Kerendia▼ (finerenone) is indicated for the treatment of chronic kidney disease (stage 3 and 4 with albuminuria) associated with type 2 diabetes in adults.

Kerendia® ▼ finerenone

Identification of diabetic kidney disease (DKD) in primary care: Testing and management including pharmacotherapy

Both eGFR and UACR are key to diagnosing CKD[1]

An increase in UACR can indicate progression of DKD[2]

UACR testing can detect early signs of DKD before significant nephron loss has occurred[3]

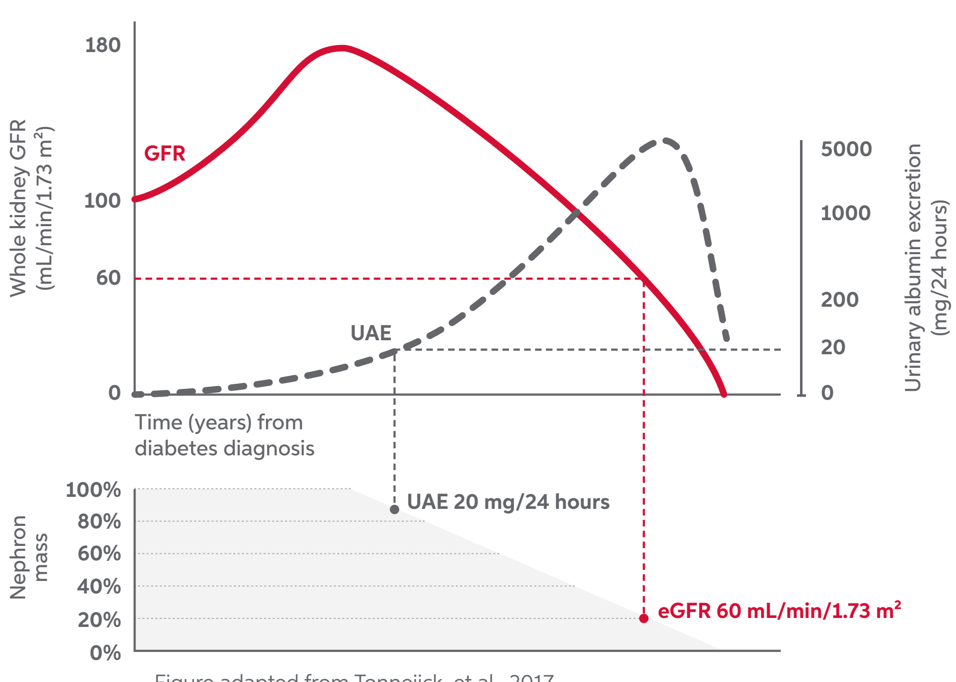
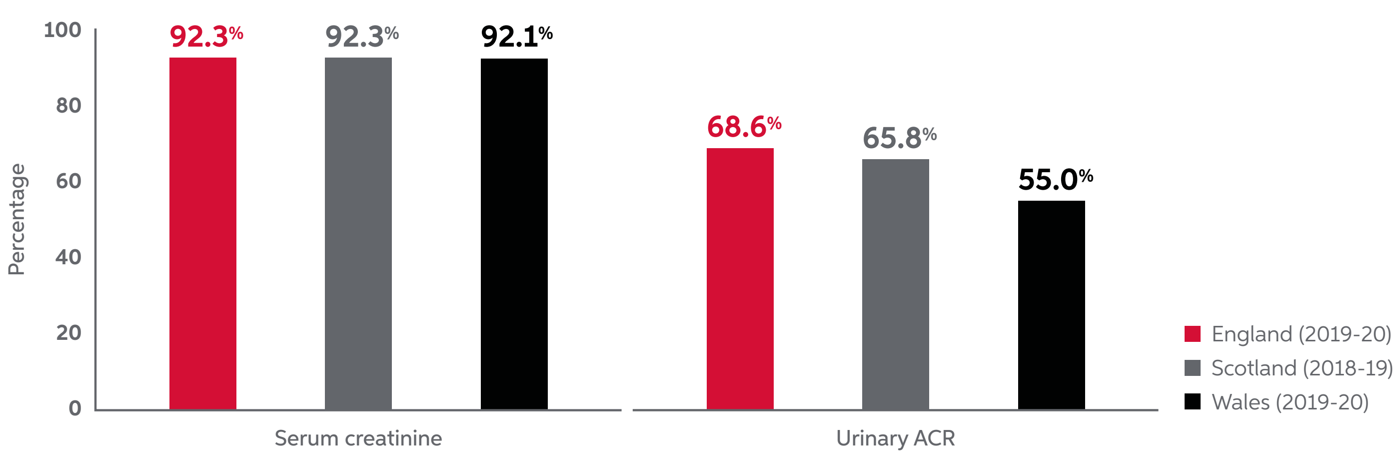


