Clinical Perspectives

The SELECT Clinical Study

Dr Sanjay Rajagopalan discusses the significance of the SELECT study on clinical practice in cardiology and obesity management

This landmark study is an exciting advancement for patients with obesity or overweight and established cardiovascular disease. In my opinion, this is a practice-changing trial that highlights the opportunity to take patients who are already on evidence-based standard of care for cardiovascular risk reduction and further lower their risk with the addition of another therapeutic approach."[1,2]

Sanjay Rajagopalan, MD, MBA is a cardiology specialist with over 20 years of experience in clinical, academic, and scientific roles. He is currently the Chief of Cardiovascular Medicine, the Chief Academic and Scientific Officer, and the Founding Director of the CINEMA cardiometabolic program at University Hospitals Harrington Heart and Vascular Institute in Cleveland, Ohio. Dr Rajagopalan is also a professor at Case Western Reserve School of Medicine.

Dr Sanjay Rajagopalan was compensated by Novo Nordisk for his participation in developing this piece.

Indications and Usage

Wegovy® (semaglutide) injection 2.4 mg is indicated in combination with a reduced calorie diet and increased physical activity:

- to reduce the risk of major adverse cardiovascular events (cardiovascular death, non-fatal myocardial infarction, or non-fatal stroke) in adults with established cardiovascular disease and either obesity or overweight
- to reduce excess body weight and maintain weight reduction long term in adults and pediatric patients aged 12 years and older with obesity and adults with overweight in the presence of at least one weight-related comorbidity

Limitations of Use

Wegovy® contains semaglutide. Coadministration with other semaglutide-containing products or with any GLP-1 receptor agonist is not recommended

Important Safety Information

WARNING: RISK OF THYROID C-CELL TUMORS

- **In rodents, semaglutide causes dose-dependent and treatment-duration-dependent thyroid C-cell tumors at clinically relevant exposures. It is unknown whether Wegovy® causes thyroid C-cell tumors, including medullary thyroid carcinoma (MTC), in humans as human relevance of semaglutide-induced rodent thyroid C-cell tumors has not been determined**
- **Wegovy® is contraindicated in patients with a personal or family history of MTC or in patients with Multiple Endocrine Neoplasia syndrome type 2 (MEN 2). Counsel patients regarding the potential risk for MTC with the use of Wegovy® and inform them of symptoms of thyroid tumors (e.g. a mass in the neck, dysphagia, dyspnea, persistent hoarseness). Routine monitoring of serum calcitonin or using thyroid ultrasound is of uncertain value for early detection of MTC in patients treated with Wegovy®**

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What clinical question was the SELECT CVOT designed to answer?

Q

What needs do you see in your practice for patients with cardiovascular disease?

Clinical Perspectives with Cardiologist Dr Sanjay Rajagopalan

A "I have seen many important therapeutic advances for patients with cardiovascular disease over the course of my 20 years in practice. Despite this, some patients remain at risk of subsequent cardiovascular events. This **residual cardiovascular risk remains even in patients receiving evidence-based standard-of-care treatments**. Just because you have patients on statins, antiplatelet agents, RAAS antagonists, etc, doesn't mean these patients have zero risk. Some continue to have events. I believe this is especially concerning **for patients with cardiovascular disease and obesity**, since we know that **despite progress in the management of cardiovascular risk factors, CVD remains their leading cause of death**."[3-5]

Q

What should clinicians know about the design and execution of the SELECT clinical study?

A "**There are several things to emphasize about this very unique study. This study evaluated the effect of semaglutide 2.4 mg on MACE risk reduction in patients with established CVD and either obesity or overweight**. It is a very large, contemporary clinical trial, the **largest CVOT that was ever completed for these patients.** Notably, patients with diabetes were excluded from this study, and the mean A1c at baseline was 5.8%.[1,2,6]

Patients enrolled in the SELECT study were already receiving evidence-based medications according to cardiovascular standard of care. At baseline, 90% of patients were on lipid-lowering therapy, 86% of patients were on platelet aggregation inhibitors, 74% of patients were on RAAS inhibitors, and 70% were on beta-blockers. Throughout the study, investigators were encouraged to adjust cardiovascular standard-of-care therapies according to clinical practice guidelines.[1]

This study enrolled patients with established cardiovascular disease, which included prior MI, prior stroke, or peripheral arterial disease. Most patients in the study, three-quarters of them, already had a prior myocardial infarction, making this a population at risk for another CV event. **SELECT was well designed to uncover the effect of adding semaglutide 2.4 mg for these patients at risk of subsequent cardiovascular events**."[1,2]

