Healthcare Improvement Scotland | SMC Advice on new medicines

SMC2486

finerenone 10mg and 20mg film-coated tablets (Kerendia®)

Bayer plc

07 October 2022

The Scottish Medicines Consortium (SMC) has completed its assessment of the above product and, following review by the SMC executive, advises NHS Boards and Area Drug and Therapeutics Committees (ADTCs) on its use in NHSScotland. The advice is summarised as follows:

ADVICE: following a full submission

finerenone (Kerendia®) is accepted for use within NHSScotland.

Indication under review: for the treatment of chronic kidney disease (stage 3 and 4 with albuminuria) associated with type 2 diabetes in adults.

In a randomised, double-blind, phase III study, the addition of finerenone to angiotensin-converting enzyme inhibitor or angiotensin receptor blocker reduced the risk of the primary composite renal outcome comprising kidney failure, a sustained decrease in estimated glomerular filtration rate of ≥40% or death from renal causes compared with placebo.

Chairman
Scottish Medicines Consortium

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Indication

For the treatment of chronic kidney disease (stage 3 and 4 with albuminuria) associated with type 2 diabetes in adults.[1]

Dosing Information

The recommended target dose of finerenone is 20mg once daily. The maximum recommended dose is finerenone 20mg once daily.

The recommended starting dose is based on the estimated glomerular filtration rate (eGFR): 20mg once daily in patients with eGFR ≥60 mL/min/1.73m^2; 10mg once daily in patients with eGFR ≥25 to <60 mL/min/ 1.73m^2. Finerenone is not recommended in patients with an eGFR <25 mL/min/1.73m^2.

The continuation of finerenone and dose adjustment is based on current serum potassium levels. Refer to the summary of product characteristics (SPC) for details.

Tablets may be taken with a glass of water and with or without food; tablets should not be taken with grapefruit juice.[1]

Product availability date

21 March 2022

Summary of evidence on comparative efficacy

The pathophysiology underlying chronic kidney disease in type 2 diabetes is complex and there are multiple factors involved, including the overactivation of mineralocorticoid receptor leading to inflammation and fibrosis. Finerenone is a novel, non-steroidal, selective antagonist of the mineralocorticoid receptor, which is activated by aldosterone and cortisol. Binding of finerenone to the mineralocorticoid receptor blocks co-activators implicated in the expression of pro-inflammatory and pro-fibrotic mediators.[1, 2]

Evidence comes from one randomised, double-blind, phase III study (FIDELIO-DKD) which compared finerenone with placebo in adult patients with chronic kidney disease and type 2 diabetes. Chronic kidney disease was defined as meeting one of the following two criteria:

- urinary albumin to creatinine ratio (UACR) of ≥30 to <300mg/g, an eGFR of ≥25 to <60mL/min/1.73m^2 and diabetic retinopathy or
- UACR of ≥300 to ≤5,000 mg/g and an eGFR of ≥25 to <75mL/min/1.73m^2.

Eligible patients had received ≥4 weeks treatment with an angiotensin-converting enzyme (ACE) inhibitor, angiotensin receptor blocker (ARB) or both and had a serum potassium ≤4.8mmol/L. The study included a run-in period of 4 to 16 weeks to optimise background therapy to only either ACE inhibitor or ARB at a maximum recommended tolerated dose and receive this stable maximum tolerated dose for ≥4 weeks before screening. Patients who remained eligible, meeting chronic

kidney disease criteria and serum potassium ≤4.8mmol/L, were randomised equally to receive finerenone or placebo. Randomisation was stratified according to geographic region, eGFR (25 to <45; 45 to <60 and ≥60 mL/min/1.73m^2) and level of albuminuria (high or very high). The starting dose of finerenone was based on the eGFR at screening: 10mg daily in patients with an eGFR of 25 to <60 mL/min/1.73m^2 and 20mg daily for patients with an eGFR of ≥60mL/min/1.73m^2. The finerenone dose could be titrated up to 20mg daily after 1 month in patients receiving 10mg daily with a serum potassium level ≤4.8 mmol/L and eGFR that had not decreased by >30% from the previous visit. The finerenone dose could be titrated down from 20mg daily to 10mg daily or from 10mg to interrupt study treatment for safety reasons only, while maintaining standard of care with ACE inhibitors or ARBs. A total of 5,734 patients were randomised but 60 patients were excluded from the full analysis set (n=5,674) due to critical Good Clinical Practice violations.[2, 3]

