



## A summary of prescribing recommendations from NICE guidance

This edition includes one NICE guideline.

## Cannabis-based medicinal products

NICE NG144: November 2019

This guideline covers prescribing of cannabis-based medicinal products for people with intractable nausea and vomiting, chronic pain, spasticity and severe treatment-resistant epilepsy.

## Definition of terms

<b>THC</b>	delta-9-tetrahydrocannabinol
<b>CBD</b>	cannabidiol
<b>THC:CBD spray</b>	licensed product containing THC combined with CBD ( <i>Sativex</i> )

## Products covered by this guideline include:

- ◆ cannabis-based products for medicinal use as set out by the UK Government in the [2018 Regulations](#),
- ◆ the licensed products THC combined with CBD (*Sativex*) and nabilone,
- ◆ plant-derived cannabinoids such as pure CBD,
- ◆ synthetic compounds which are identical in structure to naturally occurring cannabinoids such as THC, for example, dronabinol.

## Indications for cannabis-based medicinal products

## Intractable nausea and vomiting

- ◆ Consider nabilone as an add-on treatment for adults ≥18 years with chemotherapy-induced nausea and vomiting which persists with optimised conventional antiemetics (i.e. treatments commonly used in practice at an optimum tolerated dose to manage nausea and vomiting).
- ◆ When considering nabilone for adults with chemotherapy-induced nausea and vomiting, take into account potential adverse drug interactions, for example, with central nervous system depressants and other centrally active drugs.

## Chronic Pain

- ◆ Do not offer the following to manage chronic pain in adults:
  - nabilone,
  - dronabinol,
  - THC,
  - a combination of CBD with THC.
- ◆ Do not offer CBD to manage chronic pain in adults unless as part of a clinical trial.
- ◆ Adults who started cannabis-based medicinal products to manage chronic pain in the NHS before this guidance was published (November 2019) should be able to continue treatment until they and their NHS clinician think it appropriate to stop.

**Recommendations** – wording used such as ‘offer’ and ‘consider’ denote the [strength of the recommendation](#).

**Drug recommendations** – the guideline assumes that prescribers will use a drug’s [Summary of Product Characteristics \(SPC\)](#) to inform treatment decisions.

## Spasticity

- ◆ Offer a 4-week trial of THC:CBD spray to treat moderate to severe spasticity in adults with multiple sclerosis (MS), if:
  - other pharmacological treatments for spasticity are not effective (see [NICE CG186: MS in adults](#)),
  - the company provides THC:CBD spray according to its pay-for-responders scheme (see **Box 1**).
- ◆ After the 4-week trial, continue THC:CBD spray if the person has had at least a 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 MS, in line with its marketing authorisation.

## Severe treatment-resistant epilepsy

- ◆ NICE has made research recommendations on the use of cannabis-based medicinal products for severe treatment-resistant epilepsy.
- ◆ NICE is developing technology appraisal guidance on [cannabidiol with clobazam for treating seizures associated with Lennox-Gastaut syndrome](#) and [Dravet syndrome](#).

## Box 1

## Pay-for-responders scheme

According to the terms of the pay-for-responders scheme, the company will fund the first 3 x 10ml vials of THC:CBD spray if there is an agreement for continued funding for people who experience at least a 20% reduction in spasticity-related symptoms on a 0 to 10 patient-reported numeric rating scale after 4 weeks of treatment.

Prescribing of cannabis-based medicinal products  
Who should prescribe?

## Initial prescription

- ◆ Initial prescription of cannabis-based medicinal products (excluding nabilone, THC:CBD spray (*Sativex*) and cannabis-based medicines that are not classed as controlled drugs such as cannabidiol) must be made by a specialist medical practitioner (i.e. a doctor included in the register of specialist medical practitioners [the Specialist Register] under section 32D of the Medicines Act 1983).
- ◆ The prescriber should also have a special interest in the condition being treated. (See [GMC's information for doctors on cannabis-based products for medicinal use](#).)
- ◆ For children and young people under the care of paediatric services, the initiating prescriber should also be a tertiary paediatric specialist.

