

Alabama Medicaid DUR Board Meeting Minutes January 27, 2010

Members Present: Paula Thompson, David Frazer, Bernie Olin, Daniel Mims, Kevin Royal, David Harwood, Jimmy Jackson, Dan McConaghy, Denyse Thornley-Brown, Kevin Green, Kelli Littlejohn, Robert Moon

Also Present: Clemice Hurst, Tiffany Minnifield, Christina Faulkner, Hardik Patel

Members Absent: Rhonda Harden, Paul Nagrodzki

Call to Order: Daniel Mims, Chairman, called the meeting to order at 1:10 p.m.

Review and Adoption of Minutes of October 28, 2009 meeting: Daniel Mims asked if there were additions, deletions, or changes to the minutes of the October 28 meeting. Kevin Royal made a motion to approve the minutes as presented and Paula Thompson seconded the motion. A voice vote to accept the minutes as written 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 November. She reported 8,062 requests. She reported 14,236 electronic requests for the same time frame. From the Prior Authorization and Override Response Time Ratio report for November, 2010 she reported that 64% of manual PAs were responded to in less than two hours and 83-84% in less than eight hours. Kevin Green asked if HID could report multiple denials in the Total PA and Overrides report. Christina stated that HID is currently working to devise a strategy to follow a PA from start to finish.

Program Summary Review: Christina briefly reviewed the total medical costs on the first page of the Cost Management Analysis reports on page 32. She noted the change in medical costs over the year from October 2008 to September 2009. Christina then reviewed the Drug Analysis report on page 33. She noted that for the third quarter of 2009 almost 70% of claims were for generic, 20% for brand single source, 3.87% for brand multisource and 6.45% for OTC and other.

Provider Update – Statins: In response to a request by the Board at the last meeting, Christina presented a Provider Update Handout on statins. The Board requested that triglycerides information be included in the handout. The Board also asked that HID prepare an educational handout for Tamiflu for next flu season. In response to a question from the Board regarding high potency statins, Kelli stated that simvastatin is currently the preferred high potency statin.

RDUR Update: Christina reviewed the RDUR Intervention Letter Activity Report on page 38. She reported that previous data issues were resolved. She further reported 944 profiles reviewed in January 2009 and 458 profiles reviewed in November 2009. She stated that 505 letters were sent in January and 534 in November. She further reviewed the criteria picks for January and November 2009. Referring to the RDUR Response information on page 40, Christina reported 98 responses to the January intervention received thus far and 60 responses to the November intervention received thus far. Responses were very positive for both intervention cycles. David Harwood suggested a DUR cycle focusing on the use of injectable antipsychotics with other dosage forms of these drugs.

RDUR Criteria: Christina presented the set of 26 proposed criteria to the Board for their review. Board members were instructed to mark their ballots. Criteria #10 was amended as follows: the Alzheimer's diagnosis and anticonvulsants are stricken. All other criteria were unanimously 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 DUR member lists, the most recent newsletter, Alerts and the Provider Insider. She stated that effective February 1, smoking cessation products will be covered through pharmacy services as part of the maternity care waiver. PAs for those products will continue to be processed through HID. Tiffany reviewed various administrative cost saving initiatives to be implemented on March 1 such as various publications (Provider Insider and Medicaid Matters) as well as claims and remittance advice being available electronically in lieu of paper versions. She encouraged providers to sign up for Alabama Medicaid's listserv to receive the most current Medicaid news and information. Tiffany also reviewed the Alert that outlined the requirement of NDC submission on all physician administered drugs. Tiffany stated that there are currently two CE programs available on the Agency website at no charge. Finally, Tiffany reminded members to turn in consultant vouchers before leaving the meeting.

P & T Committee Update: Clemice Hurst began the P&T Update by informing the Board that at the last meeting, the Committee covered the remaining Anti-Infective Agent classes, EENT Antibacterial Agents, and Prenatal Vitamins. She stated that the next P&T meeting, which would review Behavioral Health Agents, would be held on February 10 at the Medicaid Agency.

New Business: Daniel Mims, Chairman, asked the Board if there was any new business. There being no new business brought before the Board, Daniel asked for a motion to adjourn. Kevin Royal made a motion to adjourn the meeting. The motion was seconded by Dan McConaghy. A voice vote to adjourn was unanimous. The meeting was adjourned at 2:00pm.

Next Meeting Date: The next DUR Board meeting will be held on April 28, 2010.

Respectfully Submitted,



Christina Faulkner, PharmD

**ALABAMA MEDICAID
RETROSPECTIVE DRUG UTILIZATION REVIEW
CRITERIA RECOMMENDATIONS TALLY**

Criteria Recommendations

**Approved Approved Rejected
As
Amended**

1. Iloperidone / High Dose

_____ ✓ _____ _____

Alert Message: The maximum recommended dose of Fanapt (iloperidone) is 12 mg twice daily (24 mg/day). Doses above 24 mg/day have not been systematically evaluated in clinical trials. Iloperidone must be titrated slowly from a low starting dose (1 mg twice daily) to avoid orthostatic hypotension.

