Government of **Western Australia**
Department of **Health**

Monitored Medicines Prescribing Code

Medicines and Poisons Regulations 2016

December 2024

health.wa.gov.au

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Foreword

Legislative authority

This Code is issued under provisions of the *Medicines and Poisons Act 2014* and the Medicines and Poisons Regulations 2016.

Approval

This document is approved for publication by the Director General of the Department of Health.

Version

This document is MP00002.1, approved on 05 December 2024

Definitions and Terms Used

Definitions and terms used in this document are drawn from the *Medicines and Poisons Act 2014* and Medicines and Poisons Regulations 2016.

Contacts

All queries relating to this Code should be directed to Medicines and Poisons Regulation Branch, Public and Aboriginal Health Division, Department of Health via one of the following modalities:

Postal address: PO Box 8172, Perth Business Centre, WA 6849
Contact number: 08 9222 6883
E-mail address: MPRB@health.wa.gov.au

Further information and resources are available via the Medicines and Poisons Regulation Branch webpage: www.health.wa.gov.au/Articles/J_M/Medicines-and-Poisons-Regulation-Branch

Queries relating to prescribing Schedule 8 medicines for individual patients should be directed to the **Schedule 8 Prescriber Information Service** on 08 9222 4424.

Document control

Version	Date	Reason for modification
MP00001	23.01.2017	Original approved for publication.
MP00001.1	16.03.2017	Inclusion of prescribing for end-of-life care and terminal illness.
MP00001.2	10.08.2017	Parts 2 and 4 updates.
MP00001.3	25.09.2018	Part 3, 4 and 5 updates.
MP00001.4	13.12.2023	Addition of reference to ScriptCheckWA as a resource. Inclusion of esketamine, MDMA and psilocybine. Changes to prescribing for end-of-life care and terminal illness. Inclusion of specialists providing care via telehealth in part 4. Update to parts 3 and 5 to reflect changes in approvals and references.
MP00002.0	11.11.2024	The implementation of ScriptCheckWA in 2023, provided an opportunity to reduce the regulatory burden for prescribers, without compromising the patient and public safety. Restructure and reformatting to improve clarity and user-friendliness. Inclusion of Schedule 4 Monitored Medicines, changes to stimulant prescribing and cannabis prescribing in line with regulation changes. Review of requirements for other opioids.
MP00002.1	05.12.2024	Clarification of stimulant prescribers. Inclusion of reviewing ScriptCheckWA as a component of a risk management plan for Schedule 4 Monitored Medicines.

Terms used in the Code

Term	Definition/full term
AHPRA	Australian Health Practitioner Regulation Agency
ARTG	Australian Register of Therapeutic Goods
CAS	Community Program for Opioid Pharmacotherapy (CPOP) Advisory support; provides advice on clinical management of CPOP patients
CEO	The Chief Executive Officer of the Department of Health, Western Australia
CPOP	Community Program for Opioid Pharmacotherapy
CPOP Clinical Policies and Procedures	The *Clinical Policies and Procedures for the Use of Methadone and Buprenorphine in the Treatment of Opioid Dependence*[1] and *Clinical Guidelines for use of depot buprenorphine (Buvidal and Sublocade) in the treatment of opioid dependence (CPOP Clinical Policies and Procedures)*[2]
CPP	Community Pharmacotherapy Program
The Department	The Department of Health, Western Australia
Drug Dependent	"a person who has acquired, as a result of repeated administration of drugs of addiction or Schedule 9 poisons, an overpowering desire for the continued administration of a drug of addiction or a Schedule 9 poison"[1]
Drug of addiction	"(a) a Schedule 8 poison; or (b) a Schedule 4 reportable poison"[3]
HREC	Human Research Ethics Committee
MDMA	N, α -dimethyl-3,4-(methylenedioxy) phenylethylamine
Monitored Medicine	Drug of addiction as defined above.
Oversupplied	"a person who has over a period of time obtained, or obtained prescriptions for, quantities of drugs of addiction that are greater than is reasonably necessary for therapeutic use"[1]
OST	Opioid Substitution Therapy. Treatment with specific long-acting opioids (methadone and buprenorphine) as a replacement for heroin and other opioids.
PTSD	Post-traumatic Stress Disorder
RACGP	Royal Australian College of General Practitioners
RACP	Royal Australasian College of Physicians
RANZCP	Royal Australian and New Zealand College of Psychiatrists
SAS	Special Access Scheme
S4 (Schedule 4) Monitored Medicine	S4 Reportable Poisons. These are substances in Schedule 4 of The Poisons Standard, which are considered to have a higher risk of abuse, misuse and physical or psychological dependence. These are listed in Schedule 6 of the Medicines and Poisons Regulations 2016 as defined by Regulation 7A[4]
S8 (Schedule 8) medicine	S8 Poisons. These are "substances which should be available for use but require restriction of manufacture, supply, distribution, possession and use to reduce abuse, misuse and physical or psychological dependence"[3]

[1] Community Pharmacotherapy Program. Clinical Policies and Procedures for the Use of Methadone and Buprenorphine in the Treatment of Opioid Dependence. Community Pharmacotherapy Program [2014]. https://www.mhc.wa.gov.au/about-us/our-services/community-pharmacotherapy-program/

[2] Community Pharmacotherapy Program. Clinical Guidelines for use of depot buprenorphine (Buvidal and Sublocade) in the treatment of opioid dependence (CPOP Clinical Policies and Procedures) [2023]. https://www.mhc.wa.gov.au/about-us/our-services/community-pharmacotherapy-program/

[3] *Medicines and Poisons Act 2014* (WA) s. 77.1. https://www.legislation.wa.gov.au/legislation/statutes.nsf/main_mrtitle_13172_homepage.html

[4] Medicines and Poisons Regulations 2016. https://www.legislation.wa.gov.au/legislation/statutes.nsf/law_a147008_subsidiary.html

Term	Definition/full term
ScriptCheckWA	Western Australia's Real Time Prescription Monitoring System
The Poisons Standard[5]	"The Poisons Standard is a record of decisions on the classification of medicines and chemicals into Schedules." It details which medicines/substances are included in each class. Previously known as the SUSMP.
TGA	Therapeutics Goods Administration
THC	Tetrahydrocannabinol
TRD	Treatment Resistant Depression

[5] The Poison Standard. http:/www.tga.gov.au/publication/poisons-standard-susmp

Introduction

This Monitored Medicines Prescribing Code (Code) replaces all previous versions of the Schedule 8 medicines prescribing code issued by the Department of Health.

i. Overview

This Code outlines the requirements for prescribing of monitored medicines in Western Australia (WA). Monitored Medicines include:

1. **Schedule 8 (S8) medicines**, also known as Controlled Drugs. S8 medicines are defined in the *Poisons Standard*[6] as
   "substances which should be available for use but require restriction of manufacture, supply, distribution, possession and use to reduce abuse, misuse and physical or psychological dependence."

2. **Schedule 4 (S4) Monitored Medicines** are substances in Schedule 4 of The Poisons Standard which are considered to have a higher risk of abuse, misuse and physical or psychological dependence. These are listed in Schedule 6 of the Medicines and Poisons Regulations 2016 as defined by Regulation 7A. [7]

The Code is published under the authority of the Medicines and Poisons Regulations 2016. The prescribing of all Monitored Medicines must comply with the criteria and conditions outlined in the Regulations and this document, unless otherwise approved, in writing, by the Chief Executive Officer (CEO) of the Department of Health.

ii. Scope

This Code applies to:

- all **prescriptions** for Monitored Medicines written, or dispensed, in WA; and
- all prescribers authorised under the Medicines and Poisons Regulations 2016 to **prescribe** a Monitored Medicine, irrespective of health practitioner type.

This Code does not apply to:

- **administration** of a Monitored Medicine by an authorised health practitioner, for the medical treatment of a person, under the care of that practitioner; and
- **administration** of Monitored Medicines to an animal, or supply to the owner of an animal, when for veterinary treatment and authorised by an approved veterinary surgeon.

The **administration** of S8 medicines for emergency treatment by medical practitioners and nurse practitioners is outside the scope of this Code. Injectable medicines, including from Prescriber Bag supplies or imprest stock, may be used for this purpose and do not require authorisation.

Residential care facilities can be authorised to carry medicines as imprest supplies for this purpose. A current Medicines and Poisons Permit is required.

iii. User guide

Step 1: Read the Introduction, which provides a background to the Code including its scope.

Step 2: Read and comply with the Medicines and Poisons Regulations 2016 and the requirements outlined in Part 1 of this Code; Part 1 of the Code applies to the prescribing and dispensing of all monitored medicines in WA.

[6] The Poisons Standard. http:/www.tga.gov.au/publication/poisons-standard-susmp

[7] Medicines and Poisons Regulations 2016.
https://www.legislation.wa.gov.au/legislation/statutes.nsf/law_a147008_subsidiary.html

Step 3: Also read and comply with the requirements outlined in the Part relevant to the Monitored Medicine being prescribed or dispensed.

Step 4: As a prescriber, in reviewing the Part relevant to the Monitored Medicine being prescribed you must assess whether you:

- are eligible to prescribe the intended Monitored Medicine to your patient without authorisation from the CEO; or
- require written authorisation from the CEO before prescribing the intended Monitored Medicine to your patient.

Table 1 provides a regulatory overview for the prescribing of monitored medicines in WA.

