

Alabama Medicaid DUR Board Meeting Minutes July 28, 2010

Members Present: Paula Thompson, David Frazer, Donald Marks, Bernie Olin, David Harwood, Dan McConaghy, Denyse Thornley-Brown, Kevin Green, Kelli Littlejohn, Robert Moon, and Christina Faulkner

Also Present: Clemice Hurst, Tiffany Minnifield

Members Absent: Jimmy Jackson, Kevin Royal, Rhonda Harden, Daniel Mims

Call to Order: Kevin Green, Vice-Chair, filling in for Chair, Daniel Mims, called the meeting to order at 1:00pm.

Welcome: Kevin Green welcomed the newest DUR Board member, Donald Marks, MD. Dr. Marks practices at Cooper Green Hospital in Birmingham.

Review and Adoption of Minutes of April 28, 2010 meeting: Kevin Green asked if there were additions, deletions, or changes to the minutes of the April 28 meeting. No changes were suggested. Paula Thompson made a motion to approve the minutes as discussed and Denyse Thornley-Brown seconded the motion. A voice vote to approve the minutes was unanimous.

Prior Authorization and Overrides Update: Christina Faulkner began the Prior Authorization and Overrides Update with the Monthly Manual Prior Authorizations and Overrides Report for the month of March. She reported 9,129 requests and an approval rate of 65%. She reported 14,650 electronic requests for the same time frame. From the Prior Authorization and Override Response Time Ratio report for March 2010 she reported that between 90 and 91% of all manual PAs were responded to in less than two hours and between 95 and 97% in less than 8 hours. For the month of April, Christina reported 8,440 manual PA requests and 14,296 electronic PA requests. She reported that 96.32% of PAs were responded to in less than 2 hours, 98.70% in less than 4 hours and 99.14% in less than 8 hours. For the month of May, Christina reported 7,426 manual PA requests and 12,688 electronic PA requests for the same time frame. For May, Christina reported between 94 and 95% approved in less than 2 hours and between 98 and 99% approved in less than 8 hours.

Program Summary Review: Christina briefly reviewed the Alabama Medicaid Program Summary on page 34. From the 6 Month Assessment, she noted 457,282 recipients and an average paid per prescription of \$58.68.

Cost Management Analysis: Christina reported for April 2008 an average cost per claim of \$59.88 and for March 2010 an average cost per claim of \$59.69. From the Drug Analysis 1st Quarter 2010, Christina reported 73.3% generic utilization, 16.57% brand single-source, 4.05% brand multi-source and 6.08% OTC and "other". From the Top 25 Drugs Based on Total Claims from 04/01/10-04/30/2010, Christina reported the top 5 drugs: hydrocodone-acetaminophen, amoxicillin, Singulair[®], alprazolam and azithromycin. She then reported the top 5 drugs from the Top 25 Drugs Based on Claims Cost From 04/01/10-04/30/10: Singulair[®], Abilify[®], Seroquel[®], Vyvanse[®] and Advair Diskus[®]. From the Top 15 Therapeutic Classes by Total Cost of Claims from 04/01/10-04/30/10, Christina reported the top five classes: antipsychotic agents, leukotriene modifiers, beta-adrenergic agonists, anticonvulsants and amphetamines. The Board requested that HID provide a list of drugs and number of recipients taking anticonvulsants without a diagnosis of epilepsy. Christina will provide that information to the Board at the October DUR meeting.

For the October DUR meeting the Board plans to discuss the utilization of Singulair[®], hydrocodone, Abilify[®] for depression and Seroquel[®]. Christina will provide requested utilization data at the October meeting.

Alprazolam Utilization: Christina informed the Board that Alabama Medicaid does not currently require a PA for generic alprazolam, but does have maximum quantity limits in place. Patients can receive 136 tablets per 34 days of alprazolam 0.25, 0.5 and 1mg tablets. The maximum quantity for the 2mg tablet is 102 tablets for 34 days. Quantities greater than those listed require an override, which may be obtained through the prior authorization help desk. HID recommended a hard edit allowing 102 tablets per month and 3 prescriptions per patient per year. The Board tabled this recommendation, asking for additional information. The Board requested information regarding other drugs being used with alprazolam. They also requested the dollar amount spent on clonazepam compared to alprazolam. The issue will be tabled until such information is brought back to the Board in October.