Conflict Code: ER – Over Utilization
Drug/Disease

<u>Util A</u>	<u>Util B</u>	<u>Util C (Negating – Potent 2D6 & 3A4 Inhibitors)</u>			
Iloperidone		Bupropion	Indinavir	Itraconazole	Telithromycin
		Fluoxetine	Nelfinavir	Ketoconazole	Clarithromycin
		Paroxetine	Ritonavir	Nefazodone	
		Quinidine	Saquinavir		

Max Dose: 24 mg/day

References:

Fanapt Prescribing Information, May 2009, Vanda Pharmaceuticals Inc.
Flockhart DA. Drug Interactions: Cytochrome P450 Drug Interaction Table. Indiana University School of Medicine (2007). <http://medicine.iupui.edu/clinpharm/ddis/table.asp>. Accessed June 09, 2009.

2. Iloperidone / Nonadherence

_____ ✓ _____ _____

Alert Message: Nonadherence to the prescribed antipsychotic therapy with Fanapt (iloperidone) may lead to decreased patient outcomes and additional medical cost.

Conflict Code: LR – Nonadherence
Drug/Disease

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

References:

Fanapt Prescribing Information, May 2009, Vanda Pharmaceuticals Inc.

Criteria Recommendations

Approved Approved Rejected
As
Amended

3. Iloperidone / Potent 2D6 and/or 3A4 Inhibitors _____✓_____

Alert Message: The dose of Fanapt (iloperidone) should be reduced by one-half when administered concomitantly with a strong CYP2D6 and/or CYP3A4 inhibitor. Iloperidone is metabolized by both CYP2D6 and CYP3A4 enzymes and concurrent therapy with these agents may cause increased iloperidone blood levels leading to adverse effects (e.g., QT prolongation, hypotension and tachycardia). If the inhibitor agent is withdrawn from combination therapy the iloperidone dose should be increased.

Conflict Code: DD – Drug/Drug Interaction

Drug/Disease

<u>Util A</u>	<u>Util B</u>	<u>Util C (Inclusive)</u>			
Iloperidone		Bupropion	Indinavir	Itraconazole	Telithromycin
		Fluoxetine	Nelfinavir	Ketoconazole	
		Paroxetine	Ritonavir	Nefazodone	
		Quinidine	Clarithromycin	Saquinavir	

Max Dose: 12 mg/day

References:

Fanapt Prescribing Information, May 2009, Vanda Pharmaceuticals Inc.
 Flockhart DA. Drug Interactions: Cytochrome P450 Drug Interaction Table. Indiana University School of Medicine (2007). <http://medicine.iupui.edu/clinpharm/ddis/table.asp>. Accessed June 09, 2009.

4. Iloperidone / QT Prolongation Drugs _____✓_____

Alert Message: Fanapt (iloperidone) prolongs the QT interval and may be associated with arrhythmias and sudden death. Avoid the use of iloperidone in combination with drugs that are known to prolong the QTc or inhibit iloperidone metabolism.

Conflict Code: DD – Drug/Drug Interaction

Drug/Disease

<u>Util A</u>	<u>Util B</u>	<u>Util C</u>		
Iloperidone	Alfuzosin	Doxepin	Paliperidone	Risperidone
	Amantadine	Fluconazole	Ketoconazole	Salmeterol
	Amitriptyline	Isradipine	Telithromycin	Tacrolimus
	Atazanavir	Procainamide	Lapatinib	Terbutaline
	Azithromycin	Methadone	Levofloxacin	Tizanidine
	Clomipramine	Tolterodine	Vardenafil	Trimipramine
	Dolasetron	Erythromycin	Methadone	Protriptyline
	Moxifloxacin	Lithium	Mexiletine	Solifenacin
	Sotalol	Venlafaxine	Moexipril/HCTZ	Voriconazole
	Trimethoprim-Sulfa	Felbamate	Thioridazine	Sertraline
	Chloral Hydrate	Fluoxetine	Nilotinib	Procainamide
	Ciprofloxacin	Flecainide	Nortriptyline	Chlorpromazine
	Citalopram	Foscarnet	Pentamidine	Chlorpromazine
	Clozapine	Gemifloxacin	Tamoxifen	
	Fosphenytoin	Granisetron	Octreotide	
	Nicardipine	Ziprasidone	Ondansetron	
	Quinidine	Haloperidol	Pimozide	
	Desipramine	Imipramine	Quetiapine	
	Disopyramide	Indapamide	Quinidine	
	Dofetilide	Itraconazole	Ranolazine	

References:

Fanapt Prescribing Information, May 2009, Vanda Pharmaceuticals Inc.
 ArizonaCERT: Drugs That Prolong the QT Interval and/or Induce Torsades de Pointes
 Available at: <http://www.azcert.org/consumers/interaction-advisory.cfm>

Criteria Recommendations

**Approved Approved Rejected
As
Amended**

5. Iloperidone / QT Prolongation or Problems Associated w/ Prolongation

Alert Message: Fanapt (iloperidone) prolongs the QT interval and may be associated with arrhythmias and sudden death. Avoid the use of iloperidone in patients who have congenital prolongation of the QT interval, a recent acute myocardial infarction, cardiac arrhythmia, hypokalemia and/or uncompensated heart failure.

