NICE National Institute for Health and Care Excellence

NICE Pathways

Cannabis-based medicinal products overview

NICE Pathways bring together everything NICE says on a topic in an interactive flowchart. NICE Pathways are interactive and designed to be used online.

They are updated regularly as new NICE guidance is published. To view the latest version of this NICE Pathway see:

http://pathways.nice.org.uk/pathways/cannabis-based-medicinal-products
NICE Pathway last updated: 12 November 2021

This document contains a single flowchart and uses numbering to link the boxes to the associated recommendations.

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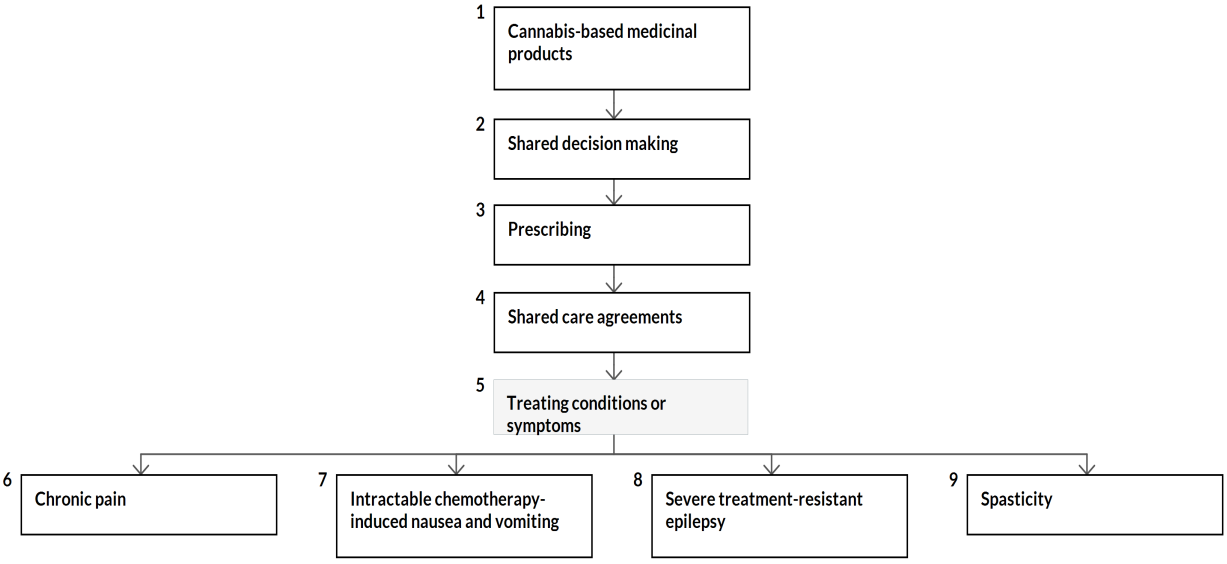

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1 Cannabis-based medicinal products

In this guidance cannabis-based medicinal products 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.

2 Shared decision making

Before prescribing cannabis-based medicinal products [See page 11], discuss with people:

- the potential benefits and harms, including any risk of dependence and 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 the 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 the 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 NICE's recommendations on shared decision making.

See the NICE guideline to find out why we made these recommendations and how they might affect practice.

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3 Prescribing

Who should prescribe?

Initial prescription of cannabis-based medicinal products[1] must be made by a specialist medical practitioner (a doctor included in the register of specialist medical practitioners (the Specialist Register[2]). They should also have a special interest in the condition being treated[3]. For children and young people under the care of paediatric services, the initiating prescriber should also be a tertiary paediatric specialist.

See the NICE guideline to find out why we made this recommendation and how it might affect practice.

Factors to think about when prescribing

When prescribing and monitoring cannabis-based medicinal products [See page 11], 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, 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[4].

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.

See the NICE Pathway on babies, children and young people's experience of healthcare.

