NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Guideline scope

Cannabis-based medicinal products[1]

The Department of Health and Social Care in England has asked NICE to develop guidance on prescribing of cannabis-based[2] 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 products for medicinal use 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.
- 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 pending a further review by the ACMD.
- In September 2018, in light of the CMO's review and in a response to the ACMD advice, Ministers announced that cannabis-based products for medicinal use will be rescheduled as Schedule 2 controlled drugs and that

[1] In July 2019, the title of the guideline was changed from 'Cannabis-based products for medicinal use' to 'Cannabis-based medicinal products'. This change reflects the inclusion in the scope of the licensed products delta-9-tetrahydrocannibinol and cannabidiol (Sativex) and nabilone, plant-derived cannabinoids such as pure cannabidiol (CBD) and synthetic compounds identical in structure to naturally occurring cannabinoids such as delta-9-tetrahydrocannabinol (THC), for example, dronabinol.

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

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 for unlicensed medicines continue to apply. As such, cannabis-based products for medicinal use should not be considered as a first-line treatment if they do not have a Medicines and Healthcare products Regulatory Agency (MHRA) marketing authorisation.

- In October 2018, the Home Office announced that from 1 November 2018 doctors on the Specialist Register of the General Medical Council will be able to prescribe cannabis-based products for medicinal use.

Key facts and figures

- Cannabis-based products have been suggested for a variety of medical conditions. A recent review by the CMO determined that there was 'conclusive evidence of the therapeutic benefit of some cannabis-based products for certain medical conditions, and reasonable evidence of therapeutic benefit in several other 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. The ACMD has identified several potential risks relating to inappropriate prescribing and diversion of cannabis-based medicinal products. The CMO's review identified risks that included 'increased risk of schizophrenia, respiratory symptoms, increased risk of road traffic accidents and heightened probability of substance abuse'.

Current practice

- In September 2018, delta-9-tetrahydrocannibinol and cannabidiol (Sativex) and nabilone were the only cannabis-based medicines licensed for use in the UK. Sativex has been licensed by the MHRA as a treatment for spasticity in multiple sclerosis and is listed under Schedule 4 of the 2001 Regulations. Nabilone has been licensed by the MHRA as a control of chemotherapy induced nausea and vomiting 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, current legislation allowed the prescribing of cannabis-based products for medicinal use 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)[3]
  - 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.'

2 Who the guideline is for

This guideline is for:

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

It may also be relevant for:

- other healthcare professionals

[3] '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).'

- health and social care regulators
- individual people and organisations delivering non-publically funded services
- the police.

NICE guidelines cover health and care in England. Decisions on how they apply in other UK countries are made by ministers in the Welsh Government, Scottish Government, and Northern Ireland Executive.

Equality considerations

NICE has carried out an equality impact assessment during scoping. The assessment:

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

The guideline will look at inequalities relating to age, pregnancy and breastfeeding, religion and belief, physical disability, learning disability and mental health problems.

3 What the guideline will cover

3.1 Who is the focus?

Groups that will be covered

All people with:

- chronic pain
- intractable nausea and vomiting
- spasticity
- severe treatment-resistant epilepsy.

Specific considerations will be given to:

- Young people, children and babies.
- Older people.

- People with mental health problems.
- People with a learning disability.
- Pregnant women and women who are breastfeeding.

3.2 Settings

Settings that will be covered

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

3.3 Activities, services or aspects of care

Key areas that will be covered

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

This guideline will consider:

- cannabis-based products for medicinal use as defined by the UK Government in November 2018 (see current practice section).
- the licensed products delta-9-tetrahydrocannibinol and cannabidiol (Sativex) and nabilone.
- plant-derived cannabinoids such as pure cannabidiol
- synthetic compounds which are identical in structure to naturally occurring cannabinoids such as delta-9-tetrahydrocannabinol (THC), for example dronabinol.

This guideline will consider unlicensed medicines and off-label use of cannabis-based medicinal products in line with the GMC's guidance, that is, when other licensed medicines haven't helped or have been discounted.
This guideline will consider the following key areas.

