NICE National Institute for Health and Care Excellence

NICE guideline

Cannabis-based medicinal products

NICE guideline

Published: 11 November 2019
www.nice.org.uk/guidance/ng144

Your responsibility

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.

All problems (adverse events) related to a medicine or medical device used for treatment or in a procedure should be reported to the Medicines and Healthcare products Regulatory Agency using the Yellow Card Scheme.

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.

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Overview

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

NICE has published technology appraisal guidance on cannabidiol with clobazam for treating seizures associated with Lennox-Gastaut syndrome and Dravet syndrome.

Products covered by the guideline include:

- cannabis-based products for medicinal use as set out by the UK Government in the 2018 Regulations
- the licensed products delta-9-tetrahydrocannibinol combined with cannabidiol (Sativex) and nabilone
- plant-derived cannabinoids such as pure cannabidiol (CBD)
- synthetic compounds which are identical in structure to naturally occurring cannabinoids such as delta-9-tetrahydrocannabinol (THC), for example, dronabinol.

Who is it for?

- Healthcare professionals
- People taking cannabis-based medicinal products, their families and carers

Recommendations

People have the right to be involved in discussions and make informed decisions about their care, as described in making decisions about your care.

Making decisions using NICE guidelines explains how we use words to show the strength (or certainty) of our recommendations, and has information about prescribing medicines (including off-label use), professional guidelines, standards and laws (including on consent and mental capacity), and safeguarding.

1.1 Intractable nausea and vomiting

1.1.1 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.

1.1.2 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.

For a short explanation of why the committee made these recommendations and how they might affect practice, see the rationale and impact section on intractable nausea and vomiting.

Full details of the evidence and the committee's discussion are in evidence review A: intractable nausea and vomiting.

1.2 Chronic pain

1.2.1 Do not offer the following to manage chronic pain in adults:

- nabilone

- dronabinol
- THC (delta-9-tetrahydrocannabinol)
- a combination of cannabidiol (CBD) with THC.

1.2.2 Do not offer CBD to manage chronic pain in adults unless as part of a clinical trial.

1.2.3 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.

For a short explanation of why the committee made these recommendations and how they might affect practice, see the rationale and impact section on chronic pain.

Full details of the evidence and the committee's discussion are in evidence review B: chronic pain.

1.3 Spasticity

1.3.1 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 (it funds the first 3 x10-ml vials if there is agreement for continued funding for people with at least a 20% reduction in spasticity-related symptoms on a 0 to 10 patient-reported numeric rating scale after 4 weeks).

  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.

1.3.2 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.

For a short explanation of why the committee made these recommendations and how they might affect practice, see the rationale and impact section on spasticity.

Full details of the evidence and the committee's discussion are in evidence review C: spasticity.

1.4 Severe treatment-resistant epilepsy

NICE has made recommendations for research on the use of cannabis-based medicinal products for severe treatment-resistant epilepsy.

NICE has published technology appraisal guidance on cannabidiol with clobazam for treating seizures associated with Lennox-Gastaut syndrome and Dravet syndrome.

For a short explanation of why the committee made the recommendation for research on CBD, and THC in combination with CBD for severe treatment-resistant epilepsy, see the rationale section on severe treatment-resistant epilepsy.

Full details of the evidence and the committee's discussion are in evidence review D: epilepsy.

1.5 Prescribing

Who should prescribe?

1.5.1 Initial prescription of cannabis-based medicinal products (excluding nabilone, THC:CBD spray [Sativex] and medicines not classed as controlled drugs such as cannabidiol) must be made by a specialist medical practitioner (a doctor included in the register of specialist medical practitioners [the Specialist Register], see section 34D of the

Medical Act 1983). They should also have a special interest in the condition being treated (see the 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 in the condition being treated.

Shared care

1.5.2 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.

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

1.5.3 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.

1.5.4 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 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).

For a short explanation of why the committee made these recommendations and how they might affect practice, see the rationale and impact section on prescribing: who should prescribe and shared care.

Full details of the evidence and the committee's discussion are in evidence review E: prescribing cannabis-based medicinal products.