Table 1: Monitored Medicines Regulatory Overview

Monitored Medicine(s)	Parts of the Code prescribing must conform with	Eligibility to prescribe without authorisation from the CEO?
S8 Opioids and Ketamine	Criteria and conditions outlined in • Part 1 **and** • Part 2	Where a prescriber answers **yes to all** three questions below, they may prescribe an S8, as specified in Part 2, **without authorisation** of the CEO. Where a prescriber answers **no to any** of the three questions below, written **authorisation from the CEO is required** before prescribing. 1. Do I as the prescriber meet the Prescriber criteria? 2. Does the patient I am prescribing for meet the Patient criteria? 3. Does the product I am prescribing meet the Product criteria?
S8 Stimulant medicines	Criteria and conditions outlined in • Part 1 **and** • Part 3	Where a prescriber answers **yes to all** four questions below, they may prescribe an S8 stimulant medicine, as specified in Part 3, **without authorisation** of the CEO. Where a prescriber answers **no to any** of the four questions below, **written authorisation from the CEO is required** before prescribing an S8 stimulant medicine. 1. Do I as the prescriber meet the Prescriber criteria? 2. Does the patient I am prescribing for meet the Patient criteria? 3. Does the product I am prescribing meet the Product criteria? 4. Does the patient meet the Frequency of review criteria?
S8 medicinal cannabis products	Criteria and conditions outlined in • Part 1 **and** • Part 4	Where a prescriber answers **yes to all** three questions below, they may prescribe an S8 medicinal cannabis product, as specified in Part 4, **without authorisation** of the CEO. Where a prescriber answers **no to any** of the three questions below, **written authorisation from the CEO is required** before prescribing S8 medicinal cannabis products. 1. Do I as the prescriber meet the Prescriber criteria? 2. Does the patient I am prescribing for meet the Patient criteria? 3. Does the product I am prescribing meet the Product criteria?
S8 Esketamine	Criteria and conditions outlined in • Part 1 **and** • Part 5	Where a prescriber answers **yes to both** questions below, they may prescribe S8 Esketamine, as specified in Part 5, **without authorisation** of the CEO. Where a prescriber answers **no to any** of the two questions below, **written authorisation from the CEO is required** before prescribing Esketamine. i. Do I as the prescriber meet the Prescriber criteria? i. Does the patient I am prescribing for meet the Patient criteria?

Monitored Medicine(s)	Parts of the Code prescribing must conform with	Eligibility to prescribe without authorisation from the CEO?
S8 MDMA and psilocybine	Criteria and conditions outlined in • Part 1 **and** • Part 5	Written **authorisation from the CEO is always required** before prescribing MDMA or psilocybine. There is no situation in which a practitioner may prescribe MDMA or psilocybine without written authorisation from the CEO.
S8 benzodiazepines, Sodium Oxybate and all other S8s not captured elsewhere in this Code	Criteria and conditions outlined in • Part 1 **and** • Part 6	Written **authorisation from the CEO is always required** before prescribing. There is no situation in which a practitioner may prescribe without authorisation from the CEO.
S8 Opioid pharmacotherapy	Criteria and conditions outlined in • Part 1 **and** • Part 7	Written **authorisation from the CEO is always required** before prescribing. There is no situation in which a practitioner may prescribe without authorisation from the CEO.
S4 Monitored Medicine	Criteria and conditions outlined in • Part 1 **and** • Part 8	Authorisation from the CEO is **not required** to prescribe S4 Monitored Medicines; however, specific circumstances, as outlined in Part 8, **require** prescribers to carefully **document a plan to mitigate the potential harms** associated with these medicines.

PART 1: General conditions for the prescribing of Monitored Medicines

1.1 Regulation of prescribing

The prescribing of Monitored Medicines is limited to lawful practice of the health practitioner, any inherent professional scope or limitations imposed by the respective National Board, and the specific limitations of this Code. To be eligible to prescribe a Monitored Medicine, a prescriber's professional registration must not have conditions or undertakings relevant to the prescribing of medicines.

The Code takes a risk-based approach to the regulation of Monitored Medicine prescribing. In certain circumstances, prescribing may:

- not require interaction with the Department of Health (the Department);
- require prescribers to carefully document a plan to mitigate harms associated with these medicines;
- require authorised prescribers to notify to the Department that they are treating a particular patient;
- require written authorisation from the CEO before prescribing can commence.

The restrictions on the prescribing of Monitored Medicines are intended to ensure both patients and the public are protected from risks associated with use of Monitored Medicines, including overdose and dependence. Where deemed necessary, the CEO may, in writing, instruct a person not to prescribe or supply to an individual patient.

The parameters of the Code have been developed with consideration of available evidence in support of best practice prescribing; however, the Code does not provide clinical endorsement of treatment in individual patients. Regardless of whether authorisation is required and irrespective of the type or duration of therapy, prescribers should carefully consider the benefits and risks of any Monitored Medicine prescribing, in each case.

1.2 Prescribing practice

Prescribers should recognise and work within the limits of their competence and scope of practice.

Prior to prescribing a Monitored Medicine, in line with the *Providing good care* section of the National Boards' Code of conduct[8] (e.g., *Good Medical Practice: a code of conduct for doctors in Australia*), it is recommended that the prescriber:

- assesses the patient, taking an accurate medical history (including medication and substance history) and undertaking clinical examination and investigations as appropriate;
- makes responsible and effective use of available resources, such as ScriptCheckWA[9] in combination with Product Information, recommendations, and best-practice guidelines that are current, approved, and published;
- considers the balance of benefit and harm in management decisions;
- has a clear diagnosis and indication for treatment; and
- formulates, implements, and documents an appropriate management plan, which considers all available treatment options including non-pharmacological strategies, regular

[8] Ahpra and National Boards. Code of conduct. https://www.ahpra.gov.au/Resources/Code-of-conduct.aspx

[9] ScriptCheckWA is Western Australia's Real Time Prescription Monitoring System; further information is available via: https://www.health.wa.gov.au/Articles/N_R/Prescription-monitoring-in-Western-Australia/About-ScriptCheckWA

review, mitigation strategies where there is a risk of overdose, diversion, or substance use disorders, and the need for a Treatment Contract.[10]

In line with good patient care a prescriber should:

- maintain clear and accurate records;
- support patients to adopt an active role in their health and management; and
- maintain and exercise clear practices towards:
    - monitoring medicine usage and adherence;
    - frequency of treatment review;
    - identifying and responding to warning flags;
    - use of urine and other drug screening tests; and
    - prescribing for first time patients.

Where possible, prescribing should be limited to a single prescriber. Where care is shared between prescribers, a management plan should be agreed between prescribers regarding responsibility for prescribing Monitored Medicines.

A prescriber must take reasonable steps to satisfy themselves that the patient does not have a relevant comorbidity or restriction that would affect treatment with an S8 medicine or require authorisation of the CEO to prescribe.

1.2.1 ScriptCheckWA and the Department's S8 Prescriber Information Service

Information from ScriptCheckWA,[11] Western Australia's real time prescription monitoring system, and the Department's S8 Prescriber Information Service[12] is provided under the authority of the *Medicines and Poisons Act 2014*.

Information will only be provided to an authorised health professional and only relating to a patient under the care of that practitioner. Any information provided must not be used for any purpose other than assisting with the management of the patient. Log in details to ScriptCheckWA must not be shared with anyone, including other health professionals or support staff.

Under Regulation 22A of the Medicines and Poisons Regulation 2016, prior to prescribing, dispensing, or supplying a Monitored Medicine, a health professional must register with ScriptCheckWA.

The use of ScriptCheckWA is strongly recommended prior to prescribing Monitored Medicines.

ScriptCheckWA is a tool intended to assist in the safe prescribing of medicines known to have a higher risk of dependence and diversion. It provides real time information that can help inform risk assessment, including prescriptions issued, prescriptions dispensed, authorisations issued to prescribers, and alerts relating to higher-risk criteria. This information can assist in assessing safety of prescribing for a patient for the first time and at regular intervals for a patient who takes Monitored Medicines for a chronic condition.

1.2.2 Informed consent

It is a general condition, that the prescriber obtains the patient's (or guardian's) informed consent to treatment with a Monitored Medicine and, where relevant, the use of an unregistered therapeutic good.

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[10] A Treatment Contract should facilitate agreement and consent between the prescriber and patient; it can be used to help clarify expectations, establish boundaries, promote collaboration, enhance accountability, and manage risk. A template Treatment Contract is available via: https://www.health.wa.gov.au/Articles/N_R/Opioids-benzodiazepines-and-other-S8-medicines

[11] Department of Health. Real time prescription monitoring [Aug 2023]. https://www.health.wa.gov.au/Articles/N_R/Prescription-monitoring-in-Western-Australia/About-ScriptCheckWA

[12] The S8 Prescriber Information Service is available 8.30 am to 4.30 pm Monday to Friday on 08 9222 4424.

Many Monitored Medicines have the potential to impact a patient's capacity to safely operate vehicles or machinery. Prescribers should ensure this forms part of the discussion on risks associated with any Monitored Medicine.

1.2.3 Prescribing for new or unknown patients

Prior to prescribing a Monitored Medicine to a new or unknown patient, prescribers

- must validate the patient's prescribing history and previous supply in ScriptCheckWA;
- should record the patient's identity and, where possible, verify it against an official source of photo identification (e.g., driver's licence).

Where it is not possible to validate a person's identity or prior history, only limited supplies should be prescribed until the required information can be obtained. It is recommended that a maximum of 2 days (or during holiday periods to the next business day) should be prescribed, where clinically appropriate and safe to do so.

