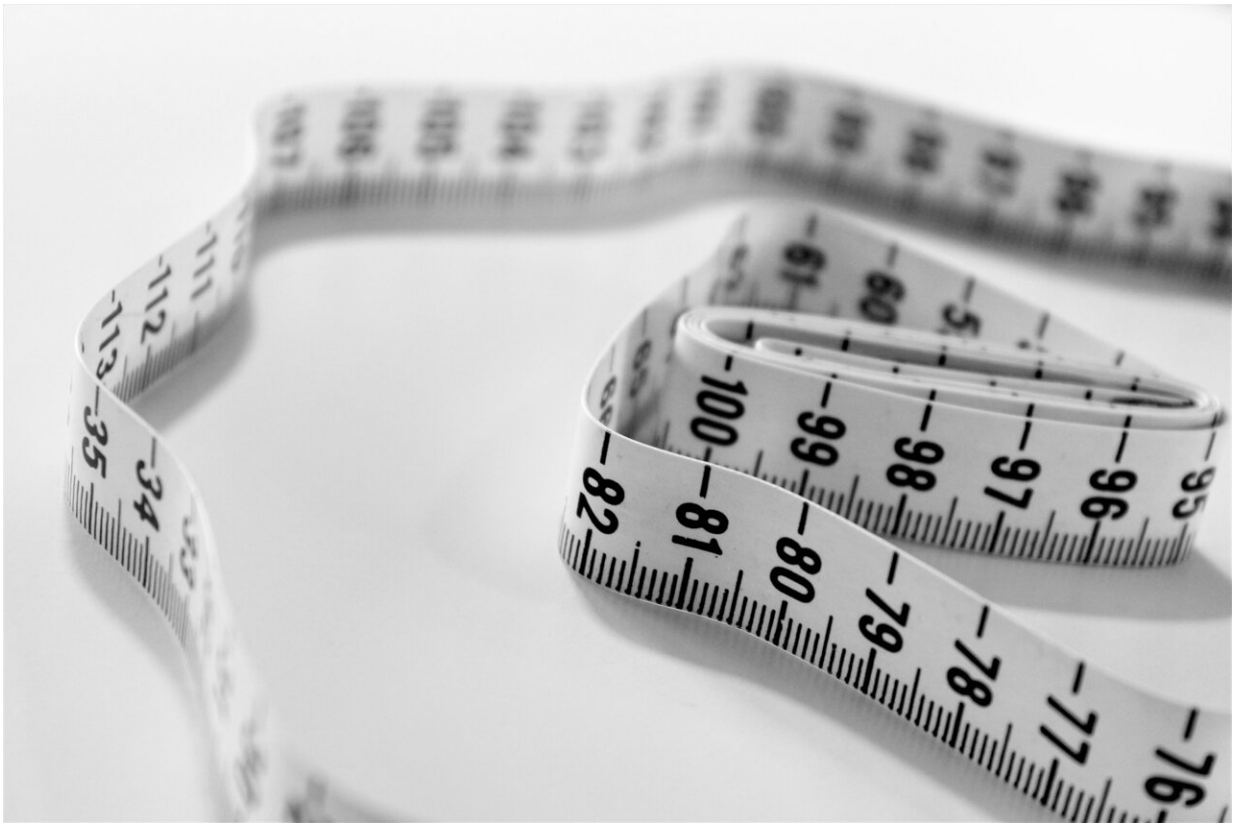


# Diabetes drug's new weight loss formula fuels cost-benefit debate

August 12 2021, by Julie Appleby

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The long list of side effects that follow ads for the newer expensive drugs to treat Type 2 diabetes sometimes include an unusual warning: They might cause weight loss. That side effect is one that many

people—especially those with Type 2 diabetes, which is associated with obesity—may desperately want.

So it's no surprise that some of the same drugs are being reformulated and renamed by manufacturers as a new obesity treatment. No longer limited to the crowded field of treatments for Type 2 diabetes, which affects about 10% of Americans, they join the far smaller number of drugs for obesity, which affects 42% of Americans and is ready to be mined for profit.

One that recently hit the market—winning Food and Drug Administration approval in June—is Novo Nordisk's Wegovy, a higher-dose version of the company's injectable diabetes [drug](#), Ozempic.

Ozempic's peppy ads suggest that people who use it might lose weight, but also include a disclaimer: that it "is not a [weight loss](#) drug." Now—with a new name—it is. And [clinical trials](#) showed using it leads to significant weight loss for many patients.

"People who go on this medication lose more weight than with any drug we've seen, ever," said Dr. Fatima Cody Stanford, an obesity medicine specialist at Massachusetts General Hospital and Harvard Medical School who was not involved with any of the clinical trials.

But that leaves employers and insurers in the uncomfortable position of deciding if it's worth it.

Wegovy's monthly wholesale price tag—set at \$1,349—is about 58% more than Ozempic's, although, the company points out, the drug's injector pens contain more than twice as much of the active ingredient. Studies so far show that patients may need to take it indefinitely to maintain weight loss, translating to a tab that could top \$323,000 over 20 years at the current price. Weight loss treatments are not universally

covered by [insurance policies](#).

The arrival of this new class of weight loss drugs—one from Lilly may soon follow—has created a thicket of issues for those who will pay for them. The decision is complicated by many unknowables concerning their long-term use and whether competition might eventually lower the price.

