Bedfordshire, Luton and Milton Keynes Health and Care Partnership

NHS

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

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

Approved by BLMK APC, October 2023
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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

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. NICE Guideline NG18 was recently updated with recommendations for additional treatments. The availability of the GLP-1 antagonist, **Dulaglutide (Trulicity®)** adds an additional option before moving to insulin.

GLP1 antagonist – Dulaglutide (Trulicity®)

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.

Dulaglutide is currently recommended for use in CYP with T2DM of 10 years of age or above if no improvement in glycaemic control (HbA1c >48mmol/mol or 6.5%) with metformin alone or with basal insulin therapy +/- diet and exercise.

Trulicity® is available in single use pre-filled pens of 4 different strengths. However, for use in CYP ≥ 10years old with T2DM only the **0.75mg** and **1.5mg** strengths are licensed. Each strength is contained in 0.5 ml solution and administered as a weekly subcutaneous (SC) injection.

Initiation of Dulaglutide (Trulicity®)

Initiation of **Dulaglutide (Trulicity®)** will be undertaken in secondary care and patients will be fully consented and counselled. The starting dose for paediatric patients 10 years and above is 0.75 mg once weekly. If needed, the dose can be increased to 1.5 mg once weekly after at least 4 weeks based on tolerability. The maximum dose is 1.5 mg once weekly.

- 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

Dulaglutide must be prescribed by the brand name of Trulicity®

- Prescribe 4 pens/devices per month.

- Each Trulicity pen is administered just one time, once used this should be disposed in an approved sharps bin.

Adverse effects & cautions

- Gastrointestinal (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.
- Hypoglycaemia risk in those taking insulin. Risk can be lowered by reducing dose of insulin.

For further details please see TRULICITY 1.5 mg solution for injection in pre-filled pen - Summary of Product Characteristics (SmPC) - (emc) (medicines.org.uk)

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 <15ml/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 and 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 it would be beneficial for patient to continue.

- At 12 months – At annual review 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 missed, it should be administered as soon as possible if there are at least 3 days (72 hours) until the next scheduled dose. If less than 3 days (72 hours) remain before the next scheduled dose, the missed dose should be skipped and the next dose should be administered on the regularly scheduled day. In each case, patients can then resume their regular once weekly dosing schedule.

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 (off-label) would be beneficial.

Key references

National Institute for Health and Care Excellence. Diabetes (type 1 and type 2) in children and young people: diagnosis and management (NICE guideline NG18). 2015. https://www.nice.org.uk/guidance/ng18.

BLMK APC Guidance for General Practitioners to support prescribing of Liraglutide for children and young people under 18 years with Type 2 Diabetes (T2DM) [July 2023] Guidance for General Practitioners to support prescribing of Liraglutide for children and young people under 18 years with Type 2 Diabetes (T2DM) – BLMKICB Medicines Management

Trulicity SPC TRULICITY 1.5 mg solution for injection in pre-filled pen - Summary of Product Characteristics (SmPC) - (emc) (medicines.org.uk)

BLMK Guidance for Prescribing Glucagon-like peptide 1 (GLP 1) agonists for adults with Type 2 Diabetes (T2DM)BLMK-APC-GLP-1-Agonist-Prescribing-Guideline-Dec-2022.pdf (icb.nhs.uk)