North Central London
Joint Formulary Committee

# Shared Care Guideline
# Sativex
# Treatment of Multiple Sclerosis related Spasticity

Dear Primary Care Prescriber.

The information in this shared care guideline has been developed in consultation with Primary Care, with agreement that shared care is appropriate.

Sharing of care assumes communication between the specialist, primary care prescriber and patient. The intention to share care should be explained to the patient by the specialist clinician when treatment is initiated. It is important that patients are consulted about treatment and are in agreement with it.

Further information on shared care, including out of area referrals, can be found in the NCL Interface Prescribing Guidance.

## Shared Care Guideline

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| **Indication** | As per local formulary agreement, Sativex® (approved name: delta-9-tetrahydrocannabinol (THC) and cannabidiol (CBD), each 100 microlitre spray contains: 2.7 mg delta-9-tetrahydrocannabinol (THC) and 2.5 mg cannabidiol (CBD) from *Cannabis sativa L.*) is licensed for moderate to severe spasticity in people with multiple sclerosis 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.<br><br>Prescribing within NCL is in line with NICE guidance (see NICE NG144 on cannabis-based medicinal products and NICE NG220 on the management of multiple sclerosis in adults). It should be initiated and supervised by a physician with specialist expertise in treating spasticity due to multiple sclerosis; in NCL, the tertiary service is currently provided at The National Hospital for Neurology and Neurosurgery (NHNN). |
| **Shared Care criteria** | Once a patient has been stabilised on treatment (which is generally 2-3 months) and has been monitored appropriately at baseline and after initiation of treatment with no problems identified during this period, a shared care arrangement with the GP will be requested. The patient should demonstrate a 20% improvement in spasticity-related symptoms after a 4 week trial. Sativex® is intended to be used in addition to the patient's current anti-spasticity medication. |

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| | **Responsibilities**<br><br>**Spasticity Consultant and /or Spasticity management Specialist Nurse:**<br><br>• Send a letter to the non-specialist clinician along with shared care criteria and transfer form requesting shared care for this patient. Indication, dose and frequency to be decided by the NHNN tertiary centre spasticity team.<br>• Discuss the benefits and side effects of treatment with the patient. Provide the patient with a Patient Information Leaflet, explain it and ensure that the patient understands the reason for the treatment, dosing regimen, potential side effects, and advise on driving.<br>• If the patient is of childbearing potential, to advise on reliable contraceptive precautions for duration of therapy (and for three months after discontinuation); inform the patient to contact the spasticity specialist team if planning pregnancy.<br>• Initiate treatment and prescribe until the primary or secondary care clinician formally agrees to share care (until patient is stabilised). Patients will be seen in clinic prior to consideration of shared care as outlined.<br>• Time = 0 months; face to face visit at NHNN and initiation of Sativex® (1 month supply given), patients also given a diary to record their NRS for Sativex®<br>• Time= 2 weeks; telephone consultation from NHNN (tertiary care) to assess response and tolerability<br>• Time= 1 month; face to face visit at NHNN; responders defined by a 20% reduction in their NRS will be given a 3 months' supply<br>• Time = 3 months; telephone consultation from NHNN to agree dose and treatment plan for primary care<br>• Discuss the shared care arrangement with the patient<br>• Ensure the patient understands that they must report the warning symptoms as listed under "adverse effects"<br>• Provide results of baseline assessments and recommend the dose (in sprays per day) and frequency of any monitoring to non-specialist clinician<br>• Send a letter to the non-specialist clinician after each clinic attendance ensuring current dose and how long each spray vial is expected to last is detailed<br>• Inform non-specialist clinician when to adjust the dose, stop treatment, or consult with the Spasticity management Team.<br>• Periodically review the patient's condition and communicate promptly with the non-specialist clinician when treatment is changed. Counsel the patient on any dose changes that are made during clinic appointments; this will be via face-to-face or video consultation from NHNN to review dose and treatment plan for primary care (6 monthly initially but minimum of annually if stable) |

