CLINICAL AUDIT

Treatment planning for **patients prescribed medicinal cannabis**

Valid to January 2027

bpac nz
better medicine

Audit focus

This audit assists healthcare professionals who have prescribed medicinal cannabis products in identifying whether an appropriate treatment plan was established. Planning is essential to assess the effectiveness and safety of medicinal cannabis for all patients.

Background

Recent regulatory changes will make medicinal cannabis products more readily accessible in primary care. As such, there is a growing need for information on their use, effectiveness and safety in clinical practice. A range of potential indications have been proposed for medicinal cannabis, but the currently available pool of peer-reviewed clinical trials in humans is limited, and the quality of evidence is not considered strong. Examples of conditions where there is some evidence of efficacy include chronic neuropathic or malignant pain, chemotherapy-related nausea and vomiting, refractory spasticity associated with multiple sclerosis, and seizures due to epilepsy. However, medicinal cannabis is not first-line for any of these indications; it should typically only be considered if (1) patients experience ongoing symptoms despite optimal dosing of available evidence-based treatments, or (2) conventional treatments are contraindicated or not tolerated.

Legislative changes now mean that medicinal cannabis products can be prescribed by registered medical practitioners (i.e. doctors) via two main pathways: (1) products that are Medsafe approved, and (2) products that are verified by the Medicinal Cannabis Agency as meeting the minimum quality standard. Unapproved products that are verified as meeting minimum quality standards can be prescribed to any patient by a medical practitioner under Section 25 of the Medicines Act 1981, and directly supplied to the patient by the prescribing medical practitioner, or via a pharmacist/supplier under Section 29 of the Medicines Act. However, this "Agency verification" is not equivalent to "Medsafe approval". Instead, the verification standard recognises a product is manufactured according to strict good manufacturing practices and meets the minimum standards of quality, e.g. there is a reduced risk of contamination being present, products contain correct ingredients consistently at the stated concentration, products remain stable throughout their shelf-life. As such, medical practitioners have an important responsibility to ensure that any unapproved products being prescribed are both effective and safe for their patient, and they must take responsibility for any clinical outcome(s).

For an up to date list of available medicinal cannabis products, see: **www.health.govt.nz/our-work/regulation-health-and-disability-system/medicinal-cannabis-agency/medicinal-cannabis-agency-information-health-professionals/medicinal-cannabis-products-meet-minimum-quality-standard**

For further information on medicinal cannabis and how it should be prescribed, see: "An overview of medicinal cannabis for health practitioners", available from: **bpac.org.nz/2022/medicinal-cannabis.aspx**

Criteria for a medicinal cannabis treatment plan

Before a medicinal cannabis product is prescribed, a range of factors should already have been considered when assessing the suitability of treatment. This includes whether the indication is appropriate, that other evidence-based treatments have been trialled first, as well other patient-specific factors that might make treatment unsuitable, e.g. unstable cardiovascular or cardiopulmonary disease, pregnancy, a history of psychiatric disorders, personal circumstances.

If a decision is ultimately made to trial medicinal cannabis, a recommended approach for assessing whether the product improves the patient's symptoms and is tolerated is to establish a treatment plan, which details:

- **Treatment objectives** – the specific symptom(s) being treated and how any improvement(s) will be assessed. This may be a metric improvement in a pain score or symptom algorithm (e.g. 30%), or an objectively measured goal such as being able to perform a daily task that they were previously unable to.
- **Timeframe** – for most patients, an initial one-month trial period is likely suitable to establish any potential benefit and adverse effects. Use of the medicinal cannabis product should stop if the desired effect is not obtained after 4 – 12 weeks.
- **Dosing** – a good rule-of-thumb is "start low, go slow". The exact starting dose and titration schedule depends on the particular product, the balance of tetrahydrocannabinol (THC):cannabidiol (CBD) content, and patient specific characteristics. Patients taking a medicinal cannabis product for the first time without a history of previous cannabis use should start with a very low dose and cease use if they experience adverse effects. Increasing the dose weekly is a pragmatic strategy unless the manufacturer instructions or Medicine datasheet (if it is an approved product, e.g. Sativex) specify otherwise. Dosing in the

evening may be preferable for formulations with higher THC content. More specific guidance on dosing is available in the international literature, however, caution should be taken when applying these recommendations in clinical practice.

