National Institute for Health and Care Excellence

Health Technology Evaluation

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

Response to stakeholder organisation comments on the draft remit and draft scope

Please note: Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees.

Comment 1: the draft remit and proposed process

Section	Stakeholder	Comments [sic]	Action
	Bayer (company)	This topic is appropriate for a NICE appraisal. Heart failure with preserved or mildly reduced ejection fraction (HFmrEF or HFpEF), is associated with an elevated lifelong risk of premature mortality, frequent hospitalisations, and poor health outcomes [1]. Additionally, overlapping comorbidities contribute to patients' risk of heart failure events and death [2]. In England, more than 670,000 people were registered as having heart failure in 2023/24. [3] HFmrEF or HFpEF represents approximately half of all heart failure cases [4]. There are limited approved treatments with proven efficacy that can modify the disease trajectory for HFmrEF or HFpEF [5]. Critical gaps in care persist, attributable to the high residual risk that remains despite available treatments. References	Thank you for your comment. No action required.

Section	Stakeholder	Comments [sic]	Action
		1. Shah, Kevin S et al. “Heart Failure With Preserved, Borderline, and Reduced Ejection Fraction: 5-Year Outcomes.” Journal of the American College of Cardiology vol. 70,20 (2017): 2476-2486. 2. Tomasoni, Daniela, et al. "The role of multimorbidity in patients with heart failure across the left ventricular ejection fraction spectrum: Data from the Swedish Heart Failure Registry." European Journal of Heart Failure 26.4 (2024): 854-868. 3. Quality and Outcomes Framework, 2023-24 - NHS Digital. Accessed May 2025 4. Owan, Theophilus E et al. “Trends in prevalence and outcome of heart failure with preserved ejection fraction.” The New England journal of medicine vol. 355,3 (2006): 251-9. 5. **Heidenreich, Paul A et al. “2022 AHA/ACC/HFSA Guideline for the Management of Heart Failure: A Report of the American College of Cardiology/American Heart Association Joint Committee on Clinical Practice Guidelines.” Journal of the American College of Cardiology vol. 79,17 (2022): e263-e421.**	
	AstraZeneca (comparator)	AstraZeneca considers the proposed evaluation of finerenone to be appropriate.	Thank you for your comment. No action required.
	British Cardiovascular Society	Satisfactory	Thank you for your comment. No action required.
	British Society for Heart Failure (BSH)	The British Society for Heart Failure (BSH) welcome the evaluation and support the single technology appraisal route.	Thank you for your comment. No action required.
	Primary Care Cardiovascular Society	This will need to be done as single TA as the heart failure guidelines are already being reviewed and are due to publication in the next 6 months	Thank you for your comment. No action required.
	Pumping Marvellous Foundation	It is appropriate to evaluate this single technology.	Thank you for your comment. No action required.

Section	Stakeholder	Comments [sic]	Action
	UKCPA	Very appropriate – currently there are limited treatments used for the management of heart failure with mildly reduced and preserved ejection fraction. Single technology appraisal	Thank you for your comment. No action required.
Wording	Bayer (company)	Yes, the wording of the remit is appropriate, as it addresses the issue(s) of clinical and cost effectiveness for this technology. The population stated in the remit corresponds with the population investigated in the FINEARTS-HF trial (i.e. people with heart failure with preserved or mildly reduced ejection fraction, left ventricular ejection fraction [LVEF]≥40) [6]. This trial is the key study for finerenone regarding this indication. References 6. Solomon, Scott D., et al. "Finerenone in heart failure with mildly reduced or preserved ejection fraction." New England Journal of Medicine 391.16 (2024): 1475-1485.	Thank you for your comment. No action required.
	AstraZeneca (comparator)	AstraZeneca considers the wording of the remit to be appropriate.	Thank you for your comment. No action required.
	British Cardiovascular Society	Satisfactory	Thank you for your comment. No action required.
	British Society for Heart Failure (BSH)	No alternative wording suggested.	Thank you for your comment. No action required.

Section	Stakeholder	Comments [sic]	Action
	Primary Care Cardiovascular Society	Yes	Thank you for your comment. No action required.
	Pumping Marvellous Foundation	The only consideration for change is the population size NG106 and NHSE in 2018 stated the population size is 920,000 people. It is recognised that primary care registries re highly inaccurate then should not be used in this TA. Also as a note NG106 is being replaced by a revised guideline and does not reflect current clinical practice in the UK so should not be used. The patients groups represented in this TA are not represented appropriately with NG106.	Thank you for your comment. The number of registrations cited in the scope uses the most recent data available and notes that it relates to registrations. A note has been added to recognise that registrations may underestimate the true prevalence. Current clinical practice will be considered within the appraisal process, with inputs from the company submission and other stakeholders.
	UKCPA	No, the current wording of the remit does not adequately reflect the key issues of clinical and cost effectiveness that NICE should consider. There is lack of reference to credible data such as the number needed to treat (NNT) to support the cost effectiveness or impact on patient outcomes. Furthermore, the remit omits mention of pivotal clinical evidence from the FINEARTS trial which is essential for evaluating the clinical value of the technology appraisal.	Thank you for your comment. Cost-effectiveness will be considered in terms of cost per QALY gained. Evidence from trials will be considered as part of

