BEDFORDSHIRE, LUTON AND MILTON KEYNES (BLMK) AREA PRESCRIBING COMMITTEE (APC)

Guidance for General Practitioners to support prescribing of Liraglutide for children and young people under 18 years with Type 2 Diabetes (T2DM)

Introduction

Type 2 diabetes (T2DM) is increasingly prevalent in children and young people (CYP) which is affected by obesity worldwide. The main risk factors for developing T2DM are excess weight, first or second degree relative with T2DM, maternal diabetes during the child's gestation, high risk race/ethnicity and insulin resistance (signs of insulin resistance include acanthosis nigricans and presence of other metabolic conditions associated with insulin resistance such as hypertension and hyperlipidaemia, polycystic ovarian syndrome (PCOS) or small for gestational age (SGA)). T2DM in young people is an aggressive disease with increased risk of complications leading to increased morbidity and mortality during most productive years of life.

The pharmacological treatment options for CYP have been limited to metformin and insulin. However, the availability of the GLP1 antagonist, liraglutide adds an additional option before moving to insulin.

As of **December 2024**, the originator product **Victoza®** has been discontinued and liraglutide biosimilars are now licensed in the UK. Zegluxen® brand approved by APC for addition to the BLMK formularies as a cost-effective choice and alternative to the originator product.

The following organisations contribute to and participate in the BLMK APC – Bedfordshire, Luton and Milton Keynes Integrated Care Board; Bedfordshire Hospitals NHS Foundation Trust; Cambridgeshire Community Services NHS Trust; Central and North West London NHS Foundation Trust; East London NHS Foundation Trust; Milton Keynes University Hospital NHS Foundation Trust

Approved by BLMK Area Prescribing Committee: July 2023. Review Date: July 2026
Version 2: Updated April 2025. Review Date: April 2028

GLP1 antagonist – Liraglutide (Biosimilar)

GLP-1 agonists bind to and activate GLP-1 receptors to stimulate insulin secretion, lowering glucagon secretion when blood glucose is high, and delaying gastric emptying in the early post-prandial phase.

Liraglutide biosimilar* (Zegluxen® brand) is licensed for treatment of type 2 diabetes in CYP aged 10 years and above if no improvement in glycaemic control (HbA1c >48mmol/mol or 6.5%) with metformin alone or with basal insulin therapy +/- diet and exercise.

Liraglutide biosimilars are now available as a 6mg/ml solution for injection in a 3ml pre-filled pen and administered as daily sub-cutaneous (s.c) injections.

***Note- For available liraglutide biosimilars, there are licensing differences for use in children and young persons (CYP).**

Initiation of liraglutide

- Initiation of liraglutide will be undertaken in secondary care and patients will be fully consented and counselled. The starting dose is 0.6mg daily, increased every 1-2 weeks up to 1.8mg based on tolerability and fasting capillary blood glucose >6mmol/l.
- S.C. administration is given in the abdomen, in the thigh or in the upper arm.
- The dose will be optimised before the GP is asked to take over prescribing.

Prescribing Guidance

Liraglutide is a biological medicine. Biological medicines must be prescribed by brand. Check for Formulary approved biosimilar brand and prescribe by brand.

The patient will also require needles and sharps bin.

Adverse effects & cautions

- GI side effects (nausea, diarrhoea, vomiting, dyspepsia) and fatigue. All disappear in the first few weeks.
- Cholelithiasis and cholecystitis are less common.
- Acute pancreatitis is rare. There is no benefit in routine amylase monitoring as it can be transiently elevated by GLP-1RA without correlation with pancreatitis risk.

For further details please see https://bnf.nice.org.uk/drugs/liraglutide/#indications-and-dose.

Monitoring

- Undertaken by secondary care:
- Baseline abdominal ultrasound and serum triglycerides to assess risk of gallstones or acute pancreatitis.
- Serum amylase / lipase.
- Full blood count, liver profile, bone profile, ferritin, folate, vitamin B12, selenium, magnesium, phosphate.

- Undertaken by secondary care at review clinics:
  - Annual U&Es.
  - Renal impairment – discontinue if creatinine clearance <30ml/min.

Follow up (in secondary care) and criteria for discontinuation

After initiation patient should be monitored/followed up at the following intervals:

- At 1 month – review compliance, injection technique, injection site and discuss any possible side-effects.
- At 3 months – check HbA1c, weight, review compliance and discuss any possible side effects.
- At 6 months – check efficacy of treatment by checking HbA1c and weight. Compare measurements with those taken at baseline and confirm whether patient meets NICE continuation criteria.
- At 12 months - Consider discontinuing treatment if the response at 6 months is not maintained, taking into consideration the progressive nature of type 2 diabetes.

Missed doses

If a dose is more than 12 hours late, the missed dose should not be taken. The next dose should be taken at the normal time.

Advice and Guidance

Healthcare professionals in General Practice may seek advice and guidance (as appropriate) from the Paediatric Diabetes consultant if:

- Problems arise tolerating the GLP 1 agonist or if the GLP 1 agonist must be discontinued for other medical reasons.
- Patient develops any acute/serious diabetes complications.
- The patient is a young woman with diabetes who is planning a pregnancy or becomes pregnant. If the patient becomes pregnant, treatment should be

stopped immediately, and the patient urgently referred to the Paediatric Consultant.

- The patient is receiving maintenance dose and following shared decision making, a higher dose (within marketing authorisation) would be beneficial.

Key references

ACDC: A Practical Approach to management of T2DM in CYP under 18 years

TYpe-2-guideline-ACDC-format-publish-2.pdf (a-c-d-c.org)

Zegluxen®(liraglutide): Zegluxen 6 mg/ml solution for injection in pre-filled pen - Summary of Product Characteristics (SmPC) - (emc) | 100225

Liraglutide: https://bnf.nice.org.uk/drugs/liraglutide/#indications-and-dose**.**

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Approved by BLMK Area Prescribing Committee: July 2023. Review Date: July 2026
Updated by BLMK Medicines Optimisation Team: April 2025. Review Date: April 2028

Version 2.0