

BSW Sativex® spray (delta-9-tetrahydrocannabinol (THC): cannabidiol (CBD)) for treatment for symptom improvement in adult patients with moderate to severe spasticity due to multiple sclerosis (MS):
Not routinely commissioned, application via exceptional funding route only.

Policy Statement

NHS BSW ICB do not commission the use of sativex for patients with moderate to severe spasticity associated with MS (see [NICE NG144](#)¹ for details).

Although studies found an improvement in patient reported spasticity there was no significant difference in patients' health related quality of life measures (see below for review of evidence) and no robust cost-effective analysis was reviewed as part of NICE guidance.

Given the significant resource required for using Sativex both in drug costs and follow up care as well as limited evidence supporting improvement in quality of life, it was determined that Sativex is unaffordable for moderate to severe spasticity in MS.

This position is likely to remain similar until such time as a full NICE Technology Appraisal becomes available.

What does NICE say?

[NICE NG144](#)¹ guidance says that sativex is an option that could be offered AFTER other pharmacological treatments for spasticity are not effective. The [NICE NG220](#)² clinical guideline for MS states:

1.5.27 Consider oral baclofen as a first-line drug treatment to treat spasticity in people with MS who have specific treatment goals such as improving mobility or easing pain and discomfort. Take into account any contraindications, comorbidities and the person's preferences. [2022]

1.5.28 If oral baclofen is not tolerated or does not provide adequate relief, consider gabapentin (off-label) as a second-line option to treat spasticity in people with MS.

1.5.30 Consider a combination of oral baclofen and gabapentin for people with MS if:

- individual medicines do not provide adequate relief or
- side effects from individual medicines prevent the dose being increased. [2022]

Reference:	Policy Name	Date of BSWXXX	Review Date	Version
BSWICB-XXXX	Sativex for spasticity in MS	XXXX2025	August 2027	2

Prescribing information³ and monitoring: ([NON-formulary](#) on BSW formulary)

Indication: Sativex is indicated as treatment for symptom improvement in adult patients with moderate to severe spasticity due to multiple sclerosis (MS) who have not responded adequately to other anti-spasticity medication and who demonstrate clinically significant improvement in spasticity related symptoms during an initial trial of therapy.

Pharmacological action: As part of the human endocannabinoid system (ECS), cannabinoid receptors, CB₁ and CB₂ receptors are found predominantly at nerve terminals where they have a role in retrograde regulation of synaptic function. THC acts as a partial agonist at both CB₁ and CB₂ receptors, mimicking the effects of the endocannabinoids, which may modulate the effects of neurotransmitters (e.g. reduce effects of excitatory neurotransmitters such as glutamate).

In animal models of MS and spasticity CB receptor agonists have been shown to ameliorate limb stiffness and improve motor function. These effects are prevented by CB antagonists, and CB₁ knockout mice show more severe spasticity. In the CREAE (chronic relapsing experimental autoimmune encephalomyelitis) mouse model, Sativex produced a dose-related reduction in the hind limb stiffness.

Presentation: Oromucosal spray, solution. 10 mL pack size allows delivery after priming of up to 90 actuations (sprays) of 100 microlitres.

Dose: A titration period is required to reach optimal dose. The number and timing of sprays will vary between patients. Maximum of 12 sprays per day.

Cost comparison (for general comparison only – therapeutic equivalence is not implied);

Cost per patient (at recommended dose, Drug Tariff August 2025)		
Sativex	6 to 12 sprays a day	£2436 to £4872 per year (£300 for 270 dose pack)
Baclofen (1 st line NICE)	60mg daily (20mg used in 3 div. doses)	£66 per year
Gabapentin (2 nd line NICE)	2400mg daily (800mg tab)	£142 per year
Other options that have been occasionally used historically:		
Diazepam	15mg daily (5mg tabs)	£26 per year
Dantrolene sodium	75mg TDS (25mg cap)	£558 per year
Tizanidine	24mg daily (3-4 div. doses)	£146 per year

Private patients

As per this policy BSW does not routinely commission Sativex. In clinically exceptional cases an Individual Funding Request (IFR) may be initiated by an appropriate secondary care specialist. Consistent with IFR policy benefit derived from treatment accessed privately cannot be considered as part of the IFR process.

