



Kansas Medical Assistance Program Drug Utilization Review Bulletin



National Provider Identifier

A state law enacted in 2006, K.S.A. 2006 Supp. 39-7,121f(c), requires all pharmacy claims submitted to Medicaid starting May 23, 2007, to contain the prescriber's unique identification number. The Kansas Medical Assistance Program (KMAP) has determined the unique identifying number will be the prescriber's National Provider Identifier (NPI).

KMAP will require all providers who prescribe for KMAP beneficiaries to obtain an individual NPI and share this with KMAP provider enrollment and dispensing pharmacies. KMAP has made prescribers' NPIs available on a secure portion of the KMAP Web site for pharmacies to access. Pharmacy claims must contain the prescriber's unique NPI for the claims to process correctly and ensure patients receive their medications. Pharmacies will not be allowed to use the provider's group NPI since this would not designate the required unique prescriber identification.

Thank you for servicing the beneficiaries of the Kansas Medical Assistance Program. Additional information regarding the KMAP implementation of NPI can be found on the following Web site, <https://www.kmap-state-ks.us/>, under the 'Publications' link.



Diabetes

Important Treatment Guidelines

Each year, the American Diabetes Association (ADA) recommends standards for medical care in diabetes. A new recommendation in 2007 is annual screening for serum creatinine, regardless of the degree of urine albumin excretion, to be used in estimating the glomerular filtration rate (GFR). Stage 3 or higher chronic kidney disease (GFR <60 ml/min per 1.73 m²) in the absence of increased urine albumin excretion occurs in a substantial percentage of adults with diabetes. Thus, screening for urine albumin excretion alone may miss chronic kidney disease cases. The ADA continues to recommend the following guidelines for your diabetic patients:

- **Hypertension:** Use of ACE inhibitors or ARBs in the absence of contraindications.
- **A1C Monitoring:** Twice yearly in controlled patients or quarterly in uncontrolled patients; with goal A1C <7% and <6% for individual high risk patients.
- **Hyperlipidemia:** Testing in adults annually, with goal LDL <100mg/dl (patients without overt CVD) or achieve a reduction in LDL of 34-40% (patients with overt CVD).
- **Antiplatelet Agents:** Aspirin is recommended in males and females >21 as secondary prevention, and as primary prevention in those with cardiovascular risk factors.
- **Nephropathy:** Annual screening for microalbuminuria and serum creatinine; treatment with an ACE inhibitor or ARB (barring any contraindications) in patients with any degree of albuminuria.
- **Retinopathy & Neuropathy:** Annual dilated eye exam and foot exam for all patients with diabetes.

Please consider these recommendations in caring for your diabetic patients.

Thiazolidinediones and Fracture Risk

In early 2007, the FDA, in coordination with the manufacturers of Actos (pioglitazone) and Avandia (rosiglitazone), announced that long-term studies had shown an increased incidence of fractures of the upper arm, hand, and distal lower limb (including the foot), in female patients taking these antidiabetic drugs, compared with other diabetes drugs or placebo. The sites of increased fracture are different from those commonly seen in postmenopausal women with osteoporosis (e.g. hip or spine). Labeling for both drugs recommends that fracture risk be considered, especially in female patients being treated with these drugs, and that special attention be given to assessing and maintaining bone health.

References:

- 1) American Diabetes Association. Standard of Medical Care in Diabetes – 2007. Diabetes Care 30 (Suppl 1):S4-S41, 2007. Available at <http://care.diabetesjournals.org>. [Accessed January 2007]
- 2) Rosiglitazone (Avandia) package labeling. GlaxoSmithKline. March 2007. Available at: http://us.gsk.com/products/assets/us_avandia.pdf. [Accessed March 2007]
- 3) Pioglitazone FDA warning: more bone fractures in women. March 12, 2007. Available at: www.natap.org. [Accessed March 2007]

Asthma

A Stepwise Approach to Management in Adults

Use of a stepwise approach in treating asthma can help patients reach their asthma goals. Adequately controlled asthma goals include: minimal or no chronic symptoms day or night, minimal or no exacerbations, no limitations on activities or missed work/school, maintenance of near normal pulmonary function, minimal use of short-acting inhaled beta2-agonists (SABAs), and minimal or no adverse events from medications. Use of SABAs >2 times a week in intermittent asthma (daily, or increasing use in persistent asthma) may indicate the need to initiate or increase long-term control therapy. Patients should be classified into a treatment

approach based on their most severe symptom feature. The following is a 4-step treatment approach from the National Asthma Education Program:

- STEP 1: **Mild intermittent:** no daily medication needed, oral steroids for exacerbations.
- STEP 2: **Mild persistent:** inhaled steroids are preferred with the following alternatives: cromolyn, leukotriene modifiers, nedocromil, or theophylline.
- STEP 3: **Moderate persistent:** medium dose inhaled steroids or low-medium dose inhaled steroids plus a long-acting inhaled beta2-agonist.
- STEP 4: **Severe persistent:** high dose inhaled steroids plus a long-acting beta2-agonist, and consideration for the addition of long-term oral steroids.