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			submissions from the company and other stakeholders.
Timing issues	Bayer (company)	Despite the recent approval of a single class of NICE-recommended medications for HFmrEF or HFpEF, treatment choices continue to be limited. While newer therapies have the potential to change the progression of the disease, there remains a lingering risk of negative cardiovascular outcomes. Notwithstanding new treatments, there were over 100,000 heart failure hospitalisations recorded in England in 2023/24 [7]. In 2024, over 400,000 people were awaiting routine cardiac care in England [8]. Waiting time targets for hospital and community services are largely unmet, with some locations reporting waits of over 100 days. Heart failure services in UK hospitals struggle to meet these waiting time targets for both referrals and post-discharge follow-ups. They offer only a limited number of weekly clinics, and nearly one-third of these services do not review patients who were primarily admitted for HFpEF. In a survey of community heart failure services in the UK, only two-thirds of the services reviewed HFmrEF, and just over half reviewed HFpEF. In contrast, all services reviewed heart failure with reduced ejection fraction (HFrEF) [9,13]. Longer waiting times for treatment increases the risk of disability from heart failure and premature death. Heart failure reduces life expectancy, with a 10-year survival rate of 24.5% [10]. Following a hospitalisation for HF, the 5-year survival rate in people with HF and an LVEF>40% is 35% [11]. Heart failure cases are projected to nearly double by 2040 [12]. Given the inadequate recording of heart failure subtypes in England [14], this number could potentially rise even further. It is crucial for NICE to evaluate finerenone. This medicine has a different mode of action compared to the currently recommended treatments for HFmrEF or HFpEF, and there is proven evidence of its benefits [6]. Additionally, considerations regarding	Thank you for your comment. The appraisal will follow scheduled timelines

Section	Stakeholder	Comments [sic]	Action
		waiting times, costly hospitalisations and disease prognosis further emphasize the importance of this appraisal. References 7. 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 May 2025 8. British Heart Foundation https://www.bhf.org.uk/what-we-do/policy-and-public-affairs/hearts-need-more/table-showing-number-of-patients-waiting-for-heart-tests-and-procedures-in-england Accessed May 2025 9. Chun et al. Heart failure services from the hospital perspective in the UK: a cross-sectional survey Br J Cardiol 2025;32:14–8 doi:10.5837/bjc.2025.001 10. Taylor, Clare J., et al. "Trends in survival after a diagnosis of heart failure in the United Kingdom 2000-2017: population based cohort study." bmj 364 (2019). 11. Shah, Sanjiv J et al. “Research Priorities for Heart Failure With Preserved Ejection Fraction: National Heart, Lung, and Blood Institute Working Group Summary.” Circulation vol. 141,12 (2020): 1001-1026. 12. NHS England :Managing heart failure@home https://www.england.nhs.uk/nhs-at-home/managing-heart-failure-at-home/ Accessed May 2025 13. Masters et al. Heart failure services from the community perspective in the UK: a cross-sectional survey Br J Cardiol 2025;32(2)doi:10.5837/bjc.2025.018 14. **Bellanca, L., Linden, S., & Farmer, R. (2023). Incidence and prevalence of heart failure in England: a descriptive analysis of linked primary and secondary care data–the PULSE study. BMC Cardiovascular Disorders, 23(1), 374**	
	AstraZeneca (comparator)	AstraZeneca notes that patients with heart failure with preserved or mildly reduced ejection fraction (HFpEF, HFmrEF) in England currently have access to two NICE-recommended treatments (dapagliflozin, TA902; empagliflozin, TA929) (1, 2).	Thank you for your comment. The appraisal will follow scheduled timelines
	British Cardiovascular Society	There are large numbers of people with heart failure with preserved or mildly reduced ejection fraction who could benefit. Early appraisal and recommendations would prevent clinical events in this population.	Thank you for your comment. The appraisal will follow scheduled timelines

Section	Stakeholder	Comments [sic]	Action
	British Society for Heart Failure (BSH)	At present, SGLT2i are the only evidence-based therapy available for patients with HFmrEF / HFpEF. Sub-group analyses from the FINEARTS-HF trail suggest that the treatment benefits from Finerenone were observed irrespective of concomitant usage of SGLT2i, suggestive of an additive benefit in reduction of CV events in this patient population (HFmrEF / HFpEF). https://doi.org/10.1161/CIRCULATIONAHA.124.072055 Patient access to nsMRA, alongside use of SGLT2i will likely yield greater benefit for patients with HFmrEF/HFpEF, where at present, little treatment options currently exist.	Thank you for your comment. The appraisal will follow scheduled timelines
	Primary Care Cardiovascular Society	Ideally this evaluation should be completed in line with the timescale of a licence for this product	Thank you for your comment. The appraisal will follow scheduled timelines
	Pumping Marvellous Foundation	Urgent as it would be only the second prognostically valuable, QOL and cost effective treatment other than SGLT2i's for HFpEF and HFmrEF.	Thank you for your comment. The appraisal will follow scheduled timelines
	UKCPA	The evaluation is urgent. HFpEF and HFmrEF together account for around 50% of heart failure cases, with prevalence expected to double in the next decade. These phenotypes are linked to high rate of emergency admissions and readmissions, placing significant strain on NHS departments such as A+E.	Thank you for your comment. The appraisal will follow scheduled timelines

Section	Stakeholder	Comments [sic]	Action
		Given the limited treatment options for these patients, timely evaluation of effective therapies could help reduce hospital burden and improve patient outcomes.	

