

Alabama Medicaid DUR Board Meeting Minutes  
January 23, 2008

**Members Present:** Kelli Littlejohn, Christina Faulkner, Tiffany Minnifield, Clemice Hurst, Robert Moon, Kevin Green, Rhonda Harden, Gurinder Doad, Bernie Olin, Jimmy Jackson, Daniel Mims, Kevin Royal, Paula Thompson, Denise Thornley-Brown

**Members Absent:** Rob Colburn, Michael Gosney

Chairman Paula Thompson called the meeting to order at 1 p.m.

**Review and Adoption of Minutes of October 24, 2007 meeting:** Paula Thompson asked if there were any additions, deletions or changes to the minutes of the October 24, 2007 meeting. It was suggested that at the July meeting the Erythropoietin Stimulating Agents (ESA) topic was tabled and should be reflected in the meeting minutes. Also, Gurinder Doad added that his place of practice is Section, AL rather than Montgomery, AL as reflected in the October minutes. Paula Thompson asked for a motion to approve the minutes with the two suggested changes. A motion was made by Daniel Mims, and seconded by Gurinder Doad. A voice vote to approve the minutes as corrected was unanimous.

**Prior Authorization and Overrides Update:** Christina Faulkner began the Prior Authorization and Overrides Update by calling members' attention to page 17 of the meeting manual, Monthly Manual Prior authorizations and Overrides for the month of November. She reported 6,887 total prior authorizations; 2,538 total overrides; and a grand total of 9,425. Christina reported a grand total of 12,849 requests for the Monthly Electronic Prior Authorizations and Overrides for the month of November. Christina then directed attention to the Response Time reports on page 20. She reported that 76.83% of manual prior authorizations and 76.28% of manual overrides were responded to in less than two hours. 90.23% of manual prior authorizations and 91.17% of manual overrides were responded to in less than four hours. 92.30% of manual prior authorizations and 93.03% of manual overrides were responded to in less than eight hours.

Christina continued the Prior Authorization and Overrides Update by directing the board members' attention to the Cost Management Analysis reports beginning on Page 21. On the Top 25 Drugs Based on Total Claims from 09/15/07-10/15/07, Christina stated that the top five drugs for the time period were hydrocodone with acetaminophen, amoxicillin, Singulair<sup>®</sup>, azithromycin and alprazolam. On the Top 25 Drugs Based on Total Claims Cost from 09/15/07-10/15/07, the top five drugs were Synagis<sup>®</sup>, Singulair<sup>®</sup>, Risperdal<sup>®</sup>, Seroquel<sup>®</sup> and Protonix<sup>®</sup>. On the Top 15 Therapeutic Classes by Total Cost of claims from 10/16/17-11/15/07 report, Christina noted the top five classes: antipsychotics (miscellaneous), anticonvulsants (miscellaneous), monoclonal antibodies, selective beta-2-adrenergic agonists and leukotriene modifiers.

In response to a request from the Board at a previous meeting, Christina provided information regarding the effects of the Alabama Prescription Drug Monitoring Program (PDMP) on the utilization of hydrocodone/acetaminophen in the Alabama Medicaid population. Christina provided data through September 2007. Physicians and pharmacists received access to the system in August 2007 and the board members determined that there was not enough data to draw a conclusion as to the effectiveness of the program.

Also, in response to a request from the Board, Christina presented information regarding the appropriate utilization of Singulair. The board members reviewed the number of patients with a diagnosis of asthma or allergic rhinitis and the number of patients without either diagnosis. Discussion followed as to whether or not this agent was being used appropriately, within its FDA approved indications. The committee discussed sending this issue to the P&T Committee, but determined that DUR letters should be sent first, to those physicians whose patients do not have an approved diagnosis on file. A recommendation was made to obtain comparison data from states close to Alabama. After the data is collected and reviewed by the DUR Board, a determination will be made if this issue needs to be presented to the Alabama Medicaid P&T Committee.

**Program Summary Review:** Christina Faulkner began the review of the program Summary on page 30 of the meeting manual by going over the 6 month assessment covering the time period April 1, 2007 through September 30, 2007. She reported a prescription claims cost of \$196,660,298.91; 3,340,474 prescriptions; 374,927 total recipients; 180,465 average recipients per month and an average paid per prescription of \$58.87. Christina began the Cost Management analysis on page 31 by reviewing the cost per claim over the last year. The committee members requested that two years of cost management data be presented at each meeting to provide more information. On page 34, the Drug analysis, she reported 62.01% generic and 11.74 % brand with no generic available.

