

Alabama Medicaid DUR Board Meeting Minutes

October 24, 2012

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

Also Present: Clemice Hurst, Tiffany Minnifield, Heather Vega, Lori Thomas, Scott Donald, Karen Marlowe, Sandy Kilgore, Nancy Bishop, Jacqueline Thomas, Alethea Howard, Shauna Dallas Ford, Jennifer Baker, Tiffany Wilson

Present via Conference Call: Chris Barwick, Kristian Testerman

Members Absent: Dan McConaghy, Robert Moon, 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 July 25, 2012 meeting were presented and reviewed. P. Thompson made a motion to approve the minutes as presented and R. Harden 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 May 2012. She reported 9,896 total requests. She then reported 23,548 electronic requests for the same time frame. From the Prior Authorization and Override Response Time Ratio report for May 2012, L. Thomas reported that approximately 90% of all manual PAs were responded to in less than two hours, about 99% in less than four hours and 99% in less than eight hours. For the month of June 2012, L. Thomas reported 8,441 manual PA requests and 18,477 electronic PA requests. She reported that about 80% of PAs were responded to in less than two hours, approximately 90% in less than four hours and 95% in less than eight hours. L. Thomas informed the Board that there was an issue with the fax server which caused a slight delay in fax completions. She reminded the Board that all contractual agreements were met even with the slight delay. For the month of July 2012, L. Thomas reported 8,938 manual PA requests and 27,674 electronic PA requests for the same time frame. For July, L. Thomas reported 92% approved in less than two hours, approximately 99% 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 4,606,864 total prescriptions, 242,848 average recipients per month and an average paid per prescription of \$59.44 for the months of January 2012 through June 2012.

Cost Management Analysis: L. Thomas reported an average cost per claim of \$59.86 for June 2011 and \$55.09 for June 2012. From the 1st Quarter 2012 Drug Analysis, L. Thomas reported 77.3% generic utilization, 11.8% brand single-source, 3.4% brand multi-source (those requests which required a DAW override) and 7.5% OTC and "other". From the Top 25 Drugs Based on Number of Claims from 04/01/2012 – 06/30/2012, L. Thomas reported the top five drugs: hydrocodone-acetaminophen, amoxicillin, Singulair[®], omeprazole, and alprazolam. She also mentioned that hydrocodone-acetaminophen and amoxicillin have held the position as the top two drugs based on number of claims for some time now. She then reported the top five drugs from the Top 25 Drugs Based on Claims Cost from 04/01/2012 – 06/30/2012: Singulair[®], Abilify[®], Vyvanse[®], Focalin XR[®], and Invega Sustenna[®]. L. Thomas mentioned that Singulair[®] is now available as a generic and that the inclusion of Invega Sustenna[®] replaced Seroquel[®] in the top five based on claims cost. 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, Leukotriene Modifiers, Hemostatics, Corticosteroids (Respiratory Tract), and Amphetamines. She pointed out that this was the same top five as reported in July 2012.

UPDATES

Hydrocodone Utilization: At the July 25, 2012 DUR Board meeting, the Board Members and Care Network Pharmacists were challenged to determine ways to contain the utilization of hydrocodone products. Numerous ideas and suggestions were gathered and it was determined that prescribers would be ranked based on their hydrocodone prescribing patterns. L. Thomas presented a letter to the Board Members that would be distributed by the HID Academic Detailers to the providers found to be the top 100 prescribers of hydrocodone for Alabama Medicaid. L. Thomas informed the Board that pain specialist would not be included in this special. D. Harwood suggested that verbiage be

included in the letter stating that. K. Littlejohn made further suggestions to the letter and she also suggested that PDMP enrollment information be distributed along with the letter. K. Marlowe mentioned several websites that relate to the appropriate use of pain medications. K. Littlejohn mentioned to the Board that Medicaid is currently working to change legislation to allow Medicaid access to PDMP data. K. Littlejohn reminded the Board that the Accumulation Edit, which was passed at the July DUR Meeting, would aid in lowering the early refill thresholds for hydrocodone products, as well. She stated the Agency was hopeful that this edit would be implemented by January 1, 2013. K. Littlejohn informed the Board that the Agency will be updating the Therapeutic Duplication edit to allow for more stringent cross-referencing within the narcotic analgesics class.

Program Integrity – Lock In Overview: S. Kilgore presented an overview of the Lock-In process to the Board. S. Kilgore reviewed the history of the Lock-In program. She detailed the process of locking a patient into a specific physician or pharmacy. She also explained the Agency's criteria for medication abuse.

Review of Annual CMS Report: L. Thomas reviewed the cost-savings portion of the Annual Report that is submitted to the Centers of Medicare and Medicaid Services (CMS). This report tracks the Agency's DUR activities and projected cost savings for Fiscal Year 2011. The total estimated drug savings for the time period October 1, 2010 to September 30, 2011, was \$461, 132. For each \$1 spent, the State saved an additional \$4.96 or 496%. L. Thomas reported that four intervention cycles were run during FY11, and that a total of 2,478 letters were sent to providers. A total of 513 responses were received (approximately 21%). L. Thomas reviewed the Cost Savings table and noted a cost savings of 11.3% for single interventions. She also reported that a total of 11,307 prescriptions were saved.

Proposed Criteria: L. Thomas presented the proposed set of 49 criteria to the Board. R. Harden suggested amending criteria #16 to add specific weight for higher weight and lower weight children. B. Olin suggested amending criteria # 17 and 18 to include specific creatinine clearance ranges for the definition of renal impairment in each criteria. P. Thompson suggested verifying the conflict code description for criteria #22. Board Members suggested rejecting criteria #5 pending clarification. T. Minnifield instructed the Board members to mark their ballots. Of the 49 criteria, results from the criteria vote returned 43 approved, 2 rejected (#5 and #29), and 4 criteria approved as amended (#13, 17, 18, and 22).

