

NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Guideline scope

Cannabis-based products for medicinal use

The Department of Health and Social Care in England has asked NICE to develop guidance on prescribing of cannabis-based¹ products for medicinal use.

The guideline will be developed using the methods and processes outlined in [developing NICE guidelines: the manual](#).

1 Why the guideline is needed

Policy, legislation and regulation

- In August 2018, [a review](#) by the Chief Medical Officer (CMO) recommended moving cannabis-based medicinal products out of Schedule 1 of the [Misuse of Drugs Regulations 2001](#) ('the 2001 Regulations') into Schedule 2, thereby allowing them to be prescribed for medicinal purposes under controlled conditions by registered medical practitioners. Before the decision to reschedule cannabis-based medicinal products to Schedule 2 controlled drugs, the only cannabis-based medicinal products available were nabiximols (Sativex) and dronabinol.
- [Advice](#) from the Advisory Council on the Misuse of Drugs (ACMD) supported the CMO's recommendation but recommended that synthetic cannabinoids should remain in Schedule 1 of the 2001 Regulations.
- In September 2018, in [a response](#) to the ACMD advice, ministers announced that cannabis-based medicinal products will be rescheduled as Schedule 2 controlled drugs and that prescribing will be restricted to doctors on the [Specialist Register of the General Medical Council](#) (GMC).
The existing [prescribing guidance and governance arrangements](#) in place

¹ The terms 'cannabis-based medicinal products' and 'cannabis-derived medicinal products' are interchangeable. For the purpose of this guideline, 'cannabis-based' will be used.

- 1 for unlicensed medicines continue to apply. As such, cannabis-based
2 products for medicinal use should not be considered as a first-line
3 treatment if they do not have a MHRA marketing authorisation.
- 4 • In October 2018, the Home Office announced that from 1 November 2018
5 doctors on the Specialist Register of the General Medical Council will be
6 able to prescribe cannabis-based medicinal products.

7 **Key facts and figures**

- 8 • Cannabis-based products have been suggested for a variety of medical
9 conditions. A recent review by the CMO determined that there was
10 'conclusive evidence of the therapeutic benefit of some cannabis-based
11 products for certain medical conditions, and reasonable evidence of
12 therapeutic benefit in several other medical conditions'.
- 13 • In line with prescribing for all medicines, the potential for harm must be
14 weighed up against the potential for benefit for individual patients. The
15 ACMD has identified several potential risks relating to inappropriate
16 prescribing and diversion of cannabis-based medicinal products. These
17 include 'increased risk of schizophrenia, respiratory symptoms, increased
18 risk of road traffic accidents and heightened probability of substance
19 abuse'.

20 **Current practice**

- 21 • In September 2018, nabiximols (Sativex) was the only cannabis-based
22 medicine licensed for use in the UK. Nabiximols has been licensed by the
23 Medicines and Healthcare products Regulatory Agency (MHRA) as a
24 treatment for spasticity in multiple sclerosis and is listed under Schedule 4
25 of the 2001 Regulations. Dronabinol is listed under Schedule 2 controlled
26 drugs but does not have a marketing authorisation from the MHRA for the
27 UK.
- 28 • Until September 2018, in cases of exceptional and unmet clinical need,
29 current legislation allowed the prescribing of cannabis-based medicinal
30 products through the granting of an individual licence. As Schedule 1
31 controlled drugs, prescribing was controlled through the licensing process
32 operated by the Home Office.

- 1 • In November 2018, the UK government set out the following requirements
2 for the prescription of a cannabis-based product.

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

- 5 – is or contains cannabis, cannabis resin, cannabidiol or a cannabidiol
6 derivative (not being dronabinol or its stereoisomers)²
7 – is produced for medicinal use in humans; and
8 – is a medicinal product, or
9 – a substance or preparation for use as an ingredient of, or in the
10 production of an ingredient of, a medicinal product."

11 **2 Who the guideline is for**

12 This guideline is for:

- 13 • healthcare professionals prescribing cannabis-based medicinal products
14 (currently doctors on the Specialist Register of the GMC)
15 • healthcare professionals providing care for people taking cannabis-based
16 medicinal products
17 • commissioners and providers of services for people taking cannabis-based
18 medicinal products
19 • people using services, their families and carers and the public.

20 It may also be relevant for:

- 21 • health and social care regulators
22 • individual people and organisations delivering non-publically funded
23 services
24 • the police.