In response to a request at the last DUR meeting, Christina presented a review of Multi-source drugs. Christina began by directing the members' attention to page 35 of the meeting manual. She first explained that the percentage is attained by data received from First DataBank (FDB). Drugs are classified with a Generic Indicator (GI) and a Generic Price Index (GPI). A GI of one indicates that a drug is multisource, or available from more than one manufacturer. A GI of two indicates that a product is single source, or available from only one manufacturer. A GPI of one indicates that the drug is priced as a generic, and a GPI of two indicates that the drug is priced as a brand. Therefore, a drug that has a GI=1 and GPI=2 would be included in the brand multisource percentage. Christina presented a table that listed drugs included in the brand multisource percentage for 2<sup>nd</sup> quarter 2007, which was presented at the October 2007 DUR Board meeting. The Board discussed these drugs and asked if a DAW edit would be possible. Kelli Littlejohn spoke briefly about what other states have in place as far as a DAW edit, which would require providers to request a prospective override when a brand name drug is dispensed where a generic alternative is available. The Agency is looking at pursuing this further

based on the information that has been brought to light through the DUR research as well as the Governor's budget.

**Intervention Activity Report/Cycle Cost Savings Report:** For the RDUR Intervention Letter Activity Report, Christina called the board members' attention to page 49 of the meeting manual. For the June – November 2007 cycle, where the focus was patients with asthma, she reported 749 profiles reviewed and 740 letters sent. As of the printing of the manual, 138 responses had been received. Of those responses received, eight physicians stated that they would reassess and modify drug therapy and 16 stated that the patient had an appointment to discuss therapy. 59 of 98 physicians reported that they found the RDUR letter "useful" or "extremely useful".

**RetroDUR Criteria:** Christina reviewed 22 sets of RDUR criteria which will be added to the base set. For criteria #11 (raltegravir/drugs that can cause myopathy and rhabdomyolysis), the recommendation was made to add daptomycin in the Util B column. Tiffany Minnifield asked board members to complete their ballots for the criteria.

**Medicaid Pharmacy Update:** Kelli Littlejohn began by notifying the Board that Dr. Ty Gibson, founder of Health Information Design (HID), very recently passed away, and wished the Board to keep the Gibson family and HID in their thoughts. Tiffany Minnifield reminded board members to turn in their criteria ballots. She then called their attention to member folders containing updated drug lists and recent Alerts. She informed the Board that on January 1, 2008 the five brand limit took effect and that all other limits remain in place. She stated that the tamper resistant requirement was delayed 6 months to be effective April 1, 2008. Tiffany reminded the Board that the new MMIS system will be implemented in February; she stated that EDS will be holding workshops around the state for providers and encouraged providers to visit our website for more information. Tiffany announced that Kevin Royal was elected vice-chair at the last meeting.

**P & T Update:** Clemice Hurst began the P & T Update by stating that most of the January 2008 changes were drugs with generics now available, and reviewed the changes that are listed on our website. She stated that the next classes to be reviewed are available on the website. She announced the next P & T meeting is scheduled for February 20 at 9 a.m.

**Next Meeting Date:** After discussion and agreement among members, Tiffany Minnifield announced that the next DUR Board meeting will be held on Wednesday, April 23, 2008 at 1:00 p.m.

Paula Thompson asked if there was any further business to be brought before the Board. There being none, she asked for a motion to adjourn. Rhonda Harden made a motion to adjourn. Denise Thornley-Brown offered a second to the motion. Chairman Thompson adjourned the meeting at 2:15 p.m.

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

*Recommendations*

*Approved    Approved    Rejected  
                  As  
                  Amended*

**1. Fentora / Therapeutic Appropriateness**

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Alert Message: Fentora (buccal fentanyl) is only approved for the treatment of breakthrough pain in patients with cancer who are already receiving and are tolerant to opioid therapy. Buccal fentanyl must not be used in opioid non-tolerant patients. The improper selection of patients, incorrect dosing, and/or improper product substitution may result in a fatal overdose with this agent.

Conflict Code: TA - Therapeutic Appropriateness

Drugs/Disease

<u>Util A</u> Fentora	<u>Util B</u>	<u>Util C (Negating)</u> Cancer ICD-9s Antineoplastic Agents
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References:

Fentora Prescribing Information, April 2007, Cephalon, Inc.

FDA News: FDA Warns of Potential Serious Side Effects with Breakthrough Cancer Pain Drug. September 26, 2007.