Patients pursuing supply, and clinicians initiating or recommending Sativex, in a private healthcare context must ensure on-going arrangements are in place for managing prescribing and follow-up. Sativex can only be initiated by a specialist due to the supply mechanism from the manufacturer.

The NHS BSW CCG definition of exceptionality can be found here: <https://bsw.icb.nhs.uk/document/bsw-ccg-exceptional-funding-requests-prior-approval-criteria-based-access-policy/>

Relevant NHS BSW CCG Medicines Management private prescribing advice can be found here: <https://bswtogether.org.uk/medicines/wp-content/uploads/sites/3/2024/01/Private-treatment-dec-2023.pdf>

Reference:	Policy Name	Date of BSWXXX	Review Date	Version
BSWICB-XXXX	Sativex for spasticity in MS	XXXX2025	August 2027	2

NICE commentary on efficacy and cost-effectiveness (NG144¹):

NICE full evidence on spasticity (p32, <https://www.nice.org.uk/guidance/ng144/evidence/c-spasticity-pdf-6963831760>):

The committee agreed that there were benefits for the use of THC:CBD spray for the treatment of spasticity in multiple sclerosis. The clinical evidence showed improvements in patient-reported spasticity and could not differentiate between adverse events for THC:CBD spray and placebo. Also, economic modelling showed that THC:CBD spray would offer sufficient QALY gains if reduction in spasticity led to a halving of management costs and acquisition cost of THC:CBD spray (Sativex) was also reduced (in addition to the existing pay-for-responders scheme). Therefore, the committee agreed that under these conditions Sativex could be recommended to treat moderate to severe spasticity in adults with multiple sclerosis if other pharmacological treatments had not been effective.

P33:

The committee noted that despite THC: CBD spray being found to be clinically effective at reducing spasticity, no studies found any significant differences in health-related quality of life (HRQoL) measures whether using the EQ-5D, SF-36 or VAS 0-100 instruments. Additionally, differences in point estimates between the two arms of all trials collecting HRQoL measures were very small. They considered that this might be because HRQoL measures have some level of insensitivity to changes in spasticity NRS and are therefore not capturing the benefits of the treatment appropriately. Another contributory factor could be condition severity in the population in the trials, as patients with advanced MS typically have many other important symptoms that can influence their HRQoL and reducing spasticity might not change their self-reported scores by much.

P221:

The base-case analysis showed that compared to standard of care alone, at the new list price of £300 per pack, THC: CBD spray + SoC was associated with an ICER of £19,512 per QALY gained over a 5-year time horizon.

Adverse effects³

The most commonly reported adverse reactions in the first four weeks of exposure were dizziness, which occurs mainly during the initial titration period, and fatigue. These reactions are usually mild to moderate and resolve within a few days even if treatment is continued. When the recommended dose titration schedule was used, the incidence of dizziness and fatigue in the first four weeks was much reduced.

References:

- 1.) NICE NG144 Cannabis-based medicinal products November 2019 (updated March 2021). <https://www.nice.org.uk/guidance/ng144/>
- 2.) NICE NG220 Multiple sclerosis in adults: management June 2022. [Overview | Multiple sclerosis in adults: management | Guidance | NICE](#)
- 3.) Summary of Product characteristics, Sativex, Electronic Medicines Compendium. <https://www.medicines.org.uk/emc/product/602>

Reference:	Policy Name	Date of BSWXXX	Review Date	Version
BSWICB-XXXX	Sativex for spasticity in MS	XXXX2025	August 2027	2