Important Safety Information

Contraindications

Wegovy® is contraindicated in patients with a personal or family history of MTC or in patients with MEN 2, and in patients with a prior serious hypersensitivity reaction to semaglutide or to any of the excipients in Wegovy®.
Serious hypersensitivity reactions, including anaphylaxis and angioedema have been reported with Wegovy®

Warnings and Precautions

- **Risk of Thyroid C-Cell Tumors:** Patients should be further evaluated if serum calcitonin is measured and found to be elevated or thyroid nodules are noted on physical examination or neck imaging

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SELECT CVOT: Study objective and design

Study Objective

- To evaluate the effect of Wegovy® 2.4 mg relative to placebo as an adjunct to cardiovascular standard of care for reducing the risk of major adverse cardiovascular events in adults with established cardiovascular disease with obesity or overweight with no prior history of diabetes[1,2]

Study Design

- Multi-national, double-blind, placebo-controlled, event-driven, superiority cardiovascular outcomes trial[1,2]
- Patients were randomized from October 2018 through March 2021, and the trial was completed in June 2023[2,7]
- Enrolled 17,604 adults who were ≥45 years old with a BMI ≥27 kg/m^2 and established CVD (prior MI, prior stroke, or PAD) without type 1 or type 2 diabetes[1]
- Patients were randomized 1:1 to receive once-weekly subcutaneous Wegovy® 2.4 mg or placebo on top of current standard of care, which included medical management of CV risk factors and individualized healthy lifestyle counseling (including diet and physical activity)[1,2]
  - Concomitant CV therapies could be adjusted at the discretion of the investigator to ensure participants were treated according to current standard of care for patients with established CVD[1]
- Median duration of follow-up was 41.8 months[1]

BMI, body mass index; CV, cardiovascular; CVD, cardiovascular disease; CVOT, cardiovascular outcomes trial; MACE, major adverse cardiovascular events; MI, myocardial infarction; PAD, peripheral arterial disease; RAAS, renin-angiotensin-aldosterone system.

Important Safety Information

Warnings and Precautions (cont'd)

- **Acute Pancreatitis:** Acute pancreatitis, including fatal and non-fatal hemorrhagic or necrotizing pancreatitis, has been observed in patients treated with GLP-1 receptor agonists, including semaglutide. Acute pancreatitis was observed in patients treated with Wegovy® in clinical trials. Observe patients carefully for signs and symptoms of acute pancreatitis (including persistent severe abdominal pain, sometimes radiating to the back, and which may or may not be accompanied by vomiting). If acute pancreatitis is suspected, discontinue Wegovy® promptly, and if acute pancreatitis is confirmed, do not restart
- **Acute Gallbladder Disease:** Treatment with Wegovy® is associated with an increased occurrence of cholelithiasis and cholecystitis. The incidence of cholelithiasis and cholecystitis was higher in Wegovy® pediatric patients aged 12 years and older than in Wegovy® adults. In clinical trials in adult patients, cholelithiasis was reported by 1.6% of Wegovy® patients and 0.7% of placebo patients. Cholecystitis was reported by 0.6% of Wegovy® patients and 0.2% of placebo patients. In a clinical trial in pediatric patients aged 12 years and older, cholelithiasis was reported by 3.8% of Wegovy® patients and 0% placebo patients. Cholecystitis was reported by 0.8% of Wegovy® pediatric patients and 0% placebo patients. Substantial or rapid weight loss can increase the risk of cholelithiasis; however, the incidence of acute gallbladder disease was greater in Wegovy® patients than in placebo patients, even after accounting for the degree of weight loss. If cholelithiasis is suspected, gallbladder studies and appropriate clinical follow-up are indicated
- **Hypoglycemia:** Wegovy® lowers blood glucose and can cause hypoglycemia. In a trial of adult patients with type 2 diabetes, hypoglycemia was reported in 6.2% of Wegovy® patients versus 2.5% of placebo patients. Patients with diabetes taking Wegovy® with an insulin or insulin secretagogue (e.g. sulfonylurea) may have an increased risk of hypoglycemia, including severe hypoglycemia. The use of Wegovy® in patients with type 1 diabetes or in combination with insulin has not been evaluated. Inform patients of the risk of hypoglycemia and educate them on the signs and symptoms. Monitor blood glucose in patients with diabetes

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Were the results of the SELECT CVOT clinically significant?

