Cannabis and Cannabis-Related Products
Position Statement

As of November 1st 2018, an amendment to the Misuse of Drugs Regulations has allowed clinicians on the specialist register to prescribe cannabis based products under certain restrictions. There are several classifications of cannabis-related products, and the differing terminology is a source of confusion. The NCL Joint Formulary Committee (JFC) has approved a method of classification to clarify the products that are within the scope of consideration by the Committee.

Prior to the change in regulations, Sativex® and nabilone were available at selected sites within NCL for use in their licensed indications. At the January 2019 NCL JFC meeting, the Committee approved the use of cannabidiol oral solution for severe childhood-onset intractable epilepsy under an early access programme. This is subject to restrictions agreed by expert clinicians and will be revisited when a funding decision is made by NHS England.

The Committee agreed that any cannabis or cannabis-related products within scope of the JFC but not on the NCL Joint Formulary would need to undergo the standard new medicine application process.

Groups / Individuals who have overseen the development of this guidance: North Central London Joint Formulary Committee

Groups which were consulted and have given approval: North Central London Joint Formulary Committee

File name: Cannabis and cannabis-related products for medicinal use – position statement

Version number: V2.1

Available on: NCL JFC website

Disseminated to: All Trusts and CCGs in NCL

Equality impact assessment: None

NCL Joint Formulary Committee Approval date: 10/04/2019

Review date: 18/02/2022
Background

- As of November 1st 2018, an amendment to the Misuse of Drugs Regulations 2018 has led to the re-classification in controlled drug scheduling of some cannabis based products for human use. This allows them to be prescribed for medicinal purposes by a clinician on the specialist register where there is an unmet clinical need.¹
- Since the change in legislation, terminology (such as “CBPM”) has been used by various national bodies to describe only those cannabis based products that have been rescheduled. This does not capture all cannabis and cannabis-related products available leading to confusion about which products are available and within the scope for prescribing considerations in North Central London (NCL).

NCL JFC Position on prescribing Cannabis and Cannabis-related products

- The NCL JFC has approved the use of three cannabis or cannabis-related products.
  - **Cannabidiol oral solution (Epidiolex®)** is approved for a specific cohort of children and adolescents (aged two years and above) with Dravet syndrome or Lennox-Gastaut syndrome under an early access programme restricted to a specialist clinic at Great Ormond Street Hospital (GOSH). Patients prescribed Epidiolex® at GOSH and transferred to adult services will still be able to obtain Epidiolex® if it is still clinically appropriate.
  - **Cannabidiol oral solution (Epidiolex®)** is also available under terms outlined by the manufacturer via an early access programme to a restricted number of adult patients with refractory epilepsy at a specialist clinic at the National Hospital for Neurology and Neurosurgery (NHNN); eligibility to access treatment under the programme is restricted to patients who have Dravet Syndrome diagnosed with a proven genetic mutation in the SCN1A gene.
  - **Cannabidiol oromucosal spray (Sativex®)** is on formulary for the treatment of severe spasticity in multiple sclerosis restricted to a specialist clinic at University College London Hospitals.
  - **Nabilone capsules** are on formulary for the treatment of chemotherapy induced nausea and vomiting at University College London Hospitals, Royal Free London, North Middlesex University Hospital and Whittington Hospital.

- At the time of writing, there is only one other unlicensed cannabis or cannabis-related product available in the UK which is not on the NCL Joint Formulary (dronabinol, an FDA approved medicine under the brand name Marinol®).

- The classification of cannabis and cannabis-related products that are currently within the scope of the NCL JFC is summarised in Appendix 1.

- A list of products that are currently available for purchasing and prescribing within the NHS in NCL is summarised in Appendix 2. NCL JFC will consider applications to use products listed in Appendix 1 for indications that are not currently on the formulary. This includes dronabinol and those other available products used in an off-label indication. This follows the usual process for any medicine to be added to the formulary for prescribing and requires a consultant to complete a new medicine application form, highlighting evidence to support the efficacy and safety rationale as well as how the product will fulfil an unmet clinical need within their speciality.
• Until the Department of Health & Social Care (DHSC) and Medicines & Healthcare products Regulatory Agency (MHRA) complete further work on importation and licensing of cannabis and cannabis-related products, no other product will be available to prescribe or supply to a patient cohort in NCL.
• New products that become available that are within the scope of the NCL JFC (i.e. fit into one of the classes in green in Appendix 1) in the future will be considered by the Committee via the new medicine application process for a cohort of patients.
• The only exemption to this position statement is where the cannabis or cannabis-related product is an investigational medicinal product within clinical trial regulations.

