

FDA approves extended-release injection for opioid use disorder

May 31 2023, by Lori Solomon



The U.S. Food and Drug Administration has approved Brixadi

(buprenorphine) extended-release injection to treat moderate-to-severe opioid use disorder.

Brixadi is approved for both weekly (8 mg, 16 mg, 24 mg, 32 mg) and monthly (64 mg, 96 mg, 128 mg) subcutaneous injectable formulations, including lower doses that may be appropriate for people not able to tolerate higher doses of extended-release buprenorphine. Furthermore, the approved lower strength weekly formulation offers a new option for people in recovery who may benefit from a weekly injection to maintain treatment adherence. Brixadi can only be administered by [health care providers](#) in a [health care](#) setting through a Risk Evaluation and Mitigation Strategy program.

The approval was based upon a randomized, double-blind, active-controlled clinical trial in 428 adults with a diagnosis of moderate-to-severe opioid use disorder. Patients were treated with weekly injections over 12 weeks and then transitioned to monthly injections for 12 weeks. The proportion of [patients](#) meeting responder criteria was 16.9 percent in the Brixadi group and 14.0 percent in the sublingual buprenorphine group.

"Today's approval expands dosing options and provides people with opioid use disorder a greater opportunity to sustain long-term recovery," FDA Commissioner Robert M. Califf, M.D., said in a statement. "The FDA will continue to take the critical steps necessary to pursue efforts that advance evidence-based treatments for [substance use disorders](#), which is a strategic priority under the FDA's Overdose Prevention Framework."

Approval of Brixadi was granted to Braeburn.

More information: [More Information](#)

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Citation: FDA approves extended-release injection for opioid use disorder (2023, May 31)
retrieved 26 April 2024 from

<https://medicalxpress.com/news/2023-05-fda-extended-release-opioid-disorder.html>

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