

Update to the Position Statement Regarding Cannabis Based Products for Medicinal Use (CBPM) in NHS Grampian. Information for Prescribers – Version 2

NHS Grampian will **only** consider requests to use a [CBPM*](#) from a **prescriber on the specialist register of the General Medical Council (GMC)** where a **patient's clinical circumstances meet all of the following criteria** (further details and explanation are provided throughout the document):

- For use in one of the specific medical conditions, as detailed below, where there is robust published evidence of benefit or accepted UK guidelines for use.
- Where there is an unmet clinical need which cannot be met by a licensed medicinal product.
- Where other established treatment options have been exhausted.
- Where any specific condition criteria or national guidance has been met.

N.B. NHS Grampian has an established policy for how it considers requests for unlicensed medicines that would apply to any request – a [link](#) is provided below.

Background

Following a Home Office review regarding the use of cannabis and cannabis-based products for medicinal use (CBPM) the UK government rescheduled certain [CBPMs*](#) through a change in regulations that came into force on 1st November 2018. Subsequently, in December 2019, NHS Grampian released a position statement regarding CBPM in NHS Grampian. This document serves as an update to the original position statement and takes into account guidance that has been released since 2018.

Guidance available

Scottish Government Guidance (2018)

The Scottish Government published [guidance](#) regarding CBPM for clinicians working in Scotland in both the NHS and private practice. This includes detailed information regarding the definition of CBPM, who can prescribe such products, the conditions and terms under which prescribing may be considered, controlled drug monitoring and audit requirements.

The National Institute for Health and Care Excellence (NICE) Guidance (released 2019 and reviewed 2021)

The National Institute for Health and Care Excellence (NICE) published [guidance](#) in November 2019 relating to cannabis-based medicinal products which was subsequently updated in March 2021. The guideline makes recommendations in relation to the use of CBPM in intractable nausea and vomiting, chronic pain, spasticity and severe treatment-resistant epilepsy alongside a detailed rationale for the recommendations.

Scottish Intercollegiate Guidelines Network (SIGN) Guidance (2021)

While there is no specific guidance from the Scottish Intercollegiate Guidelines Network (SIGN) regarding CBPM, in early 2021 they issued a [National Clinical Guideline](#) relating to the investigative procedures and management of epilepsies in children and young people where it makes reference to circumstances in which the use of CBPM would be supported.

British Paediatric Neurology Association (2018)

The British Paediatric Neurology Association has published [guidance](#) regarding the use of CBPM in children and young people with epilepsy.

Prescription of a non-licensed cannabis-based product for medicinal use should be used as a treatment of last resort for children who meet all of the following three criteria;

- Have an epilepsy that has proven intractable to treatment with conventional licensed anti-epileptic drugs given at therapeutic doses
- Have not responded to the ketogenic diet or for whom the diet is inappropriate
- Are not candidates for epilepsy surgery.

Royal College of Physicians (RCP) (2018)

Royal College of Physicians (RCP) has also published [recommendations](#) on CBPM. The RCP does not support the prescribing of CBPM for chronic pain, including chronic neuropathic pain, as there is insufficient robust evidence to support use. The RCP does not recommend the use of CBPM in palliative care or multiple sclerosis treatments.

Definition of Cannabis Based Products for Medicinal Use (CBPM)

The UK government has [defined](#) a cannabis-based product for medicinal use in humans as: “a preparation or other product, other than one to which paragraph 5 of part 1 of Schedule 4 applies, which -

- a) Is or contains cannabis, cannabis resin, cannabidiol or a cannabidiol 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.

Only products **fitting this definition** would be considered for prescribing.

Classification of Cannabis Based Products for Medicinal Use (CBPM)

CBPMs can be classified as naturally occurring or synthetic. Below is a summary of CBPM products currently available:

*Note - CBPMs are the only products affected by the changes detailed in this document.

