

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

Reference	097
Intervention:	Cariprazine hydrochloride (Reagila®) for the treatment of schizophrenia in adults (Cariprazine is a 2 nd generation, oral antipsychotic agent)
Date of Decision	January 2019, reviewed in December 2021 and recategorised from Red to Amber 2. Updated June 2023 following report on outcome data and time limit to formulary approval removed. Updated December 2025 following further outcome data and request to amend criteria for use.
Date of Issue:	Latest date of issue: February 2026. First issued: February 2019, reissued in February 2022, July 2023
Recommendation:	Amber 2 – specialist initiation and prescribing for a minimum of 12 months and until the patient is stable. GP may be requested to prescribe after this period.
Further Information:	<ul style="list-style-type: none"> • Cariprazine is approved for use in South East London (SEL) for the treatment of schizophrenia in adult patients, in line with its licensed indication. • Cariprazine may be considered as a first-line antipsychotic treatment option particularly in the following patient cohorts: <ul style="list-style-type: none"> – Patients with early psychosis or first-episode psychosis, especially patients with prominent negative symptoms where treatment options are limited – Patients with cardiovascular risk factors where cardiac neutrality is desirable • Negative symptoms include emotional apathy, lack of drive, poverty of speech, social withdrawal, and self-neglect. • Monitoring the response to cariprazine will include the patient’s overall clinical status and improvements in the Positive and Negative Syndrome Scale (PANSS-6) or Scale for the Assessment of Negative Symptoms* (SANS) score within 6 months of initiation. • Prescribing and supply will be carried out by the mental health trusts for a minimum of 12 months, under Amber 2 arrangements. Only consultants may initiate cariprazine using the internal process agreed within the Trusts. • The prescribing clinician should select the most clinically appropriate and best value antipsychotic for the individual patient based on their clinical assessment. While cariprazine may provide advantages in specific clinical scenarios, its use should not replace consideration of established, cost-effective alternatives, where these are clinically appropriate. • May 2023: The re-issued formulary recommendation in February 2022 requested a further report back to the Committee after 12 months outlining the number of patients initiated on treatment and transferred to primary care, outcomes and safety data. Primary care prescribing data demonstrates prescribing in primary care within the last 12 months. The outcomes data presented indicated improvements in SANS score, reduced hospital admissions and bed days. Whilst there were no significant safety concerns, some patients did discontinue treatment due to adverse effects. The Committee agreed the time limit on the formulary approval could be removed and requested further outcome data are presented in two years. • Dec 2025: The outcome data presented, further demonstrated improvements in SANS score (where available), reduced hospital admissions and bed days and no significant safety concerns. A request was made to the Committee to amend the agreed criteria for use for prescribing cariprazine in SEL and recommend prescribing in line with the licensed indication for cariprazine in the UK, noting the patient cohorts who might benefit the most. The use of cariprazine in line with the licensed indication and as a first line antipsychotic in a defined patient cohort was reviewed and approved by the Committee. <p>*Further information on the parameters covered by the SANS scale is available at: https://www.ncbi.nlm.nih.gov/projects/gap/cgi-bin/GetPdf.cgi?id=phd000807.2</p>
Shared Care/ Transfer of care required:	N/A