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| | • The Spasticity specialist may conduct additional investigations as required e.g. physical assessment and recording of the Ashworth Scale. The results will be sent to the primary/secondary care clinician.<br>• Evaluate adverse effects reported by non-specialist clinician or patient<br>• Report adverse events to the MHRA (via yellow card scheme www. www.mhra.gov.uk/yellowcard) and non-specialist clinician<br>• Inform non-specialist clinician of patients who do not attend clinic appointments<br>• Ensure that clear backup arrangements exist for the primary or secondary care clinician to obtain advice and support<br><br>**Non-specialist primary or secondary care clinician:**<br>• Complete transfer form and send back to NHNN tertiary centre spasticity team confirming acceptance/ rejection of shared care for patient.<br>• If the non-specialist clinician is unable to agree to shared care, inform the NHNN tertiary centre spasticity team stating reasons within ***28 days*** of receipt of request (all requests should be marked URGENT). If no response is received with 28 days, the non-specialist clinician will be contacted directly to ask for a response.<br>• If no response is received by week 6, the specialist or formulary pharmacist will liaise with the patients' local medicines optimisation team, who should be encouraged to give a response within a 7 days.<br>• Non-specialist clinician to prescribe the drug treatment as described (but not to alter the dose unless advised to do so by the Spasticity specialist). The term "as directed" **SHOULD NOT** be used.<br>• Prescribe Sativex® using the dose as specified by the specialist.<br>• Check for any interactions with any new concurrent medications.<br>• Amend the prescribed dose on the medication record as advised by the Spasticity specialist (specialist will counsel the patient on any dose changes).<br>• If the patient reports any adverse events and/or non-compliance, report this to the Spasticity specialist, where appropriate.<br>• Stop treatment on advice of Spasticity specialist.<br>• Help in monitoring any changes in the patient's level of function or symptoms of stiffness and spasms and inform the specialist team of any changes to spasticity medication.<br>• Report adverse events to the Spasticity specialist and MHRA via yellow card.<br>• All requests for repeat prescriptions should be reviewed prior to issuing. |

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| | **Patient responsibility:**<br>• Attend all hospital (and, where applicable, GP) appointments, otherwise medication supply may be delayed.<br>• Take medicines as agreed.<br>• Report to the Spasticity specialist or if they do not have a clear understanding of the treatment.<br>• Inform Spasticity specialist or primary/secondary care prescriber of any other medication being taken or changes in medication, including over-the-counter products.<br>• Report any adverse effects or warning symptoms to primary/secondary care clinician or Spasticity specialist.<br>• Inform hospital and primary/secondary care clinician of any changes in address or telephone numbers.<br><br>**Integrated Care Boards (ICB):**<br>• To provide feedback to Trusts from the standard letter, via the shared care and fact sheet group.<br>• To support primary care clinicians to make the decision whether or not to accept clinical responsibility for prescribing.<br>• To support Trusts in the resolving issues that may arise as a result of shared care. |
| **Dose** | Sativex® is formulated as an oromucosal spray with each 100 microlitre spray containing 2.7 mg delta-9-tetrahydrocannabinol (THC) and 2.5 mg cannabidiol (CBD). Each spray vial of Sativex® contains 90 actuations.<br><br>The patient self-administers Sativex® by spraying it into their mouth-cheek or under the tongue.<br><br>**Initial stabilisation (by specialist team):**<br>Dosage is between 1-12 sprays per day spread out according to the patient's needs. A titration period is required to reach optimal dose. The number and timing of sprays will vary between patients.<br><br>**Maintenance dose:**<br>Dosage is according to patient needs; between 1-12 sprays a day. Many patients take more in the evening to help with sleep.<br><br>**Conditions requiring dose adjustment**<br>Further information about prescribing in elderly, children, pregnant women and patients with hepatic or renal impairment can be found here: Summary of Product Characteristics.<br><br>**Cautions**<br>• Moderate to severe hepatic impairment<br>• Moderate to severe renal impairment<br>• Severe depression<br>• Sativex® may reduce effectiveness of systemically acting hormonal |

