RELEVANT ACUTE TRUST LOGO

WORKING IN PARTNERSHIP WITH

Surrey & North West Sussex Area Prescribing Committee (APC)

Surrey (East Surrey CCG, Guildford & Waverley CCG, North West Surrey CCG, Surrey Downs CCG & Surrey Heath) Crawley CCG and Horsham & Mid-Sussex CCG

SHARED CARE Guideline – Amber Traffic Light Classification		
Name of medicine	Dapagliflozin	
Indication (including whether for adults and/or children)	As an adjunct to insulin in Type 1 Diabetes	
APC policy statement reference (if applicable)	449-2019	
Author(s): Helen Marlow **Organisation(s): Surrey Downs CCG**		
Version: 1	**APC recommendation date: Sept 2019**	**Review date: January 2023**

The Shared Care Guideline (SCG) is intended to facilitate the accessibility and safe prescribing of complex treatments across the secondary/primary care interface.
This **AMBER** shared care sets out the patient pathway relating to this medicine and any information not available in the British National Formulary and manufacturer's Summary of Product Characteristics. Prescribing must be carried out with reference to those publications.
The SCG must be used in conjunction with the APC agreed core roles and responsibilities stated in annex A.
An agreement notification form is included in annex B for communication of request for shared care from provider and agreement to taken on prescribing by primary care.

Roles and Responsibilities

Listed below are specific medicine/indication related responsibilities that are additional to those core roles and responsibilities that apply to all SCGs listed in annex A.

Educational risk minimisation materials to help reduce the risk associated with dapagliflozin should be used.
(https://www.medicines.org.uk/emc/product/2865/rmms)

Consultant physician specialising in endocrinology and diabetes

Specialist teams planning on using dapagliflozin in type 1 diabetes should ensure all health care professionals involved in prescribing of dapagliflozin understand the risks involved, and are competent to assess, educate and monitor patients.

Pre-treatment

- Assess eligibility for treatment and complete healthcare professional checklist provided in the risk minimisation materials
- Provide dedicated education session to patient, including how to recognise risk factors for diabetic ketoacidosis (DKA), signs and symptoms, how and when to monitor blood ketone levels, what actions to take for elevated blood ketone levels, provision of patient alert card and patient and carer guide.
- Optimise insulin therapy and **check blood ketone levels are normal**
- Ensure patient has no signs of volume depletion

Starting treatment – first few weeks

- Prescribe dapagliflozin for the first three months of treatment
- Adjust insulin dose on initiation of dapagliflozin based on individuals blood glucose levels and to avoid ketosis and DKA
- Ensure regular blood ketone testing (and usual blood glucose monitoring), particularly during first two weeks of treatment.
- After three months, when insulin dose , blood glucose and blood ketones are stable, ask GP to continue to prescribe dapagliflozin
- Communicate expected frequency of blood ketone testing to the GP.

Subsequently

- Assess response to treatment – measure HbA1c at 6 months, and regularly after this. Adjust insulin dose to prevent hypoglycaemia and to avoid DKA.
- Reassess ketone monitoring frequency according to patient lifestyle/risk factors.
- If HbA1c not fallen by at least 0.3% (3.3 mmol/mol), then stop dapagliflozin
- Advise patient and GP when and how dapagliflozin treatment should be interrupted or stopped.

Primary Care Prescriber

Important advice - The repercussions of poor patient awareness of normoglycaemic diabetic ketoacidosis are very significant with this medication.

- Prescribe on-going dapagliflozin, following initial three month's supply from specialist, and provided ketone levels remain normal.
- Prescribe sufficient blood ketone test strips, in addition to blood glucose test strips.
- Ensure patient is informed how to recognise risk factors which predispose to ketosis, how to recognise signs and symptoms of DKA, and what actions to take when DKA is suspected., and has a patient alert card
- Measure blood ketone levels if patient presents with signs of, or in situations that predispose to risk of diabetic ketoacidosis. Stop dapagliflozin if DKA is suspected or diagnosed and seek specialist advice. **See blood ketone monitoring table for what action to take if result abnormal**.
- Patients presenting with a fever/malaise and severe pain, tenderness, erythema or swelling in the genital or perineal area should be considered for referral to hospital for urgent investigation of necrotising fasciitis of the perineum. Dapagliflozin should be stopped.