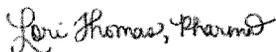
Medicaid Update: T. Minnifield reminded the Board members that all Medicaid information discussed is available online. T. Minnifield turned the Boards attention to the ALERT regarding smoking cessation products for Plan First recipients. She also announced the upcoming 2013 DUR Board meetings.

P & T Committee Update: C. Hurst began the P&T Update by informing the Board that the last meeting was held on August 8, 2012, and covered Central Nervous System agents. The next P&T meeting is scheduled to be held November 14, 2012 at 9am and will cover the First Generation Antihistamines, Estrogens, Prenatal Vitamins, and Diabetic agents. C. Hurst also discussed the PDL changes that were effective October 1, 2012. She mentioned that name brand Accolate is a preferred agent and that the pharmacy should use a DAW-9 when billing.

New Business: There being no new business, D. Thornley-Brown made a motion to adjourn the meeting. The motion was seconded by B. Olin. A voice vote to adjourn was unanimous. The meeting was adjourned at 2:45 p.m.

Next Meeting Date: The next DUR Board meeting will be held on January 23, 2013.

Respectfully submitted,



Lori Thomas, PharmD

Criteria Recommendations

*Accepted Approved Rejected
As
Amended*

4. Abiraterone / Moderate & Severe Hepatic Impairment

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Alert Message: Zytiga (abiraterone) may be over-utilized. Patients with moderately impaired hepatic function (Child-Pugh Class B) should be started at a dose of 250mg/day. The manufacturer recommends that abiraterone be avoided in patients with severe hepatic impairment (Child-Pugh Class C).

Conflict Code: ER - Overutilization

Drugs/Diseases

Util A

Util B

Util C (Include)

Abiraterone

Chronic Liver Disease
Cirrhosis

Max Dose: 250mg/day

References

Zytiga Prescribing Information, April 2011, Centocor Ortho Biotech Inc.
Clinical Pharmacology, 2012 Elsevier/Gold Standard.

5. Abiraterone / Pregnancy / Pregnancy Negating

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Alert Message: Zytiga (abiraterone) is FDA pregnancy category X and is contraindicated during pregnancy and in women of childbearing potential due to risk of potential adverse effects to the fetus.

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

Drugs/Diseases

Util A

Util B

Util C (Negating)

Abiraterone

Pregnancy ICD-9s

Delivery
Miscarriage
Abortion

References:

Zytiga Prescribing Information, April 2011, Centocor Ortho Biotech Inc.
Clinical Pharmacology, 2012 Elsevier/Gold Standard.

6. Abiraterone / History of Cardiovascular Disease

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Alert Message: Zytiga (abiraterone) should be used with caution in patients with a history of cardiovascular disease (e.g., recent myocardial infarction or ventricular arrhythmia). Abiraterone may cause hypertension, hypokalemia and fluid retention due to increased mineralocorticoid levels from CYP17 inhibition.

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

Drugs/Diseases

Util A

Util B

Util C

Abiraterone

Myocardial Infarction
Ventricular Arrhythmia

References:

Zytiga Prescribing Information, April 2011, Centocor Ortho Biotech Inc.
Clinical Pharmacology, 2012 Elsevier/Gold Standard.

7. Abiraterone / History of Heart Failure

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Alert Message: The safety of Zytiga (abiraterone) in patients with left ventricular ejection fraction < 50% or NYHA Class III or IV heart failure has not been established. If treatment with abiraterone is necessary, monitor patients for hypertension, hypokalemia and fluid retention at least once a month.

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

<u>Util A</u>	<u>Util B</u>	<u>Util C</u>
Abiraterone	Heart Failure	

References:

Zytiga Prescribing Information, April 2011, Centocor Ortho Biotech Inc.
Clinical Pharmacology, 2012 Elsevier/Gold Standard.

8. Abiraterone / Drugs that Induce or Inhibit CYP3A4

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Alert Message: Zytiga (abiraterone) is a substrate of CYP3A4. The effects of strong CYP3A4 inhibitors (e.g., ketoconazole, clarithromycin, etc.) or inducers (e.g., phenytoin, carbamazepine, etc.) on the pharmacokinetics of abiraterone have not been evaluated. Use of strong inhibitors and inducers of CYP3A4 should be avoided or used with caution during abiraterone therapy.

Conflict Code: ER – Overutilization
Drugs/Diseases

<u>Util A</u>	<u>Util B</u>	<u>Util C</u>
Abiraterone	Ketoconazole Atazanavir Telithromycin Nelfinavir Carbamazepine Rifapentine	Itraconazole Nefazodone Ritonavir Voriconazole Rifampin Phenobarbital
		Clarithromycin Saquinavir Indinavir Phenytoin Rifabutin

References:

Zytiga Prescribing Information, April 2011, Centocor Ortho Biotech Inc.
Clinical Pharmacology, 2012 Elsevier/Gold Standard.
Flockhart DA. Drug Interactions: Cytochrome P450 Drug Interaction Table. Indiana University School of Medicine. Available at: <http://medicine.iupui.edu/clinpharm/ddos/table.asp>. Accessed 04/2012.

9. Abiraterone / Substrates of CYP2D6

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Alert Message: Zytiga (abiraterone) is an inhibitor of CYP2D6. Co-administration of abiraterone and substrates of CYP2D6 with a narrow therapeutic index (e.g., thioridazine) should be avoided. If alternative treatments cannot be used, a dose reduction of the concomitant CYP2D6 drug should be considered.