Comment 2: the draft scope

Section	Consultee/ Commentator	Comments [sic]	Action
Background information	AstraZeneca (comparator)	AstraZeneca acknowledges that the NICE chronic heart failure guidelines (NG106) are currently undergoing consultation, with anticipated publication on 3 September 2025. It is recommended to highlight this in the Background section.	Thank you for your comment. The publication date of the NG106 update has been updated to September 2025 in the 'Related NICE recommendations' section.
	British Cardiovascular Society	The data from 2023/24 relate to heart failure in general rather than Heart Failure with Preserved Ejection Fraction (HFpEF) and HF with mildly reduced EF (HFmrEF). The available figures may underestimate the true burden of HFpEF and HFmrEF as these diagnoses tend to be under diagnosed and not coded in primary care. The background does not reflect the problem that many existing heart failure pathways are exclusive to HF with reduced EF (HFrEF) – so this group of people are subject to health inequalities now that effective treatments are available. It is also important to note the effects of social deprivation on health outcomes. Poor lifestyle choices can impact prognosis.	Thank you for your comment. The scope is intended to provide a brief overview of the topic. The number of registrations cited in the scope uses the most recent data available and notes that it relates to registrations.

Section	Consultee/ Commentator	Comments [sic]	Action
	British Society for Heart Failure (BSH)	Consider alignment of HFpEF definition as per ESC 2021 Guidelines: "LVEF ≥ 50% with evidence of structural and/or functional abnormalities consistent with the presence of LV diastolic dysfunction/raised LV filling pressures, including raised natriuretic peptides"	Thank you for your comment. The definition of HFpEF in the background has been updated to "preserved ejection fraction as a LVEF of 50% or more with evidence of structural and/or functional cardiac abnormalities and/or raised natriuretic peptides."
	Pumping Marvellous Foundation	OK	Thank you for your comment. No action required.
	UKCPA	1. The draft remit and background information are broadly accurate and align well with current clinical understanding and guidelines. The definition of heart failure and the classification by left ventricular ejection fraction (LVEF) follows the 2021 ESC Guidelines, which is a reliable and appropriate reference point. The description of symptoms, underlying causes, and diagnostic criteria is also clinically sound. 2. The epidemiological data provided—such as the estimated number of people in England living with heart failure and associated hospitalisation rates—are credible and appropriately sourced from recent years (2023/24), suggesting current relevance. Mortality	Thank you for your comment. Evidence from trials will be considered as part of submissions from the company and other stakeholders. The scope is intended to be brief overview of the topic and does not include the pharmacological profile

Section	Consultee/ Commentator	Comments [sic]	Action
		statistics (24% at one year; 55% at five years) are consistent with published literature and reflect the severity of the condition. 3. In terms of treatment context, the background accurately notes current NICE technology appraisal guidance for dapagliflozin (TA902) and empagliflozin (TA929), which are now key therapies for patients with preserved or mildly reduced EF. The summary of NG106 guideline recommendations is also correct and helps establish the current standard of care. 4.There is no reference to pivotal trial (FINEARTS-HF). Including such data would provide context for the expected scope of the appraisal 5.There is no mention of finerenone pharmacological profile (a non-steroidal mineralocorticoid receptor antagonist	of the treatment(s) considered.
Population	Bayer (company)	The population is defined appropriately as it is aligned with the population investigated in the FINEARTS-HF trial (i.e. people with heart failure with preserved or mildly reduced ejection fraction [LVEF≥40]), which is the pivotal study for finerenone in HFmrEF or HFpEF.	Thank you for your comment. No action required.
	AstraZeneca (comparator)	AstraZeneca considers the population to be defined appropriately.	Thank you for your comment. No action required.

Section	Consultee/ Commentator	Comments [sic]	Action
	British Cardiovascular Society	Yes	Thank you for your comment. No action required.
	British Society for Heart Failure (BSH)	Consideration of HF phenotype definitions to align with current ESC guidelines (2021) ESC 2021 HF Guidelines	Thank you for your comment. The definition of HFpEF in the background has been updated to “preserved ejection fraction as a LVEF of 50% or more with evidence of structural and/or functional cardiac abnormalities and/or raised natriuretic peptides.”
	Primary Care Cardiovascular Society	Yes – includes al HFpEF and HFmrEF	Thank you for your comment. No action required.
	Pumping Marvellous Foundation	No – population size is inaccurate – see above. HFpEF and HFmrEF population defined clinically accurate.	Thank you for your comment. The number of registrations cited in the scope uses the most recent data available and notes that it relates to registrations. A note

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			has been added to recognise that registrations may underestimate the true prevalence.
	UKCPA	1. The population is relevant and appropriate for the appraisal and is consistent with clinical classifications used by the European Society of Cardiology (ESC). However, the population definition does not include important diagnostic elements such as signs and symptoms of heart failure using NYHA class, biomarkers such as NT-proBNP and exclusion criteria such as LVEF <40%. The definition used also does not address whether people with co-morbidities such as chronic kidney disease and diabetes are included or excluded.	Thank you for your comment. The population for the appraisal will be in line with the technology's marketing authorisation.
Subgroups	Bayer (company)	Bayer do not consider that there are any subgroups relevant for this appraisal. Finerenone will be positioned as an add-on therapy to standard of care for people with HFmrEF or HFpEF. Finerenone is the first selective, non-steroidal mineralocorticoid receptor antagonist (MRA) to show significant cardiovascular benefits in heart failure with LVEF≥40 [6]. Whilst finerenone's treatment benefit is consistent across all prespecified subgroups in the FINEARTS-HF study, broad use of finerenone will support improved cardiovascular outcomes for the HFmrEF or HFpEF population.	Thank you for your comment. No action required.
	AstraZeneca (comparator)	AstraZeneca regards the population without subgroups as likely to be appropriate.	Thank you for your comment. No action required.

