Alabama Medicaid Pharmacist

Published Quarterly by Health Information Designs, Inc., Spring 2010 — A Service of Alabama Medicaid

PDL Update

Effective April 1, 2010, the Alabama Medicaid Agency updated the Preferred Drug List (PDL) to reflect the recent Pharmacy and Therapeutics (P&T) Committee recommendations as well as quarterly updates. The updates are listed below:

PDL Additions	PDL Deletions
Daytrana–ADD/ADHD-Long Acting	**Amerge**–Antimigraine Agent
	Mycostatin-Anti-infective Agent/ Antifungal
	Relpax-Antimigraine Agent

**denotes that these brands will no longer be preferred but are still covered by Alabama Medicaid and will require Prior Authorization (PA). Available covered generic equivalents (unless otherwise specified) will remain preferred.*

Also effective April 1, 2010:

All **Brand** Benzodiazepines, **with the exception of Diastat**, will no longer be covered, even with prior authorization.

*Note: The Alabama Medicaid Pharmacist Newsletter will no longer be mailed, but will be available on the web.

Inside This Issue

PDL Update	Page 1
Smoking During Pregnancy	Page 2
Hypertension in Children and Adolescents	Page 3
NDCs for Physician Administered Drugs	Page 4
MedGuides	Page 5
Flu Vaccine Identification and Distribution	Page 6

Reminder

Please fax all prior authorization and override requests *directly* to Health Information Designs at 800-748-0116. If you have questions, please call 800-748-0130 to speak with a call center representative.

Health Information Designs (HID)
Medicaid Pharmacy Administrative Services
PO Box 3210
Auburn, AL 36832-3210
Fax 800-748-0116
Phone 800-748-0130

HID Help Desk

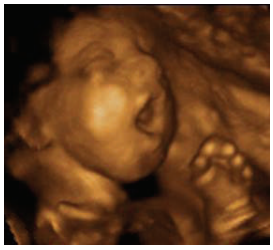
Monday–Friday

8am–7pm

Saturday

10am– 2pm

Smoking During Pregnancy? Know the Facts.



Smoking is the most common preventable cause of low birth-weight, pre-term delivery and infant morbidity and is a significant problem, especially in western countries with socially disadvantaged and low-income populations[2,3,4,5,6]. There are more than 4000 chemicals in a cigarette that could harm a baby during pregnancy; however nicotine and carbon monoxide are two of the worst[1,2]. In Alabama, approximately 15% of women smoke during pregnancy, however among women receiving Medicaid benefits, there is a substantially higher percentage[3,6].

Effects of smoking on a baby:

- Nicotine narrows the blood vessels that supply oxygen and nutrients for normal growth and development of the fetus[2,5].
- Carbon monoxide has a higher affinity for hemoglobin causing decreased oxygen in the blood cells further minimizing its delivery to the fetus[2].
- Smoking two-packs per day may decrease birth weight by up to 1 pound and may cause lifelong complications[2,6].
- Due to lack of growth and development in the womb, the baby can have underdeveloped lungs on delivery and may need to be on a respirator[2].
- Children whose mothers smoke during pregnancy have a higher incidence of asthma and may also triple the risk of sudden infant death syndrome[1,2].
- Smoking during pregnancy may also cause lifelong learning disorders, behavioral problems and relatively lower IQs[1,2].

The best way to prevent these complications is to quit smoking before conceiving. Data shows that women are more likely to quit smoking during pregnancy than they would be otherwise[3]. Recent data shows that women who quit smoking during the first trimester raise the odds of delivering a healthy full-term full-sized baby[1,3].

Effective February 1, 2010, the Alabama Medicaid Agency began covering smoking cessation products for pregnant women. Please see our website for additional information.

Works Cited:

1. Campion P, Owen L, McNeill A, McGuire C. "Evaluation of a mass media campaign on smoking and pregnancy." *Addiction* 89 (1994): 1245-54.
2. How smoking during pregnancy affects you and your baby. July 2009, Woolston C. http://www.babycenter.com/0_how-smoking-during-pregnancy-affects-you-and-your-baby_1405720.bc (Accessed January 27, 2010)
3. Frost FJ, Cawthorn ML, Tollestrup K, Kenny FW, Schrager LS,Nordlund DJ. "Smoking prevalence during pregnancy for women who are and women who are not Medicaid-funded." *American Journal of Preventive Medicine*, 1994: 91-6.
4. Lumley J, Oliver SS, Chamberlain C, Oakley L. "Interventions for promoting smoking cessation during pregnancy (Review)." *The Cochrane Collabration* (John Wiley & Sons, Ltd), no. 4 (October 2004): 1-73.
5. Quinn VP, Mullen PD, Ershoff DH. "Women who stop smoking spontaneously prior to prenatal care and predictors of relapse before delivery." *Addictive Behaviour*, 1991: 29-40.
6. Tong VT, Jones JR, Dietz PM, Angelo DD, Bombard JM. "Trends in Smoking Before, During, and After Pregnancy-Pregnancy Risk Assessment Monitoring System (PRAMS), United States, 31 Sites, 200-2005." *MMWR*, 2009: 1-31.

