NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Health Technology Evaluation

Tirzepatide for reducing the risk of major adverse cardiovascular events in people with type 2 diabetes and cardiovascular disease ID6733

Draft scope

Draft remit/evaluation objective

To appraise the clinical and cost effectiveness of tirzepatide within its marketing authorisation for reducing the risk of major adverse cardiovascular events in people with type 2 diabetes and cardiovascular disease.

Background

Diabetes mellitus is a chronic metabolic disorder characterised by elevated blood glucose levels (hyperglycaemia) resulting from a lack of the hormone insulin or resistance to its action. Type 2 diabetes results from reduced insulin secretion or reduced tissue sensitivity to insulin (known as insulin resistance).[1]

Cardiovascular disease (CVD) refers to a range of conditions affecting the health and circulatory systems. CVD is typically associated with the build-up of fatty deposits (atherosclerosis) in the blood vessels which leads to them becoming blocked, increasing a person's risk of cardiovascular events including angina, heart attacks, heart failure, arrhythmias and certain strokes.[2]

Around 4.4 million adults have been diagnosed with diabetes in the UK, with around 90% of those diagnosed living with type 2 diabetes.[3] About 7.6 million people in the UK are living with CVD.[3] Adults with diabetes are 2 to 3 times more likely to develop heart and circulatory diseases, and are nearly twice as likely to die from heart disease or stroke (as those without diabetes). In the UK, one third of adults with diabetes die from a heart or circulatory disease.[3]

Management of type 2 diabetes and CVD involves lifestyle interventions such as dietary changes, weight management, increasing physical activity and smoking cessation; along with lipid-lowering and antiplatelet treatments and treatments to control blood glucose and blood pressure.

For adults with type 2 diabetes and atherosclerotic cardiovascular disease, NICE guideline 28 type 2 diabetes in adults: management recommends offering modified-release metformin (if appropriate), an SGLT-2 inhibitor and subcutaneous semaglutide (Ozempic), up to 1 mg once weekly, for its cardiovascular, renal and glycaemic benefits.

The technology

Tirzepatide (Mounjaro, Eli Lilly) does not currently have a marketing authorisation in the UK for reducing the risk of major adverse cardiovascular events in people with type 2 diabetes and CVD. It has been studied in a phase 3 clinical trial compared with dulaglutide, for reducing major adverse cardiovascular events in people with controlled type 2 diabetes and established CVD. This included people with coronary artery disease, cerebrovascular disease or peripheral arterial disease.

Tirzepatide is already licensed for the treatment of insufficiently controlled type 2 diabetes mellitus in adults, and in adolescents and children aged 10 years and above as an adjunct to diet and exercise. It is recommended as monotherapy when metformin is considered inappropriate, or in addition to other medicinal products for the treatment of diabetes.

Intervention	Tirzepatide with established clinical management such as modified-release metformin and an SGLT-2 inhibitor
Population	Adults with controlled type 2 diabetes and established cardiovascular disease including coronary artery disease, cerebrovascular disease or peripheral arterial disease
Subgroups	If the evidence allows the following subgroups will be considered: • People with coronary artery disease • People with cerebrovascular disease • People with peripheral arterial disease • Subgroups according to calculated baseline risk of cardiovascular events • Subgroups based on body mass index (BMI)
Comparators	• Established clinical management such as modified-release metformin and an SGLT-2 inhibitor **without** subcutaneous semaglutide (Ozempic) up to 1 mg weekly • Established clinical management such as modified-release metformin and an SGLT-2 inhibitor **with** subcutaneous semaglutide (Ozempic) up to 1 mg weekly

Outcomes	The outcome measures to be considered include: • heart function • non-fatal stroke • non-fatal myocardial infarction • symptoms of heart failure • hospitalisation for heart failure • all-cause hospitalisation • mortality • cardiovascular mortality • kidney function • development of diabetes • treatment discontinuation • health-related quality of life • adverse effects of treatment
Economic analysis	The reference case stipulates that the cost effectiveness of treatments should be expressed in terms of incremental cost per quality-adjusted life year. The reference case stipulates that the time horizon for estimating clinical and cost effectiveness should be sufficiently long to reflect any differences in costs or outcomes between the technologies being compared. Costs will be considered from an NHS and Personal Social Services perspective. The availability of any commercial arrangements for the intervention, comparator and subsequent treatment technologies will be taken into account. The availability and cost of biosimilar and generic products should be taken into account.
Other considerations	Guidance will only be issued in accordance with the marketing authorisation. Where the wording of the therapeutic indication does not include specific treatment combinations, guidance will be issued only in the context of the evidence that has underpinned the marketing authorisation granted by the regulator.
Related NICE recommendations	**Related technology appraisals:** Tirzepatide for treating type 2 diabetes NICE technology appraisal guidance 924 (2023, updated 2025) Semaglutide for reducing the risk of major adverse cardiovascular events in people with cardiovascular disease

	and overweight or obesity. NICE technology appraisal guidance 1152 (2026) **Related NICE guidelines:** Type 2 diabetes in adults: management NICE guideline NG28 (2015 updated 2026) Cardiovascular disease: risk assessment and reduction, including lipid modification NICE guideline NG238 (2023) **Related quality standards:** Type 2 diabetes in adults NICE quality standard 209 (2023 updated 2026) Cardiovascular risk assessment and lipid modification NICE quality standard 100 (2015 updated 2025) Secondary prevention after a myocardial infarction NICE quality standard 99 (2015)

Questions for consultation

Where do you consider tirzepatide will fit into the existing care pathway for type 2 diabetes and cardiovascular disease?

Would tirzepatide displace semaglutide (Ozempic) for people having semaglutide (Ozempic) 1 mg weekly in combination with modified-release metformin and an SGLT-2 inhibitor, in line with NG28?

Would tirzepatide displace semaglutide (Wegovy) 2.4 mg weekly for people eligible for treatment in line with TA1152?

Please select from the following, will tirzepatide be:
A. Prescribed in primary care with routine follow-up in primary care
B. Prescribed in secondary care with routine follow-up in primary care
C. Prescribed in secondary care with routine follow-up in secondary care
D. Other (please give details):
For comparators and subsequent treatments, please detail if the setting for prescribing and routine follow-up differs from the intervention.

Would tirzepatide be a candidate for managed access?

Do you consider that the use of tirzepatide can result in any potential substantial health-related benefits that are unlikely to be included in the QALY calculation?

Please identify the nature of the data which you understand to be available to enable the committee to take account of these benefits.

NICE is committed to promoting equality of opportunity, eliminating unlawful discrimination and fostering good relations between people with particular protected characteristics and others. Please let us know if you think that the proposed remit and scope may need changing in order to meet these aims. In particular, please tell us if the proposed remit and scope:

- could exclude from full consideration any people protected by the equality legislation who fall within the patient population for which tirzepatide will be licensed;

- could lead to recommendations that have a different impact on people protected by the equality legislation than on the wider population, e.g. by making it more difficult in practice for a specific group to access the technology;

- could have any adverse impact on people with a particular disability or disabilities.

Please tell us what evidence should be obtained to enable the committee to identify and consider such impacts.

NICE intends to evaluate this technology through its Single Technology Appraisal process. (Information on NICE's health technology evaluation processes is available at https://www.nice.org.uk/about/what-we-do/our-programmes/nice-guidance/nice-technology-appraisal-guidance/changes-to-health-technology-evaluation).

References

1. NHS Diabetes. Accessed June 2026.

2. British Heart Foundation, Cardiovascular disease. Accessed June 2026.

3. British Heart Foundation, UK Factsheet. Accessed June 2026.