"The metric we try to use is value," said James Gelfand, senior vice president for [health policy](#) at the ERISA Industry Committee, or ERIC, which represents large, self-insured employers. "If we pay for this drug, how much is this going to cost and how much value will it provide to the beneficiaries?"

Weight loss treatments have had a lackluster past in this regard, with only modest results. Many employers and insurers likely remember Fen-Phen, a combination of fenfluramine and dexfenfluramine that was pulled from the market in the late 1990s for causing heart valve problems.

New drugs like Wegovy, more effective but also pricier than previous weight loss treatments, will add more fuel to that debate.

Past treatments were shown to prompt weight loss in the range of 5% to 10% of body weight. But many had relatively serious or unpleasant side effects.

Wegovy, however, helped patients lose an average of 15% of their body weight over 68 weeks in the main clinical trial that led to its approval. A comparison group that got a placebo injection lost an average of 2.5% over the same period. On the high end, nearly a third of patients in the treatment group lost 20% or more. Both groups had counseling on diet and exercise.

Side effects, generally considered mild, included nausea, diarrhea, vomiting and constipation. A few patients developed pancreatitis, a serious inflammation of the pancreas. Like the diabetes medication, the drug carries a warning about a potential risk of a type of thyroid cancer.

Weight loss in those taking Wegovy puts it close to the 20% to 25% losses seen with bariatric surgery, said Stanford at Mass General, and well above the 3% to 4% seen with diet and other lifestyle changes alone.

Participants also saw reductions in their waistlines and improvements in their blood pressure and blood sugar levels, which may mean they won't develop diabetes, said Dr. Sean Wharton, an internal medicine specialist and adjunct professor at York University in Toronto who was among the co-authors of the report outlining the results of the first clinical trial on Wegovy.

Since weight loss is known to reduce the risk of heart attack, high [blood pressure](#) and diabetes, might the new drug type be worth it?

Covering such treatment would be a sea change for Medicare, which specifically bars coverage for obesity medications or drugs for "anorexia, weight loss or weight gain," although it does pay for bariatric surgery. Pharmaceutical companies, patient advocates and some medical professionals are backing proposed federal legislation to allow coverage. But the legislation, the Treat and Reduce Obesity Act, has not made progress despite being reintroduced every year since 2012, and sponsors are now asking federal officials instead to rewrite existing rules.

Private insurers will have to consider a [cost-benefit analysis](#) of adding Wegovy to their list of covered treatments, either broadly or with limits. Obesity was first recognized as a disease by the American Medical Association, easing the path for insurance coverage, in 2013.

"Employers are going to have a bit of a challenge" deciding whether to add the benefit to insurance offerings, said Steve Pearson, founder and president of the Institute for Clinical and Economic Review, which provides cost-benefit analyses of medical treatments but has not yet looked at Wegovy.

The trade-offs are embodied in patients like Phylander Pannell, a 49-year-old Largo, Maryland, woman who said she lost 65 pounds in a clinical trial of Wegovy. That study gave the drug to all participants for the first 20 weeks, then randomly assigned patients to get either the drug or a placebo for the next 48 weeks to determine what happens when the medication is stopped. Only after the trial ended did she find out she was in the treatment group the entire time.

Her weight fell slowly at first, then ramped up, eventually bringing her 190-pound frame down to about 125. Pains in her joints eased; she felt better all around.

"I definitely feel the drug was it for me," said Pannell, who also followed the trial's guidance on diet and exercise.

The study found that both groups lost weight in the initial 20 weeks, but those who continued to get the drug lost an additional average of 7.9% of their body weight. Those who got a placebo gained back nearly 7%.

After the trial ended, and the COVID-19 pandemic hit, Pannell regained some weight and is now at 155. She is eager to get back on the medication and hopes her job-based insurance will cover it.

Many employers do cover obesity drugs. For example, about 40% of private employer plans include Novo Nordisk's once-daily injection called Saxenda on their health plans, said Michael Bachner, Novo Nordisk's director of media relations.

He said the \$1,349-a-month wholesale acquisition price of Wegovy was determined by making it equivalent to that of Saxenda, which is less effective.

Still, that is more than the \$851 monthly wholesale price of Ozempic. But, he points out, the recommended dosage of Wegovy is more than twice that of Ozempic. Four milligrams come in the Ozempic injector pens for the month, while Wegovy has 9.6.

"There's more drug in the pen," Bachner said. "That drives the price up."

He added: "This is not a 20-year-old drug that we now have a new indication for and are pricing it higher. It's a whole different clinical program," which required new trials.

Now scientists, employers, physicians and patients will have to decide whether the new drugs are worth it.

Earlier estimates—some commissioned by Novo Nordisk—of the potential cost of adding an obesity drug benefit to Medicare showed an overall reduction in spending when better health from the resulting [weight](#) loss was factored in.

Still, those earlier estimates considered much less expensive drugs, including a range of generic and branded drugs costing as little as \$7 a month to more than \$300, a small fraction of Wegovy's cost.

2021 Kaiser Health News.

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Citation: Diabetes drug's new weight loss formula fuels cost-benefit debate (2021, August 12) retrieved 10 May 2024 from <https://medicalxpress.com/news/2021-08-diabetes-drug-weight-loss-formula.html>

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