Early Refill Policy Review: Currently, Alabama Medicaid allows early refills when 75% of a prescription has been used. HID recommended to change the refill allowance to 85% for controlled substances. The Board requested information on early refills by age and drug. This issue will be tabled until such information is received.

RDUR Criteria: Christina presented the set of 23 proposed criteria to the Board for their review. Board members were instructed to mark their ballots. Criteria #1, #6, #19 and #20 were approved as amended. All other criteria were approved as presented.

Medicaid Update: Tiffany called the board members attention to their Medicaid packets and reminded them to turn in their vouchers. She noted that the packets contained the current PDL Reference Tool and the most recent Alerts. She reminded the Board that the Synagis webinar and other informational materials are still available on the Medicaid website. New information will be added as it becomes available. Tiffany reminded the Board that they would be voting for Vice-Chair. Candidates for the Vice-Chair position are Bernie Olin, Paula Thompson and Jimmy Jackson. She asked members to mark ballots and turn them in.

P & T Committee Update: Clemice Hurst began the P&T Update by informing the Board that at the last meeting, the Committee reviewed the Diabetic Agents, Estrogens and the First Generation Antihistamines. She also informed the Board that a list of First Generation Antihistamines and prenatal vitamins is now available on the Agency website. She stated that the next P&T meeting will be held on August 11. At the August meeting the committee will review the Cardiac Agents, Antihypertensive Agents and the Overactive Bladder Agents.

Kelli Littlejohn informed the Board that the Agency will be requiring NDCs on all physician administered drugs starting October 1 instead of July 1.

Board Election Results: The Board elected Paula Thompson for the new Vice-Chair position.

New Business: Kevin Green, Vice-Chair, asked the Board if there was any new business. There being no new business brought before the Board, Kevin asked for a motion to adjourn. Denyse Thornley-Brown made a motion to adjourn the meeting. The motion was seconded by David Harwood. A voice vote to adjourn was unanimous. The meeting was adjourned at 2:03pm.

Next Meeting Date: The next DUR Board meeting will be held on Wednesday, October 27, 2010.

Respectfully submitted,



Christina Faulkner, PharmD

ALABAMA MEDICAID

RETROSPECTIVE DRUG UTILIZATION REVIEW CRITERIA RECOMMENDATIONS

Criteria Recommendations

Accepted Approved Rejected
As
Amended

1. Embeda / MAO Inhibitors

_____ **X** _____

Alert Message: Embeda (morphine/naltrexone) should not be used in patients taking MAO inhibitors or within 14 days of stopping MAOI treatment. MAOIs have been reported to potentiate the effects of morphine (e.g., anxiety, confusion and significant respiratory depression or coma).

Conflict Code: DD – Drug/Drug Interaction

Drug/Disease:

<u>Util A</u>	<u>Util B</u>	<u>Util C</u>
Morphine/Naltrexone	Isocarboxazid Phenelzine Tranylcypromine Selegiline Linezolid Rasagiline	

References:

Embeda Prescribing Information, June 2009, King Pharmaceuticals, Inc.
Facts & Comparisons, 2010 Updates.

2. Embeda / Therapeutic Appropriateness

_____ **X** _____

Alert Message: Embeda (morphine/naltrexone) 100 mg/4 mg capsules are for use in opioid-tolerant patients only. Our records do not indicate the patient is opioid tolerant. Ingestion of this strength capsules may cause fatal respiratory depression when administered to patients not already tolerant to high doses of opioids.

Conflict Code: TA – Therapeutic Appropriateness (**Black Box Warning**)

Drug/Disease:

<u>Util A</u>	<u>Util B</u>	<u>Util C (Negating)</u>
Morphine/Naltrexone 100 mg/4 mg		All Other Narcotics Opioid Tolerance ICD-9

References:

Embeda Prescribing Information, June 2009, King Pharmaceuticals, Inc.
Facts & Comparisons, 2010 Updates.

3. Embeda / Alcohol Warning

_____ **X** _____

Alert Message: Embeda (morphine/naltrexone) should not be consumed with alcoholic beverages or coadministered with any other alcohol-containing medication. Concurrent use of morphine/naltrexone with alcohol may result in an increase of plasma levels and potentially fatal overdose of morphine.

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

Drug/Disease:

<u>Util A</u>	<u>Util B</u>	<u>Util C</u>
Morphine/Naltrexone	Alcohol Dependence/Abuse	

References:

Embeda Prescribing Information, June 2009, King Pharmaceuticals, Inc.
Facts & Comparisons, 2010 Updates.

