

Alabama Medicaid DUR Board Meeting Minutes

July 27, 2011

Members Present: Kevin Green, Paula Thompson, Rhonda Harden, Jimmy Jackson, Kelli Littlejohn, Bernie Olin, David Harwood, David Frazer, Denyse Thornley-Brown

Also Present: Clemice Hurst, Tiffany Minnifield, Christina Faulkner

Present via Conference Call: Chris Barwick, Cara Leos

Members Absent: Kevin Royal, Donald Marks, Daniel Mims, Dan McConaghy, Robert Moon

Call to Order: The DUR meeting was called to order by K.Green at approximately 1:00pm.

Review and Adoption of Minutes: The minutes of the January 26, 2011 meeting and the April 27, 2011 meeting were presented and reviewed. P.Thompson made a motion to approve the minutes as presented and J.Jackson seconded the motion. The motion was approved unanimously.

Prior Authorization and Overrides Update: C.Faulkner began the Prior Authorization and Overrides Update with the Monthly Manual Prior Authorizations and Overrides Report for the month of March, 2011. She reported 9,596 total requests. She reported 14,483 electronic requests for the same time frame. From the Prior Authorization and Override Response Time Ratio report for March 2011, she reported that approximately 85% of all manual PAs were responded to in less than two hours, more than 96% in less than four hours and more than 99% in less than eight hours. For the month of April 2011, C.Faulkner reported 8,273 manual PA requests and 16,095 electronic PA requests. She reported that more than 76% 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 May, C.Faulkner reported 8,431 manual PA requests and 14,599 electronic PA requests for the same time frame. For May, C.Faulkner reported between 84 and 85% approved in less than two hours, approximately 96% in less than four hours and 99% approved in less than eight hours. K.Green requested that HID determine the number of manual prior authorizations originally denied and later approved.

Program Summary Review: C.Faulkner briefly reviewed the Alabama Medicaid Program Summary. She reported 495,598 total recipients with an average paid per prescription of \$56.92 for the months of October 2010 through March 2011.

Cost Management Analysis: C.Faulkner reported an average cost per claim of \$59.31 for March 2011 and \$58.09 for April 2009. From the 1st Quarter 2011 Drug Analysis, C.Faulkner reported 73.84% generic utilization, 15.22% brand single-source, 3.91% brand multi-source and 7.03% OTC and "other". From the Top 25 Drugs Based on Number of Claims from 04/01/2011 – 04/30/2011, C.Faulkner reported the top five drugs: hydrocodone-acetaminophen, amoxicillin, Singulair®, alprazolam, and omeprazole. She then reported the top five drugs from the Top 25 Drugs Based on Claims Cost from 04/01/2011 – 04/30/2011: Singulair, Abilify®, Seroquel®, Vyvanse®, and Concerta®. From the Top 15 Therapeutic Classes by Total Cost of Claims for the same time frame, C.Faulkner reported the top five classes: Antipsychotic Agents, Adrenals, Leukotriene Modifiers, Amphetamines, and Anorex/Respir/Cerebral Stimulants, Misc. C.Faulkner then presented a report detailing the drugs included in the Adrenal AHFS class 680400.

UPDATES

Anti-convulsants, Miscellaneous AHFS Class 281292: In July 2010, the Miscellaneous Anticonvulsant class was the third leading drug class based on claims cost. There were 23,058 prescriptions reported at a cost of \$1,900,969, approximately \$82 per paid prescription. During the April 2011 meeting, the Board requested that HID provide the top diagnoses for those patients without an FDA approved use or a common unlabeled use on file. The Board also requested the top prescribers and their network regions. C.Faulkner reported that there were 6,133 unique recipients that did not have an FDA approved diagnosis on file and reported the top diagnoses on file for those recipients. The top 25 prescribers, their specialties, and their network regions were noted. K.Green requested that HID verify the top anticonvulsants used without an FDA approved diagnosis.

Low Dose Quetiapine: At the January 2011 Board meeting, it was requested that HID develop criteria for low dose Seroquel for patients on other antipsychotics. C.Faulkner presented the criteria for the Board's consideration during the April 2011 meeting. At that time, the Board recommended amending the alert message to read "please consider using an alternative agent, keeping in mind evidence based medicine and cost."

AAC Pricing: Venlafaxine and Valacyclovir: D.McConaghy requested information about how AAC pricing (effective 9/22/10) had influenced the dispensing of venlafaxine and valacyclovir. C.Faulkner provided a brief review of the total number of prescriptions and the cost per prescription.

Review of Palivizumab Utilization for the 2010-2011 Season: The 2010-11 RSV season ended on March 31, 2011. C.Faulkner provided an update which compared the results of the 10-11 season to previous seasons. C.Faulkner reminded the Board that each recipient could receive a maximum of 5 doses per season. For the 2010-11 season, there were 4,093 claims for 1,072 recipients. The average cost per claim and average cost per recipient were reviewed. There were 3,037 prior authorizations requested over the course of the season, with an approval rate of 62.3%.

Therapeutic Duplication Edit: C.Faulkner reviewed the current therapeutic duplication edit with the Board. The only drug classes currently included in the therapeutic duplication edit are: narcotic agents, antipsychotic agents, selected antihypertensive agents, diuretics and triptans. The therapeutic duplication edit is a hard edit and requires an override to process. Reasons for override may include: strength/dosage change, switch over or titration/concomitant therapy. C.Faulkner reviewed data regarding benzodiazepine utilization. In the month of April 2011, there were 735 recipients that had more than one prescription for a benzodiazepine. It was recommended to the Board that benzodiazepines be added to the therapeutic duplication edit. P.Thompson made a motion which was seconded by D.Harwood. A voice vote to approve this motion was unanimous.

Desmopressin and Enuresis Alarms: C.Faulkner presented the following background information to the Board: Nocturnal enuresis affects around 15-20% of five year olds, and up to 2% of young adults. Primary nocturnal enuresis occurs when the nocturnal urine production is more than the bladder's capacity and the child fails to awaken in response to a full bladder. Enuresis can also be secondary to a medical, psychological, or behavioral problem, although this is less common. There are several treatment options; including behavioral therapies, enuresis alarms, and pharmacological interventions. In 2009, there were 1389 children under the age of 12 using desmopressin tablets. There were a total of 4513 prescriptions at a total cost of \$724,780 (average of \$160.59 per prescription). However, with the new AAC pricing structure, the same number of prescriptions would cost approximately \$324,595, which averages out to \$71.92 per prescription. Enuresis alarms have a one-time cost of \$49.95, so if all patients were given an alarm, the cost to Medicaid would be approximately \$69,450. If the alarms worked in all cases, the savings to Medicaid would be close to \$255,000, using the new AAC pricing guidelines. C.Faulkner continued by explaining the supporting literature. According to the International Children's Continence Society, there are currently two valid first line therapies: desmopressin and enuresis alarms. Alarm therapy results in dryness in about two-thirds of children (grade Ia evidence), and should be considered for children with primary nocturnal enuresis without polyuria. Patients generally require a trial of two to three months. If positive results have not been noted at the end of this time, the alarm therapy should be discontinued. Desmopressin works best for children with nocturnal polyuria and normal bladder reservoir function, and for families in whom alarm treatment has failed. Approximately 30% of children are full responders and 40% have a partial response (grade Ia evidence). The AAFP guidelines state that there are two first-line therapies, enuresis alarms and desmopressin. The AAFP states that an enuresis alarm is effective in children with monosymptomatic nocturnal enuresis (evidence grade A) and that desmopressin is most effective in children who have enuresis with nocturnal polyuria and normal bladder capacity (evidence grade A). The article indicates that about two-thirds of children have success with the enuresis alarm and nearly one-half of children remain dry after discontinuation. There is a 60-70% response rate with desmopressin although about 80% of children relapse after discontinuing therapy. A Cochrane Literature Review of 56 studies involving 3257 children provided much the same evidence. Alarms take longer than desmopressin to reduce bedwetting, but the effects continue even after discontinuation of the alarm. Until recently, alarms have not been covered by Medicaid. They are now covered under Medicaid's DME (Durable Medical Equipment) program. C.Faulkner presented a draft letter informing prescribers of the recommended treatment options and explaining the new coverage of alarms. C.Faulkner asked the Board to consider a recommendation to Alabama Medicaid to approve the letter to be sent to the top prescribers of desmopressin. P.Thompson made a motion, B.Olin seconded the motion and it passed unanimously.

Fibromyalgia: C.Faulkner presented clinical information and data on Fibromyalgia Syndrome (FMS) and made criteria recommendations that included sending letters to providers who have patients taking benzodiazepines and opiates without at least one recommended maintenance medication for FMS.

Proposed Criteria: C.Faulkner presented the proposed set of 81 criteria to the Board. T.Minnifield instructed the Board members to mark their ballots. Of the 81 criteria, results from the criteria vote returned 64 approved, 0 rejected, and 17 criteria approved as amended (#24 – 39 and #52).