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

<u>Util A</u>	<u>Util B</u>	<u>Util C</u>
Abiraterone	Thioridazine	

References:

Zytiga Prescribing Information, April 2011, Centocor Ortho Biotech Inc.
Clinical Pharmacology, 2012 Elsevier/Gold Standard.
Flockhart DA. Drug Interactions: Cytochrome P450 Drug Interaction Table. Indiana University School of Medicine. Available at: <http://medicine.iupui.edu/clinpharm/ddos/table.asp>. Accessed 04/2012.

Criteria Recommendations

*Accepted Approved Rejected
As
Amended*

10. Methotrexate / Proton Pump Inhibitors

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Alert Message: The concurrent administration of a proton pump inhibitor (PPI) and methotrexate (primarily at high dose) may elevate and prolong serum levels of methotrexate and/or its metabolite, possibly leading to methotrexate toxicities. A temporary withdrawal of the PPI (several days before and after methotrexate administration) may be considered in some patients.

Conflict Code: TA – Therapeutic Appropriateness
Drugs/Diseases

<u>Util A</u>	<u>Util B</u>	<u>Util C</u>
Methotrexate	Omeprazole Lansoprazole Pantoprazole Rabeprazole Esomeprazole Dexlansoprazole	

References:

Bezabeh S, Mackey AC, Kluetz P et al., Accumulating Evidence for a Drug-Drug Interaction between Methotrexate and Proton Pump Inhibitors. The Oncologist. April 1, 2012;17:550-554.
Methotrexate Prescribing Information, October 2011, Hospira, Inc.
Clinical Pharmacology, 2012, Elsevier/Gold Standard.

11. Fluvoxamine IR / Dose - Children

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Alert Message: The maximum recommended dose of fluvoxamine in children 8 years of age up to the age of 11 is 200 mg per day.

Conflict Code: ER – High Dose
Drugs/Diseases

<u>Util A</u>	<u>Util B</u>	<u>Util C</u>
Fluvoxamine IR		

Age Range: 8-11 yoa
Max Dose: 200mg/day

References:

Fluvoxamine Maleate Prescribing Information, March 2011, ANI Pharmaceuticals, Inc.
Facts & Comparisons, 2012 Updates.
Clinical Pharmacology, 2012 Elsevier/Gold Standard.

12. Fluoxetine / Dose – Children (MDD)

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Alert Message: The maximum recommended dose of fluoxetine for the treatment of major depressive disorder in children 8 years and older is 20 mg per day.

Conflict Code: ER – High Dose
Drugs/Diseases

<u>Util A</u>	<u>Util B</u>	<u>Util C (Negating)</u>
Fluoxetine		Obsessive Compulsive Disorder

Age Range: 8-18 yoa
Max Dose: 20mg/day

References:

Facts & Comparisons, 2012 Updates.
Prozac Prescribing Information, June 2011, Eli Lilly and Company.

Criteria Recommendations

**Accepted Approved Rejected
As
Amended**

13. Fluoxetine / Dose – Children (OCD) _____ ✓ _____

Alert Message: The maximum recommended dose of fluoxetine for the treatment of obsessive compulsive disorder in adolescents and higher weight children is 60 mg per day. In lower weight children the maximum dose should not exceed 30mg per day.

Conflict Code: ER – High Dose
Drugs/Diseases

<u>Util A</u>	<u>Util B</u>	<u>Util C (Negating)</u>
Fluoxetine		Major Depressive Disorder

Age Range: 7-17 yoa
Max Dose: 60mg/day

References:
Facts & Comparisons, 2012 Updates.
Prozac Prescribing Information, June 2011, Eli Lilly and Company.

14. Naltrexone / Hepatic Injury (Black Box Warning) _____ ✓ _____

Alert Message: Naltrexone has the capacity to cause hepatocellular injury when given in excessive doses and is contraindicated in acute hepatitis or liver failure. Naltrexone does not appear to be a hepatotoxin at the recommended doses. Warn patients of hepatic injury and advise them to stop the use of naltrexone and seek medical attention if they experience symptoms of acute hepatitis.

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

<u>Util A</u>	<u>Util B</u>	<u>Util C</u>
Naltrexone	Acute Hepatitis Liver Failure	

References:
Naltrexone HCL Tablets Prescribing Information, May 2009, Teva Pharmaceuticals USA.
Vivitrol Prescribing Information, Oct. 2010, Alkermes, Inc.
ReVia Tablets Duramed Pharmaceuticals Feb. 2009, Daily Med Current Medication Information, Accessed 06/2012.
Available at: <http://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?id=37634>
Clinical Pharmacology, 2012 Elsevier/Gold Standard.
Facts & Comparisons, 2012 Updates.

15. Naltrexone / Hepatic Impairment / Acute Hepatitis & Liver Failure _____ ✓ _____

Alert Message: Caution should be exercised when administering naltrexone-containing products to patients with active hepatic disease. Naltrexone has the capacity to cause hepatocellular injury when given in excessive doses and is contraindicated in acute hepatitis and liver failure.

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

<u>Util A</u>	<u>Util B</u>	<u>Util C(Negating)</u>
Naltrexone	Liver disease	Acute Hepatis Liver Failure

References:
Naltrexone HCL Tablets Prescribing Information, May 2009, Teva Pharmaceuticals USA.
Vivitrol Prescribing Information, Oct. 2010, Alkermes, Inc
Clinical Pharmacology, 2012 Elsevier/Gold Standard.
Facts & Comparisons, 2012 Updates.