Clinical Perspectives with Cardiologist Dr Sanjay Rajagopalan

Q What are your thoughts on the efficacy of semaglutide 2.4 mg relative to placebo in reducing the risk of 3-part MACE, defined as CV death, non-fatal MI, or non-fatal stroke?

A "**I find the data to be impressive and I encourage other clinicians to review these significant results for themselves.**

The **1.5% absolute risk reduction** and **20% relative risk reduction, on top of standard of care**, are substantial enough to change the way I practice medicine for a number of patients with obesity or overweight who also have cardiovascular disease. Notably, the observed benefit was not impacted by various important clinical and disease factors, such as age, race, sex, ethnicity, baseline BMI, and level of renal impairment. I believe that most cardiologists would concur that this represents a robust effect with significant clinical implications, particularly in light of the potential risks these CV events pose to patients.

The fact that a medication can not only help patients manage weight but also reduce the risk of another cardiovascular event **reinforces the complex comorbid nature of obesity and CVD**, which in turn shapes the framework for how I approach clinical practice and patient care."[1,6]

Q What is your take-home message from the results?

A "This is clearly telling me that if I have a patient with obesity or overweight who has established cardiovascular disease, they are at significant risk of having another life-threatening event despite management of CV risk factors with current standard of care. **Adding semaglutide 2.4 mg** to the current cardiovascular armamentarium **is an important strategy to help mitigate their risk of subsequent cardiovascular events**."[1,2,5]

Important Safety Information

Warnings and Precautions (cont'd)

- **Acute Kidney Injury:** There have been postmarketing reports of acute kidney injury and worsening of chronic renal failure, which in some cases required hemodialysis, in patients treated with semaglutide. Patients with renal impairment may be at a greater risk of acute kidney injury, but some events have been reported in patients without known underlying renal disease. A majority of the events occurred in patients who experienced nausea, vomiting, or diarrhea, leading to volume depletion. Monitor renal function when initiating or escalating doses of Wegovy® in patients reporting severe adverse gastrointestinal reactions and in patients with renal impairment reporting any adverse reactions that could lead to volume depletion
- **Hypersensitivity Reactions:** Serious hypersensitivity reactions (e.g., anaphylaxis, angioedema) have been reported with Wegovy®. If hypersensitivity reactions occur, discontinue use of Wegovy®, treat promptly per standard of care, and monitor until signs and symptoms resolve. Use caution in a patient with a history of anaphylaxis or angioedema with another GLP-1 receptor agonist
- **Diabetic Retinopathy Complications in Patients with Type 2 Diabetes:** In a trial of adult patients with type 2 diabetes, diabetic retinopathy was reported by 4.0% of Wegovy® patients and 2.7% of placebo patients. Rapid improvement in glucose control has been associated with a temporary worsening of diabetic retinopathy. Patients with a history of diabetic retinopathy should be monitored for progression of diabetic retinopathy

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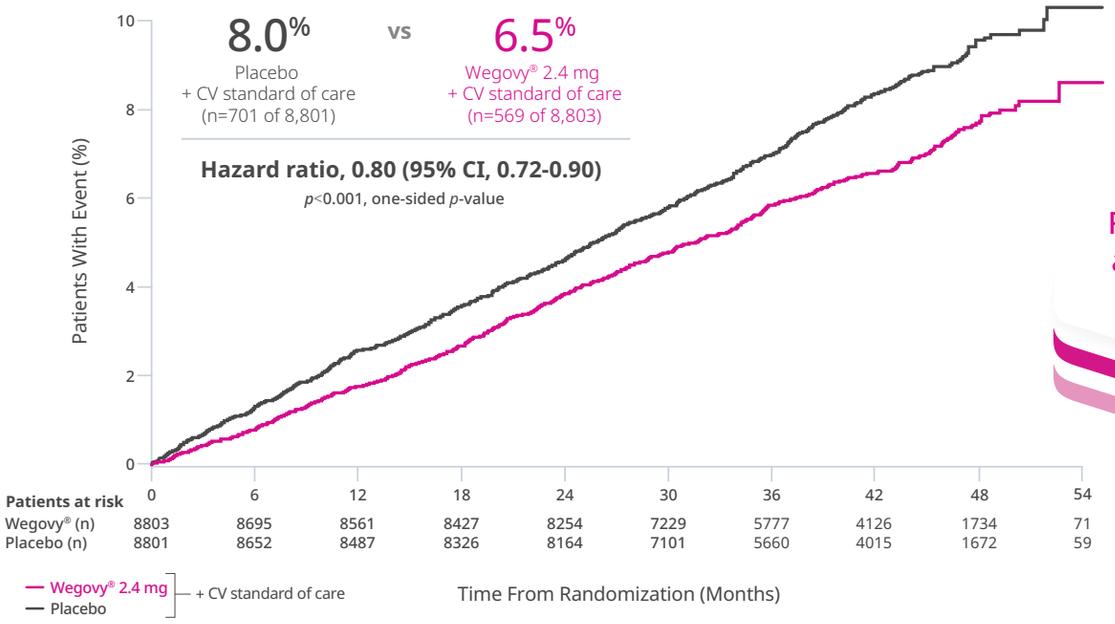
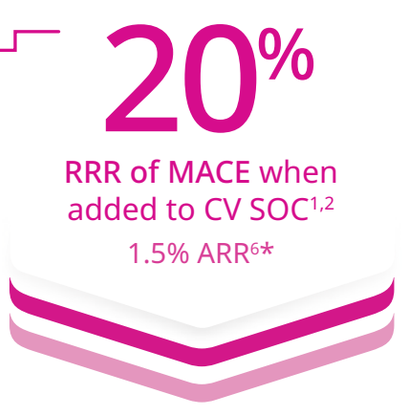
SELECT CVOT: Primary efficacy endpoint

