide) causes elevations in blood glucose levels. If hyperglycemia develops the initiation or adjustment of anti-diabetic treatment is recommended as well as intensive glucose monitoring.

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

Util A	Util B	Util C
Pasireotide	Hyperglycemia	

References:
Signifor Prescribing Information, December 2012, Novartis Pharmaceuticals Corporation.

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

62. Pasireotide / QT Prolongation ___√___ _____ _____

Alert Message: Signifor (pasireotide) is associated with QT prolongation and should be used with caution in patients who are at significant risk of developing prolongation of QTc. Monitoring QTc interval is advisable.

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

Util A	Util B	Util C
Pasireotide	Long QT Syndrome	
	Hypothyroidism	
	Bradyarrhythmias	
	Uncompensated Heart Failure	
	Hypomagnesemia	
	Hypokalemia	

References:
Signifor Prescribing Information, December 2012, Novartis Pharmaceuticals Corporation.

63. Pasireotide / Drugs Causing QT Prolongation ___√___ _____ _____

Alert Message: Signifor (pasireotide) is associated with QT prolongation and concurrent use with drugs that prolong the QT interval may have additive effects on the interval increasing the risk of life-threatening arrhythmias.

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

Util A	Util B					Util C
Pasireotide	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	Rilpivirine	
	Chlorpromazine	Fluoxetine	Nicardipine	Saquinavir	Bedaquiline	
	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:
Signifor Prescribing Information, December 2012, Novartis Pharmaceuticals Corporation.

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

64. Pasireotide / Cyclosporine ___√___ _____ _____

Alert Message: Concurrent use of Signifor (pasireotide) with cyclosporine may decrease the relative bioavailability of cyclosporine and, therefore, dose adjustment of cyclosporine to maintain therapeutic levels may be necessary.

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

Util A	Util B	Util C
Pasireotide	Cyclosporine	

References:
Signifor Prescribing Information, December 2012, Novartis Pharmaceuticals Corporation.

65. Pasireotide / Bromocriptine ___√___ _____ _____

Alert Message: Concurrent use of Signifor (pasireotide) with bromocriptine may increase the blood levels of bromocriptine. Dose reduction of bromocriptine may be necessary.

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

Util A	Util B	Util C
Pasireotide	Bromocriptine	

References:
Signifor Prescribing Information, December 2012, Novartis Pharmaceuticals Corporation.

66. Pasireotide / Pediatric Use (0-18 yoa) ___√___ _____ _____

Alert Message: The safety/effectiveness of Signifor (pasireotide) has not been established in pediatric patients.

Conflict Code: TA – Therapeutic Appropriateness
Drugs/Diseases

Util A	Util B	Util C
Pasireotide		

Age Range: 0 -18 yoa

References:
Signifor Prescribing Information, December 2012, Novartis Pharmaceuticals Corporation.

67. Pasireotide / Overutilization ___√___ _____ _____

Alert Message: The manufacturer's recommended dosage range for Signifor (pasireotide) is 0.3 to 0.9 mg by subcutaneous injection twice a day.

Conflict Code: ER - Overutilization
Drugs/Diseases

Util A	Util B	Util C (Negating)
Pasireotide		Hepatic Impairment

Max Dose: 1.8 mg/day

References:
Signifor Prescribing Information, December 2012, Novartis Pharmaceuticals Corporation.

68. Pasireotide / Overutilization Hepatic Impairment ____√____ _____ _____

Alert Message: The manufacturer's recommended daily dose of Signifor (pasireotide) in patients with moderate hepatic impairment (Child Pugh B) is 0.6 mg twice a day, due to significantly higher pasireotide exposure. Pasireotide use should be avoided in patients with severe hepatic impairment (Child Pugh C).

Conflict Code: ER - Overutilization
Drugs/Diseases

Util A	Util B	Util C (Include)
Pasireotide		Hepatic Impairment

Max Dose: 1.2 mg/day

References:
Signifor Prescribing Information, December 2012, Novartis Pharmaceuticals Corporation.

69. Lomitapide / Overutilization ____√____ _____ _____

Alert Message: The manufacturer's recommended maximum daily dose of Juxtapid (lomitapide) is 60 mg.

Conflict Code: ER - Overutilization
Drugs/Diseases

Util A	Util B	Util C (Negate)
Lomitapide		Hepatic Impairment
		ESRD
		Dialysis

Max Dose: 60 mg/day

References:
Juxtapid Prescribing Information, December 2012, Aegerion Pharmaceuticals.

70. Lomitapide / ESRD Receiving Dialysis ESRD w/ Dialysis ____√____ _____ _____

Alert Message: The manufacturer's recommended maximum daily dose of Juxtapid (lomitapide) in patients with end-stage renal disease receiving dialysis is 40 mg.