Criteria Recommendations

Accepted As Amended **Approved** **Rejected**

4. Embeda / Alcohol Warning

 X _____ _____

Alert Message: Embeda (morphine/naltrexone) should not be consumed with alcoholic beverages or coadministered with any other alcohol containing medication. Concurrent use of morphine/naltrexone with alcohol may result in an increase of plasma levels and potentially fatal overdose of morphine.

Conflict Code: DD – Drug/Drug Interactions (**Black Box Warning**)

Drug/Disease:

<u>Util A</u>	<u>Util B</u>	<u>Util C</u>
Morphine/Naltrexone	Alcohol containing meds	

References:

Embeda Prescribing Information, June 2009, King Pharmaceuticals, Inc.
Facts & Comparisons, 2010 Updates.

5. Embeda / CNS Depressants

 X _____ _____

Alert Message: Embeda (morphine/naltrexone) should be used with caution and in reduced dosage in patients who are concurrently receiving other central nervous system depressants (e.g., sedatives or hypnotics, general anesthetics, phenothiazines, other opioids and alcohol) because respiratory depression, hypotension and profound sedation or coma may result. It is recommended that the initial dose of one or both agents be reduced by at least 50%.

Conflict Code: DD – Drug/Drug Interaction

Drug/Disease:

<u>Util A</u>	<u>Util B</u>	<u>Util C</u>
Morphine/Naltrexone	Sedatives/Hypnotics Phenothiazines Opioids	

References:

Embeda Prescribing Information, June 2009, King Pharmaceuticals, Inc.
Facts & Comparisons, 2010 Updates.

6. Embeda / Muscle Relaxants

_____ X _____

Alert Message: Embeda (morphine/naltrexone) should be used with caution in patients receiving muscle relaxants. Morphine/naltrexone may enhance the neuromuscular blocking action of skeletal muscle relaxants and produce an increased degree of respiratory depression.

Conflict Code: DD – Drug/Drug Interaction

Drug/Disease:

<u>Util A</u>	<u>Util B</u>	<u>Util C</u>
Morphine/Naltrexone	Baclofen Carisoprodol Chlorzoxazone Cyclobenzaprine Metaxalone Methocarbamol Orphenadrine Tizanidine Dantrolene	

References:

Embeda Prescribing Information, June 2009, King Pharmaceuticals, Inc.
Facts & Comparisons, 2010 Updates.

Criteria Recommendations

Accepted Approved Rejected
As
Amended

7. Morphine / Paralytic Ileus

 X _____ _____

Alert Message: Morphine-containing products are contraindicated in patients with or suspected of having paralytic ileus because morphine diminishes propulsive peristaltic waves in the GI tract and may prolong the obstruction. Oral extended-release morphine preparations may remain in the stomach for a prolonged period and subsequently release a bolus of morphine when normal gut motility is restored.

Conflict Code: MC – Drug (Actual) Disease Precaution

Drug/Disease:

Util A

Morphine- All

Util B

Paralytic Ileus

Util C

References:

Facts & Comparisons, 2010 Updates.

Embeda Prescribing Information, June 2009, King Pharmaceuticals, Inc.

8. Morphine / P-Glycoprotein Inhibitors

 X _____ _____

Alert Message: Caution should be exercised when a morphine-containing product is co-administered with a P-glycoprotein (P-gp) inhibitor (e.g. quinidine, ritonavir, verapamil and ketoconazole). The P-gp inhibitor quinidine has been shown to increase the absorption/exposure of morphine sulfate by two-fold.

Conflict Code: DD – Drug/Drug Interaction

Drug/Disease:

Util A

Morphine

Util B

Amiodarone

Atorvastatin

Chlorpromazine

Clarithromycin

Cyclosporine

Diltiazem

Erythromycin

Felodipine

Fluphenazine

Hydrocortisone

Indinavir

Itraconazole

Ketoconazole

Lidocaine

Mifepristone

Nelfinavir

Nicardipine

Nifedipine

Progesterone

Propranolol

Quinidine

Reserpine

Ritonavir

Saquinavir

Tacrolimus

Tamoxifen

Testosterone

Util C

Trifluoperazine

Verapamil

References:

Embeda Prescribing Information, June 2009, King Pharmaceuticals, Inc.

Facts & Comparisons, 2010 Updates.

Hartshorn EA & Tatro DS, Principles of Drug Interactions, Facts & Comparisons, 2010 Updates.

