South East London Integrated Medicines Optimisation Committee
(SEL IMOC, formerly the SEL Area Prescribing Committee)
Formulary recommendation

Reference	**058**
Intervention:	**Insulin glargine 300units/ml (Toujeo® SoloStar® and DoubleStar® insulin pen devices) for type 2 diabetes mellitus** (Toujeo® is a high strength, long acting insulin glargine analogue)
Date of Decision:	**November 2016, updated December 2020**
Date of Issue:	**December 2016, re-issued January 2021 to include the Toujeo™ DoubleStar™ insulin pen device**
Recommendation:	**Amber 2 – initiation and first prescription supplied by the specialist diabetes team**
Further Information:	· Insulin choice in people with type 2 diabetes mellitus should be in line with NICE guideline 28. · First line insulin choice in type 2 diabetes is NPH (human) insulin. · Where a long acting insulin analogue is considered appropriate (in line with NICE criteria), biosimilar insulin glargine 100 units/ml is the preferred option locally, taking individual patient factors into account. · Toujeo® 300 units/ml (in the SoloStar® or DoubleStar® insulin pen devices) may be considered in people with type 2 diabetes mellitus prescribed a long acting insulin analogue (insulin glargine or insulin detemir 100units/ml) who meet the following criteria: 1. Experience painful injections with high volumes **(>60 units** in a single injection) of their current 100 units/ml long acting insulin analogue **AND/OR** 2. Suffer from recurrent episodes of nocturnal hypoglycaemia · The Toujeo SoloStar pen device is reserved for patients on doses greater than or equal to 60 units but less than 80 units daily of their current 100 units/ml long acting insulin analogue. · The Toujeo DoubleStar pen device is reserved for patients who are on doses greater than or equal to 80 units Toujeo 300units/ml insulin daily. · Patients should only be changed to or from Toujeo or initiated on treatment with Toujeo by a specialist in the care of diabetes. · There are a number of licensed insulin glargine preparations available within the UK, including biosimilars. · **NOTE:** Insulin glargine 100 units/ml and Toujeo 300units/ml are **NOT** bioequivalent and are **NOT** directly interchangeable. Dose adjustment is needed when people are changed over to Toujeo. · These products must be prescribed **BY BRAND** to minimise the risk of medication errors. · The potency of Toujeo is stated in units. These units are **exclusive** to Toujeo and are **NOT** the same as IU or the units used to express the potency of other insulin analogues. · The dose window of the Toujeo pen devices shows the number of Toujeo units to be injected – this differs for the two available pen devices. Patients should read and understand the patient leaflet and education material and should be provided with training on the correct use of their Toujeo pen device by their diabetes specialist. Risk minimisation materials are also available for Toujeo pen devices to support patient and healthcare professional education. · Toujeo is given once daily, preferably at the same time each day but can be up to 3 hours before or after usual time.
Shared Care/ Transfer of care required:	N/A