Patient Relatives & Carers

- Participate in a dedicated education session
- Read a copy of the Patient and Carer Guide
- Complete education worksheet with specialist, that advises them how to monitor blood ketone levels and what to do if blood ketone levels are raised
- Always carry their Dapagliflozin / Forxiga patient alert card with them

Key information on the medicine

Please refer to the current edition of the British National Formulary (BNF), available at www.bnf.org, and Summary of Product Characteristics (SPC), available at www.medicines.org.uk for detailed product and prescribing information and specific guidance.

Background to disease and use of medicine for the given indication

Indication

Dapagliflozin is indicated for treatment of type 1 diabetes as an adjunct to insulin in patients with a BMI ≥27 kg/m2, when insulin alone does not provide adequate control despite optimal insulin therapy

Dosage and Administration
5mg tablets daily: www.medicines.org.uk

Monitoring

Monitoring requirements including frequency and appropriate dose adjustments	Responsible clinician
Pre-treatment: • Blood glucose • Blood ketones • Renal function	Consultant
Initiation: • Blood glucose • Blood ketones – frequently during first two weeks of treatment	Consultant
Maintenance: • Blood glucose (patient measures according to recommendations from specialist) • Blood ketones (patient measures according to recommendations from specialist) • Renal function annually, or every four to six months if eGFR < 60mL/min (advise consultant if renal function deteriorates)	Primary care prescriber
Intercurrent illness: • Blood glucose • Blood ketones	Consultant or primary care prescriber

Action to take if blood ketone results abnormal:

Test	Abnormal Result	Action if Abnormal Result
Blood ketone	0.6 – 1.5 mmol/L	Advise patient they may need to take extra insulin and drink water. Recheck blood ketones in 2 hours. Stop dapagliflozin if blood ketone levels remain raised
	>1.5 – 3.0 mmol/L	Stop dapagliflozin and seek immediate medical advice as high risk of DKA. Recheck blood ketones in 2 hours.
	>3.0 mmol/L	Patient should go to A&E without delay and stop taking dapagliflozin

Cautions, contraindications - Refer to current Summary of Product Characteristics (SPC): www.medicines.org.uk

Adverse effects - Refer to current Summary of Product Characteristics (SPC): www.medicines.org.uk

Drug interactions - Refer to current Summary of Product Characteristics (SPC): www.medicines.org.uk

Additional reference resources to support clinicians and patients manage risks of diabetic ketoacidosis:

- International Conference on Advanced Technologies and Treatments for Diabetes (ATTD) education resources - Advanced Technologies and Treatments for Diabetes https://www.attd-education.com/my/

- Standardised education in DKA. A curriculum is established by Ketoaware at https://www.fidam.de/home

Support and Advice for the Primary Care

Name	Speciality	Telephone No.	Email address
XXXXX	XXXXX	XXXXX	XXXXX
Hospital Pharmacy	XXXXX	XXXXX	XXXXX
Out of Hours	XXXXX	XXXXX	XXXXX

Annex A: APC agreed core roles and responsibilities for the shared care of medicines