Factors to think about when prescribing

1.5.5 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, 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 (breastfeeding is a contraindication for Sativex and nabilone; there is limited evidence on the safety of cannabis-based medicinal products during pregnancy and breastfeeding).

1.5.6 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.

  NICE has produced a guideline on babies, children and young people's experience of healthcare.

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

1.5.8 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.

1.5.9 For more information on safe prescribing and use of cannabis-based medicinal products, see the recommendations in the NICE guideline on controlled drugs.

For a short explanation of why the committee made these recommendations and how they might affect practice, see the rationale and impact section on prescribing: factors to think about when prescribing.

Full details of the evidence and the committee's discussion are in evidence review E: prescribing cannabis-based medicinal products.

Supporting shared decision making

1.5.10 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 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.

1.5.11 When discussing cannabis-based medicinal products with patients and their families and carers, follow the NICE guideline on shared decision making.

For a short explanation of why the committee made these recommendations and how they might affect practice, see the rationale and impact section on prescribing: supporting shared decision making.

Full details of the evidence and the committee's discussion are in evidence review E: prescribing cannabis-based medicinal products.

Terms used in this guideline

Cannabis-based medicinal products

In this guideline 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 delta-9-tetrahydrocannibinol combined with cannabidiol (Sativex) and nabilone
- plant-derived cannabinoids such as pure cannabidiol (CBD)

- synthetic compounds which are identical in structure to naturally occurring cannabinoids such as delta-9-tetrahydrocannabinol (THC), for example, dronabinol.

Optimised conventional antiemetics

These are treatments that are commonly used in practice at an optimum tolerated dose to manage nausea and vomiting.

Recommendations for research

The guideline committee has made the following recommendations for research.

Key recommendations for research

1 Fibromyalgia or persistent treatment-resistant neuropathic pain in adults

For adults with fibromyalgia or persistent treatment-resistant neuropathic pain, what is the clinical and cost effectiveness of cannabidiol (CBD), containing no, or traces of, delta-9-tetrahydrocannabinol (THC), as an add-on to standard treatment?

For a short explanation of why the committee made the recommendation for research, see the rationale section on chronic pain.

Full details of the evidence and the committee's discussion are in evidence review B: chronic pain.

2 Chronic pain in children and young people

For children and young people with intractable cancer-related pain and pain associated with specific diseases (such as epidermolysis bullosa), what is the clinical and cost effectiveness of cannabis-based medicinal products as an add-on to standard treatment to improve symptoms compared with treatment with standard care?

For a short explanation of why the committee made the recommendation for research, see the rationale section on chronic pain.

Full details of the evidence and the committee's discussion are in evidence review B: chronic pain.

3 CBD for severe treatment-resistant epilepsy

What is the clinical and cost effectiveness of CBD in epileptic disorders in children, young people and adults?

For a short explanation of why the committee made the recommendation for research, see the rationale section on severe treatment-resistant epilepsy.

Full details of the evidence and the committee's discussion are in evidence review D: epilepsy.

4 THC in combination with CBD for severe treatment-resistant epilepsy

Does the addition of THC to CBD have an effect on seizure frequency, brain structure and neuropsychological performance when compared with both CBD alone and placebo in epileptic disorders in children, young people and adults?

For a short explanation of why the committee made the recommendation for research, see the rationale section on severe treatment-resistant epilepsy.

Full details of the evidence and the committee's discussion are in evidence review D: epilepsy.

5 Spasticity

What is the clinical and cost effectiveness of cannabis-based medicinal products other than THC: CBD spray for children, young people and adults with spasticity? In particular, what is the impact of spasticity on improvements in quality of life?

For a short explanation of why the committee made the recommendation for research, see the rationale section on spasticity.

Full details of the evidence and the committee's discussion are in evidence review C: spasticity.

Other recommendations for research

Chemotherapy-induced intractable nausea and vomiting in adults

What is the clinical and cost effectiveness of cannabis-based medicinal products as an add-on treatment for adults with chemotherapy-induced nausea and vomiting which persists with optimised conventional antiemetics?

Chemotherapy-induced intractable nausea and vomiting in babies, children and young people

What is the clinical and cost effectiveness of cannabis-based medicinal products as an add-on treatment in babies, children and young people with chemotherapy-induced nausea or vomiting which persists with optimised conventional antiemetics?

