NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Final draft guidance

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

1 Recommendation

1.1 Finerenone can be used, within its marketing authorisation, as an option to treat symptomatic chronic heart failure with preserved or mildly reduced ejection fraction in adults.

What this means in practice

Finerenone must be funded in the NHS in England for the condition and population in the recommendations, if it is considered the most suitable treatment option. Finerenone must be funded in England within 90 days of final publication of this guidance.

There is enough evidence to show that finerenone provides benefits and value for money, so it can be used routinely across the NHS in this population.

Why the committee made this recommendation

Usual treatment for heart failure with preserved ejection fraction may include dapagliflozin or empagliflozin, spironolactone and diuretics. In addition to these medicines, usual treatment for heart failure with mildly reduced ejection fraction may also include an angiotensin-converting enzyme inhibitor or angiotensin-II receptor blocker, and a beta-blocker. People with heart failure may also have related health conditions such as diabetes, kidney disease and hypertension. The treatments for

other conditions may also help with their heart failure, so treatment options are tailored for each person.

Clinical-trial evidence shows that finerenone reduces the risk of heart-failure events that need an urgent visit to hospital or hospitalisation, compared with placebo. Finerenone may also reduce the risk of dying from cardiovascular or other causes, but the evidence for this is uncertain.

Finerenone has not been directly compared in a clinical trial with spironolactone in this population. The results of an indirect comparison and analyses using real-world evidence are uncertain, so it is unclear how well finerenone works compared with spironolactone. But the indirect comparison suggests that finerenone may work as well as spironolactone.

The cost-effectiveness estimates are within the range that NICE considers an acceptable use of NHS resources. So, finerenone can be used.

2 Information about finerenone

Marketing authorisation indication

2.1 Finerenone (Kerendia, Bayer) is indicated for 'the treatment of symptomatic chronic heart failure with left ventricular ejection fraction (LVEF) ≥40% in adults'.

Dosage in the marketing authorisation

2.2 The dosage schedule is available in the summary of product characteristics for finerenone.

Price

2.3 The list price of 10 mg and 20 mg finerenone is £36.68 per 28-tablet pack (excluding VAT; BNF online accessed June 2026).

2.4 Costs may vary in different settings because of negotiated procurement discounts.

Sustainability

2.5 Information on the Carbon Reduction Plan for UK carbon emissions for Bayer will be included here when guidance is published.

3 Committee discussion

The evaluation committee considered evidence submitted by Bayer, a review of this submission by the external assessment group (EAG), and responses from stakeholders. See the committee papers for full details of the evidence.

The condition

3.1 Chronic heart failure is when the heart is unable to pump enough blood to meet the body's needs. The left ventricular ejection fraction (LVEF) is the amount of blood pumped by the left ventricle during each heartbeat. It is often used to classify chronic heart failure with:

- preserved ejection fraction (LVEF of 50% or more)
- mildly reduced ejection fraction (LVEF of 41% to 49%)
- reduced ejection fraction (LVEF of 40% or less).

Symptoms of heart failure with preserved or mildly reduced ejection fraction include breathlessness, fatigue and ankle swelling, which can be substantial and affect daily life. A patient expert explained that hospital admissions can be frequent and prolonged, with an average length of stay of about 10 days. The clinical expert submission emphasised that recurrent hospital admissions can lead to progressive functional decline and have a detrimental impact on quality of life for people with the condition and their carers. The patient expert also explained that heart failure with preserved or mildly reduced ejection fraction is often associated with comorbidities such as chronic kidney disease, diabetes and other cardiovascular conditions. This can make the condition more difficult to manage. The committee understood that heart failure at any level of ejection fraction is associated with an

increased risk of mortality, particularly as it is more commonly diagnosed in older people. It acknowledged that heart failure with preserved or mildly reduced ejection fraction can be debilitating and have a substantial effect on quality and length of life.

