NICE National Institute for Health and Care Excellence

NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

NICE indicator validity assessment

Indicator IND262

The percentage of patients on the CKD register and currently treated with an ARB or an ACE inhibitor who are also currently treated with an SGLT2 inhibitor if they have either:

- no type 2 diabetes and a urine ACR of 22.6 mg/mmol or more, or
- type 2 diabetes and a urine ACR 3 mg/mmol or more.

Indicator type

General practice indicator for use outside the Quality and Outcomes Framework.

Importance

Considerations	Assessment
Chronic kidney disease (CKD) is a long-term condition characterised by abnormal function or structure (or both) and is an important public health problem associated with significant morbidity, premature mortality and high health care costs. Management of CKD aims to prevent or delay disease progression and the development of complications. SGLT2 inhibitors can be used as an add on to standard care with ACE inhibitors and angiotensin receptor blockers (ARBs) for people with CKD as there is evidence for benefits in terms of CKD progression, cardiovascular events and mortality. NHS England commissioned the Renal Services Transformation Programme to span the full range of renal services and provide implementation of recommendations from the Getting it Right First Time review of renal medicine in March 2021.	The indicator reflects a specific priority area identified by NHS England.
Prevalence of CKD stage 3a to 5 is 4.05% according to data from the Quality and Outcomes Framework (QOF). Data from NHS England's Indicators No Longer In QOF (INLIQ) collection 2022 to 2023 showed 44% achievement for indicator CKD004 (the percentage of patients on the CKD register whose notes have a record of a urine albumin:creatinine ratio (or protein:creatinine ratio) test in the preceding 12 months).	The indicator relates to an area where there is known variation in practice. The indicator addresses under-treatment.

Data from CPRD Aurum (on file, see section below on specification) suggests low prescribing of SGLT2 inhibitors in general practice for the indicator denominator population (<10% of denominator, March 2022 release).	
SGLT2 inhibitors can be used as an add on to standard care with ACE inhibitors and angiotensin receptor blockers (ARBs) for people with CKD as there is evidence for benefits in terms of CKD progression, cardiovascular events and mortality.	The indicator will lead to a meaningful improvement in patient outcomes.

Evidence base

Considerations	Assessment
Dapagliflozin for treating chronic kidney disease. NICE technology appraisal TA775 (2022), recommendation 1.1 Type 2 diabetes in adults: management. NICE guideline NG28 (2015, updated 2021), recommendations 1.8.17 to 1.8.19 1.8.17 For adults with type 2 diabetes and CKD who are taking an ARB or an ACE inhibitor (titrated to the highest licensed dose that they can tolerate), offer an SGLT2 inhibitor (in addition to the ARB or ACE inhibitor) if: • ACR is over 30 mg/mmol and • they meet the criteria in the marketing authorisation (including relevant estimated glomerular filtration rate [eGFR] thresholds). In November 2021, not all SGLT2 inhibitors were licensed for this indication. See NICE's information on prescribing medicines. [2021] 1.8.18 For adults with type 2 diabetes and CKD who are taking an ARB or an ACE inhibitor (titrated to the highest licensed dose that they can tolerate), consider an SGLT2 inhibitor (in addition to the ARB or ACE inhibitor) if: • ACR is between 3 and 30 mg/mmol and • they meet the criteria in the marketing authorisation (including relevant eGFR thresholds). In November 2021, not all SGLT2 inhibitors were licensed for this indication. See NICE's information on prescribing medicines. [2021] 1.8.19 For guidance on dapagliflozin for adults with CKD, see NICE's technology appraisal guidance on dapagliflozin for treating chronic kidney disease. [2022].	The indicator is derived from a high-quality evidence base. The indicator aligns with the evidence base.

Specification

Considerations	Assessment
Numerator: The number of patients in the denominator who are currently treated with an SGLT2 inhibitor Denominator: The number of patients on the CKD register currently treated with an ARB or ACE inhibitor and either: • no type 2 diabetes and last urine ACR 22.6 mg/mmol or more, or • type 2 diabetes and last urine ACR 3 mg/mmol or more. Exclusions: Patients with eGFR <25 ml/min/1.73m^2. Definitions: Current treatment with an ARB or an ACE inhibitor is defined as a prescription in the last 6 months of the reporting period. This should be before the last prescription of an SGLT2 inhibitor. Personalised care adjustments or exception reporting should be considered to account for situations where the patient declines, does not attend or if treatment with an SGLT2 inhibitor is not appropriate.	The indicator has defined components necessary to construct the indicator, including numerator, denominator and exclusions.
CPRD Aurum data for March 2022 (March 2022 release; on file, approved study protocol 23_002668) shows that 0.2% of people in England are on the CKD register with ARB or an ACE inhibitor prescribed in the last 6 months and either no type 2 diabetes and the last urine albumin to creatinine ratio 22.6 mg/mmol or more or type 2 diabetes and the last urine albumin to creatinine ratio 3 mg/mmol or more: under 20 patients for an average practice with 10,000 patients. There is no minimum number of patients required for general practice indicators intended for use outside the QOF. However, consideration should be given to whether the majority of results would require suppression because of small numbers. Note on data from CPRD Aurum: This study is based in part on data from the Clinical Practice Research Datalink obtained under licence from the UK Medicines and Healthcare products Regulatory Agency. The data is provided by patients and collected by the NHS as part of their care and support. The interpretation and conclusions contained in this study are those of the author/s alone.	The indicator does outline minimum numbers of patients needed to be confident in the assessment of variation. Available data does not suggest that the number of eligible patients per average practice with 10,000 patients would be above this minimum number. The indicator would be suitable for use outside of the QOF.

