



## Briefing Paper for Surrey Heartlands Integrated Care System (ICS) Area Prescribing Committee (APC)

### NICE Technology Appraisals: Local implementation

<b>NICE TA Guidance</b>	Dapagliflozin for treating chronic kidney disease Technology appraisal guidance [TA775]		
<b>Available at</b>	<a href="https://www.nice.org.uk/guidance/ta775/resources/dapagliflozin-for-treating-chronic-kidney-disease-pdf-82611498049477">https://www.nice.org.uk/guidance/ta775/resources/dapagliflozin-for-treating-chronic-kidney-disease-pdf-82611498049477</a>		
<b>Date of issue</b>	9 March 2022	<b>Implementation deadline</b>	9 June 2022

#### Medicine details

<b>Name, brand name</b>	Dapagliflozin (Forxiga®)
<b>Manufacturer</b>	AstraZeneca UK Limited
<b>Licensed indication</b>	Forxiga® is indicated in adults for the treatment of chronic kidney disease.  The recommended dose is 10 mg dapagliflozin once daily.  (SPC Accessed 26/4/22)
<b>Formulation</b>	Film coated tablets  (SPC Accessed 26/4/22)
<b>Usual dosage</b>	The recommended dose is 10 mg dapagliflozin once daily. (SPC Accessed 26/4/22)
<b>NICE recommended dosage/schedule</b>	This is the same recommended dose and schedule as the NICE TA however the NICE TA also states: 'The recommended population should be limited to the eGFR and uACR levels included in DAPA-CKD (see <a href="#">section 3.7</a> ) to match the available evidence.'

#### Disease and potential patient group

<b>Brief description of disease</b>	<b>Chronic kidney disease (CKD) is a long-term condition where the kidneys don't work as well as they should.</b>  It's a common condition often associated with getting older. It can affect anyone, but it's more common in people who are Black or of South Asian origin. CKD can get worse over time and eventually the kidneys may stop working altogether, but this is uncommon. Many people with CKD are able to live long lives with the condition. There's no cure for CKD, but treatment can help relieve the symptoms and stop it getting worse.  CKD can range from a mild condition with no or few symptoms, to a very serious condition where the kidneys stop working, sometimes called kidney failure. Most people with CKD will be able to control their condition with medicine and regular check-ups. CKD only progresses to kidney failure in around 1 in 50 people with the condition.
-------------------------------------	---

	<p>If you have CKD, even if it's mild, you're at an increased risk of developing other serious problems, such as cardiovascular disease. This is a group of conditions affecting the heart and blood vessels, which includes heart attack and stroke.</p> <p><b>Source:</b> NHS choices Chronic Kidney Disease. Available at: <a href="https://www.nhs.uk/conditions/kidney-disease/">https://www.nhs.uk/conditions/kidney-disease/</a></p>		
<b>Potential patient numbers per 100,000</b>	<b>Recommendation of NICE TA 775</b>	<b>% of people</b>	<b>Number of people</b>
	Total population for area selected (all ages)		1,049,170
	Adult population		815,884
	Prevalence of chronic kidney disease		33,451
	People who meet the anticipated licence eligibility criteria for treatment	92.32 %	30,882
	People who have eGFR of 25 ml/min/1.73 m <sup>2</sup> to 75 ml/min/1.73 m <sup>2</sup> <b>and:</b>	100%	16,522
	-People who have type 2 diabetes <b>OR</b>	32.90 %	5,436
	For people who do not have type 2 diabetes:	67.10 %	11,086
	-People who have a uACR of 22.6 mg/mmol or more (without type 2 diabetes)	7.70%	854
<b>Eligible population</b>		<b>6,289</b>	
Potential patient numbers: 600 patients per 100,000			

## SUMMARY

### NICE recommendation

1.1 Dapagliflozin is recommended as an option for treating chronic kidney disease (CKD) in adults. 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 (eGFR) of 25 ml/min/1.73 m<sup>2</sup> to 75 ml/min/1.73 m<sup>2</sup> at the start of treatment and:
  - have type 2 diabetes or
  - have a urine albumin-to-creatinine ratio (uACR) of 22.6 mg/mmol or more.

1.2 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 clinician consider it appropriate to stop.

### Why the committee made these recommendations

Management of CKD aims to slow disease progression. Standard care is lifestyle and dietary changes, and usually ACE inhibitors or ARBs. Dapagliflozin is an oral treatment for CKD. The company proposes that

dapagliflozin would be used as an add-on to optimised standard care with ACE inhibitors or ARBs, which is narrower than its marketing authorisation.

Clinical trial evidence suggests that dapagliflozin plus standard care is more effective than standard care alone. The main clinical trial only included people with an eGFR of 25 ml/min/1.73 m<sup>2</sup> to 75 ml/min/1.73 m<sup>2</sup> and a uACR of 22.6 mg/mmol to 565 mg/mmol. Evidence is available for dapagliflozin from a different clinical trial for people with CKD and type 2 diabetes and with a uACR of less than 22.6 mg/mmol. There is no clinical trial evidence available for dapagliflozin in people with CKD without type 2 diabetes and with a uACR of less than 22.6 mg/mmol.

For the groups for which there is good enough clinical evidence, the cost-effectiveness estimates are within the range that NICE considers an acceptable use of NHS resources. So, dapagliflozin is recommended for these groups as an add-on to optimised standard care including ACE inhibitors or ARBs.