Intractable nausea and vomiting not caused by chemotherapy in adults

What is the clinical and cost effectiveness of cannabis-based medicinal products as an add-on treatment for adults with persistent nausea or vomiting not caused by chemotherapy which hasn't fully responded to optimised conventional antiemetics?

Intractable nausea and vomiting not caused by chemotherapy in babies, children and young people

What is the clinical and cost effectiveness of cannabis-based medicinal products as an add-on treatment for babies, children and young people with persistent nausea or vomiting not caused by chemotherapy which hasn't fully responded to optimised conventional antiemetics?

Rationale and impact

These sections briefly explain why the committee made the recommendations and how they might affect practice. They link to details of the evidence and a full description of the committee's discussion.

Intractable nausea and vomiting

Recommendations 1.1.1. and 1.1.2

Why the committee made the recommendations

Intractable nausea or vomiting can be defined as persistent nausea or vomiting that does not respond fully to optimised conventional antiemetics. Although there are different causes of intractable or persistent nausea and vomiting, evidence was only identified for the use of delta-9-tetrahydrocannabinol (THC), nabilone and dronabinol in people with chemotherapy-induced and radiotherapy-induced nausea and vomiting.

Limited evidence showed that nabilone, which is licensed in the UK for adults, resulted in complete or partial reduction in chemotherapy-induced nausea and vomiting. However, most of the studies were old, of low quality and used outdated antiemetic regimens that do not reflect current practice. Nabilone was also associated with more adverse events (drowsiness, dizziness and dry mouth), particularly in children. The committee noted that although use of cannabis-based medicinal products for intractable chemotherapy-induced nausea and vomiting would be short term, there was a lack of evidence on longer term adverse events, such as dependence and the development of psychological disorders. They identified this as a concern, particularly when considering repeated use. The committee also noted the limited evidence for children and young people. Based on these findings they were unable to make recommendations specifically for this group.

The committee agreed that nabilone may play a role in treating intractable chemotherapy-induced nausea and vomiting in people who have not had a full response to optimised conventional antiemetics. Based on the limited evidence, the committee only recommended that nabilone could be considered as an add-on treatment in adults with intractable chemotherapy-induced nausea and vomiting which persists despite the use of optimised conventional antiemetics.

The committee were aware that people may be taking other medication when using nabilone and were concerned about potential adverse drug interactions. They recommended that adverse drug interactions should be carefully considered when prescribing nabilone. The committee highlighted concerns for the use of nabilone with central nervous system depressants and other centrally active drugs. They recommended that healthcare professionals should think about these when considering nabilone and refer to the summary of product characteristics for further information on dosing, patient monitoring, contraindications and adverse events.

Evidence for the use of other cannabis-based medicinal products was limited and the committee were unable to make any practice recommendations. However, they made a recommendation for research to inform future guidance.

Nabilone is not currently licensed in the UK for children and young people under 18 years because its safety and efficacy has not been established. Therefore, the committee made another recommendation for research on the effectiveness of cannabis-based medicinal products in babies, children and young people with intractable nausea and vomiting.

Only 1 study was identified which included people with radiotherapy-induced nausea and vomiting. The committee noted that there are other causes of intractable nausea and vomiting but were unable to make further recommendations due to lack of evidence. Therefore, the committee made an additional recommendation for research.

How the recommendations might affect practice

The committee highlighted that the use of nabilone is uncommon in current practice and it is not used as first-line treatment for chemotherapy-induced nausea and vomiting. The recommendations could result in an increase in use of nabilone as an add-on treatment for adults with chemotherapy-induced nausea and vomiting, but the current level of use is uncertain.

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Chronic pain

Recommendations 1.2.1 to 1.2.3

Why the committee made the recommendations

Some evidence showed that CBD reduced chronic pain, but the treatment effect was modest (an average improvement of about 0.4 on a scale ranging from 0 to 10). The evidence did not show a reduction in opioid use in people prescribed medicinal cannabis. Because the number of people who might benefit is large and the cost potentially high, an economic model was developed to compare benefits with the potential costs. The model used data from the trials in the base-case analysis but also assumed a larger potential benefit from cannabis-based medicinal products in various sensitivity analyses. In all cases, the potential benefits offered were small compared with the high and ongoing costs, and the products were not an effective use of NHS resources. The evidence included CBD in combination with THC, THC alone, dronabinol and nabilone so the committee named these products in the recommendation. The committee also agreed that the recommendation should follow the evidence and specify adults.