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	British Cardiovascular Society	No	Thank you for your comment. No action required.
	British Society for Heart Failure (BSH)	Although HFmrEF and HFpEF are defined separately, the FINEARTS-HF study relates to patients with an LVEF > 40%, which encompasses both patient populations. Reference should be made to those with pre-existing chronic kidney disease (CKD) in patients with Type 2 Diabetes (T2DM), where NICE has made recommendations (TA877) for use of finerenone in this population, which frequently co-exists in patients with a diagnosis of heart failure.	Thank you for your comment. The scope is intended to be a brief overview of the topic area.
	Pumping Marvellous Foundation	No	Thank you for your comment. No action required.
	UKCPA	Yes, there are clinically relevant subgroups within the population of HFmREF and HFpEF in which finerenone may demonstrate differential clinical or cost effectiveness. Stratifying the population by 1. LVEF category – FINEARTS-HF – treatment benefit appeared more pronounced in people with LVEF 41-49% and this aligns with the observations from the SGLT2 inhibitor trials. Therefore, separating this subgroup could better identify where finerenone is most effective. 2. Presence CKD – a significant portion of enrolled patients in the FINEARTS-HF had impaired renal function therefore people with CKD and HF may derive greater absolute benefit. 3. Symptom severity – Patients with symptomatic heart failure and higher NT-proBNP experienced greater absolute risk reductions – therefore	Thank you for your comment. Subgroups for comorbidities, LVEF category and concomitant medications have been added

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		stratifying to symptomatic HF may reveal differences in the magnitude of benefit, particularly for quality of life and hospitalisation endpoints 4. Background treatments – Many patients in the FINEARTS-HF were on standard of care therapy including SGLT2 inhibitors. Therefore, evaluating cost effectiveness will require reviewing the incremental benefit of adding finerenone.	
Comparators	Bayer (company)	Bayer proposes that the most appropriate comparator, is established clinical management without finerenone, including but not limited to loop diuretics and symptomatic treatments for co-morbidities. Since being recommended by NICE in 2023, SGLT2is are considered part of established clinical management for HFmrEF or HFpEF. This is consistent with the design of the FINEARTS-HF trial, where SGLT2is were permitted background therapy as needed. In the FINEARTS-HF trial, approximately 15% of participants were on SGLT2i at baseline. [redacted] [15]. **Would finerenone be used as an alternative to empagliflozin or dapagliflozin if approved**? During multiple scientific exchanges with clinical experts across the UK, a clear consensus has emerged: finerenone and SGLT2 inhibitors are not alternative or competing therapies but rather complementary and additive treatments due to their distinct mechanisms of action. In the same way that we would not consider ACE inhibitors, beta blocker, MRA and SGLT2i alternative therapies, finerenone and SGLT2is are increasingly recognised as complementary components of a multi-pillar strategy for managing HFmrEF or HFpEF.	Thank you for your comment. Dapagliflozin and empagliflozin have been removed from the comparators section.

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		This perspective is strongly supported by the FINEARTS-HF SGLT2i subgroup analysis [18], which demonstrated that the cardiovascular benefits of finerenone were preserved irrespective of background SGLT2 inhibitor use, with no attenuation of effect. This reinforces the rationale for co-administration. The ESC-HFA 2025 Congress further validated this approach. Finerenone was prominently featured in cardio-kidney-metabolic (CKM) sessions and highlighted as the only MRA with proven efficacy in HFmrEF or HFpEF, with consistent benefits across LVEF strata. Updated international guidelines, including the iCardio Global HF Guidelines and Japanese JCS/JHFS 2025 Guideline on Diagnosis and Treatment of Heart Failure, now recognise finerenone as a core therapy in HFpEF, particularly in patients with cardiorenal comorbidities [24, 25]. Moreover, this viewpoint aligns with real-world clinical readiness, as outlined in the TITRATE-HF and STRONG-HF trials [19,20]. UK heart failure services are already experienced in initiating multiple therapies in close succession. The introduction of finerenone is not expected to necessitate significant changes to existing service structures. This seamless integration will leverage the current infrastructure and clinical expertise already embedded within heart failure services. However, the primary challenge may not lie in the use of these therapies themselves, but rather in the substantial increase in the number of patients now potentially eligible for treatment—particularly as nearly all individuals with HFpEF may qualify under the evolving evidence base and guideline updates. Advisory boards conducted across the UK confirm that clinicians view finerenone as a practical and scalable addition to the HFmrEF or HFpEF treatment pathway, particularly when used in combination with SGLT2 inhibitors.	

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		Where do you consider finerenone will fit into the existing care pathway for heart failure? Finerenone is anticipated to become an integral component in the current heart failure care pathway, particularly for patients with HFmrEF or HFpEF. These conditions impose a significant health burden, making effective treatments essential to improving outcomes. While SGLT2is are part of the standard guideline-directed medical therapy (GDMT) for these patients, they still face a considerable burden of morbidity and mortality. In the EMPEROR-PRESERVED trial, 13.8% of participants receiving SGLT2is experienced the primary endpoint of cardiovascular death or heart failure hospitalisation over a median follow up of 26 months [16]. Similarly, the DELIVER trial reported that 16.4% of patients on SGLT2is encountered occurrences of worsening heart failure or cardiovascular death over a median follow up of 2.3 years [17]. These figures underline the ongoing challenges and unmet needs in this patient population, despite the use of contemporary GDMT. This underscores the necessity for innovative therapies and better implementation strategies to further reduce risks and improve clinical outcomes for those with HFmrEF or HFpEF. Current Care Pathway and Guidelines: 1. NICE Guidelines: The NICE guideline NG106 for chronic heart failure in adults provides comprehensive recommendations for the diagnosis and management of chronic heart failure in individuals aged 18 and over. It emphasises the importance of a multi-therapy approach to optimize patient outcomes [22]. *We note that this guideline is under review*. 2. ESC Guidelines: The 2023 ESC Guidelines for the diagnosis and treatment of acute and chronic heart failure offer evidence-based recommendations for managing heart failure. These guidelines endorse the use of SGLT2 inhibitors and diuretics for patients with HFmrEF or HFpEF, underscoring the necessity of a multi-therapy strategy. Notably, the guideline	