Medicaid Update: T.Minnifield reminded the Board members that during the April 2011 meeting, it was requested that the Medicaid packet be sent electronically and that all Medicaid information discussed is available online. She informed the Board that an Alert had been sent to providers regarding the new prior authorization (PA) contractor, but that this information did not pertain to pharmacy PAs. T.Minnifield informed the Board that Medicaid recipients are currently allowed 5 brands/month and this will change to 4 brands/month beginning October 1, 2011. K.Littlejohn introduced the

Patient Care Network pharmacists. Cara Leos, PharmD, who works in East Alabama, and Christopher Barwick, RPh, who works in West Alabama. She also announced that the Positive Antipsychotic Management (PAM) workgroup would meet to discuss an appropriate use edit for antipsychotic agents on August 8, 2011. K.Littlejohn also informed the Board that the next P&T meeting would be held on August 10, 2011 at 9am. K.Littlejohn advised the Board that CMS had approved Phase 3 of the Pharmacy Reimbursement Modification Initiative, which provides for reimbursement for professional services for pharmacists and also allows for payment of a 90-days supply for certain classes of drugs.

P & T Committee Update: C.Hurst began the P&T Update by informing the Board that the next meeting will be a clinical review of antipsychotics. At the last P&T meeting, which was held May 11, the Committee reviewed the Narcotic Agents, Skeletal Muscle Relaxants, Antiemetics and PPIs. Elidel® and Protopic® now require prior authorization, as does generic buprenorphine.

New Business: T.Minnifield announced that this was K.Green's last meeting as Chair and that P.Thompson would be stepping in as Chair at the next meeting. Members were asked to vote for a new Vice-Chair, and Denyse Thornley-Brown was elected. K.Green asked for a motion to adjourn. D.Harwood 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 October 26, 2011.

Respectfully submitted,



Christina Faulkner, PharmD

ALABAMA MEDICAID RETROSPECTIVE DRUG UTILIZATION REVIEW CRITERIA RECOMMENDATIONS

Criteria Recommendations

Accepted Approved Rejected
As
Amended

1. Methadone / CNS Depressants

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Alert Message: Methadone should be used with caution and in reduced dosage in patients who are concurrently receiving other narcotic analgesics, general anesthetics, phenothiazines, other tranquilizers, sedative-hypnotics, tricyclic antidepressants, and other CNS depressants (including alcohol). Respiratory depression, hypotension, profound sedation or coma may result.

Conflict Code: DD – Drug/Drug interaction

Drugs/Diseases

<u>Util A</u>	<u>Util B</u>	<u>Util C</u>
Methadone	Narcotics Benzodiazepines Phenothiazines Barbiturates Chloral Hydrate Eszopiclone Zolpidem Zaleplon Tricyclic Antidepressants Skeletal Muscle Relaxants	

References:

Facts & Comparisons, 2010 Updates.
Dolophine Prescribing Information, Oct. 2006, Roxane Laboratories, Inc.
Clinical Pharmacology, 2010 Gold Standard.

2. Methadone / QT Prolongation Warning

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Alert Message: Methadone should be administered with particular caution to patients already at risk for development of prolonged QT interval (e.g. cardiac hypertrophy, concomitant diuretic use, hypokalemia and hypomagnesemia).

Conflict Code: MC – Drug/Disease Precaution/Warning

Drugs/Diseases

<u>Util A</u>	<u>Util B</u>	<u>Util C</u>
Methadone	Cardiomegaly Hypokalemia Hypomagnesemia Cardiac Dysrhythmia	

References:

Dolophine Prescribing Information, Oct. 2006, Roxane Laboratories, Inc.
Facts & Comparisons, 2010 Updates.
Clinical Pharmacology, 2010 Gold Standard.

3. Methadone / QT Prolongation Warning

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Alert Message: Methadone should be administered with particular caution to patients already at risk for development of prolonged QT interval (e.g. cardiac hypertrophy, concomitant diuretic use, hypokalemia and hypomagnesemia).

Conflict Code: DD – Drug/Drug interaction

Drugs/Diseases

<u>Util A</u>	<u>Util B</u>	<u>Util C</u>
Methadone	Bumetanide	Chlorothiazide
	Furosemide	Hydrochlorothiazide
	Torsemide	Indapamide
	Ethacrynate	Methyclothiazide
	Amiloride	Metolazone
	Spironolactone	
	Triamterene	

References:

Dolophine Prescribing Information, Oct. 2006, Roxane Laboratories, Inc.

Facts & Comparisons, 2010 Updates.

Clinical Pharmacology, 2010 Gold Standard.

4. Methadone / QT Prolongation Agents

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Alert Message: Extreme caution is necessary when methadone is used concurrently with any drug known to have the potential to prolong the QT interval due to risk for additive effect. The risk of QT prolongation with methadone appears to be dose-related (>200 mg/day) but has been reported in patients receiving doses commonly used for maintenance treatment of opioid addiction.

Conflict Code: DD – Drug/Drug interaction

Drugs/Diseases

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

References:

Facts & Comparisons, 2010 Updates.

Dolophine Prescribing Information, Oct. 2006, Roxane Laboratories, Inc.

Clinical Pharmacology, 2010 Gold Standard.

ArizonaCERT: Drugs That Prolong the QT Interval and/or Induce Torsades de Pointes. Available at:

<http://www.azcert.org/consumers/interaction-advisory.cfm>

5. Methadone / Opiate Antagonists, Mixed Agonist/Antagonist & Partial _____√_____

Alert Message: The concurrent use of methadone with opioid antagonists, mixed agonist/antagonists and partial agonists may result in withdrawal symptoms in patients.

Conflict Code: DD – Drug/Drug interaction

Drugs/Diseases

<u>Util A</u>	<u>Util B</u>	<u>Util C</u>
Methadone	Butorphanol Buprenorphine Pentazocine Pentazocine/Naloxone Nalbuphine	

References:

Dolophine Prescribing Information, Oct. 2006, Roxane Laboratories, Inc.
Facts & Comparisons, 2010 Updates.
Clinical Pharmacology, 2010 Gold Standard.

6. Methadone / CYP3A4 Inhibitors _____√_____

Alert Message: The concurrent use of methadone and a CYP3A4 inhibitor may cause increased methadone concentrations due to the inhibition of methadone 3A4-mediated metabolism resulting in risk of increased opiate effects and/or toxicity.

Conflict Code: DD – Drug/Drug interaction

Drugs/Diseases

<u>Util A</u>	<u>Util B</u>	<u>Util C</u>
Methadone	Ketoconazole Itraconazole Fluconazole Voriconazole Amiodarone Clarithromycin Erythromycin	Verapamil Diltiazem Aprepitant Fluoxetine Fluvoxamine Nefazodone Sertraline

References:

Dolophine Prescribing Information, Oct. 2006, Roxane Laboratories, Inc.
Facts & Comparisons, 2010 Updates.
Clinical Pharmacology, 2010 Gold Standard.

7. Methadone / CYP3A4 Inducers _____√_____

Alert Message: The concurrent use of methadone and a CYP3A4 inducer may cause decreased methadone concentrations resulting in opiate withdrawal symptoms. Methadone dose adjustment may be necessary.

Conflict Code: DD – Drug/Drug interaction

Drugs/Diseases

<u>Util A</u>	<u>Util B</u>	<u>Util C</u>
Methadone	Rifampin Phenytoin Carbamazepine Efavirenz Nevirapine Phenobarbital Oxcarbazepine	Ritonavir Abacavir Fosamprenavir Nelfinavir

References:

Dolophine Prescribing Information, Oct. 2006, Roxane Laboratories, Inc.
Facts & Comparisons, 2010 Updates.
Clinical Pharmacology, 2010 Gold Standard.
Micromedex Healthcare Series, DrugDex drug Evaluations, 2010.
Norvir Prescribing Information, April 2010, Abbott

Criteria Recommendations

**Accepted Approved Rejected
As
Amended**

8. Nuedexta / Overutilization

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Alert Message: Nuedexta (dextromethorphan/quinidine) may be over-utilized. The manufacturer’s recommended starting dose is one capsule per day for the first seven days then on day eight increase dose to two capsules per day. Periodic evaluation is recommended to assess need for continued treatment.

Conflict Code: ER - Overutilization
Drugs/Diseases

Util A Util B Util C
Nuedexta

Max Dose: > 2 capsules/day

References:
Facts & Comparisons, 2010 Updates.
Nuedexta Prescribing Information, Oct. 2010, Avanir Pharmaceuticals, LLC.

9. Nuedexta / Quinidine, Quinine & Mefloquine

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Alert Message: Concurrent use of Nuedexta (dextromethorphan/quinidine), is contraindicated with other drugs containing quinidine, quinine or mefloquine.

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

Util A Util B Util C
Nuedexta Quinidine
 Quinine
 Mefloquine

References:
Facts & Comparisons, 2010 Updates.
Nuedexta Prescribing Information, Oct. 2010, Avanir Pharmaceuticals, LLC.

10. Nuedexta / MAO Inhibitors

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Alert Message: Nuedexta (dextromethorphan/quinidine) is contraindicated in patients taking an MAO inhibitor or in patients who have taken an MAOI within the preceding 14 days, due to the risk of serious, possibly fatal interactions, including serotonin syndrome.

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

Util A Util B Util C
Nuedexta Isocarboxazid
 Phenelzine
 Tranylcypromine
 Selegiline
 Rasagiline
 Linezolid

References:
Facts & Comparisons, 2010 Updates.
Nuedexta Prescribing Information, Oct. 2010, Avanir Pharmaceuticals, LLC.