16. Naltrexone / Contraindications

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Alert Message: Naltrexone is contraindicated in patients receiving opioids, currently dependent on opioids (including those currently maintained on opiate agonists), in acute opioid withdrawal, in patients who have failed the naloxone challenge test or who have a positive urine screen for opioids, history of sensitivity to naltrexone or other components of the product and in acute hepatitis or liver failure.

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

Util A Util B Util C
Naltrexone Opiate Agonists

References:

Naltrexone HCL Tablets Prescribing Information, May 2009, Teva Pharmaceuticals USA.
Vivitrol Prescribing Information, Oct. 2010, Alkermes, Inc
Clinical Pharmacology, 2012 Elsevier/Gold Standard.
Facts & Comparisons, 2012 Updates.

17. Naltrexone Injection / Renal Impairment

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Alert Message: Caution should be exercised when administering Vivitrol (naltrexone injection) to patients with **moderate (CrCl 30-50 mL/min) to severe renal impairment (CrCl < 30 mL/min)**. Naltrexone and its active metabolite are excreted primarily in the urine and dose adjustment may be required in these patients. Dose adjustment is not required in patients with mild renal impairment.

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

Util A Util B Util C
Naltrexone Inj Renal Impairment

References:

Vivitrol Prescribing Information, Oct. 2010, Alkermes, Inc
Clinical Pharmacology, 2012 Elsevier/Gold Standard.
Facts & Comparisons, 2012 Updates.

18. Naltrexone-Oral / Renal Impairment

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Alert Message: Caution should be exercised when administering oral naltrexone to patients with **renal impairment (CrCl < 80 mL/min)**. Naltrexone and its active metabolite are excreted primarily in the urine and dose adjustment may be required in these patients.

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

Util A Util B Util C
Naltrexone-Oral Renal Impairment

References:

Naltrexone HCL Tablets Prescribing Information, May 2009, Teva Pharmaceuticals USA.
Clinical Pharmacology, 2012 Elsevier/Gold Standard.
Facts & Comparisons, 2012 Updates.

19. Mycophenolate / Proton Pump Inhibitors

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Alert Message: Caution should be exercised when co-administrating CellCept (mycophenolate) with a proton pump Inhibitor (PPI). PPIs may decrease the pH-dependent dissolution of the mycophenolate product thereby decreasing its absorption and pharmacologic effects.

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

<u>Util A</u>	<u>Util B</u>	<u>Util C</u>
Cellcept	Omeprazole Esomeprazole Lansoprazole Dexlansoprazole Pantoprazole Rabeprazole	

References:
CellCept Prescribing Information, June 2012, Genentech, Inc.
Facts & Comparisons, 2012 Updates.
Clinical Pharmacology, 2012 Elsevier/Gold Standard.

20. Short-Acting Opioids / Long-Acting Opioids (Negating)

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Alert Message: It appears that the patient may be receiving long-term therapy with short-acting opioid pain relievers in the absence of any long-acting analgesics. When treating chronic severe pain, it is typically recommended that a continuous baseline of pain coverage be established by using a long-acting opioid. This is supplemented with the addition of an immediate-release product for breakthrough pain control. If the long-acting opioid is properly adjusted and dosed on a scheduled basis, breakthrough medication should only be necessary 1 or 2 times daily, based on the patient's activity.

Conflict Code: ER – Overutilization
Drugs/Diseases

<u>Util A</u>	<u>Util B</u>	<u>Util C (Negating)</u>
Meperidine		Methadone
Morphine – IR		Morphine LA
Hydromorphone-IR		Hydromorphone LA
Oxymorphone – IR		Oxymorphone LA
Codeine		Oxycodone LA
Hydrocodone		Fentanyl LA
Oxycodone- IR		Tramadol LA
Levorphanol		Tapentadol LA
Fentanyl – IR		
Tramadol – IR		
Tapentadol – IR		
Pentazocine		

References:
Practice Guidelines for Chronic Pain Management: An Updated Report by the American Society of Anesthesiologists Task Force on Chronic Pain Management and the American Society of Regional Anesthesia and Pain Medicine. Anesthesiology. 2010; 112(4):810-833.
Institute for Clinical Systems Improvement (ICSI). Health Care Guideline: Assessment and Management of Chronic Pain. November 2011, 5th Edition.
Available at: http://www.icsi.org/pain_chronic_assessment_and_management_of_guideline.html
Brookoff D, Hospital Practice: Chronic Pain: 2 The Case for Opioids. McGraw-Hill Companies, 2000.
Brennan MJ, et.al. Pharmacologic Management of Breakthrough or Incident Pain, Medscape Clinical Update, 2003.

Criteria Recommendations

**Accepted Approved Rejected
As
Amended**

24. Darunavir / Saquinavir

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Alert Message: Appropriate doses of the combination Prezista (darunavir) and Invirase (saquinavir) have not been established. Hence, it is not recommended to co-administer saquinavir and darunavir, with or without ritonavir. A pharmacokinetic study showed that concurrent therapy with these agents resulted in a 26% decrease in darunavir AUC.

Conflict Code: DD – Drug/Drug Interaction

Drugs/Diseases

Util A Util B Util C
Darunavir Saquinavir

References:

Prezista Prescribing Information, May 2012, Janssen Products, LP.
Clinical Pharmacology, 2012 Elsevier/Gold Standard.