1.2.4 Warning flags

The following warning flags should be considered before prescribing:

- an alert notification is triggered or present in ScriptCheckWA;
- patient appears intoxicated or exhibits withdrawal symptoms;
- patient has an indeterminate diagnosis; is reluctant or refuses to obtain previous notes or undergo diagnostic assessment;
- patient refuses to sign a Treatment Contract;
- patient persistently requests a specific medicine, medicine combination, or formulation; is resistant to changes in treatment; requests increased doses or escalates dose without prescriber endorsement;
- patient requests increased quantities as a private prescription;
- patient refuses to comply with requests to provide urine drug screens;
- patient's function at work or home deteriorates;
- patient displays threatening behaviour to prescriber or staff;
- evidence of prescription forgery or multiple episodes of lost or stolen scripts;
- patient seeks additional prescriptions from other prescribers without informing the primary prescriber.

Where present, further caution should be exercised, a Monitored Medicines prescribing history of the patient should be sought, and consideration given to not prescribing Monitored Medicines.

1.2.5 Prescribing Monitored Medicines for self and family members

Prescribers may not prescribe a Monitored Medicine for themselves.

Prescribing a Monitored Medicine for a family member or relative is strongly discouraged, except in an emergency. Prescribers are referred to the Medical Board of Australia's *Good medical practice*[13], or relevant National Board standards for guidance on the appropriateness of prescribing medicines for relatives.

1.3 Authorisation from the CEO

In certain circumstances, written authorisation of the CEO is required before prescribing a particular S8 medicine. The specific circumstances where this is required and related processes are detailed within the subsequent Parts of this Code.

[13] The Medical Board of Australia. Good medical practice: a code of conduct for doctors in Australia [Oct 2020]. https://www.medicalboard.gov.au/Codes-Guidelines-Policies/Code-of-conduct.aspx

Where ScriptCheckWA displays an authorisation to prescribe specified S8 medicine(s), only the practitioner(s) named or, where relevant, practitioners practicing at the clinic named on the authorisation are permitted to prescribe these medicine(s).

1.3.1 Application outcomes

The CEO will only consider applications that are complete and contain all information required by the approved forms.

The CEO may approve or decline an application at their discretion. Applicants will be notified, in writing or electronically, of approval or declining of an application.

To inform their decision, the CEO may request the applicant provide additional information, second opinion, or clarification of information provided as necessary. Applicants will be notified, in writing or electronically, if additional information is required. Where the information requested by the CEO is not provided within the specified time frame, the CEO may consider an application as withdrawn.

To inform their decision, the CEO may seek an expert review, or other advice (relevant to the treatment with a S8 substance) on an application.

The CEO may add any conditions to an authorisation, in relation to the prescribing or dispensing of a Monitored Medicine, believed to be necessary to protect the safety of the patient.

Where an application for authorisation is not approved, the applicant may reapply with additional information, such as a second opinion/specialist support, additional clinical reports, the results of previous interventions and/or drug screens or may make a new application with modified treatment details (medicine, formulation, and/or dose).

1.3.2 Duration of an authorisation

Authorisations from the CEO are issued for a period relevant to the product and condition being treated.

The Department will issue renewal reminders prior to the date of expiry of an authorisation from the CEO as a courtesy. However, the responsibility for renewal remains with the prescriber.

Information regarding authorisations from the CEO are available to all prescribers through ScriptCheckWA.

1.3.3 Termination or variation of authorisation

At any time, a prescriber may request cancellation of a patient authorisation by writing to the CEO.

The CEO may amend, cancel, or suspend a patient authorisation, in writing, at any time.

1.4 Prescription requirements

All prescriptions must include the following information:

- name, address, and contact telephone number of the prescriber
- patient's full name, address, and date of birth;
- date of prescription;
- medicine, strength, and form;
- quantity for supply;
- precise dosing directions;
- number of times the prescription may be supplied;
- a repeat interval, if the S8 prescription is to be supplied more than once; and
- signature of the prescriber, if the prescription is handwritten or a computer-generated paper prescription.

The dosing directions should be consistent with the repeat interval or reissue of the prescription to mitigate the risk of oversupply or unauthorised dose escalation.

Prescription documents without the above details are not valid and cannot be dispensed. Such documents may be returned to the prescriber for correction or reissue.

S8 prescriptions must only contain one drug type of S8 medicine on one prescription (or same S8 drug type in more than one form). A prescription with both S8 and S4 items is not valid and cannot be dispensed.

In line with Regulation 25 of the Medicines and Poisons Regulations 2016, prior to dispensing an S8 prescription a pharmacist may need to contact the prescriber to verify the authenticity of the prescription and identity of a prescriber. Where it is not possible to verify, the pharmacist may only dispense up to two days' supply.

1.5 History of substance abuse, oversupply, or drug dependence

1.5.1 Reports of oversupply and drug dependence

An authorised health professional must make a report to the CEO, within 48 hours, when they have reason to believe that a patient is:

- Oversupplied: a person, who has over a period of time obtained, or obtained prescriptions for, quantities of drugs of addiction that are greater than is reasonably necessary for therapeutic use; or
- Drug Dependent: a person, who has acquired, as a result of repeated administration of drugs of addiction or Schedule 9 (S9) poisons, an overpowering desire for the continued administration of a drug of addiction or a S9 poison.

The CEO may decide to include the name of the person on the drugs of addiction record as an Oversupplied or Drug Dependent person.

Where a report of drug dependence or oversupply is received for a patient who is already under treatment with a Monitored Medicine, at their discretion the CEO may cancel all existing authorisations and/or issue an instruction not to prescribe or supply to the patient.

1.5.2 Treating patients with a history of substance abuse, oversupply, or drug dependence

Written authorisation from the CEO is required to prescribe S8 medicines for a person recorded as Drug Dependent or Oversupplied and/or with a history of substance abuse within the previous five years.

Treatment with the S8 medicine(s) must be supported by a relevant specialist, medically indicated and, unless being prescribed in accordance with Part 7 of this Code, must not be for the treatment of addiction. Specialist support must be in writing, be dated within the last 3 years, and be consistent with the proposed treatment regimen on the application.

A management plan, which includes mitigation strategies to address misuse and to reduce risk of abuse, must accompany the application for authorisation from the CEO. Authorisation will ordinarily require measures to limit potential misuse, which may include but are not limited to:

- signed Treatment Contracts;
- dosing restrictions, or adequate trials of lowest effective dose;
- supply limits (daily, twice weekly, or weekly dispensing);
- supply at one nominated pharmacy only;
- strict repeat intervals;
- no early or replacement prescriptions;
- regular urine drug screens;
- for S8 stimulant medicines, adequate trial of non-stimulant agents;

- for S8 stimulant medicines, use of long acting stimulants only;
- other relevant conditions.

Where available, the CEO may also require prescribing of abuse deterrent formulations.

1.6 Notifications of stimulant induced psychosis

A psychiatrist who makes a diagnosis of stimulant induced psychosis in respect of a patient must notify the CEO. The notification must be in writing, in the approved form, and must be forwarded to the Department within 72 hours of making the diagnosis.

Written authorisation from the CEO is required to prescribe an S8 stimulant medicine or medicinal cannabis product for a person with a current, or prior, history of psychosis. The treatment must be medically indicated.

Where a notification of stimulant induced psychosis is received for a patient who is already under treatment with an S8 stimulant medicine, the CEO may, at their discretion, cancel all existing authorisations and/or issue an instruction not to prescribe or supply to the patient.

1.7 Research

Prescribing Monitored Medicines in clinical research settings must comply with the provisions of this Code. If required under the provisions of this Code, an application for authorisation should be submitted prior to prescribing. A copy of the research proposal and approval by an ethics committee specific to the nature of the research, should accompany the application.

1.8 Monitoring by the Department

Records of dispensing of Monitored Medicines within WA are provided to the Department by community pharmacies, hospital pharmacies, and dispensing doctors. The records are maintained in a secure database and continuously reviewed.

The Department monitors overall patterns as well as individual patient activities for:

- oversupply;
- excessive doses;
- patients visiting large numbers of prescribers;
- prescribing without authority;
- prescribing that does not match an authority issued (wrong medicine, dose, form);
- other high-risk usage (e.g. inappropriate form, inadequate repeat intervals, excessive medicines in combination).

Where there is any concern about specific patients, the prescriber(s) may be contacted and a review of therapy requested. Prescribers will be advised to adhere to the prescribing criteria and/or any authorisation issued under the Code.

In cases of persistent non-compliance or unauthorised prescribing the Department may consider action as provided under the *Medicines and Poisons Act 2014*, which may include the revocation of S8 prescribing privileges and prosecution. If the CEO decides to revoke a practitioner's professional authority relating to S8 medicines, the Australian Health Practitioner Regulation Agency (AHPRA) will be notified and a record of notification may be published.

PART 2: S8 Opioids and ketamine

2.1 Overview

Part 2 outlines the prescribing conditions and requirements for S8 opioids and ketamine, including:

- when prescribers may prescribe them without authorisation of the CEO;
- when prescribers require written authorisation from the CEO before prescribing them.

It also details how to apply for authorisation from the CEO.

2.2 Scope

Part 2 applies to all formulations and strengths of ketamine and S8 opioid medicines for all medical indications except pharmacotherapy for opioid dependence.

2.2.1 Hospital Exemptions

Part 2 does not apply to the:

- administration of the above S8 medicines to an inpatient in hospital; **or**
- prescribing of a 14-day supply of the above S8 medicines from emergency departments or on discharge from hospital where
  - the treatment with the S8 medicine is associated with that episode of care; **and**
  - the patient is not recorded as Drug Dependent or Oversupplied.