Criteria Recommendations

**Accepted Approved Rejected
As
Amended**

11. Nuedexta / Disease Contraindications _____√_____

Alert Message: Nuedexta (dextromethorphan/quinidine) is contraindicated in patients who have prolonged QT interval, congenital long QT syndrome, history of suggestive torsades de pointes or heart failure.

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

<u>Util A</u>	<u>Util B</u>	<u>Util C</u>
Nuedexta	Congenital Long QT Interval Torsades de Pointes Heart Failure	

References:

Facts & Comparisons, 2010 Updates.
Nuedexta Prescribing Information, Oct. 2010, Avanir Pharmaceuticals, LLC.

12. Nuedexta / AV Block _____√_____

Alert Message: Nuedexta (dextromethorphan/quinidine) is contraindicated in patients with complete atrioventricular (AV) block without implanted pacemaker, or patients at high risk for complete AV block.

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

<u>Util A</u>	<u>Util B</u>	<u>Util C</u>
Nuedexta	Atrioventricular Block	

References:

Facts & Comparisons, 2010 Updates.
Nuedexta Prescribing Information, Oct. 2010, Avanir Pharmaceuticals, LLC.

13. Nuedexta / Drugs that BOTH Prolong QT Interval & are Metabolized by CYP2D6 _____√_____

Alert Message: Nuedexta (dextromethorphan/quinidine) is contraindicated in patients receiving drugs that both prolong QT interval and are metabolized by CYP2D6 (e.g., thioridazine and pimozide), as effects on QT interval may be increased resulting in potentially fatal cardiac arrhythmia.

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

<u>Util A</u>	<u>Util B</u>	<u>Util C</u>
Nuedexta	Thioridazine Pimozide Haloperidol Mexiletine Flecainide Venlafaxine Fluoxetine Paroxetine Fluvoxamine	Imipramine Nortriptyline Protriptyline Amitriptyline Trimipramine Clomipramine Desipramine Doxepin Amoxapine Quetiapine Venlafaxine Risperidone Chlorpromazine Sertraline Perphenazine Tamoxifen

References:

Facts & Comparisons, 2010 Updates.
Nuedexta Prescribing Information, Oct. 2010, Avanir Pharmaceuticals, LLC.
ArizonaCERT: Drugs That Prolong the QT Interval and/or induce Torsades de Pointes. Available at <http://www.azcert.org/consumers/interaction-advisory.cfm>
Clinical Pharmacology, 2010 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>.

14. Nuedexta / Drugs that the Prolong QT Interval

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Alert Message: Nuedexta (dextromethorphan/quinidine) can cause dose-dependent QT prolongation. The concurrent use of this agent with other drugs that prolong the QT interval may have an additive effect increasing the risk of life-threatening arrhythmias, including torsades de pointes.

Conflict Code: DD – Drug/Drug Interaction

Drugs/Diseases

<u>Util A</u>	<u>Util B*</u>		<u>Util C</u>
Nuedexta	Alfuzosin	Gemifloxacin	Procainamide
	Amantadine	Granisetron	Ranolazine
	Amiodarone	Ibutilide	Salmeterol
	Arsenic Trioxide	Indapamide	Solifenacin
	Atazanavir	Isradipine	Sotalol
	Azithromycin	Itraconazole	Tacrolimus
	Chloral Hydrate	Ketoconazole	Telithromycin
	Clarithromycin	Lapatinib	Tizanidine
	Clzapine	Levofloxacin	Tolterodine
	Disopyramide	Lithium	Vardenafil
	Dofetilide	Methadone	Voriconazole
	Dolasetron	Moexipril/HCTZ	Ziprasidone
	Droperidol	Moxifloxacin	Chloroquine
	Erythromycin	Nicardipine	Ciprofloxacin
	Felbamate	Nilotinib	Trazodone
	Fluconazole	Octreotide	Galantamine
	Foscarnet	Ondansetron	Ritonavir
	Fosphenytoin	Paliperidone	Pentamidine

*Did not include drugs that are contraindicated with Nuedexta –see #6.

References:

Facts & Comparisons, 2010 Updates.
 Nuedexta Prescribing Information, Oct. 2010, Avanir Pharmaceuticals, LLC.
 ArizonaCERT: Drugs That Prolong the QT Interval and/or induce Torsades de Pointes.
 Available at <http://www.azcert.org/consumers/interaction-advisory.cfm>

15. Nuedexta / Moderate or Strong CYP3A4 Inhibitors

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Alert Message: Caution should be exercised when using Nuedexta (dextromethorphan/quinidine) with a moderate or strong CYP3A4 inhibitor. Inhibition of quinidine CYP3A4-mediated metabolism may result in elevated quinidine concentrations increasing the risk of QTc prolongation and torsades de pointes-type ventricular tachycardia.

Conflict Code: DD – Drug/Drug Interaction

Drugs/Diseases

<u>Util A</u>	<u>Util B</u>		<u>Util C</u>
Nuedexta	Ketoconazole	Aprepitant	Atazanavir
	Itraconazole	Erythromycin	Fosamprenavir
	Ritonavir	Fluconazole	Saquinavir
	Indinavir	Verapamil	Telithromycin
	Nelfinavir	Diltiazem	
	Clarithromycin	Nefazodone	

References:

Facts & Comparisons, 2010 Updates.
 Nuedexta Prescribing Information, Oct. 2010, Avanir Pharmaceuticals, LLC.

16. Nuedexta / CYP2D6 Substrates

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Alert Message: Caution should be exercised when using Nuedexta (dextromethorphan/quinidine) with CYP2D6 substrates (e.g., carvedilol, oxycodone and duloxetine). The quinidine in Nuedexta inhibits CYP2D6-mediated metabolism which can cause accumulation of parent drug or failure of active metabolite formation. Dosage adjustment of the CYP2D6 substrate may be required or an alternative treatment option considered.

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

<u>Util A</u>	<u>Util B*</u>	<u>Util C</u>
Nuedexta	Duloxetine Perphenazine Metoclopramide Donepezil Nebivolol Ondansetron Oxycodone Promethazine	Propranolol Propafenone Aripiprazole Chlorpheniramine Atomoxetine Timolol Tramadol Mirtazapine

**Did not include drugs that are contraindicated with Nuedexta –see #6.*

References:
Facts & Comparisons, 2010 Updates.
Nuedexta Prescribing Information, Oct. 2010, Avanir Pharmaceuticals, LLC.

17. Nuedexta / Citalopram & Escitalopram

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Alert Message: Caution should be exercised when administering Nuedexta (dextromethorphan/quinidine) and citalopram or escitalopram due to the risk of serotonin syndrome (e.g., hyperthermia, hypertension, myoclonus and in rare cases, death). Discontinue if serotonin syndrome occurs.

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

<u>Util A</u>	<u>Util B</u>	<u>Util C</u>
Nuedexta	Citalopram Escitalopram	

**Did not include drugs that are contraindicated with Nuedexta –see #6 (other SSRIs and TCAs).*

References:
Facts & Comparisons, 2010 Updates.
Nuedexta Prescribing Information, Oct. 2010, Avanir Pharmaceuticals, LLC.
Clinical Pharmacology, 2010 Gold Standard.

18. Abstral / Overutilization

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Alert Message: Once a successful dose of Abstral (sublingual fentanyl) has been established, if the patient experiences greater than 4 breakthrough pain episodes per day, the dose of the maintenance (around-the-clock) opioid used for persistent pain should be re-evaluated.

Conflict Code: ER - Overutilization
Drugs/Diseases

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

Max Doses: 4 doses per day

References:
Abstral Prescribing Information, Jan. 2011, ProStrakan, Inc.

25. Olanzapine / Non-adherence

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Alert Message: Olanzapine (Zyprexa/Zyprexa Zydis) may be under-utilized. Non-adherence to the dosing regimen may result in sub-therapeutic effects, which may lead to decrease patient outcomes and additional medical cost.

Conflict Code: LR – Non-adherence

Drugs/Diseases

Util A Util B Util C
Olanzapine

References:

Perkins DO, Predictors of Noncompliance in Patients with Schizophrenia, J Clin Psychiatry, 2002;63:1121-1128.
Weiden PJ, Zygmunt A, Medication Noncompliance in Schizophrenia: Part 1: Assessment, Jnl Prac Psych and Behav Hlth, March 1997.
Weiden PJ, Olfson M, Cost of Relapse in Schizophrenia, Schizophrenia Bulletin, 1995;21(3):419-29.
Theida P, et.al., An Economic Review of Compliance with Medication Therapy in the Treatment of Schizophrenia, Psychiatric Services, 2003;54:508-516.
National Institute of Mental Health, Schizophrenia, NIH Publication No. 02-3517, 1999.

26. Risperidone / Non-adherence

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Alert Message: Risperdal (risperidone) may be under-utilized. Non-adherence to the dosing regimen may result in sub-therapeutic effects, which may lead to decreased patient outcomes and additional medical cost.

