NICE National Institute for Health and Care Excellence

Putting NICE guidance into practice

Resource impact report:
Empagliflozin for treating chronic kidney disease (TA942) and dapagliflozin for treating chronic kidney disease (TA775)

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Summary

NICE has recommended empagliflozin for treating chronic kidney disease (CKD) in adults. It is recommended according to specific criteria (see section 1).

We estimate that:

- 217,000 people with estimated glomerular filtration rate (eGFR) of 20 – 90 ml/min/1.73 m^2 and type 2 diabetes (T2D) are eligible for treatment with empagliflozin
- 241,000 people who do not have T2D and who have an eGFR of 20-45 or an eGFR of 45-90 ml/min/1.73 m^2 and also have a urine albumin-to-creatinine ratio of 22.6 mg/mmol or more are eligible for treatment with empagliflozin
- Around 26,000 people who have CKD and T2D will receive empagliflozin from 2025/26 onwards once market share has reached 12%
- Around 24,000 people who have CKD without T2D will receive treatment from 2027/28 onwards once market share has reached 10%
- Empagliflozin is a further sodium-glucose cotransporter-2 (SGLT2) inhibitor treatment option for most of the population covered by the recommendation. The additional drug cost impact is £15m, split £4m for people who have T2 diabetes and £11m for people without T2D (see table 1 below for further analysis)
- The additional drug cost per 100,000 population is around £30,000 (see table 2 of this report).

This report is supported by a resource impact template which may be used to calculate the resource impact of implementing the guidance by amending the variables. This technology is commissioned by integrated care systems/clinical commissioning groups. Providers are primary care services, NHS hospital trusts and tertiary care services.

Table 1 Estimated annual activity and the net resource impact of implementing the guidance

	2023/24 £/(£)	2024/25 £/(£)	2025/26 £/(£)	2026/27 £/(£)	2027/28 (£/(£)
People who have CKD and T2D					
Market share of empagliflozin plus standard care (%)	3	6	12	12	12
Market share of dapagliflozin plus standard care (%)	18	15	12	12	12
People receiving empagliflozin	6,000	13,000	26,000	26,000	26,000
People receiving dapagliflozin	38,000	32,000	26,000	26,000	26,000
Net impact on drug cost for empagliflozin £m	4	8	16	17	18
Net impact on drug cost for dapagliflozin £m	(4)	(8)	(12)	(12)	(12)
Total resource impact for people who have CKD and T2D £m	**0**	**0**	**4**	**5**	**6**
People who have CKD without T2D					
Market share of empagliflozin plus standard care (%)	2	4	8	9	10
Market share of dapaglflozin plus standard care (%)	4	4	4	4	4
People receiving empagliflozin	5,000	9,000	19,000	22,000	24,000
People receiving dapagliflozin	9,000	9,000	9,000	9,000	9,000
Net impact on drug cost for empagliflozin £m	3	6	12	13	14
Net impact on drug cost for dapagliflozin £m	(3)	(3)	(3)	(3)	(3)
Total resource impact for people who have CKD without T2D £m	**0**	**3**	**9**	**10**	**11**
Total drug costs £m	**0**	**3**	**13**	**15**	**17**

Notes: 1. The population eligible to receive dapagliflozin is narrower than empagliflozin (TA775: eGFR of 25 mL/min/1.73m2 to 75 mL/min/1.73m2 at the start of treatment and have T2D or have a uACR of 22.6 mg/mmol or more). This is expected increase uptake for empagliflozin in people who do not have T2D.

2. The costs reflect the net impact compared with current practice.

1 Empagliflozin

1.1 NICE has recommended empagliflozin for treating chronic kidney disease. It is recommended 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.

1.4 Management of CKD aims to slow disease progression. Standard care is lifestyle and dietary changes, and usually ACE inhibitors or ARBs. Empagliflozin is a sodium-glucose cotransporter-2 (SGLT2) inhibitor and 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 broader population to dapagliflozin (eGFR 20-90 ml/min/1.73 m^2 compared with eGFR 25-75 ml/min/1.73 m^2).

1.5 Clinical experts highlighted that the benefits of SGLT2 inhibitors are distinct from a blood glucose reduction alone, and that reducing progression to end-stage renal disease will increase quality of life. The benefits of these treatments including potential resources released were analysed in TA775 and included in the resource impact template for this guidance. Data from an indirect comparison showed no clinically meaningful differences were found between empagliflozin and dapagliflozin across any of the trial outcomes.

1.6 The current treatment and future uptake figure assumptions are based on an average of the company and NHSE estimates.

1.7 The estimated annual cost of implementing this guidance for the population of England based on the uptake in the resource impact assumptions is shown in table 1 above. The cost from year 2027/28 once steady state is reached is equivalent to £30,000 per 100,000 population (see table 2).

Table 2 Resource impact of implementing the guidance using NICE assumptions per 100,000 population

	2023/24	2024/25	2025/26	2026/27	2027/28
Market share of SGLT2 inhibitors - T2D (%)	21	21	24	24	24
Market share of SGLT2 inhibitors – no T2D (%)	6	8	12	13	14
Resource impact each year for people who have CKD and T2D £000s	0	0	7	7	7
Resource impact each year for people who do not have T2D have CKD and uACR≥22.6mg/mmol £000s	0	5	15	20	23
Net resource impact £000s	**0**	**5**	**22**	**27**	**30**

1.8 This report is supported by a resource impact template which may be used to calculate the resource impact of implementing the guidance by amending the variables.

