

COM-2024-029

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# PLEASE REVIEW Drug Information

## PharmPix Clinical Department

### Drug Information:

Remember that medical literature is dynamic and is continuously changing as new scientific knowledge is developed. We exhort the frequent revision of treatment guidelines to assure that your recommendations are consistent with the most updated information.

It is our priority to offer high-quality services and support practices for health promotion and disease prevention. If you have any questions or wish to have more information regarding this document, you can call us directly or view PharmPix communications online.

#### QUESTIONS

Call us at 787-522-5252, ext. 219.

Access our recent communications at our providers' portal:  
<https://www.pharmpix.com/providers/>.



PharmPix is committed to the health and wellness of our members.

The clinical team wants to communicate the latest up-to-date drug information requested.

## New Breakthrough Indication for Wegovy™

The U.S. Food and Drug Administration (FDA) has approved a new indication for the use of Wegovy™ (semaglutide) to reduce the risk of cardiovascular death, heart attack, and stroke in adults with established cardiovascular disease (CVD) and either obesity or overweight. The medication should be used in addition to reduced calorie diet and increased physical activity.

### Background

Wegovy™, developed by Novo Nordisk, was approved first to treat obesity in adults in June 2021. It is an injectable medication that comes as a pre-filled, single-dose pen and is self-administered by the patient or caregiver subcutaneously.

About 70% of American adults are obese or overweight. Being obese or overweight increases the risk for premature death and a variety of health problems, including heart attack and stroke.

### SELECT Clinical Trial

The approval was based on efficacy and safety in the multicentered, placebo controlled, double-blind SELECT (NCT03574597) trial, which had over 17,600 individuals in the cohort. Treatment was randomized between semaglutide or the placebo, with both groups receiving standard-of-care treatment, including management of blood pressure and cholesterol, and healthy lifestyle counseling, including diet and physical activity.

Semaglutide significantly reduced the risk of major adverse cardiovascular events (MACE) such as CVD death, heart attack, and stroke, which occurred in 6.5% of individuals in the semaglutide group compared with 8% of those in the placebo group over a 5 year period. The findings from the SELECT trial showed that the risk of MACEs was reduced by 20% compared with the placebo in combination with standard.

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REFERENCES:

1. FDA. (2024, March 8). *FDA approves first treatment to reduce risk of serious heart problems specifically in adults with obesity or overweight*. U.S. Food and Drug Administration. <https://www.fda.gov/news-events/press-announcements/fda-approves-first-treatment-reduce-risk-serious-heart-problems-specifically-adults-obesity-or>
2. Gallagher, A. (Ed.). (2024, March 8). *FDA Approves Semaglutide for New Indication Involving Cardiovascular Disease*. Pharmacy Times. <https://www.pharmacytimes.com/view/fda-approves-semaglutide-for-new-indication-involving-cardiovascular-disease>

