HERTFORDSHIRE MEDICINES MANAGEMENT COMMITTEE (HMMC): NICE TECHNOLOGY APPRAISALS – RECOMMENDED

NICE TA572 - Ertugliflozin as monotherapy or with metformin for treating type 2 diabetes, March 2019 https://www.nice.org.uk/guidance/ta572

GREEN - RECOMMENDED FOR RESTRICTED USE - for initiation in Primary, Community or Secondary care and continuation in Primary Care

NAME: GENERIC (TRADE)	WHAT IT IS	INDICATION	DATE DECISION LAST REVISED	DECISION STATUS	NICE GUIDANCE
Ertugliflozin (Steglatro®)	Sodium glucose co-transporter 2 (SGLT2) inhibitor	monotherapy or with metformin for treating type 2 diabetes	April 2019	Final	NICE TA572 – Recommended

HMMC recommendation:

Ertugliflozin is recommended for restricted use as an option as monotherapy or with metformin for treating type 2 diabetes in adults in line with the recommendations in TA 572.

Ertugliflozin for treating type 2 diabetes in adults is the commissioning responsibility of CCGs.

In line with recommendations for other SGLT2 inhibitors - only continue if the person has had a reduction of at least 5.5 mmol/mol (0.5%) in HbA1c in 6 months.

GREEEN STATUS - for initiation in Primary, Community or Secondary care and continuation in Primary Care

NICE TA572 recommendations:

1.1 Ertugliflozin as monotherapy is recommended as an option for treating type 2 diabetes in adults for whom metformin is contraindicated or not tolerated and when diet and exercise alone do not provide adequate glycaemic control, only if:

- a dipeptidyl peptidase 4 (DPP-4) inhibitor would otherwise be prescribed and
- a sulfonylurea or pioglitazone is not appropriate.

1.2 Ertugliflozin in a dual-therapy regimen in combination with metformin is recommended as an option for treating type 2 diabetes, only if:

- a sulfonylurea is contraindicated or not tolerated or
- the person is at significant risk of hypoglycaemia or its consequences.

1.3 If patients and their clinicians consider ertugliflozin to be 1 of a range of suitable treatments including canagliflozin, dapagliflozin and empagliflozin, the least expensive should be chosen.

Background Information including extracts from SPC

- Recommended starting dose of ertugliflozin is 5 mg once daily. In patients tolerating ertugliflozin 5 mg once daily, the dose can be increased to 15 mg once daily if additional glycaemic control is needed.
- 5 mg (28 tablets) or 15 mg (28 tablets): £29.40 per pack. Lower cost than other SGLT2 inhibitors (28 tablets: £36.59)

Renal impairment

The efficacy of ertugliflozin is dependent on renal function, and efficacy is reduced in patients who have moderate renal impairment and likely absent in patients with severe renal impairment

- Assessment of renal function is recommended prior to initiation and periodically thereafter

- Initiation is not recommended in patients with an estimated glomerular filtration rate (eGFR) less than 60 ml/min/1.73 m^2 or CrCl less than 60 ml/min
- Should be discontinued when eGFR is persistently less than 45 ml/min/1.73 m^2 or CrCl is persistently less than 45 ml/min.
- Should not be used in patients with severe renal impairment, with end-stage renal disease (ESRD), or receiving dialysis, as it is not expected to be effective in these patients.

Hepatic impairment
No dose adjustment is necessary in patients with mild or moderate hepatic impairment. Has not been studied in patients with severe hepatic impairment and is not recommended for use in these patients

Elderly (≥ 65 years old)
No dose adjustment recommended based on age. Renal function and risk of volume depletion should be taken into account. There is limited experience in patients ≥ 75 years of age.

Adverse reactions
Common adverse reactions include: vulvovaginal mycotic infection and other female genital mycotic infections; balanitis candida and other male genital mycotic infections; hypoglycaemia; volume depletion; increased urination; vulvovaginal pruritus; thirst

MHRA Drug Safety Updates for SGLT2 inhibitors referenced in the ertugliflozin SPC
- MHRA Drug Safety update April 2016: SGLT2 inhibitors: updated advice on the management of the risk of diabetic ketoacidosis. https://www.gov.uk/drug-safety-update/sglt2-inhibitors-updated-advice-on-the-risk-of-diabetic-ketoacidosis
- MHRA Drug Safety update June 2016: Canagliflozin (Invokana▼, Vokanamet▼): signal of increased risk of lower extremity amputations observed in trial in high cardiovascular risk patients. https://www.gov.uk/drug-safety-update/canagliflozin-invokana-vokanamet-signal-of-increased-risk-of-lower-extremity-amputations-observed-in-trial-in-high-cardiovascular-risk-patients
- MHRA Drug Safety update February 2019: SGLT2 inhibitors: reports of Fournier's gangrene (necrotising fasciitis of the genitalia or perineum). https://www.gov.uk/drug-safety-update/sglt2-inhibitors-reports-of-fournier-s-gangrene-necrotising-fasciitis-of-the-genitalia-or-perineum