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

Reference:	**116**
Intervention:	**Safinamide for the management of Parkinson's disease in adults** (Safinamide is monoamine oxidase-B (MAO-B) inhibitor)
Date of Decision:	**February 2020, reviewed in September 2021 and recategorised from Red to Amber 2 (time limited)**
Date of Issue:	**March 2020, reissued in October 2021**
Recommendation:	**Amber 2 – specialist initiation and prescribing for 3 months. GP may be requested to prescribe after 3 months (one year time limited approval)**
Further Information:	• Safinamide is accepted for use as a treatment option for Parkinson's disease in adults in line with its licence* and where the following criteria are met: – Safinamide is a **last line** oral treatment option for people with Parkinson's disease that is refractory to other oral treatments **and** – The next step in treatment would otherwise be advanced, non-oral treatments. These include: apomorphine, deep brain stimulation or co-careldopa intestinal gel **and** – Previous treatment includes an adequate trial (minimum 3 months) of at least one other MAOB-inhibitor chosen from rasagiline or selegeline (5mg or 10mg tablets) which are already included in the SEL Formulary. • This approval is **time limited to one year** to enable the applicant to collate data to demonstrate the impact that the availability of safinamide has on the use of more advanced, non-oral treatment options and identify any possible implementation issues regarding the transfer of prescribing to primary care. • The applicant will coordinate data collection across all Trusts in SEL initiating safinamide for Parkinson's disease and report data covering 12 months to the Committee outlining the following over this time: (i) Total number of patients started on safinamide and the number in South East London (by SEL borough) (ii) Whether use is in line with the criteria set out in this recommendation and the rationale for any deviation (iii) Patient outcomes, including: - Response to treatment (clinical outcomes and any safety issues) - Number of patients stopping therapy and the reasons for discontinuation - The number of patients continuing safinamide treatment who did not require advanced, non-oral treatments - The number of patients who progressed to more advanced, non-oral treatment options (and whether safinamide was discontinued) (iv) Any implementation issues identified regarding prescribing in primary care (v) The applicant has advised that only a small number of patients might be initiated on safinamide due to the ongoing COVID-19 pandemic situation. Depending on the situation, the report back to the Committee could be presented in the format of case studies. • This SEL IMOC decision is time limited and will be subject to review following submission of the 12-month report. *Safinamide 50mg and 100mg tablet (Xadago™) is licensed for the treatment of adult patients with idiopathic Parkinson's disease (PD) as add-on therapy to a stable dose of levodopa (L-dopa) alone or in combination with other PD medicinal products in mid-to late-stage fluctuating patients.

Shared Care/ Transfer of care required:	N/A
Cost Impact for agreed patient group	• Based on costing in the evidence review (February 2020), the application estimated that approximately 30-55 patients might be appropriate for treatment per annum, and that 50% would be from SE London. • This equates to costs of up to between £12,000 to £22,000 per annum vs. rasagiline or selegiline, which are available generically. • The application stated that safinamide has a significantly lower cost impact vs. advanced, non-oral therapies, such as levodopa intestinal gel and apomorphine.
Usage Monitoring & Impact Assessment	**Acute Trusts:** • Report data back to the Committee in 12 months (data to be collated and presented no later than **October 2022**)
	SEL CCG Borough Medicines Optimisation Teams: • Monitor primary care prescribing data • Exception reports from GPs if inappropriate prescribing requests are made to primary care
Evidence reviewed	**References (from evidence review)** 1. Parkinson's disease in the over 20's: Diagnosis and management. National Institute for Health and Care Excellence Clinical Guideline 35 (2006). 2. Parkinson's disease in adults. National Institute for Health and Care Excellence NG71 (2017) 3. Xadago (safinamide). Summary or Product Characteristics. Available online here (accessed 06/09/2019) 4. Xadago - Public Assessment Report. European Medicines Agency 2014. 5. Mueller T, Foley P. Clinical Pharmacokinetics and Pharmacodynamics of safinamide. Clinical Pharmacokinetics 2017 56 (3) p251-261. 6. Borgohain R, Szasz J, Stanzione P et al. Randomized trial of safinamide add-on to levodopa in Parkinson's disease with motor fluctuations. Movement Disorders 2014 29 (2) p229-237 7. Borgohain R, Szasz J, Stanzione P et al. Two-Year, randomized, controlled study of safinamide as add-on to levodopa in mid to late PD. Movement Disorders 2014 29 (10) p1273-1280 8. Schapira A, Fox S, Hauser R et al. Assessment of safety and efficacy of safinamide as a levodopa adjunct in patients with Parkinson's disease and motor fluctuations. A randomised clinical trial. JAMA Neurology 2017 74 (2) p165-173. 9. Cattaneo C, Barone P, Bonizonni E et al. Effects of safinamide on pain in fluctuating Parkinson's disease patients: A post-hoc analysis. Journal of Parkinson's Disease 2017 7 p95-101. 10. Cattaneo C, Mueller T, Bonizzoni E et al. Long-term effects of safinamide on mood fluctuations in Parkinson's disease. Journal of Parkinson's Disease 2017 7 p629-634. 11. Cattaneo C, Sardina M, Bonizzoni E. Safinamide as add-on therapy to levodopa in mid- to late-stage Parkinson's disease fluctuating patients: post hoc analysis of studies 016 and SETTLE. Journal of Parkinson's Disease 2016 6 p165-173. 12. Cattaneo C, La Ferla R, Bonizzoni E et al. Long-term effects of safinamide on dyskinesia in mid- to late-stage Parkinson's disease: A post-hoc analysis. Journal of Parkinson's Disease 2015 5 p475-481. 13. Cattaneo C, Kulisevsky J, Tubazio V et al. Long-term efficacy of safinamide on Parkinson's disease chronic pain. Advanced Therapeutics 2018 35 p515-522. 14. Binde C, Tvete I, Gasemyr J et al. A multiple treatment comparison meta-analysis of monoamine oxidase type B inhibitors for Parkinson's disease. British Journal of Clinical Pharmacology 2018 84 p1917-1927. 15. Mancini F, Di Fonzo A, Lazzeri G et al. Real life evaluation of safinamide effectiveness in Parkinson's disease. Neurological Sciences 2018 39 p733-739.

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.