When prescribing cannabis-based medicinal products, advise people to stop any non-prescribed cannabis, including over-the-counter, online and illicit products.

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[1] This excludes nabilone, THC:CBD spray (Sativex) and cannabis-based medicines that are not classified as controlled drugs such as cannabidiol. See the relevant summaries of product characteristics for further information on prescribing. See spasticity [See page 10] for information on prescribing of THC:CBD spray.

[2] See section 34D of the Medical Act 1983.

[3] See the GMC's information for doctors on cannabis-based products for medicinal use.

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

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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 NICE's recommendations on controlled drugs: safe use and management.

See the NICE guideline to find out why we made these recommendations and how they might affect practice.

4 Shared care agreements

After the initial prescription, subsequent prescriptions of cannabis-based medicinal products [See page 11] may be issued by another prescriber as part of a shared care[1] 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 (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 reported
- 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).

See the NICE guideline to find out why we made these recommendations and how they might

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[1] For more information about shared care, see NHS England's guidance on responsibility for prescribing between primary and secondary/tertiary care.

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affect practice.

5 Treating conditions or symptoms

No additional information

6 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.

See the NICE guideline to find out why we made these recommendations and how they might affect practice.

See the NICE Pathway on chronic pain (primary and secondary).

7 Intractable chemotherapy-induced nausea and vomiting

Consider nabilone as an add-on treatment for adults (18 years and over) with chemotherapy-induced nausea and vomiting which persists with optimised conventional antiemetics.

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.

See the NICE guideline to find out why we made these recommendations and how they might affect practice.

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8 Severe treatment-resistant epilepsy

NICE has made research recommendations on the use of cannabis-based medicinal products for severe treatment-resistant epilepsy. See the NICE guideline to find out why we made the research recommendations.

Cannabidiol with clobazam for treating seizures associated with Lennox–Gastaut syndrome

The following recommendations are from NICE technology appraisal guidance on cannabidiol with clobazam for treating seizures associated with Lennox–Gastaut syndrome.

Cannabidiol with clobazam is recommended as an option for treating seizures associated with Lennox–Gastaut syndrome in people aged 2 years and older, only if:

- the frequency of drop seizures is checked every 6 months, and cannabidiol is stopped if the frequency has not fallen by at least 30% compared with the 6 months before starting treatment
- the company provides cannabidiol according to the commercial arrangement.

This recommendation is not intended to affect treatment with cannabidiol, with clobazam, that was started in the NHS before this guidance was published. People having treatment outside this recommendation may continue without change to the funding arrangements in place before this guidance was published, until they and their NHS clinicians consider it appropriate to stop. For children and young people, this decision should be made jointly by the clinician and the child or young person, or the child or young person's parents or carers.

See why we made the recommendations on cannabidiol with clobazam for Lennox–Gastaut syndrome.

NICE has published information for the public on cannabidiol with clobazam for Lennox–Gastaut syndrome.

Cannabidiol with clobazam for treating seizures associated with Dravet syndrome

The following recommendations are from NICE technology appraisal guidance on cannabidiol with clobazam for treating seizures associated with Dravet syndrome.

Cannabidiol with clobazam is recommended as an option for treating seizures associated with Dravet syndrome in people aged 2 years and older, only if:

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- the frequency of convulsive seizures is checked every 6 months, and cannabidiol is stopped if the frequency has not fallen by at least 30% compared with the 6 months before starting treatment
- the company provides cannabidiol according to the commercial arrangement.

This recommendation is not intended to affect treatment with cannabidiol, with clobazam, that was started in the NHS before this guidance was published. People having treatment outside this recommendation may continue without change to the funding arrangements in place before this guidance was published, until they and their NHS clinicians consider it appropriate to stop. For children and young people, this decision should be made jointly by the clinician and the child or young person, or the child or young person's parents or carers.

See why we made the recommendations on cannabidiol with clobazam for Dravet syndrome.

