



FDA Approves Lilly's Zepbound™ (tirzepatide) for Chronic Weight Management, a Powerful New Option for the Treatment of Obesity or Overweight with Weight-Related Medical Problems

November 8, 2023

Adults taking Zepbound in a clinical trial lost on average 48 lb. at the highest dose

Zepbound is the first and only approved treatment activating two incretin hormone receptors, GIP and GLP-1, to tackle an underlying cause of excess weight

INDIANAPOLIS, Nov. 8, 2023 /PRNewswire/ -- The U.S. Food and Drug Administration (FDA) approved Eli Lilly and Company's (NYSE: LLY) Zepbound™ (tirzepatide) injection, the first and only obesity treatment of its kind that activates both GIP (glucose-dependent insulinotropic polypeptide) and GLP-1 (glucagon-like peptide-1) hormone receptors. Zepbound is indicated for adults with obesity (with a BMI of 30 kg/m² or greater), or those who are overweight (with a BMI of 27 kg/m² or greater) and also have weight-related medical problems such as hypertension, dyslipidemia, type 2 diabetes mellitus, obstructive sleep apnea or cardiovascular disease, to lose weight and keep it off. It should be used with a reduced-calorie diet and increased physical activity. Zepbound should not be used with other tirzepatide-containing products or any GLP-1 receptor agonist medicines, and it has not been studied in patients with a history of pancreatitis, or with severe gastrointestinal disease, including severe gastroparesis.

"Obesity is a chronic disease that can result in serious health complications, including heart disease, stroke and diabetes. Despite our knowledge of obesity as a treatable, chronic disease, people living with obesity still face many challenges in their health and weight management journey," said Joe Nadglowski, president and chief executive officer of the Obesity Action Coalition. "New treatment options bring hope to the many people with obesity who struggle with this disease and are seeking better options for weight management."

The approval was based on results from the phase 3 SURMOUNT-1 and SURMOUNT-2 trials. In SURMOUNT-1, a study in 2,539 adults with obesity, or excess weight and weight-related medical problems not including diabetes, people taking Zepbound as an adjunct to diet and exercise experienced substantial weight loss compared with placebo at 72 weeks. At the highest dose (15 mg), people taking Zepbound lost on average 48 lb., while at the lowest dose (5 mg), people lost on average 34 lb. (compared to 7 lb. on placebo).

Additionally, 1 in 3 patients taking Zepbound at the highest dose lost over 58 lb. (25% of body weight), compared to 1.5% on placebo, according to data not controlled for type 1 error. The average starting weight was 231 lb.

While not approved to treat these conditions, in a clinical trial, people who dieted, exercised and took Zepbound for the treatment of obesity or overweight with weight-related medical problems observed changes in cholesterol and reductions in blood pressure and waist size.

"Unfortunately, despite scientific evidence to the contrary, obesity is often seen as a lifestyle choice – something that people should manage themselves," said Dr. Leonard Glass, senior vice president global medical affairs, Lilly Diabetes and Obesity. "For decades, diet and exercise have been a go-to, but it's not uncommon for a person to have tried 20-30 times to lose weight with this approach. Research now shows that the body may respond to a calorie-deficit diet by increasing hunger and reducing feelings of fullness, making weight loss more difficult. Lilly is aiming to eliminate misperceptions about this disease and transform how it can be managed."

Zepbound use may be associated with gastrointestinal adverse reactions, sometimes severe. The most commonly reported adverse events (observed in ≥ 5% of clinical trial participants) were nausea, diarrhea, vomiting, constipation, abdominal pain, dyspepsia, injection-site reactions, fatigue, hypersensitivity reactions, eructation, hair loss and gastroesophageal reflux disease.¹ In studies, most nausea, diarrhea and vomiting occurred when people increased their dose – but the effects generally decreased over time. In studies, gastrointestinal side effects were more common in people taking Zepbound than people taking placebo, and people taking Zepbound were more likely than those on placebo to stop treatment because of these side effects. The label for Zepbound includes a Boxed Warning regarding thyroid C-cell tumors. Zepbound is contraindicated in patients with a personal or family history of medullary thyroid carcinoma, in patients with Multiple Endocrine Neoplasia syndrome type 2, and in patients with known serious hypersensitivity to tirzepatide or any of the excipients in Zepbound. See Important Safety Information below and full [Prescribing Information](#) and [Medication Guide](#).

