5.07 FINERENONE
Tablet 10 mg,
Tablet 20 mg,
Tablet 40 mg,
Kerendia®,
Bayer Australia Ltd

1 Purpose of submission

1.1 The Category 2 submission requested an Authority Required (Streamlined) listing for finerenone, for the treatment of adults with symptomatic heart failure (New York Heart Association [NYHA] Class II–IV) and left ventricular ejection fraction (LVEF) of greater than or equal to 40%. This encompasses patients with heart failure with mildly reduced or preserved ejection fraction (HFmrEF/HFpEF).

1.2 Listing was requested on the basis of a cost-effectiveness analysis versus placebo, in addition to standard care.

Table 1: Key components of the clinical issue addressed in the submission (as stated in the submission)

Component	Description
Population	Adult patients with symptomatic heart failure (NYHA Class II-IV), and LVEF ≥40%.
Intervention	Finerenone 10 mg, 20 mg, or 40 mg (oral tablet) once daily, plus standard care.
Comparator	Placebo plus standard care, which may include an SGLT2i, diuretics, and/or other concomitant medications to manage related comorbidities.
Outcomes	Reductions in cardiovascular death and heart failure events, all-cause mortality, improvements in quality of life (KCCQ-TSS).
Clinical claim	Finerenone plus standard care demonstrates superior efficacy compared to placebo plus standard care. The submission did not make a specific safety claim.

Source: Table 1-14, pp13-14 of the submission.
Abbreviations: KCCQ-TSS, Kansas City Cardiomyopathy Questionnaire - Total Symptom Score; LVEF, left ventricular ejection fraction; NYHA, New York Heart Association; SGLT2i, sodium glucose co-transporter 2 inhibitor.

2 Background

Registration status

2.1 Finerenone was approved by the TGA on 27 February 2026 in adults for the treatment of symptomatic heart failure (HF) with left ventricular ejection fraction (LVEF) of ≥40%.

2.2 Finerenone is also TGA indicated to delay progressive decline of kidney function and to reduce the risk of cardiovascular (CV) mortality and morbidity in adults with chronic kidney disease (with albuminuria) associated with Type 2 diabetes, in addition to standard of care.

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Previous PBAC consideration

2.3 Finerenone (10 mg and 20 mg tablets) was listed on the PBS for the treatment of chronic kidney disease (CKD) with type 2 diabetes (T2D) on 1 July 2023, following submissions to the PBAC in July 2022 and March 2023.

2.4 Finerenone has not previously been considered by the PBAC for the treatment of heart failure. The PBAC has previously considered the sodium glucose co-transporter 2 inhibitor (SGLT2i) medicines empagliflozin and dapagliflozin for similar restrictions, for the treatment of chronic heart failure (NYHA class II-IV) with LVEF greater than 40% (empagliflozin Public Summary Document [PSD], November 2022 PBAC meeting; dapagliflozin PSD, July 2023 PBAC meeting).

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3 Requested listing

MEDICINAL PRODUCT medicinal product pack	Dispensed Price for Max. Qty	Max. qty packs	Max. qty units	№.of Rpts	Available brands
FINERENONE					
finerenone 10 mg tablet, 28 finerenone 20 mg tablet, 28 finerenone 40 mg tablet, 28	$82.71 published price $[redacted]	1	28	5	Kerendia®
Category / Program: General Schedule					
Prescriber type: ☒ Medical Practitioners ☒ Nurse practitioners					
Restriction type: Authority Required (STREAMLINED)					
Indication: Chronic heart failure					
Treatment Phase: Initial treatment					
Clinical criteria:					
Symptomatic with NYHA classes II, III or IV prior to initiating treatment with this drug					
AND					
Clinical criteria:					
Documented left ventricular ejection fraction (LVEF) of greater than or equal to 40%					
AND					
Clinical criteria:					
Documented evidence of structural changes in the heart on echocardiography that would be expected to cause diastolic dysfunction (e.g. left ventricular hypertrophy)					
AND					
Clinical criteria:					
Documented evidence of at least one of: (i) diastolic dysfunction with high filling pressure on echocardiography, stress echocardiography or cardiac catheterisation; (ii) hospitalisation for heart failure in the 12 months prior to initiating treatment with this drug; (iii) requirement for intravenous diuretic therapy, or an urgent heart failure visit, in the 12 months prior to initiating treatment with this drug; (iv) elevated N-terminal pro brain natriuretic peptide (NT-proBNP) levels in the absence of another cause.					

Category / Program: General Schedule
Prescriber type: ☒ Medical Practitioners ☒ Nurse practitioners
Restriction type: Authority Required (STREAMLINED)
Indication: Chronic heart failure
Treatment Phase: Continuing treatment
Clinical criteria:
Patient must have previously received PBS-subsidised treatment with this drug for this condition
AND
Clinical criteria:
Symptomatic with NYHA classes II, III or IV prior to initiating treatment with this drug
AND
Clinical criteria:
Documented left ventricular ejection fraction (LVEF) of greater than or equal to 40%
AND
Clinical criteria:
Documented evidence of structural changes in the heart on echocardiography that would be expected to cause diastolic dysfunction (e.g. left ventricular hypertrophy)
AND
Clinical criteria:
Documented evidence of diastolic dysfunction with high filling pressure on echocardiography, stress echocardiography or cardiac catheterisation

Category / Program: General Schedule
Prescriber type: ☒ Medical Practitioners ☒ Nurse practitioners
Restriction type: Authority Required (STREAMLINED)
Indication: Chronic heart failure
Treatment Phase: Continuing treatment (grandfathered patients)
Clinical criteria:
The patient must have commenced treatment with this medicine for this condition prior to [Listing Date],
AND
Clinical criteria:
Symptomatic with NYHA classes II, III or IV prior to initiating treatment with this drug
AND
Clinical criteria:
Documented left ventricular ejection fraction (LVEF) of greater than or equal to 40%
AND
Clinical criteria:
Documented evidence of structural changes in the heart on echocardiography that would be expected to cause diastolic dysfunction (e.g. left ventricular hypertrophy)
AND
Clinical criteria:
Documented evidence of diastolic dysfunction with high filling pressure on echocardiography, stress echocardiography or cardiac catheterisation

3.1 The submission requested a special pricing arrangement (SPA). The requested effective DPMQ was $[redacted] (EMP $[redacted]), which was higher than the effective approved EMP for the finerenone CKD with T2D PBS listing (AEMP $[redacted]). The Pre-PBAC Response

proposed a revised effective DPMQ of $[redacted] (EMP $[redacted]), aligned with the CKD with T2D price.

3.2 The Sub-Committees noted that, due to the proposed flat pricing across the 10 mg, 20 mg and 40 mg doses, if patients were prescribed a 30 mg dose, it would require one 10 mg script and one 20 mg script, effectively doubling the cost of treatment for these patients. The Pre-PBAC Response stated that 30 mg dosing is not included in the Product Information and has not been evaluated in trials and is therefore not expected in routine practice. The Response also noted that some patients may be prescribed 20 mg or 40 mg tablets and halve them to achieve 10 mg or 20 mg doses, respectively, reducing costs to the PBS and patient.

3.3 The requested restriction was narrower than the TGA indication, limiting use to patients demonstrating diastolic dysfunction, NYHA Class II-IV symptoms, and at least one other criterion supporting a diagnosis of heart failure, and was broadly consistent with the inclusion criteria of the key FINEARTS-HF trial.

3.4 The requested restriction was based on the empagliflozin and dapagliflozin PBS listings for the treatment of chronic heart failure with NYHA class II-IV and LVEF >40%. However, the requested restriction was slightly broader, including patients with a LVEF ≥40% (consistent with the TGA indication for finerenone). In addition, the restriction expanded the clinical requirement for intravenous diuretic therapy in the 12 months prior to initiating treatment, to include urgent heart failure visits in the 12 months prior to initiating treatment. This was consistent with the inclusion criteria and primary composite outcome of the key clinical trial (FINEARTS-HF). Urgent heart failure visits was also a component of the primary composite outcome in the dapagliflozin key clinical trial (DELIVER; para 6.16, dapagliflozin PSD, July 2023 PBAC meeting), but was not included in the clinical criteria of the dapagliflozin restriction for chronic heart failure with NYHA class II-IV and LVEF >40%, which was based on the components of the empagliflozin primary composite outcome (Table 3, empagliflozin PSD, November 2022 PBAC meeting). The Sub-Committees considered that it may be appropriate to remove urgent heart failure visits from the clinical restrictions, consistent with restrictions for SGLT2is. The Sub-Committees considered that this change is unlikely to have an impact on uptake of finerenone in practice.

3.5 The Sub-Committees noted the finerenone listing for the treatment of CKD with T2D contains the caution: 'serum electrolytes should be checked regularly' and considered it would be appropriate to include the same caution for the HF listing.

3.6 The requested restriction did not include clinical criteria requiring the use of specific standard care interventions. The PBAC previously considered it was appropriate not to require concomitant use of SGLT2i medicines with optimal standard chronic heart failure treatment, given the lack of evidence for specific disease-modifying therapies for HFpEF (para 7.15, empagliflozin PSD, November 2022 PBAC meeting). However, given both empagliflozin and dapagliflozin are disease modifying therapies in HFmrEF/HFpEF, the Sub-Committees agreed with the evaluation that the PBAC may wish to consider whether finerenone should be used with or without an SGLT2i medicine, or only after initiation of an SGLT2i medicine (unless contraindicated or not

tolerated). The Pre-Sub Committee Response (PSCR) stated that the use of finerenone, irrespective of treatment with an SGLT2i, is consistent with the pivotal trial evidence and clinical guidelines. The PSCR argued that given their distinct and complementary mechanisms of action, combined use is associated with additive benefits without an observed detriment to safety. The Sub-Committees considered that, given greater awareness and more established use in practice, patients were more likely to initiate an SGLT2i prior to finerenone. The Sub-Committees also noted that while an additive effect was plausible, the evidence base was still emerging. The Pre-PBAC Response stated that the goal of treatment is to optimise risk reduction through combination therapy, rather than adopting a stepwise approach in which additional therapies are introduced only if the initial treatment proves inadequate. The Response argued that a requirement to use one therapy before the other may affect the economics, would offer no clear benefit, and would reduce clinical flexibility.

3.7 The requested PBS listing includes initial, continuing and grandfathered restrictions. The submission did not provide an estimate of the size of the grandfathered population. The grandfathered restriction may not be required, given grandfathered patients would likely meet the clinical criteria in the initial restriction. The Secretariat noted that separate initial and continuing restrictions may also be unnecessary and proposed combining into a single treatment phase agnostic restriction.

3.8 The Secretariat noted that, according to the approved TGA PI, initiation of finerenone treatment for heart failure is not recommended when serum potassium levels are >5.0 mmol/L and is also not recommended when estimated glomerular filtration rate (eGFR) is <25 mL/min/1.73 m2. The pivotal FINEARTS-HF trial also applied these parameters as exclusion criteria.

For more detail on PBAC's view, see section 7 PBAC outcome.

4 Population and disease

4.1 Heart failure is a complex clinical syndrome caused by underlying structural and/or functional impairment of cardiac ventricular filling and ejection, and is characterised by symptoms of dyspnoea, orthopnoea, paroxysmal nocturnal dyspnoea, reduced end-organ perfusion, venous congestion (elevated jugular venous pressure, hepatic enlargement, peripheral oedema, pulmonary oedema, pleural effusion, ascites), and fatigue. The symptoms of heart failure are most evident on exertion but increasingly occur at rest with disease progression. Common causes of heart failure include ischaemic heart disease, valvular heart disease, cardiomyopathies, hypertension, arrhythmias, and diabetes. Chronic heart failure refers to patients with the clinical symptoms of heart failure for at least three months.

4.2 Heart failure is classified by the severity of functional symptoms (NYHA classification) and left ventricular function (LVEF). Current heart failure guidelines identify 3 variants by LVEF: (i) HFrEF - heart failure with reduced LVEF ≤40%; (ii) HFmrEF - heart failure with mildly reduced LVEF 40%-49%; and (iii) HFpEF - heart failure with preserved LVEF

≥50%. The current submission is for the treatment of HFmrEF/HFpEF, or heart failure with LVEF ≥40%.

4.3 HFpEF is characterised by a multifactorial pathophysiology involving systemic inflammation, myocardial fibrosis, endothelial dysfunction, microvascular disease, diastolic dysfunction (impaired ventricular relaxation, elevated ventricular filling pressures), and venous congestion (McDonagh 2021; Singh-Kalsi 2022). HFpEF patients are typically older, more often female, and more likely to exhibit cardiovascular risk factors, heart failure related co-morbidities including arterial hypertension, obesity, T2D, chronic obstructive pulmonary disease (COPD), and CKD (Fayol 2021), and non-cardiovascular comorbidities, compared to HFrEF.

4.4 HFmrEF may include patients whose LVEF has improved from ≤40% or deteriorated from ≥50%, and has historically been likened to HFrEF in presentation and aetiology, with approximately 50–60% of cases related to cardiac ischemia with lower mortality (Koh 2017; ESC, McDonagh 2021). Recent international guidelines (American Heart Association/American College of Cardiology, Heidenreich 2022; iCARDIO 2025) define HFmrEF as more similar to HFpEF, with diagnostic criteria including raised left ventricular filling pressures. However, Australian guidelines (National Heart Foundation of Australia, Atherton 2018; Australian Consensus Statement on Optimisation of Patient Care After Hospitalisation for Acute Heart Failure, Sindone 2026) continue to categorise HFmrEF as an HFrEF variant with HFpEF characteristics in some patients. Generally, there is substantial overlap of clinical characteristics, risk factors, patterns of cardiac remodelling, and outcomes across all LVEF categories in heart failure (ESC, McDonagh 2021).

4.5 HFmrEF/HFpEF includes approximately half of all symptomatic heart failure cases in Australia and has been estimated to affect more than 536,000 adults (Whaddon Parsons 2020, Jeffries 2023).

4.6 Finerenone is a non-steroidal mineralocorticoid receptor antagonist (nsMRA) with a similar mechanism of action to the steroidal mineralocorticoid receptor antagonists spironolactone and eplerenone. The Sub-Committees noted that all three drugs work by blocking the action of aldosterone, inhibiting mineralocorticoid receptor-mediated sodium reabsorption and mineralocorticoid receptor overactivation associated with fibrosis and inflammation in both epithelial (kidney) and nonepithelial (heart and blood vessel) tissues. In contrast to steroidal MRAs, finerenone has no relevant affinity for androgen, progesterone, oestrogen and glucocorticoid receptors and does not cause sex hormone-related adverse events (e.g., breast tenderness and/or enlargement in men and women). The Sub-Committees noted that for patients with HFmrEF or HFpEF, steroidal MRAs have not demonstrated a consistent reduction in mortality.

4.7 Hyperkalaemia is an established risk associated with finerenone treatment, and use is only recommended in patients with a serum potassium <5.0 mmol/L, and an estimated glomerular filtration rate (eGFR) ≥25 mL/min/1.73m^2. The finerenone Product Information recommends ongoing monitoring of serum potassium, with more

frequent monitoring of patients at higher risk of hyperkalaemia, but no specific monitoring schedule is recommended.

For more detail on PBAC's view, see section 7 PBAC outcome.

5 Comparator

5.1 The submission nominated standard care as the main comparator. The submission argued that finerenone is proposed to be used as an add-on to standard care, reflected in the design of the key clinical trial (FINEARTS-HF). The choice of comparator was consistent with the comparator accepted by the PBAC in the empagliflozin submission (para 7.3, empagliflozin PSD, November 2022 PBAC meeting), for the same place in therapy, and consistent with the proposed use of finerenone as an adjunctive therapy to standard care with or without an SGLT2i.

5.2 The Sub-Committees agreed with the evaluation that standard care is the appropriate main comparator. The submission defined standard care as a heterogeneous combination of pharmacological and non-pharmacological interventions tailored to individual patient characteristics, comorbidities, and tolerability, including treatment with a diuretic and/or an SGLT2i as required. Pharmaceutical interventions used for the treatment of chronic heart failure include a diuretic (loop or thiazide), beta-blocker, angiotensin-converting enzyme inhibitor (ACEi), angiotensin receptor blocker (ARB), angiotensin receptor–neprilysin inhibitor (ARNi), mineralocorticoid receptor antagonist (MRA), and an SGLT2i.

