

Cannabis based products for medicinal use Position Statement

As of November 1st 2018, cannabis based products have been re-classified from schedule 1 to schedule 2 under amendments to the Misuse of Drugs Regulations. This has allowed clinicians on the specialist register to prescribe unlicensed cannabis based products for medicinal use in humans (unlicensed CBPMs) under certain restrictions.

In order to ensure equitable, evidence based and safe practice in the prescription and supply of unlicensed CBPMs, the Joint Formulary Committee will be conducting an evaluation on the use of unlicensed CBPMs, which will be presented in January 2019.

Until this evaluation has concluded, unlicensed CBPMs will not be available to prescribe or supply in North Central London. The only exemption to this position statement is where the unlicensed CBPM is an investigational medicinal product within clinical trial regulations.

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
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Background

- As of November 1st 2018, cannabis based products for medicinal use (CBPMs) have been re-classified from schedule 1 to schedule 2 under the [Misuse of Drugs Regulations 2018](#). This allows them to be prescribed medicinally by a clinician on the specialist register where there is an unmet clinical need.^{1,2}
- NHS England expects the following restrictions to apply to prescribing of CBPMs:
 - only for indications where there is clear published evidence of benefit or UK guidelines
 - in patients with a clinical need which cannot be met by a licensed medicine and where established treatment options have been exhausted
 - can only be prescribed by a specialist doctor on the GMC specialist register within their own area of practice and training(i.e. can NOT be prescribed by GPs)
 - decision to prescribe must be agreed by a multidisciplinary team and approval granted on a named patient basis by the Trust Drug and Therapeutics Committee Chair or Medical Director.
- NHS England will be monitoring use of CBPMs across the NHS.

Under the amended regulations, all cannabis based products (except for nabiximols (Sativex®), which is a schedule 4 cannabis-based drug with a marketing authorisation; and synthetic cannabinoids (e.g. nabilone and dronabinol)³, which are schedule 2 products to treat chemotherapy induced nausea and vomiting) are classified as unlicensed “special” medicines. These are subject to legal and local Trust governance procedures for unlicensed medicines. Prescribers should consider the relevant GMC guidance on prescribing unlicensed medicines.⁴

NHS North Central London Position on Prescribing Cannabis-Based Products

- In order to ensure equitable, evidence based and safe practice in the prescription and supply of unlicensed CBPMs, the North Central London Joint Formulary Committee will be conducting an evaluation on the use of CBPMs, which will be presented in January 2019.
- **Until this evaluation has concluded, unlicensed CBPMs will not be available to prescribe or supply in North Central London.** The only exemption to this position statement is where the unlicensed CBPM is an investigational medicinal product within clinical trial regulations.

Frequently Asked Questions

1. What could cannabis based products for medicinal use (CBPMs) be used for?

Very few people in England are likely to require a prescription for CBPMs as it is subject to the restrictions outlined by NHS England (see above under background). Currently it is anticipated that medical cannabis may be suitable for some patients unresponsive to other treatments who have specific forms of severe epilepsy (e.g. Lennox-Gastaut syndrome and Dravet syndrome) or chemotherapy induced nausea and vomiting. The Royal College of

Physicians (RCP)⁴ outline that there is currently insufficient evidence to recommend CBPMs for chronic pain and limited evidence in treatment of palliative care pain.

See patient information leaflet and resources under question 12 for further information.

2. What preparations of CBPMs are currently available?

Sativex[®] is the only licensed CBPM currently available in the UK, and is licensed as treatment for spasticity in multiple sclerosis (MS). Patients who are on Sativex[®] for MS in line with the formulary restrictions may continue on this treatment in secondary care.

There are no other CBPMs currently licensed as medicines in the UK. The North Central London Joint Formulary Team will be assessing suitability of unlicensed preparations as part of their evaluation.

3. Can CBPMs be prescribed in North Central London?

In order to ensure equitable, evidence based and safe practice in the prescription and supply of unlicensed CBPMs, the North Central London Joint Formulary Committee will be conducting an evaluation on the use of CBPMs, which will be presented in January 2019.

Until this evaluation has concluded, unlicensed CBPMs will not be available to prescribe or supply in North Central London. The only exemption to this position statement is where the unlicensed CBPM is an investigational medicinal product within clinical trial regulations.

Due to the number of possible indications the drug is considered for use in and the need to evaluate the role of the individual cannabinoids, a full review will not be available until January 2019.

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

North Central London Joint Formulary Committee (NCL JFC) manages a formulary across NCL. This is a list of evidence-based, effective and safe medicines approved for use by NHS organisations within NCL.

The Joint Formulary Committee is a multidisciplinary medical and scientific committee. A core part of their work is to evaluate medicines prior to use to ensure they are safe, clinically effective and cost-effective.⁵

This approval is required for all licensed and unlicensed medicines, including CBPMs. 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 CBPMs not available before the formulary evaluation?