Frequently Asked Questions

1. **What could cannabis or cannabis-related products be used for?**

   Very few people in England are likely to require a prescription for cannabis or cannabis-related products for medicinal purposes due to currently availability, published evidence of clinical benefit and restrictions outlined by NHS England. Three products are currently approved in NCL for patients to treat specific disease states (see Appendix 1).

   The Royal College of Physicians (RCP) outline that there is currently insufficient evidence to recommend cannabis or cannabis-related products for chronic pain and limited evidence in treatment of palliative care pain.³

   The British Paediatric Neurology Association (BPNA) state that the best evidence of efficacy and short-term safety is shown by pure cannabidiol (on formulary in NCL under an early access programme) – and do not recommend other non-licensed cannabis-based products for human use irrespective of their adherence to good manufacturing practice or good distribution practice standards.⁴

   See the document “Cannabis and Cannabis-based products – Patient information” and resources under question 12 for further information.

2. **What preparations of cannabis or cannabis-related products are currently available?**

   Four products are currently available in the UK – three of which are on the NCL Joint Formulary at certain sites within NCL for specific indications. No other cannabis or cannabis-related products are currently available in NCL. Please see Appendix 1 for more information.

3. **Can cannabis or cannabis-related products be prescribed in North Central London?**

   As noted above, please see Appendix 1 for products that can be prescribed, the indications they can be prescribed in, and at which site(s) they can be prescribed at.

   **No other cannabis or cannabis-related products are currently available to prescribe or supply to patients in North Central London.** The only exemption to this position statement is where the cannabis based product is an investigational medicinal product used within an authorised clinical trials under clinical trial regulations.

4. **Who are the North Central London Joint Formulary Committee?**

   North Central London Joint Formulary Committee (NCL JFC) manages a medicines formulary across NCL. This is a list of evidence-based, effective and safe medicines approved for use by NHS organisations within NCL in the acute, general and specialists settings.
The NCL JFC is a multidisciplinary medical and scientific committee. A core part of their work is to evaluate medicines prior to local availability to ensure they are safe, clinically effective and cost-effective.5

This approval is required for all licensed, off-label and unlicensed medicines used for a cohort of patients in NCL. The decision made by the NCL JFC will apply to all Trusts and Clinical Commissioning Groups (CCGs) in North Central London.

5. Why are prescriptions for other cannabis or cannabis-related products not available?

The amendment to the Misuse of Drugs Regulations has given the capability to specialists to prescribe certain cannabis or cannabis-related products. However, the ability to prescribe does not preclude the need for a robust assessment of the medicine for inclusion on to the NCL Joint Formulary.

The NCL JFC, in its role as a medical and scientific committee, has evaluated one product in January 2019 for inclusion in the joint formulary, adding to two cannabis or cannabis-related products available prior to the change in regulations. NCL JFC will continue to evaluate products reactively following an application for the desired cannabis or cannabis-related product that is within the remit of JFC consideration in order to ensure safe, appropriate, equitable, evidence-based and cost-effective practice in NCL.

6. Can requests for cannabis or cannabis-related products for individual patients be submitted to the local Trust?

Each Trust has their own Drugs and Therapeutics Committee (DTC), which serves as the medicines governance authority with oversight over unlicensed and non-formulary applications of medicinal products, including those required on a named-patient basis.

Named patient approval for non-formulary medications or non-formulary indications requires assurance that there is sufficient evidence for the safety, efficacy and cost-effectiveness of the product intended for use. Currently only the products in Appendix 2 are available for pharmacy departments to procure. Individual named-patient requests will need to show evidence of exceptionality.