There was no evidence for the use of CBD alone (either as a pure product or containing traces of THC). Therefore, the committee recommended that CBD should not be offered unless as part of a clinical trial. People who have fibromyalgia or persistent treatment-resistant neuropathic pain are often taking high doses of medicines for pain relief over long periods. These can cause nausea, drowsiness, mood disturbance and fatigue. The committee noted that this is a significant population of people with chronic pain (around 15%). They therefore made a recommendation for research for CBD in adults with fibromyalgia or treatment-resistant neuropathic pain.

There was no evidence for intractable cancer-related pain or pain associated with painful childhood diseases. The committee agreed that cannabis-based medicinal products could potentially offer additional benefits for this group, for example, by allowing them to receive their care in an outpatient rather than an inpatient setting or by reducing the overall opioid use. They agreed to make a recommendation for research to explore the clinical and cost effectiveness.

How the recommendations might affect practice

Prescriptions of cannabis-based medicinal products for chronic pain are currently rare. GPs refer people with chronic pain to specialist pain services where clinicians on the Specialist Register with expertise in this area decide whether cannabis-based medicinal products should be prescribed. The new recommendation might reduce the number of these prescriptions.

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Spasticity

Recommendations 1.3.1 and 1.3.2

Why the committee made the recommendations

The committee agreed that the evidence showed benefits of THC:CBD spray (licensed product in UK: Sativex) for treating spasticity in people with multiple sclerosis. There were reductions in some measures of patient-reported spasticity and no difference in adverse events in the treatment or placebo groups, although much of the evidence was assessed as low quality. The committee agreed that the longer-term benefits of THC:CBD spray are likely to outweigh any potential harms, although it was not clear how benefits related to improvements in quality of life.

The committee considered the evidence from 2 published economic evaluations but noted that they had contradictory conclusions about the cost effectiveness of THC:CBD spray and were subject to potentially serious limitations. So they considered results from a new economic model developed specifically for the cannabis guideline. The model included data from all relevant trials, longer-term registry data and data on adverse events. In reflection of the trial evidence, the model predicted that the average person would receive a quality of life (QALY) gain equivalent to around 30 days perfect health with THC:CBD spray added to standard care. The acquisition costs of the treatment are offset by predicted savings in management costs. The model estimates that THC:CBD spray would offer sufficient QALY gains if reduction in spasticity led to a halving of management costs and the acquisition cost of THC:CBD spray was also reduced (in addition to the existing pay-for-responders scheme). The committee agreed that under these conditions THC:CBD spray could be recommended to treat moderate to severe spasticity in adults with multiple sclerosis if other pharmacological treatments had not been effective.

The committee agreed that the evidence for the effectiveness and safety of other cannabis-based medicinal products was much more limited. There is also currently no evidence on the cost effectiveness of products other than THC:CBD spray and in other clinical indications (for example, motor neurone disease and spinal cord injury).

The committee acknowledged that women are more likely to receive a diagnosis of multiple sclerosis than men. However, they considered this would not cause an inequality

in relation to treatment.

Because there is limited evidence from trials on how reductions in spasticity affect quality of life and no evidence was found for conditions such as cerebral palsy, the committee agreed to make a recommendation for research to inform future guidance.

How the recommendations might affect practice

These recommendations are a change to NICE's previous guidance on treating spasticity in adults with multiple sclerosis, which did not support the use of THC:CBD spray. They are therefore expected to lead to THC:CBD spray being used as an add-on treatment for adults with treatment-resistant spasticity due to multiple sclerosis, with concomitant reductions in the need for supportive care.

