

SHARED CARE PRESCRIBING GUIDELINE

Sativex® (cannabidiol 2.5mg and Dronabinol 2.7mg per dose) for the treatment of spasticity associated with multiple sclerosis in ADULTS

|  |
| --- |
| **NOTES to the GP** |
| The information in the shared care guideline has been developed in consultation with CCGs in South East London and it has been agreed that it is suitable for shared care.  This document should provide sufficient information to enable you to make an informed decision regarding the clinical and legal responsibility for prescribing Sativex® for the treatment of spasticity associated with multiple sclerosis in  ADULTS  The questions below will help you confirm this:   * Is the patient’s condition predictable or stable? * Do you have the relevant knowledge, skills and access to equipment to allow you to monitor treatment as indicated in this shared care prescribing guideline? * Have you been provided with relevant clinical details including monitoring data?   **If you can answer YES to all these questions** (after reading this shared care guideline), then it is appropriate for you to accept prescribing responsibility.  **If the answer is NO to any of these questions** you should contact the requesting consultant or your local CCG Medicines Management Team. There may be implications for the patient where the invitation to share care is declined. For example, the patient may need to be changed to an alternative treatment regimen. It would not normally be expected that shared care prescribing would be declined on the basis of cost.  Sharing of care assumes communication between the specialist, GP and patient. The intention to share care should be explained to the patient by the doctor initiating treatment. **It is important that patients are consulted about treatment and are in agreement with it**.  Prescribing should follow requirements in the South East London Interface Prescribing Policy.  **The doctor who prescribes the medication legally assumes clinical responsibility for the drug and the consequences of its use. The patient’s best interests are always paramount.** |

**Once you have read the shared care guideline and considered the information above, please complete the GP decision form on the next page and email back to the requesting clinician if you are in agreement to participate in shared care.**

**GP DECISION FORM**

This shared care agreement outlines suggested ways in which the responsibilities for managing the prescribing of Sativex® for the treatment of spasticity associated with multiple sclerosis in adults can be shared between the specialist and general practitioner (GP). GPs are invited to participate. If the GP is not confident to undertake these roles, then he or she is under no obligation to do so. In such an event, the total clinical responsibility for the patient for the diagnosed condition remains with the specialist. If a specialist asks the GP to prescribe this drug, the GP should reply to this request as soon as practicable.

|  |  |
| --- | --- |
| **AGREEMENT TO PARTICIPATE IN SHARED CARE**  **Sativex® for treatment of spasticity associated with multiple sclerosis in adults** | |
| **Consultant/Specialist Name:** | **Patient name:** |
| **Consultant/Specialist signature:** | **Patient Hospital Number:**  **Patient NHS Number:** |
| **Date completed:** | **Patient Agreement:**  Patient agrees to shared care □  Patient does not agree to shared care □ |
| **Hospital requesting shared care:** |
| **GP Name:** | |
| **This is to confirm that I agree to participate in shared care for Sativex® for the treatment of spasticity associated with multiple sclerosis in adults** **for this patient as outlined in this shared care document** | |
| **GP Signature:** | |
| **Date signed:** | |

|  |
| --- |
| **ACTION**   1. **HOSPITAL SPECIALIST Tick to confirm (MS consultant, MS nurse or MS pharmacist)**  * Explain shared care to patient and obtain agreement Date agreement obtained: \_\_\_\_\_\_\_\_ 🞏 * Indicate requesting hospital 🞏 * Complete and sign agreement 🞏 * Email full shared care guideline (including signed agreement to GP) 🞏 * Place original in patient’s notes 🞏  1. **GP PRACTICE**  * If **in agreement** to participate in shared care, sign and email (via secure NHS.net) this sheet back **within 2 weeks** of receipt **of request from specialist** to either:   **[ADD CONTACT DETAILS for RELEVANT TRUSTS]**   * If **do not agree** to participate in shared care, contact consultant and local Primary Care CCG Medicines Management Team within 2 weeks of receipt to discuss. If after discussion it is agreed not to undertake shared care for this patient, both the consultant and the local Primary Care CCG Medicines Management team should be informed. * Once decision reached file a copy in the Patient’s medical notes. |