Cost Impact for agreed patient group	· The cost of Toujeo and other basal insulins will depend on the preparation chosen and the insulin dosage used. · Toujeo has been priced at a level to match the daily cost of Lantus on the basis of average insulin glargine usage in the EDITION trials. · The formulary application estimates 140 patients in total from King's Health Partners might be suitable for Toujeo. An estimate may therefore be 280 patients for SEL as a whole. · This equates to a total £3,360 increased costs per annum compared to Lantus and £26,900 increased costs compared to Abasaglar (on the basis of a 17% dose increase between insulin 100units/ml and Toujeo). · It should be noted that Toujeo is more expensive vs. biosimilar insulin glargine 100 units/ml. Once further brands of insulin glargine are launched savings from the use of biosimilar insulin glargine 100 units/ml will be greater. However, Toujeo will only be considered after insulin glargine 100 units per ml where the criteria outlined in the "Further Information" section are met. · No additional, significant cost impact is anticipated from the formulary inclusion of the Toujeo DoubleStar pen device (January 2021).
Usage Monitoring & Impact Assessment	· Providers to monitor use and submit usage data and audit reports (against this recommendation) upon request to the IMOC. · CCG Borough Medicines Optimisation teams to monitor ePACT 2 data and exception reports from GPs if inappropriate prescribing requests are made to primary care.
Evidence reviewed	**References (from evidence evaluation)** 1. Type 2 diabetes mellitus in adults: high-strength insulin glargine 300 units/ml (Toujeo). NICE ESNM65 2015. 2. Type 2 diabetes in adults: Diagnosis and management. NICE guideline 28 (NG28) Dec 2015. 3. Type 1 diabetes mellitus in adults: high-strength insulin glargine 300 units/ml (Toujeo). NICE ESNM62 2015 4. Type 1 diabetes in adults: diagnosis and management. NICE guideline 17 (NG17) Aug 2015 5. Summary of Product Characteristics: Toujeo. Available online here (accessed 13/05/2016) 6. Riddle MC, Bolli GB, Ziemen M et al. (2014) New insulin glargine 300 units/mL versus glargine 100 units/mL in people with type 2 diabetes using basal and mealtime insulin: glucose control and hypoglycemia in a 6-month randomized controlled trial (EDITION 1). Diabetes Care 37: 2755–62 7. Yki-Jarvinen H et al. (2014) New insulin glargine 300 units/mL versus glargine 100 units/mL in people with type 2 diabetes using oral agents and basal insulin: glucose control and hypoglycemia in a 6-month randomized controlled trial (EDITION 2). Diabetes Care 37; 3235–43 8. Bolli GB, Riddle MC, Bergenstal RM et al. (2015) New insulin glargine 300 U/ml compared with glargine 100 U/ml in insulin-naive people with type 2 diabetes on oral glucose-lowering drugs: a randomized controlled trial (EDITION 3). Diabetes, Obesity and Metabolism 17: 386–94 9. Riddle MC, Yki-Jarvinen H, Bolli GB (2015) One-year sustained glycaemic control and less hypoglycaemia with new insulin glargine 300 U/ml compared with 100 U/ml in people with type 2 diabetes using basal plus meal-time insulin: the EDITION 1 12-month randomized trial, including -month extension. Diabetes, Obesity and Metabolism 17: 835–42 10. Yki-Jarvinen H, Bergenstal RM, Bolli GB et al. (2015) Glycaemic control and hypoglycaemia with new insulin glargine 300 U/ml versus insulin glargine 100 U/ml in people with type 2 diabetes using basal insulin and oral antihyperglycaemic drugs: the EDITION 2 randomized 12-month trial including 6-month extension. Diabetes, Obesity and Metabolism 17: 1142—9 11. Ritzel R, Roussel R, Bolli GB et al. (2015) Patient-level meta-analysis of the EDITION 1, 2 and 3 studies: glycaemic control and hypoglycaemia with new insulin glargine 300 U/ml versus glargine 300 U/ml in people with type 2 diabetes. Diabetes, Obesity and Metabolism 17: 859–67 12. Home PD, Bergenstal RM, Bolli GB et al. (2015) New insulin glargine 300 units/ml versus glargine 300 units/ml in people with type 1 diabetes: a randomized, phase 3a, open-label clinical trial (EDITION 4). Diabetes Care published online before print, doi: 10.2337/dc15-0249 13. Toujeo: Public Assessment Report. European Medicines Agency, February 2015. 14. In Use Product Safety Assessment for Toujeo and Abasaglar. UKMi 2015 15. High strength, fixed combination and biosimilar insulin products: minimising the risk of medication error, Drug Safety Update, April 2015. Available online here (accessed 14/06/2016). 16. Insulin Glargine (Toujeo) Scottish Medicines Consortium September 2015. Available online here (accessed 14/06/2016) 17. Prescription Cost Analysis 2015. NHS Digital. Available online here (accessed 07/11/2016)

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