Patients
To get the most out of your treatment it's important that you work together with your specialist. You must follow these guidelines to ensure your own safety, health and wellbeing. You should be able to decline shared care If after due consideration of the available options you decide it is not in your best interests. • You must make sure that you understand about your treatment • If you do not understand ask for more information from the person prescribing the medicine • Read the Patient Information Leaflet included with your medication. It will provide you with information about your medication • You must raise concerns about your treatment with the person prescribing the medicine • Talk to the specialist and come to an agreement of how the treatment should be provided to you • Give permission to have aspects of your care communicated to healthcare providers • **Ensure that you are provided with contact details for support and help if required; both in and out of hours.** • You must attend all appointments. **Non-attendance of appointments may result in treatment being stopped** • You must keep a written list of all of the medicines you are taking • You must keep lists of any additional vitamins, minerals, or other dietary supplements • You must bring these lists with you each time you visit a healthcare provider or are admitted to a hospital • You must carry these lists on you in case of an emergency • You must not let anyone else take your medication. It is your responsibility to follow these guidelines. The guidelines are here for your safety, health and wellbeing. If you would like more information on your rights, roles and responsibilities in your healthcare please ask a NHS professional for information on the NHS constitution or visit, www.gov.uk/government/publications/the-nhs-constitution-for-england
Relatives and Carers
As a carer or relative (where it is not possible for the patient to make a decision about future treatment e.g. mental capacity, where possible you should be included in discussions about shared care. • To support the patient in fulfilling their roles and responsibilities as outlined above.
Consultant/ Specialist
Good Prescribing Guidelines • Be aware that if you recommend that a colleague, for example a junior doctor or Primary Care Prescriber, prescribes a particular medicine for a patient, you must consider their competence to do so. You must satisfy yourself that they have sufficient knowledge of the patient and the medicine, experience (especially in the case of junior doctors) and information to prescribe. You should be willing to answer their questions and otherwise assist them in caring for the patient, as required (Ref GMC). • Be aware that if you delegate assessment of a patients' suitability for a medicine, you must be satisfied that the person to whom you delegate has the qualifications, experience, knowledge and skills to make the assessment. You must give them enough information about the patient to carry out the assessment required. • Be aware that you are asking the Primary Care Prescriber to take full medico-legal responsibility for the prescription they sign(Ref GMC). For this reason the shared care guidelines (SCGs) are agreed at the APC with input from specialists and Primary Care Prescribers, and, for individual patients, the patient's Primary Care Prescriber must agree to take over responsibility before transfer of care, before the patient is discharged from specialist care. • Be aware of the formulary status and the traffic light classification of the medicine you are prescribing within the patient's CCG • Assume clinical responsibility for the guidance given in the SCG, and where there is new information needed on the SCG to liaise with your Formulary Pharmacist who will facilitate an

update via the APC

Before initiating treatment

- Evaluate the suitability of the patient for treatment, including consideration of the patient's current medication and any significant interactions.
- Discuss and provide the patient with information about the reason for choosing the medicine, the likelihood of both harm and benefits, consequences of treatment, and check that their treatment choice is consistent with their values and preferences
- Advise patient of unlicensed status of treatment (including off-label use) if appropriate and what this may mean for their treatment.
- Undertake baseline monitoring and assessment.

Initiating and continuing treatment in secondary care

- Prescribe initial treatment and provide any associated training and counselling required.
- Inform the Primary Care Prescriber when initiating treatment so that the Primary Care Prescriber is aware what is being prescribed and can add to Primary Care Prescriber clinical record
- Continue to prescribe and supply treatment with appropriate monitoring until the patient's condition is stable or predictable; the patient is demonstrably benefiting from the treatment and is free from any significant side effects.
- At any stage of treatment, advising Primary Care Prescriber of concerns regarding monitoring or potential adverse effects of treatment

Transfer of care to Primary Care prescriber

- Liaise with the primary care prescriber to agree to share the patient's care and provide relevant accurate, timely information and advice.
- Only advise the patient that shared care will take place, and prescribing will be transferred, once the primary care prescriber has agreed to share responsibility of the patient care, and that this has been confirmed in writing.
- If the primary care prescriber feels unable to accept clinical responsibility for prescribing then the consultant must continue to prescribe the treatment to ensure consistency and continuity of care.
- Ensure that the patient (and carer/relatives) are aware of their roles and responsibilities under the SCG
- Provide sufficient information and training for the patient to participate in the SCG