**Sativex® for treatment of spasticity associated with Multiple Sclerosis in ADULTS**

Spasticity is common in Multiple Sclerosis (MS) and can result in lack of movement or to uncontrolled movements, usually affecting the limbs or trunk, which may be painful and / or lead to contractures. In some people with MS it can be beneficial, e.g. increased stiffness in weak legs can aid mobility. Spasticity only requires treatment when it is causing troublesome symptoms, limiting function or having an emotional impact, e.g. depression, poor self-image.

In [2019 NICE](https://www.nice.org.uk/guidance/ng144/) recommended Sativex (Cannabidiol 2.5 mg per 1 dose, Dronabinol 2.7 mg per 1 dose) as an option for managing moderate to severe spasticity in adults with Multiple Sclerosis if other pharmacological treatments for spasticity are not effective. It is effective in approximately 50% patients. Its use may lead to improved symptom control in these patients and reduce the need for more invasive and expensive treatment.

This shared care guideline covers the use of Sativex oromucosal spray as an add-on treatment for ADULT patients (aged 18 years or over) with moderate to severe spasticity associated with MS where they have already failed to respond to two other anti-spasticity treatments. As per the local formulary agreement, initiation of Sativex will be restricted to the neurologists with a special interest in MS at King's College Hospital (KCH), Guy's and St. Thomas' Hospital (GSTFT) and Lewisham and Greenwich NHS Trust (LGT). The first 2 months will be supplied by the MS clinic, during which the dose is gradually titrated up from one spray/day (to minimise side effects, typically dizziness and fatigue) to the optimum dose (typically 4-8 sprays/day; max 12) over 2 weeks and then the response assessed after 1 month. Any patients with ongoing symptoms will be seen by the consultant / MS nurse and reassessed.

# **CIRCUMSTANCES WHEN SHARED CARE IS APPROPRIATE**

* Prescribing responsibility will only be transferred when the consultant and the GP are in agreement that the patient’s condition is stable or predictable.
* The hospital will provide the patient with the first 2 months supply of therapy (including initial supply for titration and assessment of response post 4 weeks).

