

Alabama Medicaid DUR Board Meeting Minutes

January 25, 2012

Members Present: Paula Thompson, Kelli Littlejohn, Bernie Olin, Denyse Thornley-Brown, Wendy Gomez, Dan McConaghy, Daniels Mims, Robert Moon

Also Present: Clemice Hurst, Tiffany Minnifield, Christina Faulkner, Lori Thomas

Present via Conference Call: Chris Barwick, Cara Leos, Amanda Sparkman

Members Absent: Rhonda Harden, Jimmy Jackson, David Harwood, Yves Morrisette, Donald Marks

Call to Order: The DUR meeting was called to order by P.Thompson at approximately 1:00p.m.

Review and Adoption of Minutes: The minutes of the October 26, 2011 meeting were presented and reviewed. D.Thornley-Brown made a motion to approve the minutes as presented and B.Olin seconded the motion. The motion was approved unanimously.

Prior Authorization and Overrides Update: L.Thomas began the Prior Authorization and Overrides Update with the Monthly Manual Prior Authorizations and Overrides Report for the month of August 2011. She reported 9,912 total requests. She then reported 17,745 electronic requests for the same time frame. From the Prior Authorization and Override Response Time Ratio report for August 2011, L.Thomas reported that approximately 85-86% of all manual PAs were responded to in less than two hours, more than 96% in less than four hours and more than 98% in less than eight hours. For the month of September 2011, L.Thomas reported 9,808 manual PA requests and 15,967 electronic PA requests. She reported that more than 88% of PAs were responded to in less than two hours, approximately 96% in less than four hours and approximately 99% in less than eight hours. For the month of October, L.Thomas reported 10,767 manual PA requests and 36,599 electronic PA requests for the same time frame. L.Thomas noted that the large increase in manual and electronic PA requests is due to the implementation of the antipsychotic edit. This edit was effective October 3, 2011. For October, L.Thomas reported 75% 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 4,283,783 total prescriptions, 221,759 average recipients per month and an average paid per prescription of \$58.64 for the months of April 2011 through September 2011.

Cost Management Analysis: L.Thomas reported an average cost per claim of \$59.16 for July 2011 and \$58.80 for August 2009. From the 3rd Quarter 2011 Drug Analysis, L.Thomas reported 75.03% generic utilization, 13.95% brand single-source, 3.89% brand multi-source (those requests which required a DAW override) and 7.13% OTC and "other". From the Top 25 Drugs Based on Number of Claims from 07/01/2011 – 09/30/2011, L.Thomas reported the top five drugs: hydrocodone-acetaminophen, amoxicillin, omeprazole, Singulair[®] and alprazolam. She then reported the top five drugs from the Top 25 Drugs Based on Claims Cost from 07/01/2011 – 09/30/2011: Singulair[®], Abilify[®], Seroquel[®], Vyvanse[®] and Zyprexa[®]. 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, Adrenals, Leukotriene Modifiers, Hemostatics and Amphetamines. R.Moon pointed out that these numbers were prior to the implementation of the antipsychotic clinical edit.

B.Olin noted that hydrocodone-acetaminophen was listed in the top 25 drugs based on number of claims and asked what measures were in place to help prevent abuse. K.Littlejohn responded that physicians can request access to the Prescription Drug Monitoring Program (PDMP) and that Medicaid has a monthly maximum quantity limitation on hydrocodone products. W.Gomez asked if it would be possible to change the maximum quantity on these medications. K.Littlejohn replied that the DUR Board could recommend a change to the Agency. It was suggested that HID prepare data regarding hydrocodone utilization to be presented to the Board during the April meeting. A recommendation was also made to have an overview of the PDMP during the April meeting.

UPDATES

RDUR Cost/Benefit Analysis: At the October 2011 DUR Meeting, the Board requested that HID present a cost/benefit analysis regarding increasing the number of profiles reviewed each quarter. L.Thomas presented information showing the savings per recipient during the last five years and reviewed savings/recipient for a state with a roster similar to the state of Alabama.

Proposed Criteria: L.Thomas presented the proposed set of 18 criteria to the Board. P.Thompson requested clarification on criteria #5. B.Olin made a motion to table the criteria. R.Moon seconded the motion and a voice vote was unanimous to reject and table criteria #5 until the next meeting. T.Minnifield instructed the Board members to mark their ballots. Of the 18 criteria, results from the criteria vote returned 17 approved, 1 rejected (#5) and 0 criteria approved as amended.