Post transfer of care

- Follow up and monitor the patient at appropriate intervals.
- Advise Primary Care Prescriber if treatment dose changes or treatment is discontinued
- Inform Primary Care Prescriber if patient does not attend planned follow-up

Primary Care Prescriber

- Be aware of the formulary and traffic light status of the medicine you have been asked to prescribe.
- Be aware that Amber medicines have been assessed by the APC as requiring careful transition between care settings but SCGs will be available to support safe transfer of care.
- It would be usual for Primary Care Prescribers to take on prescribing under a formal SCG. If you are uncertain about your competence to take responsibility for the patient's continuing care, you should seek further information or advice from the clinician with whom the patient's care is shared or from another experienced colleague. If you are still not satisfied, you should explain this to the other clinician and to the patient, and make appropriate arrangements for their continuing care.
- Be aware that if you prescribe at the recommendation of another doctor, nurse or other healthcare professional, you must satisfy yourself that the prescription is needed, appropriate for the patient and within the limits of your competence (Ref GMC).
- Be aware that if you prescribe, you will be responsible for any prescription you sign (Ref GMC).
- Keep yourself informed about all the medicines that are prescribed for the patient
- Be able to recognise serious and/ or frequently occurring adverse side effects, and what action should be taken if they occur.
- Make sure appropriate clinical monitoring arrangements are in place and that the patient and healthcare professionals involved understand them
- Keep up to date with relevant guidance on the use of the medicines and on the management of the patient's condition.
- Respond to requests to share care of patients in a timely manner, in writing (including use of form in annex B)

- Liaise with the consultant to agree to share the patient's care in line with the SCG in a timely manner.
- Continue prescribing medicine at the dose recommended and undertake monitoring requirements
- Undertake all relevant monitoring as outlined in the monitoring requirements section below, and take appropriate action as set out in this shared care guideline
- Monitor for adverse effects throughout treatment and check for drug interactions on initiating new treatments
- Inform the Consultant or specialist of any issues that may arise
- Ensure that if care of the patient is transferred to another prescriber, that the new prescriber is made aware of the share care guideline (e.g. ensuring the patient record is correct in the event of a patient moving practice).

All

- Where it has been identified that a SCG requires update e.g. new information needed, liaise with the SCG author and/or your organisation APC representative who will facilitate an update via the APC.

ANNEX B: Shared Care Agreement for Amber Drugs

For the attention of the Practice Manager and Primary Care Prescriber

Agreement between:

SECONDARY CARE DETAILS		PRIMARY CARE DETAILS	
Specialist name:		**Primary care prescriber name:**	
Trust:		**Practice name:**	
Speciality:			
nhs.net email:		**nhs.net email:**	

Please use nhs.net email addresses only to ensure patient confidentiality.

Patient details:

Patient name:		**Patient DOB:**	Click here to enter a date.
Patient NHS number:			
Patient hospital number:			

Medication details:

Name of medicine:	**Dapagliflozin**
Dose:	5mg daily
Formulation:	Tablets
Indication:	**Type 1 diabetes as an adjunct to insulin**
Date next Rx due:	Click here to enter a date.

Specialist responsibilities:

1. Ensure this shared care agreement has been emailed to the primary care prescriber.
2. The clinic / discharge letter must be available to the primary care team in a timely manner

Primary care responsibilities:

1. Read the associated shared care document for this drug prior to acceptance of the agreement. Please refer to one of the following, for relevant shared care documents:
   - The Surrey PAD (https://surreyccg.res-systems.net/pad/)
   - The Guildford & Waverley and Royal Surrey County Hospital Foundation Trust Joint Formulary http://www.guildfordandwaverleyformulary.nhs.uk/
   - The Crawley and Horsham & Mid Sussex CCGs Joint Formulary http://www.chmsformulary.nhs.uk/
2. Once complete, please email this form back to the relevant consultant and put a copy in the patient's notes

Agreement to undertake shared care (Yes/No):	Choose an item.
If NO, please state why:	