

NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Final draft guidance

Dapagliflozin for treating chronic kidney disease

1 Recommendations

1.1 Dapagliflozin can be used as an option to treat chronic kidney disease (CKD) in adults, if:

- it is an add-on to optimised standard care including the highest tolerated licensed dose of angiotensin-converting enzyme (ACE) inhibitors or angiotensin-2 receptor antagonists, unless these are contraindicated, and
- people have an estimated glomerular filtration rate (eGFR) of:
 - 20 ml/min/1.73 m² to less than 45 ml/min/1.73 m² or
 - 45 ml/min/1.73 m² to 90 ml/min/1.73 m², 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 healthcare professional consider dapagliflozin to be 1 of a range of suitable treatments (including empagliflozin), after discussing the advantages and disadvantages of all the options, the least expensive should be used. Administration costs, dosages, price per dose and commercial arrangements should all be taken into account.

1.3 This recommendation is not intended to affect treatment with dapagliflozin 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 healthcare professional consider it appropriate to stop.

What this means in practice

If dapagliflozin is considered the most suitable treatment option, it must be funded in the NHS in England to treat CKD in adults if:

- it is an add-on to optimised standard care including the highest tolerated licensed dose of ACE inhibitors or angiotensin-2 receptor antagonists, unless these are contraindicated, and
- people have an estimated eGFR of:
 - 20 ml/min/1.73 m² to less than 45 ml/min/1.73 m² or
 - 45 ml/min/1.73 m² to 90 ml/min/1.73 m², and either:
 - ◇ a urine albumin-to-creatinine ratio of 22.6 mg/mmol or more, or
 - ◇ type 2 diabetes.

Dapagliflozin must be funded in England within 30 days of final publication of this guidance.

There is enough evidence to show that dapagliflozin provides benefits and value for money, so it can be used routinely across the NHS in this population.

Why the committee made these recommendations

This evaluation is a review of [NICE's technology appraisal guidance on dapagliflozin for treating CKD](#). It also reviews new data submitted by the company as part of this evaluation.

Standard care for CKD includes lifestyle and dietary changes, and usually an ACE inhibitor or angiotensin-2 receptor antagonist. Some people take dapagliflozin or empagliflozin as an add-on to optimised standard care with an ACE inhibitor or angiotensin-2 receptor antagonist. The company has proposed that dapagliflozin should be available for the same population as empagliflozin. Empagliflozin is used

in a similar but broader population to dapagliflozin, but this still does not include everyone who dapagliflozin is licensed for.

In the original evaluation, clinical trial evidence suggested that dapagliflozin with standard care is more effective than standard care alone. Dapagliflozin has not been directly compared with empagliflozin in a clinical trial, but an indirect treatment comparison considered in [NICE's technology appraisal guidance on empagliflozin for treating CKD](#) suggested that they have similar effectiveness and safety. In this evaluation, the clinical evidence presented by the company does not suggest that dapagliflozin is less effective than empagliflozin in people with CKD. Also, both treatments work in a similar way so are likely to have similar clinical effectiveness and safety for the population considered for this evaluation.

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

A cost comparison suggests that the costs for dapagliflozin are similar to those for empagliflozin. So, dapagliflozin can be used in the same population as empagliflozin.

For all evidence, see the [committee papers](#). For more information on NICE's evaluation of empagliflozin, see [NICE's technology appraisal guidance on empagliflozin for treating CKD](#).

2 Information about dapagliflozin

Marketing authorisation indication

- 2.1 Dapagliflozin (Forxiga, AstraZeneca) is 'indicated in adults for the treatment of chronic kidney disease.'

Dosage in the marketing authorisation

- 2.2 The dosage schedule is available in the [summary of product characteristics for dapagliflozin](#).

Price

- 2.3 The list price of dapagliflozin is £36.59 for 28 tablets (5 mg and 10 mg) (excluding VAT; BNF online, accessed April 2025)
- 2.4 Costs may vary in different settings because of negotiated procurement discounts.

Carbon Reduction Plan

- 2.5 Information on the Carbon Reduction Plan for UK carbon emissions for AstraZeneca will be included here when guidance is published.

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 90 days of its date of publication. Because dapagliflozin has been recommended through the [cost-comparison process](#), NHS England and integrated care boards have agreed to provide funding to implement this guidance 30 days after 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 60 days 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 chronic kidney disease and the healthcare professional responsible for their care thinks that dapagliflozin 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

This topic was considered as a cost comparison evaluation by the lead team of the [highly specialised technologies evaluation committee](#), which includes the chair and vice chair.

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

Chair

Paul Arundel

Chair, highly specialised technologies evaluation committee

Iolo Doull

Vice chair, highly specialised technologies evaluation committee

NICE project team

Each evaluation is assigned to a team consisting of 1 or more health technology analysts (who act as technical leads for the evaluation), a technical adviser, a project manager and an associate director.

Anita Sangha

Technical lead

Caron Jones

Technical adviser

Kate Moore

Project manager

Janet Robertson

Associate director

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