Technology Guidance

Finerenone

for treating chronic kidney disease and albuminuria associated with type 2 diabetes

Technology Guidance from the MOH Drug Advisory Committee

Guidance Recommendations

The Ministry of Health's Drug Advisory Committee has recommended:

- ✓ Finerenone 10 mg and 20 mg tablets as an add-on therapy for adults with chronic kidney disease and albuminuria associated with type 2 diabetes:
  - who are receiving concomitant optimal standard treatment which includes an angiotensin-converting enzyme (ACE) inhibitor or angiotensin II receptor blocker (ARB) at maximum tolerated dose in combination with a sodium-glucose co-transporter 2 (SGLT2) inhibitor, unless contraindicated or not tolerated, and
  - who have estimated glomerular filtration rate (eGFR) ≥25 mL/min/1.73m^2 and urine albumin-to-creatinine ratio (UACR) ≥200 mg/g (20 mg/mmol) at the start of treatment.

Funding status

Finerenone 10 mg and 20 mg tablets are recommended for inclusion on the Medication Assistance Fund (MAF) for the abovementioned indication from 1 November 2025.

Finerenone must be initiated by, or in consultation with, a specialist physician experienced in the management of chronic kidney disease and albuminuria associated with type 2 diabetes.

Treatment with finerenone must be discontinued prior to initiating dialysis.

Updated: 16 September 2025

Technology evaluation

1.1. At the March 2025 meeting, the MOH Drug Advisory Committee ("the Committee") considered the evidence presented for the technology evaluation of finerenone for treating adults with chronic kidney disease (CKD) and albuminuria associated with type 2 diabetes. The Agency for Care Effectiveness (ACE) conducted the evaluation in consultation with clinical experts from public healthcare institutions and patient experts from local patient and voluntary organisations. Clinical and economic evidence for finerenone was considered in line with its registered indication.

1.2. The evidence was used to inform the Committee's deliberations around four core decision-making criteria:

- Clinical need of patients and nature of the condition;
- Clinical effectiveness and safety of the technology;
- Cost effectiveness (value for money) – the incremental benefit and cost of the technology compared to existing alternatives; and
- Estimated annual technology cost and the number of patients likely to benefit from the technology.

1.3. Additional factors, including social and value judgments, may also inform the Committee's funding considerations.

Clinical need

2.1. Patients with CKD and type 2 diabetes (diabetic kidney disease; DKD) are at increased risk of end-stage renal disease, and cardiovascular (CV) morbidity and mortality. Albuminuria is a common marker of kidney damage in these patients. A urine albumin-to-creatinine ratio (UACR) ≥30 mg/g represents the threshold for CKD and is associated with increased risk of adverse renal outcomes, CV and all-cause mortality.

2.2. The Committee heard that, in local practice, patients who have DKD with albuminuria can be treated with an angiotensin-converting enzyme (ACE) inhibitor or angiotensin II receptor blocker (ARB) up to the maximum tolerated dose. If albuminuria persists, patients will receive add-on treatment with a sodium-glucose co-transporter 2 (SGLT2) inhibitor.

2.3. For patients who have persistent albuminuria despite the above standard-of-care therapies, finerenone (a non-steroidal mineralocorticoid receptor antagonist) can be considered as a further add-on treatment.

2.4. The Committee considered 126 testimonials from local patients and carers about their lived experiences with DKD and the treatments they have received. The Committee noted that people with DKD get tired easily and may experience bleeding, giddiness, itchiness, pain, vision problems, persistent thirst, poor memory, weight loss and difficulty passing urine. These symptoms often led to anxiety, sadness, disturbed sleep and poor quality of life. Many of the patients also found it difficult to adjust to dietary restrictions and the loss of autonomy, but some have managed to adopt a healthier lifestyle through the support they received from their care team.

2.5. The Committee heard that none of the respondents with earlier-stage DKD were familiar with finerenone, but considered that any new treatments should be more affordable, and allow people with DKD to return to work, participate in social events, perform routine daily activities, improve their energy levels and sleep, maintain kidney function, and prolong their lifespan.

Clinical effectiveness and safety

3.1. The Committee reviewed the clinical evidence from two phase III randomised controlled trials (FIDELIO-DKD and FIGARO-DKD) and their pooled analysis (FIDELITY), which examined the use of finererone as an add-on therapy compared with placebo. The pooled population comprised 13,026 adults with DKD who mostly had UACR ≥30 mg/g and estimated glomerular filtration rate (eGFR) ≥25 mL/min/1.73 m^2 at baseline. Almost all patients were receiving an ACE inhibitor or ARB at the maximum tolerated dose, but only 877 patients (6.7%) were receiving additional SGLT2 inhibitor therapy.

3.2. The Committee acknowledged that the applicability of the trial evidence to the Singapore setting was uncertain. Locally, the target population with DKD and persistent albuminuria is expected to receive finerenone as add-on therapy after an SGLT2 inhibitor (plus an ACE inhibitor or ARB).

3.3. The Committee noted that the primary and key secondary endpoints measured in the trials were renal and CV composite outcomes. The renal composite outcome included kidney failure, sustained decrease in eGFR of ≥40% from baseline over ≥4 weeks, or death from renal causes. The CV composite outcome included death from CV causes, non-fatal myocardial infarction, non-fatal stroke, or hospitalisation for heart failure.

3.4. After a median follow-up of 3 years, results of the pooled analysis showed a modest treatment benefit with finerenone compared to placebo in reducing the composite risk of renal and CV outcomes. The renal composite outcome occurred in 13.1% vs. 15.3% of patients in the finerenone and placebo groups, respectively (hazard ratio [HR] 0.85, 95% confidence interval [CI] 0.77 to 0.93). The CV composite endpoint occurred in 12.7% vs. 14.4% of patients, respectively (HR 0.86, 95% CI 0.78 to 0.95). Exploratory analyses of the individual components suggested that finerenone reduced the risks of eGFR decline, progression to kidney failure, and hospitalisation for heart failure.