"Far too many hurdles continue to prevent people living with obesity from accessing obesity treatments that could lead to significant weight loss," said Mike Mason, executive vice president and president, Lilly Diabetes and Obesity. "Broader access to these medicines is critical, which is why Lilly is committed to working with healthcare, government and industry partners to ensure people who may benefit from Zepbound can access it."

Zepbound is expected to be available in the U.S. by the end of the year in six doses (2.5 mg, 5 mg, 7.5 mg, 10 mg, 12.5 mg, 15 mg) at a list price of \$1,059.87, which is approximately 20% lower than semaglutide 2.4 mg injection for weight loss. List price does not reflect the typical out-of-pocket cost to patients given insurance coverage and discounts. Lilly is putting a commercial savings card program in place that will help people who may benefit from Zepbound better access it.

- People who are commercially insured with coverage for Zepbound may be eligible to pay as low as \$25 for a 1-month or 3-month prescription.
- People who are commercially insured without coverage for Zepbound may be eligible to pay as low as \$550 for a 1-month prescription of Zepbound, approximately 50% lower than the list price.

Eli Lilly & Co.
Exhibit 2042
EMPOWER v. Eli Lilly
IPR2025-01024
Ex. 2042-001

People may begin using the savings card program in the days following product availability at U.S. pharmacies. To learn more about these programs, or to sign up to receive the latest news, please visit www.Zepbound.lilly.com. Terms and conditions apply.

Tirzepatide is also under regulatory review for weight management in Europe, China, the United Kingdom and several additional markets.

Click [here](#) to view the Zepbound product image.

Click [here](#) to view the Zepbound logo.

About the SURMOUNT clinical trial program

The SURMOUNT phase 3 global clinical development program for tirzepatide in chronic weight management began in late 2019 and has enrolled more than 5,000 people with obesity or overweight across six registration studies, four of which are global studies. SURMOUNT-1 and SURMOUNT-2 were submitted to the FDA and demonstrated tirzepatide significantly reduced body weight compared with placebo in people living with obesity or overweight, with or without type 2 diabetes.

About Zepbound™ (tirzepatide) injection¹

Zepbound™ (tirzepatide) injection is FDA-approved as an adjunct to a reduced-calorie diet and increased physical activity for chronic weight management in adults with obesity (BMI ≥ 30 kg/m²), or overweight (BMI ≥ 27 kg/m²) with at least one weight-related comorbid condition. Zepbound is the first and only FDA-approved obesity treatment that activates both GIP (glucose-dependent insulinotropic polypeptide) and GLP-1 (glucagon-like peptide-1) hormone receptors.

INDICATION AND SAFETY SUMMARY WITH WARNINGS

Zepbound™ (ZEHP-bownd) is an injectable prescription medicine that may help adults with obesity, or with excess weight (overweight) who also have weight-related medical problems, lose weight and keep it off. It should be used with a reduced-calorie diet and increased physical activity.

- Zepbound contains tirzepatide and should not be used with other tirzepatide-containing products or any GLP-1 receptor agonist medicines. It is not known if Zepbound is safe and effective when taken with other prescription, over-the-counter, or herbal weight loss products. It is not known if Zepbound can be used in people who have had pancreatitis. It is not known if Zepbound is safe and effective for use in children under 18 years of age.

