**National Institute for Health and Care Excellence**

**Health Technology Evaluation**

**Dapagliflozin for treating chronic kidney disease (review of TA775) [ID6411]**

**Response to stakeholder organisation comments on the draft remit and draft scope**

**Please note:** Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees.

**Comment 1: the draft remit and proposed process**

| Stakeholder | Comments [sic] | Action |
|---|---|---|
| AstraZeneca | **Summary of AstraZeneca's position of the review**<br><br>AstraZeneca would like to thank NICE for considering to review the recommendations made in TA775 for dapagliflozin in chronic kidney disease (CKD). Overall, AstraZeneca agrees with the proposed scope for the review.<br><br>AstraZeneca acknowledges the uncertainties that were present in TA775, and appreciates the opportunity to address them through recent real world evidence (RWE) and additional analyses from dapagliflozin trials in this review. | Thank you for your comment. No action required. NICE has considered the appropriateness of a cost comparison to compare dapagliflozin for treating chronic kidney disease with empagliflozin for treating chronic kidney disease (TA942). It has |

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| | Since publication of TA775, empagliflozin has now been recommended in TA942 in CKD , and is the main comparator for dapagliflozin in this targeted review. Evidence from indirect treatment comparisons presented in TA942, as well as previous empagliflozin appraisals, and from published meta-analysis, suggests similar efficacy and cost to dapagliflozin, which therefore makes this review suitable for cost comparison methodology.<br><br>Therefore, AstraZeneca proposes to consider the following populations within this targeted review for a cost comparison assessment:<br><br>1. Adults with CKD, without type 2 diabetes (T2D), and with:<br><br>a. estimated glomerular filtration rate (eGFR) between 20 and 45 ml/min/1.73m$^2$ and a urine albumin-to-creatinine ratio (uACR) < 22.6 mg/mmol (200 mg/g); or<br><br>b. eGFR > 75 – 90 ml/min/1.73m$^2$ and a uACR ≥22.6 mg/mmol (≥200 mg/g)<br><br>2. Adults with CKD, with T2D, and with:<br><br>a. eGFR between 20 and 25 ml/min/1.73m$^2$; or<br><br>b. eGFR >75 – 90 ml/min/1.73m$^2$ | decided that a cost comparison process is most appropriate. |

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| | 3. If NICE deems it appropriate to do so, AstraZeneca also believe adults with CKD with or without diabetes and with an eGFR of 15 – 20 ml/min/1.73m$^2$ could be considered<br><br>These subgroups fall within the full marketing authorisation for dapagliflozin in adults with CKD, which is also supported by RWE and additional analyses from dapagliflozin trials,[1] and are also subgroups of the population for which empagliflozin, the main comparator in this appraisal, is recommended in TA942, with the exception of patients with an eGFR 15 – 20 ml/min/1.73m$^2$.[2] | |
| Dr Paul Stevens | Kidney Disease Improving Global Outcomes (KDIGO) have recently updated their chronic kidney disease guidelines (KDIGO 2024 Clinical Practice Guideline for the Evaluation and Management of Chronic Kidney Disease published in Kidney International: Kidney International (2024) 105 (Suppl 4S), S117–S314). The relevant statements are:<br><br>Recommendation 3.7.1: We recommend treating patients with type 2 diabetes (T2D), CKD, and an eGFR ≥20 ml/min per 1.73 m2 with an SGLT2i (1A).<br><br>Recommendation 3.7.2: We recommend treating adults with CKD with an SGLT2i for the following (1A):<br>• eGFR ≥20 ml/min per 1.73 m2 with urine ACR ≥200 mg/g (≥20 mg/mmol), or<br>• heart failure, irrespective of level of albuminuria. | Thank you for your comment. No action required. |

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| | Recommendation 3.7.3: We suggest treating adults with eGFR 20 to 45 ml/min per 1.73 m2 with urine ACR <200 mg/g (<20 mg/mmol) with an SGLT2i (2B).<br><br>These recommendations were largely driven by the Lancet metanalysis (SMART-C, Lancet. 2022;400:1788–1801) and the recommendations were not specific to a single SGLT2i and therefore applied equally to Empagliflozin and Dapaglifozin. | |
| Kidney Care UK | We support the proposal to review TA775 Dapagliflozin for chronic kidney disease (CKD) via the cost comparison process. It is vital that people with CKD who may benefit from SGLT2 inhibitor drugs have prompt access to treatment and we are therefore supportive of pursuing opportunities to remove complexity from the prescribing process. | Thank you for your comment. No action required. |
| Kidney Research UK | To our knowledge, there is no direct evidence to suggest that dapagliflozin has equal efficacy to empagliflozin in the population suggested (eGFR 20 - 90 ml/min) for this appraisal. However, both drugs belong to the same class of drugs and have similar mechanism of action. A recent target trial emulation study has demonstrated that the use of SGLT2i (including both drugs) in those with eGFR <20 ml/min is associated with lower risk of dialysis, hospitalisation for heart failure and AKI (Yen F, et al. Annals of Internal Medicine, 2024). It is likely that dapagliflozin is equally effective/ beneficial and safe as empagliflozin in the suggested population. | Thank you for your comment. No action required. |

| Stakeholder | Comments [sic] | Action |
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| | In consideration of the above, the UK Kidney Association SGLT2i guideline is less restrictive – recommend using SGLT2i in those with uACR>25 mg/mmol irrespective of diabetes (except polycystic kidney disease) and eGFR. | Thank you for your comment. No action required. |
| | We agree if dapagliflozin had the same NICE recommendation as empagliflozin, it would avoid unnecessary complexity for prescribers, especially in primary care. | Thank you for your comment. No action required. |
| | The place of dapagliflozin in the existing treatment pathway is as an add-on treatment to the maximally tolerated dose of an ACEi/ ARB as described in TA942. | Thank you for your comment. No action required. |
| | For the reasons stated above, we think it is appropriate to evaluate this technology through the NICE cost comparison evaluation process. | Thank you for your comment. No action required. |
| | There are no equality issues involved to our knowledge and belief. | Thank you for your comment. No action required. |
| UK Kidney Association | I think it would be clearer for prescribers in both primary and secondary care to have the same criteria for both dapagliflozin and empagliflozin use in CKD. The licensed indication for both drugs is use in CKD, and for dapagliflozin the eGFR cut off for starting is lower than empagliflozin. So changing would not be going against the licensed indication for dapagliflozin. | Thank you for your comment. The topic will be scheduled as a cost comparison appraisal with TA942. |

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| | I haven't seen the evidence of using dapagliflozin in patients with no proteinuria but if available I would support this change | Thank you for your comment. No action required. |
| | The existing pathway would need tweaking to reflect the change but this would be simpler rather than making things more complicated | Thank you for your comment. No action required. |
| | I don't see that the expenditure would be more if the option was dapagliflozin or empagliflozin. | Thank you for your comment. No action required. |
| | I think this would simplify things for primary care where much of this prescribing should be happening | Thank you for your comment. No action required. |

**The following stakeholders indicated that they had no comments on the draft remit and/or the draft scope**

N/A