Savings and benefits

1.9 Patient experts feel that SGLT2 inhibitors offer a step change for treating CKD; because of their ability to delay disease progression they offer real hope. Disease progression can lead to an increase in healthcare costs for events such as eGFR decline of greater than or equal to 50%: chronic dialysis, acute kidney injury; hospitalisation for heart failure and kidney transplant.

1.10 The template shows the potential reduction in adverse events as a result of people receiving empagliflozin or dapagliflozin.

2 Implications for commissioners and providers

2.1 This technology is commissioned by integrated care systems/ clinical commissioning groups. Providers are primary care services, NHS hospital trusts and tertiary care services.

2.2 Empagliflozin falls within the programme budgeting category 17B Problems of the Genito Urinary System - Renal Problems.

2.3 There is likely to be a progressive increase in cost savings associated with the provision of renal dialysis services and the delay of clinical events over time after the recommendations are implemented.

3 How we estimated the resource impact

The population

3.1 The prevalence of chronic kidney disease (CKD) in the adult population is 4.19% [Quality and Outcomes Framework 2022-23 NHS Digital] which is around 1.9 million adults in England. Around 458,000 people are estimated to meet the broader eligibility criteria outlined in recommendation 1.1 (see table 3 below)

Table 3 Number of people eligible for treatment in England

Population	Proportion of previous row (%)	Number of people
Adult population 2027/28 after adjusting for population growth[1]		46,263,200
(A) Prevalence of chronic kidney disease (people diagnosed at stage G3a-5)[2]	4.19	1,900,000
(B) People who have T2D [3]	6.5	3,010,000
(A) People who do not have T2D		
Population who have CKD stages G3a to 5 and do not have T2D (A) – (C)	56.98	1,104,000
People who have CKD without T2D, with an eGFR 20–45, or eGFR 45–90 ml/min/1.73m2 and uACR ≥22.6 mg/mmol [4]	41	**453,000**
People receiving optimised standard care including highest tolerated dose of angiotensin-converting enzyme (ACE) inhibitors or angiotensin-receptor blockers (ARBs) unless contraindicated[5]	53.25	**241,000**
(B) People who have T2D		

(C) People who also have CKD[6]	27.7	834,000
-and who have eGFR of 20-90 ml/min/1.73 m2 to 75 ml/min/1.73 m2[6]	53.4	445,000
People receiving optimised standard care including ACE inhibitors or ARBs unless contraindicated[6]	48.8	**217,000**
Total number of people eligible for treatment with empagliflozin		**458,000**
Market share of empagliflozin in people with CKD and T2D from year 2026/27[7]	12	26,000
Market share of empagliflozin in people with CKD and no T2D from year 2027/28[7]	10	24,000

1.Office for National Statistics, see population data below. Population uplifted from baseline 2020 population.
2.Quality and Outcomes Framework, 2021-22 - NDRS (digital.nhs.uk)
3.Resource impact template TA984:Tools and resources | Tirzepatide for treating type 2 diabetes | Guidance | NICE
4. Based on distribution in Cook et al Table 3: e065927.full.pdf (bmj.com)
5. Crude estimate using figures from study as a proxy for non T2D population. Prescription of renin–angiotensin system blockers and risk of acute kidney injury: a population-based cohort study | BMJ Open 2016
6.Cook et al 2023 e065927.full.pdf (bmj.com) (Table 1)
7.Future market shares are NICE estimates based on an average of the company and NHSE estimates.

3.2 The approach to calculating the eligible population above is different to TA775 and considers the wider population covered in this guidance. The population covered by the guidance includes people who are at an earlier stage of disease (G2) eGFR 60-89 ml/min/1.73m2, however earlier CKD stages such as G2 are not well diagnosed or reported, with the most people diagnosed between stages G3a and 5. The population estimates above adjust for this using published eGFR distribution data (source provided in Table 3 above) and this is reflected in the total population eligible in this guidance. Localities can amend estimates in the template to assess the impact locally.

Assumptions

3.3 The resource impact template assumes that:

- population estimates for people continuing treatment each year are factored into the market share. As the market share increases this will include people from previous years and also those who start treatment in year.
- the market share of empagliflozin and dapagliflozin is assumed to be same for people who have CKD and T2D (12% for each option).
- for people who do not have T2D, the market share for empagliflozin is estimated to reach 10% by 2027/28 with market share for dapagliflozin remaining constant each year at 4%.
- The market share for empagliflozin in people who do not have T2D is assumed to come from people currently receiving standard care alone. The higher market share considers the wider population covered by this technology (eGFR of 20-90 ml/min/1.73 $m^{2)}$.
- No change is expected to the use of canagliflozin as result of this guidance, therefore it is not included in the template.
- 100% of people receive standard care, this does not change with the addition of empagliflozin, dapagliflozin or canagliflozin.

Other factors

3.4 Another SGLT2 inhibitor (canagliflozin) is recognized as a comparator for people who have diabetic kidney disease. Expert opinion indicates it is not yet widely used in diabetic kidney disease.

3.5 The resource impact is influenced by uptake of the comparator option and price differences which may be subject to commercial negotiations.

3.6 It is assumed a uACR test is not needed to determine treatment. The requirement for uACR testing is determined by criteria for when investigations should be done, this is set out in NICE clinical

guideline NG203. The cost of uACR testing is not anticipated to be significant, however the template allows the costs of tests to be assessed locally.

3.7 Commissioners of SGLT2 treatments can amend unit costs in the resource impact template for any locally negotiated prices.

About this resource impact report

This resource impact report accompanies the NICE guidance on Dapagliflozin for treating chronic kidney disease [TA942] and should be read with it.