- ☐ **Risk management strategies** – safeguards should be established. For example, if there are concerns over the potential for misuse, then dispensing frequency restrictions should be considered, and the prescriber should remain vigilant for drug seeking behaviours, e.g. early requests for repeat prescriptions, claims of lost prescriptions or requests for dose increases.
- ☐ **Monitoring** – clinical review should occur more frequently at first and then less frequently if the product is tolerated and stable dosing is established (based on clinical judgement). At each review, consider whether any functional and quality of life improvements outweigh reported adverse effects, and if the patient is exhibiting undesirable behavioural or cognitive changes. There are no specific blood testing requirements. However, baseline liver function tests should usually be performed.
- ☐ **Discontinuation plan** – outline a strategy for discontinuing use if the treatment objectives are not met, e.g. a dose reduction schedule or immediate treatment cessation.

Audit plan

Summary

This audit identifies whether a treatment plan was established for any patient prescribed a medicinal cannabis product under the current regulatory framework, and helps health practitioners decide whether further review is required.

Recommended audit standards

Ideally, all patients who have been prescribed a medicinal cannabis product should have a treatment plan documented in their notes. This may not be achieved on the first cycle of the audit but should be the aim for the second cycle.

Audit Data

Eligible people

Any patient that has been prescribed a medicinal cannabis product since 1 April 2020* is eligible for this audit.

* This was the date that the Medicinal Cannabis Scheme came into effect, and therefore should encompass all patients prescribed a medicinal cannabis product under the new regulatory criteria.

Identifying patients

You will need to have a system in place that allows you to identify eligible patients who have been prescribed a medicinal cannabis product and audit their clinical notes. Many practices will be able to identify patients by running a "query" through their PMS system.

Sample size

For the purposes of this audit, all eligible patients should be included.

Criteria for a positive result

You will need to access and review the patients' clinical notes to complete this audit. For a positive result, there should be documentation of:

- The indication the medicinal cannabis product was prescribed for and the specific treatment objective(s) that were agreed upon
- Whether specific dosing instructions were included on the prescription, i.e. rather than stating to "take as needed"
- A discussion about a specific length of time that the product would be trialled before review, and whether they had a follow up within 4 – 12 weeks or if one is scheduled
- A discussion of how and when to stop the product if it is not improving symptoms or is not tolerable

Any patient whose notes do not contain the information described above should be flagged for review. Aim for a higher number of positive results in Cycle 2.

Data analysis

Use the sheet provided to record your data. A positive result is any patient taking a medicinal cannabis product who has evidence in their clinical notes of a comprehensive treatment plan, as demonstrated by a "YES" in column E (which encompasses the criteria detailed in columns A – D). The percentage achievement can be calculated by dividing the number of patients with a positive result by the total number of patients audited.

Identifying opportunities for Audit of Medical Practice

The first step to improving medical practice is to identify the criteria where gaps exist between expected and actual performance and then to decide how to change practice. Once a set of priorities for change have been decided on, an action plan should be developed to implement any changes.

Taking action

It may be useful to consider the following points when developing a plan for action (RNZCGP 2002).

Problem solving process

- What is the problem or underlying problem(s)?
- Change it to an aim
- What are the solutions or options?
- What are the barriers?
- How can you overcome them?

