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Will Tirzepatide Vials Help Patients? Endos Weigh in

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Tirzepatide (Zepbound) is [not in shortage](#) for now, but the weight loss drug has remained inaccessible to people without insurance coverage who can't afford to pay out of pocket. Now, its manufacturer, Eli Lilly and Company, has introduced a new formulation it says will "significantly expand" the supply. But not all endocrinologists are enthusiastic.

As of August 27, LillyDirect made 2.5-mg and 5-mg [single-dose vials](#) of tirzepatide available to self-pay patients with an on-label electronic prescription. [Lilly's announcement](#) said the single-dose vials "are priced at a 50% or greater discount compared to the list price of all other incretin ([glucagon-like peptide-1 receptor agonists](#) or GLP-1) medicines for [obesity](#)."

For a 4-week supply of the weekly injections, the discount at LillyDirect translates to \$399 for a 2.5-mg single-dose vial (\$99.75 per vial) and \$549 for the 5-mg dose (\$137.25 per vial), which the company noted was "in line with the Zepbound savings program for noncovered individuals." (The new direct single-dose prescriptions cannot be filled at community or retail pharmacies.)

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"In a clinical study, the 5-mg maintenance dose helped patients achieve an average of 15% weight loss after 72 weeks of treatment and has been a powerful tool for millions of people with obesity looking to lose weight and keep it off," according to the announcement.

The clinical study, which is not named or referenced in the announcement, is [SURMOUNT-1](#), a Lilly spokesperson told *Medscape Medical News*. Yet, [that study](#) also found that patients achieved an average weight loss of 19.5% with 10-mg doses and 20.9% with 15-mg doses of tirzepatide.

Furthermore, the percentage of participants achieving body weight reductions of $\geq 5\%$ was 85% (5 mg), 89% (10 mg), and 91% (15 mg), showing the benefits of higher doses.

And there's the rub.

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'Only Two Different Doses'

Anne Peters, MD, a professor of clinical medicine and a clinical scholar at the Keck School of Medicine of the University of Southern California, Los Angeles, told *Medscape Medical News*, "My concern is, they're only providing two different doses, 2.5 mg and 5 mg. You get somebody on it, and then they still have to go back to the traditional pens. I'm very opposed to getting patients connected to a medication they can't then continue to take."

"Now we have starter doses that are easy to come by," she said. "But the problem isn't starting. The problem for all of these patients is chronic continuation of the right dose of the drug, and out-of-pocket costs become exorbitantly higher when they have to self-purchase the pens for the higher doses."

"Yes, the 5-mg dose has benefits, but not the same as higher doses," she continued. "I have nobody for whom 5 mg is the right dose. They have to take more, sometimes within a month or 2 of starting, in order to achieve the kind of weight loss they need."

If their insurance doesn't cover the drug, "What are they going to do to stay on 5 mg? Or pay a crapload of money to buy three of the 5-mg doses to reach a higher dose?"

Michael Weintraub, MD, clinical assistant professor in the Department of Medicine, Division of Endocrinology, Diabetes, and Metabolism at NYU Grossman School of Medicine in New York City, commented, "For many, this lower monthly cost is attainable and is a significant advancement in increasing access. For others, however, an out-of-pocket monthly cost of \$349-549 for a chronic medication is still unaffordable."

And like Peters, he said, "Some patients do not lose a clinically significant amount of weight with 2.5 mg or 5 mg and require higher doses. There is no way of prescribing a higher dose of Zepbound vials, so patients would have to resort to the higher-dose auto-injector pens that are still double the price."

A Lilly spokesperson countered in a comment to *Medscape Medical News*, "Offering Zepbound single-dose vials in higher dosage strengths could increase the potential for dose splitting, which

is not contemplated by the FDA-approved label and may pose patient safety risks."

But Peters wondered, "Wouldn't dose splitting of a known-to-be-pure compound be better than getting it at a compounding pharmacy that lacks purity/safety? The one message from all of this is that patients need to know what they're getting into. They're starting a drug that can help with weight loss, but they're going to be on a sub-max dose. And a higher dose is going to be double the price."

In addition, commented Robert F. Kushner, MD, a professor at Northwestern University Feinberg School of Medicine in Chicago, "For the lower-dose vials, instead of administering the drug with a self-auto-injection pen, patients will need to use a needle and syringe and draw up the dose from a vial. This will take a higher skill level and health literacy that may be challenging for some patients. Patients may need additional training on how to use this new formulation. That will take additional time and resources, such as a demonstration in the office or referral to video."

The Lilly [news release](#) noted that "patients can also purchase ancillary supplies, like syringes and needles, and will have access to important patient-friendly instructional materials on correctly administering the medicine via needle and syringe."

Protection From Compounders?

According to the Lilly spokesperson, the launch of Zepbound vials "furthers our commitment to helping patients avoid the risks associated with compounded products by providing patients another option for access to genuine Lilly medicine."

Indeed, said Jaime Almandoz, MD, medical director of the Weight Wellness Program and associate professor of internal medicine at the University of Texas Southwestern Medical Center in Dallas, "The introduction of Zepbound/tirzepatide in single-dose vials should improve access to evidence-based obesity treatments, reducing potential risks associated with compounded additives and eliminating the need for patients to calculate correct medication doses," which have led to [accidental overdoses](#) of compounded [semaglutide](#).

Lilly's spokesperson added, "We have taken multiple steps — including publishing an [open letter](#) and launching [lilly.com/real-medicine](https://www.lilly.com/real-medicine) — to warn the public about the risks posed by the proliferation of counterfeit, fake, unsafe, or untested knockoffs of Lilly's genuine medicines."

But whether these steps are strong enough to overcome the realities of cost and the need for affordable higher doses remains to be seen.

Scott Brunner, CEO of the Alliance for Pharmacy Compounding, said in a statement that the new version of Zepbound "is great news for patients. It's a much more rational and care-focused response to the remarkable demand for their drug than the lawsuits and cease-and-desist letters Lilly has been raining down on compounding pharmacies."

"For 20 months now," he continued, "compounders have been a lifeline for many patients, filling prescriptions for compounded tirzepatide injection at a time when the FDA-approved drug has been in shortage. We'll be eager to see whether Lilly's direct-to-patient approach actually works."

Almandoz affirmed, "Everyone wants to see improved access to evidence-based obesity care. It's crucial to ensure patients receive the most appropriate interventions, whether it is lifestyle changes, medications, or [bariatric surgery](#)," he told *Medscape Medical News*. "There are resources available, [including his [recent paper](#)], for nutrition and lifestyle modifications specifically for patients taking obesity medications, which can help clinicians guide their patients toward better health."

Almandoz is a member of advisory boards and consults for: Novo Nordisk, Eli Lilly and Company, and Boehringer Ingelheim. Kushner is an advisor to Eli Lilly and Novo Nordisk. Peters and Weintraub declared no competing interests.

Marilynn Larkin, MA, is an award-winning medical writer and editor whose work has appeared in numerous publications, including Medscape Medical News and its sister publication MDedge, The Lancet (where she was a contributing editor), and Reuters Health.