Prescribing Clinical Network

Surrey (East Surrey CCG, Guildford & Waverley CCG, North West Surrey CCG, Surrey Downs CCG & Surrey Heath), Crawley CCG and Horsham & Mid-Sussex CCG

Application for change in colour classification – Insulin degludec (Tresiba®) for Type 1 diabetes

GREEN - Non-Specialist Drugs GPs (or non-medical prescribers in primary care) are able to take full responsibility for initiation and continuation of prescribing
BLUE - Specialist Input WITHOUT Formal Shared Care Agreement Prescribing initiated and stabilised by specialist but has potential to transfer to primary care WITHOUT a formal shared care agreement
AMBER - Specialist Initiation WITH Shared Care Guidelines Prescribing initiated and stabilised by specialist but has potential to transfer to primary care under a formal shared care agreement
RED - Specialist ONLY drugs Treatment initiated and continued by specialist clinicians
BLACK – NOT recommended Not recommended for use in any health setting across Surrey and NW Sussex health economy

Medicine details

Name, brand name and manufacturer	Insulin degludec (Tresiba®) 100units/mL solution and 200units/mL solution. Manufacturer: Novo Nordisk Ltd. [1]	
Licensed indication, formulation and usual dosage	Treatment of diabetes mellitus in adults, adolescents and children from the age of 1 year. Insulin degludec 100units/mL solution and 200units/mL solution for injection in pre-filled pen (Tresiba® FlexTouch®) or cartridge. [1] Dose variable depending on needs of the patient.	
Traffic Light Status	**Current status** BLACK PCN policy statement: http://pad.res360.net/Content/Documents/PCN%2049-2013%20Insulin%20degludec%20for%20diabetes%20in%20adults.pdf	**Proposed status** AMBER

Reason for requested change

- **Insulin Degludec price has now dropped by 35% from £92.00 to £46.60 since the PCN issued its policy statement in Feb 2013. [2]**
- **The Scottish Medicines Consortium[3] has recommended insulin degludec as an option for adult patients with type 1 and type 2 diabetes in July 2016 following a resubmission. For more information please click HERE[3]**
- **Since the original PCN decision NICE have produced evidence summaries, ESNM241[4] and ESMN252[5] in September 2013 which evaluated degludec for type 1 and type 2 diabetes patients. The evidence in these summaries is the same as the evidence that was used to make the original PCN decision.**
- **NICE have since the PCN review issued guidance NG17[6]: Type 1 diabetes in adults: diagnosis and management in August 2015 which asks prescribers to consider other basal insulin regimens for adults with type 1 diabetes only if insulin glargine and detemir do not deliver agreed targets. When choosing an alternative insulin regimen, the person's**

preferences and acquisition cost should be taken into account. The guidance does not exclude specifically the use of insulin degludec.

- **Key evidence since the NICE evidence summaries were published is the study by Thalange[7] et al looking at use of insulin degludec in combination with bolus insulin aspart in children and adolescents with type 1 diabetes. In this study, insulin degludec (IDeg) once-daily was compared with insulin detemir (IDet) once- or twice-daily, with prandial insulin aspart in a treat-to-target, randomized controlled trial in children 1–17 yr with type 1 diabetes, for 26 wk (n=350), followed by a 26-wk extension (n=280).**
  Both treatments were well tolerated with comparable rates of adverse events. IDeg achieved equivalent long-term glycaemic control, as measured by HbA1c with a significant FPG reduction at a 30% lower basal insulin dose when compared with IDet. Rates of hypoglycaemia did not differ significantly between the two treatment groups; however, hyperglycaemia with ketosis was significantly reduced in those treated with IDeg.

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Key Considerations

Cost implications to the local health economy

Annual cost per patient:

In July 2016 the price of degludec 100units/ml was reduced from £72.00 to £46.60. Annual cost per patient depends on the dose of insulin a patient uses. [2]

Insulin	Dose Regimen	Cost per year (£)
Insulin degludec	**Dose according to requirements (eg 30 to 60 units per day) by once daily subcutaneous injection**	**339 to 678**
Insulin detemir (Levemir ®)	Dose according to requirements (eg 30 to 60 units per day) by once or twice daily subcutaneous injection	306 to 612
Insulin glargine (Lantus®)	Dose according to requirements (eg 30 to 60 units per day) by once daily subcutaneous injection	302 to 604
Insulin glargine (Toujeo®)	Dose according to requirements (eg 30 to 60 units per day) by once daily subcutaneous injection	268 to 536
Insulin glargine (Abasaglar® [biosimilar])	Dose according to requirements (eg 30 to 60 units per day) by once daily subcutaneous injection	257 to 514

Doses are for general comparison and do not imply therapeutic equivalence. The dose should be individualised according to individual patient requirements. An example dose range of 30 units to 60 units per day has been used based on average insulin doses across the studies of insulin degludec.