5.3 The submission noted that clinical trials of ACEi, ARB, ARNi (PEP-CHF, CHARM-Preserved, PARAGON-HF), and the MRA spironolactone (TOPCAT) did not meet their primary endpoints, although some benefits were observed in selected subgroups or secondary outcomes. The submission suggested these findings highlighted fundamental differences in disease biology and treatment response across the ejection fraction spectrum and underscored the lack of reliably effective disease-modifying therapies for HFmrEF/HFpEF prior to the introduction of SGLT2i medicines and finerenone. The submission argued that renin-angiotensin-system moderators (ACEi, ARB, ARNi and MRAs) are therefore not appropriate comparators. Notwithstanding weak recommendations for the use of MRAs in HFmrEF/HFpEF and low quality evidence, MRAs continue to be used in clinical practice (Atherton 2018, Heidenreich 2022, iCARDIO 2025). The Sub-Committees agreed with the evaluation that for the requested population, finerenone may replace PBS-listed spironolactone in some patients, at a substantially higher cost to the PBS. The Sub-Committees noted that the substitution of finerenone for spironolactone was not considered in the economic analysis or financial estimates. The Sub-Committees acknowledged the PSCR comments stating that spironolactone would not be an appropriate replacement therapy in the economic model due to a lack of demonstrated efficacy for patients

with HFmrEF/HFpEF, as observed in the TOPCAT trial[1], and more recently in the SPIRIT-HF trial[2]. However, the Sub-Committees also noted that there were regional variations in the patient population and outcomes in the TOPCAT trial that potentially impact the interpretation of the results.[3] The PSCR also argued that real-world PBS prescribing data suggests that that the utilisation of MRAs is low across the broader Australian heart failure population (approximately 2–3%, 4% and 12% of mono-, dual- and triple therapy, respectively).[4]

5.4 The submission argued that while SGLT2i medicines are a proven disease modifying therapy for HFmrEF/HFpEF, patients may continue to experience recurrent heart failure hospitalisations and cardiovascular death, and there is a continuing unmet clinical need for additional effective interventions. The submission argued that given the differences in mechanism of action between finerenone and SGLT2i medicines, the therapeutic benefits of finerenone were not considered contingent on concomitant SGLT2i use. Therefore, SGLT2i medicines were not considered an appropriate comparator. The evaluation considered that as SGLT2i medicines and finerenone occupy the same position in the treatment pathway (in the absence of concomitant use), the submission did not adequately define a distinct population in whom finerenone would be preferred over SGLT2i medicines. The PSCR stated that the pivotal trial evidence and clinical guidelines indicate that the use of finerenone and treatment with an SGLT2i are independent decisions; therefore, clinical preference is not a relevant driver. The Sub-Committees noted that "pill burden" may be a factor in the decision to prescribe finerenone in addition to an SGLT2.

5.5 The submission stated that there are no near-market alternative HFmrEF/HFpEF therapies likely to be available outside clinical trials or compassionate use programs. However, given the substantial overlap between patients with HFmrEF/HFpEF and those that would be eligible for PBS subsidised glucagon-like peptide-1 (GLP-1) receptor agonist therapy for established cardiovascular disease with obesity (recommended at the November 2025 PBAC meeting) and/or T2D, and clinical trials demonstrating improvements in heart failure symptoms and functional outcomes, GLP-1 receptor agonists may represent a potential near-market therapy. These agents are now included in heart failure clinical practice guidelines (American Diabetes Association Standards of Care 2025, Sindone 2026), particularly where obesity and/or

[1] Pitt B, Pfeffer MA, Assmann SF, et al. Spironolactone for heart failure with preserved ejection fraction. N Engl J Med. 2014;370(15):1383–1392.

[2] Edelmann F, et al. Spironolactone In the Treatment of Heart Failure (SPIRIT-HF). Presented at: American College of Cardiology Scientific Session (ACC.26); 29 March 2026; New Orleans, USA.

[3] Pfeffer, M.A.; Claggett, B.; Assmann, S.F.; Boineau, R.; Anand, I.S.; Clausell, N.; Desai, A.S.; Diaz, R.; Fleg, J.L.; Gordeev, I.; et al. Regional Variation in Patients and Outcomes in the Treatment of Preserved Cardiac Function Heart Failure With an Aldosterone Antagonist (TOPCAT) Trial. *Circulation* **2015**, *131*, 34–42, https://doi.org/10.1161/circulationaha.114.013255.

[4] University of South Australia (Gadzhanova S, Roughead L). Utilisation analysis of PBS-listed medicines for heart failure. Prepared for the Australian Government Department of Health and Aged Care; 1 May 2024 (Reference ID: E23-78482). Available at: https://www.pbs.gov.au/reviews/utilisation-analysis-of-pbs-listed-medicines-for-heart-fail/Utilisation-analysis-of-PBS-listed-heart-failure-medicines-report-2024.PDF

diabetes coexist, reflecting their emerging role in the broader management of heart failure populations.

For more detail on PBAC's view, see section 7 PBAC outcome.

6 Consideration of the evidence

Sponsor hearing

6.1 The sponsor requested a hearing for this item.

6.2 The clinician described the unmet clinical need among patients with heart failure and an LVEF >40%. The clinician noted that the prevalence of HFpEF has increased and now exceeds that of HFrEF. The clinician also noted that patients with HFpEF have high mortality, substantial symptom burden, limitations in usual daily activities and self-care, and may experience anxiety or depression due to the seriousness of the condition. The clinician stated that treatment options for HFpEF are limited, with SGLT2is the only therapies shown to reduce both CV mortality and heart failure hospitalisations, while ARNIs have shown reductions in hospitalisations. The clinician considered that further treatment options were needed for this population, as the residual risk of adverse CV outcomes remains high in patients with HF and LVEF ≥40%, despite the use of SGLT2is.

6.3 The clinician discussed the clinical benefit of finerenone compared with placebo observed in clinical trials. The clinician noted that US guidelines support the use of an SGLT2i and an nsMRA in patients with heart failure and LVEF >40%[5]. The clinician also noted that the European Society of Cardiology guidelines provide a strong Class I, Level B recommendation for a strategy of initiating and rapidly up-titrating evidence-based treatment before discharge and during follow-up after a HF hospitalisation[6]. The clinician further noted that an Australian consensus statement advises initiating finerenone and an SGLT2i in hospital where possible, with up-titration over the first 6 weeks[7].

Consumer inputs

6.4 The PBAC noted and welcomed the input from Hearts4Heart via the Office of Health Technology Assessment Consultation Hub. The input noted that heart failure is a serious, progressive lifelong condition that can cause fatigue, breathlessness, dizziness and fluid-related swelling, and substantially affect quality of life, independence,

[5] Shahid, I, Khan, MS, Butler, J. et al. (2025) Initiation and sequencing of guideline-directed medical therapy for heart failure across the ejection fraction spectrum. *Heart Fail Rev* 30, 515–523.

[6] McDonagh, TA, Metra, M, Adamo, M. et al…ESC Scientific Document Group (2023) Focused Update of the 2021 ESC Guidelines for the diagnosis and treatment of acute and chronic heart failure: Developed by the task force for the diagnosis and treatment of acute and chronic heart failure of the European Society of Cardiology (ESC) With the special contribution of the Heart Failure Association (HFA) of the ESC, European Heart Journal, Volume 44(37), 3627–3639.

[7] Sindone AP, Amerena J, De Pasquale CG, et al. (2026) Statement on Optimisation of Patient Care After Hospitalisation for Acute Heart Failure. Heart Lung Circ. 35(2), 157–170.

mental wellbeing, work and everyday activities. The input noted that heart failure affects up to half a million Australians and remains a major cause of hospitalisation and death. The input stated that despite existing treatments, many patients experience worsening health and repeated hospital visits, creating substantial burden for patients, carers, families and the healthcare system, particularly in rural and remote communities and among Aboriginal and Torres Strait Islander peoples. The input noted that finerenone reduced worsening heart failure events and was associated with improvements in symptoms and overall wellbeing. It also noted that, without PBS subsidy, the cost of finerenone would be substantial and unaffordable for many Australians.

Clinical trials

6.5 The submission was based on one head-to-head randomised controlled trial (FINEARTS-HF) comparing finerenone plus standard care to placebo plus standard care, in adults with HFmrEF/HFpEF (LVEF ≥40%). In addition, the submission presented the results of the FINE-HEART pooled analysis (Vaduganathan 2024), including individual patient data from the key FINEARTS-HF trial, as well as the FIDELIO-DKD and FIGARO-DKD trials (diabetic kidney disease) and a pre-specified subgroup analysis of FINEARTS-HF trial data by SGLT2i use at baseline (Vaduganathan 2025).

6.6 Details of the trials and associated reports presented in the submission are provided in Table 2.

Table 2: Trials and associated reports presented in the submission

Trial ID	Protocol title/ Publication title	Publication citation
FINEARTS-HF	A multicentre, randomised, double-blind, parallel-group, placebo controlled study to evaluate the efficacy and safety of finerenone on morbidity and mortality in participants with heart failure (NYHA II-IV) and left ventricular ejection fraction ≥40% (LVEF ≥40%).	Clinical Study Report, 19 November 2024
	Solomon SD, McMurray JJV, Vaduganathan M et al. Finerenone in heart failure with mildly reduced or preserved ejection fraction.	*New England Journal of Medicine* 2024, 391(16): 1475-1485.
	Chimura M, Yang M, Henderson AD et al. Anaemia in patients with heart failure and mildly reduced or preserved ejection fraction: A prespecified analysis of the FINEARTS-HF trial.	*European Journal of Heart Failure* 2025 27(11):2301-2312.
	Vaduganathan M et al. Effects of the nonsteroidal MRA finerenone with and without concomitant SGLT2 inhibitor use in heart failure.	*European Journal of Heart Failure* 2024, 26(6):1324-1333.
FINE-HEART	Ostrominski JW et al. Efficacy and safety of finerenone in heart failure with preserved ejection fraction: A FINE-HEART analysis.	*Journal of the American College of Cardiology Heart Failure* 2025, 13 (8): 102497.
	Vaduganathan M et al. Finerenone in heart failure and chronic kidney disease with type 2 diabetes: FINE-HEART pooled analysis of cardiovascular, kidney and mortality outcomes.	*Nature Medicine* 2024, 30:3758–3764.

Source: Table A5.5, Attachment 5 Details of systematic literature review.

6.7 The key features of the FINEARTS-HF trial are summarised in Table 3.

Table 3: Key features of the included evidence

Trial	N	Design/ duration	Risk of bias	Patient population	Outcomes	Use in modelled evaluation
FINEARTS-HF	6,016	Phase 3, multi-centre, randomised, double blind, placebo controlled trial. Median duration of follow-up 32 months	Low	Age ≥40 years Heart failure with NYHA Class II-IV LVEF >40% (prior 12 months) Treated with diuretic (prior 30 days) Evidence of structural HF abnormality Elevated NT-proBNPa eGFR ≥25 mL/min/1.73 m^2	Composite of CV death and (first and recurrent) hospitalisation for HF or urgent HF visit. Total (first and recurrent) HF event. Change from baseline in KCCQ-TSS. Improvement in NYHA class from baseline. Time to all-cause mortality EQ-5D-5L. Safety.	KCCQ-TSS scores, all-cause mortality, CV mortality, heart failure events, treatment discontinuation, EQ-5D scores, adverse events

Source: Section 2.3 and 2.4, pp43-47 of the submission.
Abbreviations: CV cardiovascular; DB, double blind; eGFR, estimated glomerular filtration rate; HF, heart failure; HHF, hospitalisation for heart failure; KCCQ, Kansas City Cardiomyopathy Questionnaire; LVEF, left ventricular ejection fraction; MC, multi-centre; NT-proBNP, N-Terminal pro b natriuretic peptide; NYHA, New York Heart Association; PC, placebo-controlled; R, randomised; TSS, Total Symptom Score.

6.8 The risk of bias was low in the FINEARTS-HF trial.

6.9 Baseline demographic and disease characteristics were generally similar between treatment arms. Patients were predominantly male (54.5%), white (78.9%), with a history of hypertension (88.7%), and at least one prior hospitalisation for a heart failure event (60.3%), with a mean age of 72 years. Most patients reported NYHA Class II heart failure symptoms (69.1%), with an LVEF <60% (80.9%). Approximately 4.5% of patients reported a prior LVEF of <40%. Comorbidities included CKD (48.1%), type 2 diabetes (40.6%), atrial fibrillation (38.2%), prior stroke (13.8%) and prior myocardial infarction (25.7%).

6.10 Baseline heart failure medicines included treatment with loop diuretics (87%) or thiazide diuretics (14%), beta-blockers (85%), ACEi/ARB (79%), SGLT2i medicines (14%) and MRAs (5%). Concomitant medicines used (one or more doses) during the FINEART-HF treatment phase included loop diuretics (48%) or thiazide diuretics (7%), beta-blockers (33.5%), ACEi/ARB (33.6%), and MRAs (13.8%). Although only 14% of patients were being treated with an SGLT2i at baseline, an additional 20% of patients commenced treatment with an SGLT2i post-baseline.

6.11 The submission claimed that patients in FINEARTS-HF are broadly representative of Australian patients with HFmrEF/HFpEF. The Sub-Committees considered that this claim was not reasonable, given a comparison of limited patient characteristics indicated differences between the FINEARTS-HF trial population and Australian population in terms of age (FINEARTS-HF 71.9 years versus Australian setting 80.1 years), comorbidities (hypertension 88.7% versus 65.5%; T2D 40.6% versus 26.6%; atrial fibrillation 38.2% versus 46.2%; CKD 48.1% versus 18.9%) and use of standard care therapies (ACEi/ARB 79.4% versus 64.5%; beta-blockers 84.9% versus 45.6%; MRAs 5.2% versus 26.6%). As age and the presence of comorbid conditions have been

identified as prognostic factors in HFmrEF/HFpEF, these differences may affect baseline risk and the absolute benefit of finerenone.

6.12 The Sub-Committees noted that the baseline use of SGLT2i medicines in FINEARTS HF was low (14%), reflecting the timing of the trial, which predated the establishment of SGLT2i medicines as disease modifying therapy in HFmrEF/HFpEF. As SGLT2i medicines are now recommended in clinical guidelines (iCARDIO Alliance Global Implementation Guidelines on Heart Failure 2025) and listed on the PBS, uptake in Australian clinical practice is expected to be substantially higher than observed in FINEARTS HF. Therefore, standard care in the trial is unlikely to be representative of current practice. Higher use of SGLT2i medicines in clinical practice may reduce the baseline risk of events in the eligible population and, consequently, the absolute benefit of finerenone treatment. The PSCR acknowledged that higher SGLT2i use would lower baseline risk, however considered that patients expected to receive finerenone in clinical practice would likely be at higher risk of events than those in the trial. The PSCR also noted that whilst 14% of patients in FINEARTS-HF were taking an SGLT2i at baseline in FINEARTS-HF, an additional 20% started SGLT2i treatment during the study. The Sub-Committees considered that this difference between the trial and clinical practice remained an applicability issue for the FINEARTS-HF trial.

6.13 Finerenone dosing and administration in the FINEARTS-HF trial was pre-specified by baseline eGFR for initial and maximum doses, and serum potassium for continuing dose titration using a strict titration protocol. Investigators were encouraged to up-titrate finerenone to the maximum dose of 20 mg (eGFR ≥25 to <60 mL/min/1.73m^2) or 40 mg (eGFR ≥60 mL/min/1.73m^2) once daily. Median treatment duration across both treatment arms was 28 months, with a median follow-up of 32 months. Finerenone dosing in the FINEARTS-HF trial was consistent with the dosing schedule recommended in the finerenone Product Information.

6.14 The FINEARTS-HF primary outcome was the composite of cardiovascular death and total (first and recurrent) heart failure events. Heart failure events included any hospitalisation for heart failure lasting at least 24 hours with exacerbation of symptoms requiring treatment intervention (hospitalisation for heart failure), or any urgent unscheduled ambulatory or emergency department visit for heart failure management requiring an intravenous diuretic, vasoactive agent or mechanical/surgical intervention for heart failure, not requiring overnight hospitalisation (urgent heart failure visit).

6.15 The FINEARTS-HF secondary outcomes were analysed in a hierarchical testing procedure to account for multiplicity. If the primary outcome was statistically significant based on a 2-sided alpha of 0.04967 (following an interim analysis), secondary outcomes were tested in order. Statistical significance was met for the primary composite outcome, and the secondary outcomes for total heart failure events and Kansas City Cardiomyopathy Questionnaire Total Symptom Score (KCCQ-TSS) outcomes. However, improvement in NYHA class did not reach statistical significance, the testing procedure was stopped and the remaining secondary renal composite endpoint was not tested formally.