2.3 Authority

Part 2 is issued under the provisions of Medicines and Poisons Regulations 2016, Part 11, Division 2.

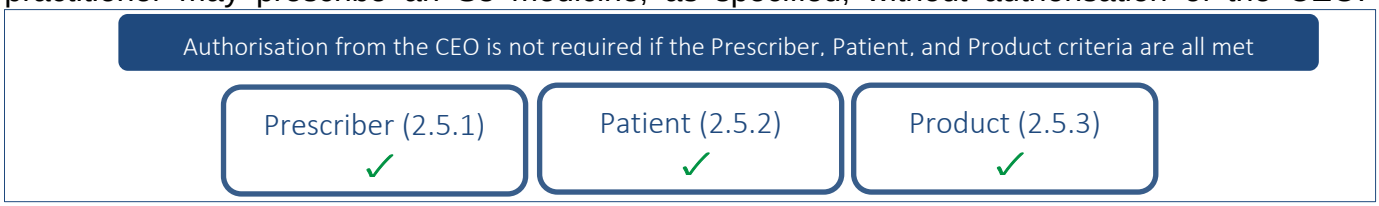
2.4 General conditions for prescribing S8 opioids and ketamine medicine

All prescribing must conform to the criteria and conditions outlined in Part 1 and Part 2 of this Code.

In line with Royal Australian College of General Practitioners (RACGP)'s guidelines for opioids in acute and chronic pain,[14] treatment with methadone should only be commenced and titrated, with caution, by specialist practitioners with appropriate expertise and experience in its use. Patients should be monitored closely during dose titration.

2.5 Eligibility to prescribe without authorisation from the CEO

If the Prescriber criteria **and all** the Patient **and** Product criteria set out in Section 2.5 are **met**, a practitioner may prescribe an S8 medicine, as specified, without authorisation of the CEO.



If the Prescriber criteria **and/or any** of the Patient **or** Product criteria set out in Section 2.5 are **not** met, written authorisation from the CEO is required before prescribing (see Section 2.6).

2.5.1 Prescriber criteria

Provided their professional registration does not have any conditions or undertakings relevant to the prescribing of S8 medicines, practitioners meeting Prescriber criteria i, ii, iii, or iv may prescribe an S8 medicine, as specified, without individual authorisation of the CEO.

[14] RACGP. Prescribing drugs of dependence in general practice [2017]. https://www.racgp.org.au/getattachment/9aba1fe0-1c8b-493f-aab4-c7e734c0f732/Evidence-based-guidance-for-opioids-in-acute-and-c.aspx

i. Medical Practitioners

When prescribing is in accordance with Section 2.5, a medical practitioner may prescribe an S8 opioid medicine, except for methadone, without authorisation for a condition within their scope of practice.

When prescribing is in accordance with Section 2.5, a medical practitioner may prescribe ketamine if they hold specialist registration on the AHPRA register of practitioners in one of the following Specialities, or Speciality Fields:

- Pain medicine
- Palliative medicine
- Paediatric palliative medicine.

ii. Nurse Practitioners

When prescribing is in accordance with Section 2.5, a nurse practitioner may prescribe an S8 opioid medicine, except for methadone, for a condition within their scope of practice.

iii. Dental Practitioners

When prescribing is in accordance with Section 2.5 and where the total duration of treatment is less than or equal to 14 days, a dental practitioner may prescribe an S8 opioid medicine (except for methadone) for the purpose of treating an acute dental condition.

iv. Endorsed Podiatric Surgeons

When prescribing is in accordance with Section 2.5 and where the total duration of treatment is less than or equal to 3 days, an endorsed podiatric surgeon may prescribe up to 10mg doses (maximum of 20mg in 24 hours) of immediate release oxycodone for the purpose of treating an acute condition in accordance with the Registration standard: Endorsement for schedule medicines, Podiatry Board of Australia[15].

2.5.2 Patient criteria

i. Age

The patient is 18 years-of-age or older.

ii. Diagnosis

The S8 opioid medicine is being prescribed to a patient for the purposes of treating a diagnosis consistent with the Australian Register of Therapeutic Goods (ARTG) approved indication of that product.

iii. Co-morbidity

The patient:

- does not have a history of substance abuse, diversion, or misuse of drugs of addiction or Schedule 9 poisons within the previous five years;
- does not have a record of Drug Dependence or Oversupply (see Section 1.5.1); and
- is not a current CPOP (opioid pharmacotherapy) patient.

2.5.3 Product criteria

i. Medicine

The S8 opioid being prescribed is not methadone.[16]

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[15] Podiatry Board of Australia. Registration Standard: Endorsement for Scheduled Medicines [August 2018]. https://www.podiatryboard.gov.au/Registration-Endorsement/Endorsement-Scheduled-Medicines

[16] ***14-day Approved Specialist Exemption:*** An Approved Specialist (see table 2) meeting the Prescriber criteria may prescribe above the specified maximum daily dose and/or injectable formulations and/or Methadone **for up to 14 days** without authorisation of the CEO **provided** the patient does **not** have a record of Drug Dependence or Oversupply. If this exemption has lapsed due to the passage of time, authorisation from the CEO is required if the Product criteria remain unmet.

ii. Dose

Doses should be safely titrated to individual patient factors and need.

For sole and combined therapy, prescribed doses of all S8 opioid medicines must **not** exceed the following maximum daily doses (unless the ***End-of-Life Care Exemption***[17] or ***14-day Specialist Exemption***[18] is met):

- 90 mg morphine equivalents per day (mEqD) of opioids in **any formulation**;
- 45 mg mEqD of **immediate** release opioids.

An exception to this dose limit applies when tapentadol is being used as a **sole** opioid **agent and**:

- immediate release formulations of tapentadol do not exceed 150 mg; **and**
- both slow and immediate release formulations of tapentadol do not exceed 500 mg.

These dose limits are intended for regulatory purposes only and indicate the point at which authorisation from the CEO is required.

Morphine equivalent comparisons for each opioid agent are detailed in figure 1. Figure 1 is intended for use to calculate morphine equivalents for the purpose of this Code; **it is NOT suitable to use for calculations when transferring patients between opioid agents**.

	Formulation	Factor to convert doses to morphine milligram (mg) equivalents
Buprenorphine	Transdermal (mcg/hr) Oral (mg)	2 37.5
Codeine	Oral (mg)	0.15
Fentanyl	Transdermal (mcg/hr)	3.6
Hydromorphone	Oral (mg)	5
Morphine	Oral (mg)	1
Oxycodone	Oral (mg)	1.5
Tapentadol	Oral (mg)	0.3*

*use conversion with caution in clinical settings as analgesic potency may differ from opioid potency.

To use this conversion chart:

1. Add all daily doses of same formulation of the same opioid agent together, to calculate the daily dose for that agent.
2. Multiply by the correct conversion factor for that opioid, to convert to morphine equivalents.
3. Repeat steps 1 and 2 for any other opioid agents taken concurrently.
4. Add all results from step 2 together.

Figure 1: Morphine Equivalent Conversion Chart

[17] ***End-of-Life Care Exemption:*** Where the S8 opioid is being prescribed to a patient with **less than two-months life expectancy**, medical and nurse practitioners meeting the Prescriber criteria may prescribe above the specified maximum daily dose and/or injectable formulations without authorisation of the CEO **provided** the patient does **not** have a record of Drug Dependence or Oversupply. If this exemption has lapsed due to the passage of time, authorisation from the CEO is required if the Product criteria remain unmet.

[18] ***14-day Approved Specialist Exemption:*** An Approved Specialist (see table 2) meeting the Prescriber criteria may prescribe above the specified maximum daily dose and/or injectable formulations and/or Methadone **for up to 14 days** without authorisation of the CEO **provided** the patient does **not** have a record of Drug Dependence or Oversupply. If this exemption has lapsed due to the passage of time, authorisation from the CEO is required if the Product criteria remain unmet.

iii. Formulation

The formulation prescribed is not injectable (unless the ***End-of-Life Care Exemption***[19] or ***14-day Specialist Exemption***[20] is met).

2.6 Authorisation from the CEO to prescribe required

Where prescribing is not in accordance with Section 2.5, written authorisation from the CEO is required prior to prescribing an S8 opioid or ketamine.

2.6.1 Applying for authorisation

Applications for authorisation must be on the approved form, which must be completed in full and, where required, be accompanied by appropriate supporting documentation (such as support from an Approved Specialist (see Section 2.6.2) or clinical documentation confirming life expectancy is less than 12 months (see Section 2.6.3)).

2.6.2 Approved Specialists

Applications for authorisation either need to be submitted by, or the proposed treatment regimen supported by, an Approved Specialist.

For the purposes of Part 2 of this Code, an Approved Specialist is a medical practitioner who holds specialist registration on the AHPRA register of practitioners in a Speciality, or Speciality Field, relevant to the diagnosed condition the S8 is being prescribed for (as set out in Table 2).

Table 2: Approved Specialists – AHPRA Speciality or Speciality Field, S8 medicine, and diagnosed condition

Specialty or Speciality Fields	S8 medicine and diagnosed condition
Addiction medicine Anaesthesia Endocrinology/Paediatric endocrinology Gastroenterology and hepatology/Paediatric gastroenterology and hepatology General medicine General paediatrics Haematology/Paediatric haematology Medical oncology/Paediatric medical oncology Neurology/Paediatric neurology Pain medicine Palliative medicine/Paediatric palliative medicine Rheumatology/Paediatric rheumatology Surgery	Methadone and other S8 opioids for the purpose of treating pain.
Pain medicine Palliative medicine/Paediatric palliative medicine	Ketamine products for the purpose of treating pain.

