



Dapagliflozin for treating chronic kidney disease

Technology appraisal guidance Published: 2 July 2025

www.nice.org.uk/guidance/ta1075

Your responsibility

The recommendations in this guidance represent the view of NICE, arrived at after careful consideration of the evidence available. When exercising their judgement, health professionals are expected to take this guidance fully into account, alongside the individual needs, preferences and values of their patients. The application of the recommendations in this guidance is at the discretion of health professionals and their individual patients and do not override the responsibility of healthcare professionals to make decisions appropriate to the circumstances of the individual patient, in consultation with the patient and/or their carer or guardian.

All problems (adverse events) related to a medicine or medical device used for treatment or in a procedure should be reported to the Medicines and Healthcare products Regulatory Agency using the <u>Yellow Card Scheme</u>.

Commissioners and/or providers have a responsibility to provide the funding required to enable the guidance to be applied when individual health professionals and their patients wish to use it, in accordance with the NHS Constitution. They should do so in light of their duties to have due regard to the need to eliminate unlawful discrimination, to advance equality of opportunity and to reduce health inequalities.

Commissioners and providers have a responsibility to promote an environmentally sustainable health and care system and should <u>assess and reduce the environmental</u> impact of implementing NICE recommendations wherever possible.

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This guidance replaces TA775.

1 Recommendations

- 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:

 - \diamondsuit 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.
- 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

Dapagliflozin must be funded in the NHS in England for the condition and population in the recommendations, if it is considered the most suitable treatment option. 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.

NICE has produced tools and resources to support the implementation of this guidance.

Why these recommendations were made

This evaluation is a review of NICE's technology appraisal guidance on dapagliflozin for treating CKD (TA775). 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 <u>committee papers</u>. 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

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

Dosage in the marketing authorisation

The dosage schedule is available in the <u>summary of product characteristics for dapagliflozin</u>.

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 For information, the Carbon Reduction Plan for UK carbon emissions is published on the <u>company's webpage on sustainability</u>.

3 Implementation

- 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.
- 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 <u>highly</u> 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

lolo 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

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