BEDFORDSHIRE, LUTON AND MILTON KEYNES AREA PRESCRIBING COMMITTEE

Prescribing Guidance for Finerenone for treating chronic kidney disease (CKD) with type 2 diabetes (T2DM)

(February 2025)

The recommendations in this prescribing guidance document have been adopted with kind permission from Buckinghamshire, Oxfordshire, and Berkshire (BOB) Integrated Care System (ICS) medicines optimisation team. It aligns with current recommendations in the NICE Technology Appraisal (NICE TA 877); Finerenone for treating chronic kidney disease in type 2 diabetes and should be read in conjunction with the corresponding Summary of Products Characteristics (SPC).

The following organisations contribute to and participate in the BLMK APC – Bedfordshire, Luton and Milton Keynes Integrated Care Board; Bedfordshire Hospitals NHS Foundation Trust; Cambridgeshire Community Services NHS Trust; Central and North West London NHS Foundation Trust; East London NHS Foundation Trust; Milton Keynes University Hospital NHS Foundation Trust

Approved by BLMK Area Prescribing Committee (APC) February 2025. Review Date: February 2028.

Finerenone Prescribing Guidance	
1. Responsibilities (please note this is **NOT** shared care. Treatment may be initiated or recommended by specialist services or GP may initiate without specialist involvement.	**1. GP** • Initiate treatment and prescribe until the dose is stable in accordance with the summary of product characteristics (SPC) or prescribing checklist. • Ensure the patient understands the nature and complications of drug therapy and their role in reporting adverse effects promptly. • Ensure all monitoring and ongoing reviews are completed in accordance with the summary of product characteristics or prescribing checklist. • Check and record results then inform the specialist of any deteriorations or abnormal results. • Notify or seek advice from the specialist to any changes in patients' condition, any adverse drug reactions or failure to attend tests. **2. Specialist** • Initiate or recommend treatment and send a letter to the GP requesting treatment continuation. • Ensure the patients understand the nature and complications of drug therapy and their role in reporting adverse effects promptly. • Check and record results then advise the GP of any deteriorations or abnormal results pertinent to the disease management. • Liaise with the GP regarding any changes in patients' condition or any adverse drug reactions. • Be available to give advice to GP and patient throughout treatment.
2. Background	Finerenone has shown promising cardiac and renoprotective benefits in treating chronic kidney disease (CKD) with type 2 diabetes. In the FIDELIO-DKD trial, finerenone reduced the incidence of a sustained decline in eGFR of 40% or greater, kidney failure, or renal death—all part of a composite end point. It also reduced the risk of cardiovascular death, non-fatal MI, non-fatal stroke, or hospitalization for heart failure as a secondary composite end point. In FIGARO-DKD, finerenone reduced the incidence of cardiovascular death, non-fatal myocardial infarction (MI), non-fatal stroke, or hospitalisation for heart failure as a main composite end point. Safety findings were satisfactory in both studies. The introduction of finerenone would provide an additional add-on treatment to standard of care with angiotensin-converting enzyme (ACE) inhibitors or angiotensin receptor blockers (ARBs) for patients with stage 3 or 4 chronic kidney disease (CKD) with albuminuria and type 2 diabetes (T2DM). Regular monitoring of potassium levels and eGFR would be required to determine the treatment dose. Finerenone provides additional renal protection through a different mechanism to standard of care.
3. Indications **(Please state whether licensed or unlicensed)**	• Licensed for the treatment of chronic kidney disease (stage 3 and 4 with albuminuria) associated with type 2 diabetes in adults. • Urinary albumin: creatinine ratio (uACR) > 3 mg/mmol
4. Locally agreed off-label use	n/a
5. Pharmaceutical form	• Finerenone (10mg & 20mg) Tablets x 28 ▼