Comparative effectiveness

Results of the FINEARTS-HF trial: whole trial population

6.16 Table 4 summarises the results of the primary composite outcome of cardiovascular death and total (first and recurrent) heart failure events and its components in the FINEARTS-HF trial.

Table 4: Results for the primary composite outcome of CV death and total (first and recurrent) HF event and components in FINEARTS-HF (FAS)

Outcome	Finerenone N=3,003		Placebo N=2,998		Ratio (95% CI)
	Events (n; %)	E/100 pt yrs	Events (n; %)	E/100 pt yrs	
Composite of CV death and total HF events	1083 (624; 20.8%)	14.88	1283 (719; 24.0%)	17.70	**Rate ratio 0.84 (0.74, 0.95)**
- CV death	242 (242; 8.1%)	3.33	260 (260; 8.7%)	3.59	csHR[b] 0.93 (0.78, 1.11)
- HF events	842 (479; 16.0%)	11.57	1024 (573; 19.1%)	14.12	**Rate ratio 0.82 (0.71, 0.94)**
- hospitalisation for HF	744 (450; 15.0%)	10.22	877 (514; 17.1%)	12.10	-
- urgent HF visit	98 (73; 2.4%)	1.35	147 (113; 3.8%)	2.03	-
Censoring events: Non-CV and undetermined death[a]	249 (249; 8.3%)	3.42	262 (262; 8.7%)	3.61	csHR[b] 0.94 (0.79, 1.12)
- Non-CV death	185 (185; 6.2%)	2.54	183 (183; 6.1%)	2.52	-
- Undetermined death	64 (64; 2.1%)	0.88	79 (79; 2.6%)	1.09	-

Source: Table 2-36, p67 of the submission.

Abbreviations: CI, confidence interval; csHR, cause-specific hazard ratio; CV, cardiovascular; E, events; FAS, full analysis set; HF, heart failure; pt. patient; yrs, years.

Note: All outcomes adjudicated by the Clinical Event Committee. Statistically significant results in bold.

[a] Censored by non-cardiovascular death and undetermined death.

[b] Cause-specific hazard ratio from stratified Cox proportional hazards model, pooled region and baseline LVEF (<60%, ≥60%) as stratification factors.

6.17 Treatment with finerenone was associated with a statistically significant reduction in the risk of the primary composite outcome of cardiovascular death and total (first and recurrent) heart failure events compared to placebo over a median duration of follow-up of 32 months.

6.18 The Sub-Committees noted that the relative treatment effect in the FINEARTS-HF primary composite outcome was primarily driven by a reduction in total heart failure events. While the proportion of patients experiencing cardiovascular deaths numerically favoured finerenone, the difference between treatment arms failed to demonstrate nominal significance. The Sub-Committees noted the lack of a statistically significant reduction in CV death was consistent with findings from SGLT2i trials in similar patient populations, e.g. EMPEROR-preserved, and DELIVER trials.

6.19 Results of a supportive analysis of time to first cardiovascular death or heart failure event (hazard ratio: 0.84; 95% CI 0.76, 0.94) and its components were generally consistent with the results of the primary composite outcome.

6.20 Finerenone was associated with a statistically significant reduction in the risk of total heart failure events compared to placebo (rate ratio: 0.82; 95% CI 0.71, 0.94); with fewer hospitalisations for heart failure (HHF) and urgent heart failure visits (UHFV) in

the finerenone arm (HHF: 744; UHFV: 98) compared to the placebo arm (HHF: 877; UHFV: 147).

6.21 Table 5 summarises the results of the key secondary outcome of change in KCCQ-TSS from baseline to combined result across Months 6, 9 and 12, in the FINEARTS-HF trial.

Table 5: Results for KCCQ-TSS LS mean change from baseline to Month 6, 9, and 12 in FINEARTS-HF (FAS)

Finerenone N=3,003			Placebo N=2,998			LS mean difference in KCCQ-TSS (95% CI)
n	Baseline Score (SD)	LS Mean change in KCCQ-TSS (95% CI)	n	Baseline Score (SD)	LS Mean change in KCCQ-TSS (95% CI)	
2,371	67.6 (23.9)	7.99 (7.37, 8.62)	2,710	66.5 (23.9)	6.43 (5.79, 7.07)	**1.56 (0.79, 2.34)**

Source: Table 2-38, p75 of the submission.
Abbreviations: CI, confidence interval; FAS, full analysis set; KCCQ, Kansas City Cardiomyopathy Questionnaire; LS, least squares; SD, standard deviation.
Note: Analysis performed using mixed-effects model for repeated measures, with treatment, baseline, study visit, baseline-by-visit interaction, and stratification factors (pooled region and baseline LVEF <60%, ≥60%) as covariates, and no imputation of missing values. Statistically significant results in bold.

6.22 Patients treated with finerenone reported slightly higher KCCQ-TSS at baseline compared to placebo (finerenone 67.6 points, placebo 66.5 points) and demonstrated a statistically significantly larger increase in KCCQ-TSS at the combined result across Months 6, 9 and 12 (least squares mean difference in KCCQ-TSS 1.56; 95% CI 0.79, 2.34). Mean increases in KCCQ-TSS were generally consistent over time.

6.23 A logistic regression analysis of KCCQ-TSS responders in FINEARTS-HF, using pre-specified thresholds of minimally improved (≥9.09 points) and moderately improved (≥19.85 points) at Months 6, 9 and 12, showed larger proportions of responders in the finerenone arm compared with placebo. However, differences between treatment arms only reached nominal significance at Month 9.

6.24 Table 6 summarises the results of a logistic regression analysis for improvement in NYHA Class from baseline to Month 12 in the FINEARTS-HF trial.

Table 6: Logistic regression of improvement in NYHA Class from baseline to Month 12 in FINEARTS-HF (FAS)

	LS Mean change in NYHA Class (95% CI)		LS mean difference in NYHA Class (95% CI)
	Finerenone N=3,003	Placebo N=2,998	
Month 12	0.179 (0.163, 0.195)	0.178 (0.162, 0.194)	1.01 (0.88, 1.15)

Source: Table 2-40, p77 of the submission.
Abbreviations: CI, confidence interval; FAS, full analysis set; NYHA, New York Heart Association.
Note: Analysis performed using mixed-effects model for repeated measures, with treatment, baseline, study visit, baseline-by-visit interaction, and stratification factors (pooled region and baseline LVEF <60%, ≥60%) as covariates, and no imputation of missing values.

6.25 Results of the logistic regression analysis for improvement in NYHA class from baseline to Month 12 showed no statistically significant difference between finerenone and placebo (odds ratio 1.01; 95% CI 0.88; 1.15). Higher proportions of patients in both treatment groups experienced improvements in NYHA class than experienced deteriorations; however, the majority of patients reported no change in NYHA class at any time on treatment (finerenone 62.8% no change; placebo 62.3% no change).

6.26 As the secondary NYHA outcome failed to reach statistical significance, the final secondary outcome, time to first occurrence of the renal composite endpoint, was not tested formally. The proportion of patients with renal composite events was

numerically higher in the finerenone group than in the placebo group (2.5% versus 1.8%, respectively); however, the difference between treatment arms did not reach nominal significance (HR 1.33; 95% CI: 0.94, 1.89).

6.27 Results for time to cardiovascular death (hazard ratio: 0.93; 95% CI 0.78, 1.11) and time to all-cause mortality (HR 0.93, 95% CI 0.83, 1.06) showed no nominally significant difference between treatment arms. The submission suggested this was due to a lack of statistical power and low event rates, rather than no differences in treatment efficacy (Kondo 2024).

6.28 EQ-5D-5L and EQ-5D VAS scores were similar between treatment arms and showed little change from baseline values over time.

Results of the FINEARTS-HF trial: subgroup analyses

6.29 Results of the pre-specified subgroup analyses of the FINEARTS-HF primary composite outcome of cardiovascular death and total (first and recurrent) heart failure were consistent with the results of the primary analysis and demonstrated no significant treatment interactions between subgroups.

6.30 The submission presented the pre-specified subgroup analysis of the efficacy and safety of finerenone by SGLT2i use at baseline. There were substantial differences in baseline demographic and disease characteristics between the SGLT2i subgroups. The subgroup of patients treated with an SGLT2i at baseline included fewer females (SGLT2i 39.2%, no SGLT2i 46.5%), and more patients of Asian race (23.6% versus 15.3%) compared to the subgroup not treated with an SGLT2i. Larger proportions of patients treated with an SGLT2i at baseline reported prior heart failure hospitalisations (71.4% versus 58.6%). In addition, higher proportions of patients in the SGLT2i subgroup had a baseline LVEF <50% (41.2% versus 35.5%), type 2 diabetes (75.4% versus 35.2%) and renal impairment (55% versus 47%). Overall, patients treated with an SGLT2i at baseline appeared to have a higher baseline risk of heart failure and cardiovascular events compared to patients not treated with an SGLT2i.

6.31 The results of the subgroup analysis of SGLT2i use at baseline (Vaduganathan 2025) showed that treatment with finerenone resulted in similar reductions in the risk of primary outcome events in patients treated with an SGLT2i (rate ratio: 0.83; 95% CI 0.60, 1.16) and without an SGLT2i at baseline (rate ratio: 0.85; 95% CI 0.74, 0.98), over a median 32 months of follow-up. Given the higher baseline risk observed in patients with SGLT2i use, the absolute rate reduction was higher with baseline SGLT2i use in all secondary outcomes. Time-updated analyses accounting for baseline and subsequent use of SGLT2i did not meaningfully alter the treatment effects of finerenone on the primary end point. The Sub-Committees noted that overall, patients experienced the benefits of treatment with finerenone with or without SGLT2i use, with patients using an SGLT2i at baseline reporting higher baseline risk, most likely associated with the comorbidity associated with the prescribed SGLT2i (CKD or T2D).

Results of the FINE-HEART pooled analysis

6.32 The FINE-HEART pooled analysis of individual patient data from the finerenone FINEARTS-HF trial (HFmrEF/HFpEF), and FIDELIO-DKD and FIGARO-DKD trials (CKD with type 2 diabetes) showed that treatment with finerenone was associated with a

statistically significant reduction in risk of all-cause mortality compared to placebo (hazard ratio: 0.91; 95% CI 0.84, 0.99). However, there was no statistically significant difference in cardiovascular deaths between treatment arms (hazard ratio: 0.89; 95% CI 0.78, 1.01); except in a sensitivity analysis that classified deaths of undetermined cause as cardiovascular deaths (hazard ratio: 0.88; 95% CI 0.79, 0.98). The Sub-Committees noted that the pooled analysis combined individual patient data from 3 trials with specific inclusion and exclusion criteria, and substantially different patient disease characteristics. The Sub-Committees noted that only 36.7% of patients in the pooled analyses had heart failure. The Sub-Committees agreed with the evaluation that the applicability of these results to the requested HFmrEF/HFpEF population was uncertain. The Sub-Committees considered that the results from the FINEARTS-HF trial remain the most relevant.

Comparative harms

6.33 Overall, the proportions of patients reporting any treatment emergent adverse events in the FINEARTS-HF trial were similar between treatment arms (finerenone 84.0% versus placebo 82.3%), but more patients treated with finerenone reported treatment related adverse events (finerenone 19.2% versus placebo 10.8%).

6.34 Table 7 summarises the most common adverse events reported by patients in either treatment group in the FINEARTS-HF trial.

Table 7: Summary of most common TEAEs in FINEARTS-HF (SAF)

Adverse events	Finerenone (N=2,993) n (%), E/100 pt-yrs	Placebo (N=2,993) n (%), E/100 pt-yrs
Patients reporting adverse events		
Any TEAE	2,515 (84.0%)	2,464 (82.3%)
Treatment related TEAE	576 (19.2%)	324 (10.8%)
TEAE leading to treatment discontinuation	96 (3.2%)	83 (2.8%)
Any serious TEAE	1,157 (38.7%)	1,213 (40.5%)
Treatment related serious adverse event	54 (1.8%)	24 (0.8%)
Serious TEAE leading to treatment discontinuation	37 (1.2%)	35 (1.2%)
Any adverse event resulting in death	382 (12.8%)	403 (13.5%)
Serious TEAE resulting in death	204 (6.8%)	239 (8.0%)
Deaths	494 (16.5%)	528 (17.6%)
Adverse events reported by ≥5% of patients		
COVID-19	346 (11.6%), 6.05	353 (11.8%), 6.12
Hyperkalaemia	264 (8.8%), 4.48	113 (3.8%), 1.85
Hypotension	218 (7.3%), 3.71	134 (4.5%), 2.21
Renal impairment	199 (6.6%), 3.35	117 (3.9%), 1.92
Anaemia	191 (6.4%), 3.18	186 (6.2%), 3.08
Dizziness	174 (5.8%), 2.92	141 (4.7%), 2.33
Diarrhoea	172 (5.7%), 2.87	132 (4.4%), 2.17
Urinary tract infection	169 (5.6%), 2.81	168 (5.6%), 2.76
Pneumonia	158 (5.3%), 2.60	175 (5.8%), 2.86
Glomerular filtration rate decreased	157 (5.2%), 2.63	108 (3.6%), 1.77
Cardiac failure	129 (4.3%), 2.13	182 (6.1%), 3.02
Hypertension	108 (3.6%), 1.78	185 (6.2%), 3.11
Hypokalaemia	89 (3.0%), 1.45	200 (6.7%), 3.33
Worsening renal function		
TEAEs related to worsening renal function	530 (17.7%)	327 (10.9%)
Renal impairment	199 (6.6%)	117 (3.9%)
Serum creatinine >0.3 mg/dL	1,208/2,897 (41.7%)[a]	759/2,888 (26.3%)[a]
Serum creatinine >0.5 mg/dL	618/2,897 (21.3%)[a]	372/2,888 (12.9%)[a]

Source: Table 2.47, p88 of the submission. Table 5-23, p109 and Table 5-30, p122 of the FINEARTS-HF Clinical Study Report.
Abbreviations: E, events; pt-yrs, patient-years; SAF, safety analysis set; TEAE, treatment emergent adverse event.
[a] Percentages by number of patients providing data.

6.35 Adverse events more frequently reported in the finerenone arm than the placebo arm were hyperkalaemia, hypotension, renal impairment, dizziness, diarrhoea and decreased GFR. Adverse events more frequently reported in the placebo arm than the finerenone arm were cardiac failure, hypertension and hypokalaemia.

6.36 The submission noted that hyperkalaemia is an expected adverse event for finerenone and serum potassium levels were closely monitored throughout FINEARTS-HF. The Sub-Committees noted that despite intensive monitoring and dose titration, finerenone was associated with a higher incidence of hyperkalaemia compared to placebo, including treatment related hyperkalaemia (6.6% versus 2.1%) and hyperkalaemia leading to hospitalisation (0.5% versus 0.2%). The Sub-Committees noted that the incidence of hyperkalaemia in the FINEARTS-HF trial was lower than for spironolactone in the TOPCAT trial (18.7% spironolactone vs 9.1% placebo), despite the patient population of FINEARTS-HF appearing to have a higher baseline risk of hyperkalaemia.

6.37 Adverse events related to worsening of renal function were more common in the finerenone arm than in the placebo arm (17.7% versus 10.9%). The most frequently reported adverse events related to worsening renal function were renal impairment (6.6% versus 3.9%), decreased GFR (5.2% versus 3.6%) and acute kidney injury (2.6% versus 1.6%). The PSCR noted that initial increases in serum creatinine and early reductions in eGFR upon finerenone initiation reflect alterations in glomerular haemodynamics, specifically reductions in intraglomerular pressure which may confer long-term benefit.[8] The PSCR noted that a respecified renal analysis of the FINEARTS-HF cohort showed that the initial acute eGFR decline with finerenone stabilises over time, with no significant difference observed in the chronic eGFR slope compared to placebo from month 3 onwards. The PSCR also argued that finerenone demonstrated strong renal parenchymal protection, reducing new-onset microalbuminuria by 24% (HR 0.76, 95% CI: 0.68, 0.83) and macroalbuminuria by 38% (HR 0.62, 95% CI: 0.53, 0.73).[9] The PSCR stated that long-term data from the FIDELIO-DKD and FIGARO-DKD trials suggest that finerenone ultimately slows chronic kidney disease progression.