The primary outcome was a composite of the first occurrence of kidney failure (defined as chronic dialysis or kidney transplantation, or a sustained [over ≥4 weeks] decrease in eGFR to <15 mL/min/1.73 m^2), a sustained decline in eGFR of ≥40% compared to baseline or death from renal causes. The study was event-driven with analysis performed in the full analysis set after ≥1,068 patients had a primary outcome event. The Bonferroni-Holm procedure was applied for the primary and key secondary outcomes in the study. If differences for both outcomes were statistically significant, the additional secondary outcomes were tested hierarchically.[2, 3]

After a median follow-up of 2.6 years, the composite renal primary outcome had occurred in significantly fewer finerenone patients compared with placebo patients (18% versus 21%) in the full analysis set. The key secondary composite cardiovascular outcome (defined as death from cardiovascular causes, non-fatal myocardial infarction, non-fatal stroke or hospitalisation for heart failure) was also significantly lower in the finerenone group compared with the placebo group (13% versus 15%). The first additional secondary outcome, death from any cause, numerically favoured finerenone over placebo (7.7% versus 8.6%) but the difference was not statistically significant and further formal testing of other secondary outcomes was not performed. Therefore, the results reported for these outcomes are descriptive only and non-inferential (no p-values reported). Other secondary outcomes included hospitalisation from any cause, change from baseline to month 4 in UACR and a second composite renal outcome (defined as onset of kidney failure, a sustained decrease of eGFR ≥57% from baseline or renal death), which all numerically favoured finerenone over placebo.[2, 3] Details of key results are presented in Table 1 together with the results for each component of the composites.

Table 1: Results for the composite primary, key composite secondary and additional secondary outcomes in the full analysis set of the FIDELIO-DKD study[1-4]

	Finerenone (n=2,833)	Placebo (n=2,841)	Hazard ratio (95% CI), p-value
Composite renal primary outcome			
Percentage of patients with event (number of patients with event/100 patient-years)	18% (7.59)	21% (9.08)	0.82 (0.73 to 0.93) p<0.001
Components of the composite outcome			
- Kidney failure			
Percentage of patients with event	7.3%	8.3%	0.87 (0.72 to 1.05)
- eGFR decrease ≥40% from baseline			
Percentage of patients with event	17%	20%	0.81 (0.72 to 0.92)
- Renal death			
Percentage of patients with event (n/N)	0.07% (2/2,833)	0.07% (2/2,841)	-
Key secondary outcome (composite cardiovascular outcome)			
Percentage of patients with event (number of patients with event/100 patient-years)	13% (5.11)	15% (5.92)	0.86 (0.75 to 0.99) p=0.03
Components of the composite cardiovascular outcome			
- Cardiovascular death			
Percentage of patients with event	4.5%	5.3%	0.86 (0.68 to 1.08)
- Non-fatal myocardial infarction			
Percentage of patients with event	2.5%	3.1%	0.80 (0.58 to 1.09)
- Non-fatal stroke			
Percentage of patients with event	3.2%	3.1%	1.03 (0.76 to 1.38)
- Hospitalisation for heart failure			
Percentage of patients with event	4.9%	5.7%	0.86 (0.68 to 1.08)

CI=confidence interval; eGFR=estimated glomerular filtration rate.

The submitting company also performed post hoc analyses in a subgroup of patients described as the "label population" which included patients with type 2 diabetes and stage 3 and 4 chronic kidney disease (with eGFR ≥25 to <60 mL/min/1.73m^2 and albuminuria). Results were similar to the full analysis set but were not formally tested for significance.[5]

Health Related Quality of Life was assessed as an exploratory outcome using the Kidney Disease Quality of Life (KDQOL-36) questionnaire and the EuroQoL Group 5-dimension, 5-level (EQ-5D-5L) questionnaire at baseline, every year and at discontinuation and the end of the study.[3] Results have not been published but suggest slightly smaller decreases from baseline over time in some scores in patients treated with finerenone compared with placebo.