Feasibility

Considerations	Assessment
Data can be extracted from the GPES system.	The indicator is repeatable.
NHS England's opinion is that this indicator is feasible. Clinical code clusters exist for:	The indicator construction is complex but is measuring

• CKD and exception codes • type 2 diabetes • ACE inhibitor and ARB prescription and contraindications New logic would be needed to introduce ACR test and value. Urine ACR is a laboratory test that may be received directly by GP systems. New clusters or reference sets needed for: • SGLT2 inhibitors and contraindications • urine ACR • PCAs Other codes to consider would be coding for diabetic kidney disease, MAL and PRT clusters. Stakeholder comments at consultation suggest SNOMED code clusters for MAL may need to be updated to include CKD A2 codes as are included in the PRT clusters.	what it is designed to measure. The indicator uses some existing clinical code clusters but others may need to be developed.

Acceptability

Considerations	Assessment
Stakeholder feedback at consultation and discussion at the indicator advisory committee suggests general practitioners are familiar with prescribing of SGLT2 inhibitors for heart failure and type 2 diabetes and are becoming more familiar with prescribing for CKD. Comments suggest that a multidisciplinary team approach with input from specialists in secondary care may be needed. Some patients eligible for treatment with an SGLT2 inhibitor may not be included in the denominator due to the complexity of the indicator, including issues with coding, frequency of urine ACR measurement and their last ACR result (see risk considerations in section below).	The indicator assesses performance that is attributable to or within the control of the audience
Data can be extracted from the GPES system.	The results of the indicator can be used to improve practice

Risk

Considerations	Assessment
The indicator advisory committee heard about poor coding of CKD and type 2 diabetes, including missing coding as well as inaccurate coding. Feedback from stakeholders during consultation and members of the indicator advisory committee noted that an indicator in this area would promote correct coding.	The indicator has an acceptable risk of unintended consequences.

The last urine ACR result is required for the denominator. Stakeholder comments at consultation and during testing suggest that this approach risks inaccurate inclusion and exclusion in the denominator, for example, people with transient proteinuria or people effectively treated with ARB and ACE inhibitors or SGLT2 inhibitors. PCAs could be used to exclude people with transient proteinuria from the denominator. The indicator advisory committee suggested that this indicator should be accompanied by introduction of indicator IND144 on annual urine ACR tests for patients with CKD. Regular urine ACR testing would ensure identification of patients with increasing proteinuria over time. QOF data for CKD004 in 2014/15 shows an intervention rate of 77% (the percentage of patients on the CKD register whose notes have a record of a urine ACR [or protein:creatinine ratio] test in the preceding 12 months). Urine ACR is a laboratory test that may be received directly by GP systems and may not be converted into an extractable format for the purpose of this indicator. This may impact on denominator numbers. Current estimates of the denominator using data from CPRD Aurum suggests low numbers for this indicator and thus risks suppression of reports from individual practices. These denominators may increase if ACR testing or coding increases. Dapagliflozin is the only SGLT2 inhibitor currently recommended by NICE as an option to treat CKD. The eGFR in the licensing criteria is eGFR between 25 and 75 ml/min/1.73m^2. The indicator excludes people with CKD who have an eGFR between 60 and 75 ml/min/1.73m^2 as these would not be included on the CKD register. The CKD register includes patients with CKD stage 3a to stage 5 as this is the cohort with moderate to severe CKD and are at moderate to very high risk of progression and risk of developing comorbidity in comparison to people with stage 2 CKD (eGFR 60 to 89 ml/min/1.73m^2). Recommendations in NG28 and TA775 are for patients to be prescribed maximally tolerated doses of ARBs and ACE inhibitors before treatment with SGLT2 inhibitors. Maximally tolerated doses are not coded and cannot be extracted from GPES. The indicator assumes patients prescribed ARBs and ACE inhibitors will be titrated to the highest tolerated doses as per advice from the indicator advisory committee and expert opinion. There are some contraindications to SGLT2 inhibitor prescribing and a risk of diabetic ketoacidosis for patients with type 2 diabetes. Modifiable risk factors should be addressed before starting an SGLT2 inhibitor. Personalised care adjustments could be used if treatment is not suitable.	

NICE indicator advisory committee recommendation

The NICE indicator advisory committee approved this indicator for publication on the menu. They advised that implementation of this indicator should be in concurrence with implementation of NICE menu indicator IND144 on annual ACR measurement.