

MID AND SOUTH ESSEX MEDICINES OPTIMISATION COMMITTEE (MSEMOC)

DAPAGLIFLOZIN FOR TREATING CHRONIC HEART FAILURE WITH REDUCED EJECTION FRACTION, NICE TA679, FEBRUARY 2021

YELLOW - RECOMMENDED FOR RESTRICTED USE - FOR HEART FAILURE SPECIALIST INITIATION AND PRIMARY CARE CONTINUATION

Name: generic (trade)	What it is	Licensed indication	Decision status	NICE guidance
Dapagliflozin (Forxiga®) 10 mg tablets	Sodium glucose cotransporter-2 inhibitor (SGLT2 inhibitor)	Treatment of symptomatic chronic heart failure with reduced ejection fraction in adults	Final	NICE TA679 – recommended

MSEMOC recommendation:

Dapagliflozin is recommended as an option for treating symptomatic chronic heart failure with reduced ejection fraction in adults in accordance with NICE technology appraisal recommendations.

[NICE TA679](#) recommendation:

- 1.1 Dapagliflozin is recommended as an option for treating symptomatic chronic heart failure with reduced ejection fraction in adults, only if it is used as an add-on to optimised standard care with:
 - angiotensin-converting enzyme (ACE) inhibitors or angiotensin-2 receptor blockers (ARBs), with beta blockers, and, if tolerated, mineralocorticoid receptor antagonists (MRAs), or
 - sacubitril valsartan, with beta blockers, and, if tolerated, MRAs.
- 1.2 Start treatment of symptomatic heart failure with reduced ejection fraction with dapagliflozin on the advice of a heart failure specialist. Monitoring should be done by the most appropriate healthcare professional.
- 1.3 These recommendations are not intended to affect treatment with dapagliflozin that was started in the NHS before this guidance was published. People having treatment outside these recommendations 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.

Background information

- The DAPA-HF clinical trial compared dapagliflozin as an add-on treatment to standard care (based on an ACE inhibitor, ARB or sacubitril valsartan) with standard care alone. Evidence from the trial shows that dapagliflozin lowers the risk of dying from cardiovascular causes, and reduces the likelihood of hospitalisation or an urgent outpatient visit because of heart failure.
- The recommended dose of dapagliflozin for heart failure is 10 mg once daily. Dapagliflozin is also licensed for the treatment of type 1 and type 2 diabetes mellitus, for which the licensed dose may be different to that used in heart failure.
- Currently, all SGLT2 inhibitors apart from dapagliflozin are NOT licensed as treatment options for symptomatic chronic heart failure with reduced ejection fraction. Therefore, apart from dapagliflozin in accordance with NICE TA679, all other SGLT2 inhibitors are NOT RECOMMENDED as treatment options for symptomatic chronic heart failure with reduced ejection fraction.

For further information refer to the [Summary of Product Characteristics for dapagliflozin \(Forxiga®\)](#) and the Mid and South Essex Health and Care Partnership dapagliflozin pathway (Appendix 1).

Providers commissioned to provide services on behalf of Mid and South Essex CCGs are reminded that they are required to follow the local joint formulary and prescribing guidance, as detailed in the medicines management service specification of their contract.

Dapagliflozin for adults with Heart Failure and a Reduced Ejection Fraction (HFREF)

Appendix 1

Dapagliflozin initiation pathway

- To be initiated by HF Specialist
- Patient on standard HFrEF Treatment*
- EF<40%
- eGFR>30 ml/min
- Symptomatic

Record HbA1c (results <3 months) prior to initiating

- Initiate dapagliflozin 10mg od*
- No dose titration required
- Check Renal Function in after one month and 6 monthly afterwards
 - Continue current HF therapies
 - Assess volume status as routine and adjust diuretics if needed
- In Type II DM, dose reduction of insulin or sulphonylurea may be needed. Therefore, liaise with endocrinologist

Give advice regarding sick days**
Give advice on genitourinary infections

**Sick Days

Treatment should be interrupted in patients who are hospitalised for major surgical procedures or acute serious medical illnesses.

Clear correspondence to GP regarding drug continuation

Usual heart failure monitoring in primary or secondary Care

*Standard HFrEF Treatment

- ACE/AIRB + BB +/- MRA
- ARNI + BB +/- MRA

*DO NOT INITIATE

- Type I DM
- Previous history of or factors that predispose to ketoacidosis
- Previous history of pancreatitis
- History of allergic reaction to dapagliflozin or any of its excipients
- eGFR<30 ml/min
- Patients on dialysis
- Pregnancy
- Breastfeeding

CAUTION

NYHA IV
Severe Hepatic Impairment

For further information:

- Dapagliflozin for treating chronic heart failure with reduced ejection fraction [TA679]: <https://www.nice.org.uk/guidance/ta679>
- For full information on side effects and cautions see Summary of Product Characteristics (SPC) for Dapagliflozin available at: www.medicines.org.uk
- Dapagliflozin in patients with heart failure and reduced ejection fraction. McMurray et.al. N Engl J Med 2019; 381:1995-2008 <https://www.nejm.org/doi/full/10.1056/NEJMoa1911303>



References	NICE TA679: Dapagliflozin for treating chronic heart failure with reduced ejection fraction: https://www.nice.org.uk/guidance/TA679
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