

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

<b>Reference:</b>	<b>025</b>
<b>Intervention:</b>	<b>Lurasidone (Latuda®) for the treatment of schizophrenia in adults aged 18 years and over</b> (Lurasidone is an oral 2 <sup>nd</sup> generation antipsychotic agent that inhibits the effect of dopamine and 5-HT)
<b>Date of Decision:</b>	<b>February 2015, updated January 2019. Updated in September 2021 – reclassified from Red to Amber 2.</b>
<b>Date of Issue:</b>	<b>March 2015, re-issued February 2019. Updated and reissued in October 2021.</b>
<b>Recommendation:</b>	<b>Amber 2 – specialist initiation and prescribing for a minimum of 3 months and until the patient is stable GP may be requested to prescribe after this period.</b>
<b>Further Information:</b>	<ul style="list-style-type: none"> <li>• Lurasidone is approved for use within its licensed indication* as a third line antipsychotic once other atypical antipsychotic options (<b>including oral aripiprazole</b>) have been considered and have either failed to manage the patient's condition or are not suitable due to a contraindication or intolerance. This includes treatment of people with schizoaffective disorder who fulfil the criteria for treatment of schizophrenia in line with NICE guidance.</li> <li>• The use of lurasidone as a first or second line agent in the above patient groups is <b>not</b> currently supported.</li> <li>• There is a lack of head to head data comparisons between oral aripiprazole and lurasidone and it is unclear if lurasidone offers advantages over aripiprazole with respect to the metabolic side effects associated with these agents. Oral aripiprazole will therefore be considered for use before lurasidone in the treatment pathway.</li> <li>• Lurasidone may be considered as the preferred antipsychotic for the treatment of people with schizophrenia who have a prolonged QTc:             <ul style="list-style-type: none"> <li>- With their current antipsychotic regimen <b>or</b></li> <li>- At baseline (i.e. first line)</li> <li>- QTc prolongation is defined as &gt;440 milliseconds for men and &gt;470 milliseconds for women</li> </ul> </li> <li>• Initial prescribing and supply will be carried out by the mental health trusts. Only consultants may initiate lurasidone using the forms agreed within the Trusts.</li> <li>• The mental health team will prescribe for a minimum of 3 months and until the patient is stable i.e. on a stable dose that is tolerated by the patient (as determined on clinical assessment by the initiating clinician).</li> <li>• No additional monitoring is required for lurasidone in primary care outside the standard annual physical health checks for patients with severe mental health illnesses.</li> </ul>
<b>Shared Care/ Transfer of care required:</b>	N/A
<b>Cost Impact for agreed patient group</b>	<ul style="list-style-type: none"> <li>• The evidence review (January 2019) estimated that up to 25 patients will be suitable for treatment each year across SEL.</li> <li>• If it is assumed that 80% of patients are controlled on 37 mg or 74 mg this equates to approximately £35,350 per annum for SE London.</li> <li>• Comparatively, the cost of aripiprazole for the same number of patients would be approximately £2,500, and therefore use of lurasidone ahead of aripiprazole for this use represents increased costs of about £30,000 per annum in SE London.</li> </ul>