1. **Areas of responsibility**

|  |
| --- |
| **Specialist team responsibilities (this may be the consultant, MS nurse or MS pharmacist)** |
| * To confirm that the patient is suitable for treatment with Sativex in line with both [the Summary of Product Characteristics (SPC)](https://www.medicines.org.uk/emc/product/602/smpc) for the drug, and the Sativex care pathway (refer to [Appendix 1](#Appendix)). Patients must have had an adequate trial of at least two alternative oral anti-spasticity treatments which have been ineffective based on the Numeric Rating Scale (NRS) measurements. Refer to “Place in Therapy” section on page 6 for treatments that should have been tried before Sativex is considered. * To confirm that the patient does not have any contraindications to treatment: * Does not have hypersensitivity to cannabinoids or any of the excipients contained in Sativex * Does not have a history of severe mental disorder, including psychotic illness * Where female, is not breastfeeding * To inform the patient of the importance of appropriate contraception. Men and women of childbearing potential should avoid pregnancy and take reliable contraceptive precautions for the duration of therapy and for 3 months after discontinuation of therapy. * To inform patients that Sativex may reduce the effectiveness of systemically acting hormonal contraceptives, and therefore women using systemically acting hormonal contraceptives should add an additional second barrier method. * To check for any interactions with Sativex and the patients other medication * To carry out baseline record of the NRS. * To inform patients of practical issues related to the use of Sativex, such as storage and maximum dose – see “Information provided to patient” section on page 8. * To initiate, stabilise and supply treatment of Sativex® over the first 2 months of treatment. The specialist team will initially supply one month’s treatment (3 x 10ml vials) and provide the patient with instructions as to how to prime the vial, administer spray and titrate the dose to the optimum amount (typically 4-8 sprays/day; max 12) over 2 weeks (see Appendix 2). During this first 2 weeks titration period the patient will be advised not to drive. Once the optimum dose has been determined, treatment can be used at any time of the day or night depending on symptoms, but leaving at least a 15-minute gap between sprays. * To provide patients with written instructions ([Patient Information Leaflet](https://www.medicines.org.uk/emc/product/602/pil))/ diary and advice on how the diary should be completed. * At the time of initiating Sativex, notify GP in writing that Sativex has been prescribed as a trial. The GP should be invited to shared care if the trial is successful. Information provided to the GP should include: * A copy of the shared care guidelines * That a prescription for a 4 week trial has been provided * Information on when the patient will next be reviewed and by whom * A request that the GP continue prescribing after the first 2 month’s supply, once the MS specialist (nurse, pharmacist or consultant) has written to the GP to confirm that benefit has been obtained from Sativex * Result of baseline NRS score * If the GP is willing to participate in shared care, to discuss the shared care arrangements with the patient. * To contact patient after 4 weeks to determine if Sativex has been beneficial (20% or greater improvement in NRS). * To inform the GP of outcome of evaluation and whether or not Sativex treatment is being continued long-term or withdrawn following the 4 week trial. * If treatment is to be continued: * To prescribe a second supply of 3 x 10ml of Sativex® following the four week assessment * Inform the GP of the current dose along with request for on-going prescriptions * To review patient at the request of GP should any problems arise (side-effects / lack of efficacy) . * To communicate promptly with the GP if treatment is changed. * To contact patient again at month 3 by telephone to review response to treatment and side effects, and write to GP to inform them of outcome of evaluation. * To communicate information on the patient’s progress with treatment or any changes in treatment, including current dose, to the GP after each review. * To monitor for efficacy and significant side-effects at least every 6-12 months whilst the patient remains on Sativex. * To report any suspected adverse effects to the MHRA: <http://www.yellowcard.gov.uk> |

|  |
| --- |
| **General Practitioner responsibilities** |
| * To consider shared care proposal within 2 weeks of receipt. * If in agreement, to continue prescribing as detailed in shared care guideline. Confirmation to the requesting consultant is required within 2 weeks of receipt of this guideline by completing and returning the agreement on page 3. * If do not agree to shared care discuss with requesting consultant or local borough medicines management team within 2 weeks of receipt of shared care request.     After agreement to shared care   * To provide ongoing prescriptions for Sativex after the first 2 months of treatment, for patients who have been found to benefit from treatment. * To adjust the dose as advised by the specialist. * To agree monitoring requirements with specialist – see page 7 of this document for GP monitoring requirements. * To report and seek advice regarding any concerns, for example: side-effects (possible allergic reactions, excessive somnolence, dizziness), co-morbidities where caution should be taken (seizures, severe cardiovascular disease, mental illness), pregnancy, lack of efficacy, or concurrent use of illicit cannabis or other drugs of abuse to the MS specialist team (MS nurse, consultant, or pharmacist). * To monitor ongoing use of Sativex to ensure appropriate quantities are ordered and to contact the MS specialist if there are any issues of concern. This includes if the patient requests excessive repeat prescriptions (i.e. using more than one 10ml vial every 10 days or more than 3 vials a month). Note a maximum of 3x10ml canisters (1 full pack) of Sativex should be prescribed per month. * To check compatibility interactions when prescribing new or stopping existing medication. Contact the specialist if advice is needed for this. * To advise the specialist if non-compliance is suspected. * To refer back to specialist if the patient's condition deteriorates. * To stop treatment on the advice of the specialist or immediately if an urgent need to stop treatment arises. * To report any suspected adverse effects to the MHRA via the Yellow Card scheme: <http://www.yellowcard.gov.uk> * To add SNOMED code for shared care prescribing “415522008” |

