Finerenone tablets (Kerendia® ▼) for treatment of CKD (3/4 with albuminuria) in adults with T2DM.

Bath and North East Somerset, Swindon and Wiltshire Together

BSW Area Prescribing Committee (BSW APC) recommends Finerenone tablets (Kerendia® ▼) for Treatment of CKD in T2DM in line with NICE TA877[1]

Traffic Light Status (TLS): AMBER following specialist* initiation.

*For the purpose of this local guidance, a **specialist** could be a prescriber with a clinical interest in renal medicine/endocrinology and experience of treating CKD. This could be a prescriber working in primary care. The NICE TA notes people who may be eligible for finerenone treatment may not always be receiving care in secondary care settings. NICE conclude that finerenone may initially be prescribed in secondary care but will likely be prescribed in primary care as experience grows. A review of TLS to GREEN will be considered once experience is gained locally.

NICE TA877 recommends finerenone as an option for treatment of CKD (3/4 with albuminuria) in adults with T2DM only if:

- it is an add-on to optimised standard care; this should include, unless they are unsuitable, the highest tolerated licensed doses of:
  - angiotensin-converting enzyme (ACE) inhibitors or angiotensin-receptor blockers (ARBs) and
  - sodium–glucose cotransporter-2 (SGLT2) inhibitors and
- the person has an estimated glomerular filtration rate (eGFR) of 25 ml/min/ 1.73 m^2 or more.

BSW APC recommend prescribing and monitoring of finerenone is retained by the specialist until stabilisation of the dose is achieved and the patient has been reviewed by the specialist. The specialist may then request the patient's GP to take over prescribing responsibilities of treatment. The specialist clinician may be situated in hospital or within a locally commissioned consultant/GP specialist-led service situated in primary care.

Cost Effectiveness (and local payment) and Clinical Effectiveness[2]

Finerenone costs £36.68 for 10mg or 20mg tablets x 28-pack (DT July 2023). Annual treatment cost per patient is £478.00.
Cost-effectiveness estimates are uncertain but within the range that NICE considers an acceptable use of NHS resources.
Finerenone will be included in the next drug LES update for all the monitoring that is required.
Finerenone is a first-in-class mineralocorticoid receptor antagonist that regulates the effects of aldosterone and cortisol.
The clinical effectiveness evidence for finerenone was from the FIDELIO-DKD trial, a randomised, double-blind, placebo-controlled, multicentre phase III study in adult patients with CKD and T2D. See NICE TA877 3.5-3.11 for more detail.

Safety and patient factors [2] (See SPC for full safety data, cautions and interactions.)

Contraindications: Addison's disease; hypersensitivity to active substance or lactose (Kerendia® contains lactose so avoid in rare hereditary problems of galactose intolerance, total lactase deficiency or glucose-galactose malabsorption) or any other excipient.
Interactions: Finerenone is cleared mainly via cytochrome P450 (CYP3A4). Concomitant use of finerenone with strong CYP3A4 *inhibitors* (e.g. itraconazole, clarithromycin, ketoconazole, ritonavir, nelfinavir, cobicistat, telithromycin or nefazodone) is contraindicated. Concomitant use with strong/moderate CYP3A4 *inducers* (e.g. carbamazepine, phenytoin, phenobarbital) is not recommended. Also avoid grapefruit or grapefruit juice during finerone treatment.
Adverse reactions: Hyperkalaemia was observed in clinical trials (18.3%). Some patients are at higher risk of hyperkalaemia – see P2. Other reported adverse effects include hyponatraemia, hypotension, pruritis and GFR decreased in investigations.
Embryo-foetal toxicity: Avoid during pregnancy unless there has been careful consideration of maternal benefit vs risk to foetus. A woman becoming pregnant while taking finerenone should be informed of potential risks to foetus. Women of childbearing potential should be advised to use effective contraception during treatment and advised not to breast-feed.

Due to limited clinical data:

- Finerenone should not be initiated in patients with eGFR < 25 mL/min/1.73 m^2 and treatment should be discontinued in patients who have progressed to end-stage renal disease (eGFR < 15 mL/min/1.73 m^2).
- Finerenone should not be initiated in patients with severe hepatic impairment; a significant increase in finerenone exposure is expected. Patients with moderate hepatic impairment may require additional monitoring due to an increase in finerenone exposure.