Treatment pathway

Current treatment and unmet need

3.2 For heart failure with preserved ejection fraction, NICE's guideline on chronic heart failure in adults: diagnosis and management (NG106) recommends considering a mineralocorticoid receptor antagonist (MRA) and a sodium-glucose co-transporter-2 (SGLT2) inhibitor. For heart failure with mildly reduced ejection fraction, NG106 recommends considering an angiotensin-converting enzyme inhibitor (or, if not tolerated, an angiotensin-II receptor blocker) and a beta-blocker in addition to treatments recommended for heart failure with preserved ejection fraction. NG106 also recommends that all people with heart failure have rehabilitation and education, and diuretics if needed for congestion and fluid retention. The committee understood that the NG106 recommendations on MRA use in heart failure with preserved or mildly reduced ejection fraction may include steroidal MRAs (such as spironolactone or eplerenone) and non-steroidal MRAs (such as finerenone). It noted that steroidal and non-steroidal MRAs would not be used together. The committee also noted that SGLT2 inhibitors for heart failure with preserved or mildly reduced ejection fraction are recommended in NICE's technology appraisal guidance on dapagliflozin (TA902) and empagliflozin (TA929).

The patient submissions and technical engagement responses emphasised concerns about side effects with steroidal MRAs. These include hyperkalaemia, renal impairment, and anti-androgenic effects specifically with spironolactone (such as gynaecomastia in men). The clinical experts explained that heart failure with preserved or mildly

reduced ejection fraction is more common in older people with frailty and multiple comorbidities. So, steroidal MRAs are often not started or are not well tolerated. They explained that finerenone has a lower risk of anti-androgenic side effects and is more likely to be suitable for people with comorbidities such as hypotension or chronic kidney disease. The committee noted that this was supported by NICE's technology appraisal guidance on finerenone for treating chronic kidney disease in type 2 diabetes (TA877). The clinical experts explained that the risk of hyperkalaemia with finerenone is likely similar to spironolactone, but may be slightly lower. The patient and clinical experts described how SGLT2 inhibitors are currently the only disease-modifying treatments recommended for heart failure with preserved or mildly reduced ejection fraction, and that additional effective options are needed to improve outcomes and broaden the care pathway.

Positioning of finerenone and comparators

3.3 The company positioned finerenone as a treatment option to be added to standard of care for heart failure with preserved or mildly reduced ejection fraction, as defined in NG106. The committee understood that the comparator in the final scope was established clinical management without finerenone, including but not limited to SGLT2 inhibitors, loop diuretics and symptomatic treatment for comorbidities. The EAG considered that the company had excluded steroidal MRAs as a part of established clinical management (referred to as standard of care from here), which may not reflect clinical practice.

At technical engagement, the company and stakeholders emphasised that the uptake of steroidal MRAs is low and variable in clinical practice and they are often used for indications other than as a primary heart failure treatment. The company also emphasised that data from FINEARTS-HF and TOPCAT (see sections 3.4 to 3.6) were used to support the recommendation for all MRAs in NG106. So, it thought that it would be inappropriate to compare finerenone with steroidal MRAs based on a

recommendation that was made partly using evidence for finerenone. It did not consider that spironolactone was an appropriate comparator. The clinical experts explained that this reflects the lack of robust evidence to show that steroidal MRAs have a disease-modifying effect in heart failure with preserved or mildly reduced ejection fraction (see sections 3.6 to 3.8). They reiterated that steroidal MRA use is limited by tolerability concerns in the relevant population, because they are often older people with frailty and multiple comorbidities. They explained that anti-androgenic side effects with spironolactone can also limit use in men. The clinical experts stated that there is evidence to support the use of steroidal MRAs in heart failure with reduced ejection fraction, but uptake is relatively limited (up to about 40% of those eligible for treatment) because of tolerability concerns. The committee acknowledged what the company had said about FINEARTS-HF supporting the class recommendation for steroidal MRAs in NG106. But NICE's technology appraisal and highly specialised technologies guidance manual only suggests that committees consider whether something is established in NHS practice (and not why). So, the committee used this principle in making its decision on the relevant comparators. The committee noted that technical engagement responses estimated the current use of steroidal MRAs in heart failure with preserved or mildly reduced ejection fraction to be about 10 to 20%. It considered that these estimates suggest that steroidal MRAs are used in clinical practice for a small proportion of people in the relevant population, but use varies depending on the prescribing setting. The committee noted that a much higher proportion (around 51%) of people with heart failure with preserved or mildly reduced ejection fraction were prescribed an SGLT2 inhibitor in 2024 to 2025 (National Heart Failure Audit Annual Report 2025) and this likely reflected a similar population who would consider finerenone as a treatment. The committee concluded that the company's positioning of finerenone was broadly appropriate. It noted the limited uptake of steroidal MRAs linked to the lack of evidence (see section 3.6) and concerns about adverse events. It concluded that

