South East London Integrated Medicines Optimisation Committee
Formulary recommendation

Reference	**111**
Intervention:	**Semaglutide (Ozempic™) 0.25mg, 0.5mg and 1mg solution for injection in a pre-filled pen for Type 2 diabetes mellitus** (Semaglutide is a long-acting glucagon-like peptide-1 [GLP-1] receptor agonist. It is administered as a once weekly injection)
Date of Decision	**September 2019, updated January 2023 following re-categorisation from Amber 3 to Amber 2**
Date of Issue:	**October 2019, re-issued June 2023**
Recommendation:	**Amber 2 – initiation and minimum one month supply by a diabetes specialist (Consultant or GPwER or appropriately trained diabetes specialist practitioner)**
Further Information	• Semaglutide is accepted for use in South East London in line with NICE Clinical Guideline 28 (last updated June 2022) on the management of Type 2 diabetes mellitus and the SEL GLP-1 pathway. • NICE recommends a GLP-1 agonist can be considered in a triple therapy regimen in combination with metformin and a sulfonylurea for patients with Type 2 diabetes if: - Triple therapy with metformin and 2 other oral agents is not effective, not tolerated or contraindicated, AND (i) BMI ≥ 35kg/m^2 (adjusted accordingly for ethnicity) **and** specific psychological or other medical problems associated with obesity **OR** (ii) BMI ≤ 35kg/m^2 **and** - For whom insulin therapy would have significant occupational implications **OR** - weight loss would benefit other significant obesity related co- morbidities • Semaglutide will be prescribed and treatment managed in line with the SEL GLP-1 pathway • The GLP-1 information sheet should be shared alongside the clinic letter when the transfer of prescribing request is made to primary care under the Amber 2 arrangement. • In line with NICE, treatment with semaglutide will only be continued if the person with Type 2 diabetes has had a beneficial metabolic response (a reduction of at least 11 mmol/mol [1.0%] in HbA1c and a weight loss of at least 3% of initial body weight in 6 months). • Semaglutide should only be offered in combination with insulin with specialist care advice and ongoing support from a consultant-led multidisciplinary team*. • The decision on choice of GLP-1 agent will be made by the initiating clinician in discussion with the patient, including individual patient factors. • To further simplify the number of GLP-1 agents on the formulary, weekly exenatide and daily lixisenatide will be removed from the formulary for new patients. * The NICE guideline notes that a consultant-led multidisciplinary team may include a wide range of staff based in primary, secondary and community care.
Shared Care/ Transfer of care required:	N/A
Cost Impact for agreed patient group	• Semaglutide is similar in cost to other GLP-1 agents, therefore its addition to the formulary is expected to be cost neutral.
Usage Monitoring & Impact Assessment	**Acute Trust/Specialist community diabetes service providers:** • Monitor use and submit usage data and audit reports (against this recommendation and the SEL GLP-1 treatment pathway) upon request to the IMOC

	SEL Borough Medicines Optimisation Teams • Monitor ePACT2 data. • Exception reports from GPs if inappropriate prescribing requests are made to primary care.
Evidence reviewed	**References (from evidence evaluation)** 1. Scottish Medicines Consortium. Semaglutide 0.25mg, 0.5mg and 1mg solution for injection in pre-filled pen (Ozempic®). SMC2092. Published 14 January 2019. 2. Summary of Product Characteristics. Ozempic. Last updated December 2018. Accessed online via: https://www.medicines.org.uk/emc/product/9728/smpc. Last accessed 03/09/19. 3. NICE. Type 2 diabetes in adults: management. NICE guideline [NG28]. Last updated August 2019. Accessed online via: https://www.nice.org.uk/guidance/ng28. Last accessed 03/09/19. 4. Prof Bo Ahrén et al. Efficacy and safety of once-weekly semaglutide versus once-daily sitagliptin as an add-on to metformin, thiazolidinediones, or both, in patients with type 2 diabetes (SUSTAIN 2): a 56-week, double-blind, phase 3a, randomised trial (2017). Lancet Diabetes and Endocrinology; 5(5): pages 341-354. 5. Ahmann A et al. Efficacy and Safety of Once-Weekly Semaglutide Versus Exenatide ER in Subjects With Type 2 Diabetes (SUSTAIN 3): A 56-Week, Open-Label, Randomized Clinical Trial (2018). Diabetes Care; 41(2): pages 258-266. 6. Aroda V et al. Efficacy and safety of once-weekly semaglutide versus once-daily insulin glargine as add-on to metformin (with or without sulfonylureas) in insulin-naive patients with type 2 diabetes (SUSTAIN 4): a randomised, open-label, parallel-group, multicentre, multinational, phase 3a trial (2017). Lancet Diabetes and Endocrinology; 5(5): pages 355-366. 7. Rodbard H et al. Semaglutide Added to Basal Insulin in Type 2 Diabetes (SUSTAIN 5): A Randomized, Controlled Trial (2018). The Journal of Clinical Endocrinology and Metabolism; 103(6): pages 2291-2301. 8. Pratley R et al. Semaglutide versus dulaglutide once weekly in patients with type 2 diabetes (SUSTAIN 7): a randomised, open-label, phase 3b trial (2018). Lancet Diabetes and Endocrinology; 6(4): pages 275-286. 9. Zinman B et al. Semaglutide once weekly as add-on to SGLT-2 inhibitor therapy in type 2 diabetes (SUSTAIN 9): a randomised, placebo-controlled trial (2019). Lancet Diabetes and Endocrinology; 7(5): pages 356-367. 10. Marso S et al. Semaglutide and Cardiovascular Outcomes in Patients with Type 2 Diabetes (2016). The New England Journal of Medicine; 375: pages 1834-1844. 11. Sorli C et al. Efficacy and safety of once-weekly semaglutide monotherapy versus placebo in patients with type 2 diabetes (SUSTAIN 1): a double-blind, randomised, placebo-controlled, parallel-group, multinational, multicentre phase 3a trial (2017). Lancet Diabetes and Endocrinology; 5(4): pages 251-260. 12. European Medicines Agency. Ozempic public assessment report. Accessed online via: https://www.ema.europa.eu/en/medicines/human/EPAR/ozempic. Last accessed 10/09/19.

NOTES:

a) SEL IMOC recommendations and minutes are available publicly on 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**