Figure adapted from Tonneijck, et al., 2017

UACR tests for people with diabetes are completed at lower rates compared with serum creatinine testing in England, Scotland and Wales[4,5]



Primary Care participation was 99.3% in England and Wales. Scottish data collates information from all 14 NHS Boards.

Barriers to UACR testing

- UACR testing rates have declined since the test was removed from QOF[6] in 2014
- HCPs may have deprioritised UACR testing due to a historic lack of treatment options and no clear explanation about why both eGFR and UACR are required to gain a holistic picture of kidney health
- Early morning UACR is recommended but specialists say that any urine sample is better than no sample[6]
- The focus on a morning urine sample further reduces the likelihood of a patient providing a sample[7]
- Other patient factors which may be a barrier to UACR testing include little or no knowledge of CKD prior to diagnosis and a lack of awareness of the link between elevated UACR and poor outcome[8]

How often should kidney function be monitored?[9]

eGFR and UACR are used to stratify risk of adverse CV and renal outcomes[6]

GFR categories, description and range (mL/min/1.73 m²)			Albuminuria stages, description and range: A1 Normal to mildly increased (<3 mg/mmol)	A2 Moderately increased (3–30 mg mmol)	A3 Severely increased (>30 mg/mmol)
Number of times per year eGFR should be monitored in patients with (or at risk of) CKD[1]					
G1	Normal or high	≥90	≤1	1	≥1
G2	Mild	60–89	≤1	1	≥1
G3a	Mild to moderate	45–59	1	1	2
G3b	Moderate to severe	30–44	1 or 2	2	≥2
G4	Severe	15–29	2	2	3
G5	Kidney failure	<15	4	≥4	≥4

Adapted from KDIGO 2022 and NICE 2021

Low risk (if no other markers of kidney disease, no CKD) · Moderately increased risk · High risk · Very high risk

Useful resource:
Winocour PH et al. Testing for kidney disease in type 2 diabetes: Consensus statement and recommendations. Diabetes & Primary Care 2020;22: 99–109

Approaches to the management of DKD[10-12]

- Blood pressure and blood glucose control
- Management of CV risk factors
- Lifestyle adjustment (e.g. weight management, exercise, smoking cessation)
- Dietary modification (e.g. low salt diet)
- Pharmacotherapy

Pharmacotherapy for diabetic kidney disease: NICE guidance[12]

Advice for adults with type 2 diabetes and CKD	
ACR ≥3 mg/mmol	Offer an ACE inhibitor or ARB and titrate to maximum tolerated / highest licensed dose
ACR 3–30 mg/mmol and patients are already taking an ACE inhibitor/ARB titrated to the highest licensed dose they can tolerate	Consider an SGLT2 inhibitor* (in addition to the ACE inhibitor/ARB) if they meet the criteria in the marketing authorisation (including relevant eGFR thresholds)
ACR >30 mg/mmol and patients are already taking an ACE inhibitor/ARB titrated to the highest licensed dose they can tolerate	Offer an SGLT2 inhibitor* (in addition to the ACE inhibitor/ARB) if they meet the criteria in the marketing authorisation (including relevant eGFR thresholds)