Conflict Code: LR – Non-adherence

Drugs/Diseases

Util A Util B Util C
Risperidone

References:

Perkins DO, Predictors of Noncompliance in Patients with Schizophrenia, J Clin Psychiatry, 2002;63:1121-1128.
Weiden PJ, Zygmunt A, Medication Noncompliance in Schizophrenia: Part 1: Assessment, Jnl Prac Psych and Behav Hlth, March 1997.
Weiden PJ, Olfson M, Cost of Relapse in Schizophrenia, Schizophrenia Bulletin, 1995;21(3):419-29.
Theida P, et.al., An Economic Review of Compliance with Medication Therapy in the Treatment of Schizophrenia, Psychiatric Services, 2003;54:508-516.
National Institute of Mental Health, Schizophrenia, NIH Publication No. 02-3517, 1999.

27. Ziprasidone / Non-adherence

_____ √ _____

Alert Message: Geodon (ziprasidone) may be under-utilized. Non-adherence to the dosing regimen may result in sub-therapeutic effects, which may lead to decreased patient outcomes and additional medical cost.

Conflict Code: LR – Non-adherence

Drugs/Diseases

Util A Util B Util C
Ziprasidone

References:

Perkins DO, Predictors of Noncompliance in Patients with Schizophrenia, J Clin Psychiatry, 2002;63:1121-1128.
Weiden PJ, Zygmunt A, Medication Noncompliance in Schizophrenia: Part 1: Assessment, Jnl Prac Psych and Behav Hlth, March 1997.
Weiden PJ, Olfson M, Cost of Relapse in Schizophrenia, Schizophrenia Bulletin, 1995;21(3):419-29.
Theida P, et.al., An Economic Review of Compliance with Medication Therapy in the Treatment of Schizophrenia, Psychiatric Services, 2003;54:508-516.
National Institute of Mental Health, Schizophrenia, NIH Publication No. 02-3517, 1999.

28. Aripiprazole / Non-adherence _____ _____ _____

Alert Message: Aabilify (aripiprazole) may be under-utilized. Non-adherence to the dosing regimen may result in sub-therapeutic effects, which may lead to decreased patient outcomes and additional medical cost.

Conflict Code: LR – Non-adherence

Drugs/Diseases

Util A

Util B

Util C

Aripiprazole

References:

Perkins DO, Predictors of Noncompliance in Patients with Schizophrenia, J Clin Psychiatry, 2002;63:1121-1128.

Weiden PJ, Zygmunt A, Medication Noncompliance in Schizophrenia: Part 1: Assessment, Jrnl Prac Psych and Behav Hlth, March 1997.

Weiden PJ, Olfson M, Cost of Relapse in Schizophrenia, Schizophrenia Bulletin, 1995;21(3):419-29.

Theida P, et.al., An Economic Review of Compliance with Medication Therapy in the Treatment of Schizophrenia, Psychiatric Services, 2003;54:508-516.

National Institute of Mental Health, Schizophrenia, NIH Publication No. 02-3517, 1999.

29. Quetiapine / Non-adherence _____ _____ _____

Alert Message: Quetiapine (Seroquel/Seroquel XR) may be under-utilized.

Non-adherence to the dosing regimen may result in sub-therapeutic effects, which may lead to decreased patient outcomes and additional medical cost.

Conflict Code: LR – Non-adherence

Drugs/Diseases

Util A

Util B

Util C

Quetiapine-All

References:

Perkins DO, Predictors of Noncompliance in Patients with Schizophrenia, J Clin Psychiatry, 2002;63:1121-1128.

Weiden PJ, Zygmunt A, Medication Noncompliance in Schizophrenia: Part 1: Assessment, Jrnl Prac Psych and Behav Hlth, March 1997.

Weiden PJ, Olfson M, Cost of Relapse in Schizophrenia, Schizophrenia Bulletin, 1995;21(3):419-29.

Theida P, et.al., An Economic Review of Compliance with Medication Therapy in the Treatment of Schizophrenia, Psychiatric Services, 2003;54:508-516.

National Institute of Mental Health, Schizophrenia, NIH Publication No. 02-3517, 1999.

30. Chlorpromazine / Non-adherence _____ _____ _____

Alert Message: Chlorpromazine may be under-utilized. Non-adherence to the dosing regimen may result in sub-therapeutic effects, which may lead to decreased patient outcomes and additional medical cost.

Conflict Code: LR – Non-adherence

Drugs/Diseases

Util A

Util B

Util C

Chlorpromazine

References:

Perkins DO, Predictors of Noncompliance in Patients with Schizophrenia, J Clin Psychiatry, 2002;63:1121-1128.

Weiden PJ, Zygmunt A, Medication Noncompliance in Schizophrenia: Part 1: Assessment, Jrnl Prac Psych and Behav Hlth, March 1997.

Weiden PJ, Olfson M, Cost of Relapse in Schizophrenia, Schizophrenia Bulletin, 1995;21(3):419-29.

Theida P, et.al., An Economic Review of Compliance with Medication Therapy in the Treatment of Schizophrenia, Psychiatric Services, 2003;54:508-516.

National Institute of Mental Health, Schizophrenia, NIH Publication No. 02-3517, 1999.

Criteria Recommendations

Accepted Approved Rejected
As
Amended

31. Fluphenazine / Non-adherence

_____ ✓ _____

Alert Message: Fluphenazine may be under-utilized. Non-adherence to the dosing regimen may result in sub-therapeutic effects, which may lead to decreased patient outcomes and additional medical cost.

Conflict Code: LR – Non-adherence

Drugs/Diseases

Util A

Util B

Util C

Fluphenazine

References:

Perkins DO, Predictors of Noncompliance in Patients with Schizophrenia, J Clin Psychiatry, 2002;63:1121-1128.

Weiden PJ, Zygmunt A, Medication Noncompliance in Schizophrenia: Part 1: Assessment, Jrnl Prac Psych and Behav Hlth, March 1997.

Weiden PJ, Olfson M, Cost of Relapse in Schizophrenia, Schizophrenia Bulletin, 1995;21(3):419-29.

Theida P, et.al., An Economic Review of Compliance with Medication Therapy in the Treatment of Schizophrenia, Psychiatric Services, 2003;54:508-516.

National Institute of Mental Health, Schizophrenia, NIH Publication No. 02-3517, 1999.

32. Perphenazine / Non-adherence

_____ ✓ _____

Alert Message: Perphenazine may be under-utilized. Non-adherence to the dosing regimen may result in sub-therapeutic effects, which may lead to decreased patient outcomes and additional medical cost.

Conflict Code: LR – Non-adherence

Drugs/Diseases

Util A

Util B

Util C

Perphenazine

References:

Perkins DO, Predictors of Noncompliance in Patients with Schizophrenia, J Clin Psychiatry, 2002;63:1121-1128.

Weiden PJ, Zygmunt A, Medication Noncompliance in Schizophrenia: Part 1: Assessment, Jrnl Prac Psych and Behav Hlth, March 1997.

Weiden PJ, Olfson M, Cost of Relapse in Schizophrenia, Schizophrenia Bulletin, 1995;21(3):419-29.

Theida P, et.al., An Economic Review of Compliance with Medication Therapy in the Treatment of Schizophrenia, Psychiatric Services, 2003;54:508-516.

National Institute of Mental Health, Schizophrenia, NIH Publication No. 02-3517, 1999.

33. Prochlorperazine / Non-adherence

_____ ✓ _____

Alert Message: Prochlorperazine may be under-utilized. Non-adherence to the dosing regimen may result in sub-therapeutic effects, which may lead to decreased patient outcomes and additional medical cost.

Conflict Code: LR – Non-adherence

Drugs/Diseases

Util A

Util B

Util C

Prochlorperazine (no suppositories)

References:

Perkins DO, Predictors of Noncompliance in Patients with Schizophrenia, J Clin Psychiatry, 2002;63:1121-1128.

Weiden PJ, Zygmunt A, Medication Noncompliance in Schizophrenia: Part 1: Assessment, Jrnl Prac Psych and Behav Hlth, March 1997.

Weiden PJ, Olfson M, Cost of Relapse in Schizophrenia, Schizophrenia Bulletin, 1995;21(3):419-29.

Theida P, et.al., An Economic Review of Compliance with Medication Therapy in the Treatment of Schizophrenia, Psychiatric Services, 2003;54:508-516.

National Institute of Mental Health, Schizophrenia, NIH Publication No. 02-3517, 1999.

Criteria Recommendations

Accepted Approved Rejected
As
Amended

34. Trifluoperazine / Non-adherence

_____ ✓ _____

Alert Message: Trifluoperazine may be under-utilized. Non-adherence to the dosing regimen may result in sub-therapeutic effects, which may lead to decreased patient outcomes and additional medical cost.

Conflict Code: LR – Non-adherence

Drugs/Diseases

Util A

Util B

Util C

Trifluoperazine

References:

Perkins DO, Predictors of Noncompliance in Patients with Schizophrenia, J Clin Psychiatry, 2002;63:1121-1128.

Weiden PJ, Zygmunt A, Medication Noncompliance in Schizophrenia: Part 1: Assessment, Jrnl Prac Psych and Behav Hlth, March 1997.

Weiden PJ, Olfson M, Cost of Relapse in Schizophrenia, Schizophrenia Bulletin, 1995;21(3):419-29.

Theida P, et.al., An Economic Review of Compliance with Medication Therapy in the Treatment of Schizophrenia, Psychiatric Services, 2003;54:508-516.

National Institute of Mental Health, Schizophrenia, NIH Publication No. 02-3517, 1999.