Hypertension in Children and Adolescents

Hypertension is not thought of as a disease of children and adolescents, but the incidence of obesity, type II diabetes, hypertension, and hyperlipidemia has increased in the pediatric and adolescent population. About five in every hundred children have higher than normal blood pressure, and fewer than one in a hundred has medically significant hypertension. The American Heart Association (AHA) recommends that all children age 3 and older have yearly blood pressure measurements. The American Academy of Pediatrics (AAP) recommends lipid screening in patients who have factors for heart disease including obesity, high blood pressure, or diabetes.

Signs and symptoms of hypertension include headache, dizziness, shortness of breath, visual disturbances, and fatigue. Because these symptoms are somewhat nonspecific, high blood pressure in children is often identified through routine screening. For children, hypertension is defined as an average systolic blood pressure (SBP) or diastolic blood pressure (DBP) that is greater than or equal to the 95th percentile for sex, age, and height on at least 3 separate occasions. Children and adolescents with blood pressure measurements of 120/80 mmHg or above, but less than the 95th percentile, should be considered prehypertensive.

It has been demonstrated that the prevalence of hypertension increases progressively with increasing body mass index (BMI), which leads to other heath concerns. Overweight children generally have some degree of insulin resistance, a prediabetic condition. These two factors are components of metabolic syndrome, which can lead to lipid abnormalities. In addition, children with hypertension should be tested for sleep disorders as there appears to be an association between the two.

Lifestyle modifications are usually the first treatment recommendation made for children. The following are suggestions that seem to be effective in helping to reduce blood pressure: weight reduction in obese or overweight individuals; increased intake of fresh vegetables, fruits, and lowfat dairy; and increased physical activity.

In children with secondary hypertension (caused by heart, kidney, or other diseases) or those with essential hypertension that have insufficient response lifestyle modifications, pharmacologic intervention may be indicated. When drug therapy is started, it should be initiated with a single drug. Acceptable drug classes for use in children include ACE inhibitors, ARBs, beta-blockers, calcium channel blockers, and diuretics. Initially, the child should be started on the lowest recommended dose. From there, the dose can be increased until the desired blood pressure goal is reached, or if the child has side effects, a second drug from a different class should be added.

Certain classes of antihypertensive drugs should be given to children with underlying medical conditions. For example, ACE inhibitors or ARBs would be of use in patients with diabetes or renal disease. Beta-blockers or calcium channel blockers would be of use in children with migraine headaches.

The blood pressure goal for children with uncomplicated primary hypertension is less than the 95th percentile for sex, age, and height. For patients with chronic renal disease, diabetes, or target-organ damage, the goal should be less than the 90th percentile for sex, age, and height.

In adults, treatment is usually long term. With children, the decision is more complex. No data is available regarding the long-term effects of antihypertensive drugs on growth and development, and also the long-term effects of untreated hypertension are unknown.

A definite indication for initiating drug therapy should be determined before any drug therapy is prescribed.

References:

1. The Fourth Report on the Diagnosis, Evaluation, and Treatment of High Blood Pressure in Children and Adolescents. U.S. Department of Health and Human Services. National Institutes of Health. National Heart, Lung, and Blood Institute. Revised May 2005.

2. High Blood Pressure in Children – American Heart Recommendation. www.americanheart.org. Accessed February 2010.

3. American Academy of Pediatrics Policy on Lipid Screening and Heart Health in Children. Policy Statement. July 2008. www.aap.org. Accessed February 2010.

4. Can Children Get High Blood Pressure? American Academy of Pediatrics. www.healthychildren.org. Accessed February 2010.

Mandatory National Drug Codes (NDCs) for All Physician Administered Drugs

In 2008, the Alabama Medicaid Agency began requiring the NDC number for the top 20+ physician-administered multiple source drugs.

Effective July 1, 2010, the NDC number will be mandatory on ALL physician –administered drugs in the following ranges: J0000 – J9999, S0000 – S9999, and Q0000 – Q9999. Physician-administered drugs include any covered outpatient drug billed either electronically or on paper CMS-1500 or UB-04 claim forms. The 11-digit NDC submitted must be the actual NDC number on the package or container from which the medicine was administered.

Effective July 1, 2010, the NDC number will be mandatory on all physician-administered drugs in the following ranges: J0000—J9999, S0000—S9999, and Q0000—Q9999.

Medicaid will provide a grace period from March 1, 2010 to June 30, 2010, to allow providers sufficient time to acclimate to the change. During this grace period, Medicaid will validate the data and will set an informational denial code, but will NOT deny the claim.

