New Drug Approvals

Generic Name (Trade Nameâ€"Company)	**Uses**/Notes
May 17, 2018	
Lofexidine hydrochloride	FDA has approved lofexidine hydrochloride, an oral, selective alpha 2-adrenergic receptor agonist that reduces the release of norepinephrine, to mitigate withdrawal symptoms from abrupt discontinuation of opioids in adults. Norepinephrine is believed to play a role in many of the symptoms of opioid withdrawal. While the agent may lessen the severity of withdrawal symptoms, it may not completely prevent them and is only approved for treatment for up to 14 days. It is not a treatment for opioid use disorder (OUD) but can be used as part of a broader, long-term treatment plan for managing OUD. In patients using opioid analgesics appropriately as prescribed, opioid withdrawal is typically managed by slow taper of the medication, which is intended to avoid or lessen the effects of withdrawal while allowing the body to adapt to not having the opioid. In patients with OUD, withdrawal is typically managed by substitution of another opioid, followed by gradual reduction or transition to maintenance therapy with FDA-approved medication-assisted treatment drugs such as methadone, buprenorphine or naltrexone; or by various medications aimed at specific symptoms, such as OTC remedies for upset stomach or aches and pains. Other treatments may also be prescribed. Safety and efficacy of lofexidine were supported by two randomized, double-blind, placebo-controlled clinical trials of 866 adults meeting Diagnostic and Statistical Manual–IV criteria for opioid dependence who were physically dependent on opioids and undergoing abrupt opioid discontinuation. The studies evaluated benefit using the Short Opiate Withdrawal Scale of Gossop (SOWS-Gossop), a patient-reported outcome instrument that assesses opioid withdrawal symptoms such as stomach cramps, muscle spasms/twitching, feeling of coldness, heart

(Lucemyra —US WorldMeds)

FDA approves first nonopioid to mitigate opioid withdrawal symptoms

pounding, muscular tension, aches and pains, yawning, runny eyes, and insomnia or problems sleeping.

For each opioid withdrawal symptom, patients are asked to rate their symptom severity using four response options (none, mild, moderate, and severe), with the SOWS-Gossop total score ranging from 0 to 30. A higher score indicated a greater withdrawal symptom severity. SOWS-Gossop scores were lower for patients treated with lofexidine compared with placebo, and more patients completed the treatment period of the studies in the lofexidine group compared with the placebo group.

The most common adverse effects included hypotension, bradycardia, somnolence, sedation, and dizziness. Lofexidine was also associated with a few cases of fainting. It also affects the heart's electrical activity, which can increase the risk of abnormal heart rhythms. When the agent is stopped, patients can experience a marked increase in blood pressure.

Safety and efficacy have not been established in children or adolescents younger than 17 years of age. After a period of not using opioid drugs, patients may be more sensitive to the effects of lower amounts of opioids if relapse does occur, and taking opioids in amounts that were used before withdrawing from opioids can lead to overdose and death.

FDA is requiring 15 postmarketing studies, including both animal and human studies.

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