

NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Health Technology Appraisal

Finerenone for treating chronic kidney disease in people with type 2 diabetes

Final scope

Final remit/appraisal objective

To appraise the clinical and cost effectiveness of finerenone within its marketing authorisation for treating chronic kidney disease in people with type 2 diabetes.

Background

Chronic kidney disease (CKD) is a condition where the kidneys do not work as well as they should¹ and is linked with adverse outcomes including cardiovascular disease². It is common in people who have diabetes (where it is known as diabetic kidney disease) because people with diabetes have too much glucose in their blood, and this can damage the tiny filters in the kidneys¹. People with CKD do not usually have symptoms during the early stages of the disease but symptoms including weight loss and poor appetite, swollen ankles, feet or hands, shortness of breath, tiredness, feeling sick and itchy skin can develop as the disease progresses¹. The severity of CKD is determined by the estimated glomerular filtration rate (eGFR) of which there are 6 categories (normal, mild reduction, mild to moderate reduction, moderate to severe reduction, severe reduction and kidney failure) and albumin to creatinine ratio (ACR) with 3 categories (normal to mild increase, moderate increase and severe increase)³. An ACR of more than 3 mg/mmol is an indicator for albuminuria, when urine protein levels are increased, resulting from damage within the kidneys³.

Approximately 3 million people are currently diagnosed with type 2 diabetes in England⁴. Around 20% of people with diabetes will need treatment for kidney disease during their lifetime and at least 10,350 people in the UK have end-stage kidney failure caused by diabetes⁵. More than 1 in 3 people who need kidney dialysis, or a transplant have diabetes⁵. End-stage renal disease is associated with significant impact on quality of life for people with the condition and their families and diabetes with early kidney involvement may be associated with shorter life expectancy⁶.

Lifestyle changes are usually recommended for people with kidney disease, including stopping smoking, eating a healthy diet and regular exercise. There is no medicine specifically for CKD, but treatment can help control many of the associated problems such as high blood pressure, high cholesterol and anaemia¹. For people with CKD and diabetes, [NICE clinical guideline 182](#) 'chronic kidney disease in adults: assessment and management' recommends aiming to keep systolic blood pressure below 130 mmHg (target range 120–129 mmHg) and the diastolic blood pressure below 80 mmHg. To control blood pressure, CG182 recommends a drug that blocks or inhibits the renin-angiotensin system including angiotensin-converting enzyme (ACE) inhibitors, angiotensin-receptor blockers (ARBs) and direct renin inhibitors if there is an ACR of 3 mg/mmol or more. People with severely reduced kidney function may need dialysis or a kidney transplant¹.

The technology

Finerenone (brand name unknown, Bayer) is a selective non-steroidal mineralocorticoid receptor inhibitor which reduces the activity of aldosterone and cortisol. Finerenone blocks the over-activation of this receptor. It is administered orally.

Finerenone does not currently have a marketing authorisation in the UK for treating chronic kidney disease in people with type 2 diabetes. It has been studied in clinical trials in addition to standard of care compared with placebo with standard of care in adults with type 2 diabetes mellitus and chronic kidney disease with persistent high albuminuria.

Intervention(s)	Finerenone
Population(s)	Adults with type 2 diabetes and chronic kidney disease
Comparators	<ul style="list-style-type: none"> Established clinical management without finerenone, alone or in combination with angiotensin-converting enzyme inhibitors, angiotensin-receptor blockers or direct renin inhibitors SGLT2 inhibitors
Outcomes	<p>The outcome measures to be considered include:</p> <ul style="list-style-type: none"> cardiovascular outcomes disease progression mortality adverse effects of treatment health-related quality of life.
Economic analysis	<p>The reference case stipulates that the cost effectiveness of treatments should be expressed in terms of incremental cost per quality-adjusted life year.</p> <p>The reference case stipulates that the time horizon for estimating clinical and cost effectiveness should be sufficiently long to reflect any differences in costs or outcomes between the technologies being compared.</p> <p>Costs will be considered from an NHS and Personal Social Services perspective.</p>
Other considerations	<p>Guidance will only be issued in accordance with the marketing authorisation. Where the wording of the therapeutic indication does not include specific treatment combinations, guidance will be issued only in the context of the evidence that has underpinned the marketing authorisation granted by the regulator.</p>
Related NICE recommendations	Appraisals in development (including suspended appraisals):

<p>and NICE Pathways</p>	<p>Canagliflozin for treating chronic kidney disease in people with type 2 diabetes. NICE technology appraisals guidance [ID1653]. Suspended.</p> <p>Related Guidelines:</p> <p>Renal replacement therapy and conservative management (2018). NICE guideline NG107.</p> <p>Chronic kidney disease in adults: assessment and management (2014, updated 2015). NICE guideline CG182.</p> <p>Type 2 diabetes in adults: management (2015, updated 2019). NICE guideline NG28.</p> <p>Chronic kidney disease: managing anaemia (2015). NICE guideline NG8.</p> <p>Guidelines in development:</p> <p>Chronic kidney disease: assessment and management (update). Publication expected July 2021.</p> <p>Related Quality Standards:</p> <p>Chronic kidney disease in adults (2011). NICE quality standard 5.</p> <p>Diabetes in adults (2011, updated 2016). NICE quality standard 6</p> <p>Related NICE Pathways:</p> <p>Chronic kidney disease overview (2020) NICE pathway</p>
<p>Related National Policy</p>	<p>The NHS Long Term Plan, 2019. NHS Long Term Plan</p> <p>NHS England (2018/2019) NHS manual for prescribed specialist services (2018/2019) Chapter 15 'Adult specialist renal services' page 65.</p> <p>Department of Health and Social Care, NHS Outcomes Framework 2016-2017: Domain 2.</p>

1. NHS - [Chronic Kidney Disease](#); accessed April 2021.
2. Levey et al. (2005) [Kidney Disease: Improving Global Outcomes \(KDIGO\)](#); *Kidney International*, 67 2089-2100
3. Kidney Research UK - [Stages of Kidney Disease](#); accessed April 2021
4. Diabetes UK - [Diabetes Prevalence 2019](#); accessed April 2021
5. Diabetes UK (2019) [Us, diabetes and a lot of facts and stats](#). Accessed April 2021.
6. Wen et al. (2017) [Diabetes with early kidney involvement may shorten life expectancy by 16 years](#); *Kidney International*, 92 (2): 388-396