*Be aware that not all SGLT2 inhibitors are currently licensed for this indication

Pharmacotherapy for diabetic kidney disease: Introducing Kerendia (finerenone)

Kerendia is a selective, non-steroidal MRA indicated for the treatment of CKD (stage 3 and 4 with albuminuria) associated with type 2 diabetes in adults[13]

In the FIDELIO-DKD phase 3 randomised, double-blind, placebo-controlled, multicentre clinical trial of 5734 adult patients with type 2 diabetes and CKD who were randomised 1:1 to receive either oral finerenone or placebo, at baseline approximately 124 (4.4%) patients in the finerenone arm and 135 (4.8%) in the placebo arm were on SGLT2 inhibitors.[14]

To find out more about the FIDELIO-DKD study, please scan the QR code, or visit go.bayer.com/fideliodkd

NICE TA877 guidance[15]

Finerenone for treating CKD in type 2 diabetes
Technology appraisal guidance [TA877]
Published: 23 March 2023

Recommendation

1.1. Finerenone is recommended as an option for treating stage 3 and 4 CKD (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:
  - ACE inhibitors or ARBs and
  - SGLT2 inhibitors and
- the person has an eGFR of 25 ml/min/1.73 m² or more.

Kerendia can be added to optimised therapy where the UACR is greater than or equal to 3 mg/mmol.[14,15]

Although recommendations for the use of an SGLT2 inhibitor in patients with CKD and type 2 diabetes were introduced after the initiation of FIDELIO-DKD in 2015, a limited number of patients received concomitant SGLT2 inhibitor treatment during the FIDELIO-DKD trial.[16]

References
1. KDIGO Diabetes Work Group. Kidney Int 2022;102:S1–127; 2. McGill JB et al. BMJ Open Diab Res Care 2022;10:e002806; 3. Tonneijck L, et al. J Am Soc Nephrol 2017;28:1023–39; 4. NHS Digital. National Diabetes Audit, Care processes and treatment targets 2019-20, interactive report England and Wales. December 2020. Available at: https://files.digital.nhs.uk/42/B253B1/National%20Diabetes%20Audit%202019-20%20Full%20Report%201.pdf (accessed July 2023); 5. NHS Scotland. Scottish Diabetes Survey 2019. Available at: https://www.diabetesinscotland.org.uk/wp-content/uploads/2020/10/Diabetes-Scottish-Diabetes-Survey-2019.pdf (accessed July 2023); 6. Winocour PH et al. Diabetes & Primary Care 2020;22: 99–109; 7. Christofides EA and Desai N. J Prim Care Community Health 2021;12:21501327211003683; 8. Willison A et al. BMJ Qual Improv Rep 2016;5:u209185.w3747; 9. NICE. Chronic kidney disease: assessment and management (NG203, August 2021). Available at: www.nice.org.uk/guidance/ng203 (accessed July 2023); 10. Hahr AJ, et al. Clin Diabetes Endocrinol 2015;1:2; 11. Healthline (2017). Chronic Kidney Disease. Available at: www.healthline.com/health/chronic-kidneydisease#treatment (accessed July 2023); 12. NICE. Type 2 diabetes in adults: Management (NG28, June 2022). Available at: https://www.nice.org.uk/guidance/ng28 (accessed July 2023); 13. Kerendia Summary of Product Characteristics; 14. Bakris GL et al. N Engl J Med 2020;383:2219–29; 15. NICE (2023). Finerenone for treating chronic kidney disease in people with type 2 diabetes [TA877] Technology Appraisal Guidance. Available at: www.nice.org.uk/guidance/ta877 (accessed July 2023); 16. Kolkhof P et al. Handb Exp Pharmacol 2017; 243: 271-305.