For products not listed in Appendix 2, there is currently insufficient information describing their safe and effective use (including the appropriate therapeutic dose, frequency and duration of treatment), route of supply and associated costs. Until the DHSC complete their work on obtaining this information, DTCs will be unable to safely approve cannabis or cannabis-related products not listed in Appendix 2 on a named-patient basis.

7. What if a patient is admitted to hospital and is already receiving a non-formulary cannabis or cannabis-related product from elsewhere?

Any patient admitted to hospital should be informed that continuation of their non-formulary cannabis or cannabis-related product is at the discretion of their consultant, DTC Chair and Medical Director. Where a consensus is reached that continuation of therapy as an inpatient is deemed clinically appropriate and does not interfere with their inpatient management, the patient will be required to have their cannabis or cannabis-related product brought into hospital alongside any associated documentation that was obtained upon ordering. This will undergo a quality assurance process to ensure that the product is suitable for use whilst in hospital. Continued supply will be via the patient’s regular route of
procurement. In circumstances where the regular route of supply is not available and continuation of the drug is deemed clinically appropriate, the local medicines management team / DTC Secretariat should be contacted for further guidance. Where a product is not regarded as being of suitable quality, it will not be continued whilst the patient is admitted to hospital; however if treatment of the condition is clinically justified a referral to the appropriate specialist should be made to identify a suitable alternative.

8. **Should patients contact their GP to prescribe cannabis or cannabis-related products?**
Cannabis or cannabis-related products can only be prescribed by a specialist hospital doctor. GPs cannot prescribe cannabis or cannabis-related products. GPs can refer patients to a specialist clinic if the clinical condition demands expert management; patients should not expect to be referred solely for an NHS prescription of a cannabis or cannabis-related product. The health community in North Central London ask that patients do not request GP referrals for cannabis or cannabis-related products.

9. **Can cannabis or cannabis-related products be bought without a prescription?**
Some cannabis or cannabis-related products are available to buy over the internet without a prescription. It is likely that some of these products – even those called "cannabidiol (CBD) oils" – will be illegal to possess or supply due to the chance of containing tetrahydrocannabinol (THC). There is also a good chance they will contain THC and may not be safe to use. It is therefore advisable **not** to buy cannabis or cannabis-related products on the internet without a prescription.

Health food stores sell certain types of "pure CBD" products, however there is no guarantee these products will be of good quality as they are not made or distributed to pharmaceutical standards and are likely to contain very small amounts of CBD. As such the medicinal effect they might have is uncertain.

10. **Will this position statement affect cannabis or cannabis-related products used in clinical trials?**
This position statement will have no impact on the supply and prescribing of cannabis or cannabis-related products that are investigational medicinal products used within an authorised clinical trials under clinical trial regulations.

11. **When will this position statement be updated?**
This position statement will be updated when one of the following occurs:
- NCL JFC completes a review of a new medicine application for a cannabis based products (as per Appendix 2) to be added to the formulary for a new indication.
- DHSC issue further guidance on importation, licensing and availability of cannabis-related products.
- NHS England issue further information on commissioning of cannabis-related products.
- NICE issue guidance on cannabis-based products for medicinal use.
12. Where can I find further information about cannabis or cannabis-related products?

NICE will be producing a clinical guideline on the prescribing of cannabis or cannabis-related products, which is anticipated to be published by October 2019. In the interim the following information is available:

- NHS Patient Information Leaflet on Medical Cannabis
  [https://www.nhs.uk/conditions/medical-cannabis/](https://www.nhs.uk/conditions/medical-cannabis/)

- NHS England Letter on Cannabis or cannabis-related products

- NHS England supplementary information on Cannabis or cannabis-related products

- NHS England frequently asked questions

- MHRA Guidance on supply, manufacture, importation and distribution of unlicensed Cannabis or cannabis-related products

- Royal College of Physicians (RCP) Recommendations on Cannabis or cannabis-related products for intractable chemotherapy induced nausea and vomiting and chronic pain.
  [https://www.rcplondon.ac.uk/projects/outputs/recommendations-cannabis-based-products-medicinal-use](https://www.rcplondon.ac.uk/projects/outputs/recommendations-cannabis-based-products-medicinal-use)