Benefits/harms

6.38 On the basis of the direct evidence presented in the submission, for every 100 patients treated with finerenone plus standard care in comparison with placebo plus standard care for a median of 32 months of treatment:

- Approximately 2 fewer patients would be hospitalised for heart failure.
- Approximately 1 fewer patient would have an urgent heart failure visit.
- There would be no difference in the number of people who die from heart-related causes.
- Approximately 5 additional patients would experience an adverse event related to high potassium levels in their blood, the majority of which were mild to moderate in intensity.
- Approximately 7 additional patients would experience worsening kidney function, the majority of which were mild to moderate in intensity.

Clinical claim

6.39 The submission described finerenone plus standard care as superior in terms of effectiveness compared with standard care alone. The Sub-Committees considered that this claim was reasonable for the primary composite outcome of CV death and total HF events, however it was noted that superiority was driven by the outcome of HF events and the impact on CV deaths remained uncertain.

6.40 No specific safety claim was proposed in the submission. The Sub-Committees considered the safety profile of finerenone in the FINEARTS-HF trial was consistent with a claim of inferior safety to standard care alone, given the increased risks of

[8] Sindone, A. P., Amerena, J., De Pasquale, C. G., Chan, A. W. P., Gan, G. C. H., Rao, S. D., Burdeniuk, C., Shah, A., & Atherton, J. J. (2026). Consensus Statement on Optimisation of Patient Care After Hospitalisation for Acute Heart Failure. *Heart, Lung and Circulation*, 35(2), 157–170

[9] Mc Causland, F, Vaduganathan, M, Claggett, B. et al. Finerenone and Kidney Outcomes in Patients With Heart Failure: The FINEARTS-HF Trial. JACC. 2025 Jan, 85 (2) 159–168.

hyperkalaemia, initial worsening renal function and increased serum creatinine. The PBAC previously considered that a claim of inferior safety for finerenone versus placebo in patients with diabetic kidney disease was reasonable (para 7.7 finerenone PSD, March 2023 PBAC meeting).

6.41 The Sub-Committees considered that the following issues should be considered:

- Standard care treatment in the FINEARTS-HF trial is unlikely to be representative of clinical practice, due to the low utilisation of SGLT2i medicines, which are now preferred therapies in treatment guidelines. Higher use of SGLT2i medicines in clinical practice may reduce the absolute risk of events in the population and therefore reduce the absolute benefit of finerenone treatment.
- The FINEARTS-HF trial managed the risk of hyperkalaemia through a combination of careful patient selection, intensive monitoring and dose adjustments. It is unclear whether comparable measures would be implemented in clinical practice. Additionally, due to the risk of hyperkalaemia in clinical practice, patients may undergo slower titration schedules, may remain on lower doses for maintenance, or experience higher discontinuation rates compared to the FINEARTS-HF trial. The PSCR argued that the TGA PI for finerenone aligns with the FINEARTS-HF protocol both in terms of maximum potassium levels at treatment initiation, dose titration and management of hyperkalaemia. The PSCR also noted that in the FINEARTS-HF trial patients receiving the higher maintenance dose (40mg) did not experience higher serum potassium levels compared to those on lower doses, which highlights the effectiveness of the protocol. The PSCR also noted that it is common for discontinuation rates in clinical practice to be higher than in a trial setting. The PSCR stated that this was reflected in the economic model by selecting a parametric function which resulted in a higher discontinuation rate than the best-fitting curve.

6.42 The PBAC considered that the claim of superior comparative effectiveness was adequately supported by the data. The PBAC noted that superiority was driven by the outcome of HF events and the impact on CV deaths remained uncertain.

6.43 The PBAC considered that a claim of inferior comparative safety would be reasonable.

Economic analysis

6.44 The submission presented a stepped economic evaluation of finerenone plus standard care versus standard care alone, in patients with HFmrEF/HFpEF. The economic evaluation was based on the results of the FINEARTS-HF trial, with additional modelled data. The economic evaluation was presented as a cost-effectiveness/cost-utility analysis.

Table 8: Key components of the economic evaluation

Component	Description
Treatments	Finerenone plus standard care versus standard care alone
Time horizon	20 years, compared to a mean duration of follow up of 29.5 months in the FINEARTS-HF trial
Outcomes	Cardiovascular events (cardiovascular death, hospitalisation for heart failure, urgent heart failure visit), life years, quality-adjusted life years

Component	Description
Methods used to generate results	Markov state transition model
Health states	4 health states based on KCCQ-TSS quartiles (<50.0; 50.0 to <69.8; 69.8 to <87.5; ≥87.5; where a higher score indicates better health status); and 2 death states (CV and non-CV)
Cycle length	28 days
Circumstances of use	The model assumed adherence to finerenone was 97.9% derived from the FINEARTS-HF trial until discontinuation, with treatment persistence derived from extrapolation of FINEARTS-HF data. Monitoring of serum potassium, recommended in the finerenone Product Information 4 weeks after treatment initiation and periodically thereafter, was not included in the economic model. The use of standard care therapies was based on the distribution of use of heart failure medicine classes at baseline in the FINEARTS-HF trial; adjusted to reflect Australian clinical practice (use of beta-blockers reduced from 84.9% to 24.0% based on 10% PBS sample data; use of SGLT2i increased from 13.6% to 44.0% based on December 2025 PBS script data and estimated overlapping use for CKD or type 2 diabetes). The model assumes perfect adherence to standard care therapies until discontinuation, with treatment persistence derived from modelled data from the empagliflozin and dapagliflozin HFmrEF/HFpEF PSDs.
Transition probabilities	KCCQ-TSS transitions KCCQ-TSS transitions for 3 time periods (baseline to month 6, month 6 to month 9, and month 9 to month 12) were based on individual patient data from FINEARTS-HF. Transition probabilities from month 9 to month 12 were used for the remaining time horizon (to 20 years). KCCQ-TSS transitions for the finerenone arm were adjusted to estimate on-treatment transitions, based on the proportion of time patients remained on treatment (91.1%; derived from the Kaplan Meier time to treatment discontinuation curve), assuming patients who discontinued treatment would have the same transition probabilities as the standard care arm. Cardiovascular death transitions CV death transitions were derived from fitting a Weibull function, with treatment and KCCQ-TSS quartiles included as covariates (predicting variables) of the function, to Kaplan Meier time to CV death curves from FINEARTS-HF, extrapolated to 20 years. CV death transitions in the finerenone arm were adjusted to derive on-treatment transition probabilities. Non-cardiovascular death transitions Non-CV death transitions were derived from estimates of all-cause mortality minus estimates of CV mortality. All-cause mortality was derived from fitting a Weibull function, with treatment and KCCQ-TSS quartiles as covariates, to Kaplan Meier time to all-cause mortality curves from FINEARTS-HF, extrapolated to 20 years. A correction was included to ensure that the monthly probability of non-CV death was not smaller than that of the Australian general population (adjusted to remove CV death). Non-CV death transitions in the finerenone arm were adjusted to derive on-treatment transition probabilities. Treatment discontinuation The per-cycle probability of treatment discontinuation in the finerenone arm was based on the log-normal function fitted to the Kaplan Meier time to treatment discontinuation curve from the FINEARTS-HF trial, extrapolated to 20 years. It was assumed that the probability of treatment discontinuation did not vary by KCCQ-TSS health state. The probability of discontinuation from standard care (11% per year), applied to drug costs only, was derived from the average of the modelled proportions of patients alive and remaining on treatment at 10 years reported in the empagliflozin and dapagliflozin HFmrEF/HFpEF PSDs. Heart failure hospitalisation event rates Event rates for heart failure hospitalisation and urgent heart failure visits were derived using generalised estimating equation models with a log link and Poisson distribution fitted to the observed data from FINEARTS-HF, with treatment and KCCQ-TSS quartiles as covariates. Probabilities were assumed to remain constant over time. Heart failure event rates in the finerenone arm were adjusted to derive on-treatment event rates. Risks of adverse events

Component	Description
	The probabilities of hyperkalaemia adverse events (treatment-related and those requiring hospitalisation) were derived from the incidence of adverse events from the FINEARTS-HF trial. The probabilities of other adverse events were derived from the rate per 100 patient years of adverse events requiring hospitalisation with an incidence of at least 1% from the FINEARTS-HF trial.
Utilities	KCCQ-TSS health state utilities were derived from EQ-5D-5L data from the FINEARTS-HF trial, applying the Australian value set (Norman 2023). The regression analysis included baseline EQ-5D-5L, KCCQ-TSS health state and patient characteristics (age, sex, race, BMI) as covariates. Utility estimates were capped based on Australian general population norms (McCaffrey 2016). KCCQ-TSS Quartile 4: 0.870; Quartile 3: 0.832; Quartile 2: 0.776; Quartile 1: 0.661. Based on the regression equation, an age-based disutility of 0.002 per year was applied. Heart failure event disutilities were derived from a separate regression analysis of EQ-5D-5L data from the FINEARTS-HF trial that included baseline EQ-5D-5L, presence/absence of the event, and patient characteristics (age, sex, race, BMI) as covariates. The disutility for HHF (-0.037) was based on the disutility at 12 months, with an assumed duration of 12 months (QALY loss 0.037); and the disutility for UHFV was based on the disutility at 6 months (-0.053), with an assumed duration of 6 months (QALY loss 0.0265). The disutilities of hyperkalaemia adverse events and other adverse events requiring hospitalisation were based on various published sources, ranging from -0.003 for urinary tract infection (Barry 1997) to -0.100 for acute kidney injury (Booth 2023). It was assumed that the duration of each adverse event was one month.
Costs	The cost of finerenone was based on the proposed effective AEMP, mark-ups from July 2026, and 97.9% adherence derived from the FINEARTS-HF trial. The cost of standard care was based on the distribution of use of heart failure medicine classes in FINEARTS-HF (with beta-blocker and SGLT2i use adjusted to better reflect Australian clinical practice), the recommended dose for each medicine based on its PI, the DPMQ and pack size from the June 2026 PBS Schedule; and assumed 100% adherence. Disease management costs were based on annual estimates of GP and cardiologist visits from a German cohort study (Biermann 2012), assumed to be constant across all health states, with unit costs based on MBS items. Heart failure hospitalisation costs were based on AR-DRG items for heart failure, using NHCDC Cost weights and numbers of separations from AR-DRG version 11.0, 2020-21 and the 2025-26 National Efficient Price ($12,150.65). The Sub-Committees noted that during the evaluation, an alternative cost of hospitalisation for heart failure was derived, based on more recent cost weights from the National Efficient Price Determination Report 2025-2026, and numbers of separations from AIHW AR-DRG data cubes (2023-2024). This resulted in a lower cost of heart failure hospitalisation ($11,196.05). The Pre-PBAC Response noted the IHACPA recently published the National Efficient Price Determination 2026–27 (NEP26), which can now be used instead (1.5426*$7,418 = $11,443). The Pre-PBAC Response included this cost in a revised base case. The cost of ambulance transport was based on the average of Ambulance Victoria's scheduled fee for a metropolitan road emergency 2025-2026 ($1,437; Victoria Department of Health 2025) and state and territory ambulance service organisations' expenditure per incident ($1,422; Productivity Commission 2026), applied to 62% of events, based on an observational study of emergency department presentations in Australia, New Zealand, and Asia (Keijzers 2017). Rehabilitation costs were based on the Tier 2 Non-Admitted Services Classification Version 9.1 cost weight for cardiac rehabilitation and the 2025-26 National Efficient Price; applied to 9.8% of events based on a Victorian registry study (Giuliano 2022); and assuming that patients would receive 10 sessions. Urgent heart failure visit costs were based on the average of Australian Emergency Care Classification Version 1.1 items for heart failure using cost weights and the 2025-26 National Efficient Price.

Component	Description
	Cardiovascular death costs were based on the cost used for heart failure hospitalisation minus the rehabilitation costs; applied to all cardiovascular deaths. It was assumed that there are no costs associated with a non-cardiovascular death. Adverse event costs were based on AR-DRG items, using NHCDC Cost weights and numbers of separations from AR-DRG version 11.0, 2020-21 and the 2025-26 National Efficient Price.
Discount rate	5% for costs and benefits
Software package	Microsoft Excel

Source: Sections 3.3 to 3.6, pp112-141 of the submission.

Abbreviations: AEMP, approved ex-manufacturer price; BMI, body mass index; CV, cardiovascular; DPMQ, dispensed price for maximum quantity; HFmrEF, heart failure with mildly reduced ejection fraction; HFpEF, heart failure with preserved ejection fraction; HHF, hospitalisation for heart failure; IHACPA, Independent Health and Aged Care Pricing Authority; NHCDC, National Hospital Cost Data Collection; KCCQ-TSS, Kansas City Cardiomyopathy Questionnaire Total Symptom Score; PI, Product Information; PSD, Public Summary Document; QALY, quality adjusted life year; SGLT2i, sodium-glucose cotransporter-2 inhibitor; UHFV, urgent heart failure visit.

6.45 The model structure was consistent with the structure of heart failure models previously considered by the PBAC (e.g. November/December 2022 empagliflozin submission; and July 2023 dapagliflozin submission for HFmrEF/HFpEF).

6.46 Patients begin the model in one of the 4 KCCQ-TSS quartile health states. During each 28-day cycle of the Markov model, patients may remain in their KCCQ-TSS quartile health state, move to another KCCQ-TSS quartile health state, or die from cardiovascular or non-cardiovascular causes. During each cycle, patients can experience hospitalisation due to heart failure, an urgent heart failure visit, or adverse events. Patients in the finerenone plus standard care arm may discontinue treatment in each cycle, and adopt the same risks as the standard care arm. Patients in each treatment arm may discontinue standard care in any model cycle, which affects standard care costs only.

6.47 The model assumes that transition probabilities between KCCQ-TSS quartile health states, derived from individual patient data from FINEARTS-HF between 9 and 12 months, are constant from month 9 to the end of the 20-year model time horizon. The analysis of individual patient data indicates that patients in both treatment arms experience initial improvement in health status, followed by stabilisation. The Sub-Committees agreed with the evaluation that it was unclear whether transitions derived from the 9–12 month period adequately reflect longer term health outcomes in a progressive disease. The Sub-Committees noted that this introduced uncertainty to the economic model.

6.48 The submission nominated a 20-year time horizon for the economic analysis to balance the need to capture long-term costs and outcomes in HFmrEF/HFpEF against uncertainty associated with extrapolating beyond the trial follow-up period. While noting that the PBAC previously accepted a 15-year time horizon for empagliflozin and dapagliflozin in HFmrEF/HFpEF (informed by the time horizon in the empagliflozin HFrEF submission), the submission argued that a longer horizon was justified for finerenone in light of the longer median follow-up in the FINEARTS-HF trial (median 32 months) compared to the empagliflozin HFrEF EMPEROR-Reduced trial (median 16 months). The Sub-Committees agreed with the evaluation that given the limited follow-up of FINEARTS-HF and the importance of maintaining consistency with prior PBAC considerations for HFmrEF/HFpEF treatments, a 15-year time horizon remains

appropriate. Reducing the time horizon from 20 years to 15 years increased the incremental cost-effectiveness ratio (ICER) from $15,000 to < $25,000 per quality adjusted life year (QALY) gained to $25,000 to < $35,000 per QALY gained. The Pre-PBAC Response proposed a revised base case which included a time horizon of 15 years.

6.49 The model applies higher rates of heart failure events, and cardiovascular and non-cardiovascular mortality to patients with poorer KCCQ-TSS scores (based on quartiles). Heart failure events are associated with a cost and disutility, but do not alter health state transitions and do not affect mortality rates. The Sub-Committees considered that this was unlikely to reflect the disease pathway, noting that the direction and magnitude of effect was uncertain. The PSCR acknowledged that this approach may not adequately reflect the progression of the disease, however noted that incorporating such cumulative effects would increase the model complexity considerably and would move away from established KCCQ-based precedents.

6.50 The Sub-Committees noted that the baseline use of SGLT2is in the FINEARTS-HF trial was low (13.6%) suggesting that the underlying risk applied to the economic model may be overestimated. The submission adjusted estimates of use of beta-blockers (reduced) and SGLT2i therapies (increased) from the FINEARTS-HF to better reflect standard care in Australian clinical practice. However, this adjustment was applied to costs only, which is inappropriate, since changes in the use of active therapies would also affect clinical outcomes. The alternative estimates of use are uncertain and not supported by robust data. In the absence of a modelling approach that appropriately captures the impact of standard care therapies on both costs and outcomes, trial-based estimates are preferred to maintain consistency with the clinical evidence. However, the cost adjustments had minimal impact on the economic model.