Warnings - Zepbound may cause tumors in the thyroid, including thyroid cancer. Watch for possible symptoms, such as a lump or swelling in the neck, hoarseness, trouble swallowing, or shortness of breath. If you have any of these symptoms, tell your healthcare provider.

- Do not use Zepbound if you or any of your family have ever had a type of thyroid cancer called medullary thyroid carcinoma (MTC).
- Do not use Zepbound if you have Multiple Endocrine Neoplasia syndrome type 2 (MEN 2).
- Do not use Zepbound if you have had a serious allergic reaction to tirzepatide or any of the ingredients in Zepbound.

Zepbound may cause serious side effects, including:

Severe stomach problems. Stomach problems, sometimes severe, have been reported in people who use Zepbound. Tell your healthcare provider if you have stomach problems that are severe or will not go away.

Kidney problems (kidney failure). Diarrhea, nausea, and vomiting may cause a loss of fluids (dehydration), which may cause kidney problems. It is important for you to drink fluids to help reduce your chance of dehydration.

Gallbladder problems. Gallbladder problems have happened in some people who use Zepbound. Tell your healthcare provider right away if you get symptoms of gallbladder problems, which may include pain in your upper stomach (abdomen), fever, yellowing of skin or eyes (jaundice), or clay-colored stools.

Inflammation of the pancreas (pancreatitis). Stop using Zepbound and call your healthcare provider right away if you have severe pain in your stomach area (abdomen) that will not go away, with or without vomiting. You may feel the pain from your abdomen to your back.

Serious allergic reactions. Stop using Zepbound and get medical help right away if you have any symptoms of a serious allergic reaction, including swelling of your face, lips, tongue or throat, problems breathing or swallowing, severe rash or itching, fainting or feeling dizzy, or very rapid heartbeat.

Low blood sugar (hypoglycemia). Your risk for getting low blood sugar may be higher if you use Zepbound with medicines that can cause low blood sugar, such as a sulfonylurea or insulin. **Signs and symptoms of low blood sugar may include** dizziness or light-headedness, sweating, confusion or drowsiness, headache, blurred vision, slurred speech, shakiness, fast heartbeat, anxiety, irritability, mood changes, hunger, weakness or feeling jittery.

Changes in vision in patients with type 2 diabetes. Tell your healthcare provider if you have changes in vision during treatment with Zepbound.

Depression or thoughts of suicide. You should pay attention to changes in your mood, behaviors, feelings or thoughts. Call your healthcare provider right away if you have any mental changes that are new, worse, or worry you.

Common side effects

The most common side effects of Zepbound include nausea, diarrhea, vomiting, constipation, stomach (abdominal) pain, indigestion, injection site reactions, feeling tired, allergic reactions, belching, hair loss, and heartburn. These are not all the possible side effects of Zepbound. Talk to your healthcare provider about any side effect that bothers you or doesn't go away.

Tell your healthcare provider if you have any side effects. **You can report side effects at 1-800-FDA-1088 or www.fda.gov/medwatch.**

Before using Zepbound

- **Your healthcare provider should show you how to use Zepbound before you use it for the first time.**
- **Tell your healthcare provider if you are taking medicines to treat diabetes including insulin or sulfonylureas which could increase your risk of low blood sugar. Talk to your healthcare provider about low blood sugar levels and how to manage them.**
- **If you take birth control pills by mouth, talk to your healthcare provider before you use Zepbound. Birth control pills may not work as well while using Zepbound.** Your healthcare provider may recommend another type of birth control for 4 weeks after you start Zepbound and for 4 weeks after each increase in your dose of Zepbound.