Applications from other specialists relevant to the diagnosis will be considered on a case-by-case basis.

[19] ***End-of-Life Care Exemption:*** Where the S8 opioid is being prescribed to a patient with **less than two-months life expectancy**, medical and nurse practitioners meeting the Prescriber criteria may prescribe above the specified maximum daily dose and/or injectable formulations without authorisation of the CEO **provided** the patient does **not** have a record of Drug Dependence or Oversupply. If this exemption has lapsed due to the passage of time, authorisation from the CEO is required if the Product criteria remain unmet.

[20] ***14-day Approved Specialist Exemption:*** An Approved Specialist (see table 2) meeting the Prescriber criteria may prescribe above the specified maximum daily dose and/or injectable formulations and/or Methadone **for up to 14 days** without authorisation of the CEO **provided** the patient does **not** have a record of Drug Dependence or Oversupply. If this exemption has lapsed due to the passage of time, authorisation from the CEO is required if the Product criteria remain unmet.

Exemptions to the requirement for specialist support for patients with a terminal illness are detailed in Section 2.6.3.

If required, specialists should apply and name a general practitioner or nurse practitioner as a co-prescriber at the time of the first prescription. If a co-prescriber is nominated, specialists should provide written advice to the co-prescriber within 30 days, specifying each S8 medicine supported, including dose and frequency, and a management plan.

2.6.2.1 Approved Specialist support

Where specialist support is required, it must be in writing, dated within the last three years, and agree with the proposed S8 regimen requested on the application. Specialist opinion is valid for a maximum period of three years, after which a review and renewed support is required. In all cases the specialist should be relevant to the condition being treated, but additional support may be required from other specialists, such as addiction medicine specialist where there is a recent history of substance misuse.

Where treatment will require specialist support, prescribers should organise specialist review in advance. This includes patients already established on S8 treatment, who may require dose increases or treatment modification that will require authorisation from the CEO.

Where there are conflicting specialist opinions, the CEO may request that a patient is referred for further opinion or multidisciplinary review, as necessary, to inform any decision.

A recent hospital discharge summary (no more than three months old) may qualify as specialist support. This will be valid for a period of three months from the application date, after which time independent specialist review is required. Prescribers are strongly advised to validate patient claims made on outdated or unfamiliar hospital discharge summaries.

2.6.3 Terminal illness

Where treatment of a patient with terminal illness requires authorisation from the CEO because the Dose and/or Formulation conditions of the Product criteria (Section 2.5.3) are unmet, practitioners may supply clinical documentation confirming life expectancy of less than 12 months, in lieu of specialist support for a specific opioid regimen. Specialist support is still required for other applications for authorisation, such as methadone and ketamine.

Authorisations may be issued to support dose titration and flexible dosing when required.

Prescribing practitioners from the same practice or team (for example Silver Chain) can apply for group authorisation in the group to allow all palliative care prescribers in the group to prescribe for a patient that is terminally ill.

2.6.5 Standard conditions of an authorisation from the CEO

Authorisations granted are issued to a named prescriber at their practice address. An authorisation allows other prescribers at the same place of practice to prescribe in accordance with the conditions of the authorisation.

Where a new authorisation is granted for a particular drug group (e.g., S8 opioid or ketamine), all prior authorisations issued for that drug group under this Part of the Code will be cancelled. The Department will notify the previously authorised prescriber or practice.

Authorised treatment must not be varied without authority and all prescribing must be consistent with the details of the authorisation. Where it is clinically necessary to vary treatment, a new application for authorisation is required.

2.7 Summary of when authorisation from the CEO is and is not required

Figure 2 summarises when authorisation from the CEO to prescribe is and is not required.

If the Prescriber criteria **and/or any** of the Patient **or** Product criteria are **not** met,
written authorisation of the CEO is required before prescribing.

If the Prescriber criteria **and** all the Patient **and** Product criteria are **met**,
a practitioner may prescribe an S8 medicine, as specified in Part 2, **without authorisation of the CEO**

Prescriber criteria (see 2.5.1)

*To be able to prescribe without authorisation, the prescriber must meet and comply with **one** of these*

The prescriber is a:

- ❑ medical or nurse practitioner prescribing an S8 opioid medicine other than methadone;

OR

- ❑ medical practitioner registered as a Pain Medicine, Palliative Medicine, or Paediatric Palliative Medicine Specialist on AHPRA prescribing ketamine;

OR

- ❑ dental practitioner prescribing an S8 opioid medicine other than methadone for the purpose of treating an acute dental condition for less than or equal to 14 days;

OR

- ❑ endorsed podiatric surgeon prescribing up to 10mg doses (maximum of 20mg in 24hours) of immediate release oxycodone for less than or equal to 3 days for the purpose of treating an acute condition in accordance with the Registration standard.

AND

Patient criteria (see 2.5.2)

*To be able to prescribe without authorisation, the patient/situation must meet **all** of these*

- ❑ The S8 opioid is being prescribed to a patient to treat a diagnosis consistent with the ARTG approved indication(s) of that product;

AND

The patient

- ❑ is 18 years-of-age or older;

AND

- ❑ has no history of substance abuse, diversion, or misuse of drugs of addiction or Schedule 9 poisons within the previous five years;

AND

- ❑ has no record of Drug Dependence or Oversupply (see Section 1.5.1);

AND

- ❑ is not a current CPOP patient.

AND

Product criteria (see 2.5.3)

*To be able to prescribe without authorisation, the prescribed S8 opioid product(s) must meet **all** of these*

- ❑ The S8 opioid medicine being prescribed is **not** methadone;†

AND

- ❑ The formulation of the prescribed S8 medicine is **not** injectable;*, †

AND

The total daily prescribed dose of S8 opioid medicine(s) in any combination **does not exceed:** *, †, ^

- ❑ 90 mg MEqD of opioids in **any formulation**;
- ❑ 45 mg MEqD of **immediate** release opioids.

- ❑ * ***End-of-Life Care Exemption***: Where the S8 opioid is being prescribed to a patient with **less than two-months life expectancy**, medical and nurse practitioners meeting the Prescriber criteria may prescribe above the specified maximum daily dose and/or injectable formulations without authorisation of the CEO **provided** the patient does **not** have a record of Drug Dependence or Oversupply.
- ❑ † ***14-day Approved Specialist Exemption:*** An Approved Specialist (see table 2) meeting the Prescriber criteria may prescribe above the specified maximum daily dose and/or injectable formulations and/or Methadone for up to 14 days without authorisation of the CEO provided the patient does not have a record of Drug Dependence or Oversupply.

If these exemptions have lapsed due to the passage of time, authorisation from the CEO is required if the Product criteria remain unmet.

- ❑ ^ An exception to this dose limit applies when **tapentadol** is being used as a **sole** opioid **agent and**:
  - **immediate release** formulations of **tapentadol** do not exceed 150 mg; **and**
  - both **slow and immediate release formulations** of **tapentadol** do not exceed 500 mg.

Figure 2: Summary of when authorisation from the CEO is and is not required for S8 opioids and ketamine

Part 3: Stimulant medicines

3.1 Overview

Part 3 outlines the prescribing conditions and requirements for S8 stimulant medicines, including:

- when prescribers may prescribe them without authorisation of the CEO;
- when prescribers require written authorisation from the CEO before prescribing them.

It also details how to apply for authorisation from the CEO.

3.2 Scope

Part 3 applies to all formulations of:

- dexamfetamine;
- lisdexamfetamine (Vyvanse®); and
- methylphenidate (Ritalin®, Ritalin LA®, Concerta®).

3.3 Authority

Part 3 is issued under the provisions of Medicines and Poisons Regulations 2016, Part 11, Division 4.

3.4 General conditions for prescribing S8 stimulant medicine

All prescribing must conform to the criteria and conditions outlined within Part 1 and Part 3 of this Code.

All prescribing should be in accordance with current published and approved Product Information, recommendations from the Royal Australian and New Zealand College of Psychiatrists (RANZCP), Royal Australasian College of Physicians (RACP), and RACGP, best practice guidelines, and evidence-based medicine standards. Treatment should be in accordance with a management plan, which considers all available treatment options, including non-pharmacological.

RANZCP's *Professional Practice Guideline 7: Guidance for psychotropic medication use in children and adolescents*[21], recommends that "The psychiatrist best placed to prescribe psychotropic medication is a child and adolescent psychiatrist with specialist training and experience with children."

3.4.1 Age restrictions

Treatment of any patient less than two years of age with an S8 stimulant medication is not permitted.

3.4.2 Urine Drug Screen

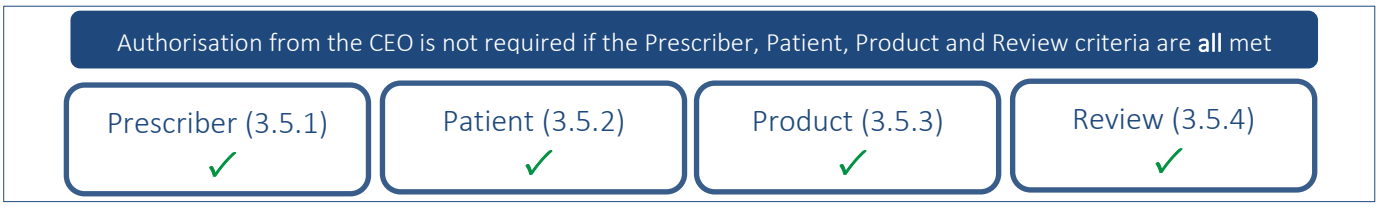
A urine drug screen conducted in accordance with *Australian/New Zealand Standard 4308* should be undertaken by all patients 16 years-of-age and older, as a risk mitigation tool, before commencing treatment with an S8 stimulant medicine. The need for further testing should form part of the management plan for each patient as indicated.