² "To note 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 (e.g. Dronabinol) or any non-natural cannabinoids obtained by chemical synthesis (nabilone)."

1 NICE guidelines cover health and care in England. Decisions on how they
2 apply in other UK countries are made by ministers in the [Welsh Government](#),
3 [Scottish Government](#), and [Northern Ireland Executive](#).

4 ***Equality considerations***

5 NICE has carried out [an equality impact assessment](#) during scoping. The
6 assessment:

- 7 • lists equality issues identified, and how they have been addressed
- 8 • explains why any groups are excluded from the scope.

9 The guideline will look at inequalities relating to age, pregnant and breast
10 feeding women, physical disability, learning disability and mental health
11 problems.

12 **3 What the guideline will cover**

13 **3.1 Who is the focus?**

14 **Groups that will be covered**

- 15 • Adults, young people, children and babies.

16 Specific considerations will be given to:

- 17 • Young people, children and babies
- 18 • Pregnant women and women who are breastfeeding.

19 **3.2 Settings**

20 **Settings that will be covered**

21 All settings, including people's own homes, where publically funded health
22 and social care is delivered.

1 **3.3 Activities, services or aspects of care**

2 **Key areas that will be covered**

3 We will look at evidence in the areas below when developing the guideline,
4 but it may not be possible to make recommendations in all the areas.

5 This guideline will consider use of cannabis-based medicinal products for the
6 following groups in line with the [GCM's guidance](#) on prescribing unlicensed
7 medicines i.e. when other treatments haven't helped or have been discounted:

- 8 • people with chronic pain
- 9 • people with intractable nausea and vomiting
- 10 • people with spasticity
- 11 • people with severe treatment-resistant epilepsy.

12 This guideline will consider the following key areas.

- 13 1 The effectiveness, safety and potential harms of cannabis-based
14 medicinal products.
- 15 2 Decision-making and individual factors for cannabis-based medicinal
16 products.
- 17 3 Prescribing requirements for cannabis-based medicinal products.

18 **Areas that will not be covered**

- 19 1 Nabiximols (Sativex). This was listed as a Schedule 4 controlled drug
20 before September 2018 and has been considered by the NICE guideline
21 on [multiple sclerosis in adults](#).
- 22 2 Synthetic cannabinoids, including versions of naturally occurring
23 cannabinoids (e.g. Dronabinol) or any non-natural cannabinoids
24 obtained by chemical synthesis (nabilone).
- 25 3 Other cannabis products such as those marketed as food supplements,
26 not covered by the November 2018 UK Government requirements of
27 cannabis-based products. This guideline covers cannabis-based
28 medicinal products that are listed as Schedule 2 controlled drugs.

1 4 Smoked cannabis-based products. As set out by the government on the
2 21 September 2018, the administration of cannabis-based products for
3 medicinal use by smoking is prohibited.

4 **Related NICE guidance**

5 ***Published***

- 6 • [NICE cancer guidance](#) (2018)
- 7 • [Parkinson's disease in adults](#) (2017) NICE guideline NG71
- 8 • [Drug misuse prevention: targeted interventions](#) (2017) NICE guideline
9 NG64
- 10 • [Cerebral palsy in under 25s: assessment and management](#) (2017) NICE
11 guideline NG62
- 12 • [Physical health of people in prison](#) (2016) NICE guideline NG57
- 13 • [Controlled drugs: safe use and management](#) (2016) NICE guideline NG46
- 14 • [Motor Neurone disease: assessment and management](#) (2016) NICE
15 guideline NG42
- 16 • [Spinal injury: assessment and initial management](#) (2016) NICE guideline
17 NG41
- 18 • [Developing and updating local formularies](#) (2014, updated 2015) NICE
19 guideline MPG1
- 20 • [Multiple sclerosis in adults: management](#) (2014) NICE guideline CG186
- 21 • [Neuropathic pain in adults: pharmacological management in non-specialist
22 settings](#) (2013, updated 2018) NICE guideline CG172
- 23 • [Epilepsies: diagnosis and management](#) (2012, updated 2018), NICE
24 guideline CG137
- 25 • [Spasticity in under 19s: management](#) (2012, updated 2016) NICE guideline
26 CG145
- 27 • [Coexisting severe mental illness \(psychosis\) and substance misuse:
28 assessment and management in healthcare settings](#) (2011) NICE guideline
29 CG120
- 30 • [Antenatal care for uncomplicated pregnancies](#) (2008, updated 2017) NICE
31 guideline CG62