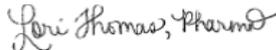
Medicaid Update: K. Littlejohn began the Medicaid Update by detailing changes made to IUD reimbursement effective January 1, 2012. K. Littlejohn also discussed upcoming CMS-required changes to provider enrollment. K Littlejohn gave an overview of the new ePrescribing tool provided by Alabama Medicaid and HP. K.Littlejohn discussed the Patient Care Networks with the Board, explaining what the pharmacists in each region are currently working on. C.Leos discussed what the focus has been in the East Alabama region. K.Littlejohn also informed the Board that the American Drug Utilization Review (ADURs) meeting will be held in Scottsdale, Arizona in February. T.Minnifield reminded the Board members that all Medicaid information discussed is available online.

P & T Committee Update: C.Hurst began the P&T Update by informing the Board that the last meeting was held on November 9, 2011 and covered the Skin and Mucous Membrane Agents. The next P&T meeting is scheduled to be held February 8, 2012 at 9am and will cover Anti-Infective agents.

New Business: There being no new business, P.Thompson asked for a motion to adjourn. 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 2:30p.m.

Next Meeting Date: The next DUR Board meeting will be held on April 25, 2012.

Respectfully submitted,



Lori Thomas, PharmD

Criteria Recommendations

**Accepted Approved Rejected
As
Amended**

4. Indacaterol / Adrenergic Drugs

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Alert Message: Caution should be exercised when Arcapta (indacaterol) is prescribed concurrently with other adrenergic sympathomimetic agents administered by any route because the sympathetic effects of indacaterol may be potentiated.

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

<u>Util A</u>	<u>Util B</u>			<u>Util C</u>
Indacaterol	Ephedrine	Methyldopa	Phentermine	Naphazoline
	Epinephrine	Tizanidine	Benzphetamine	Pirbuterol
	Pseudoephedrine	Amphetamine	Diethylpropion	Metaproterenol
	Phenylephrine	Dextroamphetamine	Phendimetrazine	Terbutaline
	Clonidine	Lisdexamfetamine	Apraclonidine	
	Guanfacine	Methylphenidate	Brimonidine	

References:
Arcapta Prescribing Information, July 2011, Novartis Pharmaceuticals Corp.
Clinical Pharmacology, 2011 Gold Standard.
Facts & Comparisons, 2011 Updates.

5. Indacaterol / Xanthines Derivatives, Steroids & K+ Sparing Diuretics

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Alert Message: Caution should be exercised when Arcapta (indacaterol) is prescribed concurrently with xanthine derivatives, steroids or diuretics because concomitant administration may potentiate the hypokalemic effect of indacaterol.

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

<u>Util A</u>	<u>Util B</u>		<u>Util C</u>
Indacaterol	Theophylline	Prednisolone	
	Aminophylline	Prednisone	
	Dyphylline	Triamterene	
	Betamethasone	Acetazolamide	
	Budesonide	Amiloride	
	Cortisone	Spironolactone	
	Dexamethasone		
	Hydrocortisone		
	Methylprednisolone		

References:
Arcapta Prescribing Information, July 2011, Novartis Pharmaceuticals Corp.
Clinical Pharmacology, 2011 Gold Standard.
Facts & Comparisons, 2011 Updates.

6. Indacaterol / Non-Potassium Sparing Diuretics

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Alert Message: Caution should be exercised when Arcapta (indacaterol) is prescribed concurrently with non-potassium-sparing diuretics because concomitant administration may potentiate the ECG changes or hypokalemia that may result from the administration of the diuretic.

Conflict Code: DD- Drug/Drug Interaction

Drugs/Diseases

<u>Util A</u>	<u>Util B</u>	<u>Util C</u>
Indacaterol	Furosemide	Indapamide
	Bumetanide	Methyclothiazide
	Torsemide	Metolazone
	Chlorothiazide	
	Chlorthalidone	
	HCTZ	

References:

Arcapta Prescribing Information, July 2011, Novartis Pharmaceuticals Corp.
 Clinical Pharmacology, 2011 Gold Standard.
 Facts & Comparisons, 2011 Updates.

7. Indacaterol / Nonselective Beta Blockers (Oral & Ophthalmic)

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Alert Message: Concurrent use of Arcapta (indacaterol) with a beta-adrenergic receptor antagonist may interfere with the effect of each other. Beta-blockers not only block the therapeutic effects of beta-agonists, but may produce severe bronchospasm in patients with asthma and COPD. If concomitant therapy cannot be avoid, consider a cardioselective beta-blocker, but administered with caution.

Conflict Code: DD- Drug/Drug Interaction

Drugs/Diseases

<u>Util A</u>	<u>Util B</u>	<u>Util C (Negating)</u>
Indacaterol	Carvedilol	Acebutolol
	Nadolol	Atenolol
	Labetalol	Betaxolol
	Penbutolol	Bisoprolol
	Pindolol	Metoprolol
	Propranolol	Nebivolol
	Sotalol	
	Timolol	

References:

Arcapta Prescribing Information, July 2011, Novartis Pharmaceuticals Corp.
 Clinical Pharmacology, 2011 Gold Standard.
 Facts & Comparisons, 2011 Updates.

8. Indacaterol / Cardiovascular, Convulsive Disorders, Thyrotoxicosis & Diabetes

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Alert Message: Arcapta (indacaterol) should be used with caution in patients with cardiovascular or convulsive disorders, thyrotoxicosis or sensitivity to sympathomimetic drugs. Indacaterol is a sympathomimetic amine and can aggravate these conditions.

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

<u>Util A</u>	<u>Util B</u>	<u>Util C</u>
Indacaterol	Arrhythmia	
	Hypertension	
	Heart Failure	
	Epilepsy	
	Seizures	
	Diabetes	

References:

Arcapta Prescribing Information, July 2011, Novartis Pharmaceuticals Corp.
Clinical Pharmacology, 2011 Gold Standard.
Facts & Comparisons, 2011 Updates.

9. Indacaterol / MAOIs, TCAs & QT Prolongation Agents

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Alert Message: Arcapta (indacaterol) should be administered with extreme caution to patients being treated with MAOIs, TCAs, or drugs known to prolong the QTc interval because the action of the adrenergic agonist, indacaterol, on the cardiovascular system may be potentiated by these agents.

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

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

References:

Arcapta Prescribing Information, July 2011, Novartis Pharmaceuticals Corp.
Clinical Pharmacology, 2011 Gold Standard.
Facts & Comparisons, 2011 Updates.

Criteria Recommendations

**Accepted Approved Rejected
As
Amended**

10. Nelfinavir / Contraindicated Drugs

Alert Message: Concurrent use of nelfinavir is contraindicated with drugs that are highly dependent on CYP3A4 for clearance and for which elevated plasma concentrations are associated with serious or life-threatening events.

Conflict Code: DD- Drug/Drug Interaction

Drugs/Diseases

<u>Util A</u>	<u>Util B</u>	<u>Util C</u>
Nelfinavir	Alfuzosin Dihydroergotamine Ergonovine Ergotamine Methylergonovine Pimozide Sildenafil (Revatio) Midazolam Triazolam	

References:

Viracept Prescribing Information, Feb. 2011, Agouron Pharmaceuticals, Inc.
Clinical Pharmacology, 2011 Gold Standard.
Facts & Comparisons, 2011 Updates

11. Lazanda - Fentanyl Nasal / Overutilization

Alert Message: The manufacturer's recommended maximum maintenance dose of Lazanda (fentanyl nasal spray) is a single spray into each nostril (total of 2 sprays) per episode; no more than 4 doses per 24 hours (total of 8 sprays). The safety and efficacy of doses higher than 800 mcg have not been evaluated in clinical studies.

Conflict Code: ER - Overutilization

Drugs/Diseases

<u>Util A</u>	<u>Util B</u>	<u>Util C</u>
Fentanyl Nasal		

Max Dose: 1 bottle per day (8 sprays/bottle)

References:

Lazanda Prescribing Information, June 2011, Archimedes Pharma US Inc.

12. Lazanda - Fentanyl Nasal / Therapeutic Appropriateness

Alert Message: Lazanda (fentanyl nasal spray) is indicated only for the management of breakthrough pain in cancer patients, 18 years of age and older, who are already receiving and who are tolerant to opioid therapy for their underlying persistent cancer pain. The product is contraindicated in patients who are not already opioid tolerant due to life-threatening respiratory depression and death.