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

<u>Util A</u>	<u>Util B</u>	<u>Util C</u>
Iloperidone	Prolongation of QT Interval Myocardial Infarction Uncompensated Heart Failure Hypokalemia Arrhythmias	

References:

Fanapt Prescribing Information, May 2009, Vanda Pharmaceuticals Inc.

6. Iloperidone / Hepatic Impairment

Alert Message: Fanapt (iloperidone) is not recommended for use in patients with hepatic impairment. No study has been conducted in patients with mild or moderate liver impairment.

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

<u>Util A</u>	<u>Util B</u>	<u>Util C</u>
Iloperidone	Hepatic Impairment	

References:

Fanapt Prescribing Information, May 2009, Vanda Pharmaceuticals Inc.

7. Iloperidone / Alpha-1 Adrenergic Receptor Blockers

Alert Message: Due to its alpha-1 adrenergic receptor antagonist properties, Fanapt (iloperidone) has the potential to enhance the effect of certain antihypertensive agents that have the same mechanism of action and may result in problematic hypotension.

Conflict Code: DD – Drug/Drug Interaction
Drug/Disease

<u>Util A</u>	<u>Util B</u>	<u>Util C</u>
Iloperidone	Silodosin Prazosin Terazosin Doxazosin Tamsulosin Alfuzosin	

References:

Fanapt Prescribing Information, May 2009, Vanda Pharmaceuticals Inc.

Criteria Recommendations

**Approved Approved Rejected
As
Amended**

8. Leukotriene Modifiers / Neuropsychiatric Events

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Alert Message: Neuropsychiatric events have been reported in some patients taking leukotriene modifiers (i.e. montelukast, zafirlukast and zileuton). These adverse events include cases of agitation, aggression, anxiousness, dream abnormalities and hallucinations, depression, insomnia, irritability, restlessness, suicidal thinking/behavior, and tremor. Consider discontinuing these medications if patients develop neuropsychiatric events.

Conflict Code: TA – Therapeutic Appropriateness

Drug/Disease

Util A Util B Util C

Montelukast

Zafirlukast

Zileuton

References:

FDA Drug Safety and Availability: Postmarket Drug Safety Information for Patients and Providers: Updated Information on Leukotriene Inhibitors: Montelukast (marketed as Singulair), Zafirlukast (marketed as Accolate), and Zileuton (marketed as Zyflo and Zyflo CR). June 12, 2009.

9. Tamoxifen / Moderate to Potent 2D6 Inhibitor Antidepressants

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Alert Message: The concurrent use of tamoxifen with an antidepressant that is a moderate or potent CYP2D6 inhibitor (e.g., paroxetine, fluoxetine, sertraline and bupropion) should be avoided. Use of tamoxifen with one of these agents may result in a reduced tamoxifen response due to inhibition of the CYP2D6-mediated drug activation. If appropriate for this patient, consider using an alternative antidepressant that has only weak CYP2D6 inhibition (e.g. citalopram, escitalopram, fluvoxamine, venlafaxine or desvenlafaxine).

Conflict Code: DD – Drug/Drug Interaction

Drugs/Disease

Util A Util B Util C (Negating)

Tamoxifen

Fluoxetine

Paroxetine

Sertraline

Bupropion

Duloxetine

References:

Facts & Comparisons, 2009 Updates.

In Brief: Tamoxifen and SSRI Interactions. Medical Letter. Volume 51 (Issue 1314), June 15, 2009.

Clinical Pharmacology, Gold Standard 2009.

Drug Interactions with Tamoxifen: A Guide for Breast Cancer Patients and Physicians. Consortium on Breast Cancer Pharmacogenomics. January 2008.

Available at: <http://medicine.iupui.edu/clinpharm/COBRA/TamoxifenGuide.pdf>

Criteria Recommendations

Approved Approved Rejected
As
Amended

10. Tamoxifen / Moderate to Potent 2D6 Inhibitors

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Alert Message: The concurrent use of tamoxifen with a moderate or potent CYP2D6 inhibitor (e.g., quinidine, amiodarone, thioridazine and cimetidine) should be avoided. Use of tamoxifen with one of these agents may result in a reduced tamoxifen response due to inhibition of the CYP2D6-mediated drug activation. If appropriate for this patient consider alternate therapy with an agent that does not inhibit the CYP2D6 enzyme.

