

NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Health Technology Evaluation

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

Final scope

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 with evidence of structural and/or functional cardiac abnormalities and/or raised natriuretic peptides.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} However, registrations may underestimate the true prevalence due to underdiagnosis or cases not being coded in primary care. 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.

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Issue Date: August 2025

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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 in combination with standard care
Population(s)	People with heart failure with preserved or mildly reduced ejection fraction
Subgroups	• Comorbidities (including but not limited to Type 2 diabetes and Chronic Kidney Disease) • Mildly reduced or preserved ejection fraction (LVEF category) • Concomitant medications (including but not limited to SGLT2 inhibitors)
Comparators	Established clinical management without finerenone, including but not limited to SGLT2 inhibitors, 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 September 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
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