#### Cost implications\*

**Cost of product: £36.59 – 28 pack**

**Annual cost per patient: £477.30**

**Has dose escalation been considered as part of the NICE costing template? N/A**

**Costing information/100,000 population and per CCG: £68K/100,000**

*NB. There is an indication that resources are released £45K/100,000 if this TA is implemented. The £68K/100,000 costing is at 5 years.*

Using the resource template on NICE for Surrey Heartlands CCG shows:

- costs in year 5 total £708K
- resource released in year 5 total £463K
- change in actual costs year on year

Y1	Y2	Y3	Y4	Y5
£50K	£121K	£163K	£199K	£246K

**Availability of PAS and details (if appropriate): No**

**Availability of homecare service (if appropriate): N/A**

*\*NICE funding requirements are based on Quality Adjusted Life Years (QALY) threshold. If there is evidence that the incremental cost rises above this threshold in the future, the APC may reconsider the commissioning status.*

#### Alternative treatments and cost per patient (per year / per month as appropriate)

**Other NICE recommended products:**

N/A

**Options not reviewed by NICE but used in standard practice:**

Canagliflozin is another SGLT2 inhibitor with a marketing authorisation for type 2 diabetes. The company did not consider canagliflozin a relevant comparator for dapagliflozin in CKD, because it noted that canagliflozin is not widely used for treating CKD with type 2 diabetes in the UK. However, the company did an indirect treatment comparison of dapagliflozin and canagliflozin in people with CKD and type 2 diabetes

Table 1: relative cost of dapagliflozin and canagliflozin.

Medicine	Cost per month	Annual cost
Dapagliflozin	£36.50	£477.30
Canagliflozin	£39.20	£509.60

Canagliflozin is being used to some extent in clinical practice. The committee therefore concluded that canagliflozin is a relevant comparator for people with CKD and T2 diabetes.

#### **Impact to patients**

Unmet need for more effective therapies for treating CKD, patients and clinicians would welcome a new treatment option

Additional treatment option to improve patient outcomes

No additional monitoring required outside standard frequency CKD review in primary care

Additional monitoring may apply to patients with concomitant CKS and T2 diabetes.

No special storage requirements

#### **Impact to primary care prescribers**

If green traffic light status drug will be initiated in primary care.

No additional specialist monitoring needed except standard CKD review which will include U+E's, eGFR, BP and ACR at diagnosis

Standard yearly CKD review satisfactory with yearly renal function review and hepatic function review.

Already prescribed in primary care for other indications.so GPs have experience with using it etc.

No additional clinic capacity/resource identified at present according to TA775

#### **Impact to secondary care**

Will be initiated in primary care so no significant increase in demand to secondary care nephrology services anticipated

No additional prescribing or monitoring in secondary care necessary beyond pre-existing CKD specialist care.

No drug cost/ non-drug cost saving anticipated as novel therapy

#### **Impact to CCGs**

The technology is commissioned by integrated care systems/clinical commissioning groups (CCGs) and they are required to comply with the recommendations in the NICE TA within 3 months of its date of publication.

#### **Implementation**

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 clinical commissioning groups, NHS England and, with respect to their public health functions, local authorities to comply with the recommendations in this appraisal within 3 months of its date of publication.
2. 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 doctor responsible for their care thinks that dapagliflozin is the right treatment, it should be available for use, in line with NICE's recommendations.
3. Specialist centres to consider an implementation pathway for use in primary care
4. Special consideration will need to be made for patients with type 2 diabetes because of the risk of diabetic ketoacidosis

## Recommendation to APC

PbRe: N



Colour classification  
guidelines

**Recommended traffic light status (see attached guidelines):  
Green**

### Additional comments:

Standard yearly CKD review satisfactory with yearly renal function review and hepatic function review. No dose escalation required.

The majority of patients to which this applies are not under the care of Nephrology and would not normally be referred to Nephrology and so BLUE traffic light status would not be appropriate

The accessibility of renal consultants to primary care physicians through *Advice and Guidance (A&G)* will allow any concerns and queries (including reassurance) to be addressed promptly. Any A&G can be converted to a referral if the Nephrologist feels this is required.

### References:

1. Summary of product characteristics Dapagliflozin (Forxiga) 10 mg film-coated tablets.  
Available at: <https://www.medicines.org.uk/emc/product/7607/smpc>. Accessed 26/4/22.

2. NICE Technology appraisal 775: Dapagliflozin for treating chronic kidney disease  
Published: 9 March 2022. Available at:  
<https://www.nice.org.uk/guidance/ta775/resources/dapagliflozin-for-treating-chronic-kidney-disease-pdf-82611498049477>. Accessed 26/4/22.

3. NHS choices Chronic Kidney Disease. Available at: <https://www.nhs.uk/conditions/kidney-disease/>. Accessed 26/04/22.

### Prepared by:

Natalia Tomasova Lead Pharmacist Cardiology, Stroke and Anticoagulation

Surrey and Sussex NHS Trust

### Declaration of Interest:

Nil

Date: 26/04/2022

### Reviewed by:

Reham Al-Shwaikh, Primary Care Pharmacist, East Surrey Place, Surrey Heartlands CCG

Tejinder Bahra, Lead Commissioning Pharmacist, East Surrey Place, Surrey Heartlands CCG

### Declaration of Interest:

Nil

Date: 03/05/2022