Sativex shared care protocol		
V1.0	April 2026	Review date: April 2029

NHS
Nottinghamshire Area Prescribing Committee

Shared care protocol:

Sativex® for moderate to severe spasticity in multiple sclerosis (MS)

As well as this protocol, please ensure that summaries of product characteristics (SPCs), British national formulary (BNF) or the Medicines and Healthcare products Regulatory Agency (MHRA) or NICE websites are reviewed for up-to-date information on any medicine.

Specialist responsibilities

- Assess the patient and provide diagnosis; ensure that this diagnosis is within scope of this shared care protocol (section 2) and communicated to primary care.
- Use a shared decision-making approach; discuss the benefits and risks of the treatment with the patient and/or their carer and provide the appropriate counselling (see section 10) to enable the patient to reach an informed decision. Obtain and document patient consent. Provide an appropriate patient information leaflet.
- Review for contraindications and cautions (see section 3) and interactions (see section 6).
- Conduct required baseline investigations and initial monitoring (see section 7).
- Initiate treatment as outlined in section 4.
- Confirm and document response and whether there is clinical benefit (e.g. improvement in spasticity) at each review and advise discontinuation if treatment response is inadequate.
- Following initial assessment, if treatment is to continue, prescribe and provide a further supply to the patient. Prescribe sufficient medication to enable transfer to primary care, including where there are unforeseen delays to transfer of care.
- When transfer to primary care is appropriate, write to the patient's GP practice and request shared care.
    - For this and after every review; communicate the diagnosis and available results to primary care. Advise primary care whether treatment should be continued, confirm the current and ongoing dose, the anticipated monthly supply requirements, and whether the ongoing monitoring outlined in section 8 remains appropriate, along with when the next monitoring is required.
    - Include contact information (section 12).

- Conduct the scheduled reviews and monitoring in section 7 and communicate the information above to primary care
- Provide advice to primary care on the management of adverse effects if required.

Primary care responsibilities

- If shared care is not accepted, inform the specialist of the decision in writing within 14 days with reasons as to why shared care cannot be entered into.
- If accepted, prescribe ongoing treatment as detailed in the specialist's request and as per section 4, taking into any account potential drug interactions in section 6. Conduct the required monitoring as outlined in section 8. Communicate any abnormal results to the specialist.
- Manage adverse effects as detailed in section 9 and discuss with specialist team when required.
- Cease shared care and refer the management back to the specialist if the patient becomes or plans to become pregnant.
- Cease shared care and refer the management back to the specialist if you are made aware that the patient is using additional cannabis products.
- Contact the specialist for advice if there is an increase in usage e.g. the patient requests prescriptions more frequently.
- Stop treatment as advised by the specialist.

Patient and/or carer responsibilities

- Take Sativex® as prescribed and avoid abrupt withdrawal unless advised by the prescriber.
- Store Sativex® securely and do not share it with others.
- Attend regularly for monitoring and review appointments with primary care and specialist and keep contact details up to date with both prescribers. Be aware that medicines may be stopped if they do not attend.
- Report adverse effects to their specialist. Seek immediate medical attention if they develop any symptoms as detailed in section 10.
- Report the use of any over the counter (OTC) medications to their prescriber and be aware they should discuss the use of Sativex® with their pharmacist before purchasing any OTC medicines.
- Not to drive or operate heavy machinery if Sativex® affects their ability to do so safely.

- Patients of childbearing potential should take a pregnancy test if they think they could be pregnant and inform the specialist or GP immediately if they become pregnant or wish to become pregnant.

1. Background

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Sativex® Oromucosal Spray (27 mg delta-9-tetrahydrocannabinol (THC) and 25 mg cannabidiol (CBD) per mL) from *Cannabis sativa* L. is indicated for the treatment of moderate to severe spasticity in adult patients with Multiple Sclerosis (MS).

Sativex® is intended to be used in addition to the patient's current anti-spasticity medication.

