NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Health Technology Evaluation

Finerenone for treating heart failure with preserved or mildly reduced ejection fraction ID6514

Draft scope

Draft remit/evaluation objective

To appraise the clinical and cost effectiveness of finerenone within its marketing authorisation for treating heart failure with preserved or mildly reduced ejection fraction.

Background

Heart failure is a complex clinical syndrome of signs and symptoms, generally defined as the inability of the heart to supply sufficient blood flow to meet the body's needs. It is caused by structural or functional abnormalities of the heart, commonly resulting from coronary artery disease. Other conditions that can increase the risk of heart failure include: atrial fibrillation, valve disease, hypertension, amyloidosis, anaemia, and thyroid gland diseases.[1] The European Society of Cardiology (ESC) defines 3 types of chronic heart failure based on left ventricular ejection fraction (LVEF), a measurement of how much blood the left ventricle pumps out with each contraction. The ESC defines heart failure with reduced ejection fraction as a LVEF of 40% or less; mildly reduced ejection fraction as a LVEF between 41% and 49%; and preserved ejection fraction as a LVEF of 50% or more.[2] NICE guideline 106 for chronic heart failure in adults (NG106) states that heart failure with preserved ejection fraction is usually associated with impaired left ventricular relaxation, rather than left ventricular contraction, and is characterised by normal or preserved LVEF with evidence of diastolic dysfunction. Symptoms of heart failure commonly include breathlessness, fatigue and ankle swelling. Quality of life is affected by the physical limitations imposed by the symptoms.

In 2023/24, there were more than 650,000 people in England registered as having heart failure, with around 50% expected to have preserved or mildly reduced ventricular ejection fraction.[2,3] There were 104,336 hospitalisations in England for heart failure in 2023/24.[4] Both the prevalence and incidence of heart failure increase with age. Around 24% of people diagnosed with heart failure die within the first year, with a 5-year mortality rate of about 55%.[5]

TA902 recommends dapagliflozin for treating chronic heart failure with preserved or mildly reduced ejection fraction. TA929 recommends empagliflozin for treating chronic heart failure with preserved or mildly reduced ejection fraction. NG106 recommends low to medium dose loop diuretics for people with chronic heart failure with preserved ejection fraction. Specialist advice is needed if the disease does not respond. People with chronic heart failure with preserved ejection fraction may also have symptomatic treatments for comorbidities, including angiotensin-converting enzyme (ACE) inhibitors, angiotensin-receptor blockers (ARBs), or beta-blockers.

The technology

Finerenone (Kerendia, Bayer) does not currently have a marketing authorisation for treating heart failure with preserved or mildly reduced ejection fraction. It has been studied in clinical trials compared with placebo in people with heart failure with preserved or mildly reduced ejection fraction.

Intervention(s)	Finerenone
Population(s)	People with heart failure with preserved or mildly reduced ejection fraction
Comparators	• Dapagliflozin • Empagliflozin • Established clinical management without finerenone, including but not limited to loop diuretics and symptomatic treatments for co-morbidities
Outcomes	The outcome measures to be considered include: • symptoms of heart failure • hospitalisation for heart failure • all-cause hospitalisation • mortality • cardiovascular mortality • kidney function • adverse effects of treatment • health-related quality of life.

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. 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 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 of any managed access arrangement for the intervention 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:** Empagliflozin for treating chronic heart failure with preserved or mildly reduced ejection fraction (2023) NICE technology appraisal guidance 929 Dapagliflozin for treating chronic heart failure with preserved or mildly reduced ejection fraction (2023) NICE technology appraisal guidance 902 **Related NICE guidelines:** Chronic heart failure in adults: diagnosis and management (2018) NICE guideline NG106 Heart failure algorithms for remote monitoring in people with cardiac implantable electronic devices (2024) NICE diagnostics guidance DG61 **Related NICE guidelines in development:**

	Chronic heart failure in adults: diagnosis and management - Pharmacological treatment of chronic heart failure partial update of NG106 publication expected August 2025 **Related interventional procedures:** Permanent His-bundle pacemaker implantation for treating heart failure (2021) NICE Interventional Procedures Guidance IPG694 Cardiac contractility modulation device implantation for heart failure (2019) NICE Interventional Procedures Guidance IPG655 Implantation of a left ventricular assist device for destination therapy in people ineligible for heart transplantation (2015) NICE Interventional procedures guidance IPG516 **Related quality standards:** Chronic heart failure in adults (2011; last updated 2023) NICE quality standard 9

Questions for consultation

Will structural heart abnormalities or n-terminal prohormone B-type natriuretic peptide levels be included in considerations of eligibility for finerenone?

Where do you consider finerenone will fit into the existing care pathway for heart failure?

Would finerenone be used as an alternative to empagliflozin or dapagliflozin if approved?

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

Do you consider that the use of finerenone 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 finerenone 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 (2024) Understanding heart failure. Available at: https://www.bhf.org.uk/-/media/images/information-support/publications/understanding-series/2024-update/bhf-heart-failure-booklet-final-artwork.pdf?rev=9de9d0e465bf469bb4b50d823fea8fe9 Accessed March 2025

2. McDonagh, T.A., Metra, M., Adamo, M., et al. (2021) ESC Guidelines for the diagnosis and treatment of acute and chronic heart failure. European Heart Journal 42.36: 3599-3726.

3. NHS Digital (2024) Quality and Outcomes Framework, 2023-24. Prevalence at regional and national level. Available at: https://digital.nhs.uk/data-and-information/publications/statistical/quality-and-outcomes-framework-achievement-prevalence-and-exceptions-data/2023-24 Accessed March 2025

4. NHS Digital (2024) Hospital admitted patient care activity, 2023-24: Primary diagnosis 3 character. Available at: https://digital.nhs.uk/data-and-information/publications/statistical/hospital-admitted-patient-care-activity/2023-24 Accessed March 2025

5. Taylor CJ, Ordonez-Mena JM, Roalfe AK et al. (2019) Trends in survival after a diagnosis of heart failure in the United Kingdom 2000-2017: population based cohort study. BMJ 364:l223