FDA NEWS RELEASE

FDA Approves New Drug Treatment for Chronic Weight Management, First Since 2014

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Español (/news-events/press-announcements/la-fda-aprueba-un-nuevo-tratamiento-farmacologico-para-el-control-de-peso-cronico-el-primero-desde)

Today, the U.S. Food and Drug Administration approved Wegovy (semaglutide) injection (2.4 mg once weekly) for chronic weight management in adults with obesity or overweight with at least one weight-related condition (such as high blood pressure, type 2 diabetes, or high cholesterol), for use in addition to a reduced calorie diet and increased physical activity. This under-the-skin injection is the first approved drug for chronic weight management in adults with general obesity or overweight since 2014. The drug is indicated for chronic weight management in patients with a body mass index (BMI) of 27 kg/m2 or greater who have at least one weight-related ailment or in patients with a BMI of 30 kg/m2 or greater.

“Today’s approval offers adults with obesity or overweight a beneficial new treatment option to incorporate into a weight management program,” said John Sharretts, M.D., deputy director of the Division of Diabetes, Lipid Disorders, and Obesity in the FDA’s Center for Drug Evaluation and Research. “FDA remains committed to facilitating the development and approval of additional safe and effective therapies for adults with obesity or overweight.”

Approximately 70% of American adults have obesity or overweight. Having obesity or overweight is a serious health issue associated with some leading causes of death, including heart disease, stroke and diabetes, and is linked to an increased risk of certain types of cancer. Losing 5% to 10% of body weight through diet and exercise has been associated with a reduced risk of cardiovascular disease in adult patients with obesity or overweight.

Wegovy works by mimicking a hormone called glucagon-like peptide-1 (GLP-1) that targets areas of the brain that regulate appetite and food intake. The medication dose must be increased gradually over 16 to 20 weeks to 2.4 mg once weekly to reduce gastrointestinal side effects.

Wegovy should not be used in combination with other semaglutide-containing products, other GLP-1 receptor agonists, or other products intended for weight loss, including prescription drugs, over-the-counter drugs, or herbal products. Wegovy has not been studied in patients with a history of pancreatitis.

Wegovy's safety and efficacy were studied in four 68-week trials. Three were randomized, double-blind, placebo-controlled trials (including 16 weeks of dose increases) and one was a double-blind, placebo-controlled, randomized withdrawal trial in which patients receiving Wegovy either continued with the treatment or switched to a placebo. More than 2,600 patients received Wegovy for up to 68 weeks in these four studies and more than 1,500 patients received placebo.

The largest placebo-controlled trial enrolled adults without diabetes. The average age at the start of the trial was 46 years and 74% of patients were female. The average body weight was 231 pounds (105 kg) and average BMI was 38 kg/m2. Individuals who received Wegovy lost an average of 12.4% of their initial body weight compared to individuals who received placebo. Another trial enrolled adults with type 2 diabetes. The average age was 55 years and 51% were female. The average body weight was 220 pounds (100 kg) and average BMI was 36 kg/m2. In this trial, individuals who received Wegovy lost 6.2% of their initial body weight compared to those who received placebo.

The most common side effects of Wegovy include nausea, diarrhea, vomiting, constipation, abdominal (stomach) pain, headache, fatigue, dyspepsia (indigestion), dizziness, abdominal distension, eructation (belching), hypoglycemia (low blood sugar) in patients with type 2 diabetes, flatulence (gas buildup), gastroenteritis (an intestinal infection) and gastroesophageal reflux disease (a type of digestive disorder).

The prescribing information for Wegovy contains a boxed warning to inform healthcare professionals and patients about the potential risk of thyroid C-cell tumors. Wegovy should not be used in patients with a personal or family history of medullary thyroid carcinoma or in patients with a rare condition called Multiple Endocrine Neoplasia syndrome type 2 (MEN 2).

Wegovy should not be used in patients with a history of severe allergic reactions to semaglutide or any of the other components of Wegovy. Patients should stop Wegovy immediately and seek medical help if a severe allergic reaction is suspected. Wegovy also contains warnings for inflammation of the pancreas (pancreatitis), gallbladder problems (including gallstones), low blood sugar, acute kidney injury, diabetic retinopathy (damage to the eye's retina), increased heart rate and suicidal behavior or thinking. Patients should discuss with their healthcare professional if they have symptoms of pancreatitis or gallstones. If Wegovy is used with insulin or a substance that causes insulin secretion, patients should speak to their health care provider about potentially lowering the dose of insulin or the insulin-inducing drug to reduce the risk of low blood sugar. Healthcare providers should monitor patients with kidney disease, diabetic retinopathy and depression or suicidal behaviors or thoughts.

The FDA granted the approval to Novo Nordisk. Semaglutide 1 mg injection (Ozempic) was first approved as a treatment for type 2 diabetes in 2017.

Related Information

- NIH: Overweight & Obesity Statistics (https://www.niddk.nih.gov/health-information/health-statistics/overweight-obesity)

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