NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Health Technology Evaluation

Semaglutide for preventing major cardiovascular events in people with cardiovascular disease and living with overweight or obesity ID6441

Draft scope

Draft remit/evaluation objective

To appraise the clinical and cost effectiveness of semaglutide within its anticipated marketing authorisation for preventing major cardiovascular events in people with cardiovascular disease and living with overweight or obesity.

Background

Cardiovascular disease 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[1]. In the UK it is estmiated that around 1 in 6 heart and circulatory deaths are associated with a high body mass index (BMI)[2]

Around 2.3 million people are living with some form of heart disease (around 1.5 million men and 830,000 women) and was the leading cause of death worldwide in 2019[3]. A number of risk factors increase the risk of both developing CVD and experiencing a CV event. These include being overweight or obese, smoking, stress, alcohol use, high blood pressure and high cholesterol. Additionally, people with a family history or CVD are at increased risk, risk increases with age, men are more likely to develop CVD earlier and people from certain ethnic backgounds are at increased risk.[1] In 2021, 26% of adults in England has obesity.

NICE Clinical Guideline 238 recommendations for the prevention of secondary cardiovascular events focuses on lowering levels of lipoproteins. It recommends offering atorvastatin for secondary prevention and, if further treatment is required, to consider other lipid-lowering treatments (such as alirocumab, evolocumab, ezetimibe and inclisiran). It recommends a low-density lipoprotein (LDL) cholesterol target of 2.0 mmol per litre or less, or non-high density lipoprotein (non-HDL) levels of 2.6 mmol per litre or less for the secondary prevention of cardiovascular disease.

NICE also recommends the following treatments for the secondary prevention of cardiovascular events

- NICE technology appraisal 805 recommends icosapent ethyl with statin therapy for reducing the risk of cardiovascular events in people with raised triglycerides
- NICE technology appraisal 607 recommends rivaroxaban for preventing atherothrombotic events in people with coronary or peripheral artery disease
- NICE technology appraisal 420 recommends ticagrelor for preventing atherothrombotic events after myocardial infarction

The technology

Semaglutide (Wegovy, Novo Nordisk) does not currently have a marketing authorisation in the UK for preventing major cardiovascular events in people with cardiovascular disease and living with overweight or obesity. It has been studied in a randomised controlled trial compared with placebo in adults aged 45 years or older with cardiovascular disease and a body-mass index of 27 or more.

Intervention(s)	Semaglutide
Population(s)	Adults with a diagnosis of cardiovascular disease and a BMI of at least 27 kg/m^2
Subgroups	None
Comparators	Established clinical management for the prevention of CV events without semaglutide
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 • health-related quality of life. • kidney function • 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:** Alirocumab for treating primary hypercholesterolaemia and mixed dyslipidaemia (2016) NICE technology appraisal guidance 393. Evolocumab for treating primary hypercholesterolaemia and mixed dyslipidaemia (2016) NICE technology appraisal guidance 394 Ezetimibe for treating primary heterozygous-familial and non-familial hypercholesterolaemia (2016) NICE technology appraisal guidance 385. Icosapent ethyl with statin therapy for reducing the risk of cardiovascular events in people with raised triglycerides (2022) NICE technology appraisal 805 Inclisiran for treating primary heterozygous-familial and non-familial hypercholesterolaemia (2016) NICE technology appraisal guidance 733. Rivaroxaban for preventing atherothrombotic events in people with coronary or peripheral artery disease (2019) NICE technology appraisal 607 Ticagrelor for preventing atherothrombotic events after myocardial infarction (2016) NICE technology appraisal 420

	Related NICE guidelines: Cardiovascular disease: risk assessment and reduction. Including lipid management (2023). NICE guideline 238. Cardiovascular disease: risk assessment and reduction. Including lipid management (2023). NICE clinical guideline 189.
Related National Policy	NHS England (2023) The NHS long term plan NHS England (2023) Manual for prescribed specialised services. Chapter 7 Adult specialist cardiac services NHS England Cardiac services: Extra corporeal membrane oxygenation service for adults with cardiac failure NHS Digital (2022) NHS Outcomes Framework England, March 2022 Annual Publication

Questions for consultation

Where do you consider semaglutide will fit into the existing care pathway for preventing cardiovascular events in people with cardiovascular disease and living with overweight or obesity?

Would semaglutide be an add-on treatment to existing therapies?

Which treatments for preventing cardiovascular events could semaglutide displace?

Please select from the following, will semaglutide 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 semaglutide be a candidate for managed access?

Do you consider that the use of semaglutide 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 semaglutide 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. British Heart Foundation. Cardiovascular heart disease (2019). Available from: https://www.bhf.org.uk/informationsupport/conditions/cardiovascular-heart-disease.

2. NHS England. Health Survey for England, 2021 part 1 (2022). Available from: https://digital.nhs.uk/data-and-information/publications/statistical/health-survey-for-england/2021/overweight-and-obesity-in-adults

3. British Heart Foundation. UK factsheet (2024). Available from: https://www.bhf.org.uk/-/media/files/for-professionals/research/heart-statistics/bhf-cvd-statistics-uk-factsheet.pdf