



Frimley Health ICS Medicines Optimisation Board

SHARED CARE Guideline – Amber Traffic Light Classification	
Name of medicine	Sativex® (Cannabis Sativa extract)
Indication (including whether for adults and/or children)	Sativex is indicated as treatment for symptom improvement in adult patients with moderate to severe spasticity due to multiple sclerosis (MS) (>4 in self-assessment score MAS>2) who have not responded adequately to at least 2 other anti-spasticity medication and who demonstrate clinically significant improvement in spasticity related symptoms during an initial trial of therapy.
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Date ratified by Frimley Health MOB (FH MOB):	27/07/22

The Shared Care Guideline (SCG) is intended to facilitate the accessibility and safe prescribing of complex treatments across the secondary/primary care interface. This **AMBER** shared care sets out the patient pathway relating to this medicine and any information not available in the British National Formulary and manufacturer's Summary of Product Characteristics. Prescribing must be carried out with reference to those publications whenever appropriate.

The SCG must be used in conjunction with the agreed core roles and responsibilities stated in annex A.

An agreement notification form is included in annex B for communication of request for shared care from provider and agreement to taken on prescribing by primary care.

Roles and Responsibilities

Listed below are specific medicine/indication related responsibilities that are additional to those core roles and responsibilities that apply to all SCGs listed in annex A.

Consultant / Specialist

Sativex will only be initiated by Multiple Sclerosis (MS) specialists.

1. Assess the patient and ensure they meet initiation criteria.
2. Complete baseline Sativex® score sheet and treatment agreement with patient.
3. Initiate treatment and counsel patients on dose titration. The initial pack will be supplied via the 'Pay for responders' scheme'.
4. MS Nurse specialist will record patient's self-reported score on Sativex® post 4-week trial score sheet.
5. If the patient has been identified to continue treatment with Sativex® (>20% reduction in spasticity in 4-week trial), it will be prescribed monthly for an initial 3-month period.
6. If the patient is stable at month 2, the MS Team will contact the GP requesting shared care for the patient, including this shared care protocol. The GP can then take over prescribing at month 4 of treatment.
7. The MS Team will presume the GP has taken over prescribing at month 4 unless they receive communication within 14 days from the GP stating otherwise.
8. The MS team will be available for verbal (or written) advice to the GP if the patient's condition changes or deteriorates. Following this advice GPs may refer patients back to the MS team if this is required.
9. The MS team will ensure the patient & carer(s) are given information regarding the treatment and a contact for the MS team if they have any concerns.

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General Practitioner's Responsibilities

1. Monitor patient's overall health and wellbeing.
2. Prescribe the drug once the patient has been stabilised and care transferred
3. Report any adverse events to the hospital specialist, where appropriate

Patient Relatives & Carers

As listed in agreed core roles and responsibilities for the shared care of medicines - annex A

Key information on the medicine

Please refer to the current edition of the British National Formulary (BNF), available at <https://bnf.nice.org.uk/> and Summary of Product Characteristics (SPC), available at www.medicines.org.uk for detailed product and prescribing information and specific guidance.

Background to disease and use of medicine for the given indication

Spasticity is a common and disabling symptom in multiple sclerosis (MS). Main treatments for generalized MS spasticity include physiotherapy and exercise and few symptomatic oral medications, the most commonly used being baclofen and tizanidine. Sativex® (50% mixture of THC:CBD in a metered Oromucosal spray) 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.

From NICE NG144 (2019) 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's guideline on multiple sclerosis in adults](#))
 - The company provides THC:CBD spray according to its pay-for-responders scheme.
 - After the 4-week trial, continue THC:CBD spray if the person has had at least 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.

The Frimley ICS MOB has approved the use of Sativex® for use in adults with MS with moderate to severe spasticity (>4 in self-assessment score MAS>2) who have failed to achieve symptom control on at least two other antispasmodic therapies at maximal tolerated dosage.

Under a shared care arrangement, treatment must be recommended by a consultant Neurologist with an interest in MS. Initiation and dose titration will be managed by the MS team. After the dose is stabilised, the patient can be transferred to the GP.

Indication

MS related spasticity (see restrictions above).