|  |
| --- |
| **Patient's / Carer’s responsibilities** |
| * To contact the specialist or GP if he or she does not have a clear understanding of any aspect of the treatment. * To inform prescribing specialist, GP and other healthcare professionals of any other medication being taken, including over the counter products, alternative therapies or recreational drugs. * To inform community pharmacists that they are using Sativex® before purchasing medication over-the-counter. * To attend all hospital and GP appointments. * To take medicines as agreed and take steps to ensure that no doses are missed and not to share medicines with others. * To read the [patient information leaflet](https://www.medicines.org.uk/emc/product/602/pil) included with the medication. * To not drive or use machinery if affected by dizziness or sommnolance * To monitor dosing requirements of Sativex® using a patient diary which will be reviewed with the specialist at their next appointment. * To report any adverse effects or warning symptoms to GP, hospital MS specialist or community nurse * To report to GP and MS team if pregnant or breastfeeding. * To inform GP and hospital of any changes in addresses or telephone contact numbers. * When travelling abroad, to check with the Home Office if Sativex is legal in the country they are due to visit and to request a letter from the MS specialist. |

1. **CLINICAL INFORMATION**

**NOTE:** The information here is not exhaustive. Please also consult the current Summary of Product Characteristics (SPC) for Sativex®prior to prescribing, for up to date prescribing information, including detailed information on adverse effects, drug interactions, cautions and contraindications (available via [www.medicines.org.uk](http://www.medicines.org.uk))