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

<u>Util A</u>	<u>Util B</u>	<u>Util C</u>
Tamoxifen	Quinidine Amiodarone Diphenhydramine Cimetidine Thioridazine	

References:

Facts & Comparisons, 2009 Updates.

Clinical Pharmacology, Gold Standard 2009.

Drug Interactions with Tamoxifen: A Guide for Breast Cancer Patients and Physicians. Consortium on Breast Cancer Pharmacogenomics. January 2008.

Available at: <http://medicine.iupui.edu/clinpharm/COBRA/TamoxifenGuide.pdf>

11. Tolvaptan / Potent CYP3A4 Inhibitors

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Alert Message: The concurrent use of Samsca (tolvaptan) with a potent CYP3A4 inhibitor is contraindicated. Tolvaptan is a CYP3A4 substrate and coadministration with inhibitors of this enzyme can lead to marked increases in tolvaptan concentrations. The use of moderate 3A4 inhibitors with tolvaptan should be avoided.

Conflict Code: DD – Drug/Drug Interaction
Drug/Disease

<u>Util A</u>	<u>Util B</u>	<u>Util C</u>
Tolvaptan	Ketoconazole Itraconazole Clarithromycin Telithromycin Ritonavir Indinavir Nelfinavir Saquinavir Nefazodone	

References:

Samsca Prescribing Information, May 2009, Otsuka American Pharmaceutical, Inc.

Flockhart DA. Drug Interactions: Cytochrome P450 Drug Interaction Table. Indiana University School of Medicine (2007). Available at: <http://medicine.iupui.edu/clinpharm/ddis/table.asp>. Accessed June 09, 2009.

Criteria Recommendations

**Approved Approved Rejected
As
Amended**

12. Tolvaptan / Moderate CYP3A4 Inhibitors

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Alert Message: The concurrent use Samsca (tolvaptan) with a moderate 3A4 inhibitor should be avoided. Tolvaptan is a CYP3A4 substrate and coadministration with inhibitors of this enzyme can lead to marked increases in tolvaptan concentrations. The use of tolvaptan with potent CYP3A4 inhibitors is contraindicated.

Conflict Code: DD – Drug/Drug Interaction
Drug/Disease

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

References:

Samsca Prescribing Information, May 2009, Otsuka American Pharmaceutical, Inc.
Flockhart DA. Drug Interactions: Cytochrome P450 Drug Interaction Table. Indiana University School of Medicine (2007). Available at: <http://medicine.iupui.edu/clinpharm/ddis/table.asp>. Accessed June 18, 2009.

13. Tolvaptan / CYP3A4 Inducers

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Alert Message: The concurrent use Samsca (tolvaptan) with a CYP3A4 inducer should be avoided. Tolvaptan is a CYP3A4 substrate and coadministration with an inducer of this enzyme may result in up to an 85% decreases in tolvaptan concentrations. The dose of tolvaptan may have to be increased.

Conflict Code: DD – Drug/Drug Interaction
Drug/Disease

<u>Util A</u>	<u>Util B</u>	<u>Util C</u>
Tolvaptan	Rifampin Efavirenz Carbamazepine Modafinil Oxcarbazepine Phenytoin Pioglitazone	Rifabutin Nevirapine Dexamethasone Prednisone Phenobarbital Mephobarbital Butobarbital Secobarbital Pentobarbital Primidone

References:

Samsca Prescribing Information, May 2009, Otsuka American Pharmaceutical, Inc.
Flockhart DA. Drug Interactions: Cytochrome P450 Drug Interaction Table. Indiana University School of Medicine (2007). Available at: <http://medicine.iupui.edu/clinpharm/ddis/table.asp>. Accessed June 18, 2009.

Criteria Recommendations

Approved Approved Rejected
As
Amended

14. Tolvaptan / P-glycoprotein Inhibitors

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Alert Message: The concurrent use Samsca (tolvaptan) with a P-glycoprotein inhibitor should be avoided. Tolvaptan is a P-gp substrate and coadministration with a P-gp inhibitor may result in a marked increase in tolvaptan concentrations. The dose of tolvaptan may need to be reduced.

Conflict Code: DD – Drug/Drug Interaction
Drug/Disease

<u>Util A</u>	<u>Util B</u>	<u>Util C</u>
Tolvaptan	Cyclosporine	Nifedipine
	Amiodarone	Progesterone
	Chlorpromazine	Propranolol
	Diltiazem	Quinidine
	Erythromycin	Reserpine
	Diltiazem	Tacrolimus
	Felodipine	Tamoxifen
	Fluphenazine	Testosterone
	Hydrocortisone	Trifluoperazine
	Lidocaine	Verapamil
	Mifepristone	
	Nicardipine	

References:

Samsca Prescribing Information, May 2009, Otsuka American Pharmaceutical, Inc.
Hartshorn ED and Tatro DS. Principles of Drug Interactions - Drug Interaction Facts, Facts & Comparisons 4.0, Wolters Kluwer Health, Inc., 2009.