25. Didanosine / Tenofovir

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Alert Message: The didanosine (Videx & Videx EC) dose should be reduced to 250mg/day (patients weighing 60kg or more) or 200mg/day (patients weighing less than 60kg) when co-administered with tenofovir-containing products (e.g., Viread & Truvada). Concurrent use of these agents may cause significantly elevated didanosine concentrations increasing the risk for didanosine-associated toxicity (e.g., pancreatitis, lactic acidosis and neuropathy). Didanosine should be discontinued in patients who develop didanosine-related adverse reactions.

Conflict Code: ER - Overutilization

Drugs/Diseases

Util A Util B Util C (Include)
Didanosine Tenofovir

Max Dose of Didanosine: 250mg/day

References:

Viread Prescribing Information, Jan. 2012, Gilead Sciences, Inc.
Videx Prescribing Information, Nov. 2011, Bristol-Myers Squibb.
Videx EC Prescribing Information, Nov. 2011, Bristol-Myers Squibb.
Truvada Prescribing Information, July 2012, Gilead Sciences, Inc.
Facts & Comparisons, 2012 Updates.
Clinical Pharmacology, 2012 Elsevier/Gold Standard.

26. Didanosine / Renal Impairment

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Alert Message: Patients with renal impairment (CrCl < 60mL/min) may be at greater risk of toxicity from didanosine (Videx & Videx EC) due to decreased drug clearance. Dose reduction is recommended in these patients. Please consult the manufacturer's prescribing information for detailed administration information.

Conflict Code: ER - Overutilization

Drugs/Diseases

Util A Util B Util C (Include)
Didanosine Renal impairment

Max Dose of Didanosine: 200mg/day

References:

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

*Cannot create dosing tables in standard alert messages. All renal dosing info written out would cause alert message to make letters roll to a second page affecting response forms etc....

Criteria Recommendations

Accepted Approved Rejected
As
Amended

27. Darunavir / Ergot Derivatives

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Alert Message: The concurrent use of Prezista (darunavir) and an ergot derivative is contraindicated due to the potential for serious and/or life-threatening events such as acute ergot toxicity.

Conflict Code: DD – Drug/Drug Interaction

Drugs/Diseases

Util A

Util B

Util C

Darunavir

Ergotamine

Dihydroergotamine

Methylergonovine

References:

Prezista Prescribing Information, May 2012, Janssen Products, LP.

Clinical Pharmacology, 2012 Elsevier/Gold Standard.

28. Darunavir / Rifampin

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Alert Message: The concurrent use of Prezista (darunavir) and rifampin is contraindicated due to the potential for a significant decrease in darunavir plasma concentrations resulting in loss of virologic effect.

Conflict Code: DD – Drug/Drug Interaction

Drugs/Diseases

Util A

Util B

Util C

Darunavir

Rifampin

References:

Prezista Prescribing Information, May 2012, Janssen Products, LP.

Clinical Pharmacology, 2012 Elsevier/Gold Standard.

29. Protease Inhibitors / Sildenafil for PAH

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Alert Message: The concurrent use of protease inhibitors and Revatio (sildenafil) is contraindicated due to the potential for sildenafil-associated adverse events (e.g., visual disturbance, hypotension, prolonged erection and syncope).

Conflict Code: DD – Drug/Drug Interaction

Drugs/Diseases

Util A

Util B

Util C

Protease Inhibitors

Revatio

References:

Prezista Prescribing Information, May 2012, Janssen Products, LP.

Clinical Pharmacology, 2012 Elsevier/Gold Standard.

Norvir Prescribing Information, March 2012, Abbot Laboratories.

Invirase Prescribing Information, Feb. 2012, Genentech.

Crixivan Prescribing Information, April. 2012, Merck & Co., Inc.

Viracept Prescribing Information, April. 2012, Pfizer, Inc.

Aptivus Prescribing Information, Feb. 2012, Boehringer Ingelheim Pharmaceuticals.

Lexiva Prescribing Information, April. 2012, ViiV Healthcare.

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

Kaletra Prescribing Information, April 2012, Abbott Laboratories.

Criteria Recommendations

**Accepted Approved Rejected
As
Amended**

30. Indinavir / Amiodarone

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Alert Message: The concurrent use of Crixivan (indinavir) and amiodarone is contraindicated due to the potential for serious and/or life-threatening reactions such as cardiac arrhythmias.

Conflict Code: DD – Drug/Drug Interaction

Drugs/Diseases

Util A

Util B

Util C

Indinavir

Amiodarone

References:

Crixivan Prescribing Information, April, 2012, Merck & Co., Inc.

Clinical Pharmacology, 2012 Elsevier/Gold Standard.

Facts & Comparisons, 2012 Updates.

31. Complera / All Other Antiretroviral Agents

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Alert Message: The patient appears to be receiving other antiretroviral therapy in addition to Complera (emtricitabine/tenofovir/rilpivirine). Complera 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

Complera

Protease Inhibitors

NRTIs

Fusion Inhibitors

NNRTIs

Integrase Inhibitor

CCR5 Antagonist

References:

Complera Prescribing Information, July 2011, Gilead Sciences, Inc.

Clinical Pharmacology, 2012 Elsevier/Gold Standard.

32. Sitagliptin / Non-adherence

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Alert Message: Based on refill history, your patient may be under-utilizing Januvia (sitagliptin). Non-adherence to the prescribed dosing regimen may result in loss of glycemic control and an increased risk of developing adverse diabetic-related complications.

Conflict Code: LR – Non-adherence

Drugs/Diseases

Util A

Util B

Util C

Sitagliptin

References:

Currie CJ, Peyrot M, Morgan CL, et al. The Impact of Treatment Noncompliance on Mortality in People With Type 2 Diabetes. Diabetes Care 35:1279-1284, June 2012.