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Monitoring

Monitoring requirements including frequency and appropriate dose adjustments	Responsible clinician
Pre-treatment: <ul style="list-style-type: none"> Baseline Sativex score 	Multiple Sclerosis team
Initiation: <ul style="list-style-type: none"> Sativex post 4-week trial score sheet 	Multiple Sclerosis team
Maintenance: <ul style="list-style-type: none"> To continue prescribing Sativex after 3 months of secondary care prescribing 	GP
If dose change when on maintenance: <ul style="list-style-type: none"> If patients spasticity is no longer managed by up to a maximum of 12 sprays per day GP to refer back to specialist in secondary care Patients can liaise directly with the MS Team through their existing channels of communication 	GP and Multiple Sclerosis Team
Acute spasms and uncontrolled spasticity: <ul style="list-style-type: none"> Exclude infection including urinalysis and CRP Consider other factors such as increase in ambient temperature, stress, anxiety, depression Consider non-disease specific conditions 	GP and Multiple Sclerosis Team

For support, please contact MS specialist team, see contact details below.

Abnormal results – actions to be taken

The GP may contact the specialist team for advice at any time if there are concerns.

Commonly reported adverse reactions during treatment with Sativex. For other side effects see SPC

Side-effect	Action
Dizziness & Somnolence	<p>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. Patients should be aware that Sativex has been known to cause a few cases of loss of consciousness.</p> <p>This medicine can impair cognitive function and can affect a patient's ability to drive safely. This class of medicine is in the list of drugs included in regulations under 5a of the Road Traffic Act 1988. When prescribing this medicine, patients should be told:</p> <ul style="list-style-type: none"> The medicine is likely to affect your ability to drive Do not drive until you know how the medicine affects you It is an offence to drive while under the influence of this medicine <p>However, the patient would not be committing an offence (called 'statutory defence') if:</p> <ul style="list-style-type: none"> the medicine has been prescribed to treat a medical problem and the patient has taken it according to the instructions given by the prescriber and in the information provided with the medicine, and it was not affecting your ability to drive safely

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Cautions, contraindications:

Refer to current Summary of Product Characteristics (SPC): www.medicines.org.uk .

Adverse effects and action to be taken (if appropriate)

Refer to current Summary of Product Characteristics (SPC): www.medicines.org.uk

Drug interactions

Refer to current Summary of Product Characteristics (SPC): www.medicines.org.uk

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Support and Advice Contact Details for Primary Care Prescribers:

Name	Speciality	Telephone No.
Dr Damian Wren	Consultant Neurologist Frimley Park Hospital	03006135721
Dr Matthew Craner	Consultant Neurologist Frimley Park Hospital	03006135713
Judith Wilton, Sue Duplock & Dani Devasia	Multiple Sclerosis Nurse Specialist. Frimley Park	07467 353692
Dr Ruth Geraldes	Consultant Neurologist Wexham Park Hospital	03006153091
Dr Silvia Messina	Consultant Neurologist Wexham Park Hospital	03006153091
Sandra Reeve & Sanum Manaf	Multiple Sclerosis Nurse Specialist. Wexham Park	03006147227
Medicines Information	Pharmacy (Frimley and Wexham)	03006134744

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Annex A: Agreed core roles and responsibilities for the shared care of medicines

Patients	
To be informed by initiating specialist, that the drug is a shared care drug and what this means.	
Relatives and Carers	
<ul style="list-style-type: none"> To support the patient. 	
Consultant/ Specialist	
<p>Good Prescribing Guidelines</p> <ul style="list-style-type: none"> Be aware that Sativex must initiated and supervised by a physician with specialist expertise in treating spasticity due to multiple sclerosis. If you recommend that a colleague, for example a junior doctor or Primary Care Prescriber, prescribes a particular medicine for a patient, you must consider their competence to do so. You must satisfy yourself that they have sufficient knowledge of the patient and the medicine, experience (especially in the case of junior doctors) and information to prescribe. You should be willing to answer their questions and otherwise assist them in caring for the patient, as required ^(Ref GMC). Be aware that if you delegate assessment of a patients' suitability for a medicine, you must be satisfied that the person to whom you delegate has the qualifications, experience, knowledge and skills to make the assessment. You must give them enough information about the patient to carry out the assessment required. Be aware that you are asking the Primary Care Prescriber to take full medico-legal responsibility for the prescription they sign^(Ref GMC). For this reason the shared care guidelines (SCGs) are agreed at the Frimley Integrated Care Medicines Optimisation Board (ICS MOB) with input from specialists and Primary Care Prescribers, and, for individual patients, the patient's Primary Care Prescriber must agree to take over responsibility before transfer of care, before the patient is discharged from specialist care. Be aware of the formulary status and the traffic light classification of the medicine you are prescribing within the Frimley Health Formulary. Assume clinical responsibility for the guidance given in the SCG, and where there is new information needed on the SCG to liaise with a member of the Pharmacy team who will facilitate an update via the Frimley ICS MOB. Counsel patient on possible benefits, risks and side effects of the drug. <p>Before initiating treatment</p> <ul style="list-style-type: none"> Evaluate the suitability of the patient for treatment, including consideration of the patient's current medication and any significant interactions. Discuss and provide the patient with information about the reason for choosing the medicine, the likelihood of both harm and benefits, consequences of treatment, and check that their treatment choice is consistent with their values and preferences Explain shared care status of drug and what this means to the patient. Undertake baseline monitoring and assessment. <p>Initiating and continuing treatment in secondary care</p> <ul style="list-style-type: none"> Prescribe initial treatment and provide any associated training and counselling required. Inform the Primary Care Prescriber when initiating treatment so that the Primary Care Prescriber is aware what is being prescribed and can add to Primary Care Prescriber clinical record. Continue to prescribe and supply treatment with appropriate monitoring until the patient's condition is stable; the patient is demonstrably benefiting from the treatment and is free from any significant side effects. At any stage of treatment, advising Primary Care Prescriber of concerns regarding monitoring or potential adverse effects of treatment 	