Conflict Code: TA - Therapeutic Appropriateness

Drugs/Diseases

<u>Util A</u>	<u>Util B</u>	<u>Util C (Negating)</u>
Fentanyl Nasal		All other Opioids

References:

Lazanda Prescribing Information, June 2011, Archimedes Pharma US Inc.

Criteria Recommendations

**Accepted Approved Rejected
As
Amended**

13. Lazanda - Fentanyl Nasal / Renal & Hepatic Disease

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Alert Message: The manufacturer recommends that Lazanda (fentanyl nasal spray) be carefully titrated to clinical effect for patients with impaired hepatic or renal function. Fentanyl is hepatically metabolized and renally excreted and fentanyl levels could be altered in these populations.

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

<u>Util A</u>	<u>Util B</u>	<u>Util C</u>
Fentanyl Nasal	Renal Impairment Hepatic Impairment	

References:

Lazanda Prescribing Information, June 2011, Archimedes Pharma US Inc.

14. Lazanda - Fentanyl Nasal / Vasoconstrictive Nasal Agents

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Alert Message: The concurrent use of Lazanda (fentanyl nasal spray) with a vasoconstrictive nasal decongestant to treat allergic rhinitis may result in lower peak plasma concentrations and delayed Tmax of fentanyl, thus impairing pain management. Additionally, in view of the possibility that the titration of a patient while they are experiencing an acute episode of rhinitis could lead to incorrect dose identification (particularly if using a vasoconstrictive decongestant), titration under these circumstances must be avoided.

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

<u>Util A</u>	<u>Util B</u>	<u>Util C</u>
Fentanyl Nasal	Oxymetazoline Phenylephrine Pseudoephedrine Propylhexedrine Levmetamfetamine Naphazoline Tetrahydrozoline Xylometazoline	

References:

Lazanda Prescribing Information, June 2011, Archimedes Pharma US Inc.

15. Fentanyl-All / CYP3A4 Inducers _____√_____

Alert Message: The concurrent use of fentanyl products with CYP3A4 inducers (e.g., carbamazepine, phenytoin, nevirapine and barbiturates) may result in a decrease in fentanyl plasma concentrations, which could decrease the efficacy of fentanyl. Patients receiving fentanyl who stop therapy with, or decrease the dose of, the CYP3A4 inducer may experience a sudden increase in fentanyl plasma concentrations requiring fentanyl dose adjustment.

Conflict Code: DD - Drug/Drug interaction

Drugs/Diseases

<u>Util A</u>	<u>Util B</u>				<u>Util C</u>
Fentanyl-All	Barbiturates	Fosphenytoin	Rifapentine	Bosentan	
	Glucocorticoids	Nevirapine	Rifampin		
	Carbamazepine	Efavirenz	Pioglitazone		
	Oxcarbazepine	Etravirine	Modafinil		
	Phenytoin	Rifabutin	Armodafinil		

References:

Facts & Comparisons, 2011 Updates.

Clinical Pharmacology, 2011 Gold Standard.

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

Available at:

<http://www.fda.gov/Drugs/DevelopmentApprovalProcess/DevelopmentResources/DrugInteractionsLabeling/ucm093664.htm#classInhibit>. Last updated 9/16/2011, Accessed: 10/12/2011

16. Duragesic, Onsolis & Fentora/CYP3A4 Inhibitors (Strong, Mod & Weak) _____√_____

Alert Message: Concurrent use of fentanyl products (Duragesic, Onsolis and Fentora) with CYP3A4 inhibitors (e.g., ritonavir, ketoconazole, itraconazole, clarithromycin, nelfinavir, and nefazodone) may result in an increase in fentanyl plasma concentrations, which could increase or prolong adverse effects and may cause potentially fatal respiratory depression. Patients receiving fentanyl and CYP3A4 inhibitors should be monitored for an extended period of time and dosage adjustments made if warranted.