6. Contraindications and cautions Please note this does not replace the Summary of Product Characteristics (SPC) and should be read in conjunction with it.	**Contraindications:** 1. Hypersensitivity to the active substance or to any of the excipients 2. Addison's disease 3. Severe hepatic impairment 4. Concomitant treatment with strong inhibitors of CYP3A4 (e.g. clarithromycin, itraconazole, ketoconazole, ritonavir). **Cautions:** 1. moderate hepatic impairment; consider additional monitoring due to increased finerenone exposure. The risk of hyperkalaemia also 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) and - other mineralocorticoid receptor antagonists (MRAs), e.g., eplerenone, spironolactone. Finerenone should be used with caution and serum potassium should be monitored when taken concomitantly with - potassium supplements. -trimethoprim or trimethoprim/sulfamethoxazole. Temporary discontinuation of finerenone may be necessary. Please see SPC for comprehensive information.
7. Initiation and ongoing dose regime Note - • If started by the specialist ongoing monitoring and prescribing will be continued in primary care. Monitoring investigations should be 4 weeks after initiation or re-start of treatment. •The duration of treatment & frequency of review will be determined by the prescriber based on clinical response and tolerability. •Dose or formulation adjustments will be done in accordance with the prescribing guide unless otherwise advised by the specialist teams. Contact specialist services for further advice if needed.	**Initial stabilisation:** Finerenone is an add-on therapy to optimised standard care; this should include, unless they are unsuitable, the highest tolerated licensed doses of: • ACE inhibitors or ARBs and; • SGLT2 inhibitors and; • patient has an eGFR of 25 mL/min/1.73 m^2 or more Threshold for treatment initiation based on potassium level: • if serum potassium ≤ 4.8 mmol/L, finerenone treatment can be initiated • if serum potassium > 4.8 to 5.0 mmol/L, initiation of finerenone treatment may be considered with additional serum potassium monitoring within the first 4 weeks based on patient characteristics and serum potassium levels • if serum potassium > 5.0 mmol/L, finerenone treatment should not be initiated. Starting dose is based on eGFR: • 10mg daily for eGFR 25-60ml/min • not recommended for eGFR < 25ml/min **Maintenance dose (following initial stabilisation):** Serum potassium and eGFR have to be remeasured 4 weeks after initiation or re-start of finerenone treatment or increase in dose: • if serum potassium ≤ 4.8mmol/L, increase finerenone from 10mg to 20mg daily; maintain finerenone dose at 10mg daily if eGFR has decreased > 30% compared to previous measurement. • if serum potassium 4.8 - 5.5 mmol/L, maintain at current finerenone dose.

<table>
<tr><td></td><td colspan="2">
if serum potassium > 5.5mmmol/L, withhold finerenone and restart at 10mg daily when serum potassium ≤ 5.0mmol/L.
<u>Conditions requiring dose adjustment:</u>
<table>
<tr><td colspan="2"></td><td colspan="2">Current finerenone dose (once daily)</td></tr>
<tr><td colspan="2"></td><td>10mg</td><td>20mg</td></tr>
<tr><td rowspan="3">Current serum potassium (mmol/L)</td><td>≤ 4.8</td><td>Increase to 20mg daily *</td><td>Continue same dose</td></tr>
<tr><td>> 4.8 to 5.5</td><td>Continue same dose</td><td>Continue same dose</td></tr>
<tr><td>> 5.5</td><td colspan="2">Withhold. Consider re-starting at 10mg daily when serum potassium ≤ 5.0mmol/L</td></tr>
</table>
*Maintain 10mg daily if eGFR has decreased > 30% compared to the previous measurement
Due to limited clinical data, finerenone treatment should be discontinued in patients who have progressed to end-stage renal disease (eGFR<15 mL/min/1.73m^2)
</td></tr>
<tr><td rowspan="3">8. Pharmaceutical aspects</td><td>Route of administration:</td><td>Oral</td></tr>
<tr><td>Formulation:</td><td>Tablet (10mg & 20mg)</td></tr>
<tr><td>Administration details:</td><td>1. Tablets should not be taken with grapefruit or grapefruit juice
2. For patients who are unable to swallow whole tablets, finerenone tablets may be crushed and mixed with water or soft foods, such as apple sauce, directly before oral use</td></tr>
<tr><td></td><td>Other important information:</td><td>n/a</td></tr>
<tr><td>9. Significant medicine interactions

For a comprehensive list consult the BNF or Summary of Product Characteristics.SPC</td><td colspan="2">The following list is not exhaustive; please see SPC for comprehensive information and recommended management.

Concomitant treatment with strong inhibitors of CYP3A4 is contraindicated, e.g., (e.g., ketoconazole, itraconazole, ritonavir, nelfinavir, cobicistat, clarithromycin telithromycin or nefazodone).