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		also include a weak recommendation for the use of MRAs in patients with HFmrEF, reflecting emerging but limited evidence in this subgroup [23]. *Proposed Integration into Care Pathway*: Finerenone should be positioned as a complementary foundational therapy within the evolving care pathway for patients with HFmrEF or HFpEF. This aligns with the structured, multi-therapy model already established in HFrEF, where the early and combined use of ACE inhibitors or ARBs, beta-blockers, MRAs, and SGLT2 inhibitors has significantly improved clinical outcomes. In HFpEF, where pathophysiology is multifactorial and heterogeneous, a similar multi-pillar approach is increasingly supported. Finerenone, a non-steroidal MRA, offers a distinct mechanism of action—targeting mineralocorticoid receptor–mediated inflammation and fibrosis—complementary to the haemodynamic and metabolic effects of SGLT2is. The FINEARTS-HF trial demonstrated a 16% relative risk reduction in the primary composite outcome of heart failure events and cardiovascular death in patients with LVEF ≥40%, primarily through reduced hospitalisations [21]. A pre-specified subanalysis confirmed that this benefit was preserved irrespective of background SGLT2i use, with no attenuation of effect, i.e. confirming the additive benefit of these complementary therapies, reinforcing the rationale for their combined use [18]. This dual-action strategy is particularly relevant in HFpEF, where inflammation, fibrosis, congestion, and metabolic dysfunction often coexist. Finerenone's favourable safety profile—characterised by a low risk of serious hyperkalaemia and androgenic & progesterone related side effects—further supports its suitability for long-term use, especially in patients with cardiorenal comorbidities. Moreover, the Heart Failure Association (HFA) has acknowledged the need to extend the multi-pillar model to HFpEF as evidence accumulates. The	

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		STRONG-HF trial and recent guideline updates underscore the value of early, combined therapy initiation to improve outcomes [19]. Finerenone's inclusion as a core therapy in the iCardio Global HF Guidelines reflects this shift in clinical practice [24]. In summary, Finerenone should be integrated as a complementary, co-foundational therapy alongside SGLT2 inhibitors in HFmrEF or HFpEF—each addressing distinct yet synergistic disease pathways to deliver additive clinical benefit within a precision-based, phenotype-driven treatment strategy. References 15. Bayer Inc. Finerenone Clinical Study Report - [CONFIDENTIAL] 16. Solomon, Scott D., et al. "Dapagliflozin in heart failure with mildly reduced or preserved ejection fraction." New England Journal of Medicine 387.12 (2022): 1089-1098 17. Anker, Stefan D., et al. "Empagliflozin in heart failure with a preserved ejection fraction." New England Journal of Medicine 385.16 (2021): 1451-1461 18. Vaduganathan, Muthiah et al. "Effects of the Nonsteroidal MRA Finerenone With and Without Concomitant SGLT2 Inhibitor Use in Heart Failure." Circulation vol. 151,2 (2025): 149-158. doi:10.1161/CIRCULATIONAHA.124.072055 19. Mebazaa, Alexandre et al. "Safety, tolerability and efficacy of up-titration of guideline-directed medical therapies for acute heart failure (STRONG-HF): a multinational, open-label, randomised, trial." Lancet (London, England) vol. 400,10367 (2022): 1938-1952. doi:10.1016/S0140-6736(22)02076-1 20. Savarese, Gianluigi et al. "Heart failure drug titration, discontinuation, mortality and heart failure hospitalization risk: a multinational observational study (US, UK and Sweden)." European journal of heart failure vol. 23,9 (2021): 1499-1511. doi:10.1002/ejhf.2271 21. Docherty, Kieran F., et al. "Efficacy and Safety of Finerenone Across the Ejection Fraction Spectrum in Heart Failure With Mildly Reduced or Preserved Ejection Fraction: A Prespecified Analysis of the FINEARTS-HF Trial." Circulation 151.1 (2025): 45-58 22. NICE guideline NG106 Chronic heart failure in adults: diagnosis and management (2018) [Accessed May 2025] 23. European Society of Cardiology (ESC), 2023. *2023 Focused Update of the 2021 ESC Guidelines for the diagnosis and treatment of acute and chronic heart failure*. [https://www.escardio.org/Guidelines/Clinical-Practice-Guidelines/Focused-Update-on-Heart-Failure-Guidelines [Accessed May 2025] 24. iCARDIO Alliance Global Implementation Guidelines on Heart Failure 2025. (2025). *Global Cardiology*. https://doi.org/10.4081/cardio.2025.70 25. Kitai, Takeshi et al. "JCS/JHFS 2025 Guideline on Diagnosis and Treatment of Heart Failure." *Circulation journal : official journal of the Japanese Circulation Society*,. 2025, doi:10.1253/circj.CJ-25-0002	

