NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Final draft guidance

Empagliflozin for treating chronic kidney disease

1 Recommendations

1.1 Empagliflozin is recommended as an option for treating chronic kidney disease (CKD) in adults, only if:

- it is an add-on to optimised standard care including the highest tolerated licensed dose of angiotensin-converting enzyme (ACE) inhibitors or angiotensin-receptor blockers (ARBs), unless these are contraindicated, and
- people have an estimated glomerular filtration rate of:
  - 20 ml/min/1.73 m^2 to less than 45 ml/min/1.73 m^2 or:
  - 45 ml/min/1.73 m^2 to 90 ml/min/1.73 m^2 and either:
    - ◊ a urine albumin-to-creatinine ratio of 22.6 mg/mmol or more, or
    - ◊ type 2 diabetes.

1.2 If people with the condition and their clinicians consider empagliflozin to be 1 of a range of suitable treatments (including dapagliflozin), after discussing the advantages and disadvantages of all the options, use the least expensive. Take account of administration costs, dosage, price per dose and commercial arrangements

1.3 This recommendation is not intended to affect treatment with empagliflozin that was started in the NHS before this guidance was published. People having treatment outside this recommendation may continue without change to the funding arrangements in place for them

before this guidance was published, until they and their NHS clinician consider it appropriate to stop.

Why these recommendations were made

Management of CKD aims to slow its progression. Standard care is lifestyle and dietary changes, and usually ACE inhibitors or ARBs. Empagliflozin is an oral treatment for CKD. The company proposes that empagliflozin would be used as an add-on to optimised standard care with ACE inhibitors or ARBs. Some people take dapagliflozin as an add-on to standard care. The company proposes that empagliflozin would be used in a similar but slightly broader population to dapagliflozin. This does not include everyone who it is licensed for.

Clinical trial evidence suggests that empagliflozin plus standard care is more effective than standard care alone. But the main clinical trial did not include people with CKD with an estimated glomerular filtration rate of less than 20 ml/min/1.73 m^2. And people with an estimated glomerular filtration rate between 45 to 90 ml/min/1.73 m^2 were only included if they also had a urine albumin-to-creatinine ratio of 22.6 g/mmol or more. There are no clinical trials directly comparing empagliflozin with dapagliflozin in people with CKD. Results of an indirect comparison suggest that empagliflozin has a similar effectiveness to dapagliflozin, and it likely has similar safety.

CKD can progress more quickly in some ethnic minority groups and, in people with type 2 diabetes, it progresses more quickly in people under 55. This was acknowledged but could not be considered in the decision making.

The cost-effectiveness estimates for empagliflozin compared with standard care are within the range NICE normally considers an acceptable use of NHS resources. Also, a cost comparison suggests that empagliflozin has similar costs to dapagliflozin. So, empagliflozin is recommended.

For all evidence see the committee papers. To see what NICE did for dapagliflozin, see the committee discussion section in NICE's technology appraisals guidance on dapagliflozin for treating chronic kidney disease.

2 Information about empagliflozin

Marketing authorisation indication

2.1 Empagliflozin (Jardiance, Boehringer Ingelheim) is indicated for the treatment of 'chronic kidney disease (CKD) in adults'.

Dosage in the marketing authorisation

2.2 The dosage schedule is available in the summary of product characteristics for empagliflozin.

Price

2.3 The list price for empagliflozin is £36.59 for 28 tablets (10 mg and 25 mg) (excluding VAT; BNF online, accessed October 2023).

2.4 Costs may vary in different settings because of negotiated procurement discounts.

3 Implementation

3.1 Section 7 of the National Institute for Health and Care Excellence (Constitution and Functions) and the Health and Social Care Information Centre (Functions) Regulations 2013 requires integrated care boards, NHS England and, with respect to their public health functions, local authorities to comply with the recommendations in this evaluation within 3 months of its date of publication.

3.2 The Welsh ministers have issued directions to the NHS in Wales on implementing NICE technology appraisal guidance. When a NICE technology appraisal guidance recommends the use of a drug or treatment, or other technology, the NHS in Wales must usually provide funding and resources for it within 2 months of the first publication of the final draft guidance.

3.3 When NICE recommends a treatment 'as an option', the NHS must make sure it is available within the period set out in the paragraphs above. This

means that, if a patient has CKD and the doctor responsible for their care thinks that empagliflozin is the right treatment, it should be available for use, in line with NICE's recommendations.

4 Evaluation committee members and NICE project team

Evaluation committee members

The 4 technology appraisal committees are standing advisory committees of NICE. This topic was considered by the chair of committee D.

Committee members are asked to declare any interests in the empagliflozin being evaluated. If it is considered there is a conflict of interest, the member is excluded from participating further in that evaluation.

The minutes of each evaluation committee meeting, which include the names of the members who attended and their declarations of interests, are posted on the NICE website.

Chair

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Chair, technology appraisal committee D

NICE project team

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