Insulin degludec (Tresiba®▼) for the treatment of diabetes mellitus in patients from the age of 1 year.

Commissioning Statement

Fylde and Wyre Clinical Commissioning Group has agreed not to fund the prescribing of Insulin degludec (Tresiba®▼) for the treatment of diabetes mellitus in patients from the age of 1 year.

This medicine is classified as BLACK for this indication

Summary of supporting evidence:

- Insulin degludec has consistently demonstrated non-inferiority to insulin glargine and insulin detemir in patients with type 1 or 2 diabetes, for reductions in $HbA1_c$.
- Due to the study design (treat-to-target) of the various studies, superiority of insulin degludec to other basal insulins could not be demonstrated.
- There were limitations with the available clinical studies due to their open label design and dose timing differences between insulin degludec and insulin glargine.
- The safety profile of insulin degludec in patients with type 1 or 2 diabetes, as monotherapy or in combination with oral antidiabetic agents, is in line with other insulin analogues.
- A meta-analysis demonstrated that incidence of nocturnal hypoglycaemia was significantly lower for insulin degludec versus insulin glargine in the type 2 diabetes studies (study identifier 3579, 3672, 3586; 3582), except for the time period 00:01 to 07:59 in the insulin naive type 2 diabetes studies. However reduction in nocturnal hypoglycaemia in type 1 diabetes was not significant according to the same meta-analysis.
- According to NICE guideline NG28 (Type 2 Diabetes in Adults: Management), patients should be initiated on isophane insulin before considering long-acting basal insulin as a treatment option.
- The LMMG has recommended that biosimilar insulin glargine can be used in type 1 and type 2 diabetes mellitus for new patients or patients assessed as requiring a medication change. For patients requiring once daily long-acting basal insulin, biosimilar insulin glargine should be considered as the first line treatment.
- The randomised controlled trials (RCTs) of insulin degludec specifically excluded patients with history of recurrent severe hypoglycaemia, or unawareness of hypoglycaemia, or cardiovascular disease. The applicability of the trial results to patients at high risk of these complications is unknown.
- Evidence from two real-world clinical studies (n=357 and n=35) concluded that insulin degludec was superior to insulin glargine in reducing hypoglycaemia in patients with

treatment-limiting problems such as recurrent severe hypoglycaemia or unawareness of hypoglycaemia.

- In paediatric patients the EMA (European Medicines Agency) concluded that glycaemic control was achieved with fewer daily insulin degludec units compared to insulin detemir.

For details around the colour classification system please refer to the website of the Lancashire Medicines Management Group at: http://www.lancsmmg.nhs.uk/