35. Thioridazine / Non-adherence

_____ ✓ _____

Alert Message: Thioridazine may be under-utilized. Non-adherence to the dosing regimen may result in sub-therapeutic effects, which may lead to decreased patient outcomes and additional medical cost.

Conflict Code: LR – Non-adherence

Drugs/Diseases

Util A

Util B

Util C

Thioridazine

References:

Perkins DO, Predictors of Noncompliance in Patients with Schizophrenia, J Clin Psychiatry, 2002;63:1121-1128.

Weiden PJ, Zygmunt A, Medication Noncompliance in Schizophrenia: Part 1: Assessment, Jrnl Prac Psych and Behav Hlth, March 1997.

Weiden PJ, Olfson M, Cost of Relapse in Schizophrenia, Schizophrenia Bulletin, 1995;21(3):419-29.

Theida P, et.al., An Economic Review of Compliance with Medication Therapy in the Treatment of Schizophrenia, Psychiatric Services, 2003;54:508-516.

National Institute of Mental Health, Schizophrenia, NIH Publication No. 02-3517, 1999.

36. Thiothixene / Non-adherence

_____ ✓ _____

Alert Message: Thiothixene may be under-utilized. Non-adherence to the dosing regimen may result in sub-therapeutic effects, which may lead to decreased patient outcomes and additional medical cost.

Conflict Code: LR – Non-adherence

Drugs/Diseases

Util A

Util B

Util C

Thiothixene

References:

Perkins DO, Predictors of Noncompliance in Patients with Schizophrenia, J Clin Psychiatry, 2002;63:1121-1128.

Weiden PJ, Zygmunt A, Medication Noncompliance in Schizophrenia: Part 1: Assessment, Jrnl Prac Psych and Behav Hlth, March 1997.

Weiden PJ, Olfson M, Cost of Relapse in Schizophrenia, Schizophrenia Bulletin, 1995;21(3):419-29.

Theida P, et.al., An Economic Review of Compliance with Medication Therapy in the Treatment of Schizophrenia, Psychiatric Services, 2003;54:508-516.

National Institute of Mental Health, Schizophrenia, NIH Publication No. 02-3517, 1999.

Criteria Recommendations

Accepted Approved Rejected
As
Amended

37. Haloperidol / Non-adherence

_____ ✓ _____

Alert Message: Haloperidol may be under-utilized. Non-adherence to the dosing regimen may result in sub-therapeutic effects, which may lead to decreased patient outcomes and additional medical cost.

Conflict Code: LR – Non-adherence

Drugs/Diseases

Util A

Util B

Util C

Haloperidol

References:

Perkins DO, Predictors of Noncompliance in Patients with Schizophrenia, J Clin Psychiatry, 2002;63:1121-1128.

Weiden PJ, Zygmunt A, Medication Noncompliance in Schizophrenia: Part 1: Assessment, Jrnl Prac Psych and Behav Hlth, March 1997.

Weiden PJ, Olfson M, Cost of Relapse in Schizophrenia, Schizophrenia Bulletin, 1995;21(3):419-29.

Theida P, et.al., An Economic Review of Compliance with Medication Therapy in the Treatment of Schizophrenia, Psychiatric Services, 2003;54:508-516.

National Institute of Mental Health, Schizophrenia, NIH Publication No. 02-3517, 1999.

38. Pimozide / Non-adherence

_____ ✓ _____

Alert Message: Pimozide may be under-utilized. Non-adherence to the dosing regimen may result in sub-therapeutic effects, which may lead to decreased patient outcomes and additional medical costs.

Conflict Code: LR – Non-adherence

Drugs/Diseases

Util A

Util B

Util C

Pimozide

References:

Perkins DO, Predictors of Noncompliance in Patients with Schizophrenia, J Clin Psychiatry, 2002;63:1121-1128.

Weiden PJ, Zygmunt A, Medication Noncompliance in Schizophrenia: Part 1: Assessment, Jrnl Prac Psych and Behav Hlth, March 1997.

Weiden PJ, Olfson M, Cost of Relapse in Schizophrenia, Schizophrenia Bulletin, 1995;21(3):419-29.

Theida P, et.al., An Economic Review of Compliance with Medication Therapy in the Treatment of Schizophrenia, Psychiatric Services, 2003;54:508-516.

National Institute of Mental Health, Schizophrenia, NIH Publication No. 02-3517, 1999.

39. Loxapine / Non-adherence

_____ ✓ _____

Alert Message: Loxapine may be under-utilized. Non-adherence to the dosing regimen may result in sub-therapeutic effects, which may lead to decreased patient outcomes and additional medical cost.

Conflict Code: LR – Non-adherence

Drugs/Diseases

Util A

Util B

Util C

Loxapine

References:

Perkins DO, Predictors of Noncompliance in Patients with Schizophrenia, J Clin Psychiatry, 2002;63:1121-1128.

Weiden PJ, Zygmunt A, Medication Noncompliance in Schizophrenia: Part 1: Assessment, Jrnl Prac Psych and Behav Hlth, March 1997.

Weiden PJ, Olfson M, Cost of Relapse in Schizophrenia, Schizophrenia Bulletin, 1995;21(3):419-29.

Theida P, et.al., An Economic Review of Compliance with Medication Therapy in the Treatment of Schizophrenia, Psychiatric Services, 2003;54:508-516.

National Institute of Mental Health, Schizophrenia, NIH Publication No. 02-3517, 1999.

40. Topiramate / Therapeutic Appropriateness

_____√_____

Alert Message: The use of Topamax (topiramate) during the first trimester of pregnancy has been shown to increase the risk for the development of oral clefts in infants. Data from the AED Pregnancy Registry shows that infants exposed to topiramate as a single therapy experienced a 1.4% prevalence of oral clefts as compared to 0.39% to 0.55% in infants exposed to other antiepileptic drugs. Females of childbearing age receiving topiramate should be warned of the potential hazard to the fetus if a woman becomes pregnant while using the drug. Topiramate is pregnancy category D.

Conflict Code: TA – Therapeutic Appropriateness

Drugs/Diseases

Util A

Util B

Util C

Topiramate

Gender: Females

Age Range: 12 – 50 yoa

References:

MedWatch FDA Drug Safety Communication: Risk of Oral Clefts in Children Born to Mothers Taking Topamax (topiramate). 03-04-2011.

Facts & comparisons, 2011 Updates.

41. Vilazodone / Overutilization

_____√_____

Alert Message: The recommended dose of Viibryd (vilazodone) is 40 mg once daily. Vilazodone should be titrated to the 40 mg dose starting with an initial dose of 10 mg/day for 7 days, followed by 20 mg/day for 7 days then 40 mg daily. Vilazodone should be taken with food to ensure adequate drug concentrations.

Conflict Code: ER - Overutilization

Drugs/Diseases

Util A

Util B

Util C

Vilazodone

Max Dose: 40 mg/day

References:

Viibryd Prescribing Information. Jan. 2010, Torvis Pharms.

Facts & comparisons, 2011 Updates.

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

42. Vilazodone / MAO Inhibitors

_____√_____

Alert Message: The use of Viibryd (vilazodone) is contraindicated with an MAO inhibitor or within 14 days of stopping or starting an MAOI due to the risk of serious, sometimes fatal, drug interactions with serotonergic drugs.

Conflict Code: DD – Drug/Drug Interaction

Drugs/Diseases

Util A

Util B

Util C

Vilazodone

Isocarboxazid

Selegiline

Phenelzine

Rasagiline

Tranylcypromine

Linezolid

References:

Viibryd Prescribing Information. Jan. 2010, Torvis Pharms.

Facts & comparisons, 2011 Updates.

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

Criteria Recommendations

**Accepted Approved Rejected
As
Amended**

43. Vilazodone 20 & 30 mg / Strong CYP3A4 Inhibitors

_____√_____

Alert Message: The dose of Viibryd (vilazodone) should not exceed 20 mg/day when co-administered with a strong CYP3A4 inhibitor (e.g., ketoconazole, ritonavir, clarithromycin and nefazodone). Vilazodone is a CYP3A4 substrate and concurrent use with a strong 3A4 inhibitor may result in a significant increase in vilazodone plasma concentrations.

Conflict Code: ER - Overutilization

Drugs/Diseases

<u>Util A</u>	<u>Util B</u>		<u>Util C</u>
Vilazodone 20 & 30	Ketoconazole	Indinavir	
	Itraconazole	Nelfinavir	
	Ritonavir	Telithromycin	
	Saquinavir	Clarithromycin	
	Atazanavir	Nefazodone	

References:

Viibryd Prescribing Information. Jan. 2010, Torvis Pharms.
Facts & comparisons, 2011 Updates.
Micromedex Healthcare Series, DrugDex Drug Evaluations, 2011 Thomson Reuters.

44. Vilazodone / CPY3A4 Inducers

_____√_____

Alert Message: The concurrent use of Viibryd (vilazodone) with a CYP3A4 inducer (e.g., carbamazepine, phenobarbital and phenytoin) may result in inadequate drug concentrations of vilazodone and diminished effectiveness.

Conflict Code: DD – Drug/Drug Interaction

Drugs/Diseases

<u>Util A</u>	<u>Util B</u>		<u>Util C</u>
Vilazodone	Carbamazepine	Barbiturates	Prednisone
	Phenytoin	Rifabutin	Oxcarbazepine
	Efavirenz	Rifampin	Modafinil
	Nevirapine	Dexamethasone	

References:

Viibryd Prescribing Information. Jan. 2010, Torvis Pharms.
Micromedex Healthcare Series, DrugDex Drug Evaluations, 2011 Thomson Reuters.
Facts & comparisons, 2011 Updates.