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| | contraceptives, therefore women using systemically acting hormonal contraception for example the oral contraceptive pill or contraceptive implant should use an additional method of contraception for the duration of therapy and for three months after discontinuation.<br>• Sativex® is a controlled drug, and its legal status varies between countries. Information on travelling abroad with Sativex® is available at www.gov.uk/travelling-controlled-drugs.<br>• Sativex® should not be used in pregnancy unless benefit of treatment outweighs risk to the foetus.<br>• Until further information is available, caution should be taken when treating patients with a history of epilepsy or recurrent seizures.<br><br>**Contraindications**<br>• With hypersensitivity to cannabinoids or to any of the excipients.<br>• With 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.<br>• Breast-feeding.<br><br>**Drug interactions**<br>• Theoretical risk that there may be an additive effect with other muscle-relaxing agents such as baclofen and benzodiazepines, thereby increasing the risk of somnolence, weakness and falls.<br>• Sativex® is metabolised by the cytochrome P-450 enzyme system, therefore enzyme inducers or inhibitors may decrease or increase the concentration of Sativex® in the circulation. Seek specialist advice if necessary.<br>• 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 method of contraception for the duration of therapy and for three months after discontinuation.<br>• Care should be taken with hypnotics, sedatives and alcohol due to the additive side effects.<br><br>For a full list of cautions, contraindications and drug interactions, refer to the Summary of Product Characteristics. |
| **Duration of treatment** | The duration of treatment will be determined by the specialist based on clinical response and tolerability. |
| **Stopping criteria and treatment discontinuation** | Treatment should only be stopped on the advice of the specialist, for example in case of adverse effects, no clinical response, pregnancy, breastfeeding and drug interaction. |

<table>
<tr><td>Baseline monitoring (by specialist)</td><td colspan="3"><u>Baseline monitoring:</u><br><br>Measure spasticity including Ashworth Scale and a Numerical Rating Scale (NRS) for spasticity and spasms.</td></tr>
<tr><td rowspan="2">Ongoing monitoring (by primary care clinician)</td><td>Test</td><td>Frequency</td><td>Action if out of range</td></tr>
<tr><td>No specific monitoring including blood monitoring is required apart from review of adverse effects, patient's impression of efficacy and their mood</td><td>At each review by primary care clinician</td><td>To inform specialist (if appropriate) but to follow local guidelines for treatment of common adverse effects (see below)</td></tr>
<tr><td>Follow up arrangements</td><td colspan="3">Once dose and treatment plan for primary care agreed, to be reviewed by specialist every 6 months or minimum annually if stable.</td></tr>
<tr><td>Adverse effects and management<br><br>For a full list of adverse effects, please refer to the <u>Summary of Product Characteristics.</u><br><br>Healthcare professionals are asked to report any suspected adverse reactions to the MHRA via the <u>Yellow Card Scheme</u>.</td><td colspan="3"><table>
<tr><th>Adverse effect</th><th>Frequency</th><th>Action for GP</th></tr>
<tr><td>Dizziness</td><td>Very common</td><td rowspan="8">Manage as per local guidelines, to be reported to specialist if appropriate.<br><br>If side effects occur the dose should be lowered by 1-2 sprays/day.<br><br>In the case of oral irritation be advised to vary the site of the patient should spray around the mouth and avoid any ulcers or irritated areas.<br><br>If the primary or secondary care clinician has any concern regarding dose changes, they may wish to contact the Spasticity Team for advice.</td></tr>
<tr><td>Fatigue</td><td>Very common</td></tr>
<tr><td>Psychiatric disorders</td><td>Common</td></tr>
<tr><td>Somnolence</td><td>Common</td></tr>
<tr><td>Light headedness</td><td>Common</td></tr>
<tr><td>Oral irritation</td><td>Uncommon</td></tr>
<tr><td>Weakness or falls</td><td>Common</td></tr>
<tr><td>Low mood</td><td>Common</td></tr>
</table></td></tr>
<tr><td>Advice to patients and carers</td><td colspan="3">The patient should be advised to report any adverse effects to their GP without delay.<br>Patients should not drive, operate machinery or engage in any hazardous activity if they are experiencing any significant CNS effects such as dizziness or somnolence.</td></tr>
<tr><td>Resources and key references</td><td colspan="3">Drugs and Driving: The Law. <u>https://www.gov.uk/drug-driving-law</u> Accessed 20/12/24<br><br>NICE guidance: Cannabis-based medicinal products. <u>https://www.nice.org.uk/guidance/ng144</u> Accessed 20/12/24</td></tr>
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| | NICE guidance: Multiple sclerosis in adults: Management. https://www.nice.org.uk/guidance/ng220 Accessed 22/11/24<br><br>Sativex® Oromucosal Spray, GW Pharma Ltd. Last updated 23/10/24. https://www.medicines.org.uk/emc/product/602/smpc#gref Accessed 22/11/24<br><br>Patient information on Sativex® – Patient information Leaflet. Last updated 23/10/24. https://www.medicines.org.uk/emc/files/pil.602.pdf Accessed 20/12/24<br><br>Driving Advice for Sativex® Users - https://www.mstrust.org.uk/sites/default/files/DfT-New%20Drug%20Driving%20Rules-Sativex-A5.pdf. Accessed 20/12/24 |

