

press release

Novo Nordisk receives FDA approval for Wegovy™ to treat adults with obesity based on unprecedented efficacy for a prescription medicine in clinical trials

- *Despite being recognized by leading authorities as a serious disease, obesity remains stigmatized, resulting in patients being underdiagnosed and significantly undertreated*
- *Approval includes results from STEP 1, a clinical trial where once-weekly, prescription GLP-1 receptor agonist Wegovy™ (semaglutide) injection 2.4 mg, demonstrated an average weight loss of ~15% at 68-weeks when used with a reduced calorie meal plan and increased physical activity*

PLAINSBORO, NJ, June 4, 2021 – Novo Nordisk today announced that the US Food and Drug Administration (FDA) has approved the new drug application (NDA) for Wegovy™ (semaglutide) injection 2.4 mg, the first-and-only prescription weight-loss medication with once-weekly dosing. Wegovy™ is used with a reduced calorie meal plan and increased physical activity for adults with obesity (BMI ≥ 30) or overweight (excess weight) (BMI ≥ 27) who also have weight related medical problems to help them lose weight and keep the weight off.¹

Approximately 42% of adults in the US live with obesity, a chronic disease which is recognized by the Centers for Disease Control and Prevention (CDC) as an epidemic.^{2,3} Obesity is a gateway disease associated with at least 60 other serious health conditions and decreased life expectancy.^{4,5}

The FDA approval of Wegovy™ was based on the results of the STEP (Semaglutide Treatment Effect in People with Obesity) clinical trial program, which included four phase 3a clinical trials involving approximately 4,500 patients. The trials demonstrated that patients taking Wegovy™ with a reduced calorie meal plan and increased physical activity achieved a significant reduction in body weight compared with placebo (reduced calorie meal plan and increased physical activity only). In the STEP 1 trial, results also showed that patients taking Wegovy™ achieved an average weight loss of 14.9% of body weight at 68-weeks vs. 2.4% for placebo. In addition, 83.5% of patients achieved 5% or more body weight reduction in the Wegovy™ arm vs. 31.1% for placebo.¹

The most frequently reported adverse events were nausea, diarrhea, vomiting, constipation, and abdominal pain.¹

“This is the first time we have seen this magnitude of weight loss with a medicine. This approval gives people with obesity a once-weekly, non-surgical option with results that have never been demonstrated with an anti-obesity medicine before,” said Dr. Robert Kushner, professor of medicine and medical education at Northwestern University, Feinberg School of Medicine, Chicago. “The approval of Wegovy™ represents a turning point for healthcare providers to embrace medical management of obesity to help improve chronic weight management for patients.”

“For more than two decades, Novo Nordisk has led the charge to translate the complex science behind obesity into medicines that can make a difference, all while partnering across industries and sectors to change how obesity is understood, diagnosed and treated,” said Doug Langa, executive vice president, North America operations and president of Novo Nordisk Inc. “With the unprecedented efficacy of Wegovy™ and our innovative, industry-leading pipeline, we have the most significant opportunity yet to drive meaningful change for people with obesity, and the providers committed to their health.”

Obesity is recognized as a chronic disease and health issue by leading health organizations, including the American Medical Association, Centers for Disease Control and Prevention, The Obesity Society, and the World Obesity Federation, among other global organizations.^{3,6,7,8} Obesity has many contributing factors, including genetics, lifestyle and environment.⁹

“It’s remarkable that obesity is still seen as a personal flaw rather than a medical condition requiring treatment, just like any other chronic disease. This disease can negatively impact one’s quality of life, both through societal weight bias and stigma, as well as its association with numerous serious health issues,” said Joe Nadglowski, president and chief executive officer of the Obesity Action Coalition. “It’s time that we recognized this national public health crisis and the need for as many tools as possible to address it. Expanding safe and clinically effective treatment options for obesity management is good news for people with obesity and the medical community.”

Novo Nordisk expects to launch Wegovy™ later this month. For further information, please visit www.Wegovy.com.

What is Wegovy™?

Wegovy™ (semaglutide) injection 2.4 mg is an injectable prescription medicine used for adults with obesity (BMI ≥30) or overweight (excess weight) (BMI ≥27) who also have weight-related medical problems to help them lose weight and keep the weight off.

- Wegovy™ should be used with a reduced calorie meal plan and increased physical activity.
- Wegovy™ contains semaglutide and should not be used with other semaglutide-containing products or other GLP-1 receptor agonist medicines.
- It is not known if Wegovy™ is safe and effective when taken with other prescription, over-the-counter, or herbal weight loss products.
- It is not known if Wegovy™ can be used safely in people with a history of pancreatitis.
- It is not known if Wegovy™ is safe and effective for use in children under 18 years of age.

Important Safety Information

What is the most important information I should know about Wegovy™?

Wegovy™ may cause serious side effects, including:

- **Possible thyroid tumors, including cancer.** Tell your healthcare provider if you get a lump or swelling in your neck, hoarseness, trouble swallowing, or shortness of breath. These may be symptoms of thyroid cancer. In studies with rodents, Wegovy™ and medicines that work like Wegovy™ caused thyroid tumors, including thyroid cancer. It is not known if Wegovy™ will cause thyroid tumors or a type of thyroid cancer called medullary thyroid carcinoma (MTC) in people.
- Do not use Wegovy™ if you or any of your family have ever had a type of thyroid cancer called medullary thyroid carcinoma (MTC) or if you have an endocrine system condition called Multiple Endocrine Neoplasia syndrome type 2 (MEN 2).^{1,10}

Do not use Wegovy™ if:

- you or any of your family have ever had a type of thyroid cancer called medullary thyroid carcinoma (MTC) or if you have an endocrine system condition called Multiple Endocrine Neoplasia syndrome type 2 (MEN 2).
- you have had a serious allergic reaction to semaglutide or any of the ingredients in Wegovy™.