- British Paediatric Neurology Association (BPNA) Guidance on use of Cannabis or cannabis-related products in children and young people with epilepsy
References


Appendix 1: North Central London classification of Cannabis and Cannabis-related products (based on constituent cannabinoid content)

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**Key**

NOC = naturally occurring cannabinoids

- **Red** = Will not be considered by NCL JFC
- **Dark Blue** = Some products considered by NCL JFC for specific indications – other Sch 1 drugs in this list will not be considered
- **Green** = Products in this list will be considered by JFC for specific indications and subject to a full formulary application
- **Orange** = Awaiting DHSC/MHRA importation and licensing review to be completed

**Synthetic cannabinoids**

Products containing a synthetic cannabinoid with or without additional constituents; Only nabilone and dronabinol are products that have a product license with proven medicinal purpose. Other drugs within this class are subject to the review by the Advisory Council on the Misuse of Drugs (ACMD).

**Pure cannabidiol**

Products containing pure cannabidiol only; These adhere to GMP/GDP standards and serve a medicinal purpose.

**Cannabis based products for human use**

These contain naturally occurring cannabinoids other than just pure CBD in known and tested quantities; these are made in accordance to GMP/GDP standards and serve a medicinal purpose.

**Other Cannabis products**

These contain an unknown or untested quantity of cannabinoids, and do not have adequate safety, tolerability or efficacy data to demonstrate the benefits in therapy of an unmet clinical need.

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North Central London Joint Formulary Committee

Cannabis and cannabis-related medicinal products – Position statement

Approval date: 10/04/2019

Version 2.0

Review date: 18/02/2022
Appendix 2: Cannabis and Cannabis-related products currently available for procurement in North Central London

The table below outlines products that are currently available to be procured via authorised pharmacies. These remain subject to prescribing and formulary restrictions, and should not be prescribed for any indications outside of formulary recommendations unless there has been local approval from the Drugs & Therapeutics Committee.

<table>
<thead>
<tr>
<th>Product</th>
<th>Constituent(s)</th>
<th>Licensing</th>
<th>CD status</th>
<th>NCL Approved Indications for Prescribing</th>
</tr>
</thead>
<tbody>
<tr>
<td>Epidiolex*</td>
<td>CBD 100mg/mL</td>
<td>Unlicensed</td>
<td>None</td>
<td>Epidiolex® is on the NCL Joint Formulary for use at Great Ormond Street Hospital (GOSH) in children and adolescents (aged two years and above) with Dravet Syndrome or Lennox-Gastaut Syndrome only under an early access programme. It has also been made available to a limited number of adult patients at the National Hospital for Neurology and Neurosurgery (NHNN); eligibility to access treatment under the programme is restricted to patients who have Dravet Syndrome diagnosed with a proven genetic mutation in the SCN1A gene.</td>
</tr>
<tr>
<td>Sativex*</td>
<td>2.7mg Δ⁹THC*: 2.5mg CBD</td>
<td>Licensed</td>
<td>Sch 4</td>
<td>Sativex® is on the NCL Joint Formulary for severe spasticity in Multiple Sclerosis and is restricted for use at UCLH only, where it is initiated and monitored by a specialist in Multiple Sclerosis.</td>
</tr>
<tr>
<td>Dronabinol</td>
<td>synthetic Δ⁹THC</td>
<td>Unlicensed</td>
<td>Sch 2</td>
<td>Dronabinol (under the brand name Marinol®) is used for the treatment of anorexia associated with weight loss in patients with AIDS, and to treat nausea and vomiting associated with cancer chemotherapy in patients who have failed to respond adequately to conventional antiemetic treatments. It is not on the NCL Joint Formulary.</td>
</tr>
<tr>
<td>Nabilone</td>
<td>1mg Nabilone</td>
<td>Licensed</td>
<td>Sch 2</td>
<td>Nabilone capsules is on the NCL Joint Formulary at UCLH, WH, NMUH and RFL. It is used for the treatment of nausea and vomiting associated with cancer chemotherapy in patients who have failed to respond adequately to conventional antiemetic treatments.</td>
</tr>
</tbody>
</table>

All products listed were available for procurement prior to the change in regulations.

*Sativex contains naturally occurring Δ⁹THC