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Severe treatment-resistant epilepsy

Recommendation for research on CBD, and THC in combination with CBD

Why the committee made the recommendations for research

The only cannabis-based medicinal product available for the treatment of epilepsy is epidyolex, which is licensed specifically for Dravet and Lennox-Gastaut syndromes. All other cannabis-based medicinal products are unlicensed for epilepsy. The committee were aware from cases highlighted by stakeholders that individual patients have reported having fewer seizures with these medicines when other treatments have not fully controlled the seizures. But current research is limited and of low quality, making it difficult to assess just how effective these medicines are for people with epilepsy. Published randomised controlled trials have focused on the use of pure CBD in people with Dravet and Lennox-Gastaut syndromes. People with these epilepsy syndromes also report a very high rate of adverse events. Open-label studies (clinical trials in which the treatment and placebo groups are not disguised) of cannabis-based medicinal products in other types of epilepsy have also shown a very high level of adverse events (in up to 98% of people), but it was not possible to determine how many of these were due to the cannabis-based products.

The committee discussed the limited evidence and agreed that it did not warrant a practice recommendation. However, they also agreed that they should not make a recommendation against the use of cannabis-based medicinal products as this would restrict further research in this area and would prevent people who are currently apparently benefiting from continuing with their treatment. Specialists, people with epilepsy and their carers should continue to make treatment decisions in the best interests of each person with epilepsy, in line with the GMC's guidance for doctors. However, people seeking treatment for severe epilepsy should be made aware that currently there is no clear evidence of the safety and effectiveness of cannabis-based medicinal products.

The committee agreed that more evidence is needed on the effectiveness of cannabis-based medicinal products in severe treatment-resistant epilepsy and made a recommendation for research to inform future practice. They discussed that some individual funding requests are denied because of lack of evidence of effectiveness. More research across different types of epilepsy may address this evidence gap.

The committee discussed the constituents of cannabis-based medicinal products. They were aware that it is difficult to extract pure CBD without other cannabinoids being present in trace amounts and this varies depending on extraction methods. Some medicines contain either purified 'pure' CBD alone (with trace amounts of other cannabinoids) or CBD combined with higher than trace amounts of THC. Most studies of cannabis-based medicinal products for severe epilepsy have evaluated 'pure' CBD, but the committee agreed it is important to know whether adding medicinal amounts of THC to CBD offers benefits or affects the type of adverse events observed. They decided to make a recommendation for research on how the constituents of a cannabis-based medicinal product influence its effectiveness.

Return to recommendation for research

Prescribing: who should prescribe and shared care

Recommendations 1.5.1 to 1.5.4

Why the committee made the recommendations

Based on current legislation, the complexity of the conditions, and the licensed (nabilone and Sativex) and unlicensed status of these medicines, the committee agreed that the initial prescription of unlicensed cannabis-based medicinal products must be made by a

specialist medical practitioner (a doctor included in the register of specialist medical practitioners [the Specialist Register]). They should also have a special interest in the condition being treated. The committee also agreed that THC:CBD spray should be initiated by a physician with special expertise in treating spasticity due to multiple sclerosis. Although there are no legal requirements for nabilone to be prescribed by a specialist prescriber.

There was limited evidence on who should prescribe and monitor cannabis-based medicinal products. Studies were conducted in Australia and Canada, and 1 study included participants from 8 different European countries. These countries have different healthcare systems, funding streams and legislation, which raised questions about their applicability to the prescribing of cannabis-based medicinal products in England. It was also not clear whether all products could be considered cannabis-based products for medicinal use as defined in the 2018 Regulations.

Guidance from the British Paediatric Neurology Association, based on current UK legislation and policy, advises that for children with intractable epilepsy, cannabis-based products should only be prescribed by a consultant paediatric neurologist. The committee agreed that for children and young people the initiating specialist prescriber for cannabis-based medicinal products should be a tertiary paediatric specialist with a special interest in the condition being treated (for example, for a child or young person with epilepsy, this would be a tertiary paediatric epilepsy specialist).

