# GOOD PRACTICE GUIDE

#### FOR PRESCRIBERS OF CBPMs



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#### ABOUT THE GOOD PRACTICE GUIDE

The prescription of cannabis-based medicinal products (CBPMs) has been legal in the UK since November 2018.

Since then, approximately 40,000 patients have been prescribed these products, and the numbers are continuing to rise.

In the private sector, there are 40 clinics and around 140 prescribers. Unfortunately, the NHS sector has not fully adopted this new medicine, despite its legality.

There are no mandatory training requirements for prescribers, and the Medical Cannabis Clinicians Society (MCCS) has noted significant variations in clinical practice.

The overarching aim of this brief guide to good practice is to help prescribers and patients access this valuable medicine.

These guidelines are specifically designed for clinics that primarily prescribe cannabis, though the foundational principles should be relevant across clinics with a broader medical focus.

Variations in application may occur, but the standards of practice are intended to be universally applicable.

The MCCS hopes that this document on good practices will be embraced by all prescribers and clinics, ensuring that patients are provided with this medicine in a manner that is both safe and supportive.

Such an approach benefits not only the patients but also enhances the overall integrity of the industry.

#### WHO CAN PRESCRIBE?

The law change in November 2018 allowed medical practitioners on the specialist register of the General Medical Council to prescribe cannabis based medicinal products (CBPMs) for any condition.

The decision to prescribe is at the discretion of the specialist, who must consider the best interest of the patient.

Once the specialist has made the initial prescription decision, other prescribers such as General Practitioners, junior doctors, or non-medical independent prescribers (pharmacists or nurses) can continue the prescription as long as the patient is stable on the treatment.[1]

It is important for the specialist to be consulted if there are significant issues with the prescription, dosage or side-effects.

Clinics should have a written policy on when the initiating specialist needs to be consulted again.

Prescribers need to be aware of the GMC guidance on prescribing[2] and it should be noted that they should only prescribe within their area of competence.

Prescribers should also be aware of the MHRA guidance on prescribing unlicensed medication[3].

#### PEER APPROVAL PROCESS

The Chief Medical Officers expect both NHS and non-NHS prescribers to make their decisions on prescriptions based on a multidisciplinary team discussion[4].

The composition of such a team is not specified, but most clinics require their prescribers to meet weekly or more often to discuss the prescribing suggestions prior to issue of the prescription.

It is advisable for the team to consist of fellow clinicians with experience in prescribing CBPMs, preferably including at least one from the same discipline.

This latter point has been emphasised in the circular issued by the Welsh government[5].

We believe that this process is essential for all new prescriptions and must be properly documented.

Follow-up prescriptions for stable patients who do not require dose or product changes may not need to be reviewed.

However, any significant changes in dose or product or emergence of troublesome side-effects would require a further documented team review.

<sup>[1]</sup> NHS England » Cannabis-based products for medicinal use (CBPMs)
[2] Keeping up to date and prescribing safely - professional standards - GMC (gmc-uk.org)
[3] Off-label or unlicensed use of medicines: prescribers' responsibilities - GOV.UK (www.gov.uk)
[4] NHS England » Cannabis-based products for medicinal use (CBPMs)
[5] the-rescheduling-of-cannabis-for-medicinal-purposes.pdf (gov.wales)

#### INITIAL CONSULTATION

Clinics should request and review at least the GP Summary Care Record (SCR) and preferably any hospital records prior to seeing the patient.

The initial consultation must be thorough and address at least the following issues based on the Australia guidelines[6] document

1. Presenting symptoms and underlying diagnosis.

- 2. Past medical history, particularly cardiovascular disease, liver disease, and renal disease.
- 3. Medication review, including treatments that have been tried and have failed, the length of time the treatments were trailed, and the reasons for ceasing.

4. Mental health history, especially a history of mental illness such as psychosis/schizophrenia.

5. Family health history, including mental health, particularly a family history of

psychosis/schizophrenia. 6. "At risk" behaviours associated with drug dependence and substance abuse disorder. While previous cannabis use may not be a contraindication, care should be taken to manage the risk of dependence.

7. Social history, including social and family support for the use of a medicinal cannabis product. Consideration should be given to family responsibilities such as caring for young children, child safety, employment (especially where it involves driving or operating machinery), "at risk" living conditions, and the risk of falls in older patients.

