

Initiating SGLT2 Inhibitors for Adults in Type 2 Diabetes and in Chronic Kidney Disease

Following the update to NICE Guidance <u>NG28 Type 2 diabetes in adults: management</u> in February 2022, the SGLT2 inhibitors (with proven cardiovascular benefit) should now be offered at diagnosis of diabetes for those who have heart failure or established atherosclerotic cardiovascular disease (CVD). In addition, they should be considered at diagnosis for those who are at high risk of developing CVD (QRisk2 or 3 ≥10%).

At any point in the management of diabetes, where there is a change to cardiovascular risk or status change, SGLT2 inhibitors ought to be considered.

Chronic Kidney Disease (CKD):

Licensed SGLT2s should also be used in the management of CKD where ACE/ARB is optimised to the maximum tolerated dose (unless contraindicated) and:

For Dapagliflozin:

- people have an estimated glomerular filtration rate (eGFR) of 25 ml/min/1.73 m 2 to 75 ml/min/1.73 m 2 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.

For Empagliflozin:

- people have an estimated glomerular filtration rate of:
 - - 20 ml/min/1.73 m 2 to less than 45 ml/min/1.73 m 2 or
 - - 45 ml/min/1.73 m 2 to 90 ml/min/1.73 m 2 and either:
 - ♦ a urine albumin-to-creatinine ratio of 22.6 mg/mmol or more, or
 - \$ type 2 diabetes.

See links for further information:

Dapagliflozin for treating chronic kidney disease: <u>NICE TA1075</u>. Empagliflozin for treating chronic kidney disease: <u>NICE TA942</u>

The aim of this guidance is to ensure that SGLT2 inhibitors are added appropriately to established therapy.

For patients with heart failure, initiation of an SGLT2 inhibitor should be undertaken by or be discussed with Specialist Teams. Please see <u>Guidelines for the use of Dapagliflozin & Empagliflozin (SGLT2) in Heart Failure</u>



The glucose lowering efficacy of SGLT2 inhibitors is reduced when eGFR is < 45 mL/min/1.73m² and is likely absent in patients with severe renal impairment. Therefore, additional glucose lowering treatment should be considered in patients with type 2 diabetes mellitus when eGFR<45.

Adjusting ORAL medication when adding SGLT2 inhibitor with proven CV benefit for cardiorenal protection

SGLT2 inhibitors with proven cardiovascular benefit indicated for T2 Diabetes: Dapagliflozin 10mg OD

Empagliflozin 10mg OD, increased to 25mg OD if necessary and tolerated.

Canagliflozin 100mg OD, increased if tolerated to 300mg OD if required.

*Note that cardiovascular benefits with Ertugliflozin have not been established.

Please see **BNF** and **SmPC** for further dose titration and renal impairment adjustment.

For simplicity, Dapagliflozin 10mg is advocated by our local specialists as no dose titration is required or dose adjustment in renal impairment, and it also has a broad product license. However, you can use an alternative SGLT2 inhibitor such as empagliflozin or canagliflozin if preferred.

Current regime includes:	Suggested adjustment following discussion with patient:	Monitoring needed:	
		HbA1c target met:	HbA1c target not met:
Metformin only	Up titrate to maximum tolerated dose of Metformin and then add SGLT2 inhibitor.	Repeat HbA1c as per normal schedule (6- 12months).	Repeat HbA1c after 3 months and escalate treatment if target still not met.
Gliclazide (or other Sulfonylurea)	Add SGLT2 inhibitor and reduce dose of Sulfonylurea by 50% where HbA1c target achieved or if within 10mmol of target. Where HbA1c exceeds target by >10mmol, add SGLT2 inhibitor.	Repeat HbA1c at 3 months. Check fasting blood g week after changes. reduced or stopped a	Gliclazide can be
Alogliptin/Linagliptin Saxagliptin/Sitagliptin	Swap for SGLT2 inhibitor. if eGFR>45. Add SGLT2 inhibitor. if eGFR <45	Repeat HbA1c as per normal schedule (6- 12months).	Repeat HbA1c after 3 months and escalate treatment if target still not met.
Pioglitazone	Add SGLT2 inhibitor.	Repeat HbA1c as per normal schedule (6- 12months).	Repeat HbA1c after 3 months and escalate treatment if target still not met.

Benefits of SGLT2 inhibitors

- Up to 10mmol/mol reduction in HbA1c (dependent on starting level)
- Low incidence of hypoglycaemia (effect proportional to blood glucose)
- Weight loss (up to 3kg)
- Cardioprotective benefit, reduces progression of chronic complications affecting cardiovascular system and kidneys. (N.B. not applicable to ertugliflozin)

SGLT2 inhibitors can drop blood pressure (~5mm/Hg) and so a review of antihypertensives may be necessary.

SGLT2 Inhibitors should NOT be used where:
History of diabetic ketoacidosis (DKA)
Ketogenic or very low carbohydrate diet
Currently unwell (acute illness, surgery or planned procedure)
Pregnancy or risk of pregnancy
Breast feeding
Type 1 diabetes
SGLT2 Inhibitors should be used with CAUTION where:
History of persistent or complicated UTI
Frail and elderly
Severe hepatic impairment
Consult <u>SmPC</u> to see if dose adjustment is required in patients with renal impairment

Provide information to the patient on:

Potential side effects and when to seek review notably to report severe pain/tenderness/erythema/swelling in the genital/perineal area and importance of preventative foot care.
Please see <u>MHRA Drug Safety Updates: SGLT2 inhibitors: reports of Fournier's gangrene</u> and SGLT2 inhibitors: updated advice on increased risk of lower limb amputation

 Sick day guidance- see below (stop Dapagliflozin if diarrhoea/vomiting or symptoms of DKA and do not restart until eating/drinking normally for at least 24 hours).

