



## The Bulletin of Medicaid Drug Utilization Review in Iowa

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## Initial Treatment with Antidepressants

The American Psychiatric Association's 2010 Practice Guidelines for the Treatment of Patients with Major Depressive Disorder (Third Edition) recommends use of an antidepressant medication as an initial treatment choice for patients with a new diagnosis of mild to moderate major depressive disorder. For most patients, a selective serotonin reuptake inhibitor (SSRI), serotonin norepinephrine reuptake inhibitor (SNRI), mirtazapine, or bupropion is an optimal first choice. When patients treated with an antidepressant fail to respond adequately after a 6-8 week trial, optimizing the medication dose is a reasonable first step if the side effect burden is tolerable and the upper limit of a medication dose has not been reached. An additional strategy recommended for non-responders is augmentation of antidepressant medications with another antidepressant, generally from a different logical class, or a non-antidepressant medication such as lithium, thyroid hormone, or a second-generation antipsychotic.<sup>1</sup> Nowhere in the guidelines does it recommend polypharmacy as an initial treatment.

With the high rate of multiple antidepressant utilization within the Iowa Medicaid population, a query was conducted to examine whether or not members with a new diagnosis of major depression were initiated on polypharmacy. The DUR recently looked at members with a new diagnosis of major depression during a six month time frame (11/1/10 through 4/30/11) to find members initiated on therapy with two or more agents. Members who were flagged as being on duplicate antidepressant therapy but who had co-morbidities for which duplicate antidepressant therapy would be appropriate (i.e. insomnia, neuropathy, GAD, OCD, premenstrual dysphoria disorder, post traumatic stress disorder, and fibromyalgia) were removed. A total of 47 members were identified that had their therapy initiated with two antidepressants.

### References:

Gelenberg AJ, Freeman MP, Markowitz JC et al. Practice guidelines for the treatment of patients with major depressive disorder: third edition. American Psychiatric Association, 2010.

[http://www.psychiatryonline.com/pracGuide/pracGuideTopic\\_7.aspx](http://www.psychiatryonline.com/pracGuide/pracGuideTopic_7.aspx). Assessed July 15, 2011.

## Annual Call for New Commission Members

**Attention Physicians and Pharmacists:**  
**Are you looking for a new professional opportunity?**

CMS requires state Medicaid programs to have a drug utilization review (DUR) program consisting of prospective DUR, retrospective DUR, and an educational program. The goal of the DUR program is to ensure appropriate medication therapy, while permitting appropriate professional judgment to individualize medication therapy. In Iowa, the DUR Board is referred to as the Iowa Medicaid DUR Commission. The Iowa DUR Commission is composed of four Iowa licensed physicians and four Iowa licensed pharmacists who serve up to two, four-year terms, as well as a representative from the Department of Human Services. The Commission meets on the first Wednesday six months of the year from 9:30 a.m. to 1:30 p.m.

The DUR Commission is currently seeking a Physician and Pharmacist who serve Medicaid Members to join the committee. Any Physician or Pharmacist interested in serving in this capacity should send a resume or curriculum vitae, as well as a letter indicating their interest to Pam Smith at the address shown below. Candidates that would like more information about the Commission or who would like to speak to a present Commissioner are encouraged to call.

**The deadline for applications is March 30, 2012.**  
**Term begins July 1, 2012**

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## Potential Complications with Daily Aspirin Regimen

