Finerenone for Treating Chronic Kidney Disease (stage 3 and 4 with Albuminuria) associated with Type 2 Diabetes in Adults - Full Clinical Guideline

Reference no.:CG-CLIN/4212/23

- Finerenone is a non-steroidal, selective mineralocorticoid receptor antagonist
- Clinical study showed that in patients with CKD (chronic kidney disease) and type 2 diabetes, treatment Finerenone resulted in **lower risks of CKD progression and cardiovascular events than placebo.**
- NICE [TA877] recommends Finerenone as an add-on to optimised standard care, if:
    - **eGFR between ≥ 25 ml/min/1.73m^2 to < 60 ml/min/1.73m^2 and**
    - CKD associated with **Type 2 diabetes and**
    - **Urine albumin-creatinine ratio (uACR) > 3mg/mmol and**
    - Patient already receiving the highest tolerated licensed doses of, unless they are unsuitable:
        - **angiotensin-converting enzyme (ACE) inhibitors or angiotensin-receptor blockers (ARBs) and**
        - **sodium-glucose co-transporter-2 (SGLT2) inhibitor and**

Treatment initiation

Serum potassium level (mmol/L)	
≤ 4.8	Start finerenone 10mg daily
4.9 to 5.0	Finerenone may be considered with additional serum potassium monitoring within the first 4 weeks, based on the patient's co-morbidities and subsequent potassium levels.
> 5.0	Do not start finerenone
eGFR (mL/min/1.73m^2)	
≥ 25 to < 60	Start 10mg daily
< 25	Do not start finerenone

The starting dose is 10mg once daily. The recommended target dose is 20mg once daily.

Treatment continuation and dose adjustment

Serum potassium (mmol/L)	**Finerenone dose (once daily)**	
	10mg	**20mg**
≤4.8	Consider increasing to 20mg OD	Maintain 20mg OD
>4.8 to 5.5	Maintain 10mg OD	Maintain 20mg OD

>5.5	Withhold Finerenone Consider restarting at 10mg once daily when serum potassium ≤5.0 mmol/L	
eGFR		
If eGFR decrease is > 30% from the previous measurement, to recheck U+E in 5-7 days. If further decline of eGFR on repeat U+E, to stop Finerenone.		

A transient decline in eGFR ((mean 2 mL/min/1.73 m2) and a drop in blood pressure (2-4 mm Hg) may be observed upon initiating treatment. Both are reversible during continuous treatment.

Due to limited clinical data, Finerenone should be discontinued in patients who have progressed to end-stage renal disease (eGFR < 15 ml/min/1.73m^2).

Monitoring

- serum potassium and eGFR must be rechecked **4 weeks after**: initiation of treatment, increment of dose or restarting of treatment.
- Thereafter, serum potassium should be remeasured periodically and as needed based on patient characteristics and serum potassium levels.

Contraindications

- An eGFR of less than 25 mL/min/1.73m2.
- Serum potassium level greater than 5.0 mmol/L.
- Severe hepatic impairment.
- Addison's disease
- Finerenone should not be used during pregnancy unless there has been careful consideration of the benefit for the mother and the risk to the foetus

Drug Interactions

Finerenone should not be taken concomitantly with

- Grapefruit or grapefruit juice
- Strong CYP3A4 inhibitors (i.e., clarithromycin, ritonavir, itraconazole)

Strong CYP3A4 inducers (i.e., rifampicin, carbamazepine, phenytoin, phenobarbital, St John's Wort)

5. References (including any links to NICE Guidance etc.)

1) Bakris G, Agarwal R and Anker S et al. Effect of Finerenone on Chronic Kidney Disease Outcomes in Type 2 Diabetes. *N Engl J Med* 2020;383:2219–2229
2) NICE TA – Finerenone for treating CKD in type 2 diabetes. Technology appraisal guidance [TA877] Published: 23 March 2023
3) SPC for Kerendia 10 mg film-coated tablets. Last updated on 21MAR2023. Accessed via https://www.medicines.org.uk/emc/product/13437/smpc#gref
4) 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.

Documentation Controls (these go at the end of the document but before any appendices)

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1. Appendices