**2. Fentora / Therapeutic Appropriateness**

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Alert Message: Fentora (buccal fentanyl) is only approved for the treatment of breakthrough pain in patients with cancer who are already receiving and are tolerant to opioid therapy. Buccal fentanyl must not be used in opioid non-tolerant patients. The improper selection of patients, incorrect dosing, and/or improper product substitution may result in a fatal overdose with this agent.

Conflict Code: TA - Therapeutic Appropriateness

Drugs/Disease

<u>Util A</u> Fentora	<u>Util B</u>	<u>Util C (Negating)</u> Meperidine Morphine Fentanyl Transdermal Fentanyl Lozenges Hydrocodone Hydromorphone	 Levorphanol Methadone Oxycodone Oxymorphone Propoxyphene Codeine
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References:

Fentora Prescribing Information, April 2007, Cephalon, Inc.

Facts & Comparisons, 2007 Updates.

**Recommendations**

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

**3. Quetiapine / Substance Abuse**

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Alert Message: Seroquel (quetiapine) should be prescribed with caution to patients with a history of substance abuse. The agent has sedative and anxiolytic properties and may be misused by some patients. Closely observe patients for signs of misuse or abuse (e.g., development of tolerance, increases in dose, drug-seeking behavior). Inappropriate use of quetiapine may put patients at risk for arrhythmias, hypotension, weight gain, and diabetes.

Conflict Code: TA - Therapeutic Appropriateness

Drugs/Disease

Util A

Util B

Util C

Quetiapine

Substance Abuse

References:

Seroquel Prescribing Information, July 2007, AstraZeneca. Pharmaceuticals LP.

Pharmacist’s Letter, Seroquel (Quetiapine) Abuse, October 2007 #ISSN #0883-0371.

Pierre JM, Shnyder I, Wirshing DA, et al., Intranasal Quetiapine Abuse, Am J Psychiatry Sept 2004, 161(9):1718.

Reeves RR, Brister JC. Additional Evidence of the Abuse of Potential of Quetiapine, South Med J 2007;100(8):834-6.

**4. Haloperidol / Therapeutic Appropriateness**

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Alert Message: Higher doses and intravenous administration of haloperidol appear to be associated with an increased risk of QT prolongation, torsades de pointes, and even sudden death. Particular caution is advised when prescribing haloperidol to patients with predisposing factors (e.g., cardiac abnormalities, hypothyroidism, and electrolyte imbalance) that could cause an even greater risk of these serious adverse effects.

Conflict Code: TA – Therapeutic Appropriateness

Drugs/Disease

Util A

Util B

Util C (Negating)

Haloperidol

Criterion will hit on patients receiving higher doses (8mg/day or above).

References:

MedWatch: The FDA Safety Information and Adverse Event Reporting Program, 2007.

**5. Haloperidol / Over-utilization**

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Alert Message: Haloperidol may be over-utilized. The recommended maximum dose is 100 mg per day. Exceeding this dose may enhance the risk of adverse effects (e.g., QT prolongation, torsades de pointes, extrapyramidal symptoms, seizures, and hypertension).

Conflict Code: HD – High Dose

Drugs/Disease

Util A

Util B

Util C (Negating)

Haloperidol

Max Dose: 100 mg/day

References:

Facts & Comparisons, 2007 Updates.

Clinical Pharmacology, Gold Standard, 2007.

MedWatch: The FDA Safety Information and Adverse Event Reporting Program, 2007.

**Recommendations**

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

**6. Pregabalin / High Dose (Fibromyalgia)**

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Alert Message: Lyrica (pregabalin) may be over-utilized. The manufacturer's recommended dose for patients with fibromyalgia is 450 mg per day. Higher doses have not been shown to confer significant additional benefit and are less well tolerated.

Conflict Code: HD – High Dose

Drugs/Disease:

<u>Util A</u>	<u>Util B</u>	<u>Util C (Inclusive)</u>
Pregabalin		Fibromyalgia

Max Dose: 450 mg/day

References:

Lyrica Prescribing Information, June 2007, Pfizer Inc.

**7. Raltegravir / Therapeutic Appropriateness**

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Alert Message: Monotherapy with Isentress (raltegravir) is not recommended. Raltegravir is approved for use in combination with other antiretroviral agents for the treatment of HIV-1 infection in treatment experienced adult patients who have evidence of replication and HIV-1 strains resistant to multiple antiretroviral agents. The safety and efficacy of raltegravir have not been established in treatment-naïve patients.