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## Cannabis-based medicinal products.....continued

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#### Shared care

- ◆ After the initial prescription, subsequent prescriptions of cannabis-based medicinal products may be issued by another prescriber as part of a shared care agreement under the direction of the initiating specialist prescriber, if:
  - shared care is appropriate and in the person's best interest,
  - the person's clinical condition is stable,
  - the other prescriber is confident to make a fully informed prescribing decision about cannabis-based medicinal products.
- ◆ Efficacy and safety of cannabis-based medicinal products should be monitored and evaluated, and doses should be adjusted by the initiating specialist prescriber as part of the shared care agreement.
- ◆ A shared care agreement for a person prescribed a cannabis-based medicinal product should include:
  - the responsibilities of all parties (i.e. the initiating specialist prescriber, the other prescriber(s), the patient, family and/or carers),
  - the nature and frequency of monitoring and how this will be recorded,
  - when treatment might be stopped, for example, if it is not effective,
  - how suspected or known adverse reactions will be managed,
  - how communication will be managed between the initiating specialist prescriber, the other prescriber, the patient, family and/or carers,
  - how the treatment will be funded,
  - how care will be maintained when the patient, initiating specialist prescriber or other prescriber moves location (including transition to adult services).

#### Factors to think about when prescribing

- ◆ When prescribing and monitoring cannabis-based medicinal products, take into account:
  - current and past use of cannabis (including any over-the-counter and online products),
  - history of substance misuse including the illicit use of cannabis,
  - potential for dependence, diversion and misuse (in particular with THC),
  - mental health and medical history, in particular, liver impairment, renal impairment and cardiovascular disease,
  - potential for interaction with other medicines, for example, central nervous system depressants and other centrally active drugs, antiepileptics and hormonal contraceptives,
  - pregnancy and breastfeeding – see **Box 2**
- ◆ When prescribing cannabis-based medicinal products for babies, children and young people, pay particular attention to the:
  - potential impact on psychological, emotional and cognitive development,
  - potential impact of sedation,
  - potential impact on structural and functional brain development.
- ◆ When prescribing cannabis-based medicinal products, advise people to stop any non-prescribed cannabis, including over-the-counter, online and illicit products.
- ◆ Prescribers should record details of treatment, clinical outcomes and adverse effects for people prescribed cannabis-based medicinal products, using local or national registers if available.
- ◆ For more information on safe prescribing and use of cannabis-based medicinal products, see the recommendations in the [NICE guideline on controlled drugs](#).

#### Supporting shared decision making

- ◆ Before prescribing cannabis-based medicinal products, discuss with people:
  - the potential benefits and harms, including any risk of dependence or interaction with other medicines,
  - the licensing status of the medicines,
  - how long they might take the medicine,
  - how long it will take to work,
  - what it has been prescribed for and how to take it,
  - how it may affect their ability to drive (see [advice from the Department of Transport on drug driving and medicine](#)),
  - the need to seek advice before travelling abroad about the legality of cannabis-based medicinal products in other countries (see [UK Government's advice on travelling with medicine containing a controlled drug](#)),
  - the importance of not allowing others to use the prescribed medicine.
- ◆ When discussing cannabis-based medicinal products with patients and their families and carers, follow the recommendations on shared decision making in the [NICE guideline on patient experience in adult NHS services](#).

#### Box 2

##### Pregnancy and breastfeeding

- ◆ Breastfeeding is a contraindication for *Sativex* and nabilone.
- ◆ There is limited evidence on the safety of cannabis-based medicinal products during pregnancy and breastfeeding.

#### Resources for further information

NICE interactive flowchart: [Cannabis-based medicinal products](#)

Shared care – NHS England guidance: [Responsibility for prescribing between primary and secondary/tertiary care](#)

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