



Medicinal cannabis: process for prescribers

If a patient has a health condition where symptoms are refractory to standard approved treatments, for example:

- ▶ chronic non-cancer pain
- ▶ epilepsy in children and young adults
- ▶ multiple sclerosis (MS)
- ▶ nausea and vomiting due to chemotherapy
- ▶ palliative care

Visit www.tga.gov.au/medicinal-cannabis-guidance-documents for clinical guidance documents on each of these conditions or download evidence summaries from www.nps.org.au/medicinal-cannabis

1. Assess for each patient:

- ▶ diagnosis for which medicinal cannabis is being considered
- ▶ symptoms refractory to current treatment
- ▶ management review – current and previously trialled treatments and reasons for ceasing them
- ▶ medical history – cardiovascular disease, liver/renal disease
- ▶ mental health – current or past mental illness, family history of schizophrenia, risk factors for substance use disorder, previous or current alcohol dependence, illicit drug use
- ▶ social history – family/social support, childcare responsibilities, employment, occupational responsibilities eg, driving, operating machinery, safety issues
- ▶ physical examination as appropriate
- ▶ ideas, concerns and expectations of treatment.

2. Before prescribing consider:

- ▶ Have I reviewed the evidence for medicinal cannabis use in the context of the patient's condition?
- ▶ Is medicinal cannabis appropriate for this patient?
- ▶ Is there the potential for drug-drug interactions?
- ▶ Will there be a need for increased therapeutic monitoring (eg, LFTs, and antiepileptic drug levels)?
- ▶ Do I have the relevant expertise to prescribe medicinal cannabis or do I need to access further educational resources?
- ▶ If my patient is in a shared care arrangement, have I discussed these considerations with the wider team?
- ▶ Do I have the product information I need?

Note that no products other than nabiximols (Sativex) have TGA approved product information.

3. Application process

- ▶ Once a decision has been made to prescribe, apply for access via steps 3a or 3b
- ▶ Consider patient's eligibility for a clinical trial – step 4

3a. TGA Special Access Scheme (SAS)

- ▶ Lodge SAS applications to Australian and state/territory health departments via the online SAS system (SAS B application submitted via the online SAS system is the preferred application pathway)
- ▶ In Tasmania, separate approval must be sought from Tasmanian Department of Health and Human Services
- ▶ See next page for SAS categories and links to the online SAS system

3b. Authorised Prescriber Scheme

Medical practitioners can apply to become an Authorised Prescriber (AP) of a specified unapproved medicinal cannabis product to specific patients (or classes of recipients) with a particular medical condition or symptom

- ▶ See next page for links to the TGA Authorised Prescriber Scheme

4. Is my patient eligible and willing to participate in a clinical trial?

- ▶ To find out about current and upcoming trials, visit the Australian New Zealand Clinical Trials Registry (ANZCTR)
- ▶ Visit: www.anzctr.org.au

Need assistance?

- ▶ Call: 1800 220 007 (or 02 6232 8866)
- ▶ Email: medicinal.cannabis@health.gov.au
- ▶ Visit: <https://www.tga.gov.au/access-medicinal-cannabis-products-1>

More information

- ▶ NSW Cannabis Medicines Advisory Service
- ▶ Visit: <https://www.health.nsw.gov.au/pharmaceutical/Pages/nsw-cmas.aspx>
- ▶ Call: 02 4923 6200

Medicinal cannabis: information for prescribers

Key resources for GPs and other prescribers – clinical guidance documents

The Therapeutic Goods Administration (TGA) has a series of clinical guidance documents for prescribers of medicinal cannabis for treating chemotherapy-induced nausea and vomiting, epilepsy, multiple sclerosis, chronic non-cancer pain as well as an overview document and patient information. These guidance documents provide a summary of evidence and clinical management. Note that prescribing medicinal cannabis products should always be considered on a case-by-case basis.

► Visit: <https://www.tga.gov.au/medicinal-cannabis-guidance-documents>

Special Access Scheme (SAS) categories:

SAS category A (SAS A)

Notification pathway for patients with life-limiting illness from which death is likely to occur within a matter of months, or from which premature death is likely to occur in the absence of early treatment.

Medicinal cannabis products supplied through SAS A must be imported by the medical practitioner on a patient-by-patient basis. Australian held stock can be accessed through SAS B applications, and consequently patient access is generally much faster through SAS B than SAS A.

SAS category B (SAS B)

Application pathway for patient who does not fit SAS A criteria. Note that SAS B or the online SAS system is the recommended application pathway.

More information can be found by visiting:

► www.tga.gov.au/form/special-access-scheme

Online SAS system: (this is the preferred application pathway)

► www.tga.gov.au/special-access-scheme-online-system

Note that in Tasmania, separate approval must be sought from Tasmanian DHHS

Medicinal cannabis manufacturers and suppliers:

Visit the Office of Drug Control website for a list of manufacturers and suppliers of medicinal cannabis products:

► www.odc.gov.au/manufacturers-and-suppliers-medicinal-cannabis-products

Authorised Prescriber (AP) Scheme:

To become an Authorised Prescriber, a medical practitioner must first obtain approval from a human research ethics committee (HREC) or endorsement from a specialist college.

Authorised Prescribers may need state/territory authorisation depending on the practitioner, type of product and the state/territory legislation.

► www.tga.gov.au/authorised-prescriber-scheme

Contact information on your state or territory's regulatory requirements:

► www.tga.gov.au/access-medicinal-cannabis-products-using-access-schemes

Prescribing guidance

The NSW Cannabis Medicines Prescribing Guidance can assist medical practitioners in their prescribing and management of cannabis medicines (for NSW patients within current regulatory frameworks and clinical practice).

► Australian Centre for Cannabinoid Clinical and Research Excellence (ACRE)

<https://www.australiancannabinoidresearch.com.au/resources>

Need assistance?

Therapeutic Goods Administration (TGA)
Special Access Scheme – Medicinal Cannabis:

Call: 1800 220 007 (or 02 6232 8866)

Email: medicinal.cannabis@health.gov.au

► <https://www.tga.gov.au/access-medicinal-cannabis-products-1>

More information

NSW Cannabis Medicines Advisory Service
for NSW registered health professionals

► <https://www.health.nsw.gov.au/pharmaceutical/Pages/nsw-cmas.aspx>

Call: 02 4923 6200

Email: HNELHD-CMAS@health.nsw.gov.au

Consumer information

Download FAQs and a consumer information sheet; *Is medicinal cannabis suitable for me?*

► www.nps.org.au/medicinal-cannabis

nps.org.au/medicinal-cannabis

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