The East of England
Priorities Advisory Committee
Hosted by PrescQIPP

GUIDANCE STATEMENT

Unlicensed cannabis based medicinal preparations

PAC statement on prescribing in primary care

This statement applies to unlicensed cannabis based medicinal products only. Refer to local policies on the use of licensed products Sativex, nabilone and Epidyolex.

1. Initiation of treatment with unlicensed cannabis based medicinal products by GPs is illegal and is not permitted.
2. GP continuation of treatment initiated by authorised specialists, including treatment initiated by authorised specialists working in the private sector, is not recommended. All prescribing should remain with the responsible specialist.
3. Patients requesting prescriptions who are currently under the care of a specialist should be advised to discuss their treatment plan with the specialist.
4. Patients requesting prescriptions who are not currently under the care of a specialist should only be referred to specialist services where clinically appropriate and in line with current pathways.
5. Information for patients on the availability of cannabis based medicinal products is available on the NHS website here https://www.nhs.uk/conditions/medical-cannabis/

Key points

- From 1st November 2018, unlicensed cannabis-based products for medicinal use were reclassified as Schedule 2 controlled drugs and are able to be prescribed medicinally where there is an unmet clinical need.
- Due to the limited evidence base and their unlicensed nature, the Government has chosen to restrict the decision to prescribe cannabis-based products for medicinal use to only those clinicians listed on the Specialist Register of the General Medical Council. This restriction has been set out in regulations.
- The NHS England Frequently Asked Questions about cannabis-based products for medicinal use state that whilst it is possible for a GP to continue prescribing legally, it is advised that all prescriptions will need to be initiated and signed by a specialist doctor.
- Due to the specialist nature of these products, PAC do not consider them to be suitable for shared care arrangements and GP prescribing is not recommended.
- Patients requesting prescriptions for cannabis based products who are already under the care of a specialist on the register should be advised to discuss their treatment plan with the specialist. Patients who are not currently under specialist care, should only be referred to a specialist where clinically appropriate and in line with current pathways.

Background

Cannabis based products for medicinal use contain cannabinoids derived from the cannabis plant, including 9-tetrahydrocannabinol (THC), cannabidiol (CBD), or a combination of THC and CBD. Synthetic cannabinoids for medicinal use typically mimic the effects of specific cannabinoids such as THC.[1]

THC is the constituent of cannabis that causes the "high", whereas CBD is not intoxicating at typical doses. THC and CBD have contrasting mechanisms of action and therapeutic indications; THC carries a higher risk of adverse events compared with CBD.[1]

The Government has defined a cannabis-based product for medicinal use in humans as:[2]

"A preparation or other product, other than one to which paragraph 5 of part 1 of Schedule 4 (of the Misuse of Drugs Act) applies, which-

A. Is or contains cannabis, cannabis resin, cannabinol or a cannabinol derivative (not being dronabinol or its stereoisomers);

B. Is produced for medicinal use in humans; and-

C. Is-

   i. a medicinal product, or

   ii. a substance or preparation for use as an ingredient of, or in the production of an ingredient of, a medicinal product;"

In June 2018 the United Kingdom Government commissioned a review into whether cannabis and cannabis-based medicinal products should be rescheduled under the Misuse of Drugs Regulations (MDR) 2001.[2]

In response to this review, from 1st November 2018, cannabis-based products for medicinal use were moved out of Schedule 1 (the category for substances with no medicinal value) and into Schedule 2 of the MDR, with the exception of synthetic cannabinoids.[2]

Under the new regime, all cannabis-based products for medicinal use (apart from Sativex, (listed in Schedule 4 of the MDR), nabilone and Epidyolex, which have market authorisations) are unlicensed medicines.[2]

NICE guideline 144 (NG144), Cannabis-based medicinal products, published in November 2019, makes recommendations on the use of cannabis-based medicinal products for the treatment of people with intractable nausea and vomiting, chronic pain, spasticity and severe treatment-resistant epilepsy.[3] The use of licensed products for these indications is not covered by this PAC document. Refer to local policies on the use of Sativex/nabilone/Epidyolex.