<p>Cost Impact for agreed patient group</p>	<ul style="list-style-type: none"> • In 2019, the local mental health trusts estimated that approximately 67 patients might be suitable for treatment with cariprazine in SEL (50 under SLaM and 17 under Oxleas). This would result in a cost impact of around £65K in SEL. • As a comparison, data presented to the Committee in December 2021 showed that 35 patients had been started on cariprazine since January 2019. There may be savings from reduced admissions and shorter inpatient stay. This is difficult to quantify but will be included as part of the data reported back to the Committee. • In December 2025, the local mental health Trusts estimated an additional 100 patients may be suitable for treatment with cariprazine in SEL when prescribed in line with the licensed indication and as a first line antipsychotic (50 under SLaM and 50 under Oxleas). This would result in an additional cost impact of approximately £105K (£5,250 per 100,000 population) in SEL.
<p>Usage Monitoring & Impact Assessment</p>	<p>Mental Health and Acute Trusts:</p> <ul style="list-style-type: none"> • Monitor use and submit usage data and audit reports upon request to the Committee. <p>SEL Borough Medicines Teams:</p> <ul style="list-style-type: none"> • Monitor ePACT2 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. Scottish Medicines Consortium. Semaglutide 0.25mg, 0.5mg and 1mg solution for injection in pre-filled pen (Ozempic®). SMC2092. Published 14 January 2019. 2. 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. 3. South East London Joint Medicines Formulary. Last accessed online here on 25/11/20. 4. South East London. glucagon-like peptide (GLP-1) analogue pathway for adults aged 18 years and over with Type 2 Diabetes Mellitus (T2DM), available here. 5. SPC. Rybelsus. Last updated May 2020. Last accessed online here on 25/11/20. 6. Rodbard HW et al (2019) Oral Semaglutide Versus Empagliflozin in Patients With Type 2 Diabetes Uncontrolled on Metformin: The PIONEER 2 Trial. Diabetes Care; 42(12):2272-2281 7. Effect of Additional Oral Semaglutide vs Sitagliptin on Glycated Hemoglobin in Adults With Type 2 Diabetes Uncontrolled With Metformin Alone or With Sulfonylurea. The PIONEER 3 Randomized Clinical Trial. JAMA; 321(15):1466-1480 8. Pieber TR et al (2019) Efficacy and safety of oral semaglutide with flexible dose adjustment versus sitagliptin in type 2 diabetes (PIONEER 7): a multicentre, open-label, randomised, phase 3a trial. The Lancet Diabetes & Endocrinology; 7(7):528-539 9. Pratley R et al (2019) Oral semaglutide versus subcutaneous liraglutide and placebo in type 2 diabetes (PIONEER 4): a randomised, double-blind, phase 3a trial. The Lancet; 394(10192):39-50 10. Yabe D et al (2020) Safety and efficacy of oral semaglutide versus dulaglutide in Japanese patients with type 2 diabetes (PIONEER 10): an open-label, randomised, active-controlled, phase 3a trial. The Lancet Diabetes & Endocrinology; 8(5):392-406 11. Zinman B et al (2019) Efficacy, Safety, and Tolerability of Oral Semaglutide Versus Placebo Added to Insulin With or Without Metformin in Patients With Type 2 Diabetes: The PIONEER 8 Trial. Diabetes Care; 42(12):2262-2271 12. Mosenzon O et al (2019) Efficacy and safety of oral semaglutide in patients with type 2 diabetes and moderate renal impairment (PIONEER 5): a placebo-controlled, randomised, phase 3a trial. The Lancet Diabetes & Endocrinology; 7(7):515-527 13. Husain M et al (2019) Oral Semaglutide and Cardiovascular Outcomes in Patients with Type 2 Diabetes. NEJM; 381:841-851 14. Yamada Y et al (2020) Dose-response, efficacy, and safety of oral semaglutide monotherapy in Japanese patients with type 2 diabetes (PIONEER 9): a 52-week, phase 2/3a, randomised, controlled trial. The Lancet Diabetes & Endocrinology; 8(5):377-391 15. Aroda VR et al (2019) PIONEER 1: Randomized Clinical Trial of the Efficacy and Safety of Oral Semaglutide Monotherapy in Comparison With Placebo in Patients With Type 2 Diabetes. Diabetes Care; 42(9):1724-1732 16. 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. 17. European Medicines Agency. Rybelsus Assessment Report. 30 January 2020. Last accessed online here on 25/11/20 18. British National Formulary. Accessed online via https://bnf.nice.org.uk/. Last accessed on 25/11/20.

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.**