

FDA approves obesity drug that helped people cut weight 15%

4 June 2021, by Linda A. Johnson



This image provided by Novo Nordisk on Friday, June 4, 2021 shows a package of injection pens for the company's semaglutide medication, named Wegovy. On Friday, the Food and Drug Administration said this new version of a popular diabetes medicine could be sold as a weight-loss drug in the U.S. Credit: Novo Nordisk via AP

Regulators on Friday said a new version of a popular diabetes medicine could be sold as a weight-loss drug in the U.S.

The Food and Drug Administration approved Wegovy, a higher-dose version of Novo Nordisk's diabetes <u>drug</u> semaglutide, for long-term <u>weight</u> management.

In company-funded studies, participants taking Wegovy had average weight loss of 15%, about 34 pounds (15.3 kilograms). Participants lost weight steadily for 14 months before plateauing. In a comparison group getting dummy shots, the average weight loss was about 2.5%, or just under 6 pounds.

"With existing drugs, you're going to get maybe 5% to 10% weight reduction, sometimes not even

that," said Dr. Harold Bays, medical director of the Louisville Metabolic and Atherosclerosis Research Center. Bays, who is also the Obesity Medicine Association's chief science officer, helped run studies of the drug.

In the U.S., more than 100 million adults—about 1 in 3—are obese.

Dropping even 5% of one's weight can bring <u>health</u> <u>benefits</u>, such as improved energy, <u>blood pressure</u>, <u>blood sugar</u> and <u>cholesterol levels</u>, but that amount often doesn't satisfy patients who are focused on weight loss, Bays said.

Bays said Wegovy appears far safer than earlier obesity drugs that "have gone down in flames" over safety problems. Wegovy's most common side effects were gastrointestinal problems, including nausea, diarrhea and vomiting. Those usually subsided, but led about 5% of study participants to stop taking it.

The drug carries a potential risk for a type of thyroid tumor, so it shouldn't be taken by people with a personal or family history of certain thyroid and endocrine tumors. Wegovy also has a risk of depression and pancreas inflammation.

Wegovy (pronounced wee-GOH'-vee) is a synthesized version of a gut hormone that curbs appetite. Patients inject it weekly under their skin. Like other weight-loss drugs, it's to be used along with exercise, a healthy diet and other steps like keeping a food diary.

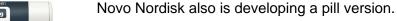
The Danish company hasn't disclosed Wegovy's price but said it will be similar to the price of its Saxenda, a weight loss drug injected daily that now typically costs more than \$1,300 per month without insurance.

Dr. Archana Sadhu, head of the diabetes program at Houston Methodist Hospital, said Wegovy's



usefulness "all depends on what the price will be." She noted patients' health insurance plans sometime don't cover weight-loss treatments, putting expensive drugs out of reach. "It helped curb my appetite and it helped me feel full faster," said Pannell. "It got me on the right path."

Shortly after she finished the study and stopped receiving Wegovy, she regained about half the weight. She's since lost much of that, started exercise classes and bought home exercise equipment. She's considering going back on Wegovy after it's approved.



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Sadhu, who has no connection to Novo Nordisk, plans to switch patients who are obese and have Type 2 diabetes to Wegovy. It makes patients feel full sooner and increases release of insulin from the pancreas to control blood sugar, she said. Patients would then be more likely to get motivated to exercise and eat healthier, she added.

Wegovy builds on a trend in which makers of relatively new diabetes drugs test them to treat other conditions common in diabetics. For example, popular diabetes drugs Jardiance and Novo Nordisk's Victoza now have approvals for reducing risk of heart attack, stroke and death in heart patients.

Phylander Pannell, 49, of Largo, Maryland, joined a patient study after cycles of losing and then regaining weight. She said she received Wegovy, worked out several times a week and lost 65 pounds over 16 months.



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