Naturally Occurring CBPMs	Current Licensed Status	CD Status	Indications	Prescribing Recommendations
*CBPMs e.g. Tilray®, Bedrocan® products	Unlicensed specials	Schedule 2	Specific medical conditions as detailed in this document where there is robust published evidence of benefit or accepted UK guidelines for use.	Specialist doctors on GMC specialist register only
Epidiolex® oral solution	Unlicensed in UK (currently going through licensing process in UK)	Non CD	Lennox-Gastaut Syndrome , Dravet Syndrome	Specialists secondary care
Sativex®	Licensed	Schedule 4	Sativex® is not recommended for use in NHS in Scotland by the Scottish Medicines Consortium (SMC). SMC advice . (If accessed privately via private consultant patients will be required to pay for supplies. This will not be transferred to NHS prescription as not approved by SMC).	

Synthetic CBPMs	Current Licensed Status	CD status	Indications	Prescribing Recommendations
Dronabinol	Unlicensed in UK	Schedule 2	Nausea, vomiting caused by chemotherapy, unresponsive to conventional anti-emetics	Specialists secondary care
Nabilone	Licensed	Schedule 2		

In the UK, currently all naturally occurring CBPM (excluding Sativex®) are unlicensed medicines. As such, CBPM are unlicensed specials and must be obtained only by suppliers who have the appropriate Medicines and Healthcare Products Regulatory Agency (MHRA) licenses and comply to MHRA standards. As unlicensed products, prescribers take on additional responsibility and liability when prescribing, which will apply to CBPMs.

Products **not meeting the definition of CBPM** cannot legally be prescribed – this would include unrefined plant materials or cannabis/hemp oils, e.g. products which can be obtained in health food shops or online. These products do not meet the MHRA standards for good manufacturing practice and good distribution practice and are not for medicinal use. These products **should not** be recommended to patients as the strength, quality and contents cannot be guaranteed.

Medical Conditions

The prescribing of a CBPM is only able to be considered for conditions where there is robust published evidence of benefit or accepted UK guidelines for use. Currently this would **ONLY** include **complex intractable epilepsy** or **chemotherapy induced nausea and vomiting**.

GPs should not refer patients with chronic pain, multiple sclerosis or any other conditions not currently recognised as appropriate, to secondary care for CBPM.

Prescribing

The current regulations only allow individuals on the specialist register of the General Medical Council (GMC) to prescribe CBPM. This limits prescribing to consultants who must only prescribe within their specialty following the local approval processes. Private and NHS consultants would be expected to follow the same regulations and guidance regarding prescribing of CBPMs.

GPs are not allowed to prescribe CBPM and prescribing must not be transferred from secondary to primary care.

Patients who have been receiving or are recommended CBPM via private practice cannot request for care to be transferred to the NHS.

Referral Process

It would only be appropriate for a patient to be referred to secondary care for consideration of CBPM if they met the criteria regarding the medical condition to be treated. Due to the nature of these conditions it is likely these patients will already have specialist secondary care input.

It is not appropriate for GPs to refer patients to secondary care services for consideration of CBPM for medical conditions not referred to in this guideline.

Approval Processes

Where the decision to prescribe a CBPM is taken the [NHS Grampian Staff Guidance for Processing Requests to Prescribe Unlicensed, Off-label or Non-formulary Medicines \(Including Medicines Awaiting Consideration by, Or Not Recommended For Use By, The Scottish Medicines Consortium\)](#) **must** be followed.

Form B must be completed and the decision making process follow the Individual Patient Treatment Request (IPTR) framework. In addition to following with IPTR process, as per government requirements final approval must be given by the NHS Grampian Director of Pharmacy or Medical Director for each individual patient treatment plan.

Only those individuals on the specialist register of the General Medical Council (GMC) to prescribe CBPM should undertake the completion of Form B when the decision to prescribe a CBPM has been taken.

Patient information

NHS Grampian has produced [Cannabis Based Products for Medicinal Use \(CBPM\) in NHS Grampian – Information for Patients/Public](#) which contains some frequently asked questions regarding the prescribing of cannabis and cannabis related products.