1 The effectiveness, safety and potential harms of cannabis-based medicinal products.
2 Decision-making and individual factors for cannabis-based medicinal products.

3 Prescribing requirements for cannabis-based medicinal products.

Areas that will not be covered

1 Synthetic compounds structurally related to naturally occurring cannabinoids that have been developed to mimic naturally occurring cannabinoids such as delta-9-tetrahydrocannabinol (THC) (with the exception of nabilone).
2 Synthetic compounds not structurally related to naturally occurring cannabinoids but which bind to cannabinoid receptors in the body.
3 Other cannabis products such as those marketed as food supplements, not covered by the November 2018 UK Government requirements of cannabis-based products.
4 Smoked cannabis-based products (excluding vaped products). As set out by the government on the 21 September 2018, the administration of cannabis-based products for medicinal use by smoking is prohibited.

Related NICE guidance

Published

- NICE cancer guidance (2018)
- Parkinson's disease in adults (2017) NICE guideline NG71
- Drug misuse prevention: targeted interventions (2017) NICE guideline NG64
- Cerebral palsy in under 25s: assessment and management (2017) NICE guideline NG62
- Physical health of people in prison (2016) NICE guideline NG57
- Controlled drugs: safe use and management (2016) NICE guideline NG46
- Motor neurone disease: assessment and management (2016) NICE guideline NG42
- Spinal injury: assessment and initial management (2016) NICE guideline NG41
- Developing and updating local formularies (2014, updated 2015) NICE guideline MPG1
- Multiple sclerosis in adults: management (2014) NICE guideline CG186

- Neuropathic pain in adults: pharmacological management in non-specialist settings (2013, updated 2018) NICE guideline CG172
- Epilepsies: diagnosis and management (2012, updated 2018) NICE guideline CG137
- Spasticity in under 19s: management (2012, updated 2016) NICE guideline CG145
- Coexisting severe mental illness (psychosis) and substance misuse: assessment and management in healthcare settings (2011) NICE guideline CG120
- Antenatal care for uncomplicated pregnancies (2008, updated 2017) NICE guideline CG62
- Drug misuse in over 16s: psychosocial interventions (2007) NICE guideline CG51

In development

- Cannabidiol for adjuvant treatment of seizures associated with Dravet syndrome. NICE technology appraisal guidance. Publication expected November 2019
- Cannabidiol for adjuvant treatment of seizures associated with Lennox-Gastaut syndrome. NICE technology appraisal guidance. Publication expected November 2019
- Chronic pain: assessment and management NICE guideline. Publication expected August 2020
- Epilepsies in adults: diagnosis and management update. NICE guideline. Publication expected January 2021
- Epilepsies in children: diagnosis and management. NICE guideline. Publication expected April 2021
- Infant, children and young people's experience of healthcare NICE guideline. Publication expected 2021
- Shared decision making. NICE guideline. Publication expected April 2021

NICE guidance about the experience of people using NHS services

NICE has produced the following guidance on the experience of people using the NHS. This guideline will not include additional recommendations on these

topics unless there are specific issues related to cannabis-based medicinal products:

- Medicines optimisation (2015) NICE guideline NG5
- Patient experience in adult NHS services (2012) NICE guideline CG138
- Service user experience in adult mental health (2011) NICE guideline CG136
- Medicines adherence (2009) NICE guideline CG76

3.4 Economic aspects

We will take economic aspects into account when making recommendations. We will develop an economic plan that states for each review question (or key area in the scope) whether economic considerations are relevant, and if so whether this is an area that should be prioritised for economic modelling and analysis. We will review the economic evidence and carry out economic analyses, using a NHS and personal social services (PSS) perspective. If appropriate, a broader perspective may be used in sensitivity analyses (for example, including non-NHS costs and consequences).

3.5 Key issues and draft questions

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

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

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

- chronic pain
- intractable nausea and vomiting
- spasticity
- severe treatment-resistant epilepsy?

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

- chronic pain
- intractable nausea and vomiting
- spasticity
- severe treatment-resistant epilepsy?

