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FDA OKs Buprenorphine Implant (*Probuphine*) for Opioid Dependence

Megan Brooks | May 26, 2016

The US Food and Drug Administration (FDA) has approved the first buprenorphine subdermal implant (*Probuphine*, Titan Pharmaceuticals/Braeburn Pharmaceuticals) for the maintenance treatment of opioid dependence, the agency announced today.

The product consists of four rods, each measuring 1 inch, that are implanted under the skin on the inside of the upper arm. It provides a constant, low-level dose of buprenorphine for 6 months in patients who are already stable on low to moderate doses of other forms of buprenorphine. It promises to be less subject to diversion, abuse, and misuse than other formulations.

Until now, buprenorphine for the treatment of opioid dependence was only available as a pill or sublingual film strip.

"While effective, a pill or film may be lost, forgotten or stolen," the FDA said in a statement. "However, as an implant, Probuphine provides a new treatment option for people in recovery who may value the unique benefits of a 6-month implant compared to other forms of buprenorphine, such as the possibility of improved patient convenience from not needing to take medication on a daily basis."

An independent FDA advisory committee supported the approval of the implant in a meeting held early this year, as reported by *Medscape Medical News*.

A "Game Changer"

"Opioid abuse and addiction have taken a devastating toll on American families. We must do everything we can to make new, innovative treatment options available that can help patients regain control over their lives," FDA Commissioner Robert M. Califf, MD, said in the statement. "Today's approval provides the first-ever implantable option to support patients' efforts to maintain treatment as part of their overall recovery program.

"Today brings a new ray of hope for many people with opioid use disorder, with the eagerly awaited" approval of Probuphine implant, Nora Volkow, MD, director of the National Institute on Drug Abuse at the National Institutes of Health, said in a blog post. "Maintenance medications can make all the difference in supporting a person's stable recovery. I expect and hope that Probuphine will be a game-changer in how we fight opioid use disorder," she added.

The implant should be used as part of a complete treatment program that includes counseling and psychosocial support, the FDA said. Administering it requires specific training and certification through the Probuphine Risk Evaluation and Mitigation Strategy (REMS) program.

The safety and efficacy of the product were demonstrated in a randomized clinical trial in opioid-dependent adults who were considered stable after prior buprenorphine treatment. In the study, 63% of the patients who received the implant had no evidence of illicit opioid use throughout the 6 months of treatment — similar to the 64% of those who responded to sublingual buprenorphine alone.

The most common side effects were implant-site pain, itching, and redness, as well as headache, depression, constipation, nausea, vomiting, back pain, toothache, and oropharyngeal pain.

The safety and efficacy of the implant have not been established in children or adolescents younger than 16 years, the FDA said, and clinical studies did not include participants older than 65 years.

A boxed warning on Probuphine notes that insertion and removal of the implant are associated with the risk for implant migration, protrusion, expulsion, and nerve damage resulting from the procedure.

"Probuphine must be prescribed and dispensed according to the Probuphine REMS program because of the risks of surgical complications and because of the risks of accidental overdose, misuse and abuse if an implant comes out or protrudes from the skin," the FDA said.

They advise that patients be seen during the first week after insertion and at least once monthly for continued counseling and psychosocial support.

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