FDA approves Ozempic® (semaglutide) as the only GLP-1 RA to reduce the risk of worsening kidney disease and cardiovascular death in adults with type 2 diabetes and chronic kidney disease

- *Ozempic® is now indicated to reduce the risk of kidney disease worsening, kidney failure, and death from cardiovascular disease in adults with type 2 diabetes and chronic kidney disease*

- *The approval is based on the results of the pivotal FLOW phase 3b kidney outcomes trial and addresses a critical need for adults with type 2 diabetes living with this common comorbidity of chronic kidney disease*

Plainsboro, N.J., January 28, 2025 – Novo Nordisk today announced that the U.S. Food and Drug Administration (FDA)

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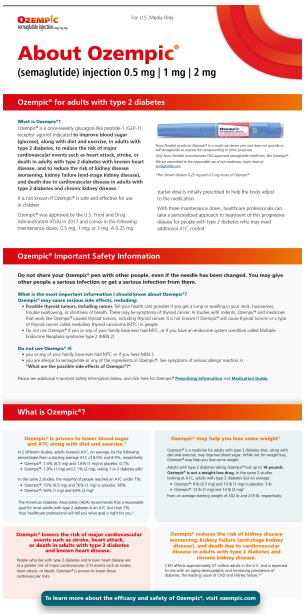
has approved Ozempic® to reduce the risk of kidney disease worsening, kidney failure (end-stage kidney disease), and death due to cardiovascular disease in adults with type 2 diabetes and chronic kidney disease (CKD).[1] This approval, along with its existing indications for adults with type 2 diabetes to improve glycemic control and to reduce the risk of major cardiovascular events in adults also with known heart disease, establishes Ozempic® (semaglutide) injection 0.5 mg, 1 mg, or 2 mg as the most broadly indicated glucagon-like peptide-1 receptor agonist (GLP-1 RA) in its class.

"Chronic kidney disease is very serious and common in patients living with type 2 diabetes and represents a critical need for adults living with these comorbidities. This approval for Ozempic® allows us to more broadly address conditions within cardiovascular-kidney-metabolic syndrome, which affects millions of adults and could have serious consequences if left untreated," Nordisk. "With this new indication, Ozempic® stands out uniquely as the most broadly indicated GLP-1 RA in its class.



Novo Nordisk Ozempic® Media Backgrounder

Novo Nordisk Ozempic® Misinformation Infographic

VIDEOS

We are proud to continue advancing innovations that will have a meaningful impact for this patient population, underscoring Novo Nordisk's commitment to cardiometabolic care."

CKD affects approximately 37 million adults in the U.S. and is expected to rise with an aging demographic and increasing prevalence of diabetes, the leading cause of CKD and kidney failure.[2,3] CKD is a common complication of type 2 diabetes, with approximately 40% of people with type 2 diabetes also experiencing CKD.[2,4] For people with type 2 diabetes, CKD can be a significant burden and can cause additional sickness, including increased risk of cardiovascular problems and death.[4,5]

This FDA approval is based on results from the FLOW phase 3b kidney outcomes trial investigating the effects of once-weekly Ozempic® injection on major kidney and cardiovascular outcomes in adults with type 2 diabetes and CKD.[1] The FLOW trial achieved its primary endpoint with Ozempic® 1 mg, demonstrating a statistically significant and superior 24% relative risk reduction of kidney disease worsening, kidney failure (end-stage kidney

Novo Nordisk CKD FDA Approval HCP Spokesperson Video

Novo Nordisk CKD FDA Approval NNI Spokesperson Video

IMAGE LIBRARY

OZEMPIC® semaglutide injection 0.5mg, 1mg, 2mg

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disease), and death due to cardiovascular disease (4.9% absolute risk reduction at 3 years) compared to placebo, when added to standard of care.[1]

“Type 2 diabetes can be challenging enough to manage without the added risk of chronic kidney disease, and I have seen in my own practice that patients with type 2 diabetes and chronic kidney disease need extra support from medications that may have a profound clinical impact by lowering the risk of major kidney and cardiovascular outcomes,” said Richard E. Pratley, MD, Medical Director at the AdventHealth Diabetes Institute Orlando, FL, and Co-Chair of the FLOW Trial. “A large portion of patients I treat experience serious kidney complications and comorbidities, with some even requiring dialysis. Today’s decision by the FDA offers hope for the millions of adults living with both conditions and provides an additional treatment option, representing a significant advancement for my patients.”

The FDA initially approved Ozempic® in 2017 to improve blood sugar (glucose), along with diet and exercise, in adults with type 2 diabetes. In 2020,

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Novo Nordisk

Ozempic® was granted an additional indication to reduce the risk of major cardiovascular events such as heart attack, stroke, or death in adults with type 2 diabetes with known heart disease. Today, the FDA has expanded the benefits of Ozempic® to a new patient population that needs critical treatment options to reduce the risk of kidney disease worsening, kidney failure (end-stage kidney disease), and death due to cardiovascular disease in adults with type 2 diabetes and chronic kidney disease.

Only Novo Nordisk manufactures FDA-approved semaglutide medicines, like Ozempic®.