<b>Usage Monitoring &amp; Impact Assessment</b>	<b>Mental Health Trusts:</b> <ul style="list-style-type: none"> <li>Monitor and submit usage and audit data on request to the SEL IMOC</li> </ul> <b>SEL CCG Borough Medicines Optimisation Teams:</b> <ul style="list-style-type: none"> <li>Monitor primary care prescribing data</li> <li>Exception reports from GPs if inappropriate prescribing requests are made to primary care</li> </ul>
<b>Evidence reviewed</b>	<b>References (from evidence review)</b> <ol style="list-style-type: none"> <li>International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10-CM). Available online at: <a href="https://www.cdc.gov/nchs/icd/icd10cm.htm">https://www.cdc.gov/nchs/icd/icd10cm.htm</a> (accessed 21/12/2018)</li> <li>Diagnostic and Statistical Manual of Mental Disorders(DSM-5). Available here (accessed 21/12/2018)</li> <li>Schizoaffective disorder – Approach. BMJ Best Practice. Available here (accessed 24/12/2018)</li> <li>Beach S, Celano C, Noseworthy P et al. QTc Prolongation, Torsades de Pointes and Psychotropic Medications. <i>Psychosomatics</i> 2013 54 p1-13.</li> <li>Polcwiartek C, Kragholm K, Schjerning O et al. Cardiovascular safety of antipsychotics: a clinical overview. <i>Expert Opinion on Drug Safety</i> 2016 DOI 10.1517/14740338.2016.1161021</li> <li>QT Interval and Drug Therapy. <i>Drug and Therapeutics Bulletin</i> 2016 54 (3) p33-36.</li> <li>Belmonte C, Ochoa D, Roman M et al. Evaluation of the relationship between pharmacokinetics and the safety of aripiprazole and its cardiovascular effects in healthy volunteers. <i>Journal of Clinical Psychopharmacology</i> 2016 36 p608-613.</li> <li>Nelson S et al. Torsades de pointes after administration of low dose aripiprazole. <i>Annals of Pharmacotherapy</i> 2013 47e11</li> <li>Poluzzi E, Raschi E, Koci A, et al. Antipsychotics and torsadogenic risk: signals emerging from the US FDA Adverse Event Reporting System database. <i>Drug Saf.</i> 2013;36(6):467–479</li> <li>Shulman M, Miller A, Misher J et al. Managing cardiovascular disease risk in patients treated with antipsychotics: a multidisciplinary approach. <i>Journal of Multidisciplinary Healthcare</i> 2014 7 489–501</li> <li>Latuda (lurasidone) Summary of Product Characteristics. Available here (accessed 07/01/2018)</li> <li>Psychosis and schizophrenia in adults: prevention and management (CG178). National Institute for Health and Care Excellence 2014.</li> <li>Ogasa M, Kimura T, Nakamura M et al. Lurasidone in the treatment of schizophrenia: a 6-week, placebo-controlled study. <i>Psychopharmacology</i> (2013) 225:519–530</li> <li>Citrome L, Cucchiario J, Sarma K et al. Long-term safety and tolerability of lurasidone in schizophrenia: a 12-month, double-blind, active-controlled study. <i>International Clinical Psychopharmacology</i> 2012, Vol 27 No 3 p165-176</li> <li>McEvoy J, Citrome L, Hernandez D. Effectiveness of lurasidone in patients with schizophrenia or schizoaffective disorder switched from other antipsychotics. A randomised 6-week open label study. <i>Journal of Clinical Psychiatry</i> 74 (2) p170-179</li> <li>Citrome L, Weiden P, McEvoy J et al. Effectiveness of lurasidone in schizophrenia or schizoaffective patients switched from other antipsychotics: a 6-month, open-label, extension study. <i>CNS Spectrums</i> (2014), 19, 330–339</li> <li>Werner P, Pikalov A, Hsu J et al. Switching to Lurasidone in Patients with Schizoaffective Disorder: Safety, Tolerability and Effectiveness. <i>CNS Spectrums</i> (2013), 18, 334–377</li> <li>Leucht S, Cipriani A, Spinel L et al. Comparative efficacy of tolerability of 15 antipsychotic drugs in schizophrenia: A multiple treatments meta-analysis. <i>Lancet</i> 2013 382 p951-962</li> <li>Latuda (lurasidone) European Public Assessment Report. Available here (accessed 07/01/2018)</li> <li>The clinical evaluation of qt/qtc interval prolongation and proarrhythmic potential for nonantiarrhythmic drugs e14. International conference on harmonisation of technical requirements for registration of pharmaceuticals for human use. May 2005.</li> <li>The ARITMO (Arrhythmogenic potential of drugs) report. European Commission 2013. Available online at: <a href="https://cordis.europa.eu/project/rcn/94061/reporting/en">https://cordis.europa.eu/project/rcn/94061/reporting/en</a> (accessed 07/01/2019)</li> <li>Raschi E, Poluzzi E, Salvo F et al. The contribution of national spontaneous reporting systems to detect signals of torsadogenicity. <i>Drug Safety</i> 2016 39 p59-68</li> <li>Polcwiartek C, Schneider B, Graff C et al. The cardiac safety of aripiprazole treatment in patients at high risk for torsade: a systematic review with meta-analytic approach. <i>Psychopharmacology</i> 2015 232 p3297-3308</li> </ol>

**NOTES:**

- SEL IMOC recommendations and minutes are available publicly via the [website](#).
- 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.
- Not to be used for commercial or marketing purposes. Strictly for use within the NHS.**