Criteria Recommendations

Accepted Approved Rejected
As
Amended

9. Pure Opioids / Mixed Agonist/Antagonist Analgesics

 X _____ _____

Alert Message: Mixed opiate agonists/antagonists (i.e., buprenorphine, butorphanol, nalbuphine or pentazocine) should be administered with caution to a patient who has received or is receiving a course of therapy with a pure opioid agonist analgesic. In this situation, mixed agonist/antagonist analgesics may reduce the analgesic effect of the pure opioid and/or may precipitate withdrawal symptoms.

Conflict Code: DD – Drug/Drug Interaction

Drug/Disease:

<u>Util A</u>	<u>Util B</u>	<u>Util C</u>
Morphine	Buprenorphine	
Meperidine	Butorphanol	
Hydromorphone	Nalbuphine	
Oxymorphone	Pentazocine	
Codeine		
Hydrocodone		
Oxycodone		
Levorphanol		
Fentanyl		
Propoxyphene		

References:

Embeda Prescribing Information, June 2009, King Pharmaceuticals, Inc.
Facts & Comparisons, 2010 Updates.
Clinical Pharmacology, 2010 Gold Standard.

10. Propylthiouracil / Methimazole (Negating)

 X _____ _____

Alert Message: Severe liver injury and acute liver failure, in some cases fatal, have been reported in patients treated with propylthiouracil. Propylthiouracil should be reserved for patients who cannot tolerate methimazole and in whom radioactive iodine therapy or surgery are not appropriate treatments for the management of hyperthyroidism.

Conflict Code: TA – Therapeutic Appropriateness (**Black Box Warning**)

Drug/Disease:

<u>Util A</u>	<u>Util B</u>	<u>Util C (Negating)</u>
Propylthiouracil		Methimazole

References:

FDA Drug Safety Communication: New Boxed Warning on Severe Liver Injury with Propylthiouracil. FDA Drug Safety Information. 04/21/2010.
Propylthiouracil Tablets, Jan. 2010, DAVA Pharmaceuticals, Inc.

11. Dalfampridine / High Dose

 X _____ _____

Alert Message: The maximum recommended dose of Ampyra (dalfampridine) is 10 mg twice daily (approximately 12 hours apart) with or without food. No additional benefit was demonstrated at doses greater than 10 mg twice daily and adverse events, including seizures, were more frequent at higher doses.

Conflict Code: ER – Overutilization

Drug/Disease:

<u>Util A</u>	<u>Util B</u>	<u>Util C</u>
Dalfampridine		

Maximum Dose: 20mg/day

References:

Ampyra Prescribing Information, 2010, Acorda Therapeutics, Inc.

Criteria Recommendations

**Accepted Approved Rejected
As
Amended**

12. Dalfampridine / History of Seizures

X _____ _____

Alert Message: Ampyra (dalfampridine) is contraindicated in patients with a prior history of seizures. This agent can cause seizures and the risk increases with increasing doses. Dalfampridine should be discontinued if seizure occurs.

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

Drug/Disease:

<u>Util A</u>	<u>Util B</u>	<u>Util C</u>
Dalfampridine	Seizure ICD-9s Epilepsy ICD-9s Convulsions ICD-9s Anticonvulsants	

References:

Ampyra Prescribing Information, 2010, Acorda Therapeutics, Inc.

13. Colchicine / P-gp & Strong 3A4 Inhibitors / Renal or Hepatic Impairment

X _____ _____

Alert Message: The use of a colchicine-containing product with P-gp inhibitors or strong CYP3A4 inhibitors is contraindicated in patients with renal or hepatic impairment. Life-threatening and fatal colchicine toxicity has been reported with concurrent use of colchicine (at therapeutic doses) with these agents in these patients.

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

Drug/Disease:

<u>Util A</u>	<u>Util B</u>	<u>Util C (Include)</u>
Colchicine	Atazanavir Clarithromycin Indinavir Itraconazole Ketoconazole Nefazodone Nelfinavir Ritonavir Saquinavir Telithromycin Testosterone	Cyclosporine Hydrocortisone Renal Impairment Hepatic Impairment Ranolazine Mifepristone Amiodarone Nicardipine Atorvastatin Nifedipine Chlorpromazine Progesterone Propranolol Quinidine Reserpine Felodipine Tacrolimus Fluphenazine Tamoxifen Trifluoperazine Verapamil

References:

Facts & Comparisons, 2010 Updates.
 Hartshorn EA and Tatro DS. Principles of Drug Interactions, Facts & Comparisons, E Answers 2010.
 Colcrys Prescribing Information, Dec. 2009, AR Scientific.
 FDA Drug Safety Information for Healthcare Professionals: Information for Healthcare Professionals: New Safety Information for Colchicine (marketed as Colcrys). 07/30/2009.
 PD Hansten and Horn JR, Drug Interactions Analysis and Management 2010.

