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Finerenone for Treating Diabetic Kidney Disease (DKD) in Adults Information Sheet

Introduction

This guideline covers the use of finerenone (Kerendia®) in patients with diabetic kidney disease. It should be utilised in conjunction with the South West London chronic kidney disease (CKD) pathway Investigation and Management of Chronic Kidney Disease CKD in Adults in Primary Care and CKD visual summary. Initiation of finerenone requires optimisation of CKD care in accordance with these pathways and is considered an add on to standard care.

Finerenone is a non-steroidal mineralocorticoid receptor antagonist (MRA) that inhibits receptor-mediated sodium reabsorption and decreases receptor overactivation, thereby reducing the inflammation and fibrosis that leads to kidney damage.

Recommendations

South West London (SWL) formulary status for finerenone is Amber 2 (initiation by a specialist, stabilisation for a 3 months, then continuation in primary care with transfer of care documentation) when prescribed in line with NICE technology appraisal [TA877] for treating chronic kidney disease in type 2 diabetes. This is based on clinical trial data from the FIGARO DKD study.

Roles and responsibility

Renal/diabetes specialist team responsibility

- Identification and initiation of eligible patients on NICE-approved finerenone, following discussion with the patient, consideration of risks/benefits, clinical considerations, current co-morbidities, contra-indications and side effects.
- Actions to take prior to initiation
  - Ensure patient is not on any potassium elevating medication or MRA.
  - Provide patient with advice on high potassium foods as per the CKD visual summary
  - Provide the patient with advice on avoiding the use of nonsteroidal anti-inflammatory drugs.
- Ensure the following is included in the transfer of care documentations:
  - Updated management/medicines optimising plan.
  - Baseline renal function, liver function, glycated haemoglobin (HbA1c), serum potassium.
  - Follow up 3-monthly blood test results.
  - Details of specialist team for advice/support.

Primary care responsibility

- Continue prescribing of finerenone following specialist initiation and stabilisation and receipt of transfer of care documentation.
- Follow monitoring requirements.
- Ongoing monitoring and support of patient adherence.

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Initiation criteria

Finerenone is recommended as an option for treating stage 3 and 4 chronic kidney disease (with albuminuria) associated with type 2 diabetes in adults. It is recommended 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 inhibitors (ACEi) or angiotensin-receptor blockers (ARBs) and
    - sodium–glucose cotransporter-2 inhibitors (SGLT2i) and
- the person has an estimated glomerular filtration rate (eGFR) of 25ml/min/1.73 m^2 or more.

Exclusions to treatment

- Non-diabetic renal disease.
- Patients with a clinical diagnosis of chronic heart failure with reduced ejection fraction (HFrEF) and persistent symptoms (New York Heart Association class II - IV) at initiation (recommendation for MRAs).
- If serum potassium greater than 5.0 mmol/L prior to initiation.

Prescribing Guidance:

Also available as a visual summary: Appendix 1

Finerenone:

Dosage:

Based on renal function:

- eGFR greater than or equal to 60mL/min/1.73m^2: 20mg once daily
- eGFR greater than or equal to 25mL/min/1.73m^2 but less than 60mL/min/1.73m^2:10mg once daily
- eGFR less than 25mL/min/1.73m^2: Initiation not recommended

Renal function:

Risk of hyperkalaemia increased with decreasing renal function.

- In patients with eGFR greater than or equal to 15 mL/min/1.73 m^2, finerenone treatment can be continued with dose adjustment based on serum potassium.
- Discontinue in patients who have progressed to end-stage renal disease eGFR less than 15 mL/min/1.73m^2.

Hepatic Impairment:

- Avoid in severe hepatic impairment.
- No dose adjustment required but consider additional serum potassium monitoring in moderate impairment. Refer to the BNF and SPC.

Contra-indications:

Do not prescribe in the following patients:

- Concomitant treatment with strong inhibitors of CYP3A4 including itraconazole, ketoconazole, ritonavir, nelfinavir, cobicistat, clarithromycin, telithromycin and nefazodone. A marked increase in finerenone exposure is expected.

- Concomitant treatment with strong induces of CYP3A4 e.g., carbamazepine, phenytoin, phenobarbital, St John's Wort) or with efavirenz and other moderate CYP3A4 inducers. These CYP3A4 inducers are expected to markedly decrease finerenone plasma concentration and result in reduced therapeutic effect.
- If serum potassium greater than 5mmol/L, consider intervention to reduce potassium.

Refer to the BNF and SPC for an up-to-date list.

Elderly: No dose adjustment required.

Contraception in females: Women of childbearing potential should use effective contraception during treatment with finerenone.