NICE Guideline NG144, Cannabis-based medicinal products. (Published: November 2019, last updated: March 2021) states:

"Offer a 4-week trial of THC:CBD spray to treat moderate to severe spasticity in adults with multiple sclerosis, if:

- other pharmacological treatments for spasticity are not effective (see the recommendations on spasticity in NICE guideline NG220 "**Multiple sclerosis in adults: management" June 2022***)
- the company provides THC:CBD spray according to its pay-for-responders scheme (it funds the first 3 x10-ml vials if there is agreement for continued funding for people with at least a 20% reduction in spasticity-related symptoms on a 0 to 10 patient-reported numeric rating scale after 4 weeks).

  After the 4-week trial, continue THC:CBD spray if the person has had at least a 20% reduction in spasticity-related symptoms on a 0 to 10 patient-reported numeric rating scale.

Treatment with THC:CBD spray should be initiated and supervised by a physician with specialist expertise in treating spasticity due to multiple sclerosis, in line with its marketing authorisation."

** 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.*

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

2. Indications

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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.

3. Contraindications and cautions

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This information does not replace the Summary of Product Characteristics (SPC) and should be read in conjunction with it. Please see BNF & SPC for comprehensive information.

Contraindications:

- hypersensitivity to cannabinoids or to any of the excipients
- any known or suspected history or family history of schizophrenia, or other psychotic illness; history of severe personality disorder or other significant psychiatric disorder other than depression associated with their underlying condition.
- breast feeding
- moderate to severe hepatic impairment (not advised due to lack of information on the potential for accumulation)

Cautions:

- Alterations in pulse rate and blood pressure have been observed following initial dose introduction so caution during initial dose titration is essential. Fainting episodes have been observed with use of Sativex®. Use of Sativex® is not recommended in patients with serious cardiovascular disease. However, following dosing in healthy volunteers with Sativex® up to 18 sprays twice daily, there were no clinically relevant changes in QTc, PR or QRS interval duration, heart rate, or blood pressure.
- History of epilepsy, or recurrent seizures.
- Sativex® may reduce the effectiveness of hormonal contraceptives
- Lower daily doses of Sativex® may be needed in patients with moderate or severe renal impairment because of increased exposures observed in a severe renal impairment study

4. Initiation and ongoing dose regimen

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A titration period is required to reach optimal dose (this will have been done by the specialist before prescribing is taken on in primary care). The number and timing of sprays will vary between patients.

The number of sprays should be increased each day following the pattern given in the table below. The afternoon/evening dose should be taken at any time between 4 pm and bedtime. When the morning dose is introduced, it should be taken at any time between waking and midday. The patient may continue to gradually increase the dose by 1 spray per day, up to a maximum of 12 sprays per day, until they achieve optimum symptom relief. There should be at least a 15-minute gap between sprays.

Day	Number of sprays in the morning	Number of sprays in the evening	Total number of sprays per day	Approx sprays per 28 days (NB: calculated on consistent usage)	Will need new prescription every:
1	**0**	**1**	1	28	126 days*
2	**0**	**1**	1	28	126 days*
3	**0**	**2**	2	56	126 days*
4	**0**	**2**	2	56	126 days*
5	**1**	**2**	3	84	90 days
6	**1**	**3**	4	112	67 days
7	**1**	**4**	5	140	54 days
8	**2**	**4**	6	168	45 days
9	**2**	**5**	7	196	38 days
10	**3**	**5**	8	224	33 days
11	**3**	**6**	9	252	30 days
12	**4**	**6**	10	280	27 days
13	**4**	**7**	11	308	24 days
14	**5**	**7**	12	336	22 days

***(each vial must be discarded 6 weeks after opening)**

Maintenance period:

Following the titration period, patients are advised to maintain the optimum dose achieved. The median dose in clinical trials for patients with multiple sclerosis is eight sprays per day. Once the optimum dose has been achieved, patients may spread the doses throughout the day according to individual response and tolerability. Re-titration upwards or downwards may be appropriate if there are any changes in the severity of the patient's condition, changes in their concomitant medication or if troublesome adverse reactions develop. Doses of greater than 12 sprays per day are not recommended.

Review by the physician

The patient's response to Sativex® should be reviewed after four weeks of treatment. If a clinically significant improvement in spasticity related symptoms is not seen during this initial trial of therapy, then treatment should be stopped. In the clinical trials this was defined as at least a 20% improvement in spasticity related symptoms on a 0-10 patient reported numeric rating scale. The value of long-term treatment should be re-evaluated periodically.

5. Pharmaceutical aspects

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Formulation:	**Sativex® Oromucosal spray** Active ingredients per single 100 microlitre spray: • 2.7 mg THC (delta-9-tetrahydrocannabinol) and • 2.5 mg CBD (cannabidiol) 90 sprays per 10ml vial/bottle, one pack contains 3 x 10ml vials 
Administration route and details:	For oromucosal use only See section 4 for initiation and ongoing dose regimen
Other important information:	**Controlled Drug (Schedule 4, Part 1) - Controlled drug prescription requirements do not apply and they are not subject to safe custody requirements. A prescription for a Controlled Drug in Schedule 4 is valid for 28 days after the date stated thereon.** Prescribe in quantities of whole packs e.g. 3 x 10ml vials – Pharmacies are unlikely to be willing to split packs

	Patients should be aware, if travelling abroad, that certain countries may not allow Sativex® to be brought into the country. Patients should check before travel. It is advisable to also carry a copy of the prescription and a letter from the specialist confirming the Sativex® prescription. Sativex® should be stored in a refrigerator (2 to 8°C) prior to opening; once opened it can be stored at room temperature (less than 25°C) and must be discarded 42 days (6 weeks) once opened.

6. Significant medicine interactions

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The following list is not exhaustive. Please see BNF or SPC for comprehensive information and recommended management. If further advice is needed, please contact the MS team

Both components of Sativex®, THC and CBD, are metabolised by the Cytochrome P-450 enzyme system, so there is the potential for interactions when co-administering it with drugs that induce or inhibit these enzymes:

- Concurrent use of strong CYP3A4 inhibitors (such as **ketoconazole, itraconazole, ritonavir, clarithromycin)** can cause increased levels of Sativex®
- Strong CYP2C9 inhibitors (such as **fluconazole, co-trimoxazole, amiodarone**) can increase THC exposure
- Strong CYP3A4 inducers (such as **rifampicin, carbamazepine, phenytoin, phenobarbital, St John's Wort**) are expected to lower THC and CBD levels

If there is a plan to start or stop any of these drugs whilst the patient is on Sativex®, please contact the MS team for advice.

- Sativex® may reduce effectiveness of systemically acting hormonal contraceptives, therefore women using systemically acting hormonal contraception for example the oral contraceptive pill or contraceptive implant should use an additional second barrier method of contraception for the duration of therapy and for three months after discontinuation.
- Cannabidiol is predicted to increase the exposure of ciclosporin
- Cannabidiol is predicted to increase the exposure to digoxin
- Cannabidiol increases the risk of increased ALT when given with valproate
- Cannabidiol can cause sedation, so if given with any medication which can cause sedation it could have an additive effect

7. Baseline investigations, initial monitoring and ongoing monitoring to be undertaken by specialist

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Monitoring at baseline and during initiation is the responsibility of the specialist; only once the patient is optimised on the chosen medication with no anticipated further changes expected in immediate future will prescribing and monitoring be transferred to primary care.

Baseline investigations:

- ☐ Spasticity assessment
- ☐ U&E
- ☐ LFT

Initial monitoring:

- ☐ Spasticity assessment at 4 weeks

Ongoing monitoring:

- ☐ Ongoing spasticity review, ongoing dosage monitoring
- ☐ Annual, or more frequently if clinically indicated, routine review to assess effectiveness and ongoing appropriateness of treatment

After every review

- ☐ Advise primary care whether treatment should be continued, confirm the ongoing dose and anticipated monthly supply requirements, and whether the ongoing monitoring outlined in section 8 remains appropriate.

8. Ongoing monitoring requirements to be undertaken by primary care

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Monitoring and advice	Frequency
☐ **U&E** ☐ **LFT** ☐ Inform specialist if liver or renal function changes significantly	**6-monthly**

☐ **Adverse effects** See section 9 for further guidance on management of adverse effects/responding to monitoring results.	