Ho PM, Rumsfeld JS, Masoudi FA, et al., Effect of Medication Nonadherence in Diabetes Mellitus, Cardiology Review, April 2007.

Miller KE, Medication Nonadherence Affects Diabetes Treatment. Am Family Phys. Vol. 75 No. 6, March 15, 2007

Lau DT, Nau DP. Antihyperglycemic Medication Nonadherence and Subsequent Hospitalization Among Individuals with Type 2 Diabetes. Diabetes Care 27: 2149-2153, 2004.

Criteria Recommendations

**Accepted Approved Rejected
As
Amended**

33. Rosiglitazone / Non-adherence

_____✓_____

Alert Message: Based on refill history, your patient may be under-utilizing Avandia (rosiglitazone). Non-adherence to the prescribed dosing regimen may result in loss of glycemic control and an increased risk of developing adverse diabetic-related complications.

Conflict Code: LR – Non-adherence

Drugs/Diseases

Util A

Util B

Util C

Rosiglitazone

References:

Currie CJ, Peyrot M, Morgan CL, et al. The Impact of Treatment Noncompliance on Mortality in People With Type 2 Diabetes. *Diabetes Care* 35:1279-1284, June 2012.

Ho PM, Rumsfeld JS, Masoudi FA, et al., Effect of Medication Nonadherence in Diabetes Mellitus, *Cardiology Review*, April 2007.

Miller KE, Medication Nonadherence Affects Diabetes Treatment. *Am Family Phys.* Vol. 75 No. 6, March 15, 2007
Lau DT, Nau DP. Antihyperglycemic Medication Nonadherence and Subsequent Hospitalization Among Individuals with Type 2 Diabetes. *Diabetes Care* 27: 2149-2153, 2004.

34. Kombiglyze XR / Non-adherence

_____✓_____

Alert Message: Based on refill history, your patient may be under-utilizing Kombiglyze XR (saxagliptin/metformin). Non-adherence to the prescribed dosing regimen may result in loss of glycemic control and an increased risk of developing adverse diabetic-related complications.

Conflict Code: LR – Non-adherence

Drugs/Diseases

Util A

Util B

Util C

Sitagliptin/metformin

References:

Currie CJ, Peyrot M, Morgan CL, et al. The Impact of Treatment Noncompliance on Mortality in People With Type 2 Diabetes. *Diabetes Care* 35:1279-1284, June 2012.

Ho PM, Rumsfeld JS, Masoudi FA, et al., Effect of Medication Nonadherence in Diabetes Mellitus, *Cardiology Review*, April 2007.

Miller KE, Medication Nonadherence Affects Diabetes Treatment. *Am Family Phys.* Vol. 75 No. 6, March 15, 2007.

Lau DT, Nau DP, Oral Antihyperglycemic Medication Nonadherence and Subsequent Hospitalization Among Individuals with Type 2 Diabetes, *Diabetes Care.* 27: 2149-2153, 2004.

35. Acarbose / Non-adherence

_____✓_____

Alert Message: Based on refill history, your patient may be under-utilizing Precose (acarbose). Non-adherence to the prescribed dosing regimen may result in loss of glycemic control and an increased risk of developing adverse diabetic-related complications.

Conflict Code: LR – Non-adherence

Drugs/Diseases

Util A

Util B

Util C

Acarbose

References:

Currie CJ, Peyrot M, Morgan CL, et al. The Impact of Treatment Noncompliance on Mortality in People With Type 2 Diabetes. *Diabetes Care* 35:1279-1284, June 2012.

Ho PM, Rumsfeld JS, Masoudi FA, et al., Effect of Medication Nonadherence in Diabetes Mellitus, *Cardiology Review*, April 2007.

Miller KE, Medication Nonadherence Affects Diabetes Treatment. *Am Family Phys.* Vol. 75 No. 6, March 15, 2007.

Lau DT, Nau DP, Oral Antihyperglycemic Medication Nonadherence and Subsequent Hospitalization Among Individuals with Type 2 Diabetes, *Diabetes Care.* 27: 2149-2153, 2004.

36. Miglitol / Non-adherence

____√____ _____ _____

Alert Message: Based on refill history, your patient may be under-utilizing Glyset (miglitol). Non-adherence to the prescribed dosing regimen may result in loss of glycemic control and an increased risk of developing adverse diabetic-related complications.

Conflict Code: LR – Non-adherence

Drugs/Diseases

Util A

Util B

Util C

Miglitol

References:

Currie CJ, Peyrot M, Morgan CL, et al. The Impact of Treatment Noncompliance on Mortality in People With Type 2 Diabetes. Diabetes Care 35:1279-1284, June 2012.

Ho PM, Rumsfeld JS, Masoudi FA, et al., Effect of Medication Nonadherence in Diabetes Mellitus, Cardiology Review, April 2007.

Miller KE, Medication Nonadherence Affects Diabetes Treatment. Am Family Phys. Vol. 75 No. 6, March 15, 2007.

Lau DT, Nau DP, Oral Antihyperglycemic Medication Nonadherence and Subsequent Hospitalization Among Individuals with Type 2 Diabetes, Diabetes Care. 27: 2149-2153, 2004.

37. Pramlintide/ Non-adherence

____√____ _____ _____

Alert Message: Based on refill history, your patient may be under-utilizing Symlin (pramlintide). Non-adherence to the prescribed dosing regimen may result in loss of glycemic control and an increased risk of developing adverse diabetic-related complications.