|  |
| --- |
| **Indication(s)** |
| Sativex oromucosal spray is indicated as treatment for symptom improvement in patients with moderate to severe spasticity due to MS who have not responded to other anti-spasticity medication (at least 2 in this case) and who demonstrate clinically significant improvement in spasticity related symptoms during an initial trial of therapy. |
| **Place in Therapy** |
| Sativex is used as an add-on treatment for the management of moderate to severe spasticity that has not responded to at least two of the treatments listed below. It is effective in approximately 50% patients. However, its use may lead to improved symptom control in these patients and reduce the need for more invasive and expensive treatment.  **Initial treatment (non-pharmacological):**   * **Avoidance of aggravating factors**, e.g. pressure ulcers, ingrowing toenails, urinary tract or other infections, constipation, inappropriately fitted mobility aids, posture and pain. * Referral to a **physiotherapist** for assessment of posture, seating etc.   **Pharmacological Treatment:**  See recommendations on spasticity in [NICE`s guideline on multiple sclerosis in adults](https://www.nice.org.uk/guidance/cg186/chapter/Recommendations)   * Encourage patients to manage their own spasticity symptoms by explaining how doses of drugs can be adjusted within agreed limits. * Gradually titrate to maximum effective and tolerated dose, ensure patient has tried the drug at an optimal dose before adding a second option. Withdraw slowly if no benefit at the maximum tolerated dose. * Combine drugs if a single drug is only partially effective / tolerated.   **First line** **pharmacological treatments**   * **Baclofen** (oral) – initial dose 5mg TDS, maximum 100mg in divided doses (effect lasts 4-6 hours). Side effects are common, especially drowsiness, confusion, dizziness and weakness. Avoid abrupt withdrawalas this can lead to hallucinations and seizures. * **Gabapentin** (oral) (off label use)– mild anti-spasticity effects but may be used in patients with co-existent neuropathic pain (typical dose 100-300mg/day gradually increased to a maximum of 900mg TDS).   **Second line** **pharmacological treatments:**   * **Tizanidine** (oral) – starting dose 2mg / day increasing by 2mg every 3-4 days usually up to 24mg in 3-4 doses/day (max 36mg). Better tolerated than baclofen but may cause drowsiness, postural hypotension and dry mouth. *Avoid abrupt withdrawal. Monitor liver function monthly for the first 4 months* and if unexplained nausea, anorexia or fatigue. * **Dantrolene** (oral) –peripherally acting drug thatworks directly on smooth muscle. Initial dose 25mg/day. This can be increased at weekly intervals to a usual dose 75mg tds (maximum dose 100mg qds). Its use is limited due to *frequent GI symptoms* such as severe diarrhoea, necessitating withdrawal. Liver function should be checked before and during treatment.   **Third line pharmacological treatments:**   * **Benzodiazepines** (oral) – *Clonazepam* most commonly used at doses of between 0.5mg nocte up to 3-4mg/day. Sedative side effects make it most effective when symptoms of spasticity are most troublesome during the night. *Diazepam* is less commonly used.   **Other treatments**   * Botulinum toxin (injections) – can be injected directly into affected muscles to weaken them. Effect can take up to 14 days and lasts approximately 3 months. Treatment should be combined with physiotherapy. * Intrathecal Baclofen – for people who cannot tolerate oral baclofen as much smaller doses can be given. Administered through a pump that is surgically implanted in the abdomen. The pump contains a reservoir that needs to be refilled regularly otherwise withdrawal side effects may occur. * Intrathecal Phenol – used to manage severe spasticity that is not responding to other treatments. It is given via lumbar puncture and permanently destroys nerve conduction. It reduces muscle tone but also affects sensation, sexual and sphincter function. * Surgery – orthopedic or neurosurgical procedures are rarely used. |
| **Dose & route of administration** |
| * Oromucosal spray. * Dose varies with individual patient. Maximum dose of 12 sprays per day with a minimum of 15 minutes between sprays. |
| **Duration of treatment** |
| Ongoing with regular review |
| **Criteria for stopping treatment** |
| * Patients with less than 20% improvement on their Numeric Rating Scale (NRS) score after 4 weeks of treatment should be advised to discontinue Sativex and consider alternative treatment. * If as part of the ongoing review, it is recognised that response has deteriorated and dose titration does not improve symptom management. * Hypersensitivity to the active ingredients or excipients. * Side effects are intolerable. |
| **Monitoring Requirements including frequency** |
| Consultant:   * Review patient at the request of GP / MS specialist nurse or pharmacist should any problems arise.   MS Nurse/MS Pharmacist:   * Monitor for efficacy, significant side-effects and overuse at 1 month, 3 months and then at least every 6 months whilst the patient remains on Sativex and inform the consultant if concerns arise.   GP:   * No additional regular review or monitoring is required by the GP. The GP should report any concerns about side-effects (possible allergic reactions, excessive somnolence, dizziness), co-morbidities (seizures, severe cardiovascular disease, mental illness), pregnancy, overuse or lack of efficacy, concurrent use of illicit cannabis or other drugs of abuse to the MS specialist team (MS nurse, consultant or pharmacist).   Routine blood monitoring is *not* required  All individuals involved on the patients care have responsibility to report any suspected adverse effects to the MHRA: <http://www.yellowcard.gov.uk> |
| **Follow up arrangements** |
| Refer to monitoring requirement above |
| **Practical issues including other relevant advice/information**  **Reminder: this list is not exhaustive - for full details of adverse effects and all potential drug interactions refer to latest Summary of Product Characteristics (SPC) for the drug, available via www.medicines.org.uk.** |
| * **Prescribing**:   + Sativex is a schedule 4 part 1 controlled drug and so ***controlled drug prescription requirements do not apply***. Please refer to the “CD and Drug Dependence” section of the current BNF for further information.   + Each vial contains approximately 90 sprays and will last around 10-15 days on average, therefore should not be prescribed more than 3 vials per month. * **Storage**: * It should be stored in the fridge but once opened it can be kept out of the fridge for up to 42 days. It should be kept upright. * **Side effects**:   + The most commonly reported side effects are dizziness and fatigue, which occur mainly during the initial titration period. These reactions are usually mild to moderate and normally resolve within a few days even if treatment is continued. * 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. * Sativex does not typically cause a ‘high’ comparable with recreational cannabis use. * There is a risk of an increase in incidence of falls in patients whose spasticity has been reduced and whose muscle strength is insufficient to maintain posture or gait. In addition to an increased risk of falls, the CNS adverse reactions of Sativex could potentially have an impact on various aspects of personal safety, such as with food and hot drink preparation. * If side effects occur the dose should be lowered by 1-2 sprays/day, in the case of oral irritation the patient should be advised to vary the site of the spray around the mouth and avoid any ulcers or irritated areas.   For a full list of side effects refer to the [Summary of Product Characteristics](https://www.medicines.org.uk/emc/product/602/smpc) (see reference).   * **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.   + Women who are breast feeding   For a full list of contraindications, refer to the [Summary of Product Characteristics](https://www.medicines.org.uk/emc/product/602/smpc) (see reference)**.**   * **Cautions**:   + Moderate to severe hepatic impairment   + Moderate to severe renal impairment   + Severe depression   + Until further information is available, caution should be taken when treating patients with a history of epilepsy or recurrent seizures.   + History of serious cardiovascular disease   + Sativex should not be used in pregnancy unless benefit of treatment outweighs risk to the foetus   For a full list of cautions, refer to the [Summary of Product Characteristics](https://www.medicines.org.uk/emc/product/602/smpc) (see reference).   * **Drug Interactions:**   + There is a 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.   + 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.   + ***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****.*   + Care should be taken with hypnotics, sedatives and alcohol due to the additive side effects.   For a full list of drug interactions, refer to the [Summary of Product Characteristics](https://www.medicines.org.uk/emc/product/602/smpc) (see reference).   * **Contraception:** Should be advised for men and women whilst taking Sativex and for three months after discontinuation. * **Travel**: When travelling abroad patient will need to check with the Home Office (see reference) if Sativex is legal in the country they are due to visit and they should request a letter from their MS specialist |
| **Information provided to the patient** |
| * Detailed patient education on how to use Sativex, the benefits, adverse effects and follow up plans will be given to the patient at the initiation appointment with the MS specialist. The patient will also be provided with a patient information leaflet on Sativex. * The patient information leaflet for Sativex can be downloaded from: <https://www.medicines.org.uk/emc/files/pil.602.pdf> |