15. Ryzolt / High Dose

_____ ✓ _____ _____

Alert Message: Ryzolt (tramadol extended-release) may be overutilized. The manufacturer's recommended maximum daily dose is 300 mg. Clinical studies of extended-release tramadol products have not demonstrated a clinical benefit at doses exceeding 300 mg per day.

Conflict Code: ER - Overutilization
Drug/Disease:

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

Max Dose: 300mg/day

References:

Ryzolt Prescribing Information, Dec. 2008, Purdue Pharma L.P.
Facts & Comparisons, 2009 Updates.

Criteria Recommendations

**Approved Approved Rejected
As
Amended**

16. Tramadol / Therapeutic Duplication

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Alert Message: Therapeutic duplication of tramadol-containing products may be occurring. The concurrent use of different tramadol-containing products is not recommended. Patients may be receiving excessive amounts of tramadol which can lead to serious adverse effects (e.g., respiratory depression, seizures and death).

Conflict Code: TD – Therapeutic Duplication

Drug/Disease:

Util A

Util B

Util C

Tramadol

References:

Ryzolt Prescribing Information, Dec. 2008, Purdue Pharma L.P.

Facts & Comparisons, 2009 Updates.

Ultracet Prescribing information, April, 2004. Ortho-McNeil Pharmaceuticals, Inc.

Ultram Prescribing Information, Feb. 2007, Ortho-McNeil, Pharmaceuticals, Inc.

17. Tramadol ER / Suicidal and Addiction

_____✓_____

Alert Message: Extended-release tramadol products (Ultram ER and Ryzolt) should not be prescribed in patients who are suicidal or addiction-prone. Many of the tramadol related deaths have occurred in patients with previous histories of misuse of tranquilizers, alcohol and other CNS-active drugs. Appropriate consideration should be given to the use of non-narcotic analgesics in these patients.

Conflict Code: MC – Drug (Actual) Disease Precaution

Drug/Disease:

Util A

Util B

Util C

Tramadol ER

Attempted Suicide

Suicidality

Drug Abuse/Dependence

References:

Ryzolt Prescribing Information, Dec. 2008, Purdue Pharma L.P.

Ultram ER Prescribing information, Dec. 2007. Ortho-McNeil Pharmaceuticals, Inc.

18. Tapentadol / Overutilization

_____✓_____

Alert Message: Nucynta (Tapentadol) may be over-utilized. The maximum recommended daily dose (after the first day) of tapentadol is 600 mg. Daily doses greater than 700mg on the first day of therapy and 600mg on subsequent days have not been studied and are not recommended.

Conflict Code: ER - Overutilization

Drug/Disease:

Util A

Util B

Util C

Tapentadol

Max Dose: 600mg/day

References:

Nucynta Prescribing Information, March 2009, Ortho-McNeil-Janssen Pharmaceuticals, Inc.

Criteria Recommendations

Approved Approved Rejected
As
Amended

19. Tapentadol / Impaired Pulmonary Function

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Alert Message: Nucynta (tapentadol) is contraindicated in patients with impaired pulmonary function (e.g. significant respiratory depression, acute or severe bronchial asthma or hypercapnia in unmonitored settings).

Conflict Code: MC – Drug (Actual) Disease Precaution

Drug/Disease:

<u>Util A</u>	<u>Util B</u>	<u>Util C</u>
Tapentadol	Impaired Respiratory Function Asthma COPD Emphysema	

References:

Nucynta Prescribing Information, March 2009, Ortho-McNeil-Janssen Pharmaceuticals, Inc. Facts & Comparisons, 2009 Updates.

20. Tapentadol / Paralytic Ileus

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Alert Message: Nucynta (tapentadol) is contraindicated in patients who have paralytic ileus or are suspected of having paralytic ileus. Tapentadol is a mu-opioid agonist and these agents can cause or exacerbate this condition.

Conflict Code: MC – Drug (Actual) Disease Precaution

Drug/Disease:

<u>Util A</u>	<u>Util B</u>	<u>Util C</u>
Tapentadol	Paralytic Ileus	

References:

Nucynta Prescribing Information, March 2009, Ortho-McNeil-Janssen Pharmaceuticals, Inc. Facts & Comparisons, 2009 Updates.

21. Tapentadol / MAO Inhibitors

_____ ✓ _____ _____

Alert Message: Nucynta (tapentadol) is contraindicated in patients who are receiving a monoamine oxidase inhibitor (MAOI) or who have taken a MAOI within the last 14 days due to the potential for elevated norepinephrine (NE) levels which may result in adverse cardiovascular effects. Tapentadol is a mu-opioid agonist as well as a NE reuptake inhibitor.

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

Drug/Disease:

<u>Util A</u>	<u>Util B</u>	<u>Util C</u>
Tapentadol	Isocarboxazid Tranlycypromine Phenelzine Selegiline	

References:

Nucynta Prescribing Information, March 2009, Ortho-McNeil-Janssen Pharmaceuticals, Inc. Facts & Comparisons, 2009 Updates.