Use of Long-Acting Beta-2 Agonists

Providers should be aware of recent guidance from the FDA on use of long-acting beta-2 agonists (LABAs) [Advair, Foradil, Serevent] for asthmatics. Specific recommendations include:

- LABAs should not be the first medicine used to treat asthma. These drugs should only be added to an asthma treatment plan if other drugs do not control asthma, including use of low-or-medium dose corticosteroids.
- Patients should not stop using a LABA medicine unless clearly instructed by their provider.
- Patients should not use a LABA to treat wheezing that is getting worse. Patients should notify their provider if wheezing worsens while using a LABA.
- LABAs do not relieve sudden wheezing. Patients should have a short acting bronchodilator for this purpose.

Reference: National Asthma Education Program, Expert Panel Report Guidelines for the Diagnosis and Management of Asthma – Update on Selected Topics 2002. Bethesda, MD: National Institutes of Health, National Heart, Lung and Blood Institute, publication no. 02-5074; June 2002. FDA Public Health Advisory. May 2006. Available at: <http://www.fda.gov/cder/drug/advisory/LABA.htm>. [Accessed April 2007]

FDA Warnings - Recently Considered By the Kansas Medical Assistance Program DUR Board

1. FDA Warns of Promethazine Use in Children < Age 2

The Food and Drug Administration (FDA) has issued a warning reminding health care providers that all promethazine containing products, in any dosage form, are contraindicated in children under age two. The notice also warns of the use of these products in older children and adolescents. According to a letter published in June of 2006 in the New England Journal of Medicine, there have been reports of adverse events in 125 pediatric patient's age 16 years or less who had received promethazine. Reported adverse events included respiratory depression, which was blamed for seven deaths in patients under age two years, apnea, cardiac arrest, seizures, other neurologic disorders, and skin reactions. Labeling for all promethazine containing products has been revised to include the contraindication and warnings about pediatric use. Other treatments should be used in place of promethazine in the pediatric population.

Reference: Promethazine (marketed as Phenergan) Information. A Food and Drug Administration Alert, April 2006. Available at: www.fda.gov/cder/drug/infopage/promethazine/default.htm

2. FDA Warns of Serious Adverse Events in Patients Receiving Methadone

The Food and Drug Administration (FDA) has issued a Public Health Advisory informing health care providers of potential life-threatening side effects, including cardiac arrhythmias and respiratory depression, in patients taking methadone. These events may not be noticed by the patient and fatalities have been reported. Most problems have occurred in patients newly starting methadone for pain control. They have been reported in patients new to narcotics as well as those who have switched to methadone after being treated for pain with other narcotic pain relievers. The adverse effects may be the result of unintentional overdoses related to methadone having an elimination half-life (8-59 hours) that is longer than its duration of analgesic action (4-8 hours), or due to incomplete cross-tolerance between methadone and other opioids. During treatment initiation, methadone's full analgesic effect is not usually attained until after 3 to 5 days of administration. Initiation and dose titration should be done cautiously and in consideration of these properties. Following chronic use, methadone may be retained in the liver and then

slowly released, prolonging the duration of action. Pharmacokinetic and pharmacodynamic drug interactions, as discussed in the prescribing information, are also possible. Methadone is an effective analgesic and may provide pain relief when other analgesics are ineffective. However, it can also cause significant toxicities. Its' prescribing information has recently been updated by the FDA, and providers who prescribe it should be familiar with these changes. Patients who receive methadone should be closely monitored, especially during treatment initiation and dose adjustments, and prescribing of the 40 mg dispersible tablets should be avoided for pain management. That product is only FDA-approved for detoxification and maintenance treatment of narcotic addiction.

Reference: Methadone Hydrochloride (marketed as Dolophine) Information. A Food and Drug Administration Alert, November 2006. Available at: <http://www.fda.gov/cder/drug/infopage/methadone/default.htm> [last accessed 4/12/07]

3. FDA Warns of Serious Adverse Events Following Venlafaxine Overdose

The Food and Drug Administration (FDA) has issued a MedWatch Safety Alert informing health care providers of dangers associated with venlafaxine overdosage, especially in combination with alcohol and/or other drugs. Overdose with venlafaxine may be associated with an increased risk of fatal outcome compared to selective serotonin reuptake inhibitor (SSRI) antidepressant products, but lower than that for tricyclic antidepressants (TCAs). The manufacturer of Effexor products, Wyeth, in a Dear Health Care Provider letter indicates that cardiac conduction effects, liver necrosis, rhabdomyolysis, and death have been reported. Wyeth also indicated that epidemiological studies have shown venlafaxine-treated patients have a higher pre-existing burden of suicide risk factors than SSRI-treated patients and this may contribute to the apparent increased toxicity. Both the manufacturer and the FDA recommend that prescriptions for venlafaxine products be written for the smallest quantity of capsules consistent with good patient management, in order to reduce the risk of overdose.

Reference: Effexor XR (venlafaxine HCL) Extended-Release Capsules and Effexor (venlafaxine HCL) Tablets, MedWatch Safety Alert. Wyeth Dear Health Care Provider Letter, October 2006. Available at: <http://www.fda.gov/medwatch/safety/2006/safety06.htm#Effexor> [last accessed 4/17/07]

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DUR Website:

[http://www.khpa.ks.gov/MedicalAssistanceProgram/PharmacyInformation/
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