Conflict Code: ER - Overutilization
Drugs/Diseases

Util A	Util B	Util C (Include)
Lomitapide	Dialysis	ESRD

Max Dose: 40 mg/day

References:
Juxtapid Prescribing Information, December 2012, Aegerion Pharmaceuticals.

71. Lomitapide / Hepatic Impairment ____√____ _____ _____

Alert Message: The manufacturer's recommended maximum daily dose of Juxtapid (lomitapide) in patients with mild hepatic impairment is 40 mg. Lomitapide use is contraindicated in patients with moderate or severe hepatic impairment or active liver disease including unexplained persistent abnormal liver function tests.

Conflict Code: ER - Overutilization
Drugs/Diseases

Util A	Util B	Util C (Include)
Lomitapide		Hepatic Impairment

Max Dose: 40 mg/day

References:
Juxtapid Prescribing Information, December 2012, Aegerion Pharmaceuticals.

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

72. Lomitapide / Nonadherence ___√___ _____ _____

Alert Message: Based on refill history, your patient may be under-utilizing Juxtapid (lomitapide). Non-adherence to the prescribed dosing regimen may result in sub-therapeutic effects which may lead to decreased patient outcomes and additional healthcare costs.

Conflict Code: LR - Nonadherence
Drugs/Diseases

Util A	Util B	Util C
Lomitapide		

References:
Juxtapid Prescribing Information, December 2012, Aegerion Pharmaceuticals.
Osterberg L, Blaschke T. Adherence to Medication. M Engl J Med. 2005;353:487-97.

73. Lomitapide / Pregnancy / Miscarriage & Abortion & Delivery ___√___ _____ _____

Alert Message: Juxtapid (lomitapide) is contraindicated during pregnancy because it may cause fetal harm. Females of reproductive potential should have a negative pregnancy test before starting lomitapide and should use effective contraception during lomitapide therapy. Lomitapide is FDA pregnancy category X.

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

Util A	Util B	Util C (Negate)
Lomitapide	Pregnancy	Miscarriage
		Abortion
		Delivery

References:
Juxtapid Prescribing Information, December 2012, Aegerion Pharmaceuticals.

74. Lomitapide / Strong & Moderate CYP3A4 Inhibitors ___√___ _____ _____

Alert Message: Concurrent use of Juxtapid (lomitapide) with a strong or moderate CYP3A4 inhibitor is contraindicated, as this can significantly increase lomitapide exposure.

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

Util A	Util B			Util C
Lomitapide	Ketoconazole	Nefazodone	Ciprofloxacin	Nelfinavir
	Itraconazole	Clarithromycin	Imatinib	Atazanavir
	Voriconazole	Telithromycin	Crizotinib	Darunavir
	Posaconazole	Erythromycin	Dronedarone	
	Fluconazole	Aprepitant	Ritonavir	
	Boceprevir	Verapamil	Saquinavir	
	Telaprevir	Diltiazem	Indinavir	

References:
Juxtapid Prescribing Information, December 2012, Aegerion Pharmaceuticals.
Flockhart DA. Drug Interactions: Cytochrome P450 Drug Interaction Table. Indiana University School of Medicine. Available at:\http://medicine.iupui.edu/clinpharm/ddos/table.asp.
FDA: Drug Development and Drug Interactions: Tables of Substrates, Inhibitors and Inducers. Available at: http://www.fda.gov/Drugs/DevelopmentApprovalProcess/DevelopmentResources/DrugInteractionLabeling/ucm093664.htm

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

75. Lomitapide / Hepatic Impairment & Active liver Disease ___√___ _____ _____

Alert Message: Juxtapid (lomitapide) can cause hepatotoxicity and its use is contraindicated in patients with moderate or severe hepatic impairment (Child Pugh B & C) and patients with active liver disease including persistent elevations of serum transaminases.

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

Util A	Util B	Util C
Lomitapide	Hepatic Impairment	
	Hepatitis	
	Cirrhosis	

References:
Juxtapid Prescribing Information, December 2012, Aegerion Pharmaceuticals.

76. Lomitapide / Weak CYP3A4 Inhibitors ___√___ _____ _____

Alert Message: The manufacturer's maximum recommended dosage of Juxtapid (lomitapide) is 30 mg daily with the concomitant use of weak CYP3A4 inhibitors.