45. Vilazodone / Non-adherence

_____√_____

Alert Message: Based on refill history, your patient may be underutilizing Viibryd (vilazodone). Non-adherence to the prescribed dosing regimen may result in sub-therapeutic effect, which may lead to decreased patient outcomes and additional healthcare costs.

Conflict Code: LR – Non-Adherence

Drugs/Diseases

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

References:

Viibryd Prescribing Information. Jan. 2010, Torvis Pharms.
Micromedex Healthcare Series, DrugDex Drug Evaluations, 2011 Thomson Reuters.
Facts & comparisons, 2011 Updates.

Criteria Recommendations

Accepted Approved Rejected
As
Amended

46. Vilazodone / Therapeutic Appropriateness

_____√_____

Alert Message: The safety and effectiveness of Viibryd (vilazodone) in the pediatric population have not been established.

Conflict Code: TA – Therapeutic Appropriateness

Drugs/Diseases

Util A

Util B

Util C

Vilazodone

Age Range: 0-17 yoa

References:

Facts & comparisons, 2011 Updates.

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

Viibryd Prescribing Information. Jan. 2010, Torvis Pharms.

47. Atorvastatin / High Dose

_____√_____

Alert Message: The maximum recommended dose of Lipitor (atorvastatin) in children and adolescents (ages 10 -17 years) is 20 mg per day (doses greater than 20 mg have not been studied in this patient population).

Conflict Code: HD – High Dose

Drugs/Diseases

Util A

Util B

Util C

Atorvastatin

Age Range: 10-17 yoa

Max Dose: 20mg/day

References:

Lipitor Prescribing Information, June 2009, Pfizer Pharmaceuticals.

Facts & Comparisons, 2011 Updates.

48. Lovastatin IR / High Dose

_____√_____

Alert Message: The maximum recommended dose of immediate-release lovastatin in children and adolescents (ages 10 -17 years) is 40 mg per day (doses greater than 40 mg have not been studied in this patient population).

Conflict Code: HD – High Dose

Drugs/Diseases

Util A

Util B

Util C

Lovastatin IR

Age Range: 10-17 yoa

Max Dose: 40mg/day

References:

Mevacor Prescribing Information, May 2010, Pfizer Pharmaceuticals.

Facts & Comparisons, 2011 Updates.

Criteria Recommendations

**Accepted Approved Rejected
As
Amended**

49. Rosuvastatin / High Dose

_____√_____

Alert Message: The maximum recommended dose of Crestor (rosuvastatin) in children and adolescents (ages 10 -17 years) is 20 mg per day (doses greater than 20 mg have not been studied in this patient population).

Conflict Code: HD – High Dose

Drugs/Diseases

Util A

Util B

Util C

Rosuvastatin

Age Range: 10-17 yoa

Max Dose: 20mg/day

References:

Facts & Comparisons, 2011 Updates.

Crestor Prescribing Information, June 2010, AstraZeneca.

50. Pravastatin / High Dose

_____√_____

Alert Message: The usual recommended dose of pravastatin in adolescent patients (ages 14 -18 years) is 40 mg per day (doses greater than 40 mg have not been studied in this patient population).

Conflict Code: HD – High Dose

Drugs/Diseases

Util A

Util B

Util C

Pravastatin

Age Range: 14-18 yoa

Max Dose: 40mg/day

References:

Facts & Comparisons, 2011 Updates.

Pravachol Prescribing Information, July 2010, Bristol-Myers Squibb Company.

Criteria Recommendations

Accepted Approved Rejected
As
Amended

51. Pravastatin / High Dose

_____√_____

Alert Message: The usual recommended dose of pravastatin in children (ages 8 -13 years) is 20 mg per day (doses greater than 20 mg have not been studied in this patient population).

Conflict Code: HD – High Dose

Drugs/Diseases

Util A

Util B

Util C

Pravastatin

Age Range: 8-13 yoa

Max Dose: 20mg/day

References:

Facts & Comparisons, 2011 Updates.

Pravachol Prescribing Information, July 2010, Bristol-Myers Squibb Company.

52. Simvastatin / High Dose

_____√_____

Alert Message: The maximum recommended dose of simvastatin in children and adolescents (ages 10 -17 years) is 40 mg per day (doses greater than 20 mg have not been studied in this patient population).

****Amended to “The maximum recommended dose of simvastatin in children and adolescents (ages 10-17 years) is 40 mg per day (doses greater than 40 mg have not been studied in this patient population).”**

Conflict Code: HD – High Dose

Drugs/Diseases

Util A

Util B

Util C

Simvastatin

Age Range: 10-17 yoa

Max Dose: 40 mg/day

References:

Facts & Comparisons, 2011 Updates.

Zocor Prescribing Information, May 2010, Merck & Co., Inc.

Clinical Pharmacology, 2011 Gold Standard.

Criteria Recommendations

**Accepted Approved Rejected
As
Amended**

53. Fluvastatin / High Dose

_____√_____

Alert Message: The maximum recommended dose of fluvastatin in children and adolescents (ages 9 - 16 years) is 80 mg per day (immediate-release product 40 mg twice daily or one extended-release 80 mg once daily).

Conflict Code: HD – High Dose

Drugs/Diseases

Util A

Util B

Util C

Fluvastatin IR & XL

Age Range: 9-16 yoa

Max Dose: 80 mg/day

References:

Facts & Comparisons, 2011 Updates.

Lescol & Lescol XL Prescribing Information, Oct. 2006, Novartis Pharmaceuticals Corp.

Clinical Pharmacology, 2011 Gold Standard.

54. Butrans / High Dose

_____√_____

Alert Message: The maximum recommended dose of Butrans (transdermal buprenorphine) is one 20 mcg system every 7 days. Exceeding this dose may increase the risk of QTc interval prolongation.

Conflict Code: HD – High Dose

Drugs/Diseases

Util A

Util B

Util C

Butrans

Max Dose: 20 mcg/hour (1 – pack of 4 units per month)

References:

Butrans Prescribing Information, June 2010, Purdue Pharma L.P.

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

Facts & Comparisons, 2011 Updates.

55. Butrans / QT Prolongation

_____√_____

Alert Message: Butrans (transdermal buprenorphine) use should be avoided in patients with long QT syndrome, family history of long QT syndrome or this taking Class 1A or Class III antiarrhythmic medications. A clinical study of the effects of buprenorphine on QTc revealed no meaningful effect at a dose of 10 mcg/hr; however a dose of 40 mcg/hr was shown to prolong the QTc interval by a maximum of 9.2 msec across the 13 assessment time points.

Conflict Code: MC – Drug Disease Precaution

Drugs/Diseases

Util A

Util B

Util C

Butrans

QT Prolongation

References:

Butrans Prescribing Information, June 2010, Purdue Pharma L.P.

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

Facts & Comparisons, 2011 Updates.

56. Butrans / Antiarrhythmics (Class 1A & Class III)

_____√_____

Alert Message: Butrans (transdermal buprenorphine) use should be avoided in patients with long QT syndrome, family history of long QT syndrome or this taking Class 1A or Class III antiarrhythmic medications. A clinical study of the effects of buprenorphine on QTc revealed no meaningful effect at a dose of 10 mcg/hr; however a dose of 40 mcg/hr was shown to prolong the QTc interval by a maximum of 9.2 msec across the 13 assessment time points.

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

<u>Util A</u>	<u>Util B</u>	<u>Util C</u>
Butrans	Quinidine Procainamide Disopyramide Amiodarone Sotalol Dofetilide	

References:
Butrans Prescribing Information, June 2010, Purdue Pharma L.P.
Micromedex Healthcare Series, DrugDex Drug Evaluations, 2011 Thomson Reuters.
Facts & Comparisons, 2011 Updates.

57. Butrans / Benzodiazepines

_____√_____

Alert Message: Caution should be exercised if Butrans (transdermal buprenorphine) is co-administered with benzodiazepines due to the potential for significant CNS depression. Patients should be warned against concomitant self-administration/misuse of these agents.

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

<u>Util A</u>	<u>Util B</u>	<u>Util C</u>
Butrans	Alprazolam Chlordiazepoxide Clonazepam Clorazepate Diazepam Lorazepam Oxazepam Estazolam Flurazepam Quazepam Temazepam Triazolam	

References:
Butrans Prescribing Information, June 2010, Purdue Pharma L.P.
Micromedex Healthcare Series, DrugDex Drug Evaluations, 2011 Thomson Reuters.
Facts & Comparisons, 2011 Updates.

Criteria Recommendations

Accepted Approved Rejected
As
Amended

58. Butrans / CYP3A4 Inducers

_____√_____

Alert Message: Concurrent use of Butrans (transdermal buprenorphine) and a CYP3A4 inducer (e.g., carbamazepine, phenytoin and rifampin) may result in increased clearance of buprenorphine. Monitor patient for reduced efficacy of buprenorphine.