Concomitant treatment with strong and moderate inducers of CYP344 is Contraindicated,
(e.g., carbamazepine, phenytoin, phenobarbital, St John's Wort) or with efavirenz and other moderate CYP3A4 inducers.</td></tr>
<tr><td>10. Baseline investigation and initial monitoring to be undertaken when initiated by the specialist</td><td colspan="2">Baseline investigations:
• eGFR and serum potassium level

Initial monitoring:
• Monitoring at baseline and during initiation is the responsibility of the specialist, only once the patient is optimised on the chosen medication</td></tr>
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<table>
<tr><td></td><td colspan="2">with no anticipated further changes expected in immediate future will prescribing and monitoring be transferred to the GP.</td></tr>
<tr><td rowspan="2">11. Ongoing monitoring requirements to be undertaken by primary care where treatment has been initiated by specialist

See section 12 for further guidance on management of adverse effects/ responding to monitoring results</td><td>Monitoring</td><td>Frequency</td></tr>
<tr><td>• eGFR
• Serum potassium level</td><td>• 4 weeks after initiation
• when restarting treatment or increasing dose
• every 4-6 months in CKD 3 and every 3 months in CKD 4</td></tr>
<tr><td rowspan="4">12. Adverse effects and managements

▼This medicinal product is subject to additional monitoring. This will allow quick identification of new safety information.

Any serious adverse reactions should be reported to the MHRA via the Yellow Card scheme
www.mhra.gov.uk/yellowcard</td><td>Result</td><td>Action for GP</td></tr>
<tr><td>Hyperkalaemia</td><td>• Repeat eGFR and serum potassium level
• Consider reducing finerenone dose or suspend treatment as required
• Contact specialist services for further advice if needed</td></tr>
<tr><td>Hyponatraemia</td><td>• Identify other causes of hyponatraemia:
1) Renal losses, i.e., diuretics, hypoadrenalism, sodium-losing nephropathies
2) Non-renal losses, i.e., diarrhoea, vomiting, pancreatitis
3) Oedematous states such as severe renal impairment, congestive heart failure, cirrhosis
4) Hypothyroidism
5) Psychogenic polydipsia
• Contact specialist services for further advice if needed</td></tr>
<tr><td>Decreased level of haemoglobin</td><td>• Identify other causes of decrease in haemoglobin:
1) cancer
2) medications, e.g. antiretrovirals
3) cirrhosis
4) iron deficiency
5) vitamin deficiency
6) bleeding events
• Contact specialist services for further advice if needed</td></tr>
<tr><td>13. Advice to patients and carers
The healthcare professional will counsel the patient about the benefits and risks of treatment and will provide the patient with any relevant information and advice, including patient information leaflets on individual medicines.</td><td colspan="2">The patient should be advised to report any of the following signs or symptoms to their GP without delay:
• Palpitations
• Shortness of breath
• Chest pain
• Nausea and/or vomiting</td></tr>
</table>

14. Pregnancy, paternal exposure and breast feeding It is the responsibility of the healthcare professional to provide advice on the need for contraception to male and female patients on initiation and at each review but the ongoing responsibility for providing this advice rests with the prescriber.	**Pregnancy:** Women of childbearing potential should use effective contraception during finerenone treatment. Studies in animals have shown reproductive toxicity. Finerenone should not be used during pregnancy unless the clinical condition of the woman requires treatment with finerenone. If the woman becomes pregnant while taking finerenone, she should be informed of potential risks to the foetus. **Breastfeeding:** Available pharmacokinetic/toxicological data in animals have shown excretion of finerenone and its metabolites in milk. Rat pups exposed via this route showed adverse reactions. A decision must be made whether to discontinue breast-feeding or to discontinue/abstain from finerenone taking into account the benefit of breast-feeding for the child and the benefit of treatment for the patient.
15. Additional information	Where patient care is transferred from one specialist service or GP practice to another, a new treatment plan must be initiated by the transferring team and communicated.
16. References	1. Bakris GL, Agarwal R, Anker SD, Pitt B, Ruilope LM, Rossing P, et al. Effect of finerenone on chronic kidney disease outcomes in type 2 diabetes. New England Journal of Medicine. 2020;383(23):2219–29. 2. Pitt B, Filippatos G, Agarwal R, Anker SD, Bakris GL, Rossing P, et al. Cardiovascular events with Finerenone in kidney disease and type 2 diabetes. New England Journal of Medicine. 2021;385(24):2252–63. 3. Bayer plc. (2022). Kerendia 10mg film coated tablets – Summary of Product Characteristics (SPC). Electronic Medicines Compendium. Online at https://www.medicines.org.uk/emc/product/13437/smpc [accessed February 2025]
17. Local arrangements for advice & referral Define the referral or advice & guidance procedure for primary care clinicians.	East and North Hertfordshire Via Advice & Guidance e-portal on SystmOne Oxfordshire and Buckinghamshire • Renal Specialist Advice: renaladvice@ouh.nhs.uk • Oxford Renal Pharmacy Team: oxfordrenalpharmacists@ouh.nhs.uk