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	AstraZeneca (comparator)	AstraZeneca recommends that the draft scope excludes SGLT2 inhibitors (dapagliflozin and empagliflozin) from the list of comparators. Finerenone is expected to be recommended as an add-on therapy to SGLT2 inhibitors, not as a replacement. There are currently no direct comparative studies between finerenone and SGLT2 inhibitors. The FINEARTS-HF trial (3) evaluated finerenone against a matched placebo alongside standard therapy, with 13.1% of patients in the finerenone group and 14.1% in the placebo group receiving SGLT2 inhibitors as part of their usual treatment at baseline. The expected positioning of finerenone as an add-on therapy to SGLT2 inhibitors would be in line with the positioning of finerenone in patients with chronic kidney disease in type 2 diabetes (TA877) (4). Therefore, including SGLT2 inhibitors as comparators does not accurately reflect the expected positioning of finerenone in clinical practice	Thank you for your comment. Dapagliflozin and empagliflozin have been removed from the comparators section.
	British Cardiovascular Society	Semaglutide is not included.	Thank you for your comment. Semaglutide does not have a marketing authorisation for treating heart failure with preserved or mildly reduced ejection fraction. There does not appear to be evidence that finerenone would displace the use of semaglutide in people with heart failure with preserved or mildly reduced ejection fraction.

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	British Society for Heart Failure (BSH)	Current comparators listed are standard treatments for management of patients with HFpEF. CV and Non-CV co-morbidity management is essential in this population and NICE may wish to consider links to existing NG documents including hypertension (NG136), atrial fibrillation NG196), type 2 diabetes (NG28), obstructive sleep apnoea (NG202), obesity (NG246) and related technologies published or under review (ID6441, TA875, TA1026). 2021 ESC HF guidelines (focused update) updated treatment options for patients with HFmrEF (LVEF 41-49%), with Class IIb ("may be considered") recommendations for ACEi/ARB/ARNI, Beta blockers and MRA. ESC 2021 HF Guidelines	Thank you for your comment. Current clinical practice will be considered within the appraisal process, with inputs from the company submission and other stakeholders.
	Primary Care Cardiovascular Society	Yes – but would need to consider this as an add-on therapy and not as an alternative to dapagliflozin/empagliflozin	Thank you for your comment. Dapagliflozin and empagliflozin have been removed from the comparators section.
	Pumping Marvellous Foundation	SGLT2i's are the only other treatment available in the NHS for HFpEF and HFmrEF patients. This doesn't mean they are comparators because they are the only potential comparator. As they are not the same drug class and there method of action is very different then we don't think there is an appropriate comparator.	Thank you for your comment. Dapagliflozin and empagliflozin have been removed from the comparators section.
	UKCPA	Yes, they are appropriate and reflect current standard care in the NHS for HFpEF and HFmrEF. All key relevant comparators have been included. It is important to clarify that finerenone is intended to be used in addition to SGLT2 inhibitors.	Thank you for your comment. Dapagliflozin and empagliflozin have been removed from the comparators section.

Section	Consultee/ Commentator	Comments [sic]	Action
Outcomes	Bayer (company)	The outcomes listed are those most clinically relevant to HFmrEF or HFpEF.	Thank you for your comment. No action required.
	AstraZeneca (comparator)	AstraZeneca considers the outcomes listed as appropriate.	Thank you for your comment. No action required.
	British Cardiovascular Society	Satisfactory	Thank you for your comment. No action required.
	British Society for Heart Failure (BSH)	Outcomes measures documented in the draft scope are appropriate.	Thank you for your comment. No action required.
	Pumping Marvellous Foundation	Symptoms of heart failure need to be better defined. Symptoms is too broad.	Thank you for your comment. The outcomes in the scope are intended to be broad and inclusive. The impact of individual symptoms will be considered in the course of the appraisal
	UKCPA	Yes, the listed outcomes are appropriate and will capture the key health-related benefits and harms of finerenone. No important outcomes appear to be missing.	Thank you for your comment. No action required.

Section	Consultee/ Commentator	Comments [sic]	Action
Equality	Bayer (company)	Recommending finerenone for HFmrEF or HFpEF and initiation in both primary and secondary care settings can help reduce the disparities in access to treatments for different socio-economic groups. This is crucial because UK data shows that in heart failure patients, survival is lower in the most deprived compared to the least deprived groups [10]. Further evidence shows that heart failure patients with lower socio-economic status have an increased risk of hospital re-admissions [26]. References 26. **Mathews, Lena, et al. "Impact of socioeconomic status on mortality and readmission in patients with heart failure with reduced ejection fraction: the ARIC study." Journal of the American Heart Association 11.18 (2022): e024057.**	Thank you for your comment. If relevant, issues related to socioeconomic status may be considered by the committee during the appraisal; this is noted in the equality impact assessment (EIA).
	AstraZeneca (comparator)	AstraZeneca does not identify any equity issues.	Thank you for your comment. No action required.
	Primary Care Cardiovascular Society	Need to consider carefully where finerenone will be prescribed. If it is limited to secondary care this will limit access to the medication as many patients will not be under the on-going secondary care follow up (particularly if they have been diagnosed some time ago and discharged to primary care for on-going management). Similarly if limited to heart failure services (secondary care or community nurse teams) the same problem will arise as this will depend on whether the service is commissioned to managed HFpEF or HFmrEF (as many HF services are commissioned based on ejection fraction and only accept HFrEF)	Thank you for your comment. NICE does not influence the prescribing location. The committee will consider the prescribing location where relevant.

