South East London Integrated Medicines Optimisation Committee
Formulary recommendation

Reference:	**136**
Intervention:	**Insulin degludec 100 units/ml and 200 units per ml (Tresiba™ FlexTouch and pen fill cartridges) for children and young people over 12 years old with Type 1 diabetes** (Insulin degludec is a high strength, long-acting insulin analogue)
Date of Decision:	**July 2022**
Date of Issue:	**October 2022 (time limited approval for 12 months)**
Recommendation:	**Amber 2 – initiation and first prescription from the specialist diabetes team [Note: Insulin degludec is for hospital only prescribing and supply when use is in children and young people with Type 2 diabetes]**
Further Information	• **This formulary recommendation supersedes the advice for children and young people eligible for treatment with Tresiba™ in formulary recommendation 059 (issued in 2017).** • Insulin choice in children and young people with Type 1 diabetes mellitus (T1DM) should be in line with NICE guideline NG18 • Insulin degludec (Tresiba™) is accepted for use in South East London as **one of the first line options alongside** other long-acting insulins (insulin glargine and insulin detemir) in children and young people **over 12 years with T1DM**. • The decision on which long-acting insulin to use is based on clinical opinion and patient factors. As these factors may be multifactorial, the clinician will make the decision based on their clinical assessment, in discussion with the patient. • There should be regular review by the paediatric diabetes specialist team of eligible patients who are initiated or switched to Tresiba™ to ensure ongoing effectiveness. • Children and young people over 12 years with T1DM established on Tresiba™ within the local paediatric diabetes service who are transitioning to local adult services should be allowed to continue on Tresiba as adults if it is clinically appropriate to do so. The same consideration should also be given to children and young people who move to SEL from another area on existing insulin degludec therapy. • Existing arrangements for the use of Tresiba™ in children and young people with **Type 2 diabetes** will remain in place. This cohort of patients may be considered for therapy in line with the criteria above but **prescribing must remain under specialist care** in view of the lack of current experience of use in this patient cohort. This will enable experience to be gained in a specialist setting and allow outcomes to be evaluated (see points below). • A report summarising outcomes in relation to the use of insulin degludec in children and young people over 12 years with T1DM will be presented back to the Committee in 1 year. This report will be co-ordinated across SEL by the original formulary applicant and will include: - The number of patients treated and the indication (Type 1 or Type 2 diabetes) - The number of patients switched to Tresiba™, [including pre and post insulin Tresiba™ dose] - Whether use is in line with this recommendation - Impact on patient related outcomes, such as (i) diabetes control [including HbA1c] (ii) adverse effects (iii) compliance (iv) hospital admissions [in particular for diabetic ketoacidosis] - The number of patients discontinuing treatment and reasons for stopping
Shared Care/ Transfer of care required:	N/A

Cost Impact for agreed patient group	• It is estimated there will be approximately 60 patients across SEL per annum (20 patients per Trust) eligible for treatment with Tresiba™ in this setting (all patients from SEL) • If Tresiba™ is used as an alternative to insulin glargine in 60 patients at a dose of 20units/day, this would equate to approximately £3,500 increase cost for SEL (~ <£500 per 100,000 population). • Costs would be lower than this if lower doses of Tresiba™ were required as compared to other insulin analogues.
Usage Monitoring & Impact Assessment	**Acute Trusts:** • Monitor and audit usage of Tresiba™ as outlined in the "For information" section and report back to the Committee in 12 months (data to be collated and presented no • later than **October 2023**).
	SEL Borough Medicines Optimisation Teams: • Monitor ePACT2 data and exception reports from GPs if inappropriate prescribing requests are made to primary care.
Evidence reviewed	**References (from evidence review)** 1. Uptodate.com. 2022. UpToDate. Available here [Accessed 10 July 2022]. 2. Medicines.org.uk. 2017. Tresiba 100 units/mL, 200 units/mL Pre filled (FlexTouch), 100 units/mL Cartridge (Penfill) - Summary of Product Characteristics (SmPC) - (emc). Available here [Accessed 10 July 2022]. 3. Nice.org.uk. 2022. Recommendations | Diabetes (type 1 and type 2) in children and young people: diagnosis and management | Guidance | NICE. Available here [Accessed 10 July 2022]. 4. Cks.nice.org.uk. 2020. Scenario: Insulin therapy - type 1 diabetes | Management | Insulin therapy in type 1 diabetes | CKS | NICE. Available here [Accessed 10 July 2022]. 5. Selondonjointmedicinesformulary.nhs.uk. 2022. South East London Joint Medicines Formulary. Available here [Accessed 10 July 2022]. 6. Thalange, N., Deeb, L., Iotova, V., Kawamura, T., Klingensmith, G., Philotheou, A., Silverstein, J., Tumini, S., Ocampo Francisco, A., Kinduryte, O. and Danne, T., 2015. Insulin degludec in combination with bolus insulin aspart is safe and effective in children and adolescents with type 1 diabetes. Pediatric Diabetes, 16(3), pp.164-176. 7. Rewers, M., Pillay, K., de Beaufort, C., Craig, M., Hanas, R., Acerini, C. and Maahs, D., 2014. Assessment and monitoring of glycemic control in children and adolescents with diabetes. Pediatric Diabetes, 15(S20), pp.102-114. 8. Battelino, T., Deeb, L., Ekelund, M., Kinduryte, O., Klingensmith, G., Kocova, M., Kovarenko, M. and Shehadeh, N., 2018. Efficacy and safety of a fixed combination of insulin degludec/insulin aspart in children and adolescents with type 1 diabetes: A randomized trial. Pediatric Diabetes, 19(7), pp.1263-1270. 9. Thalange, N., Deeb, L., Klingensmith, G., Franco, D., Bardtrum, L., Tutkunkardas, D. and Danne, T., 2019. The rate of hyperglycemia and ketosis with insulin degludec-based treatment compared with insulin detemir in pediatric patients with type 1 diabetes: An analysis of data from two randomized trials. Pediatric Diabetes, 20(3), pp.314-320. 10. Schmitt, J. and Scott, M., 2019. Insulin Degludec in Adolescents with Type 1 Diabetes: Is Newer Better? – A Retrospective Self-Control Case Series in Adolescents with a History of Diabetic Ketoacidosis. Hormone Research in Paediatrics, 92(3), pp.179-185. 11. Predieri, B., Suprani, T., Maltoni, G., Graziani, V., Bruzzi, P., Zucchini, S. and Iughetti, L., 2018. Switching From Glargine to Degludec: The Effect on Metabolic Control and Safety During 1- Year of Real Clinical Practice in Children and Adolescents With Type 1 Diabetes. Frontiers in Endocrinology, 9 Thalange, N., Gundgaard, J., Parekh, W. and Tutkunkardas, D., 2019. Cost analysis of insulin degludec in comparison with insulin detemir in treatment of children and adolescents with type 1 diabetes in the UK. BMJ Open Diabetes Research & Care, 7(1), p.e000664

NOTES:

a) SEL IMOC recommendations and minutes are available publicly via the website.

b) This SEL IMOC recommendation has been made on the cost effectiveness, patient outcome and safety data available at the time. The recommendation will be subject to review if new data becomes available, costs are higher than expected or new NICE guidelines or technology appraisals are issued.

c) **Not to be used for commercial or marketing purposes. Strictly for use within the NHS.**