6.51 Due to the uncertainty associated with the impact of higher SGLT2i use in clinical practice than in the FINEARTS-HF trial (see paragraph 6.12), the submission presented the results of a scenario analysis, based on data from the baseline SGLT2i use subgroup from the FINEARTS-HF trial (see Table 11 below). The evaluation considered that the results of the sensitivity analysis based on the FINEARTS-HF subgroup of SGLT2i users at baseline should be interpreted with caution given data informing some health state transitions were relatively sparse and may not provide reliable estimates. Further, patients treated with an SGLT2i at baseline appeared to have a higher baseline risk of cardiovascular events compared to patients not treated with an SGLT2i. This is consistent with the timing of the trial, which pre-dated the recommendation of SGLT2i therapies for heart failure and therefore patients using these therapies at baseline in the trial were likely being treated for comorbid T2D and/or CKD. As a consequence, the subgroup of SGLT2i users from the trial may not be representative of SGLT2i users with heart failure in clinical practice given the changes in practice over time.

6.52 The Pre-PBAC Response noted that while only 14% of patients were being treated with an SGLT2i at baseline in the FINEARTS-HF trial, an additional 20% of patients commenced treatment with an SGLT2i post-baseline. The Response also considered

that there were other factors expected to increase the risk of patients in clinical practice versus the trial (NYHA class mix and proportion of stable patients).

6.53 The Response stated that if the PBAC considered finerenone not cost-effective at the proposed price due to uncertainty in baseline risk, it may wish to restrict listing to patients with prior CV events, including HF hospitalisation, urgent HF visit, myocardial infarction or stroke, who comprised 81% of the FINEARTS-HF trial and were included as a subgroup in the economic model. The Response stated that prior CV events were established independent predictors of recurrent CV morbidity and mortality.[10,11,12,13] The Response noted that restricting to this sub-group increased the baseline risk by approximately 13% compared to the full population.

6.54 All transitions and event rates for finerenone were adjusted to estimate outcomes based on those who were on treatment only, by removing the impact of patients who had discontinued finerenone treatment; assuming patients who discontinued finerenone have the same risks as the standard care arm. Removing this adjustment increased the ICER from $15,000 to < $25,000 per QALY gained to $25,000 to < $35,000 per QALY gained.

6.55 In the model, CV mortality and all-cause mortality benefits for finerenone were generated from improved survival within each KCCQ-TSS health state, as well as from higher proportions of patients in the finerenone arm transitioning to KCCQ-TSS quartiles representing improved health status, which have lower mortality (and lower proportions transitioning to lower health status quartiles with higher mortality) compared with the placebo arm. Cardiovascular mortality and all-cause mortality in the base case analysis were derived from jointly fitted Weibull functions, with treatment and KCCQ-TSS quartiles used as covariates (predicting variables) for each function. The Sub-Committees noted that the exponential function was the best fitting curve for CV mortality according to Bayesian information criterion (BIC) statistics and Gompertz equally as good as Weibull. The ICER was moderately sensitive to the chosen parametric function.

6.56 The Sub-Committees also noted the inclusion of treatment as a covariate for estimating cardiovascular and all-cause mortality was not adequately justified in the submission. The PSCR argued that while FINEARTS-HF showed only numerical survival benefit, it was not powered for mortality. The PSCR stated that there is substantial overlap between HF, chronic kidney disease, and diabetes, supporting the consideration of broader evidence, such as the FINE-HEART pooled analysis (see paragraph 6.28). The PSCR argued that this analysis was powered for CV mortality and demonstrated a statistical 9% reduction in all-cause mortality. The PSCR also noted

[10] Greene SJ, Bauersachs J, Brugts JJ, et al. (2023) Worsening Heart Failure: Nomenclature, Epidemiology, and Future Directions: JACC Review Topic of the Week. Journal of the American College of Cardiology. 81(4):413-424.

[11] Docherty KF, Jhund PS, Claggett BL, et al. (2023) PREDICT-HFpEF: A multivariable risk score for heart failure with mildly reduced or preserved ejection fraction. European Journal of Heart Failure. 25(11):2014–2024.

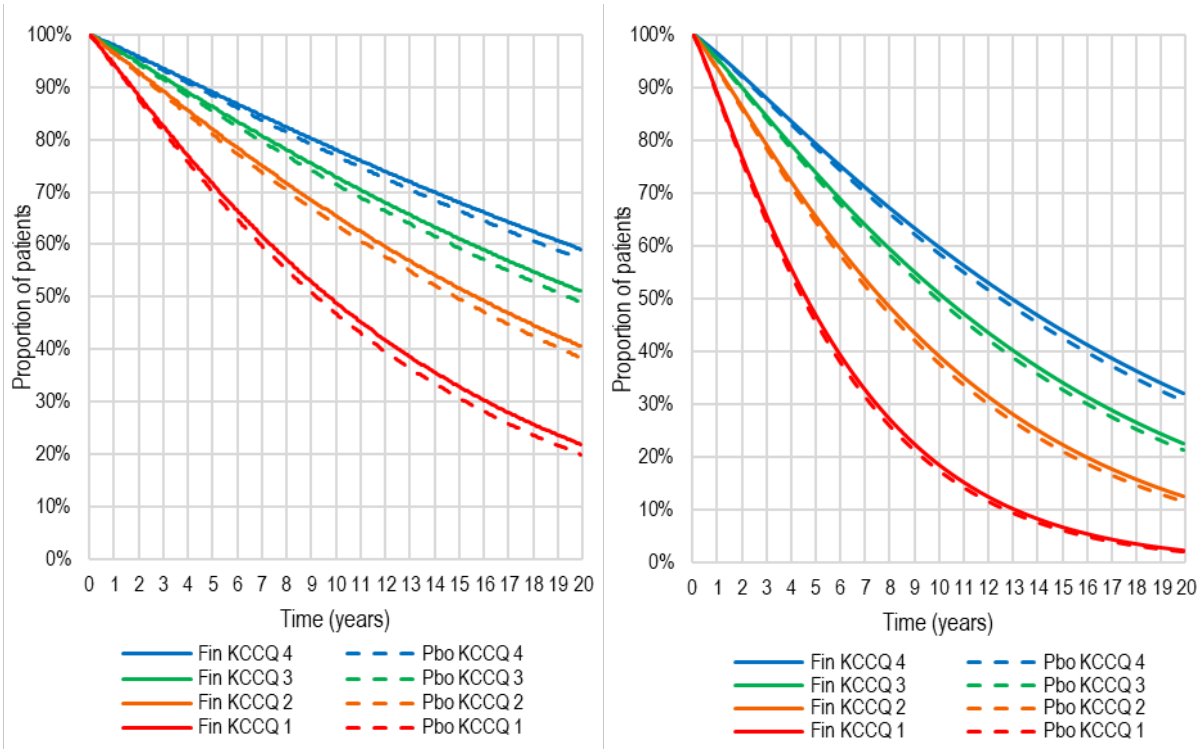
[12] Pocock SJ, A'Court C, Collier TJ, et al. (2013) Predicting survival in heart failure: a risk score based on 39 372 patients from 30 studies (MAGGIC). European Heart Journal. 34(19):1404–1413.

[13] Ndumele CE, Neeland IJ, Tuttle KR, et al. (2023) Cardiovascular-Kidney-Metabolic Health: A Presidential Advisory From the American Heart Association. Circulation. 148(20):1606–1635.

that by including both the treatment effect and KCCQ health state as covariates in the Weibull regression, the model actively prevents double-counting the mortality benefit. The Sub-Committees considered that while it is plausible that there may be an unknown level of mortality benefit not captured by KCCQ-TSS stratification, the treatment arm was not a statistically significant predictor of survival in the parametric models, suggesting that there is no evidence of an independent treatment effect on mortality after adjusting for health state. Furthermore, the relevance of the FINE-HEART pooled analysis to the requested PBS population was uncertain, given the markedly broader and less targeted population analysed. The inclusion of treatment as a covariate for estimating all-cause mortality was also inconsistent with the approach in the November 2022 empagliflozin and July 2023 dapagliflozin HFmrEF/HFpEF submissions, which included covariates for KCCQ health states only. The Sub-Committees noted that removing the direct treatment effect (covariate) of finerenone on mortality increased the ICER from $15,000 to < $25,000per QALY gained to $35,000 to < $45,000 per QALY gained.

6.57 Figure 1 below presents the CV mortality (left) and all-cause mortality (right) survival curves informing mortality transitions in the economic model. The curves illustrate the modelled mortality benefit for finerenone within each KCCQ-TSS health state.

Figure 1: Base case cardiovascular (left) and all-cause (right) survival curves informing cardiovascular and non-cardiovascular mortality transitions in the economic model



Source: 'Section_3_model' spreadsheet provided with the submission.
Abbreviations: Fin, finerenone; KCCQ, Kansas City Cardiomyopathy Questionnaire Total Symptom Score Quartile; KCCQ-TSS, Kansas City Cardiomyopathy Questionnaire Total Symptom Score; Pbo, placebo.

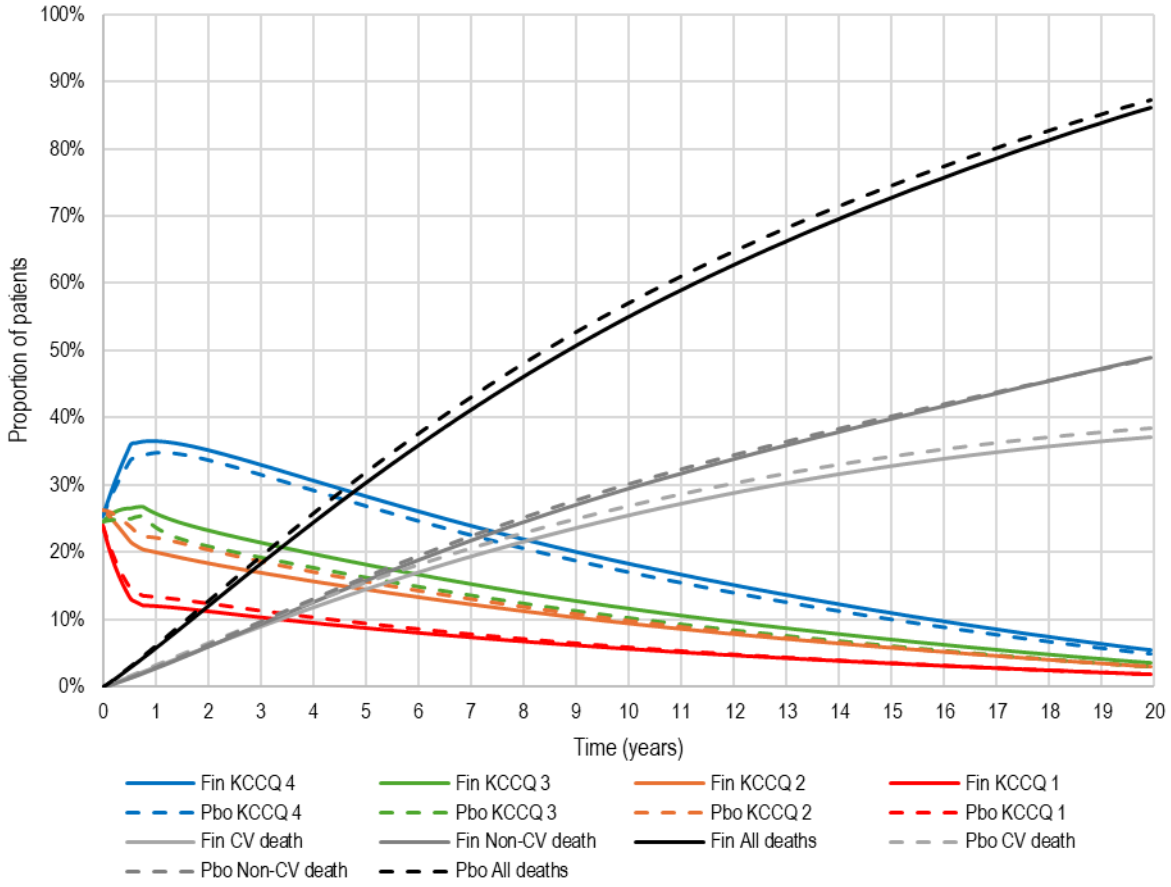
6.58 The Pre-PBAC Response updated the CV and all-cause mortality parametric survival curves to exclude the treatment covariate and include a time-varying heart failure

hospitalisation covariate. The Response stated that for all-cause mortality, the Weibull function provided the best fit, and all covariates were statistically significant ($p<0.0001$), indicating that HF hospitalisation independently predicted mortality after accounting for KCCQ health state. The Response presented only the Weibull and exponential functions; goodness-of-fit statistics were not provided.

6.59 The Response stated that the HF hospitalisation hazard ratio from the regression was upscaled to reflect a 6-cycle duration, weighted based on the probability of an event occurring each cycle and applied to the baseline risk in the survival curves. The Response stated that this approach artificially brought deaths forward in time, affecting both arms but slightly more for placebo due to more frequent events. The Response stated that to avoid complex structural modelling to account for the timing of post-HF hospitalisation mortality, a direct QALY adjustment was applied. The Response stated that the QALY adjustment was calculated by applying the model's per HF hospitalisation event lethality rate to the difference in events over the 15-year horizon between the finerenone and the SoC arms to determine the bias in life years and multiplied by the average utility value in the model to translate this into QALYs. The calculated -0.016 QALYs were then subtracted from the final model outputs.

6.60 Figure 2 below presents the model traces for the finerenone plus standard care and standard care alone arms presented in the submission base case.

Figure 2: Model trace for finerenone plus standard care and placebo plus standard care



Source: Figure 3-32, p144 of the submission; 'Section_3_model' spreadsheet provided with the submission.

Abbreviations: CV, cardiovascular; Fin, finerenone plus standard care; KCCQ, Kansas City Cardiomyopathy Questionnaire Total Symptom Score Quartile; Pbo, placebo plus standard care.

6.61 The model traces indicated that finerenone plus standard care was associated with a survival benefit compared to standard care alone, predominantly due to a reduction in CV deaths. This was inconsistent with the results of the FINEARTS-HF trial, which showed no statistically significant differences in CV or all-cause mortality between treatments.

6.62 After 20 years (in patients with a baseline age of 72 years), 86.2% of patients in the finerenone plus standard care arm, and 87.2% of patients in the placebo plus standard care arm had died.

6.63 Over the model time horizon, the finerenone plus standard care arm was associated with a higher proportion of patients with better health status (KCCQ-TSS Quartiles 3 and 4) compared with the placebo plus standard care arm, and lower proportions of patients with poorer health status (Quartiles 1 and 2).

6.64 The model estimated that on average, patients treated with finerenone plus standard care will experience 1.02 heart failure hospitalisations and 0.13 urgent heart failure visits, compared with 1.15 heart failure hospitalisations and 0.18 urgent heart failure visits in patients treated with standard care alone, over 20 years.

6.65 The model estimates that 88.6% of finerenone plus standard care patients remain on finerenone treatment at 1 year (93.7% of those remaining alive), which decreases to 56.4% at 5 years (80.5% of those remaining alive), 31.6% at 10 years (69.9% of those remaining alive) and 17.1% at 15 years (62.1% of those remaining alive). At the end of the 20-year model, 7.7% of patients remain on finerenone (55.6% of those remaining alive).

6.66 Key drivers of the economic model are summarised in Table 9.

Table 9: Key drivers of the model

Description	Method/Value	Impact
Modelled mortality benefit	The model assumes differences in time to cardiovascular death and time to all-cause death, favouring finerenone, that are not consistent with the available clinical data, although numerical results favoured finerenone. The inclusion of treatment as a covariate for estimating all-cause mortality was inconsistent with the approach in the November 2022 empagliflozin and July 2023 dapagliflozin HFmrEF/HFpEF submissions, which included covariates for KCCQ health states only. The model was highly sensitive to uncertainty associated with cardiovascular and non-cardiovascular mortality treatment effects.	High, favours finerenone
KCCQ-TSS quartile health state transitions	The model assumes that transition probabilities between KCCQ-TSS quartile health states, derived from individual patient data from FINEARTS-HF between 9 and 12 months, are constant from month 9 to the end of the 20-year model time horizon. It is unclear whether transitions derived from the 9–12 month period adequately reflect longer term health outcomes in a progressive disease.	Unclear

Source: Constructed during the evaluation with reference to Section 3 of the submission and the 'Section_3_model' spreadsheet provided with the submission.
Abbreviations: KCCQ, Kansas City Cardiomyopathy Questionnaire.