Conflict Code: LR – Non-adherence

Drugs/Diseases

Util A

Util B

Util C

Pramlintide

References:

Currie CJ, Peyrot M, Morgan CL, et al. The Impact of Treatment Noncompliance on Mortality in People With Type 2 Diabetes. Diabetes Care 35:1279-1284, June 2012.

Ho PM, Rumsfeld JS, Masoudi FA, et al., Effect of Medication Nonadherence in Diabetes Mellitus, Cardiology Review, April 2007.

Miller KE, Medication Nonadherence Affects Diabetes Treatment. Am Family Phys. Vol. 75 No. 6, March 15, 2007.

Lau DT, Nau DP, Oral Antihyperglycemic Medication Nonadherence and Subsequent Hospitalization Among Individuals with Type 2 Diabetes, Diabetes Care. 27: 2149-2153, 2004.

38. Exenatide / Non-adherence

____√____ _____ _____

Alert Message: Based on refill history, your patient may be under-utilizing Byetta (exenatide). Non-adherence to the prescribed dosing regimen may result in loss of glycemic control and an increased risk of developing adverse diabetic-related complications.

Conflict Code: LR – Non-adherence

Drugs/Diseases

Util A

Util B

Util C

Exenatide

References:

Currie CJ, Peyrot M, Morgan CL, et al. The Impact of Treatment Noncompliance on Mortality in People With Type 2 Diabetes. Diabetes Care 35:1279-1284, June 2012.

Ho PM, Rumsfeld JS, Masoudi FA, et al., Effect of Medication Nonadherence in Diabetes Mellitus, Cardiology Review, April 2007.

Miller KE, Medication Nonadherence Affects Diabetes Treatment. Am Family Phys. Vol. 75 No. 6, March 15, 2007.

Lau DT, Nau DP, Oral Antihyperglycemic Medication Nonadherence and Subsequent Hospitalization Among Individuals with Type 2 Diabetes, Diabetes Care. 27: 2149-2153, 2004.

39. Exenatide-Weekly / Non-adherence

_____√_____

Alert Message: Based on refill history, your patient may be under-utilizing Bydureon (exenatide weekly). Non-adherence to the prescribed dosing regimen may result in loss of glycemic control and an increased risk of developing adverse diabetic-related complications.

Conflict Code: LR – Non-adherence

Drugs/Diseases

Util A

Util B

Util C

Exenatide

References:

Currie CJ, Peyrot M, Morgan CL, et al. The Impact of Treatment Noncompliance on Mortality in People With Type 2 Diabetes. Diabetes Care 35:1279-1284, June 2012.

Ho PM, Rumsfeld JS, Masoudi FA, et al., Effect of Medication Nonadherence in Diabetes Mellitus, Cardiology Miller Miller KE, Medication Nonadherence Affects Diabetes Treatment. Am Family Phys. Vol. 75 No. 6, March 15, 2007.

Lau DT, Nau DP, Oral Antihyperglycemic Medication Nonadherence and Subsequent Hospitalization Among Individuals with Type 2 Diabetes, Diabetes Care. 27: 2149-2153, 2004.

Review, April 2007.

40. Clobazam / Overutilization (≥ 10 yoa)

_____√_____

Alert Message: Onfi (clobazam) may be over-utilized. Patients weighing greater than 30 kg should have therapy initiated at 10 mg daily and titrated as tolerated to a maximum of 40 mg daily. Patients weighing 30 kg or less should have clobazam therapy initiated at 5 mg daily and titrated as tolerated to 20 mg daily.

Conflict Code: ER - Overutilization

Drugs/Diseases

Util A

Util B

Util C

Clobazam

Max Dose: 40mg/day

Age Range: ≥ 10 yoa

We do not receive weight data for patients so an age range was chosen to reduce the number of false positives. The age range of 10 years of age and older was selected because the average weight of a 10 year child is 86 pounds (85 for males, 88 for females according to CDC Body Mass Index Report 2000).

References:

Onfi Prescribing Information, October 2011, Lundbeck, Inc.

41. Clobazam / Overutilization (2-9 yoa)

_____√_____

Alert Message: Onfi (clobazam) may be over-utilized. Patients weighing 30 kg or less should have clobazam therapy initiated at 5 mg daily and titrated as tolerated to 20 mg daily. Patients weighing greater than 30 kg should have therapy initiated at 10 mg daily and titrated as tolerated to a maximum of 40 mg daily .

Conflict Code: ER - Overutilization

Drugs/Diseases

Util A

Util B

Util C

Clobazam

Max Dose: 20mg/day

Age Range: 2-9 yoa

References:

Onfi Prescribing Information, October 2011, Lundbeck, Inc.

Criteria Recommendations

Accepted Approved Rejected
As
Amended

42. Clobazam / TA - Therapeutic Appropriateness (<2 yoa)

_____√_____

Alert Message: The safety and effectiveness of Onfi (clobazam) in patients less than 2 years of age have not been established.

Conflict Code: TA - Therapeutic Appropriateness

Drugs/Diseases

Util A

Util B

Util C

Clobazam

Age Range: 0-1 yoa

References:

Onfi Prescribing Information, October 2011, Lundbeck, Inc.

43. Clobazam / Nonadherence

_____√_____

Alert Message: Based on the refill history, your patient may be underutilizing Onfi (clobazam). Non-adherence to the prescribed dosing regimen may result in sub-therapeutic effects, which may lead to decreased patient outcomes and additional healthcare costs. If the patient is discontinuing clobazam it should be withdrawn gradually by decreasing the total daily dose by 5 - 10 mg/day on a weekly basis until discontinued in order to avoid seizures occurrence or withdrawal symptoms.

