

Zepbound™ (tirzepatide) is Now Available in U.S. Pharmacies for Adults Living with Obesity

December 5, 2023

Express Scripts to add Zepbound to National Preferred Formulary

INDIANAPOLIS, Dec. 5, 2023 /PRNewswire/ -- Eli Lilly and Company (NYSE: LLY) today announced that Zepbound [™] (tirzepatide) injection is now available. 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 (glucagon-like peptide-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.

Following the U.S. Food and Drug Administration (FDA) approval on Nov. 8, 2023, people living with obesity can now access Zepbound in six doses (2.5 mg, 5 mg, 7.5 mg, 10 mg, 12.5 mg, 15 mg) through a prescription that can be filled at retail and mail-order pharmacies.

"Today opens another chapter for adults living with obesity who have been looking for a new treatment option like Zepbound," said Rhonda Pacheco, group vice president, Lilly Diabetes and Obesity, U.S. "The availability of Zepbound in U.S. pharmacies is the first step, but we have to work hand-in-hand with employers, government and healthcare industry partners to remove barriers and make Zepbound available to those who need it. We are excited to see growing coverage in the marketplace, giving millions of Americans access to Zepbound."

Effective Dec. 1, 2023, Zepbound was added to the National Preferred Formulary for Express Scripts and Cigna Healthcare, and effective Dec. 15, 2023, it will be added to Cigna Healthcare's commercial formularies. Lilly's commercial savings card program is now available at U.S. pharmacies to help adults who need Zepbound 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.

To learn more about Zepbound and eligibility for the savings card program, please visit www.Zepbound.Lilly.com. Terms and conditions apply.

Lilly continues to invest in the expansion of its global manufacturing footprint to address the expected demand for innovative new treatments, like Zepbound, and help ensure the safe and reliable supply of its medicines.

About Zepbound™ (tirzepatide) injection

ZepboundTM (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 \ge 30 kg/m²), or overweight (BMI \ge 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

ZepboundTM (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 particless of kluneys, or severe problems with your stornach, 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/newsroom or follow us on Facebook, Instagram, Twitter and LinkedIn. 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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