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| **(Sativex) for patients within (Service Name)** | | | |
| **1. Background** | The NICE guidance on [Cannabis based medicinal products](https://www.nice.org.uk/guidance/ng144)2 advises that Sativex is an option if other pharmacological treatments for spasticity are not effective and the conditions of a pay-for-responders scheme are met. The manufacturer funds the first four weeks’ treatment provided that there is agreement for continued funding for people with at least a 20% reduction in spasticity-related symptoms as measured on a 0 to 10 patient reported numeric rating scale2.  See the MTRAC Commissioning Support guidance on Sativex for a summary of the evidence. | | |
| **2. Indications**  **(Please state whether licensed or unlicensed)** | Sativex is licensed for use as treatment for symptom improvement in patients with moderate to severe spasticity due to 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.3 | | |
| **3. Locally agreed off-label use** | N/A | | |
| **4. Contraindications and cautions**  Please note this does not replace the Summary of Product Characteristics (SPC) and should be read in conjunction with it. | * Mild or moderate dizziness is common, and most frequently occurs in the first few weeks of treatment. * Fainting episodes have been observed; use of Sativex is not recommended in patients with serious cardiovascular disease. * Patients 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. * Hypersensitivity to cannabinoids. * Psychiatric symptoms such as anxiety, illusions, changes in mood, and paranoid ideas have been reported during treatment with Sativex 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. * Risk of increased 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, particularly in elderly patients, could potentially have an impact on various aspects of personal safety, such as with food and hot drink preparation.   Please see [SPC](https://www.medicines.org.uk/emc/product/602) for comprehensive information. | | |
| **5. Initiation and ongoing dose regime**  Note -  •Transfer of monitoring and prescribing to primary care is normally after the patient’s dose has been optimised and with satisfactory investigation results for at least 4 weeks  •The duration of treatment & frequency of review will be determined by the specialist, based on clinical response and tolerability.  •All dose or formulation adjustments will be the responsibility of the initiating specialist unless directions have been discussed and agreed with the primary care clinician  •Termination of treatment will bethe responsibility of the specialist. | **Initial stabilisation:** The initial dose is 1 spray taken in the evening. The number of sprays should be increased each day following the schedule in the [SPC](https://www.medicines.org.uk/emc/product/602), up to a maximum of 12 sprays per day.  **The loading period** **must be prescribed by the initiating specialist.**  **Maintenance dose (following initial stabilisation):** Following titration, patients are advised to maintain the optimum dose achieved. The median dose in clinical trials involving patients with MS was eight sprays per day.  **The initial maintenance dose must be prescribed by the initiating specialist.**  **Conditions requiring dose adjustment:**  Changes in the severity of the patient’s condition, changes in concomitant medication or if troublesome adverse reactions develop. Doses of greater than 12 sprays per day are not recommended in the [SPC](https://www.medicines.org.uk/emc/product/602). | | |
| **6. Pharmaceutical aspects** | Route of administration: | Oral spray | |
| Formulation: | Oromucosal | |
| Administration details: | The spray container should be shaken before use and the spray directed at different sites each time the product is used. | |
| Other important information: | Sativex is intended for use in addition to the patient’s current anti-spasticity medication | |
| **7. Significant medicine interactions**  For a comprehensive list consult the BNF or Summary of Product Characteristics. [SPC](http://www.medicines.org.uk/emc/) | **The following list is not exhaustive; please see** [**SPC**](https://www.medicines.org.uk/emc/product/602) **for comprehensive information and recommended management.**   * Care should be taken with hypnotics, sedatives and drugs with potential sedating effects as there may be an additive effect on sedation and muscle relaxing effects. * Sativex may interact with alcohol, affecting co-ordination, concentration and ability to respond quickly. In general, alcoholic beverages should be avoided whilst using Sativex, especially at the beginning of treatment or when changing dose. * Sativex may reduce the effectiveness of systemically acting hormonal contraceptives; women using systemically acting hormonal contraceptives should add an additional second barrier method. * A component of Sativex, cannabidiol, increases risk of increased ALT concentrations when co-administered with valproate. Manufacturer advises avoid or adjust dose. | | |
| **8. Baseline investigations, initial monitoring and ongoing monitoring to be undertaken by specialist** | **Baseline investigations:**   * Evaluation of the severity of spasticity-related symptoms, and of the response to current anti-spasticity medication before treatment initiation   **Initial monitoring:**   * 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 the GP. * Response to treatment should be reviewed after four weeks. Treatment should be stopped if the person does not show a clinically significant improvement (>20% improvement in spasticity related symptoms on a 0-10 patient reported numeric rating scale)   **Ongoing monitoring:**   * Periodic review is required to assess the value of long-term treatment | | |
| **9. Ongoing monitoring requirements to be undertaken by primary care~~.~~**  See section 10 for further guidance on management of adverse effects/ responding to monitoring results. | Monitoring | | Frequency |
| Review of continuing effectiveness of treatment | |  |
| **10. Adverse effects and managements**  **Any serious adverse reactions should be reported to the MHRA via the Yellow Card scheme** [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard) | Result | | Action for GP |
| Psychiatric symptoms: anxiety, illusions, changes in mood, and paranoid ideas | | Discuss options: reduction in dose or cessation of treatment. Assess patient experience of treatment efficacy |
| **11. 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. | **The patient (or their carer) should be advised to report any of the following signs or symptoms to their GP without delay:**   * Disorientation (or confusion), hallucinations, delusional beliefs or transient psychotic reactions. In a few cases in clinical development a causal association between Sativex administration and suicidal ideation could not be ruled out * Advise that there may be an increased risk of falls, due to factors such as increased dizziness, reduced spasticity or potentially additive effects with other anti-spasticity medications on muscle relaxation | | |
| **12. Pregnancy, paternal exposure and breast feeding**  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 GP and the specialist. | **Pregnancy:** Sativex should not be used during pregnancy unless the potential risks to the fetus and/or embryo are considered to be outweighed by the benefit of treatment.  **Breastfeeding:** Sativex is excreted in breast milk and is contraindicated during breastfeeding. | | |
| **13. Specialist contact information** | Name: *[insert name]*  Role and specialty: *[insert role and specialty]*  Daytime telephone number: *[insert daytime telephone number]*  Email address: *[insert email address]*  Alternative contact: *[insert contact information, e.g. for clinic or specialist nurse]*  Out of hours contact details: *[insert contact information, e.g. for duty doctor]* | | |
| **14. Additional information** | Where patient care is transferred from one specialist service or GP practice to another, a new shared care agreement must be completed. | | |
| **15. References** | 1. NICE Guidelines Update Team. Cannabis-based medicinal products [C] Evidence review for spasticity 2019. h[ttps://www.nice.org.uk/guidance/ng144/evidence/c-spasticity-pdf-6963831760](ttps://www.nice.org.uk/guidance/ng144/evidence/c-spasticity-pdf-6963831760%20) (accessed February 2021).  2. Cannabis-based medicinal products : guidance (NG144): NICE; 2019 h[ttps://www.nice.org.uk/guidance/ng144](ttps://www.nice.org.uk/guidance/ng144%20) (accessed Jan 2021).  3. GW Pharma. Sativex Oromucosal Spray 2020. <https://www.medicines.org.uk/emc/product/602>. | | |
| **16. To be read in conjunction with the following documents** | * RMOC Shared Care Guidance * NHSE policy- Responsibility for prescribing between Primary & Secondary/Tertiary Care | | |
| **17. Local arrangements for referral**  Define the referral procedure from hospital to primary care prescriber & route of return should the patient’s condition change. | To be agreed and completed locally | | |

APC board date:

Last updated: