South East London Integrated Medicines Optimisation Committee
Formulary recommendation

Reference	**151**
Intervention:	**Lyumjev™ insulin (insulin lispro) 100 units/mL for the management of diabetes mellitus in adults** (Lyumjev™ is a fast-acting lispro formulation)
Date of Decision:	**August 2024**
Date of Issue:	**September 2024**
Recommendation:	**Amber 2 – initiation and first prescription from the specialist diabetes team**
Further Information	• Lyumjev™ is a novel formulation of insulin lispro described as ultra-rapid lispro (URLi). The addition of the locally acting excipients citrate and treprostinil result in more rapid absorption of insulin compared to the conventional insulin lispro, Humalog™. • Lyumjev™ is a mealtime insulin for subcutaneous administration up to 2 minutes before the start of the meal, with the option to administer up to 20 minutes after starting the meal. • Lyumjev™ 100 unit/mL formulations are accepted for use in South East London as a **second-line** fast acting insulin option in people with diabetes mellitus where the first line rapid acting insulin analogue does not provide adequate post-prandial plasma glucose (PPG*) control. • Use of Lyumjev™ 100 unit/mL formulations as a second-line option is approved in the following patient cohorts only: - Adult patients with Type 1 diabetes mellitus (T1DM) or cystic fibrosis related diabetes with sub-optimal control of PPG excursions that is impairing ability to achieve target glycaemic control. - Pregnant women with diabetes (T1DM or Type 2 DM) or gestational diabetes where post prandial control is of particular importance for foetal health. - Where a post-meal insulin injection would be of benefit to PPG control due to social, physiological or psychological reasons (Lyumjev™ can be administered up to 20 minutes after starting the meal versus Novorapid™ and Humalog™ which are to be administered pre-meal only). • The criteria for use of Lyumjev™ 100 unit/mL formulations are the same as the criteria for the use of Fiasp™ (fast-acting insulin aspart), as outlined in Formulary Recommendation 115. • Patients changed to Lyumjev™ must be adequately counselled on the new fast acting insulin by the initiating prescriber. • There should be regular review by the diabetes specialist of eligible patients who are switched to Lyumjev™ to ensure ongoing effectiveness. • A number of fast-acting insulins are included on the SEL formulary. Any inadvertent substitution has the potential to impact on patient safety. In view of this, these insulins must be prescribed **BY BRAND** to ensure brand continuity in people with diabetes and to minimise the risk of substitution/medication errors/patient harm. *PPG is the plasma glucose concentration after eating.
Shared Care/ Transfer of care required:	N/A

Cost Impact for agreed patient group	The cost implication from switching patients from Humalog™, Novorapid™ or Fiasp™ would be cost neutral, with some negligible price variations between certain formulations of Lyumjev™ and the alternative products. This recommendation will be subject to ongoing review in line with the availability of biosimilar preparations of insulin lispro and their implementation.
Usage Monitoring & Impact Assessment	**Acute Trusts:** • Providers to monitor use and submit usage data and audit reports (against this recommendation) upon request to the IMOC.
	SEL Borough Medicines Teams: • Monitor EPACT2 data • Exception reports from GPs if inappropriate prescribing requests are made to primary care.
Evidence reviewed	**References (from evidence evaluation)** 1. NICE Clinical Knowledge Summaries. Type 1 diabetes. Available online at https://cks.nice.org.uk/topics/diabetes-type-1/ (Accessed 07 August 2024) 2. NICE Clinical Knowledge Summaries. Type 2 diabetes. Available online at https://cks.nice.org.uk/topics/diabetes-type-2/ (Accessed 07 August 2024) 3. Type 1 diabetes in adults: Diagnosis and management: Guidance NG17 NICE. Available at: https://www.nice.org.uk/guidance/ng17 (Accessed: 07 August 2024) 4. Type 2 diabetes in adults: management: Guidance NG28 NICE. Available at: https://www.nice.org.uk/guidance/ng28 (Accessed: 07 August 2024) 5. Russell-Jones D et al. Fast-acting insulin aspart improves glycaemic control in basal-bolus treatment for Type 1 diabetes: Results of a 26-week multicentre, active-controlled, treat-to-target, randomised, parallel-group trial (Onset 1) (2017). Diabetes Care; volume 30: pages 943-950. 6. Summary of Product Characteristics. Lyumjev 100 units/mL KwikPen solution for injection in pre-filled pen. Last updated 16/07/24. Accessed online via: https://www.medicines.org.uk/emc/product/11536/smpc. (Accessed 07 August 2024) 7. Klaff L, Cao D, Dellva MA, et al. Ultra rapid lispro improves postprandial glucose control compared with lispro in patients with type 1 diabetes: Results from the 26-week PRONTO-T1D study. Diabetes Obes Metab. 2020;22: 1799–1807. https://doi.org/10.1111/dom.14100 8. Blevins T, Zhang Q, et al. PRONTO-T2D Investigators. Randomized Double-Blind Clinical Trial Comparing Ultra Rapid Lispro With Lispro in a Basal-Bolus Regimen in Patients With Type 2 Diabetes: PRONTO-T2D. Diabetes Care. 2020 Dec;43(12):2991-2998. doi: 10.2337/dc19-2550 9. Bode BW, Garg SK, et al. Compatibility and Safety of Ultra Rapid Lispro with Continuous Subcutaneous Insulin Infusion in Patients with Type 1 Diabetes: PRONTO-Pump Study. Diabetes Technol Ther. 2021 Jan;23(1):41-50. doi: 10.1089/dia.2020.0224 10. Malecki MT, Cao D, et al. Ultra-Rapid Lispro Improves Postprandial Glucose Control and Time in Range in Type 1 Diabetes Compared to Lispro: PRONTO-T1D Continuous Glucose Monitoring Substudy. Diabetes Technol Ther. 2020 Nov;22(11):853-860. doi: 10.1089/dia.2020.0129 11. Guide to HbA1c. Accessed online via: Diabetes.co.uk. (Accessed: 07 August 2024) 12. Human Medicine European 2020 Public Assessment Report (EPAR): Liumjev. Available online via: https://www.ema.europa.eu/en/documents/assessment-report/liumjev-epar-public-assessment-report_en.pdf (Accessed: 07 August 2024) 13. Summary of Product Characteristics. Treprostinil 1 mg/ml Solution For Infusion. Last updated 14/12/23. Accessed online via: https://www.medicines.org.uk/emc/product/12453/smpc (Accessed 07 August 2024) 14. Diabetes in pregnancy: management from preconception to the postnatal period. NICE NG3. Available at: https://www.nice.org.uk/guidance/ng28 (Accessed: 07 August 2024)

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