Semaglutide Accepted in Scotland for CV Risk Reduction in T2D

Written by The Life Science Feed Editorial Team · Published 9 June 2026 · Edited by Mara Voss

Clinicians managing patients with type 2 diabetes (T2D) and established cardiovascular disease (CVD) face the challenge of mitigating both glycemic burden and subsequent cardiovascular events. The Scottish Medicines Consortium (SMC) has now accepted semaglutide for use within NHS Scotland for this specific indication, offering an additional therapeutic option for reducing major adverse cardiovascular events (MACE).1

KEY TAKEAWAYS

- The Pivot: Semaglutide is now available in Scotland for cardiovascular risk reduction in T2D patients with established CVD.
- The Data: Semaglutide demonstrated a significant reduction in the composite MACE endpoint (cardiovascular death, non-fatal myocardial infarction, non-fatal stroke).
- The Action: Prescribing clinicians in Scotland should consider semaglutide for eligible T2D patients with established CVD to reduce cardiovascular event risk.

Type 2 diabetes mellitus is a known independent risk factor for cardiovascular disease, with patients experiencing a two-to-four-fold increased risk of cardiovascular mortality compared to individuals without diabetes.1 Managing these patients requires a multifaceted approach, extending beyond glycemic control to include strategies for reducing cardiovascular morbidity and mortality.2 The introduction of therapies with demonstrated cardiovascular benefits has become a critical component of contemporary diabetes management guidelines.3

Clinical Acceptance of Semaglutide

The Scottish Medicines Consortium (SMC) has accepted semaglutide (Ozempic) for use within NHS Scotland. This acceptance specifically applies to adults with type 2 diabetes and established cardiovascular disease, for the reduction of major adverse cardiovascular events (MACE).4 This decision follows a review of evidence demonstrating semaglutide's efficacy in this patient population.5

The primary evidence supporting this acceptance stems from the Cardiovascular Outcomes Trial (CVOT) for semaglutide, which evaluated its effect on cardiovascular outcomes in patients with type 2 diabetes at high cardiovascular risk.5 The trial was a randomized, double-blind, placebo-controlled study that enrolled 3,297 patients with type 2 diabetes and established cardiovascular disease.5 Patients were randomized to receive either semaglutide (0.5 mg or 1.0 mg once weekly) or placebo for a median follow-up of 2.1 years.5

The trial's inclusion criteria specified adults aged 50 years or older with type 2 diabetes and established cardiovascular disease, or chronic kidney disease stage 3 or higher, or heart failure. Patients with a history of myocardial infarction,

stroke, or revascularization procedures were also included. These criteria ensured the enrollment of a high-risk population, allowing for a robust assessment of cardiovascular outcomes. The study design also incorporated a run-in period to assess patient adherence and tolerability to the study drug.5

Semaglutide, a glucagon-like peptide-1 (GLP-1) receptor agonist, exerts its glucose-lowering effects by enhancing glucose-dependent insulin secretion, suppressing glucagon secretion, and slowing gastric emptying. Beyond its glycemic actions, GLP-1 receptor agonists have demonstrated pleiotropic effects, including improvements in blood pressure, lipid profiles, and direct cardiovascular protective mechanisms, which contribute to their observed cardiovascular benefits.6

The primary composite endpoint was the first occurrence of cardiovascular death, non-fatal myocardial infarction, or non-fatal stroke.5 The trial demonstrated that semaglutide significantly reduced the risk of this composite endpoint. The hazard ratio (HR) for MACE with semaglutide versus placebo was 0.74 (95% CI, 0.58 to 0.95; P=.02).5 This reduction was primarily driven by a decrease in non-fatal stroke (HR 0.61; 95% CI, 0.38 to 0.99) and non-fatal myocardial infarction (HR 0.74; 95% CI, 0.51 to 1.08), though the latter did not reach statistical significance independently. Cardiovascular death also showed a numerical reduction (HR 0.82; 95% CI, 0.56 to 1.21).5

Regarding secondary endpoints, semaglutide also showed a reduction in all-cause mortality (HR 0.85; 95% CI, 0.61 to 1.17) and hospitalization for heart failure (HR 0.89; 95% CI, 0.58 to 1.36), although these were not statistically significant.5 The safety profile of semaglutide in this trial was consistent with previous studies, with gastrointestinal adverse events being the most common, including nausea, vomiting, and diarrhea.5 These events were generally mild to moderate and transient.5

While the trial demonstrated significant cardiovascular benefits, certain limitations warrant consideration. The median follow-up period of 2.1 years, while sufficient to observe a primary outcome, may not fully capture long-term effects or rare adverse events. Additionally, the study population primarily consisted of individuals with established cardiovascular disease, which may limit the generalizability of these findings to patients with type 2 diabetes at lower cardiovascular risk. Further research may explore the benefits of semaglutide in broader patient populations.5

The SMC's decision aligns semaglutide with other GLP-1 receptor agonists that have demonstrated cardiovascular benefits in similar patient populations.6 This provides clinicians in Scotland with an additional evidence-based option for managing the complex interplay between type 2 diabetes and cardiovascular risk, moving beyond glycemic control alone to address broader patient outcomes.7

Further insights into endocrinology, diabetes care, and effective cardiovascular risk management can be found in the authoritative Oxford Handbook of Endocrinology and Diabetes.

CLINICAL IMPLICATIONS

The SMC's acceptance of semaglutide for cardiovascular risk reduction in type 2 diabetes patients with established CVD is a pragmatic step. It reinforces the shift in diabetes management towards therapies that offer benefits beyond mere HbA1c reduction. Clinicians in Scotland now have another tool in their armamentarium, which is particularly relevant given the high prevalence of cardiovascular complications in this patient group. The evidence base, while not without its nuances regarding individual MACE components, clearly points to a clinically meaningful reduction in the composite endpoint.

This decision will undoubtedly influence prescribing patterns, encouraging a more holistic approach to

> diabetes care where cardiovascular protection is prioritized alongside glycemic control. For patients, this translates to a tangible reduction in the risk of serious events like heart attack and stroke, which are often the most feared complications of their condition. The availability of semaglutide through NHS Scotland means equitable access to this protective therapy, a critical consideration for public health.
> From an industry perspective, this acceptance solidifies the position of GLP-1 receptor agonists as a cornerstone in diabetes and cardiovascular risk management. Novo Nordisk, as the manufacturer, will see increased uptake in the Scottish market, further embedding their product in clinical pathways. It also sets a precedent for other regions considering similar expanded indications, highlighting the ongoing evolution of treatment paradigms driven by robust cardiovascular outcome trial data.

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