Conflict Code: ER - Overutilization
Drugs/Diseases

Util A	Util B	Util C (Include)	
Lomitapide		Alprazolam	Lapatinib
		Amiodarone	Nilotinib
		Atorvastatin	Oral Contraceptives
		Bicalutamide	Pazopanib
		Cilostazol	Ranitidine
		Cimetidine	Ranolazine
		Cyclosporine	Tipranavir/Ritonavir
		Fluoxetine	Ticagrelor
		Fluvoxamine	Zileuton
		Isoniazid	

Max Dose: 30mg/day

References:
Juxtapid Prescribing Information, December 2012, Aegerion Pharmaceuticals.

77. Lomitapide / Warfarin ___√___ _____ _____

Alert Message: Concurrent use of Juxtapid (lomitapide) and warfarin may result in increased plasma concentrations of warfarin. Patients on warfarin should undergo regular monitoring of INR, especially after changes in lomitapide dosage. The dose of warfarin should be adjusted as clinically indicated.

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

Util A	Util B	Util C
Lomitapide	Warfarin	

References:
Juxtapid Prescribing Information, December 2012, Aegerion Pharmaceuticals.

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

78. Lomitapide / Simvastatin 40 mg Containing Products ___√___ _____ _____

Alert Message: While taking Juxtapid (lomitapide), the maximum daily dose of a simvastatin-containing product is 20 mg (or 40 mg daily for patients who have previously tolerated simvastatin 80 mg daily for at least one year without evidence of muscle toxicity). Concurrent use of lomitapide (CYP3A4 inhibitor) and simvastatin has been shown to approximately double the exposure of simvastatin increasing the risk of statin-related myopathy/rhabdomyolysis.

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

Util A	Util B	Util C (Negate)
Lomitapide	Simvastatin 40 mg	Simvastatin 80 mg (*If patient was on 80mg and now on 40mg prescriber has made appropriate dose adjustment.*)

References:
Juxtapid Prescribing Information, December 2012, Aegerion Pharmaceuticals.

79. Lomitapide / Simvastatin 80mg Containing Products ___√___ _____ _____

Alert Message: While taking Juxtapid (lomitapide), the maximum daily dose of a simvastatin-containing product is 20 mg (or 40 mg daily for patients who have previously tolerated simvastatin 80 mg daily for at least one year without evidence of muscle toxicity). Concurrent use of lomitapide (CYP3A4 inhibitor) and simvastatin has been shown to approximately double the exposure of simvastatin increasing the risk of statin-related myopathy/rhabdomyolysis.

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

Util A	Util B	Util C
Lomitapide	Simvastatin 80 mg	

References:
Juxtapid Prescribing Information, December 2012, Aegerion Pharmaceuticals.

80. Lomitapide / Lovastatin ___√___ _____ _____

Alert Message: Concurrent use of Juxtapid (lomitapide) and a lovastatin-containing product may increase the exposure to lovastatin potentiating the risk of statin-related myopathy/rhabdomyolysis. Reducing the dose of lovastatin should be considered when initiating lomitapide.

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

Util A	Util B	Util C
Lomitapide	Lovastatin	

References:
Juxtapid Prescribing Information, December 2012, Aegerion Pharmaceuticals.

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

81. Lomitapide / P-gp substrates ___√___ _____ _____

Alert Message: Concurrent use of Juxtapid (lomitapide), a P-gp inhibitor, with a P-gp substrate (e.g., aliskiren, colchicine and ranolazine) may increase the absorption of the substrate. Dose reduction of the P-gp substrate should be considered when used concomitantly with lomitapide.

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

Util A	Util B	Util C
Lomitapide	Aliskiren	
	Ambrisentan	
	Colchicine	
	Dabigatran	
	Digoxin	
	Everolimus	
	Fexofenadine	
	Imatinib	
	Lapatinib	
	Linagliptin	
	Maraviroc	
	Nilotinib	
	Posaconazole	
	Ranolazine	
	Saxagliptin	
	Silodosin	
	Sirolimus	
	Sitagliptin	
	Tolvaptan	
	Topotecan	

References:
Juxtapid Prescribing Information, December 2012, Aegerion Pharmaceuticals.
FDA: Drug Development and Drug Interactions: Tables of Substrates, Inhibitors and Inducers. Available at: http://www.fda.gov/Drugs/DevelopmentApprovalProcess/DevelopmentResources/DrugInteractionsLabeling/ucm093664.htm

P-gp substrates that are also strong, moderate or weak CYP3A4 inhibitors are in the specific criteria above because the drugs are either contraindicated or have specific dosing limits.

Stephanie McGee Azar, Acting Commissioner (X) Approve ( ) Deny 6-11-13 Date

R Moon MD
Robert Moon, M.D., Deputy Commissioner and Medical Director (X) Approve ( ) Deny 6-10-13 Date

Kathy Hall, Deputy Commissioner (X) Approve ( ) Deny 6/6/13 Date