Pregnancy and breastfeeding: Avoid.

Side effects:

- Refer to BNF and SPC full list of other potential side effects.
- The most frequently reported adverse reaction was hyperkalaemia, electrolyte imbalance, pruritus, glomerular filtration decreases.

Interactions:

- Full list of documented interactions can be found: BNF and SPC.
- In patients taking finerenone concomitantly with moderate or weak CYP3A4 inhibitors, potassium supplements, trimethoprim, or trimethoprim/sulfamethoxazole, additional serum potassium monitoring and adaptation of monitoring according to patient characteristics should be considered.
- Grapefruit or grapefruit juice should not be consumed during finerenone treatment, as it is expected to increase the plasma concentrations of finerenone through inhibition of CYP3A4.

Monitoring Requirements

eGFR:

- should be measured at 4 weeks after initiation or re-start of finerenone treatment or after a dose increase.
  Note: if eGFR has decreased greater than 30% compared to the previous measurement maintain finerenone 10mg once daily.

Serum potassium:

- should be measured at 4 weeks after initiation (in secondary care) or re-start of finerenone treatment or after a dose increase (to determine if continuation of finerenone treatment and dose adjustment).
- Thereafter, serum potassium should be measured periodically and as needed based on patient characteristics and serum potassium levels. As a minimum this should be every 3 months.
- See below guidance on continuation of finerenone treatment and dose adjustments based on serum potassium:

- Serum potassium (less than or equal to 4.8mmol/L): Increase or maintain 20mg once daily dose.
- Serum potassium (greater than 4.8mmol/L but less than or equal to 5.5mmol/L): maintain once daily dose.
- Serum potassium (more than 5.5mmol/L): withhold finerenone (Consider re-starting finerenone 10 mg once daily when serum potassium less than or equal to 5.0 mmol/L).

Counselling:

Missed Dose:

A missed dose should be taken as soon as possible, but only on the same day. You should not take 2 doses to make up for a missed dose.

Precaution/ Side effects:

- Do not eat grapefruit or drink grapefruit juice while you are using this medicine.
- This medicine may cause hyperkalaemia (high potassium in the blood). Check with your doctor right away if you have confusion, irregular heartbeat, nausea or vomiting, nervousness, numbness or tingling in the hands, feet, or lips, stomach pain, trouble breathing, or weakness or heaviness of the legs. For a full list of side effects refer to the Patient Information Leaflet (PIL)
- Do not take other medicines unless they have been discussed with your doctor. This includes prescription or nonprescription (over-the-counter [OTC]) medicines and herbal or vitamin supplements (e.g., potassium supplements).

References:

1. Overview | Finerenone for treating chronic kidney disease in type 2 diabetes | Guidance | NICE, Published: 23 March 2023.
2. Finerenone in the management of Diabetic Kidney Disease: A consensus statement by the Association of British Clinical Diabetologists and UK Kidney Association
3. Effect of Finerenone on Chronic Kidney Disease Outcomes in Type 2 Diabetes | NEJM
4. Kerendia 10 mg film coated tablets - Summary of Product Characteristics (SmPC) - (emc) (medicines.org.uk)

Document History

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Appendix 1: Finerenone for diabetic kidney disease pathway

Criteria for finerenone initiation
1. Type 2 diabetes
2. CKD with GFR ≥ 25 mL/min with A2 or A3 albuminuria

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Exclusion criteria
1. Non diabetic renal disease
2. Chronic heart failure with reduced ejection fraction (HFrEF) and persistent symptoms (New York Heart Association class II - IV) at initiation

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Serum potassium ≤5 mmol/L → NO → Consider interventions to reduce potassium ≤5 mmol/L then reconsider

↓ YES

Dose at initiation according to eGFR	
eGFR (mL/min/1.73m²)	**Starting dose (once daily)**
≥ 60	20 mg
≥ 25 to <60	10mg
<25	Not recommended

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Week 4: Serum potassium and eGFR check

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		Current Finerenone dose (once daily)	
		10 mg	20 mg
Current serum potassium (mmol/L)	≤ 4.8	Increase to 20 mg Finerenone once daily*	Maintain 20 mg once daily
	>4.8 to 5.5	Maintain 10 mg once daily	Maintain 20 mg once daily
	>5.5	Withhold Finerenone Consider re-starting at 10 mg once daily when serum potassium ≤ 5.0 mmol/L	Withold Finerenone Restart at 10 mg once daily when serum potassium <5.0 mmol/L

*Maintain 10mg once daily, if eGFR has decreased >30% compared to the previous measurement

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Repeat potassium and eGFR following any escalation in dose

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Ongoing serum potassium and eGFR check at least every 3 months