

Prescribing Guidance Update

Dapagliflozin (Forxiga®) or Empagliflozin (Jardiance®) for treating heart failure

January 2024 v4.0

Key Message

Dapagliflozin and Empagliflozin have been commissioned as **ADVICE - GP may initiate Dapagliflozin or Empagliflozin following specialist recommendation** for use across Norfolk and Waveney, in line with the recommendations stated in the NICE guidance documents listed below.

A 'Specialist' can be defined as a member of the Community or Secondary Care Heart Failure Multidisciplinary Team.

ADVICE - GP may initiate Dapagliflozin or Empagliflozin following specialist recommendation

Indications covered by this guidance

- [TA679](#) - Dapagliflozin for treating chronic heart failure with reduced ejection fraction – February 2021
- [TA773](#) - Empagliflozin for treating chronic heart failure with reduced ejection fraction – March 2022
- [TA902](#) - Dapagliflozin for treating chronic heart failure with preserved or mildly reduced ejection fraction – June 2023
- [TA929](#) - Empagliflozin for treating chronic heart failure with preserved or mildly reduced ejection fraction – November 2023

Background to treatment

Dapagliflozin and Empagliflozin are SGLT- 2 (Sodium- glucose co transporter 2) inhibitor. Sodium-glucose cotransporter 2, expressed in the proximal renal tubules, is responsible for most of the reabsorption of filtered glucose from the tubular lumen. Therefore, by inhibiting SGLT2, these drugs reduce reabsorption of filtered glucose and thereby promote urinary glucose excretion.

Dapagliflozin and Empagliflozin also reduce sodium reabsorption and increase the delivery of sodium to the distal tubule. This may influence several physiological functions including, but not restricted to, lowering both pre- and afterload of the heart and downregulation of sympathetic activity, and decreased intraglomerular pressure, which is believed to be mediated by increased tubuloglomerular feedback.

Form and strength

- Dapagliflozin 10mg and 5mg tablets.
- Empagliflozin 10mg and 25mg tablets

In patients with severe hepatic impairment: start at dose of dapagliflozin 5mg daily and increase if tolerated to 10mg daily. Otherwise, there is no indication for using the lower dose of dapagliflozin (5mg daily) or the higher dose of empagliflozin (25mg daily) in the treatment of HF.

Side effects, interactions and contraindications

Side Effects	Drug Interactions	Contraindications
Forxiga 10 mg film-coated tablets - Summary of Product Characteristics (SmPC) - (emc) (medicines.org.uk)	Forxiga 10 mg film-coated tablets - Summary of Product Characteristics (SmPC) - (emc) (medicines.org.uk)	Dapagliflozin SPC
Jardiance 10 mg film-coated tablets – Summary of Product Characteristics (SmPC) – (emc)	Jardiance 10 mg film-coated tablets – Summary of Product Characteristics (SmPC) – (emc)	Empagliflozin SPC

Treatment **should not** be initiated in patients with:

- symptomatic hypotension
- eGFR <30 ml/ min/ 1.73m² (If eGFR is less than 30ml/min/1.73m² patient should be under Specialist care)
- Type 1 diabetes mellitus
- History diabetic ketoacidosis
- Acute decompensated heart failure

Cautions:

- No dose adjustment is required but renal function should be checked after 4 weeks (eGFR often dips by 15-20% which usually resolves in 1-3 months). Do not withdraw treatment without specialist discussion
- As per [Dapagliflozin SPC](#) and [Empagliflozin SPC](#), no dose adjustment is necessary for patients with mild or moderate hepatic impairment.
- As noted above, in patients with severe hepatic impairment, start at dose of dapagliflozin 5mg daily and increase if tolerated to 10mg daily.

Dose, administration and supply

To be initiated by GP following recommendation from heart failure specialist.

The recommended dose of dapagliflozin is 10 mg once daily. It can be taken orally once daily at any time of day, with or without food. Tablets are to be swallowed whole.

The recommended dose of Empagliflozin is also 10 mg once daily.

Dose adjustments should only be made by, or after discussion with, the specialist team.

Treatment is lifelong unless discontinued due to lack of efficacy / futility or because of adverse events e.g., patient entering end of life care, development of end stage renal.

