

**South East London Area Prescribing 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
Date of Issue:	February 2019
Recommendation:	RED – suitable for prescribing and supply by hospital only
Further Information	<ul style="list-style-type: none"> • Cariprazine is approved for restricted use in adult patients with schizophrenia who: <ul style="list-style-type: none"> - Continue to have prominent and debilitating negative symptoms on their current antipsychotic regimen and - Have a Scale for the Assessment of Negative Symptoms* (SANS) score of ≥50. • 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 SANS score. The SANS score should be measured at baseline and again at 6 months. Treatment with cariprazine will only be continued if there is a ≥50% improvement in the SANS score. • Prescribing and supply will be carried out by the mental health trusts. Only consultants may initiate cariprazine using the internal process agreed within the Trusts. • The use of cariprazine as a first line antipsychotic agent is not supported by this recommendation. • The mental health trusts will report data covering 12 months to the Committee outlining the following over this time: <ul style="list-style-type: none"> (i) Total number of patients started on cariprazine and the number in South East London (by SEL borough). (ii) Whether use of cariprazine is in line with this recommendation and the rationale for any deviation. (iii) Patient outcomes, including: <ul style="list-style-type: none"> - Response to treatment (clinical outcomes and improvements in SANS). - The previous number of antipsychotics tried. - Number of patients stopping cariprazine therapy and the reasons for discontinuation. - Baseline number of admissions/year for a psychotic event (pre-initiation of cariprazine) and number of admissions post initiation of cariprazine. - Impact of cariprazine on inpatient stay. - An safety issues identified (including ECG related) • This APC decision will be subject to review following submission of the 12 month report. <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
Cost Impact for agreed patient group	<ul style="list-style-type: none"> • The local mental health trusts have 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. • 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.

Usage Monitoring & Impact Assessment	Mental Health Trusts: <ul style="list-style-type: none"> Monitor and audit usage of cariprazine as agreed and report back to the Committee in 12 months (data to be collated and presented no later than April 2020). CCGs: <ul style="list-style-type: none"> Monitor ePACT2 data Monitor exception reports from GPs if inappropriate transfer of prescribing to primary care is requested.
Evidence reviewed	References (from evidence evaluation) <ol style="list-style-type: none"> 1) Taylor. The Maudsley Prescribing Guidelines in Psychiatry. 13th Ed. 2) NICE Clinical guideline [CG178] Published date: February 2014. Psychosis and schizophrenia in adults: prevention and management 3) EPAR https://www.ema.europa.eu/en/medicines/human/EPAR/reagila 4) Garnock-Jones. Cariprazine A review in schizophrenia. CNS Drugs 2017; 31: 513- 525. 5) Németh G et al. Cariprazine versus risperidone monotherapy for treatment of predominant negative symptoms in patients with schizophrenia: a randomised, double-blind, controlled trial. The Lancet 18 March 2017; 389: p1103-1113. 6) Durgam S et al. An evaluation of the safety and efficacy of cariprazine in patients with acute exacerbation of schizophrenia: A phase II, randomized clinical trial. Schizophrenia Research 152 (2014) 450–457 7) Kane et al. Efficacy and Safety of Cariprazine in Acute Exacerbation of Schizophrenia Results from an International, Phase III Clinical Trial. Journal of Clinical Psychopharmacology August 2015; 35 (4): p367–373. 8) Durgam et al. Cariprazine in Acute Exacerbation of Schizophrenia: A fixed dose, phase 3, randomised, double-blind, placebo-and active-controlled trial. J Clin Psych 2015; 76 (12): e1574 – e1582. 9) Durgam, S., et al., Long-term cariprazine treatment for the prevention of relapse in patients with schizophrenia: A randomized, double-blind, placebo-controlled trial. Schizophr. Res. 2016; 176: 264-271.), http://dx.doi.org/10.1016/j.schres.2016.06.030 10) Earley et al. Efficacy of cariprazine on negative symptoms in patients with acute schizophrenia: a post hoc analysis of pooled data. Schizophrenia Research 2018. https://doi.org/10.1016/j.schres.2018.08.020 11) Durgam S et al. Cariprazine in the treatment of schizophrenia: a proof of concept trial. Int Clin Psychopharmacol 20167; 31: 61-18.

NOTES:

- Area Prescribing Committee recommendations, position statements and minutes are available publicly via the [APC website](#).
- This Area Prescribing Committee 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.
- Not to be used for commercial or marketing purposes. Strictly for use within the NHS.**