Clinical Protocol: Switching SGLT2 Inhibitors to Dapagliflozin

Bath and North East Somerset, Swindon and Wiltshire Together

Purpose

To provide a safe and consistent approach for switching patients from other SGLT2 inhibitors (e.g. empagliflozin, canagliflozin, ertugliflozin) to dapagliflozin, where clinically appropriate.

Background

Dapagliflozin, empagliflozin, canagliflozin and ertugliflozin are all SGLT2 inhibitors recommended by NICE (TA390) for adults with type 2 diabetes when metformin is unsuitable and lifestyle measures alone are insufficient; additionally, dapagliflozin is approved for use in chronic heart failure (TA679, TA902) and chronic kidney disease (TA1075), supporting its broader therapeutic role. Dapagliflozin and empagliflozin are also recommended in local BSW guidelines for heart failure BSW guidelines for heart failure, dapagliflozin further recommended in the BSW Initiating SGLT2 Inhibitors for Adults in Type 2 Diabetes, CKD and CKD Management Outline.

Note that *generic* Dapagliflozin is not to be used in CKD *without* T2DM due to an ongoing patent for the brand*

Timely switching should be prioritised for the following reasons:

- In line with NHSE recommendation letter Sept 2025
- Formulary alignment
- Cost-effectiveness
- Adverse effects
- Renal function considerations
- Heart failure or CKD indications (dapagliflozin has broader licensing)

Objectives

- **Align with NICE and NHSE Recommendations**
  Ensure prescribing is consistent with NICE technology appraisals (TA390, TA679, TA902, TA1075) supporting dapagliflozin for type 2 diabetes, heart failure and CKD and in line with NHSE recommendation as per NHSE letter September 2025
- **Broaden Therapeutic Coverage**
  Optimise treatment for patients with multiple comorbidities (e.g. diabetes, heart failure, CKD) using a single agent with proven cardio-renal benefits.
- **Simplify Prescribing and Monitoring**
  Streamline medication regimens and reduce complexity by standardising to a preferred agent with a once-daily dose and no need for titration.
- **Support Formulary and Cost Efficiency**
  Cost saving and good use of NHS resources. Promote use of locally preferred SGLT2 inhibitor to support formulary compliance and potential cost savings.
- **Enhance Continuity of Care**
  Facilitate consistent prescribing across primary and secondary care settings, improving communication and reducing variation.
- **Improve Patient Outcomes**
  Leverage evidence-based benefits of dapagliflozin in reducing hospitalisations for heart failure, slowing CKD progression, and lowering cardiovascular risk.

Summary of Licensed Indications and Renal Function Limits

Drug Name	Licensed Indications	Initiation eGFR Threshold	Continuation eGFR Threshold	Hepatic Impairment	Notes
Dapagliflozin	Type 2 Diabetes, Chronic Kidney Disease, Heart Failure	≥ 15 mL/min/1.73m² (CKD), ≥ 45 mL/min/1.73m² (T2DM)	No lower limit for CKD/HF; consider additional glucose-lowering if <45ml/min for T2DM	No dose adjustment in mild/moderate hepatic impairment. In severe impairment, start at 5mg; increase to 10mg if tolerated.	Licensed for CKD with T2DM; broader HF indication including preserved EF
Empagliflozin	Type 2 Diabetes, Chronic Kidney Disease, Heart Failure	≥ 20 mL/min/1.73m² (CKD), ≥ 45 mL/min/1.73m² (T2DM)	No lower limit for CKD/HF; consider additional glucose-lowering if < 45 for T2DM	No dose adjustment for mild/moderate hepatic impairment. Not recommended for use in patients with severe hepatic impairment.	Licensed for CKD with or without T2DM; HF indication includes preserved EF
Canagliflozin	Type 2 Diabetes, Diabetic Kidney Disease	≥ 30 mL/min/1.73m² (CKD) ≥ 60 mL/min/1.73m² (T2DM)	Continue to dialysis/transplant if uACR ≥ 33.9 mg/mmol	No dose adjustment for mild/moderate hepatic impairment. Not recommended for use in patients with severe hepatic impairment.	Licensed for CKD with T2DM only; reduced glycaemic efficacy if eGFR < 45
Ertugliflozin (NON-FORMULARY)	Type 2 diabetes	≥45 mL/min/1.73 m²	Stop if eGFR persistently <30 mL/min/1.73 m²	No dose adjustment required in mild/moderate hepatic impairment. Use with caution in severe hepatic impairment due to limited data	Only licensed for type 2 diabetes

Eligibility Criteria

- No history of intolerance to dapagliflozin.
- No current or recent history of diabetic ketoacidosis (DKA).
- No active genitourinary infections.

Interactions (see SPC for comprehensive information)

Dapagliflozin can be taken at any time of day and does not need to be taken with food, unlike canagliflozin. It also has fewer drug interactions compared to canagliflozin and empagliflozin, making it a more flexible option for prescribing.

Exclusion Criteria

Do not switch if:

- Patient has CKD **without** T2DM (dapagliflozin brand has patent protection on this indication)
- Patients with complex clinical needs requiring individualised review prior to any treatment change
- Patients with a known allergy or intolerance to dapagliflozin or its excipients.
- Patients who have previously failed a trial of dapagliflozin
- Patient is <18 years old

Implementation

1. **Clinical Review:**
    - Assess renal function (eGFR).
    - Review cardiovascular and heart failure status.
    - Check for history of adverse effects with dapagliflozin.
    - Discuss rationale and obtain informed consent.
2. **Discontinue Current SGLT2 Inhibitor:**
    - Stop empagliflozin or canagliflozin.
    - No washout period required unless adverse effects are present.
3. **Initiate Dapagliflozin:**
    - Dose: 10 mg once daily.
    - 5mg dose should only be used in patients with severe hepatic impairment.
    - Can be taken with or without food.
    - Continue other antidiabetic agents as previously prescribed.
4. **Monitoring:**
    - There is no indication for additional testing for either eGFR and/or urine ACR when making the switch to generic dapagliflozin - Use of generic dapagliflozin in CKD: UKKA statement | UK Kidney Association
    - Monitor HbA1c at the routine interval. Consider an earlier review for patients who are high-risk or have complex clinical needs.
    - Watch for signs of DKA, especially in patients with low carbohydrate intake or acute illness.
    - Monitor for genitourinary infections.
    - Patient information – Remind patient of sick day rules

Safety Considerations

MHRA alerts on SGLT2 inhibitors include risks of:

- DKA (especially in insulin-treated patients) MHRA risk of diabetic ketoacidosis MHRA monitor ketones in blood during treatment interruption
- Fournier's gangrene MHRA: reports of Fournier's gangrene
- Lower limb amputation (mainly with canagliflozin) MHRA: increased risk of lower-limb amputation (mainly toes)
- UTIs
- Ensure patients are aware of symptoms and when to seek help.

Governance and Audit

- Record all medication switches, including rationale and clinical justification.
- Document all patient discussions regarding medication changes, ensuring informed consent and shared decision-making are clearly noted.
- Maintain a central log or database for tracking switches and patient
- Quantify and report cost savings resulting from prescribing changes,

Specialist contact information:

SFT Consultants/Nurse Specialists Contact via Secretaries		
Consultants' secretaries	Phone	01722-429229
Advice & Guidance	Email	shc-tr.diabetes@nhs.net
RUH Consultants/Nurse Specialists		
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