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Wegovy cardiovascular study has doctors seeing new possibilities in weight loss drug

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The momentum around weight loss drugs is about to get even bigger in the wake of Novo Nordisk's announcement that its semaglutide drug Wegovy cut the risk of cardiovascular disease by 20% in its large SELECT trial.

The full results of the study, funded by Novo, will be presented at a scientific conference later this year. Doctors and researchers say they expect the findings to have a big impact on how clinicians approach the treatment of both obesity and cardiovascular disease, as well as increase the likelihood that prescriptions for obesity drugs will be covered by insurance.

But experts who spoke with STAT also cautioned that the long-term safety and efficacy of Wegovy and other weight loss drugs remain unknown. The SELECT study has yet to be peer-reviewed, and not enough information is yet available to make independent assessments of the results.

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"This is incredibly encouraging, equally important on a number of fronts," echoed Anthony Comuzzie, CEO of The Obesity Society. "At a broader level, this really helps us pushing the narrative and talking about these as anti-obesity medications and not just weight loss medications," he said. Comuzzie said the findings will also help address what he called the misconception — both within the medical field and in the broader population — that treating obesity is a cosmetic choice, rather than a medical necessity.

"People in the field are obviously really enthusiastic; some of them are ecstatic," said Sriram Machineni, an obesity medicine specialist at Albert Einstein College of Medicine in New York. "It's always been a question of whether it's worthwhile treating people with obesity — previously there was no study that this treatment was helping them live longer," he said,

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assuming the findings shared in Novo Nordisk's press release are confirmed in a peer-reviewed study that more transparently breaks down the results.

Doctors say Wegovy trial results could change prescription practices

If the Wegovy trial findings are confirmed by additional studies, its impact on cardiovascular disease would increase the likelihood that physicians will prescribe it, said Joseph C. Wu, the president of the American Heart Association and director of the Stanford Cardiovascular Institute. "It is quite surprising that semaglutide […] can have such a dramatic result over the 5-year trial period," he said via email.

Wu also struck a note of caution in extrapolating too much from the study, saying that it's yet to be seen whether the cardiovascular benefits remain if patients don't maintain the weight loss while on Wegovy, or if patients go off semaglutide but maintain weight loss through other means.

It's also unclear how Wegovy's apparent heart-health benefits intersect with other treatments for cardiovascular disease, such as statins. "The Wegovy trial enrolled obese individuals who are ages 45 and older and without type 2 diabetes, and presumably some of these patients are already on statins, ACE inhibitors, and/or beta blockers," said Wu.

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The possibility of using weight loss drugs as an additional way of reducing cardiovascular risk is intriguing, according to Joshua Knowles, a cardiologist at Stanford. "When you're adding on a therapy, it's hard to make somebody that's good, better," he said. "Cardiologists love data, and we love drugs that improve cardiovascular outcomes."

However, none of the five cardiologists interviewed by STAT thought semaglutide would replace existing heart disease drugs. Statins, for example, have a much higher risk reduction at 40-50%, according to John Ryan, a cardiologist at the University of Utah, who welcomes the possibility of adding another tool to fight cardiovascular disease. "I don't think it's a case of either/or; I think it's a case of now you're adding this on top of statin therapy," he said.

Because the details of the study are not yet public, it's hard for physicians to make definitive claims on what this will mean for their prescribing practices. If the results are confirmed, interviews with clinicians suggest, it is likely that obesity drugs will be prescribed even more frequently — just as SGLT-2 inhibitors, which started as diabetes drugs, are now standard treatment for other conditions, too. "When SGLT-2 inhibitors were shown to be beneficial for heart failure, almost overnight it became much easier for us to get them to patients," said Knowles.

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The findings from the SELECT trial may also help patients become more comfortable with taking these drugs, said Nadia Hameed, an endocrinologist at Overlake Medical Center in Bellevue, Wash.