3.5. No significant between-group differences were observed for the secondary trial endpoints of all-cause mortality and all-cause hospitalisation.

3.6. In prespecified subgroup analyses of the renal composite outcome, finerenone showed a treatment benefit over placebo for patients with baseline UACR ≥300 mg/g (HR 0.81, 95% CI 0.73 to 0.89). However, for patients with lower baseline UACR of 30 to <300 mg/g, the results did not suggest a treatment effect with finerenone (HR 1.11, 95% CI 0.88 to 1.39). Given this, the Committee noted that it was more appropriate to consider funding finerenone in patients with high albuminuria levels, similar to funding recommendations made by overseas HTA agencies.

3.7. The Committee reviewed post-hoc analysis results provided by the company for a subgroup of patients in the pooled population who had UACR ≥200 mg/g and were receiving an SGLT2 inhibitor at baseline. While acknowledging the uncertainty associated with the analyses, the Committee considered that the results were supportive of a treatment benefit with finerenone over placebo in terms of renal and CV outcomes for patients in this subgroup.

3.8. In terms of safety, the Committee heard that more treatment-related adverse events of hyperkalaemia were reported with finerenone compared to placebo in the trials.

Cost effectiveness

4.1. The Committee reviewed an economic model that assessed the cost-effectiveness of finerenone versus placebo for treating DKD in adults with UACR ≥200 mg/g and SGLT2 inhibitor use at baseline. Results from the FIDELITY pooled analysis and data inputs provided by the company were used to inform the model.

4.2. At the price proposed by the company, finerenone had a base-case incremental cost-effectiveness ratio (ICER) between SG$15,000 and SG$45,000 per quality-adjusted life year gained compared with placebo.

4.3. However, the Committee noted several limitations with the model that could not be addressed. These included the uncertain applicability of trial results to the local patient population, the use of external data (from an SGLT2 inhibitor trial with different patient baseline characteristics) to adjust for SGLT2 inhibitor treatment effects, and the possible overestimation of finerenone's treatment effect on CV outcomes. The Committee also noted that the ICER was sensitive to the modelled time horizon, treatment effects of finerenone on CV and renal outcomes, and the cost of finerenone.

4.4. Overall, the Committee considered that the cost-effectiveness estimates were highly uncertain and likely underestimated. Hence, the use of finerenone in patients with DKD and albuminuria was not likely to represent an acceptable use of healthcare resources at the price proposed by the company.

Estimated annual technology cost

5.1. The Committee noted that the estimated cost impact to the public healthcare system was between SG$1 million and SG$3 million in the first year, and between SG$3 million and SG$5 million in the fifth year of listing finerenone on the MOH List of Subsidised Drugs for treating adults with DKD and UACR ≥200 mg/g.

Recommendations (March 2025)

6.1. Based on available evidence, the Committee recommended not listing finerenone on the MOH List of Subsidised Drugs as an add-on to standard of care for treating adults with CKD and albuminuria associated with type 2 diabetes. This decision was based on finerenone being unlikely to represent an acceptable use of healthcare resources at the price proposed by the company.

Updated recommendations (June 2025)

7.1. Following a negative recommendation by the Committee at the March 2025 meeting, the company of finerenone submitted a revised pricing proposal for funding consideration.

7.2. The Committee considered that the revised proposal was adequate to improve the cost-effectiveness of finerenone compared with placebo and manage the overall budget impact.

7.3. Hence, the Committee recommended finerenone 10 mg and 20 mg tablets be listed on the Medication Assistance Fund (MAF) as an add-on therapy for adults with CKD and albuminuria associated with type 2 diabetes:

- who are receiving concomitant optimal standard treatment which includes an ACE inhibitor or ARB at maximum tolerated dose in combination with an SGLT2 inhibitor, unless contraindicated or not tolerated, and
- who have eGFR ≥25 mL/min/1.73m^2 and UACR ≥200 mg/g (20 mg/mmol) at the start of treatment.

7.4. To govern appropriate use of this treatment in local practice, the Committee also recommended that:

- finerenone must be initiated by, or in consultation with, a specialist physician experienced in the management of CKD and albuminuria associated with type 2 diabetes, and
- treatment with finerenone must be discontinued prior to initiating dialysis.

VERSION HISTORY

Guidance on finerenone
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This Version History is provided to track any updates or changes to the guidance following the first publication date. It is not part of the guidance.

1. **Publication of guidance**
   Date of Publication 4 Jun 2025

2. **Guidance updated to include finerenone on the Medication Assistance Fund**
   Date of Publication 16 Sep 2025

Agency for Care Effectiveness - ACE Agency for Care Effectiveness (ACE)

About the Agency

The Agency for Care Effectiveness (ACE) was established by the Ministry of Health (Singapore) to drive better decision-making in healthcare through health technology assessment (HTA), clinical guidance, and education.

As the national HTA agency, ACE conducts evaluations to inform government funding decisions for treatments, diagnostic tests and vaccines, and produces guidance for public hospitals and institutions in Singapore.

This guidance is not, and should not be regarded as, a substitute for professional or medical advice. Please seek the advice of a qualified healthcare professional about any medical condition. The responsibility for making decisions appropriate to the circumstances of the individual patient remains with the healthcare professional.

Find out more about ACE at www.ace-hta.gov.sg/about

Agency for Care Effectiveness
Email: ACE_HTA@moh.gov.sg