8. Physical examination/investigations as appropriate.

9. Consideration of any contraindications. (see contraindication section below)

We believe that sufficient time must be allocated during the appointment to allow such discussion and it must be properly documented.

#### TWO LICENSED MEDICINES?

The regulations do not stipulate that two licensed medications must have been tried before prescribing a CBPM.

However, the MCCS consider it reasonable for the patient to try licensed medicines or licensed medicines "offlabel" before the specialist considers prescribing a CBPM.

Currently, CBPMs are not considered first line medicines. Questions arise when the patient has tried alternative therapies but not necessarily a licensed medicine.

Common examples include over-thecounter analgesics or non-steroidal anti-inflammatory medicines for pain or valid alternatives such as acupuncture or physiotherapy for pain, or CBT or relaxation techniques for anxiety.

The MCCS feel that prescribers must make a judgement on this issue and prescribe if they believe it is in the Best Interest of the patient.

#### PUBLISHED GUIDELINES

Prescribers should familiarise themselves with the following published guidelines, regardless of the stance of the document on medicinal cannabis.

1. Recommendations and Guidance on Medical Cannabis under Prescription with the All-Party Parliamentary Group for Medical Cannabis under Prescription
The Medical Cannabis Clinicians Society, 2020

The Guidance, revised in 2021, includes information about who can prescribe medical cannabis, prescribing and prescriptions, conditions, funding and more.

### 2. <u>Cannabis-based medicinal products</u> <u>- guideline [NG144]</u>, <u>updated October</u> 2021

NICE, November 2019

This guideline covers prescribing of cannabis-based medicinal products for people with intractable nausea and vomiting, chronic pain, spasticity and severe treatment-resistant epilepsy. The update guidance (October 2021) is important with regard to a loosening of recommendations about paediatric epilepsy prescribing. Overall, the guidelines are not supportive mainly because of their focus on double-blind placebo-controlled trials and ignoring real-world evidence and foreign language publications.

#### **3.** Recommendations on cannabisbased products for medicinal use Royal College of Physicians, October 2018

The RCP has jointly produced recommendations on cannabis-based products for medicinal use (CBPM) with the Royal College of Radiologists (RCR) and in liaison with the Faculty of Pain Medicine of the Royal College of Anaesthetists. The guidelines are unhelpful and do not recommend prescribing for pain, contrary to overwhelming evidence to the contrary.

## 4. <u>Guidance on the use of cannabis-based products for medicinal use in children and young people with epilepsy</u>

British Paediatric Neurology Association, 2018

The BPNA highlights the key questions specialist clinicians should address before considering prescribing and also provide guidance on appropriate dosage and treatment regimes. However, these guidelines are extraordinary in their bias against medicinal cannabis and are deeply unhelpful.

# 5. The supply of unlicensed medicinal products 'specials', guidance note 14 Medicines and Healthcare products Regulatory Agency, 2014 with recent updates

Guidance on manufacturing, importing, distributing and supplying specially manufactured or ordered products, including cannabis-based products for medicinal use in humans (CBPMs), known as 'specials'.

#### 6. <u>Cannabis-based medicinal products</u> PS05/19

The Royal College of Psychiatrists, November 2019

Guidance from other countries is also useful.

- Australia <u>Guidance for the use of medicinal cannabis in Australia:</u>
   Overview | Therapeutic Goods Administration (TGA)
- Canada <u>Canada's 7lower-risk</u> <u>cannabis use guidelines - Canada.ca</u>
- And others, especially in individual US States

#### CONTRAINDICATIONS TO PRESCRIBING

A personal history of psychosis or schizophrenia is the main contraindication to prescribing a THC-containing CBPM.

The MCCS does not consider that such diagnosis should lead to a life-long contraindication.

Careful and cautious re-evaluation at a future time could make such an individual a candidate for therapy.

It is worth noting that CBD is antipsychotic and safe to prescribe.[7]

Other relative contraindications include:

- A history of hypersensitivity to cannabis products (albeit rare)
- Severe or unstable cardiopulmonary disease or recent history of myocardial infarction or stroke
- Cardiac dysrhythmia, especially if may be adversely affected by tachycardia

- Hepatitis C
- Previous or current mental health condition other than psychosis, such as mania
- Pregnancy or breastfeeding
- Younger patients, less than 21 years. Not a contraindication but caution is required with, for example, THC strength and dosing.
- Severe liver disease
- Severe renal disease
- Individuals with concomitant medication with known interactions with cannabis. Most other medications do not have an adverse interaction with cannabis but caution needs to be exercised with some medications including, but not limited to,: warfarin, theophylline, chlorpromazine, tacrolimus, buprenorphine, clobazam and sodium valproate.
- History of cannabis dependency syndrome

#### MAIN INDICATIONS

In the UK there are no indications that are illegal, but prescription must always be in the best Interest of the individual.