|  |
| --- |
| **Evidence Base for treatment and key references** |
| * Multiple Sclerosis in adults: management. NICE (2014). Accessed from: <https://www.nice.org.uk/guidance/cg186>. Last updated November 2020. * Cannabis based medicinal products. NICE (2019). Accessed from: <https://www.nice.org.uk/guidance/ng144/chapter/recommendations> Last accessed December 2020. * British National Formulary 80. September 2020-March 2021. Accessed from: <https://www.medicinescomplete.com> . Last accessed December 2020 * Summary of Product Characteristics. Sativex oromucosal Spray. Accessed from: <https://www.medicines.org.uk/emc/product/602/smpc>. Last accessed December 2020. * Package leaflet: Information for the patient Sativex Oromucosal Spray. Accessed from: <https://www.medicines.org.uk/emc/files/pil.602.pdf>. Last accessed December 2020 * Multiple Sclerosis Trust, Sativex (nabiximols). Accessed from: <https://www.mstrust.org.uk/a-z/sativex-nabiximols>. Last accessed December 2020. * Sativex [www.sativex.co.uk](http://www.sativex.co.uk). Last accessed December 2020. * Bringing medicine containing a controlled drug into the UK (gov.UK). Accessed from: <https://www.gov.uk/travelling-controlled-drugs>. Last accessed December 2020 |

