

**South East London Integrated Medicines Optimisation Committee
Formulary recommendation**

Reference	053
Intervention:	Dulaglutide (Trulicity™) 0.75mg, 1.5mg, 3mg and 4.5mg solution for injection for Type 2 diabetes mellitus (Dulaglutide is a long-acting glucagon-like peptide-1 (GLP-1) receptor agonist. It is administered as a once weekly injection)
Date of Decision	August 2016, updated January 2023 following re-categorisation from Amber 3 to Amber 2 and formulary inclusion of the 3mg and 4.5mg strength preparations
Date of Issue:	September 2016, 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	<ul style="list-style-type: none"> • Dulaglutide 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. • 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: <ul style="list-style-type: none"> - Triple therapy with metformin and 2 other oral agents is not effective, not tolerated or contraindicated, AND (i) BMI $\geq 35\text{kg/m}^2$ (adjusted accordingly for ethnicity) and specific psychological or other medical problems associated with obesity OR (ii) BMI $\leq 35\text{kg/m}^2$ and - For whom insulin therapy would have significant occupational implications OR - weight loss would benefit other significant obesity related co- morbidities • Dulaglutide 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 dulaglutide 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). • Dulaglutide should only be offered in combination with insulin with specialist care advice and ongoing support from a consultant-led multidisciplinary team*. • To simplify the number of GLP-1 agents on the formulary, twice daily exenatide will be removed from the formulary. <p>* The NICE guideline notes that a consultant-led multidisciplinary team may include a wide range of staff based in primary, secondary and community care.</p>
Shared Care/ Transfer of care required:	N/A
Cost Impact for agreed patient group	<ul style="list-style-type: none"> • Dulaglutide 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	<p>Acute Trust/Specialist community diabetes service providers:</p> <ul style="list-style-type: none"> • Monitor use and submit usage data and audit reports (against this recommendation and the SEL GLP-1 treatment pathway) upon request to the IMOC

	<p>SEL Borough Medicines Optimisation Teams:</p> <ul style="list-style-type: none"> • Monitor ePACT2 prescribing data. • Exception reports from GPs if inappropriate prescribing requests are made to primary care.
<p>Evidence reviewed</p>	<p>References (from evidence evaluation)</p> <ol style="list-style-type: none"> 1. NICE advice [ESNM59]. Type 2 diabetes: dulaglutide. June 2015. Available at: https://www.nice.org.uk/advice/esnm59/chapter/Key-points-from-the-evidence [accessed 22/03/2016] 2. Summary of Products Characteristics. Available at: https://www.medicines.org.uk/emc/medicine/29747 [accessed 22/03/2016] 3. NICE guidelines [NG28]. Type 2 diabetes in adults: management. December 2015. Available at https://www.nice.org.uk/guidance/ng28/chapter/1-Recommendations#blood-glucose-management-2 [accessed 22/03/2016] 4. Wysham C, Blevins T, Arakaki R et al. (2014) Efficacy and safety of dulaglutide added onto pioglitazone and metformin versus exenatide in type 2 diabetes in a randomized controlled trial (AWARD-1). <i>Diabetes Care</i>. 37:2159–67 5. Nauck M, Weinstock RS, Umpierrez GE et al. (2014) Efficacy and safety of dulaglutide versus sitagliptin after 52 weeks in type 2 diabetes in a randomized controlled trial (AWARD-5). <i>Diabetes Care</i>. 37:2149–58 6. Dungan KM, Povedano ST, Forst TG et al. (2014) Once-weekly dulaglutide versus once-daily liraglutide in metformin treated patients with type 2 diabetes (AWARD-6): a randomised, open label, phase 3, non-inferiority trial. <i>The Lancet</i> 384:1349–57 7. European Medicines Agency (2014) European public assessment report for dulaglutide (Trulicity) EMA/CHMP/524604/2014 [online; accessed 01 April 2016]

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**