6.67 The modelled economic evaluation presented in the submission is shown in Table 10.

Table 10: Results of the economic evaluation

Component	Finerenone plus standard care	Standard care	Increment
Costs	$[redacted]	$23,594	$[redacted]
Life years	7.1905	7.0100	0.1805
QALYs	5.7284	5.5544	0.1740
Incremental cost/life year gained			**$[redacted][1]**
Incremental cost/QALY gained			**$[redacted][1]**

Source: Table 3-77, p147 of the submission; 'Section_3_model' spreadsheet provided with the submission.
Abbreviations: QALY, quality adjusted life year.
The redacted values correspond to the following ranges:
[1] *$15,000 to < $25,000*

6.68 Based on the economic evaluation presented in the submission, treatment with finerenone plus standard care was associated with an incremental cost per QALY gained of $15,000 to < $25,000 compared to standard care alone for the treatment of patients with HFmrEF/HFpEF.

6.69 The Sub-Committees noted that the finerenone model generates incremental life years and incremental QALYs for finerenone plus standard care versus standard care alone that are approximately twice the incremental outcomes generated by the economic models in the November/December 2022 empagliflozin and July 2023 dapagliflozin submissions for the SGLT2i plus standard care versus standard care alone. The Sub-Committees considered that the submission did not provide any evidence to support larger health gains in HFmrEF/HFpEF for patients treated with finerenone compared to an SGLT2i. The Sub-Committees considered that overall, comparison with the outcomes generated in the SGLT2i submissions suggested that the base case of the economic model had overestimated the health benefits associated with finerenone.

6.70 In the model 69.5% of incremental costs and 89.4% of incremental QALYs are accrued in the extrapolated period beyond the mean duration of follow-up of the FINEARTS-HF trial (29.47 months).

6.71 On average, for every patient treated with finerenone plus standard care versus standard care alone, and followed up for 20 years, the (undiscounted) economic model estimates that there would be:

- Additional finerenone and standard care costs of $[redacted] and additional costs of treating adverse events of $364.
- Additional survival of 3.56 months, associated with additional disease management costs of $125 and a reduction in the costs associated with cardiovascular death of $164.
- An additional 6.00 months spent in health states with higher quality of life (KCCQ-TSS quartiles 3 and 4), and 2.44 fewer months spent in health states with lower quality of life (KCCQ-TSS quartiles 1 and 2).
- A reduction of 0.14 heart failure hospitalisations (14 events per 100 patients) and a reduction of 0.05 urgent heart failure visits (5 events per 100 patients), which would be associated with a reduction in costs of $1,887, and improved quality of life.

6.72 Table 11 summarises the results of key sensitivity analyses presented in the submission and conducted during the evaluation. The results of sensitivity analyses indicated that the model is most sensitive to differences between treatment arms in KCCQ-TSS health state transitions, heart failure event rates, assuming no finerenone treatment effect on mortality beyond that associated with improved health status, shorter time horizons, and the price of finerenone.

6.73 The Sub-Committees considered that overall, the base case of the economic model had overestimated the health benefits associated with finerenone. The Sub-Committees considered a revised base case should be considered, including a 15-year time horizon, exclusion of the mortality treatment covariate, and a lower heart failure hospitalisation cost. The Sub-Committees noted that this increased the ICER by [redacted]%.

6.74 The Pre-PBAC Response presented a revised economic model with the following revisions:

- Reduction to the EMP of finerenone from $[redacted] to $[redacted];
- Reduction of the time horizon from 20 years to 15 years;
- Reduction of the HF hospitalisation cost from $12,150.60 to $11,443; and
- Revision of the CV and all-cause mortality parametric survival curves to exclude the treatment covariate
- Inclusion of a time-varying HF hospitalisation covariate
- A QALY adjustment to reduce the survival benefit that the Response attributed to bringing deaths forward under the revised regression and extrapolations (see paragraphs 6.57–6.58).

Table 11: Results of key sensitivity analyses

Analysis	Incremental cost ($)	Incremental QALYs	ICER ($)	% change
Base case	[redacted]	**0.1740**	[redacted][2]	-
FINEARTS-HF subgroup of baseline SGLT2i users	[redacted]	0.4460	[redacted][1]	[redacted]
Discount rate (base case: 5% costs and outcomes)				
0%	[redacted]	0.2754	[redacted][2]	[redacted]
3.5%	[redacted]	0.1979	[redacted][2]	[redacted]
Time horizon (base case: 20 years)				
5 years	[redacted]	0.0468	[redacted][5]	[redacted]
10 years	[redacted]	0.1052	[redacted][3]	[redacted]
15 years	[redacted]	0.1493	[redacted][3]	[redacted]
Lifetime (28 years; maximum age 100 years)	[redacted]	0.1856	[redacted][2]	[redacted]
Adjustment for finerenone treatment effects (base case: trial based (ITT) estimates adjusted for those who were on-treatment only)				
No adjustment for on-treatment outcomes	[redacted]	0.1578	[redacted][3]	[redacted]
Health state transitions (base case: based on FINEARTS-HF individual patient data)				
Finerenone transitions set equal to placebo transitions	[redacted]	0.0824	[redacted][5]	[redacted]
Placebo transitions set equal to finerenone transitions	[redacted]	0.0823	[redacted][5]	[redacted]
Heart failure event rates (base case: derived using generalised estimating equation models with a log link and Poisson distribution fitted to FINEARTS-HF data; probabilities vary by KCCQ-TSS state and treatment)				
Halve incremental difference between finerenone and placebo	[redacted]	0.1714	[redacted][3]	[redacted]

Analysis	Incremental cost ($)	Incremental QALYs	ICER ($)	% change
Base case	[redacted]	**0.1740**	[redacted][2]	-
Constant event rate based on FINEARTS-HF (HHF: finerenone 0.0078, placebo 0.0093; UHFV: finerenone 0.0093, placebo 0.0016)[a]	–	0.1567	[redacted][4]	+[redacted]
All-cause mortality (base case: finerenone and placebo arms jointly fitted, with Weibull function fitted to FINEARTS-HF time to all-cause mortality data, with treatment and KCCQ-TSS quartiles as covariates)				
Exponential function	–	0.1672	[redacted][3]	+[redacted]
Gompertz function	–	0.1479	[redacted][2]	+[redacted]
Loglogistic function	–	0.1523	[redacted][3]	+[redacted]
Lognormal function	–	0.1422	[redacted][3]	+[redacted]
Generalised gamma function	–	0.1670	[redacted][3]	+[redacted]
CV and all-cause mortality treatment effects (covariate) (base case: cardiovascular and all-cause mortality were estimated assuming a treatment effect for finerenone beyond the mortality benefits associated with improved health status with lower mortality)				
No finerenone treatment effect on mortality beyond that associated with improved health status (covariate removed)[b]	–	0.0968	[redacted][4]	+[redacted]
Adverse events (base case: derived from event rates in FINEARTS-HF)				
Exclude adverse events	–	0.1741	[redacted][2]	-[redacted]
Heart failure hospitalisation cost (base case: $12,150.65)				
$11,196.05 (see Table 8 – alternative cost from evaluation)	–	0.1740	[redacted][2]	+[redacted]
$7,418.00 (see Table 8 – alternative cost from PSCR)	–	0.1740	[redacted][3]	+[redacted]
Health state utilities (base case: derived from FINEARTS-HF EQ-5D-5L data; utility estimates were capped based on Australian general population norms (McCaffrey 2016); an age-based disutility of 0.002 per year was applied).				
Remove age-based disutility	–	0.2034	[redacted][2]	-[redacted]
Sub-Committee revised base case analyses				
15 year time horizon + No finerenone treatment effect on mortality beyond that associated with improved health status (covariate removed)[b] + alternative heart failure hospitalisation costs ($11,196.05).	–	0.085	[redacted][5]	+[redacted]
Pre-PBAC Response				
Finerenone DPMQ of $[redacted] + 15 year time horizon + mortality treatment covariate removed + mortality HHF covariate added + QALY adaptation + alternative heart failure hospitalisation costs ($11,443).	–	0.132	[redacted][2]	-[redacted]
Subgroup analysis: History of CV event subgroup Finerenone DPMQ of $[redacted] + 15 year time horizon + mortality treatment covariate removed + mortality HHF covariate added + QALY adaptation + alternative heart failure hospitalisation costs ($11,443).	–	0.168	[redacted][2]	-[redacted]

Source: Table, p148 of the submission; 'Section_3_model' spreadsheet provided with the submission. Additional analyses were conducted during the evaluation and during the development of the ESC DUSC advice. Pre-PBAC Response (Table 1, p1) and economic model: '5.07 Pre-PBAC Response Finerenone - Kerendia - Bayer Section_3_model.xlsm'.

Abbreviations: AEMP, approved ex-manufacturer price; CKD, chronic kidney disease; CV, cardiovascular; DPMQ, dispensed price for maximum quantity; HHF, hospitalisation for heart failure; ICER, incremental cost effectiveness ratio; KCCQ-TSS, Kansas City Cardiomyopathy Questionnaire Total Symptom Score; QALY, quality adjusted life year; SGLT2i, sodium-glucose cotransporter-2 inhibitor; UHFV, urgent heart failure visit.

[a] HHF event rate calculated during the evaluation based on 10.22 events per 100-patient years for finerenone and 12.10 events per 100-patient years for placebo; converted to an event rate per patient per 28 day cycle. UHFV event rate calculated during the evaluation based on 1.35 events per 100-patient years for finerenone and 2.03 events per 100-patient years for placebo; converted to an event rate per patient per 28 day cycle.

[b] Note that this analysis still generates a survival advantage for finerenone given different survival curves are generated for each KCCQ-TSS health state, and the model generates differences between treatment arms in KCCQ-TSS health state membership, with higher

proportions of patients in health states with higher survival and lower proportions in health states with lower survival in the finerenone arm compared with the standard care arm.
The redacted values correspond to the following ranges:
[1] *$5,000 to < $15,000*
[2] *$15,000 to < $25,000*
[3] *$25,000 to < $35,000*
[4] *$35,000 to < $45,000*
[5] *$45,000 to < $55,000*

Drug cost/patient/year

6.75 The submission proposed a flat pricing structure across all dose strengths (10, 20 and 40 mg) of finerenone. The estimated drug cost for finerenone per patient per year was $[redacted] (based on the Pre-PBAC Response proposed effective DPMQ of $[redacted] for 28 tablets × 365.25/28 packs per year × 97.9% treatment adherence). The estimated annual drug cost for SoC in the economic model was $376.70 (excluding SGLT2i) and $677.95 (including SGLT2i).

6.76 The financial impact model included estimates of treatment persistence, which does not appear appropriate given the prevalence-based approach.

6.77 Table 12 presents a comparison of drug costs for finerenone included in the economic model and financial estimates.

Table 12: Drug cost per patient per year for finerenone

	FINEARTS-HF trial	Economic model		Financial estimates
Daily dose	10, 20 or 40 mg daily	10, 20 or 40 mg daily		10, 20 or 40 mg daily
Cost per pack of 28 tablets (proposed DPMQ) [a]	-	Submission: $[redacted] Pre-PBAC Response: $[redacted]		Submission: $[redacted] Pre-PBAC Response: $[redacted]
Adherence	97.9% [b]	97.9% [b]		97.9% [b]
Number of scripts per year	-	12.77		12.77
Cost per year	-	Submission: $[redacted] Pre-PBAC Response: $[redacted]		Submission: $[redacted] Pre-PBAC Response: $[redacted]
Proportion of patients on treatment (persistence)	At median follow-up 32 months, 87.4% of patients in the finerenone arm remained on treatment [c]	On tx [d] 88.58% 79.10% 70.67% 63.13% 56.35% 50.27%	On tx | alive [e] 93.73% 89.62% 86.21% 83.23% 80.55% 78.10%	Yr 1: 100% [f] Yr 2: 97.65% Yr 3: 96.33% Yr 4: 95.82% Yr 5: 95.64% Yr 6: 95.22%

Source: Table 1-18, p32 of the submission 'Section_3_model' and 'Section_4_model' provided with the submission; 'bay948862_20103_query48_monthly_tablet_intake' provided by the sponsor during the evaluation.
[a] Using mark-ups from July 2026.
[b] Based on the average number of finerenone tablets taken per 28 day period in FINEARTS-HF.
[c] Derived from Kaplan Meier time to treatment discontinuation data in the economic model.
[d] Estimated proportion of patients remaining on treatment at the end of each year.
[e] Estimated proportion of patients remaining on treatment at the end of each year as a proportion of those remaining alive.
[f] The submission stated that estimates were based on patients remaining on treatment out of those alive in the economic model. These estimates could not be verified during the evaluation.

Estimated PBS usage & financial implications

6.78 This submission was considered jointly by the DUSC and ESC.

6.79 The submission used an epidemiological approach to estimate the utilisation and financial impact of listing finerenone on the PBS/RPBS for the treatment of HFmrEF/HFpEF.

6.80 The submission noted that SGLT2i medicines are currently the only medicines listed on the PBS for the treatment of HFmrEF/HFpEF but could not provide reliable market share data given their recent listing (empagliflozin October 2023; dapagliflozin March 2024) and immature uptake, necessitating the use of an epidemiological approach. The evaluation considered that this was appropriate.

6.81 The submission adopted a similar approach to estimating the utilisation and financial impact of finerenone on the PBS/RPBS for the treatment of HFmrEF/HFpEF as used in the November 2022 empagliflozin and July 2023 dapagliflozin submissions, using many of the same data sources and assumptions.

6.82 Key inputs for the financial estimates are summarised in Table 13.

Table 13: Data sources and parameter values applied in the utilisation and financial estimates

Parameter	Value	Source	Comment
Adult Australian population	Yr 1: 22,277,628 Yr 2: 22,641,368 Yr 3: 22,989,790 Yr 4: 23,327,752 Yr 5: 23,653,957 Yr 6: 23,963,117	Australian Bureau of Statistics population projection (3222.0 Series B; 2027 base year) 2027-2032	The evaluation considered that this was reasonable.
Heart failure prevalence	2,199 per 100,000 adults (2.2%)	Based on the age-adjusted prevalence of definite or probable heart failure in Liew 2020 (SHAPE study), a retrospective review of medical records from adult patients attending 43 Australian general practices between July 2013 and June 2018.	This source was used in the empagliflozin and dapagliflozin HFmrEF/HFpEF submissions. However, it is based on older data, and may not reflect changing diagnostic trends in HFmrEF/HFpEF. The publication noted that the prevalence of HF may have been underestimated given the difficulty in identifying HF patients with LVEF >40% as this condition is not as well recognised and at the time there were no disease-specific therapies. The PSCR acknowledged that the population estimate was likely slightly underestimated, as the data were from 2013–2018. The Sub-Committees noted a recent global review estimated the prevalence of heart failure in adults to be between 1% and 3%[14] and considered the submission's estimate to be reasonable given the lack of recent Australian data.
Proportion of patients with HFmrEF/HFpEF (LVEF >40%)	53.0%	Assumed, based on the range of values from Australian epidemiological studies (52–59%) reported in the empagliflozin November 2022 PSD (para 6.62, empagliflozin PSD, November 2022 PBAC meeting).	The empagliflozin November 2022 pre-PBAC response proposed the percentage of patients with LVEF >40% was more likely 55%, agreeing with the evaluation that Australian epidemiological studies reported a proportion ranging from 52% to 59%. Alternative estimates were explored in sensitivity analyses. The Sub-Committees considered this parameter to be underestimated and suggested it be revised to 57.6% based

[14] Shahim, B., Kapelios, C. J., Savarese, G., & Lund, L. H. (2023). Global Public Health Burden of Heart Failure: An Updated Review. *Cardiac failure review*, *9*, e11. https://doi.org/10.15420/cfr.2023.05