This requirement applies to:

- All fee-for-service providers
- HCPCS codes in the ranges J0000 – J9999, S0000 – S9999, and Q0000 – Q9999.
- Both electronic and paper submissions

This requirement does NOT apply to:

- 340-B Providers enrolled on the HHS website
- Providers paid on a per diem, encounter or other type of rate, which includes, but may not be limited to:

  Inpatient Hospitals

  Nursing Facilities

  Federally Qualified Health Centers

  Rural Health Centers

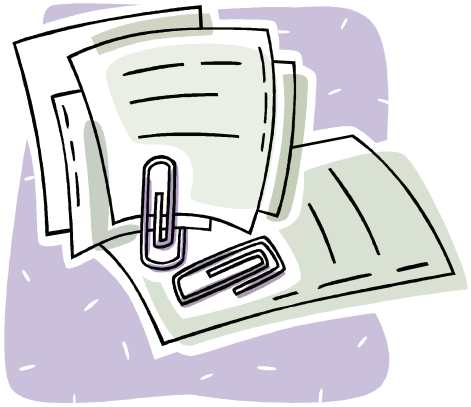
  Ambulatory Surgical Centers

  Home Health Agencies

- Vaccines or other drugs in the CPT code rage 01000 – 99999

As this process is to facilitate Medicaid drug rebates from manufacturers for physician-administered drugs, providers are encouraged to utilize drugs manufactured by companies who hold a federal rebate agreement. In the future, these NDCs will be the only ones Medicaid will cover for payment. A list of those drug manufacturers who hold a federal rebate agreement, as well as their labeler codes (the first 5 digits of the NDC number), are listed on the Medicaid website at http://www.medicaid.alabama.gov/programs/pharmacy_svcs/resources_providers.aspx?tab=4.

Providers are encouraged to begin providing the NDC for all physician-administered drugs immediately; however, it is not required until July 1, 2010. Refer to the Alabama Medicaid Provider Manual for billing instructions.



Common Questions About MedGuides

Medication guides ('MedGuides') are FDA-approved patient education handouts that are considered part of a drug's labeling. For certain drugs/drug classes, pharmacists are required to give them to patients.

Common Questions Regarding MedGuides:

Are MedGuides available in other languages?

There is no requirement to provide a MedGuide in a patient's native language. However, if a patient doesn't speak English and/or is not able to read the mechanism, consider using an alternate mechanism to communicate important content.

Is the MedGuide content for a brand drug and its generic the same? Can you use the MedGuide for a brand name when the generic is dispensed if a MedGuide for the generic is not readily available?

The content of a generic drug's MedGuide is the same as the brand drug's MedGuide. However, the FDA discourages substituting one manufacturer's MedGuide for another because it may cause confusion for the patient.

What is the difference between a MedGuide and a Patient Package Insert?

MedGuides are required for those drugs that pose the most serious and significant public heath concern. The FDA has determined that this information is necessary for the patient to have if they are to use the drug safely and effectively.

Drugs that are required to have patient package inserts (PPIs) dispensed with them (eg. oral contraceptives, estrogens, etc.) are not considered by the FDA to carry the same serious public health concerns as those drugs with MedGuides. PPIs are intended to fully inform the patient of the risks and benefits of a drug.

Must MedGuides be provided with samples when dispensed from a doctor's office? Do phyicians who dispense drugs in a clinic have to give MedGuides if the drug requires one?

Yes, MedGuides must be dispensed with samples and with drugs dispensed to outpatients in a clinic setting.

Can a prescriber request that a patient NOT receive a MedGuide?

Yes, a physician can request that a patient not receive a MedGuide. However, if the patient asks for information, the MedGuide must be given to them, regardless of the request by the physician.

Is the pharmacist allowed to edit the content of a MedGuide to shorten it or to make it easier to understand?

No. MedGuides contain FDA-approved wording and their content should not be altered in any way.

Are MedGuides required with prescription refills?

Yes.

Are MedGuides required for inpatients? What about other settings, such as nursing homes or infusion centers?

The FDA has determined that MedGuides are not required for inpatients because the medications are being dispensed by healthcare professionals who are readily available to answer questions.

However, patients in outpatient clinics (dialysis centers, infusion centers, etc,) should be given MedGuides to take home with them.

References:

Frequently asked questions about MedGuides. Pharmacist's Letter/Prescriber's Letter 2009;25(12):251209.

Yearly Steps to Influenza Vaccine Identification and Distribution

1. Influenza disease surveillance by the World Health Organization (WHO) begins.
2. The Food and Drug Administration (FDA) and WHO review data to recommend the makeup of the influenza vaccine for the next flu season.
3. In February, the FDA's Vaccine and Related Biological Products Advisory Committee meets and recommends the three strains of influenza virus to include in the United States vaccine.
4. The viruses are adapted for use in manufacturing.
5. U.S. licensed vaccine manufacturers obtain reference influenza viruses from WHO to generate the 'seed virus' for further vaccine manufacturing.
6. Manufacturers, in collaboration with the FDA, test their vaccine for potency and safety.
7. Vaccine is formulated into standard dosages. Manufacturers finish the process, putting the vaccine into their final containers.
8. Each vaccine lot must meet the FDA's rigorous standards for safety and efficacy.
9. FDA releases lots and the manufacturers begin shipping vaccine.

Taken from the FDA website. www.fda.gov. Accessed February 2010.

Health Information Designs, Inc.
391 Industry Drive
Auburn, AL 36832
Ph 800-748-0130
Fax 800-748-0116