Primary composite endpoint: Time to first occurrence of MACE (CV death, non-fatal MI, or non-fatal stroke)[1,2]





Cumulative incidence function: Time to first occurrence of 3-part MACE. Data from the in-trial period.[1,2]

SELECT: A multi-national, double-blind, placebo-controlled, event-driven CV outcomes trial of 17,604 adults with BMI ≥27 kg/m^2 and established CVD (prior MI, prior stroke, or PAD) designed to assess superiority of once-weekly Wegovy® 2.4 mg vs placebo (1:1 randomization) for time to first MACE. Both groups received current standard of care, including CV risk factor management and individualized healthy lifestyle counseling (including diet and physical activity); concomitant CV therapies could be adjusted at the discretion of the investigator to ensure participants were treated according to the current standard of care for patients with established CVD. Patients with a history of type 1 or type 2 diabetes were excluded. Median duration of follow-up was 41.8 months. During the trial, 31% of patients in the Wegovy® arm discontinued treatment compared with 27% in the placebo arm. 16% of Wegovy®-treated patients and 8% of placebo-treated patients discontinued study drug due to an adverse event.[1,2]

The exact mechanism of cardiovascular risk reduction of Wegovy® has not been established.[1]

*1.5% ARR at 40 months (mean duration of follow-up).[6]

ARR, absolute risk reduction; BMI, body mass index; CI, confidence interval; CV, cardiovascular; CVD, cardiovascular disease; CVOT, cardiovascular outcomes trial; MACE, major adverse cardiovascular events; MI, myocardial infarction; PAD, peripheral arterial disease; RRR, relative risk reduction; SOC, standard of care.

Important Safety Information

Warnings and Precautions (cont'd)

- **Heart Rate Increase:** Mean increases in resting heart rate of 1 to 4 beats per minute (bpm) were observed in Wegovy® adult patients compared to placebo in clinical trials. More Wegovy® adult patients compared with placebo had maximum changes from baseline of 10 to 19 bpm (41% versus 34%) and 20 bpm or more (26% versus 16%). In a clinical trial in pediatric patients aged 12 years and older with normal baseline heart rate, more patients treated with Wegovy® compared to placebo had maximum changes in heart rate of 20 bpm or more (54% versus 39%). Monitor heart rate at regular intervals and instruct patients to report palpitations or feelings of a racing heartbeat while at rest. If patients experience a sustained increase in resting heart rate, discontinue Wegovy®

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In addition to MACE risk reduction, what else did we learn about Wegovy® in the SELECT CVOT?

Clinical Perspectives with Cardiologist Dr Sanjay Rajagopalan

Q: What role do the confirmatory and other secondary endpoints play in clinical decision-making?

A: "The study used a gate-keeping testing strategy with statistical significance at each step required to test the next hypothesis. CV death was the first confirmatory secondary endpoint tested, and superiority was not confirmed. Therefore, all-cause death was not statistically significant. The other secondary endpoints shown in the table to the right were not included in the prespecified testing hierarchy. Nevertheless, **I consider this important hypothesis-generating information and share it with my patients as appropriate**."[1,2]

Q: What do the cardiometabolic findings, assessed as supportive secondary endpoints, reveal about semaglutide 2.4 mg?