She notes that in 2016, Novo's SUSTAIN-6 trial showed that semaglutide reduced the risk of cardiovascular disease — but its findings were specific only to patients with diabetes. In her experience, 80% of patients with diabetes start off feeling hesitant about taking an injectable weight loss drug. But when she shares that they can reduce the risk of heart attacks, strokes, and cardiovascular deaths, that's what often seals the deal. "If we give them the long-term benefits in terms of cardiovascular risk," said Hameed, "people find it much more accepting, and they're more excited to start this medication."

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Will insurers be more likely to cover weight loss drugs?

Endocrinologists have also had something of a head start in learning how coverage of GLP-1 drugs can change after results showing cardiovascular benefits come out.

"Previously, this was a very common denial that we would get from insurance companies" when prescribing GLP-1 drugs like semaglutide, said Hameed. "After that data came out, it allowed us to use these more effective medications rather than going to a second or third choice."

So far, the high price of obesity drugs, the complexity of obesity diagnosis and treatment, the cultural issues around body weight, and the popularity of weight loss drugs among online prescribers have made insurers hesitant to cover them. But experts expect the SELECT trial results to change that.

Related: **Alarmed by popularity of Ozempic and Wegovy, insurers wage multi-front battle**

"To have some cardiovascular benefit, this changes the view of insurance, and it's just undeniable that they kind of have to cover it," said Juliana Simonetti, an obesity medicine specialist at University of Utah. "How can they deny a medication that can be life-saving and has cardiovascular impacts and improves so many other measures? But I'm always surprised by how insurance interprets information and the decisions they make."

One indication of where insurance will fall on this may come from the Treat and Reduce Obesity Act, a bipartisan proposal to expand coverage of weight management medications for Medicare recipients, which was first introduced in 2013 and in every subsequent Congress since, most recently in July. "This is a very timely result because now there is more strength for approving treatments for obesity because you're not just talking about reducing weight," said Machineni.

Yet the demonstrable lifesaving effects of obesity drugs don't change a core issue: They are expensive.

"Any coverage decision will necessarily be colored by the incredibly high price attached to this drug," a spokesperson with the Association for Community Affiliated Plans, a trade group that represents not-for-profit health insurers, said via email. "Based on list prices here ($88 in U.K. — let's call it $100 — vs. $1,349 in the U.S.), it's cheaper to fly from Indianapolis to London every month to pick up each dose than it is to buy it at the CVS in Carmel, Indiana. That's what our plans are working through."

"If targeted appropriately with clinical guardrails, these new therapies offer hope to many patients. At the same time, the outrageous prices should give everyone pause," said Ceci Connolly, CEO of the Alliance of Community Health Plans, a trade group that represents health insurance companies that are also owned by hospital systems. "The U.S. is in desperate need of rational, transparent pharmacy strategies that put safety, efficacy, and affordability at the top of the agenda, not drug company profits over all else."

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David Rind is a primary care physician and chief medical officer at the Institute for Clinical and Economic Review, a group that reviews evidence of drugs' effectiveness and comes up with fair prices. He said that he had already been prescribing semaglutide drugs for weight loss under the assumption there were also cardiovascular benefits. To see Novo's results is "really exciting," he said.

"People really want these drugs," Rind said. "They work. We haven't really had something before that worked."

ICER's recent review of semaglutide assumed the drugs lowered cardiovascular events, but by less than Novo's study found. Based on that, ICER determined the fair price would be between $7,500 and $9,800 per year. That assumes a discount from manufacturers of between 44% and 57%.

Once Novo releases detailed results from its trial, ICER may increase its fair price, given the larger cardiovascular event reduction.

ICER suggests a cost-effective range for a drug, but Rind encourages manufacturers to come in below that. They'll still make a ton of money, and they'll be able to treat many more people, he said.

Drugs like Wegovy are going to have a huge impact on the budgets of the employers and insurers that cover them, Rind said. "The costs are enormous," he said. "Anybody who decides they're covering these drugs is going to have to figure out where the money is coming from. That means shifting it away from other things they're doing or raising premiums, and that's a big deal."

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