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## **Dear Colleagues**

Since 1<sup>st</sup> November 2018 specialist doctors on the Specialist Register of the General Medical Council (GMC) have been able to decide whether to prescribe Cannabis-based products for medicinal use (CBPMs) where there is an unmet clinical need.

This letter highlights some new resources to support you and remind you of the process for prescribing CBPMs, given that they are almost all unlicensed medicines.

## Training for health professionals

We commissioned the University of Birmingham to develop an e-learning module to support health professionals in their discussions with patients and to ensure appropriate access to CBPMs. All UK healthcare professionals are able to access this through the Health Education England learning platform, e-learning for health:

https://www.e-lfh.org.uk/programmes/cannabis-based-products-for-medicinal-use/

The e-learning module includes information on the pharmacology of cannabis, legislation governing medical use, therapeutic areas and the evidence available to support the prescription of a CBPM. It will be updated as more information becomes available.

We have also updated the <u>Frequently asked questions</u> on the NHS England website to support prescribers.

Further support for prescribers in the form of the <u>NICE guideline on Cannabis-Based Medicinal Products</u>, <u>NG144</u> has been published recently. This guideline recommends that nabilone can be considered as an add-on treatment for adults with chemotherapy-induced nausea and vomiting which persists despite optimised conventional antiemetics. The guideline also recommends offering a 4-week trial of THC:CBD spray (Sativex®) to treat moderate to severe spasticity in adults with multiple sclerosis, if other pharmacological treatments for spasticity are not effective.

NICE has published Technology Appraisals for the use of cannabidiol (Epidyolex®) for severe treatment-resistant epilepsies. The appraisals look at the clinical and cost effectiveness of cannabidiol in conjunction with clobazam for adjuvant treatment of seizures associated with <a href="Lennox-Gastaut">Lennox-Gastaut</a> and <a href="Dravet syndromes">Dravet syndromes</a>. Both appraisals recommend cannabidiol with clobazam as an option for treating seizures associated with these syndromes in people aged 2 years and older, subject to adequate



monitoring and supply arrangements. For those patients that fulfil the criteria funding has been fast-tracked and will be in place from the 6<sup>th</sup> January 2020.

## **Process for prescribing a CBPM**

Currently almost all CBPMs prescribed by specialist doctors are unlicensed medicines. GMC guidance states that prescribing of an unlicensed medicine may be necessary where there is no suitably licensed medicine that will meet the patient's need.

Specialist doctors must take into consideration the clinical evidence base, and the <u>guidance from the GMC</u> on licensed, off label and unlicensed medicines and local governance systems when making a decision to prescribe.

Specialist doctors must decide whether it is clinically appropriate to prescribe a CBPM, but it is vital that individual patients or their carers are able to discuss and determine the best treatment for them through shared decision making.

People should be at the centre of decisions about their own treatment and care and as part of this you should explore all treatment options with your patients, along with their risks and benefits. You should discuss the different options available to patients and you should explain and clearly document the rationale for the prescribing decision made by specialist clinicians. As recommended in the NICE guideline on cannabis-based medicinal products, specialists should where available record details of treatment, clinical outcomes and adverse effects using local or national registries as these emerge.

Specialist doctors must also consider local procedures supporting prescribing and funding decisions for unlicensed medicines, which may vary between individual Trusts. However, most will include an application by the specialist clinician for approval to prescribe to the Trust Drug and Therapeutics Committee (DTC).

DTCs should assess medicines against the following factors: clinical evidence of efficacy for the specific indication under consideration, patient safety and cost impact. If DTC approval is granted Trusts should then consider funding.

CBPMs are not routinely commissioned. Trusts are expected to meet any costs in the first instance for their patients where there is an unmet clinical need.

However, if a drug is deemed to be high-cost, then an application for funding can be made to the responsible commissioner under an Individual Funding Request (IFR). Following approval <a href="MHRA quality checklists">MHRA quality checklists</a> should be followed at each stage of the supply process to ensure that the prescription of the specialist doctor is fulfilled to the required standards.

Following publication of NICE Technology Appraisals for the use of cannabidiol in conjunction with clobazam for Lennox-Gastaut and Dravet syndromes, NHS England Specialised Commissioning will make any funding decisions in the usual way.



## Other steps

This letter is one of several steps we are taking to ensure that patients can access a CBPM where clinically appropriate. We are also implementing other recommendations from the report on <a href="Barriers to accessing cannabis-based products for medicinal use on NHS prescription">Barriers to accessing cannabis-based products for medicinal use on NHS prescription</a>, including establishing a UK-wide paediatric specialist clinical network, clinical trials, and an alternative study for children and young people already in receipt of a CBPM.

Thank you for helping ensure that CBPMs are available and accessible to the right patients at the right time to achieve optimal outcomes.

Yours sincerely

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