steroidal MRAs were an appropriate comparator, but only for a limited portion of the population in this appraisal (see section 3.8).

Clinical evidence

Data source for finerenone

3.4 The key clinical evidence for finerenone came from FINEARTS-HF. This was a phase 3, double-blind, randomised controlled trial. The population included people 40 years and over with chronic heart failure with preserved or mildly reduced ejection fraction (LVEF of 40% or higher). People in the trial were randomised to take finerenone plus standard of care (n=3,003) or placebo plus standard of care (n=2,998). Finerenone was titrated to 20 mg once daily if the baseline estimated glomerular filtration rate (eGFR) was less than 60 ml/min/1.73 m^2, or to 40 mg once daily if the baseline eGFR was 60 ml/min/1.73 m^2 or higher. Standard-of-care treatments included diuretics, beta-blockers, renin-angiotensin-aldosterone system inhibitors, statins and SGLT2 inhibitors. Randomisation was stratified by geographic region and baseline LVEF. The trial was done in 37 countries across the Americas, Asia, Europe (including the UK) and Oceania. The EAG thought that FINEARTS-HF was at low risk of bias. It noted that the exclusion criteria in the trial included continuous (90 days or more) treatment with an MRA within 12 months before screening. Because of this, it stated that the comparator arm likely underrepresented the proportion of people who use steroidal MRAs in clinical practice. The EAG also noted that SGLT2 inhibitors were approved for chronic heart failure part way through FINEARTS-HF, so were likely to have been prescribed for other indications such as type 2 diabetes. The committee concluded that FINEARTS-HF was appropriate for decision making but did not directly compare finerenone with a steroidal MRA. It noted that was no direct evidence comparing finerenone with a steroidal MRA in heart failure with preserved or mildly reduced ejection fraction.

Clinical effectiveness

3.5 The primary outcome in FINEARTS-HF was a composite of total worsening heart-failure events (including first and recurrent hospitalisation for heart failure or urgent heart failure visit) and death from cardiovascular causes. In the full analysis set, finerenone plus standard of care significantly reduced the risk of the primary composite endpoint compared with placebo plus standard of care (rate ratio 0.84, 95% confidence interval [CI] 0.75 to 0.95, p=0.007). The committee noted that the treatment effect of finerenone on the primary composite endpoint was largely driven by the significant reduction in total worsening heart-failure events (rate ratio 0.82, 95% CI 0.71 to 0.94), with no significant reduction in death from cardiovascular causes (hazard ratio [HR] 0.93, 95% CI 0.78 to 1.11). It noted that all-cause mortality slightly favoured finerenone, but the difference was not significant between the treatment arms (HR 0.93, 95% CI 0.83 to 1.06). It concluded that finerenone was effective in reducing total worsening heart-failure events, but there is uncertainty about whether it would reduce the risk of death from cardiovascular or other causes.

Indirect treatment comparison

3.6 TOPCAT was a randomised controlled trial that compared spironolactone plus standard of care with placebo plus standard of care in people with symptomatic chronic heart failure with an LVEF of 45% or higher (n=3,445). The trial included sites in the Americas, Russia and Georgia. TOPCAT did not meet its primary endpoint, a composite of cardiovascular death, aborted cardiac arrest or hospitalisation for heart failure (HR 0.89, 95% CI 0.77 to 1.04; p=0.14). The clinical experts explained that there are no randomised controlled trials of eplerenone in the relevant population. At technical engagement, the company submitted an indirect treatment comparison (ITC) to compare finerenone with spironolactone in response to a request in the EAG's report. The company did not think this analysis was appropriate because of limitations with TOPCAT. These included

regional heterogeneity (low event rates and concerns about adherence to spironolactone in the Russia-Georgia group) and limited evidence of a heart failure diagnosis in many participants. The company did a Bucher ITC using FINEARTS-HF and TOPCAT data, with standard of care as a common comparator. The ITC results for the full TOPCAT population numerically favoured spironolactone, but suggested no statistically significant differences between finerenone and spironolactone in the risk of