BASAL INSULIN	Price per pack of pre-filled pens	Price per 100 units of insulin for comparison[2]
Insulin isophane 100units/ml **(Insuman® Basal Solostar®)** 3ml x 5	£19.80	£1.32
Insulin insulatard 100units/ml **(Innolet® device only)** 3ml x 5	£20.40	£1.36
Insulin isophane 100units/ml **(Humulin® I KwikPen®)** 3ml x 5	£28.44	£1.90
Insulin glargine 100units/ml (**Abasaglar® KwikPen®**) 3ml x 5	£35.28	£2.35
Insulin glargine 300units/ml (**Toujeo® SoloStar®**) 1.5ml x 3	£33.13	£2.45
Insulin glargine 100units/ml (**Lantus® SoloStar®**) 3ml x 5	£41.50	£2.77
Insulin Detemir 100units/ml (**Levemir® FlexPen®**) 3ml x 5	£42.00	£2.80
Insulin degludec 100units/ml (**Tresiba® FlexTouch®**) 3ml x 5	£46.60	£3.11
Insulin degludec 200units/ml (**Tresiba® FlexTouch®**) 3ml x 3	£55.92	£3.11

Availability of patient access scheme and details (if appropriate): N/A

Availability of homecare service (if appropriate): N/A

Impact to current prescriber or medication initiator

- **Insulin degludec currently has a black status and as such prescription is currently not recommended (although there is some prescribing happening).**
- **If the traffic light status was to be changed to amber this would provide an increased choice of therapy for patients who are very unstable.**
- **Insulin degludec would be considered for patients:**
    - **In whom the basal insulins glargine and detemir have been used/considered in patients but these insulins have not been effective enough to achieve agreed targets in line with NICE NG17.**
    - **Who persistently suffer from nocturnal hypoglycaemia and may otherwise have to start pump therapy.**
    - **Who recurrently attend hospital for recurrent DKA- there is local data that is available to show benefit for this that was presented at the May16 Diabetes UK conference.**
    - **Who significantly suffer from day to day fluctuations of their blood glucose levels and have tried other basal insulins such as detemir and glargine.**

Impact to proposed prescriber or medication initiator

- **Prescribers and other healthcare professionals who currently manage insulin patients in primary care may need some education about the new insulin and the use of the new pen device.**
- **Insulin degludec offers a further treatment option to those requiring insulin therapy, which provides an extended duration of action and the ability to change the time of day when it can be administered, thus providing greater flexibility for those healthcare professionals or carers administering insulin to patients in the community.**

Impact to patients

- **Access to a therapy that could improve diabetes control.**
- **Insulin degludec offers a further treatment option to those requiring insulin therapy, which provides an extended duration of action and the ability to change the time of day when it can be administered, thus providing greater flexibility. [1]**
- **Potentially patients would experience fewer episodes of hypoglycaemia especially nocturnal hypoglycaemia.[3]**
- **Patients who use a large volume of insulin to have access to a wider choice of more concentrated insulins (currently the only more concentrated insulin available is insulin glargine which comes in a 300units/ml formulation). This will help to reduce occurrence of lipohypertrophy, be less painful for these patients when injecting the insulin and more convenient for those with dexterity problems.**

Additional comments

The Scottish Medicines Consortium produced the following advice on 8th August 2016:
Following a second resubmission insulin degludec (Tresiba®) is accepted for use within NHS Scotland for the treatment of diabetes mellitus in adults. In three phase III studies in adults with type 1 diabetes mellitus, and five phase III studies in adults with type 2 diabetes mellitus, insulin degludec was non-inferior to other long-acting insulin analogues, assessed by the mean change in glycosylated haemoglobin (HbA1c).

Insulin degludec is also indicated for the treatment of diabetes mellitus in adolescents and children from the age of 1 year. The holder of the marketing authorisation has not made a submission to SMC regarding this indication and as a result SMC cannot recommend its use within NHS Scotland.

Identified lead for development of necessary documents e.g. shared care agreement

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Declaration of interest

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References

1. Summary of Product Characteristics: Tresiba: Novo Nordisk https://www.medicines.org.uk/emc/medicine/27359 Accessed August 2016.
2. Drug tariff: https://www.drugtariff.co.uk/DrugInfo/drugsearch.aspx?search=degludec Accessed August 2016.
3. Scotttish Medicines Consortium advice: insulin degludec (Tresiba) https://www.scottishmedicines.org.uk/SMC_Advice/Advice/856_13_insulin_degludec_Tresiba/insulin_degludec_Tresiba_2nd_Resubmission Accessed August 2016.
4. National Institute of Care and clinical Excellence: Type 1 diabetes: insulin degludec NICE advice [ESNM24]; Accessed August 2016: https://www.nice.org.uk/advice/esnm24/chapter/Key-points-from-the-evidence
5. National Institute of Care and clinical Excellence: Type 2 diabetes: insulin degludec NICE advice [ESNM25]; Accessed August 2016: https://www.nice.org.uk/advice/esnm25/chapter/key-points-from-the-evidence
6. National Institute of Care and clinical Excellence: Type 1 diabetes in adults: diagnosis and management: NG17; https://www.nice.org.uk/guidance/ng17/chapter/1-Recommendations#insulin-therapy-2 Accessed August 2016.
7. Thalange et al: Insulin degludec in combination with bolus insulin aspart is safe and effective in children and adolescents with type 1 diabetes; Paediatric Diabetes : Volume 16, Issue 3, pages 164–176, May 2015.