Conflict Code: TA – Therapeutic Appropriateness

Drugs/Disease:

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

References:

Isentress Prescribing Information, Oct. 2007, Merck & Co., Inc.

**8. Raltegravir / High Dose**

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Alert Message: Isentress (raltegravir) may be over-utilized. The manufacturer's maximum recommended daily dose of raltegravir is 800 mg (400 mg twice a day).

Conflict Code: HD – High Dose

Drugs/Disease:

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

Max Dose: 800 mg/day

References:

Isentress Prescribing Information, Oct. 2007, Merck & Co., Inc.

**9. Raltegravir / Therapeutic Appropriateness**

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Alert Message: The safety and efficacy of Isentress (raltegravir) have not been established in patients less than 16 years of age.

Conflict Code: TA – Therapeutic Appropriateness

Drugs/Disease:

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

Age Range: 0 – 16 years of age

References:

Isentress Prescribing Information, Oct. 2007, Merck & Co., Inc.

**Recommendations**

*Approved Approved Rejected*  
*As*  
*Amended*

**10. Raltegravir / Rifampin**

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**Bolded words added**

Alert Message: Caution should be exercised when co-administering Isentress (raltegravir) with rifampin or other potent UGT1A1 inducers. ~~Raltegravir~~ **Concurrent administration** may result in decreased raltegravir plasma concentrations and diminished antiviral effect.

Conflict Code: DD – Drug/Drug Interaction

Drugs/Disease

Util A                      Util B                      Util C  
Raltegravir                      Rifampin

References:

Isentress Prescribing Information, Oct. 2007, Merck & Co., Inc.

**11. Raltegravir / Drugs that can cause Myopathy & Rhabdomyolysis**

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**Daptomycin (IV) added to Util B**

Alert Message: Elevated creatine kinase levels (Grade 2 – 4), myopathy, and rhabdomyolysis have been reported in subjects receiving raltegravir. Use caution when co-administering raltegravir with agents known to cause these conditions.

Conflict Code: DD – Drug/Drug Interaction

Drugs/Disease

Util A                      Util B                      Util C  
Raltegravir                      Statins  
  Ezetimibe  
  Fibric Acid Derivatives  
  Colchicine  
  Glucocorticoids  
  Zidovudine  
  Penicillamine  
  Chloroquine  
  Hydroxychloroquine  
  **Daptomycin (IV)**

References:

Isentress Prescribing Information, Oct. 2007, Merck & Co., Inc.

**12. Raltegravir / Nonadherence**

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Alert Message: A review of the patient's prescription refill history suggests that the patient may not be taking the drug in the manner it was prescribed. 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 – Under use/Nonadherence

Drugs/Disease:

Util A                      Util B                      Util C  
Raltegravir

References:

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>

**Recommendations**

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

**13. Immediate Release Stimulants / Drug Abuse / Negating Agents**

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Alert Message: The patient has a diagnosis of substance use disorder (SUD) and is receiving immediate-release stimulant medication. Treatment recommendations for patients with the dual diagnosis of ADHD and SUD suggest that ADHD be treated with non-stimulant agents, extended-release stimulants, or transdermal stimulant formulations to reduce the potential for misuse, abuse, and/or diversion.

Conflict Code: TA – Therapeutic Appropriateness

Drugs/Disease

<u>Util A</u>	<u>Util B</u>	<u>Util C (Negating)</u>
Methylphenidate IR	Drug Abuse	Extended-release Stimulants
Dexmethylphenidate IR		Non-stimulant ADHD Med
		Transdermal Stimulant

References:

Upadhyaya HP, Managing Attention-Deficit/Hyperactivity Disorder in the Presence of Substance Use Disorder. J Clin Psychiatry 2007;68[suppl 11]:23-30.  
 Mariani JJ, Levin FR, Treatment Strategies for Co-Occurring ADHD and Substance Use Disorders. Am J Addict. 2007, 16 suppl 1:45-54.  
 Wilens TE, Impact of AHDA and Its Treatment on Substance Abuse in Adults. J Clin Psychiatry 2004;65[supple 3]:28-45.

**14. Modafinil / Therapeutic Appropriateness**

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Alert Message: Provigil (modafinil) may cause serious skin reactions, including Stevens-Johnson syndrome and other serious hypersensitivity reactions. Instruct all patients to immediately discontinue modafinil if rash or any hypersensitivity reaction occurs.

Conflict Code: TA – Therapeutic Appropriateness

Drugs/Disease

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

References:

Med Watch: The FDA Safety Information and Adverse Event Reporting Program, 2007.