The most prescribed indications and those with supportive evidence are:

- Chronic pain
- Anxiety and related conditions, such as PTSD
- Epilepsy
- Other longer term neurological conditions, including Tourette's, dystonia, Parkinson's disease, multiple sclerosis and conditions with marked spasticity
- Symptoms associated with chronic concussion

- Inflammatory bowel disease
- Life threatening cancer (as quality-oflife treatment)
- Sleep disorders

A prescriber should stay updated with the latest literature on the evidence base for cannabis.

The MCCS has an evidence base available to members and Maple Tree Consultants is producing a series of booklets on the evidence base for different conditions in 2024 (mapletreeconsultants.co.uk)

#### WHAT CAN BE PRESCRIBED

The law defines a CBPM and the requirements can be seen here - Rescheduling of cannabis-based products for medicinal use in humans (accessible version) (www.gov.uk).

Essentially, prescribers can be reassured that products on a clinic formulary or available through an independent pharmacy specialising in cannabis will meet the defined requirements.

The MHRA will have verified that the product has been produced in compliance with EU GMP regulations and meets the necessary safety and purity criteria, before the issue of an import license by the Home Office.

UK growers are likewise inspected against stringent criteria.

Prescribers should review and understand the Certificate of Analysis that should accompany the product.

This will allow them to examine the cannabinoid and, preferably, terpene composition.

The product "strain name" or cultivar should not be relied upon to predict the final composition.

Although genetics provide a guide, the ultimate cannabinoid and terpene profile will be influenced by factors such as grow conditions, induction of flowering and time of harvest.

#### APPROPRIATE TERMINOLOGY

The MCCS recommend that producers avoid using "recreational" names such as Girl Scout Cookies, Gorilla Glue, etc as they do not convey useful information about the medical value of the plant.

The MHRA have now issued guidance on product names and agree with this stance:

"There are rules and conventions in naming medicinal products. CBPMs are medicinal products, and as such are bound by these rules.

We haven't enforced them extensively since we rely on the common sense of importers and manufacturers to identify that names such as Atomic Sour Grapefruit or Pink Monkey .... are not appropriate names for the very serious matter that are human medicines.

Given we are receiving more and more exotic names that can pose a real risk to patients, and also be bordering on undue advertising, a more strict enforcement is taking place of what should really be common sense"

The MCCS also feels that clinicians should refrain from relying on the terms "sativa" and "indica" as the distinction is only a general classification and not a clinical distinction that can be relied upon.

This practice should be abandoned. (7)

#### OVERALL PRESCRIBING PLAN

Cannabis medicine is highly personalised and dosage can vary depending on the indication and individual factors.

It is not appropriate to dictate strict guidelines but some basic principles can be applied.

The key is "start low and go slow" to minimise potential side effects and accommodate diverse dosing needs. Many experts suggest starting with a high CBD / low THC full spectrum oil product, especially in cannabis naïve individuals.

The same basic principles can be applied to cannabis experienced users, but the escalation period may be quicker and / or the dosage increments larger.

The MCCS is producing guidelines on the dosing of oils and the reader is referred to those guidelines for more detail.

Once stability is achieved with oil, a vaping option using flower could be considered to help manage breakthrough pain or for sudden pain attacks such as trigeminal neuralgia, cluster headaches or migraine aura to prevent an attack.

The MCCS acknowledges that some patients, particularly those with experience, prefer flower over oil and many clinicians start with a flower prescription.

In such cases, it is recommended to carefully document the reason for this preference.

#### **OUTCOME MEASURES**

We advise clinicians to outline clearly the treatment goals and the methods to monitor progress towards those goals.

Outcome measures can be as simple as a visual analogue scale for pain or a simple count of seizures, but it is good practice to include an objective outcome measure.

#### FLOWER PRESCRIBING GUIDELINES

Flower is primarily used for managing breakthrough pain or acute pain episodes, such as trigeminal neuralgia or acute panic attacks.

However, some experienced patients prefer the immediate effect of vaping flower several times a day over the longer-term effect of oil.

While this preference may be reasonable, it is important to thoroughly document the reasons behind it.