• Staying hydrated.

Risk of DKA and SGLT2 inhibitors

The risk of DKA must be considered in the event of non-specific symptoms such as nausea, vomiting, anorexia, abdominal pain, excessive thirst, difficulty breathing, confusion, unusual fatigue or sleepiness.

Patients should be assessed for ketoacidosis immediately if these symptoms occur, regardless of blood glucose level.

Test strips for monitoring ketone levels should not routinely be prescribed in T2D patients who take SGLT2 inhibitors. A strong emphasis should be placed on patient education of symptoms of DKA and seeking urgent medical assessment in the event of symptoms rather than encouraging home monitoring.

Please see <u>MHRA Drug Safety Updates: SGLT2 inhibitors: updated advice on the risk of diabetic ketoacidosis</u> and <u>SGLT2</u> inhibitors: monitor ketones in blood during treatment interruption for surgical procedures or acute serious medical illness

Written Information for Patients

Trend leaflet Type 2 diabetes: What to do when you are ill - Trend Diabetes

Arden's have information leaflets [Medicines and Dehydration "Medicine Sick Day Guidance" and Sodium-glucose Co-transporter (SGLT2) Inhibitors – see appendix for images] that can be personalised and a read code can be input to document that advice has been provided [Y3767 *information given re sick day rules or* Y308a *Medication side-effect education:SGLT2i*].

Seek advice from Specialist Teams if guidance required.

Specialist Team	Telephone	Email
BaNES DSN	07876 265064	ruh-tr.communitydsn@nhs.net
Swindon DSN	01793 463841	SWICCG.CommunityDiabetesService@nhs.net
Wiltshire DSN	North, East and West 01248 456	whc.diabetesnurses@nhs.net
	483	
	South 012722 425 176	

References

- National Institute for Health and Care Excellence. NG203. Chronic kidney disease: assessment and management, updated November 2021. Available from https://www.nice.org.uk/guidance/conditions-and-diseases/kidney-conditions/chronic-kidneydisease
- 2. National Institute for Health and Care Excellence. NG 28. Type 2 diabetes in adults: management, updated March 22. Available from https://www.nice.org.uk/guidance/ng28
- 3. National Institute for Health and Care Excellence. British National Formulary. Accessed May 2022. Available from https://bnf.nice.org.uk
- 4. Summary of Product Characteristics. Accessed May 2022. Available from https://www.medicines.org.uk
- 5. National Institute of Clinical Excellence. TA 775. Dapagliflozin for treating chronic kidney disease. Published March 2022. Available from https://www.nice.org.uk/guidance/ta775

Appendix

Arden's Information leaflets

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Dehydration is due to a loss of fluid from your body. Vo			Sodium-alu	cose Co-transporter	2 (SGLT2) Inhibitors
shaking) can make you dehydrated. If you are sick once or have diarrhoea once, then you are unlikely to become dehydrated. Having two or more episodes of vomiting or diarrhoea or having a prolonged fever can lead to dehvdration.			Dear <patient na<="" td=""><td>-</td><td></td></patient>	-	
				taking a SGLT2 inhibitor called	-Medicafion-
Taking certain medicines when you are dehydrated can result in you developing a more serious illness.				s from your prescriber. Please make sure you understand	
Medicines that make dehydration more likely are: Diuretics Sometimes called "water pills"		denter a la contra la contra de la contra		edicine and ask if you have any	
Diureics Sometimes called 'water pills' Medicines that can stop your kidneys working if you ABESIN the stop of the stop of the stop of the stop ABESIN the decidence names ending in storm NSAIDs Anti-inflammatory pain killers Medicines that make you more likely to have a side Medicine in a medicine for albetes SGLT2's Medicine names ending in 'pilficuit' Medicine's CADy Guidance'' If you develop a dehydrating illness. Then it is impor- professional. This may be your GP, Nurse or Phan- mediciations which lower your blood pressure for a sho kilone's functions. Remember to keep dinking small amo onip passing small amounts of urine you may need adm only passing small amounts of urine you may need adm on the stop of the store of the stop withmere.	bu are dehydrated are: eg Lisinopril, perindop eg Losartan, candesa eg ibuprofen, diolofen e effect called lactic acid eg Canaglifozin, Dapa ortant that you discuss armaoist. You may be out time and a blood test out time and a blood test out time and a blood test	tan, valsartan as, naproxen dosis if dehydrated are: gliflozin, Empagliflozin arbited to discontinue taxing will be arranged to check your n your sick days too. If you are ou should aler your GP to this.	Hypoglyc diabetes Dehydrai dehydrai Genhal in risk of ink in rare cases, 55 Fournier's gange the following: Feeling of Fast and Sweet or Different - Different -	aemia (low blood glucose) – Th medicines and your prescriber on – This medicine increases y on, you must drink at least two fections – As this medicine incr cition, such as ential thrush, avoid wearing tight underwear LT2 Inhibitors can cause more ne and lower-limb amputation. Ight loss being sick, or stomach pain deep breathing metallic taste in the mouth sdour to your breath, urine or s	serious side effects, including diabetic ketoacidosis (DKA), Please seek medical advice immediately if you have any of
volumes. I (<patient name="">) am on the following medication dehydrated: <medication> Please cut out the alert card below and place in your wallet</medication></patient>	ns that put me at risk o	of acute kidney injury if I am	It is important you If you become un when you are bet advice from your The following blox	attend for regular foot checks i well and have vomiting, diarrho ter (eating and drinking normall GP, Pharmacist or NHS 111. xd tests are required to monitor	ea, or fever, you should stop this medication. You can restart y), however if you remain unwell after 48 hours seek medical your treatment, at least once a year. If you haven't had one
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