Abbreviations
ACE: angiotensin converting enzyme; **ACR:** albumin creatinine ratio; **ARB:** angiotensin receptor blocker; **CI:** confidence interval; **CKD:** chronic kidney disease; **CV:** cardiovascular; **DKD:** diabetic kidney disease; **eGFR:** estimated glomerular filtration rate; **HCP:** healthcare professional; **HR:** hazard ratio; **MRA:** mineralocorticoid receptor antagonist; **NICE:** National Institute for Health and Care Excellence; **QOF:** Quality and Outcomes Framework; **SGLT2:** sodium-glucose co-transporter-2; **UACR:** urine albumin creatinine ratio; **UAE:** urinary albumin excretion.

This promotional material has been developed and funded by Bayer plc.
Date of preparation: July 2023
Job code: PP-KER-GB-0502

▼ **Kerendia® (finerenone) 10 mg, 20mg film-coated tablets**
Prescribing Information: Great Britain
(Refer to full Summary of Product Characteristics (SmPC) before prescribing)

Presentation: 10 mg/ 20 mg finerenone tablet. **Indication:** Kerendia is indicated for the treatment of chronic kidney disease (stage 3 and 4 with albuminuria) associated with type 2 diabetes in adults. **Posology & method of administration:** ***Adults:*** Estimated glomerular filtration rate (eGFR) and serum potassium have to be measured to determine if treatment can be initiated. The starting dose for patients with eGFR ≥ 25 to < 60 mL/min/1.73 m² is 10 mg once daily if serum potassium ≤ 4.8 mmol/L; if serum potassium > 4.8 to 5.0 mmol/L, starting 10 mg once daily 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, treatment should not be initiated. Four weeks after initiation, serum potassium and eGFR have to be remeasured. If serum potassium ≤4.8 mmol/L and eGFR has not decreased by >30% compared to previous measurement, increase to 20mg once daily; if serum potassium >4.8 to 5.5 mmol/L maintain 10 mg once daily; if serum potassium >5.5 mmol/L withhold finerenone & consider re- starting at 10 mg once daily when serum potassium ≤ 5.0 mmol/L. eGFR and serum potassium have to be remeasured 4 weeks after a dose increase or re-start of treatment. Thereafter, serum potassium has to be remeasured periodically and as needed based on patient characteristics and serum potassium levels. Maintain current dose of 10 mg or 20 mg once daily if serum potassium > 4.8 to 5.5 mmol/L. Withhold 10 mg once daily treatment if serum potassium >5.5 mmol/L and consider re-starting at 10 mg once daily when serum potassium ≤ 5.0 mmol/L. Withhold 20 mg once daily treatment if serum potassium >5.5 mmol/L and re-start at 10 mg once daily when serumpotassium ≤ 5.0 mmol/L. Ongoing monitoring of renal functionshould be performed as needed according to standard practice.Tablets may be taken with a glass of water and with or without food.For patients who are unable to swallow whole tablets, Kerendiatablets may be crushed and mixed with water or soft foods, such asapple sauce, directly before oral use. Tablets should not be takenwith grapefruit or grapefruit juice. Missed doses should be taken assoon as the patient realises but only on the same day. The patientshould not take 2 doses to make up for a missed dose. ***Children &adolescents:*** The safety and efficacy of finerenone in children andadolescents aged under 18 years have not yet been established.No data are available. ***Elderly:*** No dose adjustment is necessaryin elderly patients. ***Renal impairment:*** Initiation of treatment: Inpatients with eGFR < 25 mL/min/1.73 m², finerenone treatmentshould not be initiated due to limited clinical data. Continuation oftreatment: In patients with eGFR ≥ 15 mL/min/1.73 m², finerenonetreatment can be continued with dose adjustment based on serumpotassium. eGFR should be measured 4 weeks after initiationto determine whether the starting dose can be increased to therecommended daily dose of 20 mg. Due to limited clinical data,finerenone treatment should be discontinued in patients who haveprogressed to end-stage renal disease (eGFR < 15 mL/min/1.73m²). ***Hepatic impairment:*** No initial dose adjustment is required for mild/ moderate hepatic impairment (moderate: consider additionalserum potassium monitoring and adapt