**15. Mycophenolate / Pregnancy / Delivery, Abortion & Miscarriage**

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Alert Message: The use of CellCept (mycophenolate) has been shown to increase the risk of first trimester pregnancy loss and congenital malformations. Female patients with childbearing potential must be informed of the potential risks and receive contraceptive counseling along with effective contraception. Mycophenolate is pregnancy category D.

Conflict Code: TA – Therapeutic Appropriateness

Drugs/Disease

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

References:

Med Watch: The FDA Safety Information and Adverse Event Reporting Program, 2007.

**Recommendations**

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

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**16. Atypical Antipsychotics / Metabolic Syndrome**

Alert Message: The use of second-generation antipsychotics (SGAs) has been associated with the development of serious health risks (e.g., cardiovascular disease, diabetes, dramatic weight gain, and atherogenic lipid profiles). All patients should receive baseline screenings for risk factors associated with metabolic syndrome before receiving a SGA and regular monitoring of metabolic parameters throughout therapy. If metabolic risk factors cannot be controlled consider switching, if clinically possible, to a SGA with a more favorable metabolic risk profile.

Conflict Code: MC – Drug (Actual) Disease Precaution

Drugs/Disease

Util A                      Util B                      Util C (Negating)

- Clozapine
- Olanzapine
- Risperidone
- Quetiapine

Age Range: > 18 years of age

References:

Lieberman JA, Stroup S., McEvoy JP, et al, Effectiveness of Antipsychotic Drugs in Patients with Chronic Schizophrenia (CATIE Trial). N Engl J Med 2005;353(12):1209-1223.

Third Report of the National Cholesterol Education Program (NCEP) Expert Panel on Detection, Evaluation and Treatment of High Blood Cholesterol in Adults (Adult Treatment Panel III) Executive Summary. National Institutes of Health. NIH Publications No. 02-5215, Sept. 2002.

Nasrallah HA, The Roles of Efficacy, Safety and Tolerability in Antipsychotic Effectiveness: Practical Implications of the CATIE Schizophrenia Trial. J Clin Psychiatry 2007;68[ suppl 1]:5-11.

Weiden PJ, Preskorn SH, Fahnstock PA, et al. Translating the Psychopharmacology of Antipsychotics to Individualized Treatment for Severe Mental Illness: A Roadmap, J Clin Psychiatry 2007;68[Suppl 7]:3-48.

**Criteria Recommendations**

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

**17. Atypical Antipsychotics / Pediatric Patients**

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Alert Message: The effects of prolonged use of atypical antipsychotics in pediatric patients are unknown. Preliminary evidence suggests that pediatric patients experience more prevalent and severe adverse effects than those reported in adults (e.g., weight gain, extrapyramidal side effects, and insulin resistance). If therapy with these agents is clinically necessary use the lowest effective dose and observe patients closely for adverse events. If adverse effects cannot be controlled consider switching, if clinically possible, to a SGA with a more favorable adverse effect profile.

Conflict Code: TA – Therapeutic Appropriateness

Drugs/Diseases:

Util A

Util B

Util C

Clozapine  
Risperidone  
Olanzapine  
Quetiapine  
Ziprasidone  
Aripiprazole  
Paliperidone

References:

Facts & Comparisons, 2007 Updates.

Age Range: < 19 years of age

References:

Kumra S, Oberstar JV, Sikich L et al., Efficacy and Tolerability of Second Generation Antipsychotics in Children and Adolescents with Schizophrenia. Schizophrenia Bulletin. 2008 Oct 8.

Cook S, Weitzman M, Auinger P, et al. Prevalence of a metabolic syndrome phenotype in adolescents: findings from the third National Health and Nutrition Examination Survey, 1988-1994. Arch Pediatr Adolesc Med 2003, 157:821-827.

Correll CU, Carlson HE, Endocrine and metabolic adverse effects of psychotropic medications in children and adolescents, J Am Acad Child Adolesc Psychiatry (2006)45:771-791.

Nasrallah HA, The Roles of Efficacy, Safety and Tolerability in Antipsychotic Effectiveness: Practical Implications of the CATIE Schizophrenia Trial. J Clin Psychiatry 2007;68[suppl 1]:5-11.

Weiden PJ, Preskorn SH, Fahnstock PA, et al. Translating the Psychopharmacology of Antipsychotics to Individualized Treatment for Severe Mental Illness: A Roadmap, J Clin Psychiatry 2007;68[Suppl 7]:3-48.

Cada DJ, Baker DE, Levien T, Formulary Drug Reviews: Paliperidone, Hospital Pharmacy, 2007;42(7):637-647.

**Criteria Recommendations**

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

**18. Buprenorphine / Opioids**

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Alert Message: The presence of the buprenorphine-containing products (Suboxone/ Subutex) suggests that the patient is in an opioid dependence treatment program. The drug history review revealed that the patient is still receiving opioid agonists. Concurrent use of buprenorphine and pure opioid agonists may have additive or antagonistic effects and can result in withdrawal symptoms. Reassess the patient's suitability for an office-based dependence treatment program.

Conflict Code: DD - Drug/Drug Interaction

Drugs/Disease

<u>Util A</u>	<u>Util B</u>	<u>Util C</u>
Subutex	Meperidine	Oxycodone
Suboxone	Morphine	Fentanyl
	Methadone	Propoxyphene
	Hydromorphone	Opium
	Oxymorphone	Hydrocodone
	Codeine	Levorphanol

References:

- Facts & Comparisons, 2007 Updates.
- Micromedex Healthcare Series, DrugDex Drug Evaluations, 2007.
- Clinical Pharmacology, Gold Standard 2007.
- AHFS Drug Information, 2007 Edition.

**19. Immediate Release Opioids / Long-Acting Opioids (Negating)**

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

Conflict Code: ER – Over utilization

Drugs/Disease

<u>Util A</u>	<u>Util B</u>	<u>Util C (Negating)</u>
Immediate Release Opioids		Long-Acting Opioids

References:

- Brookoff D, Hospital Practice: Chronic Pain: 2 The Case for Opioids. McGraw-Hill Companies, 2000.
- Brennan MJ, et al. Pharmacologic Management of Breakthrough or Incident Pain, Medscape Clinical Update, 2003.

**20. Modafinil / Therapeutic Appropriateness**

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Alert Message: Caution should be exercised when prescribing Provigil (modafinil) to

patients with a history of psychosis, depression, or mania. Psychiatric adverse experiences (anxiety, mania, hallucinations and suicidal ideation) have been reported in patients treated with modafinil. Monitor the patient closely for adverse effects if modafinil therapy cannot be avoided.

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

Drugs/Disease

<u>Util A</u>	<u>Util B</u>	<u>Util C</u>
Modafinil	Psychosis	
	Depression	
	Mania	
	Antidepressants	
	Antipsychotics	

References: Med Watch: The FDA Safety Information and Adverse Event Reporting Program, 2007.

**Criteria Recommendations**

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

**21. Rosiglitazone / Therapeutic Appropriateness**

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Alert Message: Rosiglitazone-containing products (Avandia/Avandamet/Avandaryl) may increase the risk of myocardial ischemia, especially in patients with underlying heart disease. Patients receiving nitrates and/or insulin concurrently with rosiglitazone are at an even higher risk of ischemic cardiovascular events. If rosiglitazone therapy is clinically necessary, monitor the patient closely for signs and symptoms of myocardial ischemia.

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

Drugs/Disease

<u>Util A</u>	<u>Util B</u>	<u>Util C</u>
Rosiglitazone	Myocardial Ischemia Myocardial Infarction Coronary Artery Disease Angina Arrhythmias Heart Failure	

References:

Med Watch: The FDA Safety Information and Adverse Event Reporting Program, 2007.

**22. Rosiglitazone / Insulin & Nitrates**

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Alert Message: Co-administration of rosiglitazone-containing products (Avandia/Avandamet/Avandaryl) and insulin or nitrates is not recommended. The concurrent use of either agent with rosiglitazone may increase the patient's risk for myocardial ischemia (e.g., angina and myocardial infarction).

Conflict Code: DD – Drug/Drug Interaction

Drugs/Disease

<u>Util A</u>	<u>Util B</u>	<u>Util C</u>
Rosiglitazone	Insulin Nitrates	

References:

Med Watch: The FDA Safety Information and Adverse Event Reporting Program, 2007.

The minutes of the January 23, 2007 DUR Board Meeting have been reviewed and approved as submitted.

Carol H. Steckel (X) Approve ( ) Deny 3-10-08  
Carol H. Steckel, Commissioner Date

Kathy Hall (X) Approve ( ) Deny 2/27/08  
Kathy Hall, Deputy Commissioner Date

R Moon M.D (X) Approve ( ) Deny 3-7-08  
Robert Moon, M.D., Medical Director Date