

NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Health Technology Evaluation

Empagliflozin for preventing cardiovascular events after acute myocardial infarction ID6240

Draft scope

**Draft remit/evaluation objective**

To appraise the clinical and cost effectiveness of Empagliflozin within its marketing authorisation for the treatment of adults to prevent cardiovascular events after an acute myocardial infarction.

**Background**

Acute Myocardial Infarction (AMI) is a health emergency where the heart's blood supply is suddenly blocked, often by a clot. Following AMI people may develop heart failure, in which the heart cells are damaged, and the heart is unable to pump blood around the body properly (HF). Symptoms of heart failure include breathlessness, feeling lightheaded or fainting, coughing, swollen ankles, less ability to exercise, and tiredness.

In England, 2021-22 data showed 5,848 cases of AMI, leading to 2,838 hospital admissions.<sup>1</sup> AMI is more common in men than women.<sup>2</sup>

NICE [guideline 185 for acute coronary syndromes](#) recommends offering drug therapy for secondary prevention after a myocardial infarction. These include angiotensin-converting enzyme (ACE) inhibitors, dual anti-platelet therapy, beta-blockers, and statins. For people who are intolerant to ACE inhibitors an angiotensin II blocker may be offered. For people for whom beta-blockers are contraindicated or need to be discontinued, diltiazem or verapamil may be considered. For people who have had an acute MI and who have symptoms and/or signs of heart failure and reduced left ventricular ejection fraction an aldosterone antagonist licensed for post-MI treatment may be used.

**The technology**

Empagliflozin (Jardiance, Boehringer Ingelheim) currently has marketing authorisation in the UK for treating chronic heart failure with reduced ejection fraction and chronic heart failure with preserved or mildly reduced ejection fraction. Empagliflozin does not currently have a marketing authorisation in the UK for use after an acute myocardial infarction.

It has been studied in clinical trials compared with placebo in adults who have had a myocardial infarction. In these trials people had usual standard care alongside empagliflozin or placebo. The purpose of the trials was to assess whether empagliflozin reduced heart failure and death following an acute myocardial infarction.

<b>Intervention(s)</b>	Empagliflozin as an add on treatment to standard management
<b>Population(s)</b>	Adults who have had an acute myocardial infarction (AMI)
<b>Comparators</b>	<p>Established clinical management without empagliflozin which may include:</p> <ul style="list-style-type: none"> <li>• ACE inhibitors (or angiotensin-II receptor antagonists)</li> <li>• aldosterone antagonists in people with HF with reduced ejection fraction</li> <li>• dual anti-platelet therapy</li> <li>• beta-blockers</li> <li>• calcium channel blockers such as diltiazem or verapamil) if <math>\beta</math>-blockers are contraindicated or need to be discontinued)</li> <li>• statins</li> </ul>
<b>Outcomes</b>	<p>The outcome measures to be considered include:</p> <ul style="list-style-type: none"> <li>• heart function</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>• adverse effects of treatment</li> <li>• health-related quality of life.</li> </ul>

<p><b>Economic analysis</b></p>	<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>If the technology is likely to provide similar or greater health benefits at similar or lower cost than technologies recommended in published NICE technology appraisal guidance for the same indication, a cost comparison may be carried out.</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>
<p><b>Other considerations</b></p>	<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>
<p><b>Related NICE recommendations</b></p>	<p><b>Related technology appraisals:</b></p> <p><a href="#">Empagliflozin for treating chronic heart failure with preserved or mildly reduced ejection fraction</a>. NICE guideline [TA929] Published date: 1 March 2023</p> <p><a href="#">Empagliflozin for treating chronic heart failure with reduced ejection fraction</a>. NICE guideline [TA773] Published date: 9 March 2022</p> <p><b>Related NICE guidelines:</b></p> <p><a href="#">Acute coronary syndromes</a>. NICE guideline [NG185] Published date: 18 November 2020</p> <p><a href="#">Chronic heart failure in adults: diagnosis and management</a>. NICE guideline [NG106] Published date: 12 September 2018</p> <p><a href="#">Secondary prevention after a myocardial infarction</a>. NICE Quality standard [QS99] Published: 04 September 2015</p> <p><a href="#">Acute heart failure: diagnosis and management</a>. NICE Clinical guideline [CG187] Published date: 08 October 2014</p>

	<p><b>Related NICE guidelines in development:</b>  <a href="#">Chronic heart failure in adults: diagnosis and management - Pharmacological treatment of chronic heart failure</a>. In development [GID-NG10405] Expected publication date: TBC</p>
<p><b>Related National Policy</b></p>	<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 <a href="#">Cardiac services: 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>

### Questions for consultation

Where do you consider empagliflozin will fit into the existing care pathway people who have had an acute myocardial infarction?

Are the outcomes appropriate?

Would empagliflozin be a candidate for managed access?

Do you consider that the use of empagliflozin 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 empagliflozin 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>).

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### References

1. NHS Digital. Hospital Admitted Patient Care Activity, 2021-22. 2022. Available from: <https://digital.nhs.uk/data-and-information/publications/statistical/hospital-admittedpatient-care-activity/2021-22>
2. Gale C. Acute coronary syndrome in adults: Scope of the problem in the UK. Br J Cardiol. 2017;24:3-9. <http://dx.doi.org/10.5837/bjc.2017.s01>.