Criteria Recommendations

Approved Approved Rejected
As
Amended

22. Tapentadol / Seizures

_____✓_____

Alert Message: Nucynta (tapentadol) should be prescribed with caution in patients with a history of seizure disorder or any condition that would put the patient at risk of seizures.

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

Drug/Disease:

<u>Util A</u>	<u>Util B</u>		<u>Util C</u>
Tapentadol	Epilepsy	Lacosamide	Tiagabine
	Seizures	Rufinamide	Valproic
	Convulsions	Oxcarbazepine	Zonisamide
	Carbamazepine	Methsuximide	Ethosuximide
	Phenytoin	Felbamate	Primidone
	Lamotrigine	Gabapentin	
	Topiramate	Levetiracetam	

References:

Nucynta Prescribing Information, March 2009, Ortho-McNeil-Janssen Pharmaceuticals, Inc. Facts & Comparisons, 2009 Updates.

23. Tapentadol / Opiates & Alcohol Dependence / Abuse

_____✓_____

Alert Message: Nucynta (tapentadol) should be prescribed with caution in patients receiving other CNS depressants (e.g. opioid analgesics, phenothiazines, and sedatives) including alcohol. The concurrent use of tapentadol with any of these agents may result in respiratory depression, hypotension, profound sedation, coma or death. If combination therapy is necessary, a dose reduction of one or both agents should be considered.

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

Drug/Disease:

<u>Util A</u>	<u>Util B</u>	<u>Util C</u>
Tapentadol	Opioid Analgesics	Sedating Antihistamines
	Phenothiazines	Muscle Relaxants
	Sedative/Hypnotics	Antipsychotics
	Anxiolytics	Alcohol Dependence
	Anticonvulsants	

References:

Nucynta Prescribing Information, March 2009, Ortho-McNeil-Janssen Pharmaceuticals, Inc. Facts & Comparisons, 2009 Updates.

Criteria Recommendations

Approved Approved Rejected
As
Amended

24. Tapentadol / Serotonergic Drugs

_____ ✓ _____ _____

Alert Message: Nucynta (tapentadol) should be prescribed with caution in patients taking serotonergic drugs (e.g. SSRIs, SNRI, triptans and MAOIs) due to the risk of developing potentially life-threatening serotonin syndrome.

Conflict Code: DD – Drug/Drug Interaction

Drug/Disease:

<u>Util A</u>	<u>Util B</u>		<u>Util C</u>
Tapentadol	Triptans	TCA's	Lithium
	Tramadol	Mirtazapine	Fentanyl
	SSRIs	Bupropion	Zyvox
	SNRIs	Trazodone	Nefazodone
	MAOIs	Meperidine	

References:

Nucynta Prescribing Information, March 2009, Ortho-McNeil-Janssen Pharmaceuticals, Inc. Facts & Comparisons, 2009 Updates.

25. Tapentadol / Severe Renal Impairment

_____ ✓ _____ _____

Alert Message: The safety and effectiveness of Nucynta (tapentadol) has not been established in patients with severe renal impairment and its use is not recommended in this population.

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

Drug/Disease:

<u>Util A</u>	<u>Util B</u>	<u>Util C</u>
Tapentadol	Stage IV Kidney Disease	
	Stage V Kidney Disease	
	ESRD	
	PhosLo	
	Renagel	
	Zemplar	
	Hectorol	
	Fosrenol	

References:

Nucynta Prescribing Information, March 2009, Ortho-McNeil-Janssen Pharmaceuticals, Inc. Facts & Comparisons, 2009 Updates.

Criteria Recommendations

**Approved Approved Rejected
As
Amended**

26. Tapentadol / Hepatic Impairment

_____ ✓ _____

Alert Message: Nucynta (tapentadol) should be used with caution in patients with moderate hepatic impairment due to the potential for higher serum levels and risk for adverse effects. Treatment should be initiated at 50 mg with the interval between doses no less than every 8 hours (max 3 doses in 24 hrs). **Further treatment should reflect maintenance of analgesia with acceptable tolerability, to be achieved by either shortening or lengthening the dosing interval.** Tapentadol has not been studied in patients with severe hepatic impairment and its use is not recommended in this population. (Wording in **BOLD** has been added.)

Conflict Code: MC – Drug (Actual) Disease Precaution

Drug/Disease:

<u>Util A</u>	<u>Util B</u>	<u>Util C</u>
Tapentadol	Hepatic Impairment	

References:

Nucynta Prescribing Information, March 2009, Ortho-McNeil-Janssen Pharmaceuticals, Inc. Facts & Comparisons, 2009 Updates.

27. Tapentadol / Pancreatic & Biliary Tract Disease

_____ ✓ _____

Alert Message: Nucynta (tapentadol) should be used with caution in patients with biliary tract disease, including acute pancreatitis. Tapentadol is a mu-opioid receptor (MOR) agonist and may cause spasms of the Sphincter of Oddi.