The committee noted that NICE's guideline on controlled drugs recommends that no more than a 30-day supply of a controlled drug is prescribed at any one time. Once their condition is stable, people taking cannabis-based medicinal products are likely to need repeat prescriptions. They will also need close monitoring of effectiveness and adverse effects, and dose adjustments. The committee agreed that there are potential burdens for patients associated with limiting prescribing and monitoring to tertiary care. They were aware of electronic prescription systems that could help patients to access prescriptions locally, but knew that these services vary by location. The committee discussed whether shared care would be appropriate and in the patient's best interest. They agreed that a shared care agreement could be considered, which could involve other healthcare professionals such as GPs and non-medical prescribers if they were confident to take on the responsibility of prescribing. The committee endorsed and agreed to reference NHS England's guidance on responsibility for prescribing between primary and secondary/ tertiary care.

The committee agreed that after the initial assessment and prescription by a specialist, allowing other prescribers to prescribe cannabis-based products under specialist direction would improve access for patients.

The specialist initiating treatment should also be involved in monitoring, evaluation and dose adjustment. This should be part of a shared care plan with a clear division of responsibilities between the initiating specialist prescriber and the prescriber acting under their direction.

The committee noted that a shared care agreement should detail the responsibilities of all parties, including the patient and their family and/or carers. The committee highlighted that the agreement should include details of how communication between parties would be managed, how funding would be obtained and the frequency and nature of monitoring.

Because some patients may need long-term treatment, the agreement should ensure continuity of care by setting out what should happen when the patient, other prescriber or specialist moves location. This should include handover of responsibilities to other specialists or prescribers.

How the recommendations might affect practice

Currently, prescribing and monitoring cannabis-based medicinal products takes place in tertiary care. The recommendations focus on shared care after the initial prescription with the involvement of other healthcare professionals such as non-medical prescribers and GPs. This will allow a more holistic approach to care. Moving away from tertiary care may be cost saving for the NHS.

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Prescribing: factors to think about when prescribing

Recommendations 1.5.5 to 1.5.9

Why the committee made the recommendations

The committee agreed a number of factors that should be considered before prescribing

cannabis-based medicinal products, based on study data, summaries of product characteristics and committee experience. They highlighted these in a recommendation along with some of the contraindications from the studies of the effectiveness and safety of cannabis-based medicinal products for nausea and vomiting, chronic pain, epilepsy and spasticity.

The committee also discussed whether there were any particular considerations when prescribing cannabis-based medicinal products for babies, children and young people. They discussed the limited evidence about the effects in this group and were mindful about the potential effects on cognitive function. The committee agreed that when considering the balance of benefits and harms, it would be prudent to take into account the potential impact of treatment on brain and cognitive development, and the effect of sedation.

The committee discussed the importance of collecting data on the treatment, clinical outcomes and adverse events experienced by people prescribed cannabis-based medicinal products, to inform future guidance and use. They noted the ambition to develop a UK register outlined in NHS England and NHS Improvement's barriers to accessing cannabis-based products for medicinal use on NHS prescription, and supported this.

Many people use non-prescribed, over-the-counter or over-the-internet, cannabis-based food supplements. The committee agreed that when someone is prescribed cannabis-based medicinal products they should be advised to stop using any non-prescribed cannabis products. This will reduce the risk of any drug interactions and reduce the potential for people taking a higher dose of cannabis than prescribed.

How the recommendations might affect practice

These recommendations will help to guide prescribers on some of the important issues to consider when prescribing cannabis-based medicinal products. This may result in more prescriptions for cannabis-based medicinal products, which may increase costs to the NHS. However, if symptoms are reduced with the use of cannabis-based medicinal products this may ultimately reduce the cost of other treatment for these patients, either through primary care or urgent care services.

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Prescribing: supporting shared decision making

Recommendations 1.5.10 and 1.5.11

Why the committee made the recommendations

Limited evidence was identified on the support prescribers and people may need when making decisions on cannabis-based medicinal products. Some evidence identified the need for training and further education for prescribers, while international guidelines described the overarching support that people seeking cannabis-based medicinal products may need.

The committee agreed that the key theme was the need for prescribers to discuss the risks, benefits and alternatives to cannabis-based medicinal products with people seeking treatment. The committee noted that with the change in legislation people may require licensed or unlicensed medicines, which would also be a key area for discussion. This recommendation should encourage shared decision making and allow people to make informed decisions about their care.

