South East London Integrated Medicines Optimisation Committee
Position Statement

Reference	**PS-002**
Intervention:	**Sativex™ oromucosal spray for the treatment of moderate to severe spasticity due to multiple sclerosis (MS) in adults** (Sativex is a cannabinoid medicine in an oral spray formulation which contains delta-9-tetrahydrocannabinol and cannabidiol)
Date of Decision:	**November 2015. Updated March 2021, updated March 2022**
Date of Issue:	**December 2015. Re-issued: April 2021 – re-categorised from Red to Amber 3. Re-issued April 2022 following report on patient numbers and shared care implementation process.**
Recommendation:	**Amber 3: Initiation and supply by named MS consultants. GPs may be requested to take on prescribing after 2 months under shared care.**
Further Information:	• Sativex™ oromucosal spray is supported for use in SEL as an add-on treatment for adult patients with MS who have moderate to severe spasticity that has not responded to at least two of the following oral treatments: – baclofen (up to 100mg/day; 1st line option) – gabapentin (up to 1.8g/day; 1st line option) – tizanidine (up to 24mg/day) – dantrolene (up to 400mg/day) – benzodiazepines (clonazepam preferred, up to 2mg/day; 3rd line option) • These treatments should have been tried at **maximum** tolerated doses prior to consideration of Sativex™ oromucosal spray **and** must have been ineffective based on Numeric Rating Scale (NRS) measurements. The NRS is a subjective pain scale between 0-10 [moderate-severe spasticity ≥ 4]. • Prescribing is restricted to named MS consultants within each Trust. • The first 2 months of treatment will be prescribed and supplied by the hospital. Patients will be reviewed at 4 weeks by the specialist MS Team to confirm that they have responded adequately to the initial month's trial with Sativex™ oromucosal spray, at which point the second month's supply will be made. • Further information on the use of Sativex™ oromucosal spray for moderate to severe spasticity associated with MS can be found in NICE guideline 144: Cannabis based medicinal products (November 2019). • Information on the management of spasticity associated with MS can be found in the NICE clinical guideline on the management of MS in adults (October 2014, last updated November 2019). • Patients will remain under specialist supervision and ongoing review. • Further information about Sativex™ oromucosal spray may be found in the Summary of Product Characteristics (SPC) and the patient information leaflet. • **April 2022:** Following the recategorisation of Sativex™ from Red to Amber 3 (shared care) in March 2021, the Committee requested a report on patient numbers and the implementation process of the shared care guideline after 1 year of use. The report was presented in March 2022 and the report indicated a lower number of patients transferred to shared care than estimated which was due to the COVID-19 pandemic. Appropriate implementation of the shared care guideline was also noted. Committee members supported the continuation of the existing shared care arrangements for Sativex™.
Shared Care/Transfer of Care required?	Yes – shared care guideline

Cost Impact for agreed patient group	The local Trusts estimate: • That at steady state (year 4) the numbers of patients receiving Sativex™ oromucosal spray in this setting across SEL will rise from the baseline of 15 patients to ~ 66 patients • The additional cost of treating these patients will be ~£3,000 per 100,000 population in year 1 of implementation (~£57,000 for SEL), rising to ~£9,000 per 100,000 population at year 4 (steady state; £171,000 total for SEL). • No cost is included for people who do not respond to treatment because the initial trial period of 4 weeks is under the pay-for-responders scheme (refer to the NICE guideline on cannabis-based medicinal products for further information on this scheme). • The eligible population will remain the same, due to increases in the prevalent population matching the number of people discontinuing treatment each year.
Usage Monitoring & Impact Assessment	**Acute Trusts:** • Monitor use and report back to SEL IMOC upon request.
	SEL Borough Medicines Optimisation Teams: • Monitor ePACT2 data • Monitor reports from GP practices where inappropriate transfer of prescribing to primary care is requested.
Evidence reviewed	**Key References** 1. NICE guideline 144: Cannabis based medicinal products, available at: https://www.nice.org.uk/guidance/ng144 (last accessed 19th March 2021) 2. NICE costing report for guideline 144, available at: https://www.nice.org.uk/guidance/ng144/resources (last accessed 19th March 2021) 3. NICE clinical Guideline on the management of Multiple Sclerosis in adults (CG 186), October 2014 4. Expert opinion of local neurologists and specialist neurology pharmacists

NOTES:

a) SEL IMOC recommendations, position statements and minutes are available publicly via the Committee website.

b) This SEL IMOC position statement has been made on the cost effectiveness, patient outcome and safety data available at the time. The position statement 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.