Conflict Code: MC – Drug (Actual) Disease Precaution

Drug/Disease:

<u>Util A</u>	<u>Util B</u>	<u>Util C</u>
Tapentadol	Acute Pancreatitis Cholelithiasis Obstruction of Bile Duct Spasm of Sphincter of Oddi	

References:

Nucynta Prescribing Information, March 2009, Ortho-McNeil-Janssen Pharmaceuticals, Inc. Facts & Comparisons. 2009 Updates.

28. Lacosamide / Overutilization

_____ ✓ _____

Alert Message: Vimpat (lacosamide) may be over-utilized. The recommended maintenance dosage range is 200 to 400 mg/day. In clinical trials, the 600 mg daily dose was not more effective than the 400 mg daily dose and was associated with a substantially higher rate of adverse reactions.

Conflict Code: ER - Overutilization

Drug/Disease:

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

Max Dose: 400 mg/day

References:

Vimpat Prescribing Information, Jan. 2009, Schwarz Biosciences. Facts & Comparisons, 2009 Updates.

Criteria Recommendations

Approved Approved Rejected
As
Amended

29. Lacosamide / PR Prolongation Drugs

_____ ✓ _____

Alert Message: Vimpat (lacosamide) should be used with caution in patients receiving other drugs that prolong the PR interval (e.g. beta blockers, calcium channel blockers, digoxin and 1A & 1C antiarrhythmics) due to risk of additive effect on the PR interval. Lacosamide can cause a small dose-dependent increase in the mean PR interval (4.2-4.6 ms).

Conflict Code: DD – Drug/Drug Interaction

Drug/Disease:

<u>Util A</u>	<u>Util B</u>	<u>Util C</u>
Lacosamide	Beta Blockers Digoxin Atazanavir Ritonavir Dihydropyridine CCBs Amiodarone	Quinidine Procainamide Disopyramide Flecainide Propafenone

(wording in **BOLD** has been added)

References:

Vimpat Prescribing Information, Jan. 2009, Schwarz Biosciences.
Facts & Comparisons, 2009 Updates.

30. Lacosamide / Cardiac Conduction Problems

_____ ✓ _____

Alert Message: Vimpat (lacosamide) should be used with caution in patients with known cardiac conduction problems (e.g. marked 1st degree AV block, 2nd degree or higher AV block, sick sinus syndrome without pacemaker) or with severe cardiac disease (myocardial ischemia and heart failure). Lacosamide can cause a small dose-dependent increase in the mean PR interval (4.2-4.6 ms) potentially exacerbating existing conditions.

Conflict Code: MC – Drug (Actual) Disease Precaution

Drug/Disease:

<u>Util A</u>	<u>Util B</u>	<u>Util C</u>
Lacosamide	1st Degree AV Block 2nd Degree AV Block Myocardial Ischemia Heart Failure	

References:

Vimpat Prescribing Information, Jan. 2009, Schwarz Biosciences.

31. Lacosamide / Severe Renal Impairment

_____ ✓ _____

Alert Message: A maximum dose of 300 mg per day of Vimpat (lacosamide) is recommended for patients with severe renal impairment (CrCl ≤ 30mL/min) and end stage renal disease. In clinical trials the AUC of lacosamide was increased 60% in patients with severe renal impairment.

Conflict Code: ER – Overutilization (Disease State)

Drug/Disease:

<u>Util A</u>	<u>Util B</u>	<u>Util C</u>
Lacosamide		Severe Renal Impairment End Stage Renal Disease

Maximum Dose: 300mg/day

References:

Vimpat Prescribing Information, Jan. 2009, Schwarz Biosciences.
Facts & Comparisons, 2009 Updates

Criteria Recommendations

Approved Approved Rejected
As
Amended

32. Lacosamide / Hepatic Impairment

Alert Message: A maximum dose of 300 mg per day of Vimpat (lacosamide) is recommended for patients with mild to moderate hepatic impairment. In clinical trials, the AUC of lacosamide was increased 50 - 60% in patients with mild to moderate hepatic impairment. Lacosamide use has not been evaluated in patients with severe hepatic impairment and is therefore not recommended.

_____✓_____

Conflict Code: ER – Overutilization (Disease State)

Drug/Disease:

Util A

Util B

Util C

Lacosamide

Hepatic Impairment

Maximum Dose: 300mg/day

References:

Vimpat Prescribing Information, Jan. 2009, Schwarz Biosciences.
Facts & Comparisons, 2009 Updates

33. Propoxyphene / Black Box Warning

Alert Message: Propoxyphene-containing products should not be prescribed to patients who are suicidal or addiction prone. Many propoxyphene-related deaths have occurred in patients with histories of emotional disturbances, suicidal ideation or attempts, or misuse of tranquilizers, alcohol, and other CNS-active drugs.