Overcoming barriers to promote change

- Identifying barriers can provide a basis for change
- What is achievable – find out what the external pressures on the practice are and discuss ways of dealing with them in the practice setting
- Identify the barriers
- Develop a priority list
- Choose one or two achievable goals

Effective interventions

- No single strategy or intervention is more effective than another, and sometimes a variety of methods are needed to bring about lasting change
- Interventions should be directed at existing barriers or problems, knowledge, skills and attitudes, as well as performance and behaviour

Review

Monitoring change and progress

It is important to review the action plan develop previously against the timeline at regular intervals. It may be helpful to review the following questions:

- Is the process working?
- Are the goals for improvement being achieved?
- Are the goals still appropriate?
- Do you need to develop new tools to achieve the goals you have set?

Following the completion of the first cycle, it is recommended that the doctor completes the first part of the Audit of Medical Practice summary sheet (Appendix 1).

Undertaking a second cycle

In addition to regular reviews of progress with the practice team, a second audit cycle should be completed in order to quantify progress on closing the gaps in performance.

It is recommended that the second cycle be completed within 12 months of completing the first cycle. The second cycle should begin at the data collection stage. Following the completion of the second cycle it is recommended that practices complete the remainder of the Audit of Medical Practice summary sheet.

The Royal New Zealand College of General Practitioners

Claiming credits for Continuing Professional Development (CPD)

This audit has been endorsed by The Royal New Zealand College of General Practitioners (RNZCGP) and has been approved for 10 CME credits for a first cycle and 10 CME credits for a second cycle for Continuing Professional Development (CPD) purposes. The second cycle is optional and only two cycles are permissible.

To claim points go to the RNZCGP website: **www.rnzcgp.org.nz**

Record your completion of the audit on the CPD Online Dashboard, under the Audit of Medical Practice section. From the drop down menu select "Approved practice/PHO audit" and record the audit name.

General practitioners are encouraged to discuss the outcomes of the audit with their peer group or practice.

As the RNZCGP frequently audit claims you should retain the following documentation, in order to provide adequate evidence of participation in this audit:

1. A summary of the data collected
2. An Audit of Medical Practice (CQI) Activity summary sheet (included as Appendix 1).

Data sheet – cycle 1

Treatment planning for patients prescribed medicinal cannabis

Patient prescribed a medicinal cannabis product	A	B	C	D	E	F
	Indication and treatment objectives documented	Specific dosing instructions provided on prescription	Timeframe for review agreed and follow-up undertaken (or scheduled)	Discontinuation plan documented	Tick in all four columns? Yes/No	If no, flagged for review
1						
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Audit outcome: Patients with "YES" in column E divided by the total number of patients audited:

Please retain this sheet for your records to provide evidence of participation in this audit.

Data sheet – cycle 2

Treatment planning for patients prescribed medicinal cannabis

Patient prescribed a medicinal cannabis product	A	B	C	D	E	F
	Indication and treatment objectives documented	Specific dosing instructions provided on prescription	Timeframe for review agreed and follow-up undertaken (or scheduled)	Discontinuation plan documented	Tick in all four columns? Yes/No	If no, flagged for review
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Audit outcome: Patients with "YES" in column E divided by the total number of patients audited:

Please retain this sheet for your records to provide evidence of participation in this audit.

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Te Whare Tohu Rata o Aotearoa

APPENDIX 1

SUMMARY SHEET
Audit of medical practice (CQI activity)

Topic:
Treatment planning for patients prescribed medicinal cannabis

Date:

Activity designed by (name of organisation, if relevant):
Bpac^{nz}

Doctor's name:

Results discussed with peer group or colleagues?
☐ Yes ☐ No

Date:

FIRST CYCLE

DATA: Date of data collection:

CHECK: Describe any areas targeted for improvement as a result of analysing the data collected. (If the findings have any implications for health equity, please include this.)

ACTION: Describe how these improvements will be implemented.

MONITOR: Describe how well the process is working. When will you undertake a second cycle?

AUGUST 2016

SECOND CYCLE

DATA: Date of data collection:

CHECK: Describe any areas targeted for improvement as a result of analysing the data collected. (If the findings have any implications for health equity, please include this.)

ACTION: Describe how these improvements will be implemented.

MONITOR: Describe how well the process is working.

COMMENTS:

AUGUST 2016