NICE has published information for the public on cannabidiol with clobazam for Dravet syndrome.

9 Spasticity

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 NICE's recommendations on managing spasticity in people with multiple sclerosis)
- the company provides THC:CBD spray according to its pay-for-responders scheme.[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 multiple sclerosis, in line with its marketing authorisation.

See the NICE guideline to find out why we made these recommendations and how they might affect practice.

[1] According to the terms of the pay-for-responders scheme, the company will fund the first 3 x10-ml 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 to10 patient-reported numeric rating scale after 4 weeks of treatment.

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Glossary

CBD

cannabidiol

Optimised conventional antiemetics

(these are treatments that are commonly used in practice at an optimum tolerated dose to manage nausea and vomiting)

THC

delta-9-tetrahydrocannabinol

Sources

Cannabis-based medicinal products (2019) NICE guideline NG144

Cannabidiol with clobazam for treating seizures associated with Lennox–Gastaut syndrome (2019) NICE technology appraisal guidance 615

Cannabidiol with clobazam for treating seizures associated with Dravet syndrome (2019) NICE technology appraisal guidance 614

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Your responsibility

Guidelines

The recommendations in this guideline represent the view of NICE, arrived at after careful consideration of the evidence available. When exercising their judgement, professionals and practitioners are expected to take this guideline fully into account, alongside the individual needs, preferences and values of their patients or the people using their service. It is not mandatory to apply the recommendations, and the guideline does not override the responsibility to make decisions appropriate to the circumstances of the individual, in consultation with them and their families and carers or guardian.

Local commissioners and providers of healthcare have a responsibility to enable the guideline to be applied when individual professionals and people using services wish to use it. They should do so in the context of local and national priorities for funding and developing services, and in light of their duties to have due regard to the need to eliminate unlawful discrimination, to advance equality of opportunity and to reduce health inequalities. Nothing in this guideline should be interpreted in a way that would be inconsistent with complying with those duties.

Commissioners and providers have a responsibility to promote an environmentally sustainable health and care system and should assess and reduce the environmental impact of implementing NICE recommendations wherever possible.

Technology appraisals

The recommendations in this interactive flowchart represent the view of NICE, arrived at after careful consideration of the evidence available. When exercising their judgement, health professionals are expected to take these recommendations fully into account, alongside the individual needs, preferences and values of their patients. The application of the recommendations in this interactive flowchart is at the discretion of health professionals and their individual patients and do not override the responsibility of healthcare professionals to make decisions appropriate to the circumstances of the individual patient, in consultation with the patient and/or their carer or guardian.

Commissioners and/or providers have a responsibility to provide the funding required to enable the recommendations to be applied when individual health professionals and their patients wish to use it, in accordance with the NHS Constitution. They should do so in light of their duties to

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have due regard to the need to eliminate unlawful discrimination, to advance equality of opportunity and to reduce health inequalities.

Commissioners and providers have a responsibility to promote an environmentally sustainable health and care system and should assess and reduce the environmental impact of implementing NICE recommendations wherever possible.

Medical technologies guidance, diagnostics guidance and interventional procedures guidance

The recommendations in this interactive flowchart represent the view of NICE, arrived at after careful consideration of the evidence available. When exercising their judgement, healthcare professionals are expected to take these recommendations fully into account. However, the interactive flowchart does not override the individual responsibility of healthcare professionals to make decisions appropriate to the circumstances of the individual patient, in consultation with the patient and/or guardian or carer.

Commissioners and/or providers have a responsibility to implement the recommendations, in their local context, in light of their duties to have due regard to the need to eliminate unlawful discrimination, advance equality of opportunity, and foster good relations. Nothing in this interactive flowchart should be interpreted in a way that would be inconsistent with compliance with those duties.

Commissioners and providers have a responsibility to promote an environmentally sustainable health and care system and should assess and reduce the environmental impact of implementing NICE recommendations wherever possible.

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