Patients with diagnosed heart failure with reduced ejection fraction and New York Heart Association II-IV were excluded from the phase III clinical study.

Produced by Dr R Hobson, NHS BSW Meds Opt team. Approved at BSW APC July 23
Review date: Apr 2026 (or earlier if there is significant new evidence relating to this recommendation) Version: 1.0

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Prescribing information, including initiation and monitoring[2]

Serum potassium and estimated glomerular filtration rate (eGFR) must be measured to determine if finerenone treatment can be initiated and to determine the starting dose.

Initiation and continuation of treatment:

- If serum potassium > 5.0 mmol/L, finerenone treatment should not be initiated.
- If serum potassium > 4.8 to 5.0 mmol/L, initiation of finerenone may be considered with additional serum potassium monitoring within first 4 weeks based on patient characteristics and serum potassium levels.
- If serum potassium > 5.5 mmol/L, finerenone treatment must be withheld. Local guidelines for the management of hyperkalaemia must be followed.
- Once serum potassium ≤ 5.0 mmol/L, finerenone treatment can be restarted at 10 mg once daily.
- No dose adjustment is necessary in elderly patients.

Initiation of finerenone treatment vs renal function:

eGFR (mL/min/1.73 $m^{2)}$	Starting dose (once daily)
≥ 60	20 mg
≥ 25 to < 60	10 mg
< 25	Not recommended

Continuation of finerenone treatment vs potassium level and dose adjustment:

Current serum potassium (mmol/l)	Current finerenone dose (once daily)	
	10mg	**20mg**
≤ 4.8	Increase to 20mg OD *(maintain 10mg daily if eGFR has decreased >30% compared to previous measurement).*	Maintain 20mg OD
> 4.8-5.5	Maintain 10mg OD	Maintain 20mg OD
> 5.5	Withhold finerenone. Consider re-starting at 10mg OD when potassium ≤5.0mmol/l.	Withhold finerenone. Re-start at 10mg OD when potassium ≤5.0mmol/l.

- The risk of hyperkalaemia may increase with the intake of concomitant medications that may increase serum potassium. Finerenone should not be given concomitantly with:
  - potassium-sparing diuretics (e.g., amiloride, triamterene) or
  - other mineralocorticoid receptor antagonists, e.g., eplerenone, spironolactone.
- Finerenone should be used with caution and serum potassium should be monitored when taken concomitantly with:
  - potassium supplements or
  - trimethoprim, or trimethoprim/sulfamethoxazole. Temporary discontinuation of finerenone may be necessary when patients have to take trimethoprim products. See SPC for details.
- The risk of hyperkalaemia may increase with decreasing renal function. Ongoing monitoring of renal function should be performed according to standard practice.
- Some patients are at higher risk of developing hyperkalaemia. Risk factors include low eGFR, higher serum potassium and previous episodes of hyperkalaemia. In these patients more frequent monitoring must be considered.

Serum potassium and eGFR must be remeasured 4 weeks after initiation, re-start or increase in dose of finerenone. Thereafter, serum potassium must be assessed periodically, considering patient characteristics and serum potassium levels.

Tablets should be taken with a glass of water and with or without food. If unable to swallow whole tablets, finerenone may be crushed and mixed with water or soft foods, such as apple sauce, directly before oral use.

References:

1. National Institute for Health and Care Excellence. Technology appraisal 877; Finerenone for treating chronic kidney disease in type 2 diabetes. 23 March 2023. Accessed 12/5/23
2. Bayer plc. Summary of Product Characteristics; Kerendia film coated tablets. Accessed 12/5/23
3. Bakris et al. Effect of finerenone on chronic kidney disease outcomes in type 2 diabetes. *NEJM*. 2020;383:2219-29. DOI: 10.1056/NEJMoa2025845 Effect of Finerenone on Chronic Kidney Disease Outcomes in Type 2 Diabetes | NEJM

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