- hospitalisation because of heart failure (HR 1.04, 95% CI 0.83 to 1.29)
- cardiovascular mortality (HR 1.03, 95% CI 0.78 to 1.36) and
- all-cause mortality (HR 1.02, 95% CI 0.83 to 1.26).

The ITC results for a subgroup from TOPCAT (excluding participants enrolled in Russia and Georgia) were consistent with those for the full population. The company noted important differences between FINEARTS-HF and TOPCAT including setting, geographical coverage and inclusion criteria (including LVEF). The company also highlighted that because FINEARTS-HF (2020 to 2023) was more recent than TOPCAT (2006 to 2012), it better reflected current clinical practice and standard of care. It stated that these differences between the trials could bias the ITC results. The EAG stated that the company had not explained why these differences would be treatment effect modifiers. So, it thought that the relative effect estimates from the ITCs should be appropriate if there is no evidence of effect modification. The committee acknowledged that the Bucher ITC preserves randomisation. But it would have also liked to have seen a population-adjusted indirect comparison (PAIC) to explore whether differences in baseline characteristics between the trials were treatment effect modifiers. It concluded that the ITC suggested that finerenone and spironolactone may have similar efficacy but the results were uncertain given the reported heterogeneity, which had not been explored using a PAIC.

Real-world evidence analyses

3.7 In response to technical engagement the company also presented analyses using real-world evidence (RWE) to estimate the relative efficacy of finerenone compared with spironolactone. The relevant evidence included 2 retrospective, observational cohort studies (Almas et al. 2026 and Wu et al. 2025) in adults with heart failure with preserved ejection fraction. The studies used propensity score matching to balance baseline characteristics between steroidal and non-steroidal MRA treatment groups identified from a global database of patient health records. The results of both studies numerically favoured finerenone for all outcomes, with statistically significant benefits for all-cause mortality and worsening heart failure.

Mortality:

- Almas et al. 2026 HR 0.38 (95% CI 0.23 to 0.64)
- Wu et al. 2025 HR 0.51 (95% CI 0.32 to 0.81).

Worsening heart failure:

- Almas et al. 2026 HR 0.63 (95% CI 0.54 to 0.74)
- Wu et al. 2025 HR 0.6 (95% CI 0.45 to 0.79).

The company considered that the populations in the RWE studies and FINEARTS-HF did not closely align with differences in baseline risk, comorbidity burden and background therapy use. The EAG agreed that the differences between the populations could be potential treatment effect modifiers, so the relative treatment effects estimated in the RWE studies may be different from those in the FINEARTS-HF population. It also noted that the all-cause mortality hazard ratios for finerenone compared with spironolactone from the RWE studies (0.38 from Almas et al. 2026 and 0.51 from Wu et al. 2025) were much lower than for finerenone compared with placebo from FINEARTS-HF (0.93). The EAG stated this implied that placebo has better efficacy than

spironolactone, which it thought lacked face validity. The company also stated that Wu et al. 2025 included mixed steroidal MRA use, which could mean that there is additional clinical heterogeneity. The committee noted that finerenone was unlikely to have been prescribed primarily for chronic heart failure in Almas et al. 2026 because it was not licensed for this indication at the time of the study. It thought that finerenone had likely been prescribed for chronic kidney disease with type 2 diabetes in people who also had heart failure with preserved ejection fraction. This was reflected in the higher prevalence of diabetes in the finerenone group (91.1%) compared with the spironolactone group (50.3%) before matching. Because of this, the committee thought it was unclear whether the treatment effect for finerenone in Almas et al. 2026 was being driven by differences in comorbidities between the treatment groups. It noted that the company and EAG agreed that RWE analyses were unlikely to be robust for decision making. The committee considered the real-world evidence in line with the section on methods for real-world studies of comparative effects, in NICE's real-world evidence framework. The EAG also explained that RWE studies can be prone to bias (particularly because of unmeasured confounding), and that the results should be interpreted with caution. The committee appreciated the company's efforts to include RWE, but concluded that the RWE analyses were highly uncertain for estimating the relative treatment effect of finerenone compared with spironolactone. But it considered that the ITCs and RWE studies did not suggest that finerenone would be less effective than spironolactone.