Conflict Code: DD - Drug/Drug interaction (Black Box Warning)

Drugs/Diseases

<u>Util A</u>	<u>Util B (Strong, Moderate & Weak Inhibitors)</u>				<u>Util C</u>
Duragesic	Nefazodone	Saquinavir	Ciprofloxacin	Bicalutamide	Ranitidine
Fentora	Erythromycin	Ritonavir	Atazanavir	Cilostazol	Ranolazine
Onsolis	Clarithromycin	Nelfinavir	Aprepitant	Cimetidine	Zileuton
	Telithromycin	Indinavir	Fosamprenavir	Cyclosporine	Zafirlukast
	Ketoconazole	Boceprevir	Dronedarone	Fluoxetine	
	Itraconazole	Telaprevir	Delavirdine	Fluvoxamine	
	Voriconazole	Diltiazem	Amiodarone	Isoniazid	
	Posaconazole	Verapamil	Amlodipine	Lapatinib	
	Fluconazole	Imatinib	Atorvastatin	Nilotinib	

References:

Facts & Comparisons, 2011 Updates.

Clinical Pharmacology, 2011 Gold Standard.

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

Available at:

<http://www.fda.gov/Drugs/DevelopmentApprovalProcess/DevelopmentResources/DrugInteractionsLabeling/ucm093664.htm#classInhibit>. Last updated 9/16/2011, Accessed: 10/12/2011

Duragesic Prescribing Information, July 2009, Janssen Pharms.

Fentora Prescribing Information, Jan. 2011, Cephalon.

Onsolis Prescribing Information, May 2010, Meda Pharms.

17. Lazanda, Actiq & Abstral / Strong & Moderate CYP3A4 Inhibitors _____[√]_____

Alert Message: Concurrent use of fentanyl products (Lazanda, Actiq & Abstral) with strong or moderate CYP3A4 inhibitors (e.g., ritonavir, ketoconazole, itraconazole, clarithromycin, nelfinavir, and nefazodone) may result in an increase in fentanyl plasma concentrations, which could increase or prolong adverse effects and may cause potentially fatal respiratory depression. Patients receiving fentanyl and CYP3A4 inhibitors should be monitored for an extended period of time and dosage adjustments made if warranted.

Conflict Code: DD - Drug/Drug interaction (Black Box Warning – specifically says strong & moderate)
Drugs/Diseases

<u>Util A</u>	<u>Util B (Strong & Moderate Inhibitors)</u>		<u>Util C</u>
Actiq	Nefazodone	Saquinavir	Ciprofloxacin
Abstral	Erythromycin	Ritonavir	Atazanavir
Lazanda	Clarithromycin	Nelfinavir	Aprepitant
	Telithromycin	Indinavir	Fosamprenavir
	Ketoconazole	Boceprevir	Dronedarone
	Itraconazole	Telaprevir	Delavirdine
	Voriconazole	Diltiazem	
	Posaconazole	Verapamil	
	Fluconazole	Imatinib	

References:

Facts & Comparisons, 2011 Updates.

Clinical Pharmacology, 2011 Gold Standard.

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

Available at:

<http://www.fda.gov/Drugs/DevelopmentApprovalProcess/DevelopmentResources/DrugInteractionsLabeling/ucm093664.htm#classInhibit> Last updated 9/16/2011, Accessed: 10/12/2011

Lazanda Prescribing Information, June 2011, Archimedes Pharma US Inc.

Actiq Prescribing Information, July 2011, Cephalon.

Abstral Prescribing information, Jan. 2011, ProStrakan, Inc.

18. Ticagrelor / Simvastatin & Lovastatin _____[√]_____

Alert Message: Concurrent use of Brilinta (ticagrelor) and simvastatin or lovastatin may result in higher serum concentrations of simvastatin or lovastatin resulting in the increase risk of statin-related adverse effects (e.g., myopathy and/or rhabdomyolysis). Avoid doses of simvastatin or lovastatin greater than 40 mg per day.

Conflict Code: ER – Overutilization

Drugs/Diseases

<u>Util A</u>	<u>Util B</u>	<u>Util C (Include)</u>
Simvastatin		Ticagrelor
Lovastatin		

Max Dose of Simvastatin: 40mg/day

Max Dose of Lovastatin: 40mg/day

References:

Brilinta Prescribing Information, July 2011, AstraZeneca.

Micromedex Healthcare Series, DrugDex Drug Evaluations, 2011 Thomson Reuters

R. Bob Mullins, Jr. Approve () Deny 2-27-12
R. Bob Mullins, Jr., M.D., Commissioner Date

R. Moon Approve () Deny 2-27-12
Robert Moon, M.D., Deputy Commissioner and Medical Director Date

Kathy Hall Approve () Deny 2/21/2012
Kathy Hall, Deputy Commissioner Date