*Other data were also assessed but remain confidential.**

Summary of evidence on comparative safety

In the FIDELIO-DKD study, the mean and median durations of treatment in the finerenone and placebo groups was approximately 27 months. Safety data were presented for the safety population only (all randomised patients with no critical Good Clinical Practice violations who had received at least one dose of study medication) and not for the slightly smaller label population. Any treatment-emergent adverse event (AE) was reported by 87% (2,468/2,827) of patients in the finerenone group and 88% (2,478/2,831) in the placebo group and these were considered treatment-related in 23% and 16% respectively. In the finerenone and placebo groups respectively, patients with a reported serious AE were 32% versus 34% and patients discontinuing therapy due to an AE was 7.3% versus 5.9%.[2, 3]

The most frequently reported treatment-emergent AEs of any grade in the finerenone and placebo group respectively were: hyperkalaemia (16% versus 7.8%), nasopharyngitis (8.5% versus 8.8%), hypertension (7.5% versus 9.5%), anaemia (7.4% versus 6.7%), peripheral oedema (6.6% versus 11%), diarrhoea (6.5% versus 6.7%), upper respiratory tract infection (6.4% versus 6.7%), decreased eGFR (6.3% versus 4.7%), urinary tract infection (6.3% versus 6.8%), back pain (6.2% in both), hypoglycaemia (5.3% versus 6.9%), dizziness (5.2% versus 5.4%), arthralgia (5.0% versus 5.3%), bronchitis (4.7% versus 5.3%), constipation (4.6% versus 5.8%) and pneumonia (4.5% versus 6.4%).[3]

Using investigator-reported hyperkalaemia, the incidence was doubled in the finerenone versus placebo group (18% versus 9.0%) and this was considered related to the mode of action of finerenone. Hyperkalaemia led to more discontinuations (2.3% versus 0.9%) and hospitalisations (1.4% versus 0.3%) with finerenone than placebo. There were no deaths due to hyperkalaemia. The SPC notes that finerenone should not be started in patients with a serum potassium >5.0 mmol/L. For patients receiving finerenone, it is recommended that serum potassium and eGFR are remeasured 4 weeks after starting and that the dose is guided by remeasured serum potassium levels.[1-3]

The eGFR decreased in 6.3% of finerenone patients compared with 4.7% of placebo patients. In patients treated with finerenone, the majority of cases were mild or moderate and resolved. Patients on finerenone experienced an initial decrease in eGFR (mean 2 mL/min/1.73 m^2) that attenuated over time compared to placebo. This decrease appeared to be reversible during continuous treatment.[1, 2]

Summary of clinical effectiveness issues

Chronic kidney disease is a serious progressive condition with an age-standardised prevalence of 6% to 11% in the UK. It is estimated that 20% to 40% of patients with type 2 diabetes develop chronic kidney disease, characterised by progressive damage and irreversible loss of renal function resulting in renal failure. Chronic kidney disease is also associated with cardiovascular disease and increased risk of heart failure, premature death and reduced quality of life. The presence of

albuminuria, in patients with or without diabetes, represents a significant risk of more rapid reductions in kidney function. The prevention and treatment of chronic kidney disease in patients with type 2 diabetes includes dietary and lifestyle interventions and medicine management to optimise glycaemic control, blood pressure and blood lipid levels. Inhibition of the renin-angiotensin system, with ACE inhibitors or ARBs, is an established standard of care, recommended by guidelines. Guidelines have recently been updated to recommend the use of sodium-glucose co-transporter 2 (SGLT2) inhibitors (canagliflozin and dapagliflozin) in patients with chronic kidney disease and type 2 diabetes. However, the risk of cardio-renal events remains high despite these treatments.[2, 6, 7] In May 2022, dapagliflozin was accepted for restricted use in NHSScotland for the treatment of CKD (SMC2428); due to the recent nature of this advice, dapagliflozin has not been considered a comparator for this submission. Clinical experts consulted by SMC considered that finerenone fills an unmet need providing a further treatment option to reduce the renal risks in these patients.