Parameter	Value	Source	Comment
			on the pooled estimate of two of the most recent Australian studies[15,16]. **Study** / **Data years** / **HFmrEF/ HFpEF** / **Total HF cohort** / **Proportion** Newton 2020 / 2013 / 366 / 650 / 56.3% Sindone 2021 / 2013-15 / 403 / 686 / 58.7% **Pooled** / / **769** / **1,336** / **57.6%**
NYHA Class II - IV	95.0%	Assumed, based on the July 2023 dapagliflozin submission (para 6.59, dapagliflozin PSD, July 2023 PBAC meeting).	Notwithstanding this estimate was based on patients with HFrEF (Sacubitril with valsartan PSD, July 2016 PBAC meeting), the PBAC has accepted this estimate in previous HFmrEF/HFpEF submissions (empagliflozin PSD, November 2022 PBAC meeting; dapagliflozin PSD, July 2023 PBAC meeting). The evaluation considered that given patients with NYHA Class I HF symptoms are substantially less likely to seek treatment or be diagnosed, this estimate is most likely appropriate.
Proportion of patients not using finerenone for the CKD/T2D listing	94.47%	Calculated: based on the proportions of patients with heart failure and CKD/T2D (16%; Lawson 2021), the proportion of patients with UACR ≥200 mg/g despite treatment with an SGLT2i (69.1%; DAPA-CKD trial); and an assumed finerenone CKD/T2D market share of 50%. [1 - [0.16 × 0.691 × 0.5] = 0.9447]	Lawson (2021) included all HF variants and a fixed distribution of comorbidities. The evaluation considered that given patients with HFpEF typically have more comorbidities than other HF variants, the proportion of patients eligible for finerenone in the CKD/T2D listing was most likely underestimated. The assumed market share of 50% was not adequately justified and may have further underestimated the proportion of excluded patents. The proportion of patients eligible for finerenone for HFmrEF/HFpEF was likely overestimated. The Sub-Committees considered this parameter to be slightly underestimated. The Sub-Committees noted the utilisation estimates for finerenone for CKD with T2D (Year 2: 75% uptake, 25,717 treated patients). Based on PBS data provided by the DUSC secretariat, there were 10,363 patients treated with finerenone for CKD with T2D ,40% of the 2025 forecast. Based on this, the Sub-Committees noted this corresponded to a 30% uptake in finerenone for CKD/T2D (calculated as 75% × 40%). Based on the 30% uptake in finerenone for CKD/T2D, the Sub-Committees suggested the percentage of patients not using finerenone for the CKD/T2D listing be revised to 96.68% [1 - [0.16 × 0.691 × 0.3].
Proportion of patients with eGFR ≥25 mL/min /1.73 m²	96.0%	Assumed based on the estimated prevalence of patients with eGFR <30 mL/min/1.73 m² in the EMPEROR-Preserved	The cited percentages of patients with eGFR <30 mL/min/1.73 m² (7–10%; Anker 2021; Solomon 2022), and the distribution of patients by eGFR <30 mL/min/1.73 m² could not be identified in the sources, and the estimated proportions of HFmrEF/HFpEF patients with eGFR <25 or

[15] Newton, P. J., Si, S., Reid, C. M., Davidson, P. M., Hayward, C. S., & Macdonald, P. S. (2020). Survival After an Acute Heart Failure Admission. Twelve-Month Outcomes From the NSW HF Snapshot Study. *Heart Lung Circ*, *29*(7), 1032-1038.

[16] Sindone, A. P., Haikerwal, D., Audehm, R. G., Neville, A. M., Lim, K., Parsons, R. W., Piazza, P., & Liew, D. (2021). Clinical characteristics of people with heart failure in Australian general practice: results from a retrospective cohort study. *ESC Heart Fail*, *8*(6), 4497-4505. https://doi.org/10.1002/ehf2.13661

Parameter	Value	Source	Comment
		and DELIVER trials (7–10%; Anker 2021; Solomon 2022), and the distribution of eGFR in patients with eGFR <30 mL/min/1.73 m² (3–5%; Bruck 2016, Murphy 2016). 4% of patients with HFmrEF/ HFpEF are likely to be excluded from treatment due to eGFR <25 mL/min/1.73 m².	≥25 mL/min/1.73 m² ineligible under the requested finerenone restriction could not be verified during the evaluation. The Sub-Committees agreed with the evaluation and noted in the DELIVER trial, 1.4% of participants were excluded due to an eGFR <25 mL/min/1.73 m². Given this, the Sub-Committees suggested the percentage of patients with eGFR ≥25 mL/min/1.73 m² be revised to 98.6%.
Uptake of finerenone	Yr 1: [redacted]% Yr 2: [redacted]% Yr 3: [redacted]% Yr 4: [redacted]% Yr 5: [redacted]% Yr 6: [redacted]%	Based on the PBS dispensing data for sacubitril with valsartan (PBS items 11122J, 11123K, 11131W, 13445P, 13511D, 13570F).	The evaluation considered it uncertain how dispensing data were used to derive uptake rates. The sacubitril with valsartan listings were restricted to HFrEF, predate the listing of SGLT2i medicines for HFmrEF/HFpEF and are not an appropriate proxy for the uptake of finerenone in the HFmrEF/HFpEF population. The evaluation considered that the estimated uptake rates are highly uncertain. The PSCR stated that SGLT2is were considered a potential analogue, however were discounted due to their use in multiple indications with considerable patient population overlap with HFmrEF/HFpEF, therefore the sacubitril with valsartan annual utilisation growth rate based on PBS script data was used to inform the uptake curve, which was adjusted down in Years 1, 5 and 6 to better match internal forecasting. The Sub-Committees considered that the treatment uptake for finerenone was overestimated. The Sub-Committees commented that uptake of finerenone may be limited as patients would likely be older and frailer with comorbid disease and additional safety monitoring associated with hyperkalaemia. The Sub-Committees noted the utilisation of PBS listed SGLT2i medicines for HFmrEF/HFpEF: dapagliflozin and empagliflozin (total 60,662 and 90,762 patients in 2024 and 2025, respectively). The Sub-Committees noted that data from the DUSC Secretariat indicated that uptake of finerenone for CKD/T2D was substantially lower than predicted. The Sub-Committees advised that the projected finerenone patient numbers increased more steeply from year 2 onwards than appeared plausible. The Sub-Committees suggested that more appropriate rates would be: Yr 1: [redacted]%, Yr 2: [redacted]%, Yr 3: [redacted]%, Yr 4: [redacted]%, Yr 5: [redacted]%, Yr 6: [redacted]%. The Sub-Committees noted that the financial estimates were sensitive to this parameter.
Discontinuation rate	Yr 1: 0% Yr 2: 2.35% Yr 3: 3.67% Yr 4: 4.18%	Based on patients remaining on treatment out of those alive in the economic model.	The derivation of the discontinuation rates from the economic model could not be verified during the evaluation. The Sub-Committees agreed with the evaluation that given the prevalence-based approach used to derive the financial

Parameter	Value	Source	Comment
	Yr 5: 4.35% Yr 6: 4.78%		estimates, the implementation of a discontinuation rate in the budget impact model may not be appropriate. The Sub-Committees advised that this parameter should be removed from the financial estimates, as discontinuation would be captured in the uptake rates applied each year.
Adherence	97.9%	Based on the average number of finerenone tablets taken per 28 day period in FINEARTS-HF [27.4 / 28 = 0.9785].	The Sub-Committees agreed with the evaluation that treatment adherence observed in a tightly regulated clinical trial setting may not represent adherence in clinical practice and is likely overestimated. The Sub-Committees noted a study[17] showed compliance among HF patients to be 80%.
Scripts per year	12.77	Calculated: Days per year / 28 days per month × adherence. [365.25 / 28 × 0.9785 = 12.77].	Based on the revised adherence of 80%, the Sub-Committees noted the number of scripts of year to be 10.43 [365.25 / 28 × 0.80 = 10.43].
Finerenone cost per script	Submission: Published DPMQ $[redacted] Effective DPMQ $[redacted] Pre-PBAC Response: Effective DPMQ $[redacted]	Proposed. DPMQ calculated using the 1 July 2026 wholesaler markup reduction (7.52% to 4.3%).	The submission proposed flat pricing across the finerenone 10 mg, 20 mg and 40 mg dose strengths.
PBS/RPBS distribution	PBS: 97.51% RPBS: 2.49%	Based on the 2025 PBS data for empagliflozin (Item 14073Q) and dapagliflozin (Item 13695T), for HFmrEF/HFpEF.	The evaluation considered that this was reasonable.
Patient copayment	PBS: $8.25 RPBS: $3.47		

Source: Table 4-80, p153, and Section 4.2-4.3 of the submission.
Abbreviations: CKD, chronic kidney disease; eGFR, estimated glomerular filtration rate; HF, heart failure; HFmrEF, heart failure with mildly reduced ejection fraction; HFpEF, heart failure with preserved ejection fraction; HFrEF, heart failure with reduced ejection fraction; LVEF, left ventricular ejection fraction; NYHA, New York Heart Association; PBS, Pharmaceutical Benefits Scheme; RPBS, Repatriation Pharmaceutical Benefits Scheme; SGLT2i, sodium glucose co-transporter 2 inhibitor; T2D, type 2 diabetes; UACR, urinary albumin-creatinine ratio.

6.83 Table 14 presents the estimated use and financial impact of finerenone to the PBS/RPBS.

[17] Jankowska-Polańska B, et al. (2020) Patient-Reported Compliance in older age patients with chronic heart failure. PLoS ONE 15(4): e0231076

Table 14: Estimated use and financial implications

	Year 1	Year 2	Year 3	Year 4	Year 5	Year 6
Estimated extent of use						
Number of patients treated	[redacted][1]	[redacted][2]	[redacted][3]	[redacted][4]	[redacted][4]	[redacted][4]
Number of scripts dispensed	[redacted][5]	[redacted][6]	[redacted][7]	[redacted][7]	[redacted][7]	[redacted][7]
Estimated financial implications of finerenone						
Cost to PBS/RPBS ($)	[redacted][8]	[redacted][9]	[redacted][10]	[redacted][11]	[redacted][11]	[redacted][11]
Patient copayment ($)	-[redacted][12]	-[redacted][12]	-[redacted][12]	-[redacted][12]	-[redacted][12]	-[redacted][12]
Total cost to PBS/RPBS (less copayment) ($)	[redacted][13]	[redacted][9]	[redacted][14]	[redacted][10]	[redacted][11]	[redacted][11]
Pre-PBAC Response (revised price)						
Cost to PBS/RPBS ($)	[redacted][13]	[redacted][15]	[redacted][16]	[redacted][10]	[redacted][11]	[redacted][11]
Patient copayment ($)	-[redacted][12]	-[redacted][12]	-[redacted][12]	-[redacted][12]	-[redacted][12]	-[redacted][12]
Total cost to PBS/RPBS (less copayment) ($)	[redacted][13]	[redacted][15]	[redacted][9]	[redacted][16]	[redacted][10]	[redacted][10]

Source: Table 4.8, p244; Table 4.9, p245; Table 4.10, p245; Table 4.11, p245; Table 4.12, p246; Table 4.13, p246 of the submission. Calculated based on the revised price proposed for finerenone in the Pre-PBAC Response using the submission workbook: Section_4_model.xlsm

Abbreviations: DPMQ, dispensed price per maximum quantity; PBS, Pharmaceutical Benefits Scheme; RPBS, Repatriation Pharmaceutical Benefits Scheme.

The redacted values correspond to the following ranges:

[1] *30,000 to < 40,000*
[2] *70,000 to < 80,000*
[3] *90,000 to < 100,000*
[4] *100,000 to < 200,000*
[5] *400,000 to < 500,000*
[6] *900,000 to < 1,000,000*
[7] *1,000,000 to < 2,000,000*
[7] *$0 to < $10 million*
[8] *$30 million to < $40 million*
[9] *$60 million to < $70 million*
[10] *$90 million to < $100 million*
[11] *$100 million to < $200 million*
[12] *net cost saving*
[13] *$20 million to < $30 million*
[14] *$80 million to < $90 million*
[15] *$50 million to < $60 million*
[16] *$70 million to < $80 million*

6.84 Based on the proposed price in the Pre-PBAC Response, the estimated net cost to the PBS/RPBS for finerenone was $20 million to < $30 million in Year 1, increasing to $90 million to < $100 million in Year 6, with a cumulative total of $400 million to < $500 million over the first 6 years of listing.

6.85 The utilisation/financial estimates for finerenone are highly uncertain, and expected to be overestimated, noting the following issues:

- The estimated prevalence of HFmrEF/HFpEF in the Australian clinical setting was uncertain, given the data used to estimate prevalence was collected between 2013–2018, and was retrieved from medical records with poor reporting of heart failure generally (data included confirmed as well as potential diagnoses). Given the difficulty in identifying HFmrEF/HFpEF in the clinical setting, the age of the data, and changing trends in HFmrEF/HFpEF diagnosis and treatment, the estimate is highly uncertain. The Sub-Committees considered the prevalence was reasonable as it was consistent with a pooled estimate of the most recent Australian studies, however it was noted in sensitivity analyses that expenditure

varies between -9.4% to +11.3% with a 5% variation in estimated proportion of patients with HFmrEF/HFpEF (see Table 15).

- The uptake of finerenone was based on the uptake of sacubitril with valsartan in PBS listings for HFrEF, predating the listing of SGLT2i medicines for HFmrEF/HFpEF. The Sub-Committees considered that the estimated uptake of finerenone was overestimated. The Sub-Committees considered that treatment uptake would be limited due to additional safety concerns and monitoring requirements associated with hyperkalaemia. The Sub-Committees advised that more appropriate rates would be : Year 1: [redacted]%, Year 2: [redacted]%, Year 3: [redacted]%, Year 4: [redacted]%, Year 5: [redacted]%, Year 6: [redacted]%. The Response argued that finerenone uptake in HFmrEF/HFpEF would be faster than in CKD with T2D because eligible patients are more readily identified through cardiology pathways and HF clinics, while CKD with T2D uptake is constrained by low UACR testing and GP-led management.. The Response considered the Sub-Committee's uptake estimates too low, noting that PBS services data for SGLT2is in HF (LVEF>40%) indicate that uptake exceeded 40% by year 2. The Response proposed revised uptake of [redacted]%, [redacted]%, [redacted]%, [redacted]%, [redacted]% and [redacted]% over years 1 to 6, and stated it was supported by clinician feedback suggesting substantial early review of eligible HFpEF patients.
- The estimated finerenone treatment adherence was based on the FINEARTS-HF trial (97.9%). The Sub-Committees considered that treatment adherence observed in a tightly regulated clinical trial setting may not represent adherence in clinical practice and is likely overestimated. The Sub-Committees noted a study[18] showed adherence among HF patients to be 80%. The Pre-PBAC Response argued that this study's methodology was not appropriate for calculating adherence. The Response noted that the PBAC had previously accepted adherence rates of approximately 90% for both empagliflozin and vericiguat, which were slight reductions from their trial data. The Response stated it supported an assumption of 90% adherence.

6.86 The results of sensitivity analyses presented in the submission and conducted during the evaluation, are summarised in Table 15.

[18] Jankowska-Polańska B, et al. (2020) Patient-Reported Compliance in older age patients with chronic heart failure. PLoS ONE 15(4): e0231076

Table 15: Sensitivity analyses on the net financial impact to the PBS

Sensitivity analysis	Net cost to PBS/RPBS over 6 years (Effective price from submission)
Base case	$[redacted][2]
Proportion of patients with HFmrEF/HFpEF (53% base case)	
- 59% (high range)	$[redacted][2] (+[redacted]%)
- 56% (+5%)	$[redacted][2] (+[redacted]%)
- 48% (-5%)	$[redacted][1] (-[redacted]%)
Proportion with HFmrEF/HFpEF and NYHA Class II-IV (95% base case)	
- 85% (-10%)	$[redacted][1] (-[redacted]%)
Proportion of patients not eligible for finerenone CKD/T2D (94.47% base case)	
- 85%	$[redacted][1] (-[redacted]%)
Proportion of patients eligible for finerenone with eGFR ≥25 mL/min/1.73m^2 (96% base case)	
- 90%	$[redacted][1] (-[redacted]%)
Treatment discontinuation (from 0% in Year 1 to 4.78% in Year 6)	
- 0 (removed)	$[redacted][2] (+[redacted]%)

Source: Table 4.86, p161 of the submission.

Abbreviations: CKD, chronic kidney disease; eGFR, estimated glomerular filtration rate; HFmrEF, heart failure with mildly reduced ejection fraction; HFpEF, heart failure with preserved ejection fraction; NYHA, New York Heart Association; PBS, Pharmaceutical Benefits Scheme; RPBS, Repatriation Pharmaceutica l Benefits Scheme; T2D, type 2 diabetes.