For patients with at least moderate risk for a coronary event (based on age and cardiac risk factor profile with a 10-year risk of a cardiac event of > 10%), a daily aspirin regimen is recommended.<sup>1</sup> Additionally, patients that have a past medical history of heart attack, arrhythmia, and/or stroke are also recommended to initiate a daily aspirin regimen unless contraindications are present.<sup>2,3</sup> Due to the high prevalence of cardiovascular disease, many Iowa Medicaid members are using a daily aspirin regimen. While aspirin has been proven to be very beneficial in preventing cardiovascular events, it can create issues with increased drug:drug interactions, and drug:disease state interactions. Recently, data have emerged that suggest that certain NSAIDs, specifically ibuprofen and naproxen, may decrease the cardioprotective effects of low-dose aspirin when administered concurrently.<sup>4,5,6</sup> Aspirin and NSAIDs are both cyclo-oxygenase inhibitors; aspirin is an irreversible inhibitor whereas other NSAIDs are reversible inhibitors. It is proposed that ibuprofen has a greater affinity than aspirin for the active sites on the cyclo-oxygenase enzyme and inhibition of cyclo-oxygenase would be limited in favor of the reversible inhibition. As a result, the cardio-protective benefits of aspirin are reduced.<sup>7</sup>

Additionally, the combination of daily aspirin with NSAIDs in patients with gastroesophageal reflux disease (GERD) or Peptic Ulcer Disease (PUD) without adequate GI protection with a proton pump inhibitor or histamine<sub>2</sub> blocker is also frequently observed.<sup>7</sup> The combination can lead to further GI problems including worsening GERD symptoms, ulcers, and/or GI bleeds.

Recently, the DUR looked at Iowa Medicaid Members to determine how many members have naproxen or ibuprofen added to their daily aspirin regimen. Pharmacy claims were reviewed over a three month time frame (2/1/11 through 4/30/11). A total of 67 unique members were identified as combining a daily aspirin regimen with ibuprofen or naproxen.

A second analysis of daily aspirin users focused on members who also had claims within the same 30 day time frame for any NSAID. The analysis showed a high percentage of these members who combined daily aspirin plus scheduled NSAIDs also had a diagnosis of GERD or PUD. Thirty-two (32) members were found to be combining a daily aspirin regimen with NSAIDs with twenty-one (21) members having a diagnosis of GERD/PUD. Six (6) of these members were not receiving treatment with a histamine<sub>2</sub> blocker or PPI.

Educational letters have been sent to the providers of the members identified in this study.

### References:

1. Becker RC, Meade TW, Berger PB, et al. The primary and secondary prevention of coronary artery disease. American College of Chest Physicians evidence-based clinical practice guidelines (8th edition). *Chest* 2008;133(6 Suppl):776S-814S.
2. Singer DE, Albers GW, Dalen JE, et al. Antithrombotic therapy in atrial fibrillation: American College of Chest Physicians Evidence-Based Clinical Practice Guidelines (8th Edition). *Chest* 2008;133(6 Suppl):546S-592S.
3. Adams RJ, Albers G, Alberts MJ, et al. American Heart Association, American Stroke Association. Update to the AHA/ASA recommendations for the prevention of stroke in patients with stroke and transient ischemic attack. *Stroke* 2008;39:1647-52.
4. MacDonald TM and Wei L, "Effect of Ibuprofen on Cardioprotective Effect of Aspirin," *Lancet*, 2003, 361(9357):573-4. [PubMed 12598144]
5. Catella-Lawson F, Reilly MP, Kapoor SC, et al, "Cyclooxygenase Inhibitors and the Antiplatelet Effects of Aspirin," *N Engl J Med*, 2001, 345(25):1809-17. [PubMed 11752357]
6. Capone ML, Sciulli MG, Tacconelli S, et al, "Pharmacodynamic Interaction of Naproxen with Low-Dose Aspirin in Healthy Subjects," *J Am Coll Cardiol*, 2005, 45(8):1295-301. [PubMed 15837265]
7. Drug Facts and Comparisons. Drug Facts and Comparisons 4.0 [online]. 2011. Available from Wolters Kluwer Health, Inc. Accessed July 2011.

