Shared Care Guideline for Sativex oromucosal spray (GP Summary)

It is essential that a transfer of care only takes place with agreement of the GP and when sufficient information has been received. If the GP does not agree to share care they will inform the Consultant responsible for the patient's care.

Basingstoke, Southampton & Winchester District Prescribing Committee

Specialist Contact Details	**Patient ID Label**
Name:_____	**Surname:**_____
Location:_____	**Forename:**_____
Date:_____	**NHS Number:**_____
Tel:_____	**Date of Birth:**_____

Indications	For people 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.
Exclusions	History of hypersensitivity to cannabinoids. 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. Pregnancy and breast feeding.
Dose & response	Each single 100 microlitre spray contains: 2.7 mg delta-9-tetrahydrocannabinol (THC) and 2.5 mg cannabidiol (CBD) from *Cannabis sativa L*. There is an initial titration period during which the number of sprays should be increased each day following a prescribed pattern. 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.
Specialist responsibilities	1. Initial assessment to determine eligibility for treatment, ensuring there are no interactions with concurrent therapy or disease states. 2. To prescribe the initial 4 week trial of therapy. 3. Notify the patient's GP that treatment has commenced. 4. To assess response to the initial 4 week trial using a 0-10 spasticity numerical rating scale. 5. If there is a clinically significant improvement without major tolerability issues then to prescribe a further 2 months of Sativex therapy 6. Approach GP requesting shared care once the patient's medicine regimen is stable. 7. Ensure patient is fully informed of potential benefits and side effects of treatment 8. Ensure patient's guardian/carer is fully informed of the treatment 9. Provide a comprehensive treatment package in addition to medications including appropriate information sheet(s) 10. Ensure that shared care arrangements are in place before transfer of treatment: 11. Ensure the patient knows what significant adverse effects/events to report urgently and to whom they should report (specialist or GP) 12. Any dose changes once the patient is established on treatment will be conveyed in writing to the GP for the GP to prescribe 13. Monitor response to treatment and side effects of medication via 6 monthly routine out-patient visits 14. Report adverse events to the MHRA.

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GP Responsibilities	**Key roles to be undertaken in primary care once a decision to work under shared care is made** 1. To continue to prescribe Sativex at the dose recommended by the specialist. 2. At each appointment ensure that the patient/carer is clear what is being monitored and by whom. 3. Check drug interactions with any new medication started or any new conditions diagnosed. Contact Specialist Team if possible interactions found and discuss with Specialist. 4. Confirm the Specialists have provided the patient/carer with appropriate information sheet(s) for monitoring. 5. Amend prescription as per requests from specialist for dose changes in patients on established treatment. 6. Seek Specialist advice promptly as advised in the shared care arrangement guidelines or if signs/ symptoms or changes occur consistent with an adverse reaction. 7. Report adverse events to the MHRA. 8. Report adverse events to the Specialist sharing the care of the patient 9. Stop treatment on advice of Specialist, or immediately if intolerable side effects occur provided that it is safer to do so than to continue. If in doubt contact the Specialist. 10. When a patient is initiated on therapy by specialist centre and shared share is requested, GP to promptly respond to requests.
Primary care monitoring	• 12 monthly patient review for treatment response and side effects. Patient will also be reviewed yearly by secondary care.
Contra-indications	• History of hypersensitivity to cannabinoids. • 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. • Pregnancy and breast feeding.
Cautions	• Moderate to Severe hepatic impairment • Renal impairment • Epilepsy • Cardiovascular disease
Important adverse effects & management	Dizziness and fatigue (very common) – continue if tolerable or reduce dose Depression, disorientation, dissociation, euphoric mood, paranoia – continue if tolerable or reduce dose Delusion, hallucination, suicidal ideation – stop treatment and inform specialist Dry mouth, glossodynia, mouth ulceration, oral pain – vary site of spray application within the mouth. Do not continue spraying onto a sore or inflamed mucous membrane. For persistent problems interrupt treatment until resolution occurs.
Important drug interactions	Sativex may reduce the efficacy of systemically acting hormonal contraceptives. Alternative contraception such as copper intrauterine device, progestogen-only injectable: depot medroxyprogesterone acetate or levonorgestrel-releasing intrauterine system should be used for the duration of therapy and 3 months after the last dose if the patient is a woman of child bearing age. Use care if combining with other hypnotics or sedatives. Avoid co-administration with sodium valproate.

The manufacturer's summary of product characteristics (SPC) and the most current edition of the British National Formulary should be consulted for full information on contraindications, warnings, side effects and drug interactions.