Urine drug screens can support the identification of any undisclosed substance use. They can also help verify a person's compliance with S8 stimulant medication treatment.

[21] RANZCP. Professional Practice Guideline 7: Guidance for psychotropic medication use in children and adolescents [Nov 2015]. https://www.ranzcp.org/clinical-guidelines-publications/clinical-guidelines-publications-library?publicationtype=ClinicalGuideline

3.5 Eligibility to prescribe without authorisation from the CEO

If the Prescriber criteria **and all** of the Patient, Product, **and** Review criteria outlined in Section 3.5 are **met**, a practitioner may prescribe an S8 stimulant medicine, as specified, without authorisation of the CEO.



If the Prescriber criteria **and/or any** of the Patient, Product, **or** Review criteria are **not** met, written authorisation from the CEO is required before prescribing (for process, see Section 3.6).

3.5.1 Prescriber criteria

Provided their professional registration does not have conditions or undertakings relevant to the prescribing of S8 medicines, practitioners meeting Prescriber criteria i or ii may prescribe an S8 stimulant medicine without authorisation of the CEO.

i. Approved Specialists

For the purposes of Part 3 of this Code, an Approved Specialist is a medical practitioner who holds specialist registration on the AHPRA register of practitioners in a Speciality, or Speciality Field, relevant to the diagnosed condition the S8 stimulant medicine is being prescribed for (as set out in Table 3) or other medical practitioner approved under Regulation 128.

When prescribing is in accordance with Section 3.5, Approved Specialists may prescribe an S8 stimulant medicine for an Approved Diagnoses as set out in Table 3.

Table 3: Approved Specialists (AHPRA Speciality or Speciality Field) and Approved Diagnoses

AHPRA Speciality or Speciality Fields	Approved Diagnoses
Neurology Paediatric neurology	Acquired Brain Injury Attention Deficit Hyperactivity Disorder (ADHD)[22] Narcolepsy
Paediatrics and child health	ADHD[22]
Psychiatry	Acquired Brain Injury ADHD[22] Moderate-Severe Binge Eating Disorder in an adult[23] Depression
Rehabilitation medicine Paediatric rehabilitation medicine	Acquired Brain Injury
Respiratory and sleep medicine	Narcolepsy

ii Medical practitioners and nurse practitioners when under a Shared Care Model

When prescribing is in accordance with Section 3.5.2, 3.5.3, and 3.5.4, and ScriptCheckWA does not display an authorisation for prescribing S8 stimulant medicines for the patient, a medical practitioner or nurse practitioner may prescribe continuing S8 stimulant medication for a patient under a Shared Care Model[24] provided:

[22] ICD-10 or DSM-5 diagnostic criteria must be met.

[23] In line with Product Information, lisdexamfetamine is the only S8 stimulant medicine that can be prescribed for the purposes of treating Moderate-Severe Binge Eating Disorder without authorisation of the CEO.

[24] RACGP. Shared Care Model between GP and non-GP specialists for complex chronic conditions. https://www.racgp.org.au/advocacy/position-statements/view-all-position-statements/clinical-and-practice-management/shared-care-model-between-gp-and-non-gp-specialist

- the S8 stimulant medication was initiated by an Approved Specialist for the purpose of treating an Approved Diagnoses (Table 3);
- the patient is under ongoing treatment with the S8 stimulant;
- the prescribing (including medication name, formulation, and dose) is consistent with the Approved Specialist's written instructions **or** the latest prescription on ScriptCheckWA for the S8 stimulant medicine; **and**
- the practitioner has reviewed the patient and is satisfied it is safe to prescribe stimulants.

Medical practitioners who are not an Approved Specialist and nurse practitioners are not permitted to:

- initiate an S8 stimulant medicine;
- alter an S8 stimulant dose without written authority of the Approved Specialist;
- prescribe an S8 stimulant medicine for a patient that has an authority displayed on ScriptCheckWA; or
- alter the S8 stimulant type or formulation.

Where necessary, an Approved Specialist may withdraw from the Shared Care Model by providing written notice to the other practitioner(s).

3.5.2 Patient criteria

i. Age

Where the S8 stimulant medicine being prescribed is **lisdexamfetamine**, the patient is 6 years-of-age or older.

Where the S8 stimulant medicine being prescribed is **methylphenidate or dexamfetamine**, the patient is 4 years-of-age or older.

ii. Diagnosis

The S8 stimulant medicine is being prescribed for the purpose of treating an Approved Diagnoses (Table 3).

iii. Comorbidity

The patient:

- does not have a history of stimulant induced psychosis (see Section 1.6);
- does not have a history of psychosis or bipolar disorder;
- does not have a history of substance abuse, diversion, or misuse of drugs of addiction or S9 poisons within the previous five years;
- does not have a record of Drug Dependence or Oversupply (see Section 1.5.1); or
- is not a current CPOP participant.

Where prescriber subsequently becomes aware of a relevant history for a patient, stimulant treatment is to be reviewed. If continuation of stimulant treatment is desired, then authorisation to prescribe is required from the CEO.

3.5.3 Product criteria

i. Dose

Doses should be safely titrated to individual patient factors and need.

For sole therapy, prescribed doses must not exceed the approved maximum daily doses set out in Figure 3. The dose limits in Figure 3 apply to the combined total daily dose of both short- and long-acting formulations when used together.

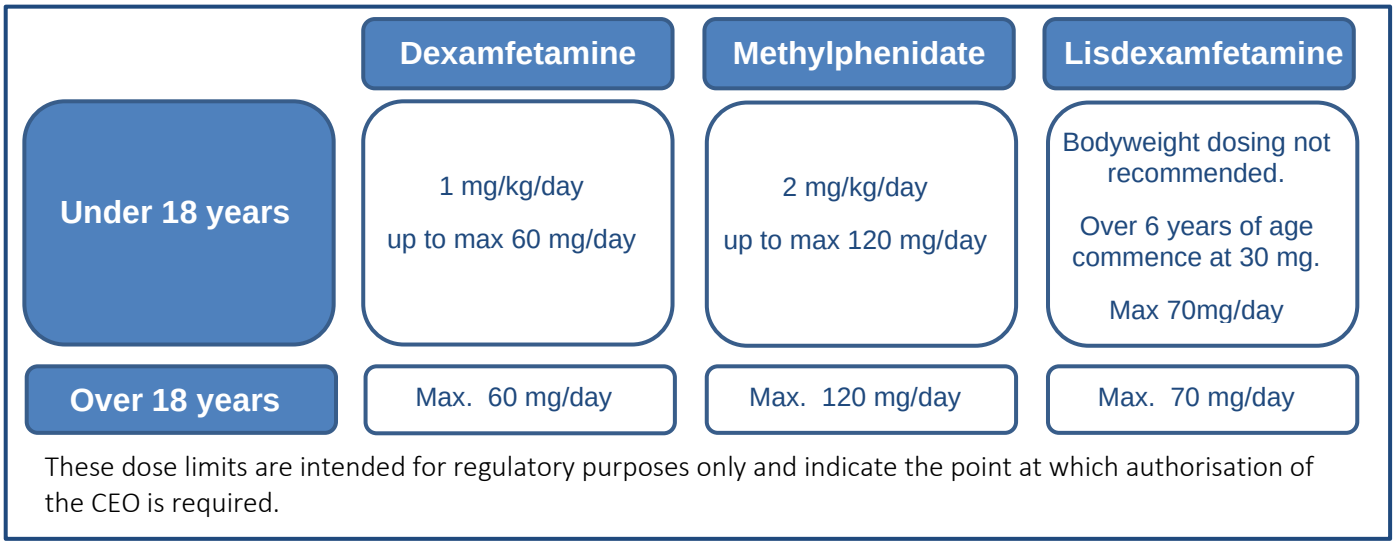


Figure 3: Approved maximum stimulant doses

For any combination therapy of dexamfetamine, methylphenidate, and lisdexamfetamine, the total combined dose of all stimulants must not exceed an equivalent dexamfetamine dose of:

- 1 mg/kg/day, up to a maximum of 60 mg/day, for patients under 18 years;
- a maximum of 60 mg/day for patients greater than or equal to 18 years.

Where any combination of dexamfetamine, methylphenidate, and lisdexamfetamine are prescribed together, the dose of all agents must be converted to an equivalent daily dose of dexamfetamine and added together using the conversion chart below (Figure 4).