## FDA Update

The FDA has notified health care providers that the black box warning and Warnings and Precautions sections of labeling for the entire class of tumor necrosis factor-alpha (TNF-alpha) blockers has been updated to include the risk of infection from two bacterial pathogens, Legionella and Listeria. TNF-alpha blockers are indicated for treatment of Crohns disease, ulcerative colitis, rheumatoid arthritis, ankylosing spondylitis, psoriatic arthritis, plaque psoriasis, and/or juvenile idiopathic arthritis. Patients treated with TNF-alpha blockers are at an increased risk for developing serious infections due to bacterial, mycobacterial, fungal, viral, parasitic, and other opportunistic pathogens. Any adverse events that may be related to the use of this product should be reported to the FDA's MedWatch Adverse Event Reporting program.

## New and Updated Drug Prior Authorization Criteria (changes italicized)

### Extended Release Oxycodone (OxyContin®)

Extended release oxycodone/OxyContin® is non-preferred except for patients being treated for cancer related pain. Prior authorization at any dose twice daily for cancer related pain will be approved. For all other diagnoses, *payment will be considered under the following conditions:*

- 1. There is documentation of previous trials and therapy failures with two (2) chemically distinct preferred long-acting narcotics (such as an extended-release morphine sulfate and methadone) at therapeutic doses, and*
- 2. A trial and therapy failure with fentanyl patch at maximum tolerated dose, and*
- 3. A signed chronic opioid therapy management plan between the prescriber and patient must be included with the prior authorization, and*
- 4. The prescriber must review the patient's use of controlled substances on the Iowa Prescription Monitoring Program website at <https://pmp.iowa.gov/IAPMPWebCenter/> prior to requesting prior authorization.*
- 5. Requests will only be considered for 12 hour dosing.*

*The required trials may be overridden when documented evidence is provided that use of these agents would be medically contraindicated.*

### Hepatitis C Protease Inhibitors

Prior authorization is required for all oral hepatitis C protease inhibitors. Payment will be considered under the following conditions:

1. A diagnosis of hepatitis C genotype 1, and
2. Patient is 18 years of age or older, and
3. Administered in combination with peginterferon alfa and ribavirin.
4. HCV-RNA results are required at treatment week 4 for telaprevir (Incivek™). Additional prior authorization will be considered with documentation of response to treatment, measured by HCV-RNA levels. A maximum 12 weeks of therapy will be allowed for telaprevir (Incivek™).
5. HCV-RNA results are required at treatment week 8, 12, and 24 (including lead in period) for boceprevir (Victrelis™) and patient must not be a prior null responder to standard treatment. Additional prior authorizations will be considered with documentation of response to treatment, measured by HCV-RNA levels. Prior authorizations will be approved for a maximum of 24, 32, or 40 weeks of therapy with boceprevir (Victrelis™) based on response.

**Medicaid Statistics for Prescription Claims  
from July 1, 2011 to September 30, 2011\***

Number of claims paid: 1,067,331

Average amount paid per claim: \$60.27

Total dollars paid: \$64,316,343.34

Average amount paid per claim, brand: \$212.79

Percent controlled substances: 18.42%

Average Amount paid per claim, generic: \$11.56

<b>Top Drugs by Number of Prescriptions</b>	<b>Top Drugs by Dollars Spent</b>	<b>Top Therapeutic Class by Dollars Spent</b>
Hydrocodone/APAP 5-500 \$4.79/RX	<i>Concerta</i> 36mg \$1,341,125 \$247.49/RX	Antipsychotics – Atypicals \$12.3 million
Loratadine 10mg \$8.47/RX	<i>Abilify</i> 5mg \$1,269,086 \$477.30/RX	Stimulants – Amphetamines – Long Acting \$4.4 million
<i>ProAir HFA</i> \$46.24/RX	<i>Abilify</i> 10mg \$1,008,891 \$479.95/RX	Stimulants – Methylphenidate- Long Acting \$3.4 million
Lorazepam 0.5mg \$5.30/RX	Singulair 10mg \$992,662 \$153.41/RX	Antidepressants – Selected SSRIs \$3.2 million
Tramadol HCl 50mg \$5.43/RX	<i>Lexapro</i> 20mg \$942,702 \$105.73/RX	Anticonvulsants \$3.2 million

\*All dollars reported are Pre-Rebate