Conflict Code – LR - Nonadherence

Drugs/Diseases

Util A

Util B

Util C

Clobazam

References:

Onfi Prescribing Information, October 2011, Lundbeck, Inc.

44. Clobazam / Moderate & Strong CYP2C19 Inhibitors

_____√_____

Alert Message: Onfi (clobazam) is a CYP2C19 substrate and concurrent use with a strong or moderate CYP2C19 inhibitor may result in increased exposure to the active metabolite of clobazam (N-desmethyloclobazam). Dosage adjustment of clobazam may be necessary.

Conflict Code: DD – Drug/Drug Interaction

Drugs/Diseases

Util A

Util B

Util C

Clobazam

Fluconazole

Fluvoxamine

Ticlopidine

Omeprazole

Esomeprazole

Fluoxetine

Voriconazole

References:

Onfi Prescribing Information, October 2011, Lundbeck, Inc.

FDA Drug Development and Drug Interactions: Table of Substrates, Inhibitors and Inducers: Table of Substrates, Inhibitors.

Available at: <http://www.fda.gov/drugs/developmentapprovalprocess/developmentresources/druginteractionslabeling/ucm093664.htm>

Criteria Recommendations

**Accepted Approved Rejected
As
Amended**

45. Clobazam / CNS Depressants

____/____ ____

Alert Message: Onfi (clobazam) has a CNS depressant effect and concurrent use with other CNS depressants may result in potentiated depressants effects.

Conflict Code

Drugs/Diseases

Util A

Util B

Util C

Clobazam

Narcotics

Barbiturates

Benzodiazepines

Sedative/Hypnotics

Muscle Relaxants

Antihistamines

Antipsychotics

References:

Onfi Prescribing Information, October 2011, Lundbeck, Inc.

Micromedex Healthcare Series, DrugDex Drug Evaluations, 2011 Thomson Reuters.

46. Clobazam / CYP3A4 Metabolized Hormonal Contraceptives

____/____ ____

Alert Message: Onfi (clobazam) is a weak CYP3A4 inducer and concurrent use with CYP3A4-metabolized hormonal contraceptives may diminish the effectiveness of the contraceptive agent. The manufacturer recommends the use an additional non-hormonal form of contraception when using clobazam.

Conflict Code: DD – Drug/Drug Interaction

Drugs/Diseases

Util A

Util B

Util C

Clobazam

CYP3A4 Metabolized Hormonal Contraceptives

References:

Onfi Prescribing Information, October 2011, Lundbeck, Inc.

Micromedex Healthcare Series, DrugDex Drug Evaluations, 2011 Thomson Reuters.

47. Clobazam / Substance Abuse

____/____ ____

Alert Message: Onfi (clobazam) should be use with caution in patients with a history of substance abuse because of the predisposition of such patients to habituation and dependence. Clobazam is a benzodiazepine and in clinical trials, cases of dependency were reported following abrupt discontinuation of clobazam.

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

Drugs/Diseases

Util A

Util B

Util C

Clobazam

Drug Abuse

References:

Onfi Prescribing Information, October 2011, Lundbeck, Inc.

Criteria Recommendations

*Accepted Approved Rejected
As
Amended*

48. Clobazam / CYP2D6 Metabolized Drugs

_____✓_____

Alert Message: Onfi (clobazam) is a CYP2D6 inhibitor and concurrent use with drugs metabolized by CYP2D6 may cause increased plasma concentrations of the substrate. Dosage adjustment of the CYP2D6 substrate may be required.

Conflict Code: DD - Drug/Drug Interaction

Drugs/Diseases

Util A

Util B

Util C

Clobazam	Dextromethorphan	Aripiprazole	Paroxetine	Ondansetron
	Atomoxetine	Carvedilol	Propafenone	Promethazine
	Metoprolol	Duloxetine	Propranolol	Chlorpheniramine
	Nebivolol	Flecainide	Risperidone	
	Perphenazine	Fluoxetine	Tamoxifen	
	Tolterodine	Fluvoxamine	Timolol	
	Venlafaxine	Haloperidol	Tramadol	
	Thioridazine	Mexiletine	Amphetamine	
	Tricyclic Antidepressants	Oxycodone	Donepezil	

References:

Onfi Prescribing Information, October 2011, Lundbeck, Inc..

FDA Drug Development and Drug Interactions: Table of Substrates, Inhibitors and Inducers: Table of Substrates, Inhibitors.

Available at: <http://www.fda.gov/drugs/developmentapprovalprocess/developmentresources/druginteractionslabeling/ucm093664.htm>

Micromedex Healthcare Series, DrugDex Drug Evaluations, 2011 Thomson Reuters.

49. Clobazam / Alcohol Abuse/Dependence

_____✓_____

Alert Message: A review of the patient's diagnostic profile reveals that they may consume alcohol. The concurrent use of Onfi (clobazam) with alcohol has been reported to increase the maximum plasma exposure of clobazam by approximately 50%. Caution patients against use of alcohol while taking clobazam.

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

Drugs/Diseases

Util A

Util B

Util C

Clobazam	Alcohol Dependence	
	Acute Alcohol Intoxication	
	Other/Unspecified Alcohol Dependence	

References:

Onfi Prescribing Information, October 2011, Lundbeck, Inc.

Stephanie McGee Azar Approve () Deny 12-13-12
Stephanie McGee Azar, Commissioner Date

Robert Moon Approve () Deny 12-13-12
Robert Moon, M.D., Deputy Commissioner and Medical Director Date

Kathy Hall Approve () Deny 12/12/12
Kathy Hall, Deputy Commissioner Date