# **COMMUNICATION AND SUPPORT**

|  |  |  |
| --- | --- | --- |
| **King’s College and Princess Royal Hospitals switchboard: 0203 299 9000** | | |
| **Consultant/specialist team (Kings College Hospital)**  Dr Peter Brex (Neurology Consultant)  Dr Eli Silber (Neurology Consultant)  Dr Victoria Williams (Neurology Consultant)  Dr Yasser Falah (Neurology Consultant)  Dr Rhian Raftopoulos (Neurology Consultant)  Secretary for Neurology consultants  Gosia Kuran (Clinical Nurse Specialist, Multiple Sclerosis)  Miranda Keates (Multiple Sclerosis pathway coordinator) | | Email: [p.brex@nhs.net](mailto:p.brex@nhs.net)  Email: [eli.silber@nhs.net](mailto:eli.silber@nhs.net)  Email: [Victoria.williams25@nhs.net](mailto:Victoria.williams25@nhs.net)  Email: [y.falah@nhs.net](mailto:y.falah@nhs.net)  Email: [r.raftopoulos@nhs.net](mailto:r.raftopoulos@nhs.net)  Tel:020 3299 2994  [Tel: 020](Tel:020) 3299 5193  Email: [gosia.kuran@nhs.net](mailto:gosia.kuran@nhs.net)  Tel: 020 3299 8344  Email: [miranda.keates@nhs.net](mailto:miranda.keates@nhs.net) |
| **Consultant/specialist team (Princess Royal University Hospital)**  Dr Peter Brex (Neurology Consultant)  Dr Yasser Falah (Neurology Consultant)  Dr Rhian Raftopoulos (Neurology Consultant)  Maureen Ennis(Clinical Nurse Specialist, Multiple Sclerosis)  Lisa Marsh(Clinical Nurse Specialist, Multiple Sclerosis) | | Email: [p.brex@nhs.net](mailto:p.brex@nhs.net)  Email: [y.falah@nhs.net](mailto:y.falah@nhs.net)  Email: [r.raftopoulos@nhs.net](mailto:r.raftopoulos@nhs.net)  Email: [maureen.ennis@nhs.net](mailto:maureen.ennis@nhs.net)  Email: [**l.marsh1@nhs.net**](mailto:l.marsh1@nhs.net)  Tel: 01689 863886 |
| **Medication – Prescribing advice, interactions, availability of medicines**  Deborah Clark (Principal Pharmacist – Neuroscience)    Shelley Jones (Consultant Pharmacist – Neuroscience) | | Tel: 020 3299 9000 (35717)  Email: [Deborah.clark7@nhs.net](mailto:Deborah.clark7@nhs.net)  Tel: 020 3299 9000 (35717)  Email: [Shelley.jones1@nhs.net](mailto:Shelley.jones1@nhs.net) |
| **Guy’s and St. Thomas’ Hospital switchboard: 0207 188 7188** | | |
| **Consultant/specialist team**  Dr Victoria Williams (Neurology Consultant)  Makeda Best (Clinical Nurse Specialist, Multiple Sclerosis) | | Tel: 020 7188 3957  Email: [Victoria.williams25@nhs.net](mailto:Victoria.williams25@nhs.net)  Email: [Makeda.best@gstt.nhs.uk](mailto:Makeda.best@gstt.nhs.uk) |
| **Medication – Prescribing advice, interactions, availability of medicines**  Anushka Dewan (Pharmacist) | | Tel: 020 7188 8748  Email: [NeurologyPharmacists@gstt.nhs.uk](mailto:NeurologyPharmacists@gstt.nhs.uk) |
| **Lewisham and Greenwich Hospitals switchboard 020 8836 6000** | | |
| **Consultant/specialist team**  Dr Eli Silber (Neurology Consultant)  Secretary for Neurology consultants  Kitty McCarthy (Clinical Nurse Specialist, Multiple Sclerosis)  Lisa Perfect (Clinical Nurse Specialist, Multiple Sclerosis) | | Email: [eli.silber@nhs.net](mailto:eli.silber@nhs.net)  [Tel: 020](Tel:020) 8836 5575  Email: [kmccarthy@nhs.net](mailto:kmccarthy@nhs.net)  Email:[lisa.perfect@nhs.net](mailto:lisa.perfect@nhs.net)  Tel: 020 8836 4963 |
| **Medication – Prescribing advice, interactions, availability of medicines**  Lewisham and Greenwich Medicines Information | | Email: [LG.QE-MedInfo@nhs.net](mailto:LG.QE-MedInfo@nhs.net)  Tel: 020 8836 4900 |
| **Neuroscience-Medicines Helpline for South London and Surrounding areas** | | |
| The helpline can be contacted for any questions about medicines used in the management of a neurological or neurosurgical condition and may be accessed by patients, carers and healthcare professional across South London and surrounding areas. | Monday to Friday 10am to 4pm  Tel: 020 3299 4162 | |