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

<u>Util A</u>	<u>Util B</u>	<u>Util C</u>
Butrans	Carbamazepine Phenytoin Rifampin Rifapentine Rifabutin Efavirenz Phenobarbital	

References:

Butrans Prescribing Information, June 2010, Purdue Pharma L.P.
Micromedex Healthcare Series, DrugDex Drug Evaluations, 2011 Thomson Reuters.
Facts & Comparisons, 2011 Updates.
Clinical Pharmacology, 2011 Gold Standard.

59. Butrans / Skeletal Muscle Relaxants

_____√_____

Alert Message: Concurrent use of Butrans (transdermal buprenorphine) and a skeletal muscle relaxant may enhance neuromuscular blocking action and increase respiratory depression.

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

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

References:

Butrans Prescribing Information, June 2010, Purdue Pharma L.P.
Micromedex Healthcare Series, DrugDex Drug Evaluations, 2011 Thomson Reuters.
Facts & Comparisons, 2011 Updates.

60. Butrans / Severe Hepatic Impairment

_____√_____

Alert Message: Butrans (transdermal buprenorphine) has not been evaluated in patients with severe hepatic impairment. Because transdermal buprenorphine is only intended for 7-day application, consider use of an alternate analgesic that may permit more flexibility with the dosing in this patient population.

Conflict Code: MC – Drug Disease Precaution
Drugs/Diseases

<u>Util A</u>	<u>Util B</u>	<u>Util C</u>
Butrans	Chronic Passive Congestion of the Liver Hepatic Encephalopathy Cirrhosis	

References:

Butrans Prescribing Information, June 2010, Purdue Pharma L.P.
Micromedex Healthcare Series, DrugDex Drug Evaluations, 2011 Thomson Reuters.
Facts & Comparisons, 2011 Updates.

Criteria Recommendations

**Accepted Approved Rejected
As
Amended**

61. Linagliptin / High Dose

Alert Message: Tradjenta (linagliptin) may be over-utilized. The recommended maximum daily dose is 5 mg.

_____√_____

Conflict Code: HD – High Dose

Drugs/Diseases

Util A

Util B

Util C

Linagliptin

Max Dose: 5mg/day

References:

Tradjenta Prescribing Information, May 2011, Boehringer Ingelheim.

62. Linagliptin / Non-adherence

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

_____√_____

Conflict Code: LR – Non-adherence

Drugs/Diseases

Util A

Util B

Util C

Linagliptin

References:

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

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

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

Tradjenta Prescribing Information, May 2011, Boehringer Ingelheim.

63. Linagliptin / Sulfonylureas

Alert Message: The concurrent use of Tradjenta (linagliptin) with a sulfonylurea may result in hypoglycemia. A dose reduction of the sulfonylurea may be necessary to reduce the risk of hypoglycemia.

_____√_____

Conflict Code: DD – Drug/Drug Interactions

Drugs/Diseases

Util A

Util B

Util C

Linagliptin

Sulfonylureas

References:

Tradjenta Prescribing Information, May 2011, Boehringer Ingelheim.

Criteria Recommendations

Accepted Approved Rejected
As
Amended

64. Linagliptin / Type 1 Diabetes & Diabetic Ketoacidosis

Alert Message: Tradjenta (linagliptin) should not be used in patients with type 1 diabetes mellitus or for the treatment of diabetic ketoacidosis.

_____√_____

Conflict Code: MC – Drug/Actual Disease Precaution

Drugs/Diseases

Util A

Util B

Util C

Linagliptin

Type 1 Diabetes

Diabetic Ketoacidosis

References:

Tradjenta Prescribing Information, May 2011, Boehringer Ingelheim.

65. Linagliptin / Strong P-gp or CYP3A4 Inducers

Alert Message: Concurrent use of Tradjenta (linagliptin) and a strong P-gp or CYP3A4 inducer may result in decreased linagliptin exposure and reduced efficacy. The manufacturer strongly recommends use of an alternative to linagliptin if therapy with a strong inducer is required.

_____√_____

Conflict Code: DD – Drug/Drug Interaction

Drugs/Diseases

Util A

Util B

Util C

Linagliptin

Rifampin

Ritonavir

Efavirenz

Nevirapine

Carbamazepine

Dexamethasone

Phenytoin

Phenobarbital

References:

Tradjenta Prescribing Information, May 2011, Boehringer Ingelheim.

66. Linagliptin / Pediatric Patients (0-17 yoa)

Alert Message: Safety and effectiveness of Tradjenta (linagliptin) in patients below the age of 18 have not been established.

_____√_____

Conflict Code: TA – Therapeutic Appropriateness

Drugs/Diseases

Util A

Util B

Util C

Linagliptin

Age Range: 0-18 yoa

References:

Tradjenta Prescribing Information, May 2011, Boehringer Ingelheim.

67. Azilsartan / High Dose

Alert Message: Edarbi (azilsartan) may be over-utilized. The recommended maximum daily dose is 80 mg taken once daily. If patient is treated with high doses of diuretics consider starting dose of 40 mg per day.

_____√_____

Conflict Code: ER - Overutilization

Drugs/Diseases

Util A

Util B

Util C

Azilsartan

Max Dose: 80mg/day

References:

Facts & Comparisons, 2011 Updates.

Edarbi Prescribing information, March 2011, Takeda Pharms.

68. ARBs / Non-adherence

_____√_____

Alert Message: After reviewing your patient's refill frequency of the angiotensin II receptor blocker containing product we are concerned that they may be non-adherent to the prescribed dosing regimen which may lead to sub-therapeutic effects.

Conflict Code: LR – Non-adherence

Drugs/Diseases

Util A Util B Util C

- Losartan
- Valsartan
- Irbesartan
- Eprosartan
- Candesartan
- Olmесartan
- Telmisartan
- Azilsartan

References:

Osterberg L, Blaschke T. Adherence to medication. N Engl J Med 2005;353:487-97.
Munger MA, Van Tassel BW, La Fleur J, Medication Nonadherence: An Unrecognized Cardiovascular Risk Factor. MedGenMed. Sep. 2007;19;9(3):58.
Available at: <http://www.medscape.com/viewarticle/561319>
Chobanian AV. Impact of Nonadherence to Antihypertensive Therapy. Circulation. 2009;120:1558-1560.

69. Hydrocodone & Oxycodone / Fibromyalgia / Negating Preferred TX & DZ

_____√_____

Alert Message: A recent review of the patient's diagnostic and prescription history suggests that he/she has fibromyalgia syndrome (FMS) and is receiving opioid therapy without evidence of the use of recommended fibromyalgia treatment. There is insufficient clinical evidence to suggest opioid therapy is effective in FMS, particularly monotherapy. Opiates have a significant adverse effect profile including addiction and opioid-induced hyperalgesia. If no contraindications exist, consider use of a recommended agent(s) for the treatment of FMS in order to address all aspects of the syndrome.

Conflict Code: MC – Drug/Disease Precaution

Drugs/Diseases

<u>Util A</u>	<u>Util B</u>	<u>Util C (Negating)</u>	
Hydrocodone	Fibromyalgia (729.1*)	SSRIs	Spinal Cord Problems
Oxycodone		SNRIs	Cancers
		NSAIDs	
		Tramadol	
		Amitriptyline	
		Cyclobenzaprine	
		Pregabalin	
		Gabapentin	

References:

Arnold LM. Biology and Therapy of Fibromyalgia. New Therapies in Fibromyalgia. 06/23/2006;Arthritis Research & Therapy. 2006. Available at: http://www.medscape.com/viewarticle/536239_print
Ngian GS, Guymer EK and Littlejohn GO. The Use of Opioids in Fibromyalgia. Int J Rheum dis. 2011 Feb;14(1):6-11.
Goldenberg DL, Burckhardt C and Crofford L Management of Fibromyalgia Syndrome. JAMA. 2004;292(19):2388-2395.
Burkhardt C, Goldenberg DL, Crofford LJ, et al.. "Guideline for the Management of Fibromyalgia Syndrome Pain in Adults and Children". APS Clinical Practice Guidelines Series, No. 4, 2005.

70. Benzodiazepines / Fibromyalgia / Negating Preferred TX & DZ _____√_____

Alert Message: A recent review of the patient’s diagnostic and prescription history suggests that he/she has fibromyalgia syndrome (FMS) and is receiving benzodiazepine therapy without evidence of the use of other recommended fibromyalgia treatment. There is insufficient clinical data to suggest benzodiazepine monotherapy is effective in FMS. Benzodiazepines have addiction potential and can exacerbate symptoms of FMS. If no contraindications exist, consider use of a recommended FMS agent(s) for the treatment of FMS in order to address all aspects of the syndrome.

Conflict Code: MC – Drug/Disease Precaution

Drugs/Diseases

<u>Util A</u>	<u>Util B</u>	<u>Util C(Negating)</u>
Benzodiazepines	Fibromyalgia (729.1*)	SSRIs SNRIs NSAIDs Tramadol Amitriptyline Cyclobenzaprine Pregabalin Gabapentin
		Spinal Cord Problems Cancers

References:

Arnold LM. Biology and Therapy of Fibromyalgia. *New Therapies in Fibromyalgia*. 06/23/2006;Arthritis Research & Therapy. 2006. Available at: http://www.medscape.com/viewarticle/536239_print

Burckhardt C, Goldenberg DL, Crofford LJ, et al.. "Guideline for the Management of Fibromyalgia Syndrome Pain in Adults and Children". *APS Clinical Practice Guidelines Series, No. 4, 2005*.