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Transfer of care to Primary Care prescriber

- Liaise with the primary care prescriber to agree to share the patient's care and provide relevant accurate, timely information and advice.
- Only advise the patient that shared care will take place, and prescribing will be transferred, once the primary care prescriber has agreed to share responsibility of the patient care.
- If the primary care prescriber feels unable to accept clinical responsibility for prescribing then the consultant must continue to prescribe the treatment to ensure consistency and continuity of care.
- Ensure that the patient (and carer/relatives) are aware of their roles and responsibilities under the SCG
- Provide sufficient information and training for the patient to participate in the SCG

Primary Care Prescriber

- Be aware of the formulary and traffic light status of the medicine you have been asked to prescribe.
- Be aware that Amber medicines have been assessed by the Frimley Integrated Care System Medicines Optimisation Board (ICS MOB) as requiring careful transition between care settings but SCGs will be available to support safe transfer of care.
- It would be usual for Primary Care Prescribers to take on prescribing under a formal SCG. If you are uncertain about your competence to take responsibility for the patient's continuing care, you should seek further information or advice from the clinician with whom the patient's care is shared or from another experienced colleague. If you are still not satisfied, you should explain this to the other clinician and to the patient, and make appropriate arrangements for their continuing care.
- Be aware that if you prescribe at the recommendation of another doctor, nurse or other healthcare professional, you must satisfy yourself that the prescription is needed, appropriate for the patient and within the limits of your competence (Ref GMC).
- Be aware that if you prescribe, you will be responsible for any prescription you sign (Ref GMC).
- Keep yourself informed about all the medicines that are prescribed for the patient
- Be able to recognise serious and/ or frequently occurring adverse side effects, and what action should be taken if they occur.
- Keep up to date with relevant guidance on the use of the medicines and on the management of the patient's condition.
- Respond to requests to share care of patients in a timely manner, in writing (including use of form in annex B)
- Liaise with the consultant to agree to share the patient's care in line with the SCG in a timely manner.
- Continue prescribing medicine at the dose recommended and undertake monitoring requirements
- Monitor for adverse effects throughout treatment and check for drug interactions on initiating new treatments
- Inform the Consultant or specialist of any issues that may arise
- Ensure that if care of the patient is transferred to another prescriber, that the new prescriber is made aware of the share care guideline (e.g. ensuring the patient record is correct in the event of a patient moving practice).

All

- Where it has been identified that a SCG requires update e.g. new information needed, liaise with the SCG author and/or your organisation's Frimley Health Foundation ICS MOB representative who will facilitate an update at the Committee.

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Annex B

SHARED CARE PRESCRIBING GUIDELINE:
Shared care agreement notification form for medicines and indications approved as
amber on the Frimley Health Foundation Trust Formulary

Agreement for transfer of prescribing to GP

Patient details

Name.....

Address.....

.....

.....

DOB.....

Hospital No.....

NHS No.....

Name of medicine	Sativex®
Discharge Dose	
Indication	

Hospital/ Patient information		Practice information	
Consultant Making Request		GP Name:	
Consultant Speciality Details:		Practice:	
Patient Name:		I agree to undertake shared care:	
Patient NHS Number:		I do not agree to undertake shared care:	
Patient Hospital Number:		If NOT please give reasons:	
Patient DOB:		Signed:	
Drug Name/ Dose:		Date:	
Next Prescription Due:		Please return form to:	
Clinic/ Discharge letter written and sent:			
Please refer to the Frimley Health Foundation Trust Formulary for relevant shared care documents.			

Primary Care Prescriber should respond to the request for shared care in writing. It is asked that this be undertaken within 14 days of the request being made, where possible.

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