9. Adverse effects and other management

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Any serious adverse reactions should be reported to the Specialist Clinician as well as the MHRA via the Yellow Card scheme. Visit www.mhra.gov.uk/yellowcard

For information on incidence of ADRs see relevant summaries of product characteristics

10. Advice to patients and carers

The specialist will counsel the patient with regard to the benefits and risks of treatment and will provide the patient with any relevant information and advice, including patient information leaflets on individual medicines Back to top

The patient should be advised to report any of the following signs or symptoms to their primary care prescriber without delay:

Psychiatric symptoms such as anxiety, illusions, changes in mood, and paranoid ideas. These are likely to be the result of transient CNS effects and are generally mild to moderate in severity and well tolerated. They can be expected to remit on reduction or interruption of Sativex® medication.

Disorientation (or confusion), hallucinations and delusional beliefs or transient psychotic reactions have also been reported and in a few cases a causal association between Sativex® administration and suicidal ideation could not be ruled out. In any of these circumstances, Sativex ® should be stopped immediately and the patient monitored until the symptom has completely resolved.

The patient should be advised: Stop Sativex® and contact the specialist team

Patient information

Sativex Oromucosal Spray - Patient Information Leaflet (PIL) - (emc) | 602

11. Pregnancy, paternal exposure and breast feeding

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It is the responsibility of the specialist to provide advice on the need for contraception to male and female patients on initiation and at each review, but the ongoing responsibility for providing this advice rests with both the primary care prescriber and the specialist.

There is insufficient experience in humans regarding the effects of Sativex® on reproduction. Although no effect has been seen on fertility, independent research in animals found that cannabinoids affected spermatogenesis

Therefore, men and women of childbearing potential should take reliable contraceptive precautions for the duration of therapy and for three months after discontinuation of therapy.

Patients on hormonal contraceptives should be advised to use an additional alternative, non-hormonal/reliable barrier method of birth control during Sativex® therapy.

Breastfeeding:

Available pharmacodynamics / toxicological data in animals have shown excretion of Sativex® / metabolites in milk. A risk to the breastfed child cannot be excluded. Sativex® is contraindicated during breast-feeding

12. Specialist contact information

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Email: NUHNT.MS@NHS.NET
Telephone: (0115) 849 3285

13. Additional information

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Where patient care is transferred from one specialist service or GP practice to another, a new shared care agreement must be completed. Ensure that the specialist is informed in writing of any changes to the patient's GP or their contact details.

Patients should be advised that if they travel to another country, it may not be legal for them to take this medicine into some countries. They should be encouraged to check the legal status before travelling with Sativex®.

14. References

Sativex® Oromucosal Spray. Date of revision of the text: 11/7/2025. Accessed via https://www.medicines.org.uk/emc/product/602/smpc on 3/3/2026

NICE Guideline NG144, last updated 22 March 2021. Accessed via https://www.nice.org.uk/guidance/ng144 on 3/3/2026

NICE guideline NG220, last updated 22 June 2022. Accessed via on https://www.nice.org.uk/guidance/ng220 3/3/2026

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15. Other relevant national guidance

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- N/A

16. Local arrangements for referral

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Define the referral procedure from hospital to primary care prescriber & route of return should the patient's condition change.

- The request for shared care should be accompanied by individual patient information, outlining all relevant aspects of the patient's care and which includes direction to the shared care protocols on the APC website.
- The specialist will request shared care with the GP in writing.
- If the GP doesn't agree to shared care, they should inform the specialist of their decision in writing within 14 days, outlining the reason for the decline. The agreement can be assumed if the GP does not provide a written decline.
- In cases where shared care arrangements are not in place or where problems have arisen within the agreement, and patient care may be affected, the responsibility for the patient's management, including prescribing, reverts back to the specialist.
- Should the patient's condition change, the GP should contact the relevant specialist using the details provided with the shared care request letter.

17. Version Control – Sativex® shared care protocol

Version	Author(s)	Date	Changes
V1.0	Anna Hill	April 26	

	Specialist Clinical Pharmacist, Neurology. (NUH)		