



STATE OF TENNESSEE
DEPARTMENT OF FINANCE AND ADMINISTRATION
DIVISION OF HEALTH CARE FINANCE AND ADMINISTRATION
BUREAU OF TENNCARE
310 Great Circle Road
NASHVILLE, TENNESSEE 37243

TennCare Drug Safety Alert to Providers

The U.S. Food and Drug Administration (FDA) has issued two (2) communications (please see attached FDA communications of August 15, 2012 <http://www.fda.gov/Drugs/DrugSafety/ucm313631.htm> and February 20, 2013 <http://www.fda.gov/Drugs/DrugSafety/ucm339112.htm>) regarding a known safety concern with codeine use in certain children after tonsillectomy and/ or adenoidectomy (surgery to remove the tonsils and/ or adenoids). The FDA is also conducting a safety review of codeine to determine if there are additional cases of inadvertent over dosage or death in children taking codeine, and if these adverse events occur during treatment of other kinds of pain, such as post-operative pain following other types of surgery or procedures.

The Problem

Codeine is an opioid pain reliever- narcotic analgesic medication used to treat mild to moderate pain. When codeine is ingested it is converted to morphine in the liver by an enzyme called cytochrome P450 2D6 (CYP2D6). Some people have DNA variations that make this enzyme more active, causing codeine to be converted to morphine faster and more completely than in other people. These “ultra-rapid metabolizers” are more likely to have higher than normal amounts of morphine in their blood after taking codeine. High levels of morphine can result in breathing difficulty, which may be fatal.

Some children may be at higher risk because of underlying diseases – having sleep apnea or other respiratory conditions.

The estimated number of “ultra-rapid metabolizers” is 1 to 7 per 100 people, but may be as high as 28 per 100 people in some ethnic groups.

Health Care Professionals

Health care professionals should be aware of the risks of using codeine in children. Health professionals should consider prescribing alternative analgesics for post-operative pain control in children. There are several very good alternatives. It is also important to emphasize that all drugs have risks. Health care professionals should always weigh the benefits versus the risks before prescribing any medication.