A: "I found the improvements in several cardiometabolic risk factors, including body weight, blood pressure, and atherogenic lipids were as **expected based on the results from its prior studies**. Overall, these findings have further shaped my perspective and understanding of semaglutide 2.4 mg." [1,2]

Q: As a cardiologist, how do you discuss the weight loss shown in the SELECT clinical study?[1,2]

A: "For my patients with cardiovascular disease and obesity or overweight, **weight can be an important consideration**. I find it helpful that in addition to impacting the risk of a subsequent MACE, semaglutide 2.4 mg also has the added benefit of weight loss. That is how I characterize it with my patients."[1,2,4,8,9]

Important Safety Information

Warnings and Precautions (cont'd)

- **Suicidal Behavior and Ideation:** Suicidal behavior and ideation have been reported in clinical trials with other weight management products. Monitor patients for depression, suicidal thoughts or behavior, and/or any unusual changes in mood or behavior. Discontinue Wegovy® in patients who experience suicidal thoughts or behaviors and avoid in patients with a history of suicidal attempts or active suicidal ideation

Adverse Reactions

Most common adverse reactions (incidence ≥5%) are: nausea, diarrhea, vomiting, constipation, abdominal pain, headache, fatigue, dyspepsia, dizziness, abdominal distention, eructation, hypoglycemia in patients with type 2 diabetes, flatulence, gastroenteritis, gastroesophageal reflux disease, and nasopharyngitis

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SELECT CVOT: Secondary endpoints

Treatment effect for other events in SELECT[1]

	Patients with events n (%)		
Key secondary endpoints	Wegovy® N=8,803	Placebo N=8,801	Hazard Ratio (95% CI)
CV death*	223 (2.5%)	262 (3.0%)	0.85 (0.71; 1.01)
All-cause death†	375 (4.3%)	458 (5.2%)	0.81 (0.71; 0.93)
Other secondary endpoints			
Fatal or non-fatal myocardial infarction‡	243 (2.8%)	334 (3.8%)	0.72 (0.61; 0.85)
Fatal or non-fatal stroke‡	160 (1.8%)	178 (2.0%)	0.89 (0.72; 1.11)

*CV death was the first confirmatory secondary endpoint in the testing hierarchy and superiority was not confirmed.
†Confirmatory secondary endpoint. Not statistically significant based on the prespecified testing hierarchy.
‡Not included in the prespecified testing hierarchy for controlling type-I error.

Mean changes in cardiometabolic parameters in SELECT[1,2]

Supportive secondary endpoints§	Wegovy® change from baseline to Week 104	Placebo change from baseline to Week 104
Body weight‖	↓ 9.4%	↓ 0.9%
Waist circumference	↓ 3 inch	↓ 0.4 inch
Systolic blood pressure	↓ 3.8 mmHg	↓ 0.5 mmHg
Diastolic blood pressure	↓ 1.0 mmHg	↓ 0.5 mmHg
Heart rate	↑ 3.8 bpm	↑ 0.7 bpm
A1c	↓ 0.3%	0.0% change
Total cholesterol	↓ 4.6%	↓ 1.9%
LDL	↓ 5.3%	↓ 3.1%
HDL	↑ 4.9%	↑ 0.6%
Triglycerides	↓ 18.3%	↓ 3.2%

Wegovy® is not indicated to treat hypertension, type 2 diabetes, or dyslipidemia.[1]

§Supportive secondary efficacy endpoints were not included in the statistical testing hierarchy and, as such, the analyses were not adjusted for multiplicity.[1,2]
‖Mean baseline body weight: Wegovy®=212.8 lbs, placebo=213.4 lbs.[1]

A1c, glycated hemoglobin; bpm, beats per minute; CI, confidence interval; CV, cardiovascular; CVOT, cardiovascular outcomes trial; HDL, high-density lipoprotein; LDL, low-density lipoprotein; MACE, major adverse cardiovascular events.