Basket comparator approach

3.8 The committee noted that the technical engagement responses emphasised that steroidal and non-steroidal MRAs are not typically considered interchangeable in clinical practice. It noted a comment highlighting that treatment decisions are often guided by the strength of efficacy evidence and tolerability. The committee acknowledged that

evidence of efficacy for spironolactone in the relevant population is limited, contributing to low and variable uptake in clinical practice. It also noted that the technical engagement responses had highlighted the SPIRIT-HF trial, which has not yet been published. This randomised controlled trial compared spironolactone with placebo in people with heart failure with preserved or mildly reduced ejection fraction (n=730). It did not meet its primary composite endpoint of cardiovascular death and total heart failure hospitalisations at 2 years (rate ratio 1.32, 95% CI 0.79 to 2.21) and enrolled fewer than half of the planned number of participants. The committee thought that SPIRIT-HF added further uncertainty about the disease-modifying effect of spironolactone in the relevant population. It acknowledged that spironolactone is often not well tolerated so may have to be stopped. The clinical expert explained this was consistent with SPIRIT-HF, in which about 40% to 50% of people stopped treatment. They explained that anti-androgenic side effects were less common with eplerenone, but it is rarely used in the relevant population because the evidence base is even more limited than for spironolactone (see section 3.6). The committee acknowledged concerns about efficacy and side effects with spironolactone, but noted that steroidal MRAs are being used in a small but relevant proportion of the population (see section 3.3). It considered that, if finerenone was recommended, it would be expected to displace any usage of spironolactone. But for most people in the relevant population, finerenone would be used in addition to standard of care. So, the committee decided that a basket comparator approach was appropriate. It understood this to mean a weighted comparator reflecting the mix of treatments displaced in clinical practice. The committee concluded that this approach best reflected both the limited evidence base for spironolactone and its restricted but relevant use in NHS clinical practice.

Economic model

Company's modelling approach

3.9 The company presented a state transition model. The model used total symptom score (TSS) on the Kansas City Cardiomyopathy Questionnaire (KCCQ) to define heart failure severity. KCCQ data was collected in FINEARTS-HF at baseline and at about 6, 9 and 12 months after randomisation. KCCQ scores ranged from 0 to 100, with lower scores indicating worse symptoms, more severe limitations, or both. The model included 6 main health states: KCCQ-TSS quartiles 1 to 4 (with 1 being the worst and 4 the best), death from cardiovascular causes and death from other causes. It also included 2 transient health states for hospitalisation because of heart failure and urgent heart failure visits. The population and comparator (placebo plus standard of care) included in the model aligned with FINEARTS-HF. The company used a regression model to estimate health state utilities for each of the KCCQ-TSS quartile health states using EQ-5D-5L data (mapped to EQ-5D-3L) from FINEARTS-HF. The model included a 28-day cycle and applied a half-cycle correction over a lifetime time horizon.

The company updated its model after technical engagement to align with the EAG's preference of using independently fitted Weibull parametric distributions to estimate all-cause and cardiovascular mortality for the finerenone and placebo arms using FINEARTS-HF data. The committee understood that the comparator arm in the company's model excluded steroidal MRAs in line with FINEARTS-HF. It noted the company had separately modelled comparisons of finerenone with spironolactone, based on the results from an ITC and analyses using RWE (see sections 3.6 to 3.7). The EAG thought there were no key issues relating to the company's updated model. The committee concluded that the company's model was appropriate for decision making.

