

## NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

## Health Technology Evaluation

## Semaglutide for preventing major cardiovascular events in people with cardiovascular disease and overweight or obesity [ID6441]

## Final scope

**Remit/evaluation objective**

To appraise the clinical and cost effectiveness of semaglutide within its marketing authorisation for reducing the risk of major cardiovascular events in people with cardiovascular disease and 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<sup>1</sup>. In the UK it is estimated that around 1 in 6 heart and circulatory deaths are associated with a high body mass index (BMI).<sup>2</sup>

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<sup>3</sup>. A number of risk factors increase the risk of both developing CVD and experiencing a CV event. These include overweight or obesity, smoking, stress, alcohol use, high blood pressure, high cholesterol, chronic kidney disease and diabetes. Additionally, people with a family history of CVD are at increased risk, risk increases with age, men are more likely to develop CVD earlier and people from certain family and socioeconomic backgrounds are at increased risk.<sup>1</sup> In 2021, 26% of adults in England had 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.

Final scope for the evaluation of semaglutide for preventing major cardiovascular events in people with cardiovascular disease and living with overweight or obesity [ID6441]

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### The technology

Semaglutide (Wegovy, Novo Nordisk) has a marketing authorisation in the UK 'as an adjunct to 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 (BMI  $\geq$  27 kg/m<sup>2</sup>)'. It has been studied in a randomised controlled trial compared with placebo in adults aged 45 years or older with cardiovascular disease and a BMI of 27 or more. People with type 1 or type 2 diabetes were excluded. Semaglutide has also been studied in a randomised controlled trial compared with placebo in adults with insufficiently controlled type 2 diabetes and at high risk of cardiovascular events.

<b>Intervention(s)</b>	Semaglutide (Wegovy)
<b>Population(s)</b>	Adults with established cardiovascular disease (previous myocardial infarction, stroke or symptomatic peripheral arterial disease) and a BMI of at least 27 kg/m <sup>2</sup>
<b>Subgroups</b>	<p>If the evidence allows the following subgroups will be considered:</p> <ul style="list-style-type: none"> <li>• People with BMI &gt; 35</li> <li>• People with previous myocardial infarction</li> <li>• People with previous stroke</li> <li>• People with symptomatic peripheral arterial disease</li> <li>• People with heart failure</li> <li>• People with chronic kidney disease</li> <li>• Subgroups according to calculated baseline risk of cardiovascular events</li> </ul>
<b>Comparators</b>	Established clinical management for the prevention of CV events without semaglutide

<b>Outcomes</b>	<p>The outcome measures to be considered include:</p> <ul style="list-style-type: none"> <li>• heart function</li> <li>• non-fatal stroke</li> <li>• non-fatal myocardial infarction</li> <li>• symptoms of heart failure</li> <li>• hospitalisation for heart failure</li> <li>• all-cause hospitalisation</li> <li>• mortality</li> <li>• cardiovascular mortality</li> <li>• kidney function</li> <li>• development of diabetes</li> <li>• treatment discontinuation</li> <li>• health-related quality of life</li> <li>• adverse effects of treatment</li> </ul>
<b>Economic analysis</b>	<p>The reference case stipulates that the cost effectiveness of treatments should be expressed in terms of incremental cost per quality-adjusted life year.</p> <p>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.</p> <p>Costs will be considered from an NHS and Personal Social Services perspective.</p> <p>The availability of any commercial arrangements for the intervention, comparator and subsequent treatment technologies will be taken into account.</p> <p>The availability and cost of biosimilar and generic products should be taken into account.</p>
<b>Other considerations</b>	<p>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.</p>
<b>Related NICE recommendations</b>	<p><b>Related technology appraisals:</b></p> <p>Alirocumab for treating primary hypercholesterolaemia and mixed dyslipidaemia (2016) <a href="#">NICE technology appraisal guidance 393</a>.</p>

	<p>Evolocumab for treating primary hypercholesterolaemia and mixed dyslipidaemia (2016) <a href="#">NICE technology appraisal guidance 394</a></p> <p>Ezetimibe for treating primary heterozygous-familial and non-familial hypercholesterolaemia (2016) <a href="#">NICE technology appraisal guidance 385</a></p> <p>Icosapent ethyl with statin therapy for reducing the risk of cardiovascular events in people with raised triglycerides (2022) <a href="#">NICE technology appraisal 805</a></p> <p>Inclisiran for treating primary heterozygous-familial and non-familial hypercholesterolaemia (2016) <a href="#">NICE technology appraisal guidance 733</a></p> <p>Rivaroxaban for preventing atherothrombotic events in people with coronary or peripheral artery disease (2019) <a href="#">NICE technology appraisal 607</a></p> <p>Ticagrelor for preventing atherothrombotic events after myocardial infarction (2016) <a href="#">NICE technology appraisal 420</a></p> <p>Semaglutide for managing overweight and obesity (2023) <a href="#">NICE technology appraisal 875</a></p> <p><b>Related NICE guidelines:</b></p> <p>Cardiovascular disease: risk assessment and reduction. Including lipid management (2023). <a href="#">NICE guideline 238</a>.</p> <p>Cardiovascular disease: risk assessment and reduction. Including lipid management (2023). <a href="#">NICE clinical guideline 189</a>.</p>
<b>Related National Policy</b>	<p>NHS England (2023) <a href="#">The NHS long term plan</a></p> <p>NHS England (2023) Manual for prescribed specialised services. Chapter <a href="#">7 Adult specialist cardiac services</a></p> <p>NHS England Cardiac services: <a href="#">Extra corporeal membrane oxygenation service for adults with cardiac failure</a></p> <p>NHS Digital (2022) <a href="#">NHS Outcomes Framework England, March 2022 Annual Publication</a></p>

## 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>