NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Health Technology Appraisal

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

Draft scope

Draft 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 should[1] and is linked with adverse outcomes including cardiovascular disease[2]. 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 kidneys[1]. 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 progresses[1]. 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 kidneys[3].

Approximately 3.3 million people are currently diagnosed with type 2 diabetes in England[4]. Around 20% of people with diabetes will need treatment for kidney disease during their lifetime[5] and at least 10,350 people in the UK have end-stage kidney failure caused by diabetes[5]. More than 1 in 3 people who need kidney dialysis, or a transplant have diabetes[5].

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 anaemia[1]. 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 transplant[1].

The technology

Finerenone (brand name unknown, Bayer) is a selective non-steroidal mineralocorticoid receptor inhibitor which reduces the activity of aldosterone and

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cortisol. Finerenone blocks the over-activation of this receptor which usually leads to increases in blood pressure. It is administered orally.

Finerenone does not currently have a marketing authorisation in the UK for treating diabetic 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 diabetic kidney disease with persistent high albuminuria.

Intervention(s)	Finerenone
Population(s)	Adults with type 2 diabetes and diabetic kidney disease
Comparators	• Established clinical management without finerenone • SGLT2 inhibitors
Outcomes	The outcome measures to be considered include: • cardiovascular outcomes • disease progression • HbA1c control • diabetic ketoacidosis risk • mortality • adverse effects of treatment • health-related quality of life.
Economic analysis	The reference case stipulates that the cost effectiveness of treatments should be expressed in terms of incremental cost per quality-adjusted life year. 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. Costs will be considered from an NHS and Personal Social Services perspective.
Other considerations	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.
Related NICE recommendations and NICE Pathways	**Appraisals in development (including suspended appraisals):**

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

Questions for consultation

Have all relevant comparators for finerenone been included in the scope?

The draft update to the clinical guideline Chronic kidney disease: assessment and management (expected publication date July 2021) currently recommends the following pharmacotherapy for proteinuria in adults with chronic kidney disease and diabetes (type 1 or 2):

- an ACE inhibitor or an ARB if ACR is 3 mg/mmol or more
- an SGLT2 inhibitor, in addition to an ACE inhibitor or an ARB, if they have type 2 diabetes, an ACR of 30 mg/mmol or more and meet the criteria in the marketing authorisation (including relevant eGFR thresholds); monitor for volume depletion and eGFR decline.

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Is it appropriate to include SGLT2 inhibitors as comparators? If so, should it be limited to any specific SGLT2 inhibitors?

Is it anticipated that finerenone would be given in addition to an ACE inhibitor or an ARB?

Which treatments are considered to be established clinical practice in the NHS for chronic kidney disease in people with type 2 diabetes? Which treatments would finerenone be likely to displace in this population?

Are the outcomes listed appropriate?

Are there any subgroups of people in whom finerenone is expected to be more clinically effective and cost effective or other groups that should be examined separately?

Where do you consider finerenone will fit into the existing NICE pathway, chronic kidney disease?

NICE is committed to promoting equality of opportunity, eliminating unlawful discrimination and fostering good relations between people with particular protected characteristics and others. Please let us know if you think that the proposed remit and scope may need changing in order to meet these aims. In particular, please tell us if the proposed remit and scope:

- could exclude from full consideration any people protected by the equality legislation who fall within the patient population for which finerenone will be licenced;
- could lead to recommendations that have a different impact on people protected by the equality legislation than on the wider population, e.g. by making it more difficult in practice for a specific group to access the technology;
- could have any adverse impact on people with a particular disability or disabilities.

Please tell us what evidence should be obtained to enable the committee to identify and consider such impacts.

Do you consider finerenone to be innovative in its potential to make a significant and substantial impact on health-related benefits and how it might improve the way that current need is met (is this a 'step-change' in the management of the condition)?

Do you consider that the use of finerenone can result in any potential significant and substantial health-related benefits that are unlikely to be included in the QALY calculation?

Please identify the nature of the data which you understand to be available to enable the appraisal committee to take account of these benefits.

To help NICE prioritise topics for additional adoption support, do you consider that there will be any barriers to adoption of this technology into practice? If yes, please describe briefly.

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NICE intends to appraise this technology through its Single Technology Appraisal (STA) Process. We welcome comments on the appropriateness of appraising this topic through this process. (Information on the Institute's Technology Appraisal processes is available at http://www.nice.org.uk/article/pmg19/chapter/1-Introduction).

References

1. NHS - Chronic Kidney Disease; accessed December 2020.

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 December 2020

4. Diabetes UK - Diabetes Prevalence 2019; accessed December 2020

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