Criteria Recommendations

**Accepted Approved Rejected
As
Amended**

14. Colchicine / Antihyperlipidemics

___X___

Alert Message: Concomitant use of a colchicine-containing product and agents that are associated with myotoxicity (e.g. atorvastatin, simvastatin, pravastatin, fluvastatin, gemfibrozil, and fenofibrate) may potentiate the development of myopathy and rhabdomyolysis. Elderly patients and those with renal dysfunction are at increased risk. Patients on concurrent therapy should be monitored for signs of symptoms of myotoxicity.

Conflict Code: DD – Drug/Drug Interaction

Drug/Disease:

<u>Util A</u>	<u>Util B</u>	<u>Util C</u>
Colchicine	Atorvastatin Simvastatin Pravastatin Fluvastatin Lovastatin Rosuvastatin Gemfibrozil Fenofibrate	

References:

Colcrys Prescribing Information, Dec. 2009, AR Scientific.
Facts & Comparisons, 2010 Updates.
Clinical Pharmacology, 2010 Gold Standard.

15. Colchicine / P-gp & Strong 3A4 Inhibitors / Renal or Hepatic Impair.

___X___

Alert Message: Concurrent use of a colchicine-containing product with P-gp inhibitors and strong CYP3A4 inhibitors may result in colchicine toxicity which may be fatal. If concurrent use is warranted the colchicine dose should be reduced or interrupted depending on condition and original intended dose. Refer to colchicine prescribing information for specific dosing adjustment.

*There are multiple dosage reductions depending on condition being treated – too much to get in an alert message so referred physician to prescribing information dosing table.

Conflict Code: DD – Drug/Drug Interaction

Drug/Disease:

<u>Util A</u>	<u>Util B</u>		<u>Util C (Negate)</u>
Colchicine	Atazanavir Clarithromycin Indinavir Itraconazole Ketoconazole Nefazodone Nelfinavir Ritonavir Saquinavir Telithromycin Testosterone	Cyclosporine Ranolazine Amiodarone Atorvastatin Chlorpromazine Clarithromycin Diltiazem Erythromycin Felodipine Fluphenazine Trifluoperazine	Hydrocortisone Mifepristone Nicardipine Nifedipine Progesterone Propranolol Quinidine Reserpine Tacrolimus Tamoxifen

References:

Colcrys Prescribing Information, Dec. 2009, AR Scientific.
Facts & Comparisons, 2010 Updates.
Clinical Pharmacology, 2010 Gold Standard.

Criteria Recommendations

Accepted Approved Rejected
As
Amended

16. Colchicine / Moderate 3A4 Inhibitors

 X _____ _____

Alert Message: Concurrent use of a colchicine-containing product with moderate CYP3A4 inhibitors may result in a significant increase in colchicine plasma concentrations. If concurrent use is warranted the colchicine dose should be reduced depending on condition and original intended dose. Refer to colchicine prescribing information for specific dosing adjustment.

*There are multiple dosage reductions depending on condition being treated – too much to get in an alert message so referred physician to prescribing information dosing table.

Conflict Code: DD – Drug/Drug Interaction

Drug/Disease:

<u>Util A</u>	<u>Util B</u>	<u>Util C</u>
Colchicine	Amprenavir Aprepitant Diltiazem Erythromycin	Fluconazole Fosamprenavir Verapamil

References:

Colcrys Prescribing Information, Dec. 2009, AR Scientific.
Facts & Comparisons, 2010 Updates.
Clinical Pharmacology, 2010 Gold Standard.

17. Colchicine / Digoxin

 X _____ _____

Alert Message: Concurrent use of a colchicine-containing product and digoxin may cause elevated colchicine levels resulting in the myopathy and/or rhabdomyolysis due to competitive inhibition of P-gp. Patients on concurrent therapy should be monitored for signs of symptoms of myotoxicity.