Before using Wegovy™, tell your healthcare provider if you have any other medical conditions, including if you:

- have or have had problems with your pancreas or kidneys.
- have type 2 diabetes and a history of diabetic retinopathy.
- have or have had depression, suicidal thoughts, or mental health issues.
- are pregnant or plan to become pregnant. Wegovy™ may harm your unborn baby. You should stop using Wegovy™ 2 months before you plan to become pregnant.
- are breastfeeding or plan to breastfeed. It is not known if Wegovy™ passes into your breast milk.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. Wegovy™ may affect the way some medicines work and some medicines may affect the way Wegovy™ works. Tell your healthcare provider if you are taking other medicines to treat diabetes, including sulfonylureas or insulin. Wegovy™ slows stomach emptying and can affect medicines that need to pass through the stomach quickly.

What are the possible side effects of Wegovy™?

Wegovy™ may cause serious side effects, including:

- **inflammation of your pancreas (pancreatitis).** Stop using Wegovy™ 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.
- **gallbladder problems.** Wegovy™ may cause gallbladder problems, including gallstones. Some gallstones may need surgery. Call your healthcare provider if you have symptoms, such as pain in your upper stomach (abdomen), fever, yellowing of the skin or eyes (jaundice), or clay-colored stools.
- **increased risk of low blood sugar (hypoglycemia) in patients with type 2 diabetes, especially those who also take medicines for type 2 diabetes such as sulfonylureas or insulin.** This can be both a serious and common side effect. Talk to your healthcare provider about how to recognize and treat low blood sugar and check your blood sugar before you start and while you take Wegovy™. Signs and symptoms of low blood sugar may include dizziness or light-headedness, blurred vision, anxiety, irritability or mood changes, sweating, slurred speech, hunger, confusion or drowsiness, shakiness, weakness, headache, fast heartbeat, or feeling jittery.
- **kidney problems (kidney failure).** In people who have kidney problems, diarrhea, nausea, and vomiting may cause a loss of fluids (dehydration) which may cause kidney problems to get worse. It is important for you to drink fluids to help reduce your chance of dehydration.
- **serious allergic reactions.** Stop using Wegovy™ 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.
- **change in vision in patients with type 2 diabetes.** Tell your healthcare provider if you have changes in vision during treatment with Wegovy™.
- **increased heart rate.** Wegovy™ can increase your heart rate while you are at rest. Tell your healthcare provider if you feel your heart racing or pounding in your chest and it lasts for several minutes.
- **depression or thoughts of suicide.** You should pay attention to any mental changes, especially sudden changes in your mood, behaviors, thoughts, or feelings. Call your healthcare provider right away if you have any mental changes that are new, worse or worry you.
- **the most common side effects of Wegovy™ may include:** nausea, diarrhea, vomiting, constipation, stomach (abdomen) pain, headache, tiredness (fatigue), upset stomach, dizziness, feeling bloated, belching, gas, stomach flu and heartburn.

Please see Prescribing Information, including Medication Guide, at <https://www.novo-pi.com/wegovy.pdf>

About the STEP clinical trial program

STEP (Semaglutide Treatment Effect in People with Obesity) is a phase 3 clinical development program with once-weekly subcutaneous semaglutide 2.4 mg in obesity. The global clinical phase 3a program consists of four trials and has enrolled approximately 4,500 adults with overweight or obesity.¹

About Wegovy™

Wegovy™ is a GLP-1 receptor agonist.¹ It is currently under review in the European Union and other countries.¹¹

About obesity

Obesity is a chronic, progressive and misunderstood disease that requires long term medical management.^{6,12,13} One key misunderstanding is that this is a disease of willpower, when in fact there is underlying biology that prevents people from losing weight and keeping it off.⁹ Obesity is influenced by a variety of factors, including genetics, appetite signals, behavior and the environment.⁹ It is a gateway disease and is associated with at least 60 other health conditions.⁴ The current COVID-19 pandemic has highlighted that obesity also increases the risk for severe illness and hospitalization due to COVID-19.¹⁴⁻¹⁷

The global increase in the prevalence of obesity is a public health issue that has severe cost implications to healthcare systems.^{18,19} In the United States, more than 42% of adults live with obesity.²

About Novo Nordisk

Novo Nordisk is a global healthcare company that's been making innovative medicines to help people with diabetes lead longer, healthier lives for 95 years. This heritage has given us experience and capabilities that also enable us to help people defeat other serious diseases including obesity, hemophilia and growth disorders. We remain steadfast in our conviction that the formula for lasting success is to stay focused, think long-term and do business in a financially, socially and environmentally responsible way. With U.S. headquarters in New Jersey and production and research facilities in six states, Novo Nordisk employs nearly 6,000 people throughout the country. For more information, visit novonordisk.us, [Facebook](#), [Instagram](#) and [Twitter](#).

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