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DUR DIGEST

# *The Bulletin of Medicaid Drug Utilization Review in Iowa*



## Commission Welcomes New Member

Brett Faine, Pharm.D.

Dr. Faine is a Clinical Pharmacy Specialist in Emergency Medicine at the University of Iowa Hospital. He serves as a preceptor to residents and Pharm.D. students in the Emergency Treatment Center. Dr. Faine received his Pharm.D. degree from the University of Iowa and completed an ASHP-accredited PGY1 Pharmacy Residency at the University of Iowa Hospitals and Clinics. Dr. Faine was appointed to the DUR Commission in 2010; his first term will expire in June 2014.

## Annual Call for New Commission Member

Attention Physicians: 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 Prescriber who serves Medicaid Members to join the committee. Any Physician 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 April 1, 2011.**

Pam Smith, R.Ph.
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# Prevention and Management of Diabetes Complications - Dyslipidemia

The Standards of Medical Care in Diabetes are revised annually by the American Diabetes Association (ADA) to incorporate new evidence into the standards of care. The recommendations provided by the ADA include screening, diagnostic, and therapeutic actions that are known or believed to positively affect health outcomes in patients with diabetes.

Cardiovascular disease (CVD) is the major cause of morbidity and mortality for patients with diabetes. Controlling cardiovascular risk factors is important in patients with diabetes in preventing or slowing CVD. Hypertension/blood pressure control, dyslipidemia/lipid management, antiplatelet agents, smoking cessation, and coronary heart disease screening and treatment are addressed in the position statement. It is well established that patients with type 2 diabetes have an increased prevalence of lipid abnormalities. Clinical trials have demonstrated significant effects of pharmacologic therapy (primarily statins) on CVD on outcomes in patients with CHD and for primary prevention of CVD. Recently, the DUR looked specifically at patients with a new diagnosis for diabetes that had at least one diagnosis code for CVD in their medical claims history that never filled a statin within the Iowa Medicaid population. The inquiry found 2,773 members that did not have a claim for a statin.

The 2010 ADA position statement recommends measuring fasting lipids at least annually in most diabetics. In patients with low-risk lipid values (LDL < 100mg/dl, HDL > 50mg/dl, TG < 150mg/dl), lipid assessments can be done every 2 years. Life style modifications, weight loss, and increased physical activity are recommended to improve lipid profiles in patients with diabetes. Regardless of baseline lipid levels, statin therapy should be added to lifestyle therapy for diabetic patients with overt CVD or those without overt CVD who are over the age of 40 and have one or more other CVD risk factors. For those patients without overt CVD and under the age of 40, statin therapy should be considered in addition to lifestyle modifications if LDL remains > 100mg/dl or in those with multiple CVD risk factors. The primary goal for LDL is < 100mg/dl in patients without overt CVD and < 70mg/dl in those with overt CVD. While LDL cholesterol targeted statin therapy is the preferred strategy, TG levels < 150mg/dl and HDL > 40mg/dl in men and > 50mg/dl in women are recommended. Combination therapy with a statin and another lipid-lowering agent (niacin, fenofibrate, ezetimibe, or bile acid sequestrants can also assist in lowering LDL) can be considered to reach lipid targets if they are not reached on maximally tolerated doses of statins.

Recommendations for Glycemic, Blood Pressure, and Lipid Control in Adults with Diabetes

| | |
|---|---|
| A1C | < 7.0% |
| Blood Pressure | < 130/80 mmHg |
| LDL Cholesterol | < 100mg/dl without overt CVD<br><br>< 70mg/dl with overt CVD |

**References:**

American Diabetes Association. Standards of medical care in diabetes – 2010 [guideline on the Internet]. Diabetes care. 2010. 2010 Jan [cited 2010 June 15]; 33 suppl 1:S11-61. Available from: http://care.diabetesjournals.org/content/33/Supplement_1/S11.full.pdf+html

# FDA Updates, Clonidine Poisoning, Chronic Pain Syndromes PA

## FDA Update

- In 2008, the FDA required a warning label for anticonvulsants regarding the increased risk of suicidal thoughts and behaviors. A recent exploratory study published in *The Journal of the American Medical Association* reported certain anticonvulsant medications are associated with increased risks of suicide, attempted suicide, and violent deaths. The study found 26 completed suicides, 801 attempted suicides, and 41 violent deaths in 297,620 new episodes of anticonvulsant treatment in adults. The findings suggest that the use of gabapentin, lamotrigine, oxcarbazepine, and tiagabine, compared with the use of topiramate, may be associated with an increased risk of suicidal acts or violent deaths. Further studies are needed to clarify the relationship between anticonvulsant medication use and suicide risk.