Important Safety Information

Drug Interactions

- The addition of Wegovy® in patients treated with insulin has not been evaluated. When initiating Wegovy®, consider reducing the dose of concomitantly administered insulin secretagogues (such as sulfonylureas) or insulin to reduce the risk of hypoglycemia
- Wegovy® causes a delay of gastric emptying and has the potential to impact the absorption of concomitantly administered oral medications. Monitor the effects of oral medications concomitantly administered with Wegovy®

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"Typically, cardiologists are obsessed with CV outcomes, endocrinologists are focused on metabolic conditions, and obesity medicine specialists zone in on weight management, so **the SELECT study may be relevant across specialties.**"

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Considerations for clinicians, including cardiologists

Before the SELECT clinical study, **in my practice** I immediately initiated or optimized cardiovascular standard-of-care therapies in patients with obesity or overweight and established CVD to manage their CV risk. I also counseled those patients on weight management strategies, given the connection between obesity (especially visceral adiposity) and CVD risk. Today, I take all those steps and **consider adding semaglutide 2.4 mg to their treatment plan, in combination with lifestyle modifications, because it has been proven effective at lowering the risk of MACE and also helping patients manage their weight.**"[1,2,4,8,9]

For clinicians outside of cardiology, you may have engaged in challenging discussions about lifestyle adjustments for some time with your patients with obesity as a critical step toward providing care. The SELECT study emphasizes the importance of exploring additional treatment options for addressing CV risk in patients with obesity and established CVD. It provides another rationale for **considering semaglutide 2.4 mg in addition to its impact on long-term weight management for patients requiring pharmacological support.**"[1]

As clinicians, **we should aim for a comprehensive approach to health care**. Managing obesity and CVD is not territorial. It's not organ-based, it's not specialty-based. **Managing obesity needs to be everybody's responsibility**."

To learn more about the SELECT clinical study, please visit

WegovyPro.com

CV, cardiovascular; CVD, cardiovascular disease; MACE, major adverse cardiovascular events.

Important Safety Information

Use in Specific Populations

- **Pregnancy:** May cause fetal harm. When pregnancy is recognized, discontinue Wegovy®. Discontinue Wegovy® in patients at least 2 months before a planned pregnancy
- **Pediatric**: Adverse reactions with Wegovy® in pediatric patients aged 12 years and older were similar to those reported in adults. Pediatric patients ≥12 years of age treated with Wegovy® had greater incidences of cholelithiasis, cholecystitis, hypotension, rash, and urticaria compared to adults treated with Wegovy®. There are insufficient data in pediatric patients with type 2 diabetes treated with Wegovy® for obesity to determine if there is an increased risk of hypoglycemia with Wegovy® treatment similar to that reported in adults
- **Geriatric**: In the cardiovascular outcomes trial, patients aged 75 years and older reported more hip and pelvis fractures on Wegovy® than placebo. Patients aged 75 years and older (Wegovy® and placebo) reported more serious adverse reactions overall compared to younger adult patients

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References: 1. Wegovy® [package insert]. Plainsboro, NJ: Novo Nordisk Inc. **2.** Lincoff AM, Brown-Frandsen K, Colhoun HM, et al. Semaglutide and cardiovascular outcomes in obesity without diabetes. *N Engl J Med*. 2023;389(24):2221-2232. **3.** Khafagy R, Dash S. Obesity and cardiovascular disease: the emerging role of inflammation. *Front Cardiovasc Med.* 2021;8:768119. doi:10.3389/fcvm.2021.768119. **4.** Powell-Wiley TM, Poirier P, Burke LE, et al; American Heart Association Council on Lifestyle and Cardiometabolic Health; Council on Cardiovascular and Stroke Nursing; Council on Clinical Cardiology; Council on Epidemiology and Prevention; Stroke Council. Obesity and cardiovascular disease: a scientific statement from the American Heart Association. *Circulation.* 2021;143(21):e984-e1010. **5.** Dhindsa DS, Sandesara PB, Shapiro MD, Wong ND. The evolving understanding and approach to residual cardiovascular risk management. *Front Cardiovasc Med.* 2020;7:88. doi:10.3389/fcvm.2020.00088. **6.** Data on file. Plainsboro, NJ: Novo Nordisk Inc. 2024. **7.** Semaglutide effects on heart disease and stroke in patients with overweight or obesity (SELECT). ClinicalTrials.gov identifier: NCT03574597. Updated February 14, 2024. Accessed March 21, 2024. https://classic.clinicaltrials.gov/ct2/show/NCT03574597. **8.** Lopez-Jimenez F, Almahmeed W, Bays H, et al. Obesity and cardiovascular disease: mechanistic insights and management strategies. A joint position paper by the World Heart Federation and World Obesity Federation. *Eur J Prev Cardiol.* 2022;29(17):2218-2237. **9.** Tondt J, Freshwater M, Hurtado Andrade M, et al. Obesity algorithm 2024. Obesity Medicine Association. January 2024. Accessed March 21, 2024. https://obesitymedicine.org/resources/obesity-algorithm/.

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