Section	Consultee/ Commentator	Comments [sic]	Action
		Therefore – to enable access the best option is to limit to those with a HF diagnosis (based on NTproBNP and echo) but to allow prescribing and follow up in primary care This is the same approach that has been taken for finerenone in diabetic CKD (as many of these patients do not fall under the umbrella of specialist renal services)	
	Pumping Marvellous Foundation	OK	Thank you for your comment. No action required.
	UKCPA	The FINEARTS-HF trial enrolled over 6,000 patients with LVEF >40%. Although older adults with frailty, people with disabilities, and some ethnic groups remain under-represented, the trial notably included 43% women, a higher proportion than is typically seen in other heart failure trials. Similarly, while the majority of participants were white, the level of ethnic diversity aligns with that seen in other heart failure studies. Careful consideration is still needed to ensure the results are applicable across all demographic groups and to avoid unintentional exclusion of populations protected under the Equality Act.	Thank you for your comment. The committee will consider the baseline characteristics and generalisability of the trial during the appraisal.
Other considerations	Pumping Marvellous Foundation	What is the route to prescribing this medication and who prescribes it due to the fact that the vast majority of patients with HFpEF and HFmrEF reside in primary care with many legacy patients under primary care care, treatment and prescribing.	Thank you for your comment. NICE does not influence the prescribing location. The committee will consider the prescribing location where relevant.

Section	Consultee/ Commentator	Comments [sic]	Action
	UKCPA	1. Subgroup analyses by ejection fraction – HFmrEF vs HFpEF 2. Evaluation in people with CKD to determine if there are differential effectiveness or cost effectiveness in this subgroup 3. Clarify finerenone role relative to the SGLT2 inhibitors - whether as an alternative, an adjunct or use in specific subgroups	Thank you for your comment. The committee will consider whether there is evidence to suggest that HFmrEF and HFpEF should be considered separately
Questions for consultation	Bayer (company)	**Will structural heart abnormalities or n-terminal prohormone B-type natriuretic peptide levels be included in considerations of eligibility for finerenone?** The license indication in the Summary of Product Characteristics (SmPC) is anticipated to state: "[redacted]". The prescribing criteria are in line with NICE guideline 106, which recommends referring people with suspected heart failure and an NT-proBNP level between 400 and 2,000 ng/litre (47 to 236 pmol/litre) for specialist assessment and transthoracic echocardiography within 6 weeks. This was mirrored in the FINEARTS-HF study, which included patients with: • Evidence of structural heart disease • Elevated levels of natriuretic peptides: • NT-proBNP ≥300 pg/mL or BNP ≥100 pg/mL (sinus rhythm)	Thank you for your comment. The eligibility criteria for the appraisal will be in line with the technology's marketing authorisation.

Section	Consultee/ Commentator	Comments [sic]	Action
		• NT-proBNP ≥900 pg/mL or BNP ≥300 pg/mL (atrial fibrillation) This alignment ensures that no additional diagnosis or testing outside current recommended practice is needed to prescribe finerenone. Structural heart disease confirmation via echocardiography is a routine diagnostic procedure. 1. **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): Finerenone can be prescribed in both primary and secondary care settings, depending on the specific clinical context and care pathway. According to the prescribing model outlined in NICE TA877 for chronic kidney disease (CKD) associated with type 2 diabetes [27], Finerenone, may initially be prescribed in secondary care. However, as experience with the medication increases, it is likely to be prescribed more frequently in primary care. The NICE guideline on chronic heart failure [22] in adults emphasizes that a specialist heart failure multidisciplinary team should collaborate with the primary care team to initiate new medications that require specialist supervision. **For comparators and subsequent treatments, please detail if the setting for prescribing and routine follow-up differs from the intervention**. Comparators and subsequent treatments would be prescribed and followed up in the same setting.	

Section	Consultee/ Commentator	Comments [sic]	Action
		Would finerenone be a candidate for managed access? No. Bayer considers that the evidence for finerenone in HFmrEF or HFpEF is adequate to support the decision for routine commissioning in the NHS. No managed access arrangement is anticipated for finerenone in HFmrEF or HFpEF. Finerenone is currently recommended within its licensed authorisation for CKD in type 2 diabetes (TA877) and there is no managed access arrangement in place. Reference 27. Finerenone TA877 Finerenone in CKD with type 2 diabetes in adults available at https://www.nice.org.uk/guidance/ta877 **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**? Benefits likely underrepresented in conventional health economic assessments: *Reduction in New-Onset Diabetes* In the FINEARTS-HF trial, Finerenone was associated with a greater than 20% reduction in new-onset diabetes compared to placebo. This outcome has significant implications for long-term morbidity and healthcare resource use, particularly in patients with HFpEF who are already at elevated cardiometabolic risk [28]. *Lower Risk of New-Onset Atrial Fibrillation (AF)*	