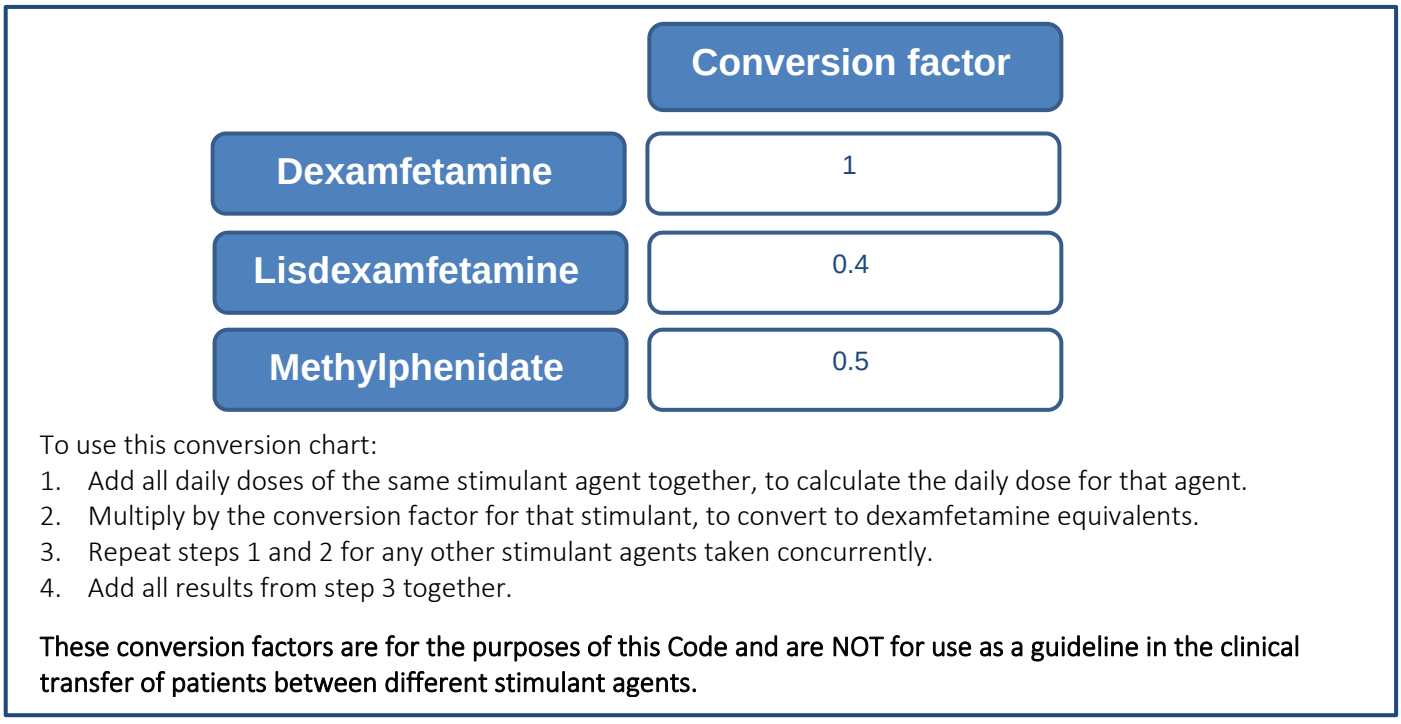


Figure 4: Conversion chart for calculating dexamfetamine equivalents

3.5.4 Frequency of review

Optimal frequency of specialist review for the continuation of appropriate S8 stimulant treatment depends on individual patient factors. At a minimum, a patient being prescribed an S8 stimulant medication who:

- is under the age of 18 years and/or has a listed comorbidity (see iii in Section 3.5.2) must be reviewed by an Approved Specialist on an annual basis;

- is aged 18 years or older without a listed comorbidity (see Section 3.5.2) must have been reviewed by an Approved Specialist within the last 3 years.

3.6 Authorisation from the CEO to prescribe required

Where prescribing is not in accordance with Section 3.5, written authorisation of the CEO is required prior to prescribing an S8 stimulant medication.

The CEO may refer applications to the Stimulant Assessment Panel for clinical advice.

3.6.1 Applying for authorisation

Where authorisation to prescribe S8 stimulant medication is required an Approved Specialist must apply to the CEO for authorisation. The application must be on the approved form, which must be completed in full and be accompanied by supporting documentation as outlined on the form.

3.6.2 Standard conditions of an authorisation from the CEO

Authorisations are specific for the medicine(s), form(s), and maximum dose requested. Treatment may not be varied without authority and all prescribing must match the approved therapy. Where it is clinically necessary to vary treatment, a new application for authorisation is necessary.

Ordinarily, authorisation will only be granted to one prescriber at a time, the applying Approved Specialist. Applications requesting authorisation of an additional prescriber who is involved in a collaborative care arrangement, will be considered on a case-by-case basis.

Where a new stimulant authorisation is requested and granted, all prior stimulant authorisations are cancelled. The Department will notify the previously authorised prescriber.

Where an authorisation is in place, other prescribers may not prescribe S8 stimulant medicines, irrespective of the type of practitioner, patient, or stimulant medicine.

3.7 Notification requirements for ceasing an S8 stimulant medicine

Where an S8 stimulant medicine is being ceased because of one or more of the following reasons, prescribers must notify the CEO in writing:

- the patient experienced stimulant induced psychosis;
- the patient developed drug dependence, substance abuse, diversion, or misuse of an S8 stimulant medication; or
- the patient has been oversupplied S8 stimulant medication (see Section 1.5.1).

3.7.1 How to notify

For each patient a notification must be made on the approved form and include the following information:

- prescriber details: name, practice address, and contact number;
- patient details: name, address, and date of birth;
- diagnosis for which the S8 stimulant was being prescribed;
- relevant comorbidities;
- stimulant medicine(s), strength, formulation, and daily dose; and
- reason for terminating stimulant treatment.

The notifying prescriber must also inform any prescribers they have a shared care arrangement with.

3.8 Custodial settings and hospital exemption

A medical or nurse practitioner, who is not an Approved Specialist, may prescribe continuing S8 stimulant medication for a person in custody or while an inpatient in hospital provided:

- the S8 stimulant medication was

    - initiated by an Approved Specialist for the purpose of treating an Approved Diagnoses (Table 3) prior to admission; or
    - being prescribed in compliance with an authorisation issued by the CEO prior to admission;
- the patient is under ongoing treatment with the S8 stimulant
- the prescribing (including medication name, formulation, and dose) is consistent with the Approved Specialist's written instructions or the latest prescription on ScriptCheckWA for the S8 stimulant medicine;
- the practitioner is satisfied it is safe to prescribe stimulants; and
- treatment is for no more than three months.

The Approved Specialist prescriber should be contacted prior to a change in dose or where the medicine has been ceased due to adverse events.

Outside these conditions written authorisation of the CEO is required prior to prescribing.

3.9 Summary of when authorisation from the CEO is and is not required

Figure 5 (on the next page) summarises when authorisation from the CEO to prescribe an S8 stimulant medicine is and is not required.

If the Prescriber criteria **and/or any** of the Patient, Product, **or** Review criteria are **not** met,
written authorisation of the CEO is required before prescribing.

If the Prescriber criteria **and** all the Patient, Product, **and** Review criteria are **met**,
a practitioner may prescribe an S8 medicine, as specified in Part 3, **without authorisation of the CEO**.

Prescriber criteria (see 3.5.1)

*To be able to prescribe without authorisation, the prescriber must meet and comply with **one** of these*

The prescriber is a:

- ❑ Approved Specialist prescribing an S8 stimulant medicine for an Approved Diagnosis as set out in Table 3;
  OR
- ❑ medical practitioner or nurse practitioner prescribing **continuing** S8 stimulant medication under a Shared Care Model in compliance with the provisions set out in **Section 3.5.1**

AND

Patient criteria (see 3.5.2)

*To be able to prescribe without authorisation, the patient/situation must meet **all** of these*

- ❑ The S8 stimulant is being prescribed to a patient to treat an Approved Diagnoses listed in Table 3;
  AND

The patient

- ❑ is either prescribed lisdexamfetamine and is 6 years-of-age or older **OR** prescribed dexamfetamine or methylphenidate and is 4 years-of-age or older;
  AND
- ❑ has no history of psychosis (including stimulant induced psychosis, see Section 1.6) or bipolar disorder
  AND
- ❑ has no history of substance abuse, diversion, or misuse of drugs of addiction or Schedule 9 poisons within the previous five years;
  AND
- ❑ has no record of Drug Dependence or Oversupply (see Section 1.5.1);
  AND
- ❑ is not a current CPOP patient.

AND

Product criteria (see 3.5.3)

To prescribe without authorisation, prescribed stimulants must meet this

- ❑ The dose of S8 stimulant medicine(s) prescribed is/are under the dose limit outlined in **Section 3.5.3**

AND

Frequency of review (see 3.5.4)

*To prescribe without authorisation, prescribed stimulants must **one** of these*

- ❑ The patient is under the age of 18 years **and/or** has a listed comorbidity (see Section 3.5.2) **and** has been seen by an Approved Specialist in the **past year;**
  OR
- ❑ The patient is 18 years or older **without** a listed comorbidity (see Section 3.5.2) and has been seen by an Approved Specialist in the **past 3 years**

Figure 5: Summary of when authorisation from the CEO is and is not required for S8 stimulant medicines

Part 4: Medicinal cannabis products

4.1 Overview

Part 4 outlines the prescribing conditions and requirements for S8 medicinal cannabis products, including:

- when prescribers may prescribe them without authorisation of the CEO;
- when prescribers require written authorisation from the CEO before prescribing them.

It also details how to apply for authorisation from the CEO.

4.2 Scope

Part 4 applies to medicinal cannabis products in S8, which include all formulations of:

- cannabis;
- dronabinol;
- nabilone;
- nabiximols;
- tetrahydrocannabinols (THC); and
- any other synthetically or botanically derived cannabinoids included in S8.

4.2.1 Hospital Exemptions

Part 4 does not apply to:

- the administration of a medicinal cannabis product for an inpatient in a hospital; **or**
- prescribing of a 14-day supply of medicinal cannabis product from emergency departments or on discharge from hospital where
    - the treatment with S8 medicines is associated with that episode of care; **and**
    - the patient is not recorded as Drug Dependent and/or Oversupplied.