NG144 only recommends the prescribing of CBD to manage chronic pain in adults if it is part of a clinical trial. NG144 does not recommend the use of nabilone, dronabinol, THC, or a combination of CBD with THC for the treatment of chronic pain. NICE have made research recommendations on the use of cannabis-based medicinal products to treat severe treatment-resistant epilepsy, and do not currently recommend use.[4] Separate NICE technology appraisals have been published on the use of the licensed product Epidyolex to treat Lennox-Gastaut syndrome and Dravets syndrome.[4,5]

The Government has chosen to restrict the decision to prescribe unlicensed cannabis-based products for medicinal use to only those clinicians listed on the Specialist Register of the General Medical Council. NHS England expects that cannabis-based products for medicinal use should only be prescribed for indications where there is clear published evidence of benefit or UK guidelines, and in patients where there is a clinical need which cannot be met by a licensed medicine and where established treatment options have been exhausted. In addition, a Specialist doctor on the General Medical Council Specialist Register should only make the decision to prescribe within their own area of practice and training (e.g. physicians for adults should not be prescribing for children) and the decision to prescribe should be agreed by the multidisciplinary team.[2]

NHS England guidance states that any decision to prescribe unlicensed cannabis-based products must take into account the relevant GMC guidance and the relevant NHS Trust governance procedures for unlicensed medicines in the normal way. As a minimum, they expect that approval for use is granted on a named patient basis by the Drug and Therapeutics Committee Chair or Trust Medical Director. They also advise that it is good practice to discuss use of cannabis-based products for medicinal use with a peer clinician in the same Specialist Register of the General Medical Council. Any such discussions should be appropriately documented.[2]

As with any unlicensed medicines or "specials", the prescribing of such products must be on a "named patient" basis. It is therefore expected that rigorous and auditable safeguards around prescribing of an unlicensed product will be followed, alongside existing protocols on controlled drugs.[2]

The Care Quality Commission (CQC) interim policy position on cannabis-based medicinal products sets out what the CQC requires of any registered providers and prospective registrants including those working in the private sector. Specialist doctors who work in independent healthcare must register with the CQC for the regulated activity of treatment of disease, disorder and injury. If they intend to prescribe and treat patients with cannabis-based medicinal products, they must be able to provide assurance and demonstrate that they deliver safe and effective care in line with relevant legislation and guidance.[6]

Prescribing responsibility

Due to the limited evidence base and their unlicensed nature, the Government has chosen to restrict the decision to prescribe unlicensed cannabis-based products for medicinal use to only those clinicians listed on the Specialist Register of the General Medical Council. This restriction has been set out in regulations.[2]

NHS Guidance on cannabis-based products for medicinal use states that "the regulations are drafted in such a way that cannabis-based products for medicinal use can be supplied under the prescription or direction of a specialist doctor. NHS England are exploring how this may work under shared care arrangements, however in the first instance they expect specialist prescribing only. Trusts will be expected to meet the costs of this, where necessary."[2]

NHS England Cannabis-based products for medicinal use: Frequently Asked Questions provides further clarity on the legal position with regards to GP prescribing and states:[7]

'Q. What about Shared Care arrangements?

A. The law requires that these products be supplied under either the prescription or direction of a clinician on the General Medical Council's Specialist Register.

However, whilst it is possible for a GP to continue prescribing legally, it is advised that all prescriptions will need to be initiated and signed by a specialist doctor. Consideration will be given to how shared care arrangements should or could work, including determining whether it is indeed appropriate to have such arrangements in place. If a doctor prescribes a medicine under shared care arrangements, he or she accepts clinical and professional responsibility for that prescribing decision.'[7]

Due to the specialist nature of these unlicensed cannabis-based products and in line with NHS England guidance, PAC do not currently consider them to be suitable for shared care arrangements, and GP prescribing is not recommended.

This recommendation also applies to patients whose treatment has been initiated by an authorised specialist working in the private sector. In line with the principles defining the boundaries between NHS and private healthcare, continued prescribing by GPs would not be permitted as this treatment is not currently available as part of NHS commissioned care.[8]

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Document history

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References

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