

Surrey and North West Sussex Area Prescribing Committee (APC)

Surrey (East Surrey CCG, Guildford & Waverley CCG, North West Surrey CCG, Surrey Downs CCG & Surrey Heath), Crawley CCG and Horsham & Mid-Sussex CCG

Title of paper:	Cannabis-based medicinal products (unlicensed / off-label use)		
Meeting date:	8 th January 2020		
Agenda item:	To be completed by PCN secretary	Attachment(s):	2
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Paper type	NICE NG144		
For:	For recommendation		
<p>Executive Summary: NICE NG144 discusses cannabis-based medicinal products (CBMP) and their therapeutic uses. It covers the prescribing of CBMP for people with intractable nausea and vomiting, chronic pain, spasticity and severe treatment-resistant epilepsy. The products covered by this guideline include:</p> <ul style="list-style-type: none"> • CBMP as set out by the UK Government in The Misuse of Drugs (Amendments) (Cannabis and Licence fees) (England, Wales and Scotland) Regulations 2018. • The licensed products Sativex (THC combined with CBD) and nabilone • Plant-derived cannabinoids such as pure CBD (cannabidiol) • Synthetic compounds which are identical in structure to naturally occurring cannabinoids such as THC, for example, dronabinol <p>This paper discusses the off-label and unlicensed use of CBMP and makes recommendation to the APC with regards to traffic-light status according to indication, rather than to specific products, at this time.</p> <p>Please note;</p> <ul style="list-style-type: none"> • All unlicensed products must be prescribed by a doctor on the Specialist Register of the General Medical Council unless the patient is taking part in an official clinical trial. All other prescriptions of unlicensed CBPM will be illegal. • However, if a product is covered by a marketing authorisation (product licence), it can be prescribed by any practitioner, such as a General Practitioner, with the authority to do so under the Misuse of Drugs Regulations 2001, even if it is for an off-label indication. This is because its quality, safety and efficacy have been established for its indicated uses. • Nabilone and Sativex are discussed in separate papers. • The Epidyolex brand of pure CBD (cannabidiol) <u>is</u> excluded from the National Tariff for its licensed indications. Both licensed indications are commissioned by NHS England only. • It is possible that GPs will be asked to continue prescribing of Epidyolex under some form of shared care agreement by a tertiary centre, (NHS England have advised that this is not their intention for the licensed indications) – primary care prescribers are advised to contact their prescribing advisor BEFORE agreeing to <u>any</u> shared care 			

agreement or prescription arrangement, even if the patient is at risk of missing doses. **The reputational and professional risk to primary care prescribers of inadvertently writing an illegal prescription (if unlicensed) or of prescribing a dangerous dose is extremely high if advice is not sought.**

- It is likely that the CCG will receive requests to fund CBMP for off-label uses via the Individual Funding Request (IFR) route; however cannabidiol is only excluded from the National Tariff for epilepsy indications, and not for any other indication.
- Therefore it is likely that individual providers will be solely liable for the total cost of any off-label / unlicensed CBMP prescribing at this time.
- All prescribers and advisors are advised to access further information on this subject via the Health Education England (HEE) e-learning module: [Cannabis-based products for medicinal use](#)
- CBD that can be bought online or in retail outlets in the UK is not classified as a “drug” as the purity and content of these products is doubtful. If a patient says they are using these products and/or using cannabis illegally, this should be recorded in the patient’s notes for safety purposes, as CBD has known drug interactions.

Summary: *(What is the APC being asked to do and why)*

The APC is asked to consider the above information and to assign traffic light status to the following:

CBMP for all unlicensed / off-label indication (incl. chronic pain) – BLACK

- All unlicensed products must be prescribed by a doctor on the Specialist Register of the General Medical Council unless the patient is taking part in an official clinical trial. Prescription of unlicensed CBPM from other prescribers will be illegal.
- Off-label indications are not recommended within NICE NG144 due to lack of evidence on clinical efficacy and cost-effectiveness.
- Shared care agreements would not be supported for these indications at this time.
- Chronic pain - NICE NG144 recommends that prescribers **do NOT offer** nabilone, dronabinol, THC or a combination of CBD with THC to manage chronic pain in adults due to a lack of evidence on clinical efficacy, opioid reduction and cost-effectiveness. There is likely to be even less evidence available for children and young people, so recommendation should apply to all ages. There should be no distinction between sexes.
- Investigational medical products (IMP) – products used within an official clinical trial will be prescribed and supplied under a strict process and those providers taking part in the trial will be liable for all NHS costs associated with the trial.
- Individual providers participating in an official clinical trial might wish to follow internal governance process and apply a different prescribing status i.e. RED to IMPs, as shared care would not be supported for IMPs.

CBMP for epilepsy (other than Lennox-Gastaut / Dravet syndrome) – RED

- This would be an off-label or unlicensed use of a high cost product, funding (if approved via IFR) is likely to only be awarded to an individual provider, reimbursement to a primary care budget is not planned, therefore shared care is not anticipated at this time.

Accompanying papers (please list):

1. NICE NG144 Cannabis-based medicinal products 11 November 2019
2. NICE Bites November 2019: No. 123