## Contact Details

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| Trust name<br><br>The National Hospital for Neurology and Neurosurgery | Specialist service contact details:<br><br>Consultant: Val Stevenson<br>020 3448 3439<br>Val.stevenson1@nhs.net<br><br>Specialist or Dept sister: Liz Keenan<br>020 3448 3439<br><br>Specialist Pharmacist: Brina Bharkhada<br>brina.bharkhada1@nhs.net<br><br>Spasticity Helpline:<br>020 3448 3439<br><br>For clinical queries:<br>uclh.referrals.admin.spasticity@nhs.net |

## Document control

| Date | Version | Amendments |
|---|---|---|
| 14/12/2020 | V1.0 | New document |
| 22/12/2020 | V1.1 | Minor amends made in formatting and wording in Section 1 and contact details |
| 10/08/2021 | V1.2 | Protocol wording amended to make applicable for shared care with both primary or secondary care clinicians; section 3.2 updated |
| 20/12/2024 | V1.3 | Current guideline transferred to new template and resources and key references updated with current links |

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| Groups / Individuals who have overseen the development of this guidance: | Dr Val Stevenson – Consultant, NHNN<br>Brina Bharkhada – Specialist Pharmacist, NHNN<br>NCL ICB Medicines Optimisation team<br>JFC Support Pharmacists |
| Groups which were consulted and have given approval: | NCL Shared Care and Fact Sheet Group |
| File name: | Sativex® for multiple sclerosis related spasticity |
| Version number: | V1.3 |
| Available on: | https://nclhealthandcare.org.uk/our-working-areas/medicines-optimisation/shared-care-guidelines-and-factsheets/ |
| Disseminated to: | Formulary pharmacists and commissioners |
| Equality impact assessment: | Nil identified |
| NCL Shared Care Group Approval date: | 10/06/2025 |
| Review date: | 10/06/2027 |

## Appendix 1: Sativex® transfer form: from NHNN to GP practice

**Section A: to be completed by secondary care** *Send to practice*

*This document is to request the shared care pathway of your patient and comprises an agreement between the GP a named consultant. The patient will continue to be seen by the named consultant as regular follow up.*

| *Fix address label here (ensure NHS Number on)* | Clinic stamp *or give details below* |
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| Department | | | |
| Clinic phone | | | |
| Consultant | | Email | |
| Indication for prescription | | | |
| Drug prescribed | | | |
| Date Drug started | | Current dose | |
| Relevant conditions | | | |
| Monitoring variations | | | |
| Date next blood test | | Next disease review due in | months' time. |

**Section B: [Accept Shared Care] to be completed by practice**

*Send back **FAO referring consultant** above*

The above patient has been accepted into our monitoring service.

Practice date for next blood test

Signed /

Designation

Date

Practice stamp

**Section B: [Reject Shared Care] to be completed by practice**

*Send back **FAO referring consultant** above*

The above patient has not been accepted into our monitoring service.

Reason

Signed /

Designation

Date

Practice stamp