Conflict Code: DD – Drug/Drug Interaction

Drug/Disease:

<u>Util A</u>	<u>Util B</u>	<u>Util C</u>
Colchicine	Digoxin	

References:

Colcrys Prescribing Information, Dec. 2009, AR Scientific.
Clinical Pharmacology, 2010 Gold Standard.

18. Tramadol Extended-Release / Severe Renal Impairment

 X _____ _____

Alert Message: Extended-release tramadol products should not be used in patients with severe renal impairment. The limited availability of dose strengths of the extended-release product does not permit the dosing flexibility required for safe use in patients with severe renal impairment.

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

Drug/Disease:

<u>Util A</u>	<u>Util B</u>	<u>Util C</u>
Tramadol ER Ultram ER Ryzolt	Severe Renal Impairment Stage IV & V – ICD-9s PhosLo Renagel Zemplar Renvela Fosrenol	

References:

Facts & Comparisons, 2010 Updates.
Ultram ER Prescribing Information, June 2009, Ortho-McNeil Pharmaceuticals, Inc.
Ryzolt Prescribing Information, Feb. 2010, Purdue Pharma, L.P.
Clinical Pharmacology, 2010 Gold Standard.

Criteria Recommendations

Accepted Approved Rejected
As
Amended

19. Tramadol Extended-Release / Severe Hepatic Impairment

_____ X _____

Alert Message: Extended-release tramadol products should not be used in patients with severe hepatic impairment (Child-Pugh Class C). The limited availability of dose strengths of the extended-release product does not permit the dosing flexibility required for safe use in patients with severe hepatic impairment.

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

Drug/Disease:

Util A Util B Util C
Tramadol ER Severe Hepatic Impairment ICD-9s
Ultram ER

References:

Facts & Comparisons, 2010 Updates.

Ultram ER Prescribing Information, June 2009, Ortho-McNeil Pharmaceuticals, Inc.

Clinical Pharmacology, 2010 Gold Standard.

****Criteria #19 and #20 will be combined.**

20. Ryzolt / Hepatic Impairment

_____ X _____

Alert Message: Ryzolt (extended-release tramadol) should not be used in patients with hepatic impairment. The limited availability of dose strengths of the extended-release product does not permit the dosing flexibility required for safe use in patients with hepatic impairment.

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

Drug/Disease:

Util A Util B Util C
Ryzolt Hepatic Impairment ICD-9s

References:

Ryzolt Prescribing Information, Feb. 2010, Purdue Pharma, L.P.

****Criteria #19 and #20 will be combined.**

21. Tramadol + APAP / Hepatic Impairment

_____ X _____

Alert Message: Ultracet (tramadol/acetaminophen) should not be use in patients with hepatic impairment. Both agents in the fixed dose combination product are extensively metabolized by the liver.

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

Drug/Disease:

Util A Util B Util C
Tramadol/APAP Hepatic Impairment ICD-9s

References:

Facts & Comparisons, 2010 Updates.

Ultracet Prescribing Information, March 2008, Ortho-McNeil Pharmaceuticals, Inc.

Micromedex Healthcare Series, DrugDex Drug Evaluations, 2010.

Criteria Recommendations

Accepted Approved Rejected
As
Amended

22. Tramadol + APAP / Severe Renal Impairment

___X___ _____ _____

Alert Message: The dose of Ultracet (tramadol/acetaminophen) in patients with creatinine clearance of less than 30 mL/min should not exceed 2 tablets every 12 hours. The combination product has not been studied in patients with impaired renal function but experience with tramadol suggests that impaired renal function results in decreased rate and extent of excretion of tramadol and its active metabolite.

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

Drug/Disease:

Util A

Util B

Util C (Include)

Tramadol/APAP

Severe Renal Impairment Stage IV & V-ICD-9s

PhosLo

Renagel

Zemplar

Renvela

Fosrenol

Max Dose: 150 mg tramadol/day

References:

Facts & Comparisons, 2010 Updates.

Ultracet Prescribing Information, March 2008, Ortho-McNeil Pharmaceuticals, Inc.

Micromedex Healthcare Series, DrugDex Drug Evaluations, 2010.

The minutes of the July 28, 2010 DUR Board Meeting have been reviewed and approved as submitted.

Carol H. Steckel
Carol H. Steckel, Commissioner

Approve () Deny

10/4/10
Date

Kathy Hall
Kathy Hall, Deputy Commissioner

Approve () Deny

9/17/10
Date

R Moon MD
Robert Moon, M.D., Medical Director

Approve () Deny

10-2-10
Date