The amendment to the Misuse of Drugs Regulations has given the capability to specialists to prescribe cannabis based medicinal products. However, the ability to prescribe does not preclude the need for a robust assessment of the medicine for inclusion on to the joint formulary.

Therefore, the NCL JFC, in its role as a medical and scientific committee, will evaluate cannabis use in the desired indications in order to ensure safe, appropriate, equitable, evidence-based and cost-effective practice in North Central London.

6. Can requests for CBPMs for individual patients be submitted to the local Trust?

Each Trust has their own Drugs and Therapeutics Committee (DTC), with oversight over unlicensed and non-formulary applications of medicinal products on a named-patient basis.

Named patient approval requires assurance that there is sufficient evidence for the safety, efficacy and cost-effectiveness of the product intended for use. This evaluation is being undertaken by the NCL JFC on behalf of the individual Trust DTCs to ensure equitable decision making for patients across North Central London.

Requests for individual patients should not be made to local Trusts until the NCL JFC evaluation has concluded.

7. What if a patient is admitted to hospital with CBPM therapy?

Any patient admitted to hospital should be informed that continuation of their CBPM therapy is at the discretion of their consultant and the DTC Chair. Where a consensus is reached that continuation of therapy as an inpatient is deemed clinically appropriate, the patient will be required to have their CBPM 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 patients regular route of procurement. 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 is clinically justified a referral to the appropriate specialist will be made to identify a suitable alternative.

8. Should patients contact their GP to prescribe CBPMs?

CBPMs can only be prescribed by a specialist hospital doctor. GPs cannot prescribe CBPMs. Until the NCL formulary position for cannabis has been established, GPs should not refer patients to a hospital specialist. The health community in North Central London ask that patients do not request GP referrals for CBPMs.

9. Can CBPMs be bought without a prescription?

Some cannabis-based products are available to buy over the internet without a prescription. It's likely most of these products – even those called "cannabidiol (CBD) oils" – will be illegal to possess or supply. There's a good chance they will contain THC, and may not be safe to use. Health stores sell certain types of "pure CBD". However, there's no guarantee these products will be of good quality and as they often contain very small amounts of CBD, the effect they might have is uncertain.

It is therefore advisable not to buy CBPMs on the internet or without a prescription.

10. Will this position statement affect CBPM clinical trials?

This position statement will have no impact on the supply and prescribing of unlicensed CBPMs that are investigational medicinal products under clinical trial regulations

11. When will this position statement be updated?

This position statement will be updated after the NCL JFC formulary review and discussion of an implementation plan. The target date for this is January 2019.

12. Where can I find further information about CBPMs?

NICE will be producing a clinical guideline on the prescribing of CBPMs, 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/>
- NHS England Letter on CBPMs
<https://www.england.nhs.uk/wp-content/uploads/2018/10/letter-guidance-on-cannabis-based-products-for-medicinal-use..pdf><https://www.england.nhs.uk/wp-content/uploads/2018/10/letter-guidance-on-cannabis-based-products-for-medicinal-use..pdf>
- MHRA Guidance on supply, manufacture, importation and distribution of unlicensed CBPMs
https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/752796/Cannabis_Guidance_unlicensed_CBPMs_-_Final_311018.pdf
- Royal College of Physicians (RCP) Recommendations on CBPMs for intractable chemotherapy induced nausea and vomiting and chronic pain.
<https://www.rcplondon.ac.uk/projects/outputs/recommendations-cannabis-based-products-medicinal-use>
- British Paediatric Neurology Association (BPNA) Guidance on use of CBPMs in children and young people with epilepsy
<https://bpna.org.uk/?page=c Demp>

References

1. Home Office. The Misuse of Drugs (Amendments) (Cannabis and Licence Fees) (England, Wales and Scotland) Regulations 2018. 8
2. Davies, S., Powis, S. & Ridge, K. Cannabis based products for medicinal use. *NHS England* Available at: <https://www.england.nhs.uk/wp-content/uploads/2018/10/letter-guidance-on-cannabis-based-products-for-medicinal-use..pdf>. (Accessed: 6th November 2018)
3. NHS England. Supplementary information on cannabis -based products for medicinal use. (2018). Available at: <https://www.england.nhs.uk/wp-content/uploads/2018/11/letter-additional-guidance-on-cannabis-based-products-for-medicinal-use.pdf>. (Accessed: 5th December 2018)
4. Medicines and Healthcare product Regulatory Agency. The supply of unlicensed medicinal products specials. Available at: https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/373505/The_supply_of_unlicensed_medicinal_products__specials_.pdf. (Accessed: 6th November 2018)

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6. North Central London Joint Formulary Committee. Terms of Reference. (2018). Available at: https://www.ncl-mon.nhs.uk/wp-content/uploads/2017/07/JFC_Terms-of-Reference.pdf. (Accessed: 6th November 2018)