_____✓_____

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

Drug/Disease:

Util A

Util B

Util C

Propoxyphene

Suicidality
Addiction

References:

FDA News & Events, FDA Takes Action on Darvon, other Pain Medications Containing Propoxyphene. July 7, 2009.
Available at: www.fda.gov/NewsEvent/Newsroom/PressAnnouncements/ucm170769.htm
Facts & Comparisons, 2009 Updates.

34. Propoxyphene / Black Box Warning

Alert Message: The maximum recommended dose of propoxyphene napsylate is 600 mg per day and 390 mg per day for propoxyphene hydrochloride. Exceeding the maximum dose of propoxyphene may result in accumulation of the parent compound and the active metabolite causing an increased risk of adverse reactions and sometimes fatal overdose. Fatalities within the first hour of overdose are not uncommon.

_____✓_____

Conflict Code: ER – Overutilization – Black Box Warning

Drug/Disease:

Util A

Util B

Util C

Propoxyphene

Max Dose: 600mg/day napsylate and 390mg/day hydrochloride

References:

FDA News & Events, FDA Takes Action on Darvon, other Pain Medications Containing Propoxyphene. July 7, 2009.
Available at: www.fda.gov/NewsEvent/Newsroom/PressAnnouncements/ucm170769.htm
Facts & Comparisons, 2009 Updates.

Criteria Recommendations

**Approved Approved Rejected
As
Amended**

35. Propoxyphene / CNS Depressants or Alcohol Dependence (Black Box)

Alert Message: Propoxyphene-containing products should be prescribed with caution in patients receiving other CNS depressants (e.g. tranquilizers, antidepressants, opiates and antipsychotics) or who use alcohol in excess. Concurrent use may lead to additive CNS depression.

Conflict Code: DC – Drug/Drug Marker and/or Diagnosis (**Black Box Warning**)

Drug/Disease:

Util A

Util B

Util C

Propoxyphene Opioid Analgesics
 Phenothiazines
 Sedative/Hypnotics
 Anxiolytics
 Anticonvulsants
 Antipsychotics
 Muscle Relaxants
 Alcohol Dependence

References:

FDA News & Events, FDA Takes Action on Darvon, other Pain Medications Containing Propoxyphene. July 7, 2009. Available at: www.fda.gov/NewsEvent/Newsroom/PressAnnouncements/ucm170769.htm
Facts & Comparisons, 2009 Updates.

36. Selegiline ODT / Duplicate Therapy

Alert Message: Zelapar (selegiline orally disintegrating tablets) should not be administered with other selegiline products because of the increased risk of nonselective MAO inhibition that may lead to a hypertensive crisis. At least 14 days should elapse between discontinuation of orally disintegrating tablets and initiation of treatment with other selegiline products.

Conflict Code: TD – Therapeutic Duplication

Drug/Disease:

Util A

Util B

Util C

Selegiline ODT Selegiline
 Regular Tablets, Capsules & Transdermal patch

References:

Facts & Comparisons, 2009 Updates.
Zelapar Prescribing Information, February 2008, Valeant Pharmaceuticals of North America.

37. Atomoxetine / Liver Injury

Alert Message: Postmarketing reports indicate that Strattera (atomoxetine) can cause severe liver injury. Atomoxetine should be discontinued in patients with jaundice or laboratory evidence of liver injury, and should not be restarted. Liver enzyme levels should be obtained at the first sign or symptom of liver dysfunction.

Conflict Code: TA – Therapeutic Appropriateness

Drug/Disease:

Util A

Util B

Util C

Atomoxetine

References:

Strattera Prescribing Information, June 2009, Eli Lilly and Company.
Facts & Comparisons, 2009 Updates.
Clinical Pharmacology, Gold Standard 2009.

Criteria Recommendations

Approved Approved Rejected
As
Amended

38. Atomoxetine / Orthostatic Hypotension & Syncope

Alert Message: Orthostatic hypotension and syncope have been reported in patients taking Strattera (atomoxetine). Atomoxetine should be used with caution in any condition that may predispose patients to hypotension, or conditions associated with abrupt heart rate or blood pressure changes.

_____✓_____

Conflict Code: TA – Therapeutic Appropriateness

Drug/Disease:

Util A

Util B

Util C

Atomoxetine

References:

Strattera Prescribing Information, June 2009, Eli Lilly and Company.

Facts & Comparisons, 2009 Updates.

Clinical Pharmacology, Gold Standard 2009.

The minutes of the October 28, 2009 DUR Board Meeting have been reviewed and approved as submitted.



Carol H. Steckel, Commissioner

Approve () Deny

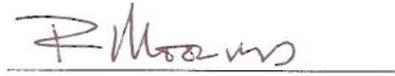
4/1/10
Date



Kathy Hall, Deputy Commissioner

Approve () Deny

3/17/10
Date



Robert Moon, M.D., Medical Director

Approve () Deny

3-19-10
Date