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

- chronic pain
- intractable nausea and vomiting
- spasticity
- severe treatment-resistant epilepsy?

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

- chronic pain
- intractable nausea and vomiting
- spasticity
- severe treatment-resistant epilepsy?

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

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

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

3 Prescribing requirements for cannabis-based medicinal products

3.1 Who should prescribe cannabis-based medicinal products?

Additionally the guideline will consider:

- Formulation, quality assurance, procurement considerations. The guideline will cross-refer to UK Government agencies and regulators as appropriate

- The NICE guideline on controlled drugs: safe use and management contains prescribing requirements. The guideline will cross-refer to these recommendations as appropriate.

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

3.6 Main outcomes

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

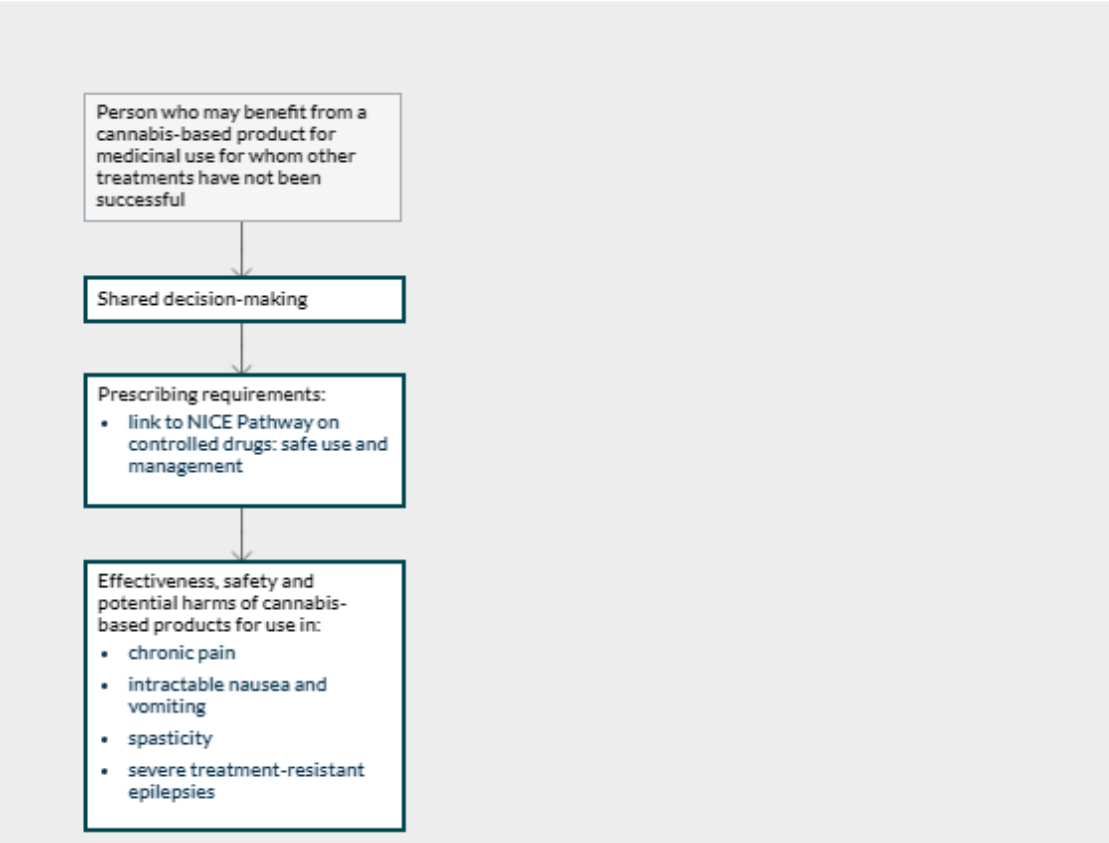
1 clinical outcomes and effectiveness
2 quality of life
3 patient satisfaction
4 carer satisfaction
5 adverse effects and safety.

4 NICE Pathways

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

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

Cannabis-based products for medicinal use overview



5 Further information

This is the final scope, incorporating comments from registered stakeholders during consultation.

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.