Section	Consultee/ Commentator	Comments [sic]	Action
		Finerenone also demonstrated a reduced incidence of new-onset AF—a condition that substantially increases the risk of stroke, hospitalization, and mortality [29]. **Please identify the nature of the data which you understand to be available to enable the committee to take account of these benefits**. References 28. Butt, Jawad H., et al. "Finerenone and new-onset diabetes in heart failure: a prespecified analysis of the FINEARTS-HF trial." The Lancet Diabetes & Endocrinology 13.2 (2025): 107-118. **29.** Matsumoto, Shingo et al. “Finerenone and Atrial Fibrillation in Heart Failure: A Secondary Analysis of the FINEARTS-HF Randomized Clinical Trial.” JAMA cardiology, e250848. 29 Mar. 2025, doi:10.1001/jamacardio.2025.0848	
	AstraZeneca (comparator)	**Where do you consider finerenone will fit into the existing care pathway for heart failure?** SGLT2 inhibitors (dapagliflozin and empagliflozin) are the current standard of care for patients with HFpEF/HFmrEF in England. The European Society of Cardiology (ESC) guidelines recommend SGLT2 inhibitors as a Class I treatment for HFpEF/HFmrEF (evidence and/or general agreement that a given treatment or procedure is beneficial, useful, effective) (5). The NICE chronic heart failure guidelines (NG106) (6) are currently undergoing a consultation to be updated, and the positioning of SGLT2 inhibitors in these guidelines is expected to align with the ESC guidelines as both dapagliflozin and empagliflozin have received a technology appraisal guidance (1, 2). AstraZeneca believe that finerenone is expected to be recommended as an add-on therapy to SGLT2 inhibitors based on the trial evidence available in FINEARTS-HF (3), which evaluated finerenone against a matched placebo alongside standard therapy. As there are no direct comparative studies between finerenone and the current standard of care, SGLT2 inhibitors, finerenone should only be used as an add-on to SGLT2 inhibitors.	Thank you for your comment. Dapagliflozin and empagliflozin have been removed from the comparators section.

Section	Consultee/ Commentator	Comments [sic]	Action
		Would finerenone be used as an alternative to empagliflozin or dapagliflozin if approved? As stated above, AstraZeneca do not believe that finerenone would be used as an alternative to empagliflozin or dapagliflozin, as there are no direct comparative studies between finerenone and SGLT2 inhibitors. **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):** AstraZeneca believe that finerenone would be prescribed in the same setting as SGLT2 inhibitors, which includes all the above settings. **For comparators and subsequent treatments, please detail if the setting for prescribing and routine follow-up differs from the intervention.** AstraZeneca believe the prescribing and routine follow-up setting would be the same for all treatments in HFpEF/HFmrEF. **Would finerenone be a candidate for managed access?** AstraZeneca do not believe that finerenone would be a candidate for managed access.	

Section	Consultee/ Commentator	Comments [sic]	Action
	British Cardiovascular Society	Will structural heart abnormalities or n-terminal prohormone B-type natriuretic peptide levels be included in considerations of eligibility for finerenone? Yes they should be. This is particularly important in accurate diagnosis of patients with Heart Failure and preserved ejection fraction (HFpEF). Where do you consider finerenone will fit into the existing care pathway for heart failure? This needs to take into account that many current HF pathways are focused on HFrEF and exclude people with HFpEF and HFmrEF. However, increasingly HF of all types is managed by multidisciplinary teams in community and primary care. There is no reason why finerenone could not be included in management pathways based in community or primary care. The majority of eligible patients are in primary care and are not seen routinely in secondary care. Would finerenone be used as an alternative to empagliflozin or dapagliflozin if approved? No. Please select from the following, will finerenone be: A. Prescribed in primary care with routine follow-up in primary care Yes B. Prescribed in secondary care with routine follow-up in primary care Yes	Thank you for your comment. The eligibility criteria for the appraisal will be in line with the technology's marketing authorisation.

Section	Consultee/ Commentator	Comments [sic]	Action
		C. Prescribed in secondary care with routine follow-up in secondary care No D. Other (please give details): Should not be restricted to 'specialist' initiation, but can be initiated by any healthcare professional (HCP) with appropriate training and support from a multidisciplinary team with relevant expertise when needed. The majority of eligible patients are in primary care and are not seen routinely in secondary care. 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? No 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? No Please identify the nature of the data which you understand to be available to enable the committee to take account of these benefits. Finearts trial Finerenone in Heart Failure with Mildly Reduced or Preserved Ejection Fraction | New England Journal of Medicine	
	UKCPA	1. Yes, both structural heart abnormalities and NT-pro BNP should be considered when determining eligibility for finerenone in the evaluation. This will ensure the appraisal is in line with the evidence	Thank you for your comments. The eligibility criteria for the

Section	Consultee/ Commentator	Comments [sic]	Action
		base, ensure clinical relevance and enables appropriate targeting of finerenone to patients most likely to benefit, improving both cost effectiveness and clinical outcomes 2. Finerenone to be used as an adjunctive therapy to standard treatment in patients who remain symptomatic or recurrent hospitalisations particularly in patients with CKD or T2DM and have an elevated NT-proBNP and evidence of structural cardiac changes. 3. No. It should be positioned as an add-on therapy in patients with HFmrEF and HFpEF who continue to be symptomatic despite being prescribed SGLT2 inhibitors. No evidence currently supports its use instead of SGLT2 inhibitors in standard practice. 4. Finerenone should be available for prescription across all care sectors, consistent with the access provided for other mineralocorticoid receptor antagonists such as spironolactone and eplerenone. Ensuring unrestricted availability is essential to prevent barriers to uptake and to reduce health inequalities. 5. No. FINEARTS-HF was a large randomised controlled trial with a well-defined population powered to detect relevant outcomes. Furthermore, finerenone builds on an established drug class with known blood monitoring requirements. 6. No. 7. Must explicitly include and take account of key clinical evidence from the FINEARTS-HF trial.	appraisal will be in line with the technology's marketing authorisation. Dapagliflozin and empagliflozin have been removed from the comparators section of the scope.
Additional comments on the draft scope		No comments	

The following stakeholders indicated that they had no comments on the draft remit and/or the draft scope

List here