In the FIDELIO-DKD study, the addition of finerenone to standard of care, comprising optimised ACE inhibitor or ARB use, significantly reduced the risk of the primary composite renal outcome of kidney failure, a sustained decline in eGFR of ≥40% or death from renal causes by 18% relative to placebo. The absolute reduction in risk was modest at 3.3% but was considered clinically relevant. The treatment effect was mainly driven by the reduced risk of sustained decline in eGFR by ≥40% from baseline. The duration of follow-up is relatively short for a long-term treatment, however Kaplan-Meier curves for the primary composite outcome illustrate that the treatment effect increased with time; evident from 12 months with a 2.9% reduction at 24 months and 3.4% at 36 months. The key secondary composite cardiovascular outcome also significantly favoured finerenone over placebo. Although statistically significant, the small absolute reduction of 1.8% over the study period was not considered convincing enough to determine a cardiovascular indication for finerenone by the regulators.[2, 3]

The licensed indication includes patients with stage 3 and 4 chronic kidney disease which in practice would include patients with an eGFR of ≥15 to <60 mL/min/1.73m^2. However, due to limited clinical data, it is not recommended that finerenone is started in patients with an eGFR of <25 mL/min/1.73m^2. The eGFR of study patients was slightly broader, including some patients with eGFR of <25 and ≥60mL/min/1.73m^2. Results from post hoc analyses in the large subgroup of patients considered to reflect the licensed population (eGFR ≥25 to <60 mL/min/1.73m^2) were presented by the company. These were similar to results in the full analysis set but should be treated with caution since they were not planned.[1-3]

Several factors may affect the generalisability of study results to clinical practice. FIDELIO-DKD excluded patients with New York Heart Association class II to IV and heart failure with reduced ejection fraction; patients with severe hepatic impairment were also excluded and the SPC notes that there are no data available for these patients. The study excluded patients with a glycated haemoglobin >12% which prevented patients with poor glycaemic control to enter. However, randomised patients in the full analysis set had good glycaemic control (glycated haemoglobin 7.7%). At baseline, study patients had a mean systolic blood pressure of 138 mmHg suggesting they did not have good blood pressure control. Only 4.7% of study patients were black and this may affect the generalisability of study results to black patients in clinical practice.[1-3]

Only 4.6% of patients in the full analysis set of the FIDELIO-DKD study were receiving SGLT2 inhibitor therapy but since they are now recommended in guidelines, their use in clinical practice may be higher. There are limited data on concomitant use from FIDELIO-DKD and the study results may not be generalisable to patients taking SGLT2 inhibitors in practice.[3, 6, 7]

The introduction of finerenone would provide an additional add-on treatment to standard of care with ACE inhibitors or ARBs for patients with stage 3 or 4 chronic kidney disease with albuminuria and type 2 diabetes. Regular monitoring of potassium levels and eGFR would be required to determine the treatment dose. Given the increasing use in clinical practice of SGLT2 inhibitors, which have a different mode of action, there may be some uncertainty around finerenone's place in therapy. Clinical experts consulted by SMC considered that finerenone is a therapeutic advancement as it provides additional renal protection through a different mechanism to standard of care.

Summary of comparative health economic evidence

The company submitted a cost-utility analysis of finerenone in combination with current standard of care for adults with chronic kidney disease (stage 3 and 4 with albuminuria) with eGFR ≥25ml/min/1.73m^2 and type 2 diabetes. Standard of care established in clinical practice was the comparator in the analysis. Current standard of care includes use of ACE inhibitors or ARBs and background therapies such as beta-blockers, diuretics, calcium antagonists, statins and glucose-lowering agents.