**Appendix 1: Care Pathway for Sativex Oromucosal spray for treating spasticity in Multiple Sclerosis (MS)**

**This flowchart covers the responsibilities of the specialist MS team and is provided here for the GP’s information**.

Patient has MS of any sub-type and complains of **moderate to severe** spasticity causing painful spasms or limiting activity / affecting care

MS specialist team to record baseline spasticity severity on the **Numeric Rating Scale (0 – 10).** [Moderate-severe spasticity ≥ 4]. Document NRS score in clinic letter and copy to MS nurse

Address any **aggravating factors** for spasticity, e.g. UTI, constipation, depression, pressure sores etc. Consider referral to **physiotherapy**

Patient has had an adequate trial of at least two oral alternative anti-spasticity treatments, however, these have been ineffective based on the NRS ((Baclofen & Gabapentin recommended in MS NICE guidelines as first line treatment)

**Consider Sativex at this point**

Ask about any contraindication to Sativex (known hypersensitivity to cannabinoids, breastfeeding, personal or family history of significant psychiatric disorder other than depression, serious cardiovascular disease). Men and women of childbearing potential should avoid pregnancy and take reliable contraceptive precautions for the duration of therapy and for 3 months after discontinuation of therapy. Use with caution if history of seizures.

Prescribe **3 x 10ml vials of Sativex** from Trust pharmacy. Patient should be instructed to take one spray on the first day and then **increase by one spray per day** until spasticity has improved or the **maximum dose of 12 sprays** per day with a **minimum of 15 minutes between sprays**. Warn patients that only 50% patients respond to Sativex and it will be discontinued if ineffective

Contact GP to request shared care

MS nurse to contact patient after 4 weeks to record severity of spasticity on NRS.

Patients with an improvement of **20% or more** should be advised to continue with treatment. The MS specialist will arrange a second prescription, 3 x 10ml of Sativex® (to cover the 2nd month of treatment) and contact the GP to confirm shared care and request ongoing prescribing.

For patients who do not respond, Sativex® should be discontinued and alternative treatment options considered.

**Numeric Rating Scale (NRS):** Ask patient to assess the average level of spasticity-related symptoms over the past 24 hours – 0 (no spasticity) to 10 (worst possible spasticity). Moderate / severe spasticity should be defined as patients with a score of more than 4/10.

**Appendix 2: Titration Schedule over first 2 weeks of treatment with Sativex®**

|  |  |  |  |
| --- | --- | --- | --- |
| **Day** | **Number of sprays in the morning** | **Number of sprays in the evening** | **Total number of sprays per day** |
| 1 | 0 | 1 | 1 |
| 2 | 0 | 1 | 1 |
| 3 | 0 | 2 | 2 |
| 4 | 0 | 2 | 2 |
| 5 | 1 | 2 | 3 |
| 6 | 1 | 3 | 4 |
| 7 | 1 | 4 | 5 |
| 8 | 2 | 4 | 6 |
| 9 | 2 | 5 | 7 |
| 10 | 3 | 5 | 8 |
| 11 | 3 | 6 | 9 |
| 12 | 4 | 6 | 10 |
| 13 | 4 | 7 | 11 |
| 14 | 5 | 7 | 12 |