monitoring accordingto patient characteristics); finerenone should not be initiated inpatients with severe hepatic impairment: **Contra-indications:** Hypersensitivity to the active substance or to any of the excipients;concomitant treatment with strong inhibitors of CYP3A4; Addison'sdisease. **Warnings & precautions:** Hyperkalaemia has beenobserved in patients treated with finerenone. Risk factors to develophyperkalaemia include low eGFR, higher serum potassium andprevious episodes of hyperkalaemia. In these patients more frequentmonitoring has to be considered. Finerenone treatment shouldnot be initiated in patients with serum potassium >5.0 mmol/L,with eGFR < 25 mL/min/1.73 m², or severe hepatic impairment.If serum potassium >5.5 mmol/L, finerenone treatment has to bewithheld. Serum potassium and eGFR have to be remeasured in all patients 4 weeks after initiation, re-start or increase in dose of finerenone. Due to limited clinical data, finerenone treatment should be discontinued in patients who have progressed to end stage renal disease (eGFR < 15 mL/min/1.73 m²). This medicinal product contains lactose and sodium. **Interactions:** Concomitant use of Kerendia with strong CYP3A4 inhibitors is contraindicated. Serum potassium should be monitored during concomitant use of finerenone with moderate or weak CYP3A4 inhibitors. Finerenone should not be used concomitantly with strong or moderate CYP3A4 inducers. Grapefruit or grapefruit juice should not be consumed during finerenone treatment. Kerendia should not be used concomitantly with potassium-sparing diuretics and other mineralocorticoid receptor antagonists. Kerendia 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 when patients have to take trimethoprim, or trimethoprim/sulfamethoxazole. The risk for hypotension increases with concomitant use of multiple other antihypertensive medicinal products. In these patients, blood pressure monitoring is recommended. **Pregnancy & lactation:** There are no data from the use of finerenone in pregnant women. Studies in animals have shown reproductive toxicity. Women of childbearing potential should use effective contraception during finerenone treatment. Kerendia 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. It is unknown whether finerenone/metabolites are excreted in human milk. A risk to the newborns/infants cannot be excluded. A decision must be made whether to discontinue breast-feeding or to discontinue/abstain from Kerendia therapy taking into account the benefit of breast-feeding for the child and the benefit of therapy for the woman. **Undesirable effects:** Very common: hyperkalaemia. Common: hyponatraemia, hyperuricaemia, hypotension, pruritus, glomerular filtration rate decreased. Prescribers should consult the SmPC in relation to other side effects. **Overdose:** The most likely manifestation of overdose is anticipated to be hyperkalaemia. If hyperkalaemia develops, standard treatment should be initiated. Finerenone is unlikely to be efficiently removed by haemodialysis given its fraction bound to plasma proteins of about 90%. **Legal Category:** POM. **Package Quantities & Basic NHS Costs:** 10mg 2 x 14 blister pack: £36.68. 20mg 2 x 14 blister pack: £36.68 OR 10mg 28 tablets: £36.68. 20mg 28 tablets: £36.68. **MA Number(s):** *Great Britain* - PLGB 00010/0751 (10 mg), PLGB 00010/0752 (20 mg). **Further information available from:** Bayer plc,400 South Oak Way, Reading RG2 6AD, United Kingdom. Telephone: 0118 206 3000. **Date of preparation:** July 2023. Kerendia® is a trademark of the Bayer Group

Reporting adverse events and quality complaints
▼ This medicine is subject to additional monitoring. This will allowquick identification of new safety information. Adverse events shouldbe reported. Reporting forms and information can be found at http://yellowcard.mhra.gov.uk/ or search MHRA Yellow Card in Google Play or Apple App Store. Adverse events should also be reported to Bayer plc. If you want to report an adverse event or quality complaint, reports can be directed to: Tel: 0118 2063500 or Email: pvuk@bayer.com Further information is available on the "contact" tab at www.bayer.co.uk