A cohort-level, state-transition Markov model was developed to estimate the cost effectiveness of finerenone plus standard of care versus placebo plus standard of care. The model included health states reflecting the four stages of CKD progression (CKD1/2, CKD 3, CKD 4, CKD 5 without dialysis) and two stages of end stage renal disease (ESRD): dialysis, post-transplant. A sub-model duplicates all the six health states after a cardiovascular event. The model terminates at a final absorbing state of death. Patients enter the model in one of the CKD stages before the occurrence of a cardiovascular event (for example non-fatal MI, non-fatal stroke, hospitalisation for heart failure [HF]). Patients can remain in the same CKD stage or move to a more/less advanced CKD stage, and/or experience a first modelled cardiovascular event, or death.

The model adopted a lifetime horizon and a 4-month cycle length to correspond with assessment of endpoints in the FIDELIO-DKD study and to reflect disease progression accurately.

Key effectiveness data for finerenone was obtained from the FIDELIO-DKD study. This included input parameters for transition probabilities between states, risk of first cardiovascular event, risk and duration of other health events, rates of mortality and patient utilities. For modelling CKD progression, patient level data from the FIDELIO-DKD study were used to calculate transition probabilities. The transition probabilities for both arms in the model were calculated as the average probabilities over the four years duration of FIDELIO-DKD. The transition probabilities did not change over time.

In terms of the other health outcomes, it was possible to model clinical benefits of finerenone by using relative measures obtained within the trial applied to the absolute estimates for standard of care.

Utility values were based on EQ-5D-5L data from the FIDELIO-DKD study mapped to a 3-level value set. Age and adverse event related disutilities were applied.

Acquisition and administration costs for finerenone and background therapies used in CKD patients with diabetes were included in the analysis. To estimate the daily cost of background therapies, a representative drug was chosen for each class of drug. It was the most common drug from a given class used in the FIDELIO-DKD trial. The cost of background therapies was the sum of all background treatments weighted by percentage of patients who used each therapy in FIDELIO-DKD. Unit costs for disease management in health states, managing cardiovascular health events, managing adverse events, dialysis and death were also included in the analysis.

The base case analysis presented by the submitting company produced an incremental cost-effectiveness ratio (ICER) of £11,578 versus standard of care. This results from an estimated quality-adjusted life-year (QALY) gain of 0.09 and an estimated difference in costs of £1,008.

Table 2: Base case results

Technologies	Total costs	Total LYG	Total QALY	Incremental costs	Incremental LYG	Incremental QALY	ICER (£/QALY)
Finerenone + background therapies	£43,069	7.33	5.47	£1,008	0.11	0.09	£ 11,578
Background therapies	£42,061	7.23	5.38				

Abbreviations: ICER, incremental cost-effectiveness ratio; LYG, life years gained; QALY, quality-adjusted life year

The company provided probabilistic sensitivity analysis (PSA), deterministic sensitivity analysis (DSA) and scenario analysis. The DSA tested a range of parameters including baseline patient distribution, health state costs, utility values, hazard ratios (HR) for events and mortality risks. The parameters with the greatest impact on ICER were utility values for health states, baseline patient distribution, HR: first cardiovascular event, and HR: cardiovascular death.

The company also conducted scenario analyses to test the impact of several assumptions. Table 3 below contains some of the results from scenario analyses.

Table 3: Selected scenario analysis

	Scenario	ICER
	Base case	*£11,578*
1	Population: Full Analysis data set	£10,869
2	Alternate utilities from literature	£9,976
3	Long term effectiveness: No efficacy waning with finerenone	£3,183
4	No treatment discontinuation on finerenone	£13,215
5	Finerenone discontinued after start of dialysis	£10,125

6	Time horizon: 15 years	£12,312
7	Delayed progression to dialysis	£12,130

Abbreviations: ICER, incremental cost-effectiveness ratio

There were some limitations with the analysis which include the following:

- The model operates under the simplifying assumption of constant transition probabilities over time. Hence the probability of transitioning from one state to another is repeated for the duration of the model. Time varying risks are only accounted for by virtue of variable cardiovascular risk by age. The impact of time-invariant transition probabilities on the model is not known, particularly as the uncertainty around these parameters was not tested as part of the sensitivity analysis. However, the company provided additional analyses comparing data from FIDELIO-DKD to the model results for time to event data and patients' distribution across various health states. The model predictions were sufficiently aligned with FIDELIO-DKD data and hence provides some external validation for the use of constant probabilities.
- There is uncertainty regarding treatment discontinuation and the long-term effectiveness of finerenone. In the base case, the company assumed that patients would discontinue finerenone at the rate observed in FIDELIO-DKD. After discontinuation, patients would accrue the costs and benefits from standard of care. Due to the absence of long term data on the effectiveness of finerenone beyond 4 years, there is uncertainty about the benefits of finerenone being maintained in patients discontinuing treatment. The base case model also assumes that patients could continue on finerenone after starting dialysis. However, clinical opinion seems to suggest that finerenone would be discontinued at the point of dialysis initiation. The impact of both discontinuation related assumptions were explored in the scenario analyses and were found to not be critical drivers of cost-effectiveness.
- It is anticipated that SGLT2 inhibitors will increasingly be prescribed in this patient population. There is some uncertainty regarding finerenone's place in therapy with respect to SGLT2 inhibitors (i.e. as an add-on or after) and any incremental treatment effect arising from the use of both medicines.

Despite these limitations, the economic case was demonstrated.

Summary of patient and carer involvement

The following information reflects the views of the specified Patient Groups.

- We received patient group submissions from Kidney Care UK and Kidney Research UK, which are both registered charities.
- Kidney Care UK has received 1.99% pharmaceutical company funding in the past two years, with none from the submitting company. Kidney Research UK has received 6% pharmaceutical company funding in the past two years with none from the submitting company.

- A diagnosis of CKD has huge implications for a person's quality of life. Challenges include the stress of coming to terms with a diagnosis of an incurable, progressive condition, as well as difficult decisions about treatment options and the strain of adjusting to new treatments. Many patients must also adhere to strict medication regimes and dietary restrictions. Symptoms include debilitating fatigue, significant pain, itching, swelling, restless leg syndrome, muscle cramps and sleep problems. People's capacity to stay in work, maintain relationships and quality of life can be severely compromised.

- Type 2 diabetes is the leading cause of chronic kidney disease worldwide so the development of new treatment options for kidney disease in people with type 2 diabetes is of significant interest to patients, and having alternative treatments to offer if the first option is not suitable would be very welcome.

- The progressive damage to the kidneys that occurs in people with diabetes is complex and not fully understood. This medicine provides another option to slow down the progression of the disease, delaying the need for dialysis or a kidney transplant. Treatments for people with renal failure are extremely onerous and therefore any treatments that can delay progress to this stage of the disease have the potential to bring huge benefits to patients.

Additional information: guidelines and protocols

The Scottish Intercollegiate Guidelines Network (SIGN) published "Management of diabetes: a national clinical guideline" in March 2010 which was updated in November 2017.[9] This has a section on the management of kidney disease in diabetes which recommends that treatment should aim to reduce proteinuria regardless of baseline urinary protein excretion with no lower target as the greater the reduction from baseline, the greater the effect on slowing the rate of loss of GFR. It recommends that blood pressure should be reduced to the lowest achievable level to slow the rate of decline in GFR and reduce proteinuria. Patients with type 1 diabetes and microalbuminuria should be treated with an ACE inhibitor and with type 2 diabetes with an ACE inhibitor or ARB, irrespective of blood pressure. ACE inhibitors and / or ARBs should be used as agents of choice in patients with chronic kidney disease and proteinuria to reduce the rate of progression of chronic kidney disease.

This guideline predates the availability of SGLT2 inhibitors (for this indication) and finerenone.

The National Institute for Health and Care Excellence (NICE) published 'Chronic Kidney Disease: Assessment and Management' [NG203] in August 2021.[10] These defined the levels of eGFR and UACR used to classify chronic kidney disease into stages with varying risk of adverse outcomes. Recommendations are made in regards to the treatment of risk factors associated with chronic kidney disease progression; such as cardiovascular disease, diabetes, hypertension and proteinuria. For adults with chronic kidney disease and diabetes (type 1 or 2) an ARB or an ACE inhibitor are recommended (titrated to the highest licensed dose that the person can tolerate) if albumin: creatinine ratio (ACR) is 3mg/mmol or more. The guideline cross-references to NICE

guidance 28 (below) and the NICE technology appraisal on dapagliflozin for treating chronic kidney disease.

