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FDA Update: OxyContin approved for opioid-tolerant pediatric patients

November 18, 2015

Food and Drug Administration Office of Pediatric Therapeutics, Division of Pediatric and Maternal Health, and Division of Anesthesia, Analgesia, and Addiction Products

Article type: FDA Update

Topics: Addiction, Anesthesiology/Pain Medicine, Hospital Medicine, Pharmacology

The Food and Drug Administration (FDA) recently approved OxyContin, an extended-release version of oxycodone, to manage pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate in opioid-tolerant pediatric patients 11 years of age and older who are already receiving and tolerate a minimum daily opioid dose of at least 20 milligrams oxycodone orally or its equivalent.

This approval was not intended to expand or otherwise change the pattern of use of extended-release opioids in pediatric patients. The FDA was aware that practitioners already were prescribing OxyContin to children off-label, without safety and efficacy data in hand with regard to the pediatric population. The agency wanted to fill that knowledge gap. Since the drug was being used to treat children, the FDA wanted prescribers to have the information they needed to ensure safety and efficacy.

Pediatric patients who are considered for pain management with OxyContin already should have been treated with an opioid pain medicine, and their health care practitioners should be well-trained in managing children with opioid analgesics for pain that cannot be managed adequately with non-opioid analgesics or immediate-release opioid products.

The FDA is concerned about the opioid and heroin addiction epidemics. However, the agency also is concerned about the need to have treatment options available for physicians to use as they treat patients who suffer from often chronic pain in the U.S.

At this time, Duragesic (fentanyl) and OxyContin are the only extended-release opioid products with FDA-approved pediatric labeling.

The FDA requested the manufacturer of OxyContin submit studies under the Best Pharmaceuticals for Children Act to obtain pediatric-specific information about oxycodone, including its use as OxyContin.

Safety and efficacy were evaluated in pediatric patients who were expected to require long-term pain management with an opioid (e.g., chronic pain due to conditions like cancer, extensive spinal surgery, sickle cell disease). The studies supported the pediatric indication for patients 11-16 years old who already are tolerating a minimum of 20 milligrams of oxycodone immediate release or its equivalent per day and are expected to need around-the-clock treatment with an opioid analgesic for an extended period of time.

FDA efforts continue to ensure that new pediatric pain management options are safe and effective for children.

Resources

- FDA Q&A about OxyContin label changes
- OxyContin labeling
- AAP News article “Opioid prescribing in children requires multipronged approach"