Nebraska Medicaid

DUR Matters

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FDA Warns About Use of Codeine and Tramadol in Children

On April 20, 2017, the Food and Drug Administration (FDA) issued a Drug Safety Communication against the use of prescription codeine pain and cough medicines and tramadol-containing medicines for children. The communication also recommends against use of codeine and tramadol for breastfeeding women. This was not the first warning from the FDA about the use of opioids in children. A warning regarding slowed or difficult breathing observed in patients under the age of 18 years while taking a codeine-containing cough syrup was issued on July 1, 2015. In 2013, the FDA released a warning about the use of codeine in pediatric patients after tonsillectomy and/or adenoidectomy for obstructive sleep apnea syndrome.

In the liver, codeine is converted to morphine by the cytochrome P450 2D6 (CYP2D6) enzyme. Some patients, referred to as "ultra-rapid metabolizers", have variations in the CYP2D6 enzyme which causes them to more rapidly and completely convert codeine to morphine. In some ultra-rapid metabolizers, the high blood levels of morphine have resulted in respiratory depression and, in some cases, death.

The FDA is requiring the manufacturers of codeine and tramadol products to add to the Contraindications section of the product labeling that in children younger than 12 years codeine should not be used to treat pain or cough and tramadol should not be used to treat pain. The labeling information for tramadol products will warn against use in children younger than 18 years to treat pain after surgery to remove the tonsils and/or adenoids. Information will be added to the Warnings section of the labeling of codeine and tramadol containing products recommending against use in adolescents between 12 and 18 years who are obese or have conditions such as obstructive sleep apnea or severe lung disease, which may increase the risk of serious breathing problems. A strengthened Warnings section will be added to the labeling of codeine- and tramadol-containing products that breastfeeding is not recommended when taking codeine or tramadol medicines due to the risk of serious adverse reactions in breastfed infants. These can include excess sleepiness, difficulty breastfeeding, or serious breathing problems that could result in the infant's death.

According to the FDA information: "Health care professionals should be aware that tramadol and single-ingredient codeine medicines are FDA-approved only for use in adults. Consider recommending over-the-counter (OTC) or other FDA-approved prescription medicines for cough and pain management in children younger than 12 years and in adolescents younger than 18 years, especially those with certain genetic factors, obesity, or obstructive sleep apnea and other breathing problems. Cough is often secondary to infection, not serious, and usually will get better on its own so treatment may not be necessary."

Resources

- FDA Drug Safety Communication: FDA restricts use of prescription codeine pain and cough medicines and tramadol pain medicines in children; recommends against use in breastfeeding women.
  https://www.fda.gov/Drugs/DrugSafety/ucm549679.htm
- FDA Drug Safety Communication: Codeine use in certain children after tonsillectomy and/or adenoidectomy may lead to rare, but life-threatening adverse events or death.
  https://www.fda.gov/Drugs/DrugSafety/ucm313631.htm

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