Cost-effectiveness estimates

Acceptable ICER

3.10 NICE's technology appraisal and highly specialised technologies guidance manual notes that, above a most plausible incremental cost-effectiveness ratio (ICER) of £25,000 per QALY gained, judgements about the acceptability of a technology as an effective use of NHS resources will take into account the degree of certainty around the ICER. The committee will be more cautious about recommending a technology if it is less certain about the ICERs presented. But it will also take into account other aspects including uncaptured health benefits and health inequalities. The committee noted the high level of uncertainty, specifically:

- uncertainty about whether finerenone reduces the risk of cardiovascular and all-cause mortality compared with standard of care based on FINEARTS-HF (see section 3.5)
- no direct evidence comparing finerenone with a steroidal MRA in people with heart failure with preserved or mildly reduced ejection fraction (see section 3.4)
- uncertainty in the relative efficacy of finerenone compared with spironolactone using indirect treatment comparisons and RWE (see sections 3.6 to 3.7).

So, the committee concluded that an acceptable ICER would be towards the lower end of the range NICE considers a cost-effective use of NHS resources (£25,000 to £35,000 per QALY gained).

Company and EAG cost-effectiveness estimates

3.11 After technical engagement, the company's and EAG's base case assumptions were aligned (see section 3.9). The company and EAG base case probabilistic ICER comparing finerenone plus standard of care with standard of care alone was £12,764 per QALY gained. The committee concluded that finerenone was cost effective when compared with

standard of care alone. It also noted that the company had presented an alternative base case including SGLT2 inhibitor use at baseline from FINEARTS-HF (13.6%), which significantly reduced the ICER. This was because the company assumed that finerenone would likely be used alongside SGLT2 inhibitors in clinical practice. The committee recalled that SGLT2 inhibitor use in the trial was likely because of indications other than for heart failure. It agreed with the EAG that the subgroup was unlikely to be generalisable to people who are taking SGLT2 inhibitors for heart failure with preserved or mildly reduced ejection fraction. The company also presented cost-effectiveness estimates for finerenone compared with spironolactone based on the Bucher ITC and the RWE studies (see sections 3.6 and 3.7). Using the Bucher ITC, finerenone was dominated by spironolactone in all the company's scenarios. Using the RWE studies, the ICERs comparing finerenone with spironolactone were all below £8,000 per QALY gained. The committee acknowledged that the company's analyses comparing finerenone with spironolactone were uncertain and this was reflected in the wide variation in the cost-effectiveness estimates depending on the choice of analyses used. It concluded that the company's cost-effectiveness estimates mostly reflected its preferred assumptions, but it preferred to use a basket comparator approach to reflect the limited use of spironolactone in NHS clinical practice (see section 3.8 and section 3.12).

Decision risk with using a basket comparator

3.12 The committee's preferred basket comparator reflected a mix of treatments used in clinical practice for heart failure with preserved or mildly reduced ejection fraction (see section 3.8). This primarily included standard of care (based on FINEARTS-HF) and a small proportion of people having spironolactone. The committee considered that the uptake of finerenone would likely be much higher than spironolactone, and it would expect people currently taking spironolactone to switch to finerenone if it were recommended. The committee noted there were specific characteristics that meant some people could not take steroidal

MRAs, but acknowledged it might be difficult to identify a subgroup of people for whom spironolactone would be unsuitable in practice. It acknowledged that restricting the use of finerenone to people who cannot have spironolactone may not be appropriate because most people would then have spironolactone first, and it is often not well tolerated. The committee noted section 6.2.32 of the NICE technology appraisal manual, which states 'When considering uncertainty, the committee should take into account the likelihood of decision error and its consequences for patients and the NHS'. So, it decided it is appropriate to weigh the benefit of using finerenone in the total eligible population against the risk that spironolactone was equally efficacious but cheaper. It noted that the higher the current usage (and displacement) of spironolactone in NHS practice, the higher the risk that finerenone would not be a good use of NHS resources. Conversely, it also noted that the greater the expected uptake of finerenone in the total eligible population, the lower the risk that finerenone would not be a good use of NHS resources. The committee considered a threshold analysis that varied the proportion of spironolactone use and explored the expected uptake of finerenone needed to offset any potential net monetary loss at different willingness to pay thresholds (assuming there was equal efficacy between finerenone and spironolactone). The committee recalled that about 51% of people with heart failure with preserved or mildly reduced ejection fraction were recently prescribed an SGLT2 inhibitor (see section 3.3). It thought that the uptake of finerenone would likely be lower than this, because SGLT2 inhibitors are unlikely to cause hyperkalaemia, which is a recognised side-effect of MRAs. The committee thought that there was likely to be enough uptake of finerenone in NHS practice to mitigate any risk that spironolactone (as part of the basket of comparators) was equally effective as finerenone. So, the committee concluded that finerenone is likely to be cost effective at its preferred ICER threshold when using a basket comparator approach.