Review these questions with your healthcare provider:

- ☐ Do you have other medical conditions, including problems with your pancreas or kidneys, or severe problems with your stomach, such as slowed emptying of your stomach (gastroparesis) or problems digesting food?
- ☐ Do you take diabetes medicines, such as insulin or sulfonylureas?
- ☐ Do you have a history of diabetic retinopathy?
- ☐ Do you take any other prescription medicines or over-the-counter drugs, vitamins, or herbal supplements?
- ☐ Are you pregnant, plan to become pregnant, breastfeeding, or plan to breastfeed? Zepbound may harm your unborn baby. Tell your healthcare provider if you become pregnant while using Zepbound. It is not known if Zepbound passes into your breast milk. You should talk with your healthcare provider about the best way to feed your baby while using Zepbound.

- **Pregnancy Exposure Registry:** There will be a pregnancy exposure registry for women who have taken Zepbound during pregnancy. The purpose of this registry is to collect information about the health of you and your baby. Talk to your healthcare provider about how you can take part in this registry, or you may contact Lilly at 1-800-LillyRx (1-800-545-5979).

How to take

- Read the **Instructions for Use** that come with Zepbound.
- Use Zepbound exactly as your healthcare provider says.
- Zepbound is injected under the skin (subcutaneously) of your stomach (abdomen), thigh, or upper arm.
- **Use Zepbound 1 time each week, at any time of the day.**
- Change (rotate) your injection site with each weekly injection. **Do not** use the same site for each injection.
- If you take too much Zepbound, call your healthcare provider, seek medical advice promptly, or contact a Poison Center expert right away at 1-800-222-1222.

Learn more

Zepbound is a prescription medicine. For more information, call 1-800-LillyRx (1-800-545-5979) or go to www.zepbound.lilly.com.

This summary provides basic information about Zepbound but does not include all information known about this medicine. Read the information that comes with your prescription each time your prescription is filled. This information does not take the place of talking with your healthcare provider. Be sure to talk to your healthcare provider about Zepbound and how to take it. Your healthcare provider is the best person to help you decide if Zepbound is right for you.

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About Lilly

Lilly unites caring with discovery to create medicines that make life better for people around the world. We've been pioneering life-changing discoveries for nearly 150 years, and today our medicines help more than 51 million people across the globe. Harnessing the power of biotechnology, chemistry and genetic medicine, our scientists are urgently advancing new discoveries to solve some of the world's most significant health challenges, redefining diabetes care, treating obesity and curtailing its most devastating long-term effects, advancing the fight against Alzheimer's disease, providing solutions to some of the most debilitating immune system disorders, and transforming the most difficult-to-treat cancers into manageable diseases. With each step toward a healthier world, we're motivated by one thing: making life better for millions more people. That includes delivering innovative clinical trials that reflect the diversity of our world and working to ensure our medicines are accessible and affordable. To learn more, visit Lilly.com and Lilly.com/newsroom or follow us on [Facebook](https://www.facebook.com/lilly), [Instagram](https://www.instagram.com/lilly), [Twitter](https://twitter.com/lilly) and [LinkedIn](https://www.linkedin.com/company/lilly). P-LLY

Lilly Cautionary Statement Regarding Forward-Looking Statements

This press release contains forward-looking statements (as that term is defined in the Private Securities Litigation Reform Act of 1995) about Zepbound (tirzepatide) as a potential treatment for adults with obesity or overweight and the timeline for additional regulatory submissions, future readouts, supply and commercialization of Zepbound, presentations, and other milestones relating to Zepbound and reflects Lilly's current belief and expectations. However, as with any pharmaceutical product, there are substantial risks and uncertainties in the process of drug research, development, and commercialization. Among other things, there can be no guarantee that planned or ongoing studies will be completed as planned, that future study results will be consistent with the results to date, that Zepbound will receive additional regulatory approvals, or that Zepbound will be commercially successful or that we will meet anticipated timelines for its commercialization. For further discussion of these and other risks and uncertainties, see Lilly's most recent Form 10-K and Form 10-Q filings with the United States Securities and Exchange Commission. Except as required by law, Lilly undertakes no duty to update forward-looking statements to reflect events after the date of this release.

References

1. Zepbound. Prescribing Information. Lilly USA, LLC.

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