GP prescribing responsibilities

- Initiate treatment at request of heart failure specialist
- Ensure patient is aware of risk of genitourinary tract infections and when to seek help
- Ensure there are no interactions with any other medications initiated in primary care.
- Monitor concordance with therapy and raise concerns with the specialist team as appropriate.
- Discontinue the drug as directed by the specialist if required
- Identify adverse events if the patient presents with any signs and liaise with the hospital specialist where necessary.
- Report adverse events to specialist and the Commission on Human Medicines/MHRA (Yellow card scheme).

GP monitoring responsibilities

Baseline

- Renal function
- Blood pressure

Ongoing

- Measure and record blood pressure if patient has symptoms suggestive of hypotension
- Monitor renal function and electrolytes every six months and more often during periods of illness.
- Consider referral where any significant decrease in renal function is noted. Significant decrease would be defined as 15-20% reduction in eGFR from the baseline recorded following transfer of care. Do not withdraw treatment without specialist discussion
- Note heart failure symptoms such as ankle swelling

Patient responsibilities

- Ensure patient is aware of sick day rules
- Contact details and patient information leaflet should be provided at the point of dispensing.

Indications for referral back to specialist

Stop treatment and refer to specialist if:

- eGFR falls below 30 ml/ min/ 1.73m² in patients without diabetes
- eGFR falls below 45ml/min/1.73m² in patients WITH type 2 diabetes
- Significant hypotension
- Fourier's gangrene
- Diabetic Ketoacidosis

Continue treatment but refer to specialist if:

- Deterioration in the patient's heart failure symptoms.

Title	Dapagliflozin (Forxiga®) or Empagliflozin (Jardiance®) for treating heart failure
Description of policy	<i>To inform healthcare professionals</i>
Scope	<i>Norfolk and Waveney Integrated Care System</i>
Prepared by	Norfolk and Waveney ICB Medicines Optimisation Team
Impact Assessment (Equalities and Environmental)	<p><i>Please indicate impact assessment outcome:</i></p> <p><i>Positive impact</i></p> <p><i>Adverse impact - low - action plan completed as per guidance</i></p> <p><i>Adverse impact - medium - action plan completed as per guidance</i></p> <p><i>Adverse impact - high - action plan completed as per guidance</i></p> <p><i>No impact</i></p> <p>No policy will be approved without a completed equality impact assessment</p>
Other relevant approved documents	
Evidence base / Legislation	<p>Level of Evidence:</p> <p><i>A. based on national research-based evidence and is considered best evidence</i></p> <p>B. mix of national and local consensus</p> <p><i>C. based on local good practice and consensus in the absence of national research based information.</i></p>
Dissemination	Is there any reason why any part of this document should not be available on the public web site? <input type="checkbox"/> Yes / No <input checked="" type="checkbox"/>
Approved by	<i>Norfolk & Waveney Therapeutics Advisory Group (TAG) – Feb 2024</i>
Authorised by	<i>Norfolk & Waveney Drug and Therapeutics Committee – Feb 2024</i>
Review date and by whom	TAG – Jan 2026
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Version Number	Author	Purpose / Change	Date
1.0	First draft for review by CCG Cardiovascular Group. Authors as stated above. Transferred to new template by JC, TAG Lead Technician, AGEM CSU	New document	August 2021
1.1	JC TAG Lead Technician, AGEM CSU	Updated front page as per TAG comments in August (Specialist to prescribe for at least 8 weeks before transfer to primary care). Submitted to Sept D+TC for further discussion, with comments	Sept 2021
1.2	JC TAG Lead Technician, AGEM CSU	Agreed by TAG, D+TC and CVD working group. Ratified by CCG Governing Body Nov 2021	Nov 2021
1.3	JC, TAG Lead Technician, AGEM CSU	Following comments from GP Clinical Lead for Diabetes, added note to say not to withdraw treatment without specialist consultation if eGFR drops on initiation. Also for patients to be aware of risk of genitourinary tract infections and when to seek help	Dec 2021
2.0	JC, TAG Lead Technician, AGEM CSU	Added Empagliflozin info to SCA following publication of TA773. Comments from Dr Sunil Nair. To submit to TAG June 2022	April 2022
3.0	JC, TAG Lead Technician, NWICB	Empagliflozin added to existing Dapagliflozin shared care agreement after formulary application was accepted by TAG. (Draft SCA doc had already been agreed in Apr 22 but not published)	July 2023
4.0	JC, TAG Lead Technician, NWICB	Classification amended from shared care Guidance to Advice. Content transferred to Prescribing Guidance template	Jan 2024