About FLOW
FLOW was an international, randomized, double-blind, parallel-group, placebo-controlled, event-driven superiority trial comparing once-weekly Ozempic® 1 mg with placebo as an adjunct to standard of care on kidney outcomes for reducing the incidence of the primary composite endpoint of a sustained decline in eGFR of ≥50%, sustained eGFR <15 mL/min/1.73 m^2, chronic renal replacement therapy, renal death, and CV death in adults with type 2 diabetes and CKD.

3,533 adults (1,767 in the Ozempic® group and 1,766 in the placebo group) were enrolled in the trial conducted in 28 countries at approximately 400 investigator sites. The FLOW trial was initiated in 2019. At the recommendation from an Independent Data Monitoring Committee, the FLOW study was stopped early due to meeting pre-specified efficacy criteria after a median follow-up of 3.4 years.[6]

What is Ozempic®

Ozempic® (semaglutide) injection 0.5 mg, 1 mg, or 2 mg is an injectable prescription medicine used:

- along with diet and exercise to improve blood sugar (glucose) in adults with type 2 diabetes
- to reduce the risk of major cardiovascular events such as heart attack, stroke, or death in adults with type 2 diabetes with known heart disease
- to reduce the risk of kidney disease worsening, kidney failure (end-stage kidney disease), and death due to cardiovascular disease in adults with type 2 diabetes and chronic kidney disease

It is not known if Ozempic® is safe and effective for use in children.

Important Safety Information

Do not share your Ozempic® pen with other people, even if the needle has been changed. You may give other people a serious infection or get a serious infection from them.

What is the most important information I should know about Ozempic®?
Ozempic® may cause serious side effects, including:

- **Possible thyroid tumors, including cancer.** Tell your health care 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, Ozempic® and medicines that work like Ozempic® caused thyroid tumors, including thyroid cancer. It is not known if Ozempic® will cause thyroid tumors or a type of thyroid cancer called medullary thyroid carcinoma (MTC) in people
- Do not use Ozempic® if you or any of your family have ever had MTC, or if you have an endocrine system condition called Multiple

Endocrine Neoplasia syndrome type 2 (MEN 2)

Do not use Ozempic® if:

- you or any of your family have ever had MTC or if you have MEN 2
- you are allergic to semaglutide or any of the ingredients in Ozempic®. See symptoms of serious allergic reaction in **"What are the possible side effects of Ozempic®?"**

Before using Ozempic®, tell your health care provider if you have any other medical conditions, including if you:

- have or have had problems with your pancreas
- have a history of diabetic retinopathy
- have severe problems with your stomach, such as slowed emptying of your stomach (gastroparesis) or problems with digesting food
- are scheduled to have surgery or other procedures that use anesthesia or deep sleepiness (deep sedation)
- are pregnant or breastfeeding or plan to become pregnant or breastfeed. It is not known if Ozempic® will harm your unborn baby or pass into your breast milk. You should

stop using Ozempic® at least 2 months before you plan to become pregnant

Tell your health care provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, herbal supplements, and other medicines to treat diabetes, including insulin or sulfonylureas.

What are the possible side effects of Ozempic®?
Ozempic® may cause serious side effects, including:

- **inflammation of your pancreas (pancreatitis).** Stop using Ozempic® and call your health care 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
- **changes in vision.** Tell your health care provider if you have changes in vision during treatment with Ozempic®
- **low blood sugar (hypoglycemia).** Your risk for getting low blood sugar may be higher if you use Ozempic® with another medicine that can cause low blood sugar, such as a sulfonylurea or insulin.

Signs and symptoms of low blood sugar may include: dizziness or lightheadedness, blurred vision, anxiety, irritability or mood changes, sweating, slurred speech, hunger, confusion or drowsiness, shakiness, weakness, headache, fast heartbeat, and feeling jittery

- **dehydration leading to kidney problems.** 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. Tell your health care provider right away if you have nausea, vomiting, or diarrhea that does not go away
- **severe stomach problems.** Stomach problems, sometimes severe, have been reported in people who use Ozempic®. Tell your health care provider if you have stomach problems that are severe or will not go away
- **serious allergic reactions.** Stop using Ozempic® 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

- **gallbladder problems**. Gallbladder problems have happened in some people who take Ozempic®. Tell your health care provider right away if you get symptoms which may include: pain in your upper stomach (abdomen), fever, yellowing of the skin or eyes (jaundice), or clay-colored stools
- **food or liquid getting into the lungs during surgery or other procedures that use anesthesia or deep sleepiness (deep sedation).** Ozempic® may increase the chance of food getting into your lungs during surgery or other procedures. Tell all your health care providers that you are taking Ozempic® before you are scheduled to have surgery or other procedures

The most common side effects of Ozempic® may include nausea, vomiting, diarrhea, stomach (abdominal) pain, and constipation.

About Novo Nordisk
Novo Nordisk is a leading global healthcare company that's been

making innovative medicines to help people with diabetes lead longer, healthier lives for more than 100 years. This heritage has given us experience and capabilities that also enable us to drive change to help people defeat other serious chronic diseases such as obesity, rare blood, and endocrine 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 commercial, production, and research facilities in seven states plus Washington DC, Novo Nordisk employs approximately 8,000 people throughout the country. For more information, visit novonordisk-us.com, Facebook, Instagram, and X.

Novo Nordisk is committed to the responsible use of our semaglutide-containing medicines which represent distinct products with different indications, dosages, prescribing information, titration schedules, and delivery forms. These products are not interchangeable and should not be used outside of their approved indications.

This information is intended for US media audiences only.

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