- 1 • [Drug misuse in over 16s: psychosocial interventions](#) (2007) NICE guideline
2 CG51

3 ***In development***

- 4 • [Chronic pain: assessment and management](#) NICE guideline. Publication
5 expected August 2020
- 6 • [Epilepsies in adults: diagnosis and management update](#). NICE guideline.
7 Publication expected January 2021
- 8 • [Epilepsies in children: diagnosis and management](#). NICE guideline.
9 Publication expected April 2021
- 10 • [Infant, children and young people's experience of healthcare](#) NICE quality
11 standard. Publication expected 2021
- 12 • [Shared decision making](#). NICE guideline. Publication expected April 2021
- 13 • [Cannabidiol for adjuvant treatment of seizures associated with Dravet](#)
14 [syndrome or Lennox-Gastaut syndrome](#). NICE technology appraisal
15 guidance. Publication expected November 2019.

16 **NICE guidance about the experience of people using NHS services**

17 NICE has produced the following guidance on the experience of people using
18 the NHS. This guideline will not include additional recommendations on these
19 topics unless there are specific issues related to cannabis-based medicinal
20 products:

- 21 • [Medicines optimisation](#) (2015) NICE guideline NG5
- 22 • [Patient experience in adult NHS services](#) (2012) NICE guideline CG138
- 23 • [Service user experience in adult mental health](#) (2011) NICE guideline
24 CG136
- 25 • [Medicines adherence](#) (2009) NICE guideline CG76

26 **3.4 Economic aspects**

27 We will take economic aspects into account when making recommendations.
28 We will develop an economic plan that states for each review question (or key
29 area in the scope) whether economic considerations are relevant, and if so
30 whether this is an area that should be prioritised for economic modelling and

1 analysis. We will review the economic evidence and carry out economic
2 analyses, using a NHS and personal social services (PSS) perspective. If
3 appropriate, a broader perspective may be used in sensitivity analyses (for
4 example, including non-NHS costs and consequences).

5 **3.5 Key issues and draft questions**

6 While writing this scope, we have identified the following key issues and draft
7 questions related to them. Where appropriate the guideline will cross refer to
8 the NICE guideline on [controlled drugs: safe use and management](#).

9 1 The effectiveness, safety and potential harms of cannabis-based
10 medicinal products

11 1.1 What is the clinical and cost effectiveness of cannabis-based
12 medicinal products for people with:

- 13 – chronic pain
- 14 – intractable nausea and vomiting
- 15 – spasticity
- 16 – severe treatment-resistant epilepsy?

17 1.2 What are the side effects, adverse effects or complications of
18 cannabis-based medicinal products for people with:

- 19 – chronic pain
- 20 – intractable nausea and vomiting
- 21 – spasticity
- 22 – severe treatment-resistant epilepsy?

23 1.3 What are the contraindications, potential interactions and risks and
24 cautions for use of cannabis-based medicinal products for people with:

- 25 – chronic pain
- 26 – intractable nausea and vomiting
- 27 – spasticity
- 28 – severe treatment-resistant epilepsy?

29 1.4 What are the individual patient monitoring requirements, treatment
30 durations, reviewing and stopping criteria, including how should
31 treatment be withdrawn or stopped, for use of cannabis-based medicinal
32 products for people with:

- 1 – chronic pain
- 2 – intractable nausea and vomiting
- 3 – spasticity
- 4 – severe treatment-resistant epilepsy?

5 2 Decision-making and individual factors for cannabis-based medicinal 6 products

7 2.1 What individual treatment factors need to be taken into account
8 when considering prescribing and obtaining patient consent for
9 cannabis-based medicinal products?

10 2.2 What support is needed to help prescribers and patients (or their
11 family members or carers) make decisions about cannabis-based
12 medicinal products?

13 3 Prescribing requirements for cannabis-based medicinal products

14 3.1 Who should be prescribe cannabis-based medicinal products?

15 3.2 The guideline will cross refer to relevant guidance on prescribing
16 requirements including formulation and quality assurance from UK
17 government agencies and regulators as appropriate.

18 3.3 The NICE guideline on [controlled drugs: safe use and management](#)
19 contains prescribing requirements. The guideline will cross-refer to these
20 recommendations as appropriate.