- The FDA has approved revised labeling requirements for long-acting beta-agonists (LABAs). In February 2010, the FDA announced it was requiring changes to the labels of LABAs due to an increased risk of severe exacerbation of asthma symptoms possibly leading to hospitalization or death in pediatric and adult patients. The new recommendations only apply to the treatment of asthma, and do not apply to the use of LABAs in COPD. The updated labels state the use of a LABA alone without use of a long-term asthma control medication, such as an inhaled corticosteroid, is contraindicated in the treatment of asthma. They should only be used in patients whose asthma is adequately controlled on low or medium dose inhaled corticosteroids and should only be used as additional therapy for patients with asthma who are currently taking but are not adequately controlled on a long-term asthma control medication. Once asthma control is achieved and maintained, patients should be assessed at regular intervals and step down therapy should begin with the intention of discontinuing the LABA, if possible, without the loss of asthma control. Patients should continue to be treated with a long-term asthma control medication. Pediatric and adolescent patients who require the addition of a LABA to an inhaled corticosteroid should use a combination product containing both an inhaled corticosteroid and a LABA, to ensure adherence with both medications.

- The FDA is conducting a review of primary results from 2 long-term clinical trials, ROADMP and ORIENT, to determine if type 2 diabetics taking *Benicar* (olmesartan) have a higher rate of death due to cardiovascular causes compared with those taking placebo. Patients in these trials were given *Benicar* or placebo to determine if the medication would decrease kidney disease progression. It was observed that a greater number of deaths from a cardiovascular cause (heart attack, sudden death, or stroke) occurred in the *Benicar*-treated patient group. The FDA believes that the benefits of *Benicar* in the treatment of hypertension outweigh its potential risks until further information is available.

- A new drug warning has been issued by Ortho-McNeil-Janssen and the FDA notifying health care professionals of changes to the Warnings section of the prescribing information for *Ultracet* (tramadol/acetaminophen) and *Ultram* (tramadol). The new information highlights the risk of suicide for patients who are addiction prone or taking tranquilizers or antidepressant drugs, as well as the risk of overdosage.

## Clonidine Poisoning

There has been an increase in cases of pediatric clonidine poisoning, which mimics opioid poisoning. Toxicity cases present with myosis, hypotension, bradycardia, and respiratory and central nervous system depression. Naloxone is used in the treatment of clonidine poisoning, but in larger doses than those used in adult heroin addicts. Supportive care is also provided, consisting of intubation, along with volume therapy and pressors to support blood pressure. Recovery time varies, but children who have taken clonidine pills usually improve in about 24 hours and it may take a few days if a child ingests a clonidine extended-release patch.

## Chronic Pain Syndromes PA (*Savella, Lyrica, Cymbalta*)

The PA form for *Lyrica* has been changed. It is now named Chronic Pain Syndromes and the medications *Cymbalta* and *Savella* have been added to the PA form. The new PA form is two pages long, the first two page PA form for Iowa Medicaid. This combined PA form accounts for all FDA approved diagnoses for the three medications. Diagnoses listed on the PA form include fibromyalgia, post-herpetic neuralgia, diabetic peripheral neuropathy, partial onset seizures, and major depressive disorder or generalized anxiety disorder. Refer to the PA form at iowamedicaidpdl.com for the required trials for each indication. The PA unit will consider other conditions as listed in the compendia on an individual basis for the aforementioned medications after reviewing documentation submitted regarding the medical necessity.

## Medicaid Statistics for Prescription Claims

## from April 1, 2010 to June 30, 2010

Number of claims paid: 1,061,660

Total dollars paid: $61,625,689

Percent controlled substances: 18.96%

Average amount paid per claim: $58.05

Average amount paid per claim, brand: $199.16

Average Amount paid per claim, generic: $11.60

| Top Drugs by Number of Prescriptions | Top Drugs by Dollars Spent (Pre-Rebate) | Top Therapeutic Class by Dollars Spent (Pre-Rebate) |
|---|---|---|
| *ProAir HFA*<br>$44.86/RX | Concerta 36mg<br>$1,024,243<br>$203.42/RX | Antipsychotics – Atypicals<br>$10.9 million |
| Hydrocodone/APAP 5-500<br>$4.66/RX | *Abilify* 5mg<br>$984,861<br>$413.63/RX | Stimulants – Amphetamines – Long Acting<br>$4.2 million |
| *Lexapro* 20mg<br>$89.61/RX | *Adderall* XR 20mg<br>$930,740<br>$255.26/RX | Anticonvulsants<br>$3.6 million |
| Loratadine 10mg<br>$7.32/RX | *Abilify 10mg*<br>$877,459<br>$416.05/RX | Antidepressants – Selected SSRI's<br>$3.4 million |
| Tramadol 50mg<br>$5.52/RX | *Lexapro* 20mg<br>$858,822<br>$89.61/RX | Stimulants – Methylphenidate-Long Acting<br>$2.8 million |