Another drug is approved to help the obese

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The Food and Drug Administration has approved a drug that may be help some of the millions of Americans resolving to lose weight this year.

The daily injectable drug, liraglutide, is part of a new class of diabetes medicines that prompt the pancreas to make extra insulin after meals.

Novo Nordisk first got approval to sell liraglutide five years ago as a diabetes therapy, brand name Victoza. The new, higher-dose prescription product, Saxenda, is specifically for weight loss in obese patients, and in overweight adults who have at least one weight-related problem such as high cholesterol, high blood pressure, or diabetes.

Liraglutide offers a novel way to complement the venerable but vexing prescription of diet and exercise. In addition to boosting insulin, it works in the digestive system and the brain to increase the feeling of fullness and suppress appetite.

"Approximately 80 million people are suffering with obesity," said Cherie L. Vaz, an endocrinologist at Temple University School of Medicine. "In general, diet drugs have modest effectiveness, but you want to be able to offer patients everything you can."

Still, there is no escaping the larger context of liraglutide's debut: Diet drugs have demonstrated, again and again since the 1950s, how little medical science really understands the biology of obesity. Every breakthrough has led to new puzzles and unforeseen dangers.

Obesity is a major public health issue, so in theory, a safe, effective treatment would be an automatic blockbuster.

Yet three diet drugs have been approved since 2012 - Belviq, Qsymia, and Contrave - and none has been a big seller, according to market analysts.

Partly, this is because "effective" does not mean the patient gets skinny. The FDA considers a drug effective if, with diet and exercise, it enables a 5 percent weight loss - because that is enough to spark health improvements such as lower blood pressure. But for people 30 percent over healthy weight - obese - that effect may be a letdown.

The medication has to be taken indefinitely and most insurers will not pay for drugs prescribed specifically for weight loss.

A spokesman for Novo Nordisk, a Danish pharmaceutical company with U.S. headquarters in Princeton, N.J., said it was in talks with insurers and had not yet set a price for Saxenda.

"The biggest downside for my patients is the cost" of diet drugs, said Ramsey Dallal, chief of bariatric surgery at Einstein Healthcare Network, based in Elkins Park, Pa. "They're often enthusiastic until they get to 'It's not covered by insurance.' "

Another damper on diet drugs' popularity is the checkered safety history. Two generations ago, the addictive dangers of amphetamines gave obesity drugs a bad reputation. Related drugs that acted on neurotransmitters (nerve-signaling chemicals) involved in mood and satiety were believed to be safer. Then two popular ones - fenfluramine and dexfenfluramine - were removed from the market in 1997 after evidence that a third of users could develop heart-valve damage.

That same year, sibutramine, which also acted on a neurotransmitter, was approved. It was withdrawn in 2010 because of links to heart attacks and strokes.

The three newest diet medications - Belviq, Qsymia, and Contrave - work in part by tinkering with neurotransmitters.

Liraglutide works primarily by imitating a molecule, called GLP-1 (glucagon-like peptide-1), that the body produces to stimulate the release of insulin.

While the real thing stops working after only a few minutes in the body, liraglutide works for 13 hours, explained Matthew R. Hayes, a Penn nutritional neuroscientist. During that period, the drug slows the passage of food from the stomach to the small intestine, bolstering the "I'm full" signal in the brain.

"Like the other drugs, it does get into the brain, which was taboo for a while," Hayes said. "But it helps control satiation."

In a pivotal clinical trial of more than 3,700 patients, 64 percent taking Saxenda for a year lost at least 5 percent of their weight, and 33 percent lost at least 10 percent. In the placebo group, 27 percent of patients had a 5 percent weight loss, and 10 percent had a 10 percent loss.

Saxenda's main side effects, researchers found, are nausea, diarrhea, and vomiting that went away within days. It is the first injectable diet drug, with a penlike dispenser.

The big question is long-term safety. A trial had begun to evaluate cardiovascular effects, and the FDA is requiring post-marketing studies in children, and to look for breast cancer and thyroid cancer risks.