NICE guideline [NG28] on "Type 2 diabetes in adults: management" includes a section on chronic kidney disease.[7] Updated in November 2021, this recommends that for adults with type 2 diabetes and chronic kidney disease who are taking an ARB or an ACE inhibitor (titrated to the highest licensed dose that they can tolerate), an SGLT2 inhibitor (in addition to the ARB or ACE inhibitor) should be offered if ACR is over 30mg/mmol and they meet the criteria in the marketing authorisation (including relevant eGFR thresholds) and it should be considered if ACR is between 3 and 30mg/mmol and they meet the criteria in the marketing authorisation (including relevant eGFR thresholds).

The UK Kidney Association published "Clinical Practice Guideline: Sodium-Glucose Co-transporter-2 (SGLT-2) Inhibition in Adults with Kidney Disease" in October 2021. [6] This guideline recommends the initiation of SGLT-2 inhibitors in people with kidney disease caused both by type 2 diabetes and other causes down to an eGFR of 25mL/min/1.73m^2, if albuminuria exceeds 25mg/mmol. The guideline highlights that the evidence for this is strongest in people with type 2 diabetes. In addition, the guideline recommends initiation of SGLT-2 inhibitors in people with chronic kidney disease and a history of heart failure. Once initiated, this guideline recommends that the SGLT-2 inhibitor can be continued until the individual reaches end-stage kidney disease.

These guidelines predate the availability of finerenone.

Additional information: comparators

Standard of care alone (ACE inhibitors or ARBs)

Additional information: list price of medicine under review

Medicine	Dose Regimen	Cost per year (£)
finerenone	**10mg or 20mg orally once daily**	**477**

Costs from eMC Dictionary of Medicines and Devices Browser on 10 August 2022.

Additional information: budget impact

SMC is unable to publish the budget impact due to commercial in confidence issues. A budget impact template is provided in confidence to NHS health boards to enable them to estimate the predicted budget.

*Other data were also assessed but remain confidential.**

References

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4. Bayer, Data on file, Clinical Study Report (CSR). Efficacy and safety of finerenone in subjects with type 2 diabetes mellitus and the clinical diagnosis of diabetic kidney disease. FIDELIO-DKD. 29th July 2020. Contract No.: PH-39746.
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7. National Institute for Health and Care Excellence (NICE) guideline [NG28]. Type 2 diabetes in adults: management, November 2021. Available at: www.nice.org.uk/
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9. Scottish Intercolliegate Guidelines Network (SIGN). Management of diabetes; a national clinical guideline. Last updated November 2017. Available at www.sign.ac.uk.
10. National Institute for Health and Care Excellence (NICE). Chronic kidney disease: assessment and management, August 2021. Available at: www.nice.org.uk/.

This assessment is based on data submitted by the applicant company up to and including 13 September 2022.

**Agreement between the Association of the British Pharmaceutical Industry (ABPI) and the SMC on guidelines for the release of company data into the public domain during a health technology appraisal:*https://www.scottishmedicines.org.uk/about-us/policies-publications/

Medicine prices are those available at the time the papers were issued to SMC for consideration. SMC is aware that for some hospital-only products national or local contracts may be in place for comparator products that can significantly reduce the acquisition cost to Health Boards. These contract prices are commercial in confidence and cannot be put in the public domain, including via the SMC Detailed Advice Document. Area Drug and Therapeutics Committees and NHS Boards are therefore asked to consider contract pricing when reviewing advice on medicines accepted by SMC.

Advice context:

No part of this advice may be used without the whole of the advice being quoted in full.

This advice represents the view of the Scottish Medicines Consortium and was arrived at after careful consideration and evaluation of the available evidence. It is provided to inform the considerations of Area Drug & Therapeutics Committees and NHS Boards in Scotland in

determining medicines for local use or local formulary inclusion. This advice does not override the individual responsibility of health professionals to make decisions in the exercise of their clinical judgement in the circumstances of the individual patient, in consultation with the patient and/or guardian or carer.