The committee also recommended that prescribers follow the NICE guideline on patient experience in adult NHS services. This has specific recommendations on shared decision making and details the support prescribers can provide when discussing treatment options.

How the recommendations might affect practice

The recommendations promote shared decision making and allow people to make informed decisions about their care. The committee noted that there may be situations in which a multidisciplinary team may help to reach a decision on treatment, such as the care of babies, children or young people. A multidisciplinary team may also need to be involved when decisions need to be made that are in the patient's best interest. This may not be feasible in all specialist care settings because staffing and structure of care provision varies.

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Context

Cannabis-based medicinal products have been suggested for a variety of medical conditions. In line with prescribing for all medicines, the potential for harm must be weighed up against the potential for benefit for individual patients.

Current practice

At the time of developing this guideline, delta-9-tetrahydrocannibinol combined with cannabidiol (Sativex), nabilone and cannabidiol (Epidyolex) were the only cannabis-based medicines licensed for use in the UK. Delta-9-tetrahydrocannibinol combined with cannabidiol (Sativex) has been licensed by the MHRA as a treatment for spasticity in adults with multiple sclerosis and is listed under Schedule 4 of the Misuse of Drugs Regulations 2001 ('2001 Regulations'). Nabilone has been licensed by the MHRA as a control of chemotherapy-induced nausea and vomiting in adults and is listed under Schedule 2 of the 2001 Regulations. Cannabidiol (Epidyolex) has been licensed by the MHRA as an add-on treatment for seizures associated with Lennox-Gastaut syndrome or Dravet syndrome, in conjunction with clobazam, for people aged 2 years and over and is listed under Schedule 2 of the 2001 Regulations. Dronabinol is listed under Schedule 2 controlled drugs but does not have a marketing authorisation from the MHRA in the UK.

Until September 2018, in cases of exceptional and unmet clinical need, legislation allowed the prescribing of cannabis-based medicinal products through the granting of an individual licence. As Schedule 1 controlled drugs, prescribing was controlled through the licensing process operated by the Home Office.

In November 2018, the UK Government set out the following requirements for the prescription of a cannabis-based product:

'A preparation or other product, other than one to which paragraph 5 of part 1 of schedule 4 applies, which:

- is or contains cannabis, cannabis resin, cannabinol or a cannabinol derivative (not being dronabinol or its stereoisomers)
- is produced for medicinal use in humans; and

- is a medicinal product, or
- a substance or preparation for use as an ingredient of, or in the production of an ingredient of, a medicinal product.'

Cannabis-based products for medicinal use related only to cannabis and cannabis preparations (such as extracts from cannabis as well as cannabinoids isolated from cannabis). It does not include synthetic versions of naturally occurring cannabinoids (for example, dronabinol) or any non-natural cannabinoids obtained by chemical synthesis (nabilone).

In this guideline, 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 delta-9-tetrahydrocannibinol combined with cannabidiol (Sativex) and nabilone
- plant-derived cannabinoids such as pure cannabidiol (CBD)
- synthetic compounds which are identical in structure to naturally occurring cannabinoids such as delta-9-tetrahydrocannabinol (THC), for example, dronabinol.

Finding more information and committee details

To find NICE guidance on related topics, including guidance in development, see the NICE topic pages on neurological conditions and chronic pain.

For full details of the evidence and the guideline committee's discussions, see the evidence reviews. You can also find information about how the guideline was developed, including details of the committee.

NICE has produced tools and resources to help you put this guideline into practice. For general help and advice on putting NICE guidelines into practice, see resources to help you put guidance into practice.

Update information

March 2021: We produced a statement clarifying our recommendations on unlicensed cannabis-based medicinal products for severe treatment-resistant epilepsy, which should be read alongside the recommendations.

Minor changes since publication

October 2022: In recommendation 1.5.1 and the March 2021 clarification statement we clarified that the initiating prescriber of cannabis-based medicinal products for children and young people under the care of paediatric services should also be a tertiary paediatric specialist in the condition being treated.

October 2021: We added a link to NICE's guideline on babies, children and young people's experience of healthcare in recommendation 1.5.6 and to NICE's guideline on shared decision making in recommendation 1.5.11.

ISBN: 978-1-4731-3578-9

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