21 The key issues and draft questions will be used to develop more detailed
22 review questions, which guide the systematic review of the literature.

23 **3.6 Main outcomes**

24 The main outcomes that may be considered when searching for and
25 assessing the evidence are:

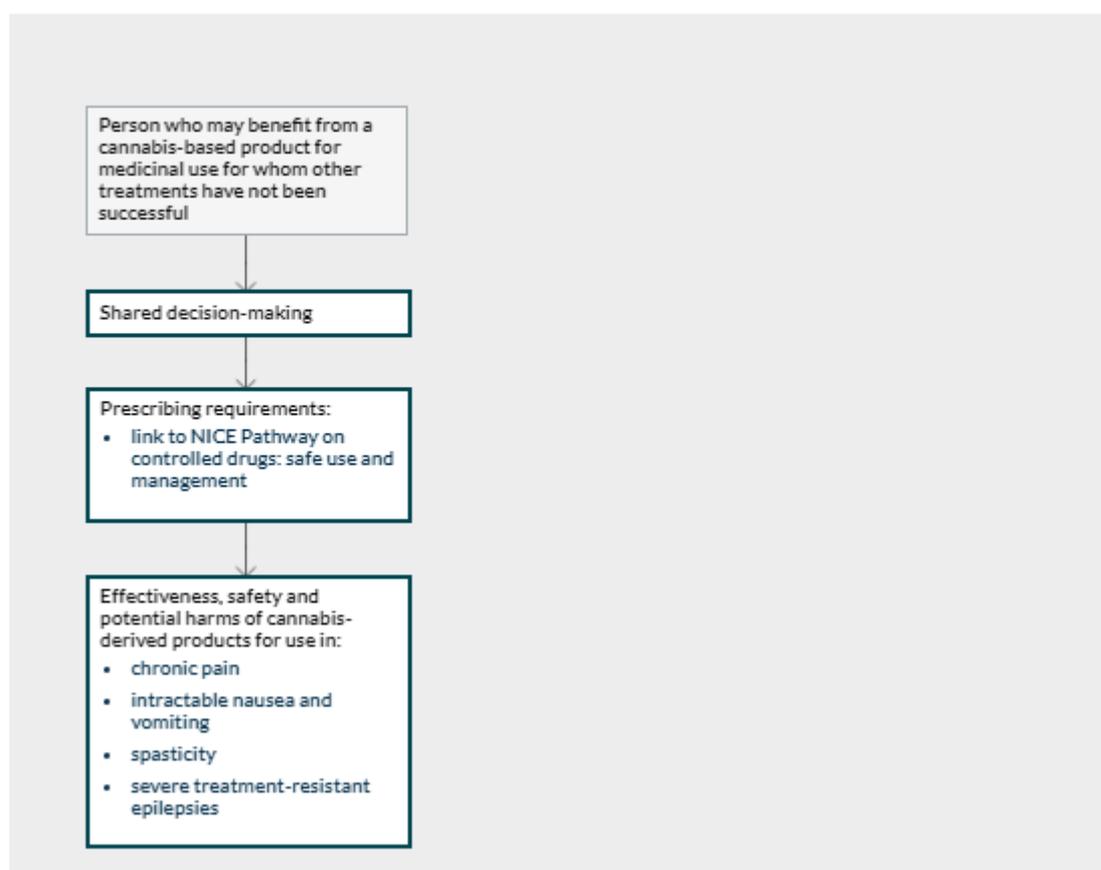
- 26 1 clinical outcomes and effectiveness
- 27 2 quality of life
- 28 3 service user satisfaction
- 29 4 carer satisfaction
- 30 5 adverse effects and safety.

1 **4 NICE Pathways**

2 [NICE Pathways](#) bring together everything we have said on a topic in an
3 interactive flowchart. When this guideline is published, the recommendations
4 will be included in the NICE Pathway on cannabis-based products for
5 medicinal use (in development).

6 An outline based on this scope is included below. It will be adapted and more
7 detail added as the recommendations are written during guideline
8 development. Links will be added between relevant NICE Pathways.

Cannabis-based products for medicinal use overview



9

10 **5 Further information**

This is the draft scope for consultation with registered stakeholders. The consultation dates are 13 November to 4 December 2018.

The guideline is expected to be published in October 2019.

You can follow progress of the [guideline](#).

Our website has information about how [NICE guidelines](#) are developed.

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