Other factors

Equality

3.13 The committee considered issues that had been raised during the evaluation process. It understood that people do not have equal access to specialist heart-failure services, as this varies depending on the different heart-failure subtypes and where a person lives. It noted stakeholder comments that finerenone should be available to prescribe across both primary and secondary care settings to improve access to treatment for people with heart failure with preserved or mildly reduced ejection fraction. The clinical experts explained that because finerenone is usually better tolerated than spironolactone, they would expect it to be more easily prescribed in primary care and need less monitoring. It understood that people living in more deprived areas may have a higher risk of hospital re-admissions for heart failure and are less likely to have access to specialist care. It noted that heart failure with preserved ejection fraction may disproportionately affect people from certain groups. It recalled that spironolactone would be less suitable for some people (see sections 3.2 and 3.3) and finerenone would provide an alternative treatment option for these people. But it concluded that the recommendations would not have a different effect on people protected by equality legislation than on the wider population.

Uncaptured benefits

3.14 The committee acknowledged that because of how finerenone works, it may be better tolerated than spironolactone in people with certain comorbidities, and has a lower risk of anti-androgenic side effects. It recalled that this may mean less monitoring is needed when prescribing finerenone, compared with spironolactone. The committee considered whether there were any uncaptured benefits of finerenone. It did not identify additional benefits of finerenone not captured in the economic modelling. So, the committee concluded that all additional benefits of finerenone had already been taken into account.

Conclusion

Recommendation

3.15 The committee took into account its preferred assumptions, key uncertainties in the evidence, and the likelihood that finerenone was cost effective against a basket representing standard of care across the NHS practice population in its decision making. It concluded the cost-effectiveness estimates are within the range that NICE normally considers an acceptable use of NHS resources. So, finerenone can be used.

4 Implementation

4.1 Section 7 of the National Institute for Health and Care Excellence (Constitution and Functions) and the Health and Social Care Information Centre (Functions) Regulations 2013 requires integrated care boards, NHS England and, with respect to their public health functions, local authorities to comply with the recommendations in this evaluation within 90 days of its date of publication.

4.2 The Welsh ministers have issued directions to the NHS in Wales on implementing NICE technology appraisal guidance. When a NICE technology appraisal guidance recommends the use of a drug or treatment, or other technology, the NHS in Wales must usually provide funding and resources for it within 60 days of the first publication of the final draft guidance.

4.3 When NICE recommends a treatment ‘as an option’, the NHS must make sure it is available within the period set out in the paragraphs above. This means that, if a patient has chronic heart failure with preserved or mildly reduced ejection fraction and the healthcare professional responsible for their care thinks that finerenone is the right treatment, it should be available for use, in line with NICE’s recommendations.

5 Evaluation committee members and NICE project team

Evaluation committee members

The 4 technology appraisal committees are standing advisory committees of NICE. This topic was considered by committee C.

Committee members are asked to declare any interests in the technology being evaluated. If it is considered there is a conflict of interest, the member is excluded from participating further in that evaluation.

The minutes of each evaluation committee meeting, which include the names of the members who attended and their declarations of interests, are posted on the NICE website.

Chair

James Fotheringham

Chair, technology appraisal committee C

NICE project team

Each evaluation is assigned to a team consisting of 1 or more health technology analysts (who act as technical leads for the evaluation), a technical adviser, a project manager, and an associate director or principal technical adviser.

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