The redacted values correspond to the following ranges:

[1] *$400 million to < $500 million*

[2] *$500 million to < $600 million*

6.87 The results of the sensitivity analyses indicated that the budget impact estimate was most sensitive to the estimated proportion patients with HFmrEF/HFpEF; using the high range value from the Australian literature (59%) increased the financial impact of finerenone by [redacted]%. The budget estimates were also sensitive to the proportion of patients with NYHA Class II-IV, and the proportions of patients not eligible for finerenone under the CKD/T2D listing.

6.88 The Sub-Committees considered the following adjustments should be made to the estimates (see also discussion in Table 13):

- Revise the percentage of patients not using finerenone under the existing CKD/T2D eligibility criteria from 94.47% to 96.68%.
- Revise the percentage of patients with eGFR ≥25 ml/min/1.73m² from 96% to 98.6%.
- Removal the discontinuation rate.
- Update adherence from 97.90% to 80%, resulting 10.44 scripts/year.

The Sub-Committees noted the net financial impact to the PBS/RPBS over 6 years with these adjustments was $400 million to < $500 million.

6.89 The Sub-Committees requested that additional sensitivity analyses be conducted, addressing the issues listed in paragraph 6.85. The results of these additional sensitivity analyses can be found in Table 16.

- (A) Percentage of patients with HFmrEF or HFpEF (i.e. LVEF >40) updated from 53% to 57.6%.

- (B) Patients electing treatment (%) updated from Yr 1: [redacted]%, Yr 2: [redacted]%, Yr 3: [redacted]%, Yr 4: [redacted]%, Yr 5: [redacted]%, Yr 6: [redacted]% to Yr 1: [redacted]%, Yr 2: [redacted]%, Yr 3: [redacted]%, Yr 4: [redacted]%, Yr 5: [redacted]%, Yr 6: [redacted]%.
- (C) = Both (A) + (B).

Table 16: Additional sensitivity analyses on the net financial impact to the PBS/RPBS

Sensitivity analysis		Net cost to PBS/RPBS over 6 years (Effective price from submission)
Base case		**$[redacted][3]**
A	Proportion of patients with HFmrEF/HFpEF 57.6%	$[redacted][3] (+[redacted]%)
B	Revised uptake rates (Yr 1: 10%, Yr 2: 18%, Yr 3: 25%, Yr 4: 30%, Yr 5: 34%, Yr 6: 37%)	$[redacted][1] (-[redacted]%)
C	A+B	$[redacted][2] (-[redacted]%)

Source: conducted by the secretariat using the finerenone financial workbook
Abbreviations: HFmrEF, heart failure with mildly reduced ejection fraction; HFpEF, heart failure with preserved ejection fraction; PBS, Pharmaceutical Benefits Scheme; RPBS, Repatriation Pharmaceutical Benefits Scheme
The redacted values correspond to the following ranges:
[1] *$200 million to < $300 million*
[2] *$300 million to < $400 million*
[3] *$500 million to < $600 million*

Quality Use of Medicines

6.90 Quality use of medicines was not discussed in the submission.

6.91 The Sub-Committees noted the required safety monitoring due to the risk of hyperkalaemia.

For more detail on PBAC's view, see section 7 PBAC outcome.

7 PBAC Outcome

7.1 The PBAC did not recommend finerenone for the treatment of adults with symptomatic heart failure (New York Heart Association [NYHA] Class II–IV) and left ventricular ejection fraction (LVEF) of greater than or equal to 40%. This encompasses patients with heart failure with mildly reduced or preserved ejection fraction (HFmrEF/HFpEF). The PBAC considered that the evidence demonstrated finerenone was more effective than standard of care (SoC) in reducing heart failure (HF) events, however the effect on cardiovascular (CV) death remained uncertain. The PBAC noted the Sub-Committees considered the economic model provided in the submission overestimated the benefits of finerenone and that several parameter changes were required. The PBAC noted the pre-PBAC Response reduced the price of finerenone and made substantial changes to the economic model to address the Sub-Committees' concerns but these changes could not be evaluated based on the information provided and were not reasonable to present at that stage of the PBS submission process. The PBAC considered that a further price reduction would be required to achieve an incremental cost-effectiveness ratio (ICER) of less than $15,000 to < $25,000 per quality adjusted life year (QALY) gained after revising the model parameters. The PBAC considered that the financial estimates also required revision, as outlined by the Sub-

Committees. The PBAC advised that the outstanding issues could be addressed in an early re-entry resubmission if using the parameters in the Sub-Committees' revised economic model, otherwise, a standard re-entry resubmission would be required.

7.2 The primary reason for this outcome was due to the economic evaluation presented.

7.3 The PBAC noted and welcomed comments from Hearts4Heart via the Office of Health Technology Assessment Consultation Hub. The PBAC noted that heart failure was described as a serious lifelong condition that substantially affects quality of life and remains a major cause of hospitalisation and death in Australia. The input noted that despite existing treatments, many patients continue to experience worsening health and repeated hospital visits, highlighting a clinical need for additional effective therapies. The input noted that without PBS subsidy finerenone would be unaffordable for many patients. The PBAC acknowledged that HFmrEF/HFpEF is becoming more common and that there remains a clinical need for treatment options in addition to sodium-glucose cotransporter-2 inhibitors (SGLTis).

7.4 The PBAC considered that clinicians will increasingly diagnose HFmrEF/HFpEF as patient numbers are increasing in association with diabetes, ageing, obesity, chronic obstructive pulmonary disease (COPD), and chronic kidney disease (CKD). The PBAC noted that finerenone was proposed as an add-on to current SoC, which may include an SGLT2i, diuretics and/or other medicines for related comorbidities, and considered this clinical place to be reasonable. The PBAC considered it was most likely that finerenone would be prescribed as add-on therapy to a SGLT2i.

7.5 The PBAC noted the following points regarding the restriction for finerenone:

- It would be reasonable for restrictions to use the LVEF cut-off of ≥40%, consistent with the TGA indication for finerenone.
- It is not required to specify whether finerenone is used with, before or after an SGLT2i; this should be left to clinician discretion.
- A clinical criterion should be added to exclude concomitant treatment with all steroidal and non-steroidal mineralocorticoid receptor antagonist (MRA) therapies, e.g. "Patient must not be receiving treatment with another mineralocorticoid receptor antagonist, a renin inhibitor or a potassium-sparing diuretic".
- The TGA PI notes that initiation of finerenone treatment for heart failure is not recommended when serum potassium levels are > 5.0 mmol/L and is also not recommended when estimated glomerular filtration rate (eGFR) is < 25 mL/ min/1.73 m^2. The PBAC considered that these requirements should also be included in the restrictions for finerenone.
- Urgent heart failure visits should be removed from the clinical criteria, consistent with the restrictions for SGLT2is.
- The caution: 'serum electrolytes should be checked regularly' should be included in the restriction.

- It would be preferable to combine the initial, continuing and grandfather restrictions into a single treatment phase agnostic restriction, for simplicity. Wording of the restrictions may need to be amended such that patients would only need to meet certain criteria at initiation of treatment.

7.6 The submission nominated SoC as the main comparator. The PBAC noted that pharmaceutical interventions used for the treatment of chronic heart failure include a diuretic (loop or thiazide), beta-blocker, angiotensin-converting enzyme inhibitor (ACEi), angiotensin receptor blocker (ARB), angiotensin receptor–neprilysin inhibitor (ARNi), mineralocorticoid receptor antagonist (MRA), and an SGLT2i. The PBAC considered that this was reasonable.

7.7 The PBAC noted that the submission was primarily based on one head-to-head randomised controlled trial (FINEARTS-HF) comparing finerenone plus SoC to placebo plus SoC, in adults with HFmrEF/HFpEF (LVEF ≥40%). In addition, the submission presented the results of the FINE-HEART pooled analysis (Vaduganathan 2024), including individual patient data from the key FINEARTS-HF trial, as well as the FIDELIO-DKD and FIGARO-DKD trials (diabetic kidney disease) and a pre-specified subgroup analysis of FINEARTS-HF trial data by SGLT2i use at baseline (Vaduganathan 2025).

7.8 In FINEARTS-HF, the PBAC noted that treatment with finerenone was associated with a statistically significant reduction in the risk of the primary composite outcome of CV death and total (first and recurrent) HF events compared to placebo over a median duration of follow-up of 32 months. However, the PBAC noted that the effect on the primary composite outcome was mainly driven by a reduction in total HF events for patients treated with finerenone (see Table 4). Although CV deaths were numerically lower with finerenone, the difference was not nominally significant, which was consistent with findings from SGLT2i trials in similar populations, including EMPEROR-preserved and DELIVER trials. The PBAC recalled that in its consideration of empagliflozin in November 2022, it was noted that a meta-analysis that pooled data from EMPEROR-Preserved and DELIVER2 found that SGLT2 inhibitors reduced CV mortality by 12% with nominal significance and no statistically significant heterogeneity (HR 0.88; 95% CI: 0.77,1.00) (para 6.18, empagliflozin PSD, November 2022 PBAC meeting). Coupled with the clinically meaningful improvements in KCCQ clinical summary scores for empagliflozin, the PBAC had considered that some CV mortality benefit could plausibly be expected (para 7.6, empagliflozin PSD, November 2022 PBAC meeting).

7.9 The PBAC noted the submission included the FINE-HEART pooled analysis to provide additional statistical power to investigate the risk of cardiovascular and all-cause mortality with finerenone. The PBAC agreed with the Sub-Committees that the applicability of FINE-HEART was uncertain as only 36.7% of patients in the pooled analyses had heart failure (see paragraph 6.32). The PBAC noted that in FINEARTS-HF statistical significance was met for the secondary outcomes of total heart failure events and Kansas City Cardiomyopathy Questionnaire Total Symptom Score (KCCQ-TSS) outcomes. However, the PBAC considered the clinical relevance of the statistically

significant KCCQ-TSS improvement uncertain, given the small absolute difference on a 100-point scale (see Table 5).

7.10 The PBAC noted that improvement in NYHA class did not reach statistical significance and EQ-5D-5L and EQ-5D VAS scores were similar between treatment arms and showed little change from baseline values over time.

7.11 The PBAC noted that the baseline use of SGLT2i medicines in FINEARTS-HF was lower than would be expected in current clinical practice (14% at baseline with another 20% initiating during the trial), reflecting the timing of the trial, which predated the establishment of SGLT2i medicines as disease modifying therapy in HFmrEF/HFpEF. In FINEARTS-HF patients receiving an SGLT2i at baseline reported higher baseline risk, most likely reflecting comorbidities associated with SGLT2i prescribing, such as CKD or type 2 diabetes. The PBAC noted that subgroup analyses indicated finerenone's treatment effect was generally consistent across subgroups, including by baseline SGLT2i use (Vaduganathan 2025).

7.12 Overall, the PBAC considered that the claim of superior comparative effectiveness was adequately supported by the data. However, the observed benefit was driven by reductions in HF events, while the effect on CV death remained uncertain.

7.13 The PBAC noted that the overall incidence of treatment-emergent adverse events in FINEARTS-HF was similar between treatment arms, although treatment-related adverse events were more common with finerenone. Events reported more frequently with finerenone included hyperkalaemia, worsening renal impairment, hypotension, dizziness and diarrhoea. Reflecting on evidence from another MRA trial, the PBAC noted that hyperkalaemia rates were lower for finerenone in FINEARTS-HF than for spironolactone in the TOPCAT trial, despite the FINEARTS-HF population appearing to have a higher baseline risk of hyperkalaemia. Overall, the PBAC considered that a claim of inferior comparative safety to SoC would be appropriate.

7.14 The PBAC noted that the submission presented a cost-utility analysis to support the cost-effectiveness of finerenone plus SoC versus SoC alone for patients with HFmrEF/HFpEF. The PBAC agreed with the Sub-Committees that the submission model relied on overly optimistic assumptions and overestimated the health benefits associated with finerenone, as it generated approximately twice the incremental life years and QALYs of previous SGLT2i submissions without evidence supporting larger gains and without clinical data supporting an effect on CV death. The PBAC noted that the Sub-Committees proposed a revised base case that included a 15-year time horizon, a lower HF hospitalisation cost, and exclusion of treatment as a covariate in the CV and all-cause mortality analyses. The PBAC noted that the Pre-PBAC Response provided an updated economic model in response to concerns raised by the Sub-Committees (paragraphs 6.73–6.74). The PBAC noted that the updated model included a lower price for finerenone, a lower HF hospitalisation cost, and a 15-year time horizon. However, the PBAC noted that the revised model also included updated CV and all-cause mortality parametric survival curves which replaced the treatment covariate with a time-varying HF hospitalisation covariate. The model also applied a QALY adjustment to reduce the survival benefit that the Pre-PBAC Response

attributed to bringing deaths forward under the revised regression and extrapolations (see paragraphs 6.57–6.58). The PBAC noted that the model only included the Weibull and exponential functions and goodness-of-fit statistics were not provided for the revised extrapolations. The PBAC considered this a substantial model change that had not been evaluated and could not be verified based on the information provided prior to PBAC consideration.

7.15 The PBAC noted that with the price proposed in the Pre-PBAC Response the ICER of the ESC revised base case was $35,000 to < $45,000 per QALY gained. The PBAC considered that, an ICER below $15,000 to < $25,000 per QALY gained would be required for finerenone to be considered cost-effective. The PBAC noted that this was consistent with previously accepted ICERs for medicines in this therapeutic area, with an ICER of $15,000–$25,000 per QALY gained recommended for empagliflozin (paragraph 7.9 and 12.2, empagliflozin PSD, November 2022 PBAC meeting, December addendum). The PBAC noted that the Pre-PBAC Response suggested that, if finerenone was not considered cost-effective at the proposed price due to uncertainty in baseline risk, the PBAC may wish to consider restricting the PBS listing to patients with prior CV events, including HF hospitalisation, urgent HF visit, myocardial infarction or stroke. The PBAC considered that listing finerenone for the proposed broader population would be preferable.

7.16 The PBAC noted that, based on the proposed price in the Pre-PBAC Response, the estimated net cost to the PBS/RPBS for finerenone was $400 million to < $500 million over the first 6 years of listing. The PBAC considered the financial impact of listing finerenone was high and uncertain, with key uncertainties regarding the prevalence of HFmrEF/HFpEF, the estimated percentage of patients eligible for treatment, and uptake estimates. The PBAC noted the Sub-Committees suggested changes to: incorporate a revised percentage of patients not using finerenone under the existing chronic kidney disease/type 2 diabetes eligibility criteria (from 94.47% to 96.68%), revise the percentage of patients with eGFR ≥25 ml/min/1.73m² (from 96% to 98.6%), remove of the annual discontinuation rate and revise adherence (from 97.90% to 80%) (paragraph 6.88). The PBAC agreed with the Sub-Committees' proposed revisions to the financial estimates.

7.17 The PBAC considered the outstanding issues could be easily resolved in a simple resubmission for finerenone using the early re-entry pathway. If the sponsor accepts this pathway, the following changes may address these outstanding issues without requiring further re-evaluation:

- Adopt the parameters used in the Sub-Committees' revised economic model: a 15-year time horizon, exclusion of the mortality treatment covariate, and a lower heart failure hospitalisation cost (see paragraph 7.14).
- A price reflective of an ICER of less than $15,000 to < $25,000 per QALY gained with above changes to the economic evaluation; and
- Updated financial estimates as per paragraph 7.16 and addressing the outstanding uncertainties.

- Include detail of the proposed risk-sharing arrangement, as offered in the pre-PBAC response.

The early re-entry resubmission must be lodged by week 7 of the current PBAC cycle or the next cycle. If the issues cannot be addressed by the sponsor in a simple resubmission and the early re-entry timing is not acceptable, a standard re-entry pathway is available.

7.18 The PBAC noted that this submission is eligible for an Independent Review.

Outcome:
Not recommended

8 Context for Decision

The PBAC helps decide whether and, if so, how medicines should be subsidised through the Pharmaceutical Benefits Scheme (PBS) in Australia. It considers applications regarding the listing of medicines on the PBS and provides advice about other matters relating to the operation of the PBS in this context. A PBAC decision in relation to PBS listings does not necessarily represent a final PBAC view about the merits of the medicine or the circumstances in which it should be made available through the PBS. The PBAC welcomes applications containing new information at any time.

9 Sponsor's Comment

The sponsor had no comment.