Hauser W, Bernardy K, Arnold B et al., Efficacy of Multicomponent Treatment in Fibromyalgia Syndrome: A MetaAnalysis of Randomized Controlled Clinical Trials. *Arth & Rheum*. 2009 Feb 15;61(2):216-224.

Boomershine CS and Crofford LJ. A Symptom-Based Approach to Pharmacologic Management of Fibromyalgia. *Nat Rev Rheumatol*. 2009;5:191-199.

71. Rilpivirine / Nonadherence _____√_____

Alert Message: Nonadherence to antiretroviral therapy may result in insufficient plasma levels and partial suppression of viral load leading to the development of resistance, HIV progression and increased mortality.

Conflict Code: LR - Nonadherence

Drugs/Diseases

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

References:

Edurant Prescribing Information, May 2011, Tibotec Pharmaceuticals.

Hoffman C, Mulcahy F, Goals and Principles of Therapy, Eradication, Cost, Prevention and Adherence. In: Hoffman C, Rockstroh J, Kamps BS, eds. *HIV Medicine*, Flying Publishers-Paris, Cagliari, Wuppertal, Sevilla, 2005:167-173.

Cheever LW, Chapter V: Adherence to HIV Therapies. In: *A Guide to Clinical Care of Women with HIV/AIDS*, 2005 Edition, HIV/AIDS Bureau, US Department of Health and Human Services. <http://hab.hrsa.gov/publications/womencare05/WG05chap5.htm>

Guidelines for the Use of Antiretroviral Agents in HIV-1-Infected Adults and Adolescents. Developed by the DHHS Panel on Antiretroviral Guidelines for Adults and Adolescents - A Working Group of the Office of AIDS Research Advisory Council. January 10, 2011.

72. Rilpivirine / Contraindicated Drugs

_____√_____

Alert Message: Co-administration of Edurant (rilpivirine) is contraindicated with drugs where significant decrease in rilpivirine plasma concentrations may occur due to CYP3A4 enzyme induction or gastric pH increase, which may result in loss of virologic response and possible resistance and cross-resistance.

Conflict Code: Drugs/Diseases

<u>Util A</u>	<u>Util B</u>	<u>Util C</u>
Rilpivirine	Carbamazepine Oxcarbazepine Phenobarbital Phenytoin Rifabutin Rifampin Rifapentine	Omeprazole Esomeprazole Lansoprazole Pantoprazole Rabeprazole Dexamethasone (> 1 day supply)

References:

Edurant Prescribing Information, May 2011, Tibotec Pharmaceuticals.
Micromedex 2.0 Healthcare Series, DrugDex Evaluations, Thomson Reuters, 2011.

73. Rilpivirine / NNRTIs

_____√_____

Alert Message: Edurant (rilpivirine) should not be used in combination with other NNRTIs. Concurrent use of rilpivirine with delavirdine may cause increases in rilpivirine plasma concentrations and use with the other NNRTIs, efavirenz, etravirine or nevirapine, may cause a decrease in rilpivirine plasma concentrations.

Conflict Code: DD – Drug/Drug Interactions

Drugs/Diseases

<u>Util A</u>	<u>Util B</u>	<u>Util C</u>
Rilpivirine	Delavirdine Efavirenz Etravirine Nevirapine	

References:

Edurant Prescribing Information, May 2011, Tibotec Pharmaceuticals.

74. Rilpivirine / Antacids

_____√_____

Alert Message: Caution should be exercised when Edurant (rilpivirine) is prescribed concomitantly with antacids (e.g., aluminium or magnesium hydroxide, calcium carbonate) as antacid increase gastric pH which may cause significant decreases in rilpivirine plasma concentrations. Rilpivirine requires an acidic environment for optimal absorption. Antacids should be administered either at least 2 hours before or at least 4 hours after rilpivirine.

Conflict Code: DD – Drug/Drug Interaction

Drugs/Diseases

<u>Util A</u>	<u>Util B</u>	<u>Util C</u>
Rilpivirine	Aluminum Hydroxide Magnesium Hydroxide Calcium Carbonate	

References:

Edurant Prescribing Information, May 2011, Tibotec Pharmaceuticals.

75. Rilpivirine / H2-Blockers

_____√_____

Alert Message: Concurrent use of Edurant (rilpivirine) and a H2-receptor antagonist may cause significant decreases in rilpivirine plasma concentrations due to H2-receptor antagonist-induced increased gastric pH. Rilpivirine requires an acidic environment for optimal absorption. All H2-receptor antagonists should be administered at least 12 hours before or at least 4 hours after rilpivirine.

Conflict Code: DD – Drug/Drug Interaction

Drugs/Diseases

<u>Util A</u>	<u>Util B</u>	<u>Util C</u>
Rilpivirine	Cimetidine Famotidine Nizatidine Ranitidine	

References:

Edurant Prescribing Information, May 2011, Tibotec Pharmaceuticals.

76. Rilpivirine / Certain Macrolides

_____√_____

Alert Message: Concurrent use of Edurant (rilpivirine) with clarithromycin, erythromycin or telithromycin may cause an increase in rilpivirine plasma concentrations due to inhibition by the macrolide of rilpivirine CYP3A4-mediated metabolism. When possible, alternatives such as azithromycin should be considered.

Conflict Code: DD – Drug/Drug Interaction

Drugs/Diseases

<u>Util A</u>	<u>Util B</u>	<u>Util C</u>
Rilpivirine	Erythromycin Clarithromycin Telithromycin	

References:

Edurant Prescribing Information, May 2011, Tibotec Pharmaceuticals.

77. Rilpivirine / Methadone

_____√_____

Alert Message: The concurrent use of Edurant (rilpivirine) and methadone may result in decreased methadone plasma concentrations. Methadone maintenance therapy may need to be adjusted in some patients.

Conflict Code: DD – Drug/Drug interactions

Drugs/Diseases

<u>Util A</u>	<u>Util B</u>	<u>Util C</u>
Rilpivirine	Methadone	

References:

Edurant Prescribing Information, May 2011, Tibotec Pharmaceuticals.

78. Rilpivirine / All other Antiretrovirals (Negating)

_____√_____

Alert Message: Monotherapy with an NNRTI is not recommended in HIV-1-infected patients. Drug resistant virus emerges rapidly when an NNRTI is administered as single agent therapy.

Conflict Code: TA - Therapeutic Appropriateness

Drugs/Diseases

<u>Util A</u>	<u>Util B</u>	<u>Util C (Negating)</u>
Rilpivirine		All other Antiretroviral Agents

References:

Edurant Prescribing Information, May 2011, Tibotec Pharmaceuticals.

Criteria Recommendations

Accepted Approved Rejected
As
Amended

79. Rilpivirine / Severe Renal Impairment & ESRD

_____√_____

Alert Message: Caution should be exercised when using Edurant (rilpivirine) in patients with severe renal impairment or end-stage renal disease. Rilpivirine plasma concentrations may be increased due to alteration in drug absorption, distribution and metabolism, secondary to renal function. Monitor patient for rilpivirine adverse effects.

Conflict Code: MC - Drug (Actual) Disease Precaution

Drugs/Diseases

<u>Util A</u>	<u>Util B</u>	<u>Util C (include)</u>
Rilpivirine		Stage 4 CKD Stage 5 CKD ESRD

References:

Edurant Prescribing Information, May 2011, Tibotec Pharmaceuticals.

80. Rilpivirine / Azole Antifungals

_____√_____

Alert Message: Concurrent use of Edurant (rilpivirine) and an azole antifungal may result in elevated rilpivirine plasma concentrations and/or decreased azole plasma concentrations. Monitor patients for rilpivirine adverse effects as well as breakthrough fungal infections.

Conflict Code: TA - Therapeutic Appropriateness

Drugs/Diseases

<u>Util A</u>	<u>Util B</u>	<u>Util C</u>
Rilpivirine	Ketoconazole Itraconazole Fluconazole Voriconazole Posaconazole	

References:

Edurant Prescribing Information, May 2011, Tibotec Pharmaceuticals.

Brown KC, Sunita P and Kashuba ADM. Drug Interactions with New and Investigational Antiretrovirals. 2009;48(4):211-241.

81. Rilpivirine / Depressive Disorders

_____√_____

Alert Message: Severe depressive disorders have been reported with Edurant (rilpivirine). Immediate medical evaluation is recommended if the patient reports severe depressive symptoms to assess the possibility that the symptoms are related to rilpivirine, and if so, to determine whether the risks of continued therapy outweigh the benefits.

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

Drugs/Diseases

<u>Util A</u>	<u>Util B</u>	<u>Util C</u>
Rilpivirine	Major Depressive Disorder Suicidal Ideation (V-code V62.84)	

References:

Edurant Prescribing Information, May 2011, Tibotec Pharmaceuticals.

Micromedex 2.0 Healthcare Series, DrugDex Evaluations, Thomson Reuters, 2011.

R. Bob Mullins, Jr.
R. Bob Mullins, Jr., M.D., Commissioner

Approve () Deny

9-15-11
Date

Kathy Hall
Kathy Hall, Deputy Commissioner

Approve () Deny

9/13/11
Date

RM
Robert Moon, M.D., Medical Director

Approve () Deny

9-15-11
Date