On average, most individuals are suited to around 1g of flower per day, but approximately 10% may require up to 2g of flower daily.

A very small minority of patients may require even higher amounts, especially for severe pain. This can be a sensitive issue, as some experienced patients may request a high daily volume of flower, not solely for medical reasons.

Prescribing cannabis should always be a collaborative discussion between the patient and the clinician.

However, the clinician ultimately bears the responsibility for the prescription and must feel justified and comfortable with the prescribed dosage.

Pressure from the patient to exceed appropriate dosages should be resisted.

The GMC provide clear guidance on the doctor-patient partnership and the principles on which good clinical decisions should be based.[8]

In the case of flower, the MCCS recommend that a prescription of over 2g daily should always be subject to approval by a peer panel.

There is a tendency for some patients to request a flower with a high THC content, even up to 30%.

However, flowers with very high THC flowers will naturally have fewer minor cannabinoids and terpenes, potentially reducing their medical value.

Research in this area is currently limited.

We recommend that a prescription drug over 22% THC by weight should be approved by peers before being prescribed.

High THC doses should not be prescribed initially, but increased over time, if indicated, with careful documentation of the effects.

#### **PRESCRIPTION**

Prescriptions in the private sector for controlled drugs need to written on the "pink pad" – FP10PCD.

The proscribed format for controlled prescriptions (with, for example, numbers written in figures and words) must be followed.[9]

Pharmacies cannot dispense medication without a valid prescription.

Since cannabis products are often out of stock, it is good practice to confirm with the pharmacy that a prescribed product is available.

Additionally, prescriptions should be sent electronically so that the pharmacy can reserve the stock while awaiting the physical prescription.

#### SCRIPT DIRECTION

Once a prescription is written, the patient has a right for it to be dispensed at any pharmacy.

Many clinics have linked pharmacies but it should not be mandatory for the prescription to be sent to a specific pharmacy.

Also, clinicians should not be restricted to prescribing from a linked pharmacy's formulary. They should have the freedom to prescribe any suitable product available from any formulary deemed appropriate for the patient.

Directing patients to a specific pharmacy is unethical and should be reported to the clinic and the General Pharmaceutical Council.

Additionally, pharmacies that charge other pharmacies a premium for providing a particular product should be reported as well.

#### FOLLOW-UP CONSULTATIONS

Follow-up consultations can be conducted by medical practitioners and pharmacy and nursing prescribers with appropriate qualifications.

If there are any concerns during follow-up, especially regarding major dose adjustments, product changes, or troublesome side effects, the initiating specialist prescriber should be consulted.

It is advisable for all clinics to have a written policy on when the initiating consultant needs to be consulted again. If a patient is stable and only requires a repeat prescription, a face-to-face consultation may not be necessary.

However, it is good practice to review the patient face-to-face at least every four months for the first 12 months, regardless of prescription stability.

After the first 12 months, face-to-face consultations could be at the discretion of the prescriber, as long as the patient remains stable.

#### **TRAINING**

Cannabis medicine is quite distinct from other medical fields.

Any prescriber should have completed a training programme and obtained certification before beginning to prescribe.

The MCCS offers a monthly 3-hour training programme.

It is also essential to have mentoring in the initial months of prescribing, which is likely to be provided through the multi-disciplinary prescription review process.[10]

#### THE MEDICAL CANNABIS CLINICIANS SOCIETY

#### INDEPENDENT, EXPERT SUPPORT FOR CLINICIANS

The Medical Cannabis Clinicians Society is an independent community of medical cannabis pioneers – the first prescribers of this treatment in the UK.

We believe that every patient who could benefit from medical cannabis should have access to it.

We provide the medical and scientific community interested in supporting patients with medical cannabis with high-quality training and expert support.

Membership is open to those with a professional interest in medical cannabis, including clinicians, nurses, GPs, allied health professionals (AHPs), medical students, healthcare scientists, pharmacists and those working across acute, primary and community healthcare.

As part of the UK's leading group of medical cannabis experts, members have access to information to inform treatment decisions, up-to-date product guidance and support to ensure clinicians can become as confident in prescribing medical cannabis as they are with first line treatments.

With the most respected medical cannabis clinicians in the country providing support, members are better able to help their patients.

Annual membership is £99 for consultants, GPs and others and £49 for nurses and AHPs. Membership is free for medical students and we welcome international members.

Join online at www.ukmccs.org.

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