4.3 Authority

Part 4 is issued under the provisions of Medicines and Poisons Regulations 2016, Part 11, Division 2

4.4 General conditions for the prescribing of medicinal cannabis products

All prescribing must conform to the criteria and conditions outlined in Part 1 and Part 4 of this Code.

Prescriptions for S8 medicinal cannabis products must be written for a specific product. Category authorisations are issued by both TGA and the CEO of health; however, prescribing by broad category is not permitted under Regulation 10. Where multiple products are prescribed, prescribers must be aware of the total dose of THC and ensure directions and / or repeat intervals support patients accessing the intended dose.

In line with the TGA[25] guidance, prior to prescribing an unapproved medicinal cannabis product, approved medicines should have been adequately trialled, or deemed inappropriate, for the relevant condition and found to be either not suitable or not adequately effective.

The Commonwealth Department of Health and Aged Care, together with state and territory governments, have developed a series of clinical guidance documents relating to the prescribing of medicinal cannabis. These, along with reviews of clinical evidence, are available on the TGA website.[26]

[25] Australian Government. Department of Health and Aged Care Therapeutics Goods Administration. Guidance for the use of medicinal cannabis in Australia: Patient information [2017]. https://www.tga.gov.au/resources/resource/guidance/guidance-use-medicinal-cannabis-australia-patient-information

[26] Australian Government Department of Health and Aged Care Therapeutics Goods Administration. Medicinal Cannabis-guidance documents [2023]. https://www.tga.gov.au/medicinal-cannabis-guidance-documents

Medicinal cannabis products must meet all criteria for inclusion in S8 of the Poisons Standard, specifically:

- products manufactured in accordance with the *Narcotic Drugs Act 1967*; or
- therapeutic goods imported and supplied in accordance with the *Therapeutic Goods Act 1989.*

A prescription for a medicinal cannabis product only authorises the supply of that product as an S8 product by a pharmacist in accordance with the Medicines and Poisons Regulations 2016 and does not authorise any other activity.

This Code cannot be applied to any product that is not lawfully sourced or is included in S9. This Code does not apply to research conducted using cannabis or any cannabis related substance in S9 of the Poisons Standard.

4.4.1 Medicinal cannabis products not registered on the ARTG

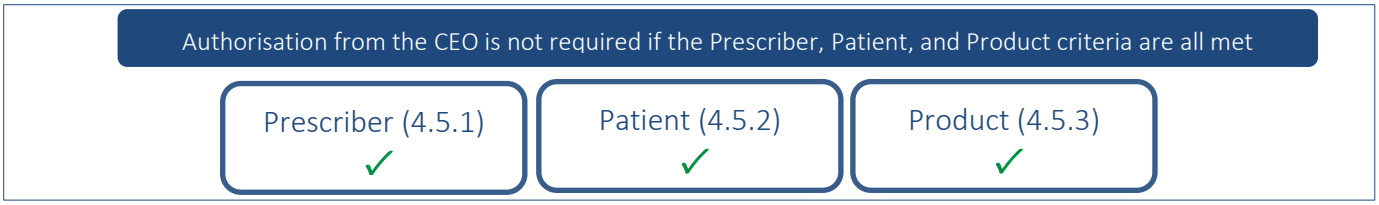
To prescribe an unapproved medicinal cannabis product (a product not registered on the ARTG), the prescriber will need to follow one of the TGA pathways for approval to supply the medicinal cannabis product, through the Special Access Scheme (SAS) or Authorised Prescriber Scheme. They must also adhere to the criteria and conditions set out in Part 1 and Part 4 of this Code.

4.4.2 Medicinal cannabis products registered on the ARTG

To prescribe a medicinal cannabis product registered on the ARTG, the prescriber must adhere to the criteria and conditions set out in Part 1 and Part 4 of this Code.

4.5 Eligibility to prescribe without authorisation from the CEO

If the Prescriber criteria **and all** of the Patient **and** Product criteria set out in Section 4.5 are **met**, a practitioner may prescribe a medicinal cannabis product, as specified, without authorisation of the CEO.



If the Prescriber criteria **and/or any** of the Patient **or** Product criteria are **not** met, written authorisation from the CEO is required before prescribing (for process see Section 4.6).

4.5.1 Prescriber criteria

Provided their professional registration does not have conditions or undertakings relevant to the prescribing of S8 medicines, practitioners meeting Prescriber criteria i, ii, or, iii may prescribe an S8 medicinal cannabis product without the authorisation of the CEO.

i. TGA Authorised Prescriber

When prescribing is in accordance with Section 4.5, a TGA Authorised Prescriber may prescribe medicinal cannabis products in accordance with their Human Research Ethics Committee (HREC) approval or in line with the products on the established history of use list.

In Part 4, the term ‘TGA Authorised Prescriber’ is used to refer to a medical practitioner with a current authority as an ‘Authorised Prescriber’ for medicinal cannabis products, under Commonwealth legislation, granted by the TGA.

ii. Medical or nurse practitioner prescribing through the SAS

When prescribing is in accordance with Section 4.5, medical practitioners and nurse practitioners accessing medicinal cannabis products through the TGA's SAS may prescribe medicinal cannabis products in accordance with their SAS notification/approved application.

iii. Medical practitioner or nurse practitioner prescribing a product on the ARTG

When prescribing is in accordance with the Product Information and with Section 4.5, a medical practitioner or nurse practitioner can prescribe a medicinal cannabis product on the ARTG.

4.5.2 Patient criteria

i. Age

The patient is 18 years-of-age or older.

iii. Diagnosis

The medicinal cannabis product is being prescribed to a patient for the purpose of treating a diagnosis consistent with the:

- ARTG approved indication of a product (e.g., Multiple Sclerosis);
- treatment indications specified on the prescriber's approval as an TGA Authorised Prescriber; or
- treatment indications specified on the prescriber's SAS notification/approved application.

iii. Comorbidity

The patient:

- does not have a history of psychosis (including stimulant induced psychosis, see Section 1.6) or bipolar disorder;
- does not have a history of substance abuse, diversion, or misuse of drugs of addiction or S9 poisons within the previous five years;
- does not have a record of Oversupply or Drug Dependence (see Section 1.5.1); or
- is not a current CPOP participant.

Where a prescriber subsequently becomes aware of a relevant history for a patient, medicinal cannabis product treatment is to be reviewed. If continuation of medicinal cannabis product treatment is desired, then authorisation to prescribe is required from the CEO.

4.5.3 Product criteria

i. Dose limit

Doses should be safely titrated to individual patient factors and need.

For sole and combined therapy, prescribed doses must not exceed the maximum daily dose of

- 40 mg of THC per day orally across all Categories; and
- 300 mg of THC per day across all products for inhalation/vaporisation.

Figure 6 provides an example to support dose calculation for vaporised products. The Department may be contacted for further advice or support in dose calculation.

To calculate the daily dose of THC:

1. Determine the amount of THC in the product using the Product Information.
2. Calculate daily dose of THC content using the concentration or percentage THC in the product.

Example:

Where the dose prescribed is 1 g per day of a vaporisation product THC25 (25%, THC, < 1% CBD) product:

1. *The amount of THC in this product is 25%*
2. *THC content in 1 g dose*

= 25% of 1 g
= 0.25 g THC
= 250 mg THC

*Therefore, the prescribed daily dose of THC in this example is **250 mg per day**.*

Figure 6: How to calculate the daily dose of THC

4.6 Authorisation from the CEO to prescribe required

Where prescribing is not in accordance with Section 4.5, written authorisation of the CEO is required prior to prescribing an S8 medicinal cannabis product.

4.6.1 Applying for authorisation

Where authorisation to prescribe an S8 medicinal cannabis product is required and a Category B SAS approval to prescribe is **not** required from the TGA, the prescriber must be a TGA Authorised Prescriber and must apply to the CEO for authorisation. The application must be on the approved form, which must be completed in full and be accompanied by supporting documentation as outlined on the form.

Where authorisation to prescribe an S8 medicinal cannabis product is required from the CEO and a Category B SAS approval to prescribe **is** required from the TGA, this can be done through the cannabis TGA SAS Dashboard by checking the box related to the requirement for state or territory health department applications. The application must be on the approved form, which must be completed in full, and be accompanied by supporting documentation as outlined on the form.

The applicant must obtain the patient's (or carer's) consent to allow the provision of information contained in the application to the TGA and/or the CEO, for the purposes of administering their respective legislative obligations, and for the CEO to share information with the TGA relating to the prescribing of a medicinal cannabis product to that patient, for the purposes of communicating a decision to the applicant.

4.6.2 Relevant Specialists

Applications to the CEO for authorisation either need to be submitted by, or the proposed treatment regimen supported by, a medical practitioner who holds specialist registration on the AHPRA register of practitioners in a Speciality, or Speciality Field, relevant to the diagnosed condition the S8 is being prescribed for. For example, a medical practitioner who holds specialist registration on the AHPRA register of practitioners in the Speciality of 'Psychiatry' would be considered a Relevant Specialist for the purpose of treating anxiety.

TGA Authorised Prescribers approved under a HREC program may apply to the CEO for authorisation of doses up to and including the doses recommended by the HREC, with their approved protocols or guidelines as support. Applications will be considered on a case-by-case basis.

Exemptions to the requirement for specialist support for patients with a terminal illness are detailed in Section 4.6.3.

4.6.2.1 Relevant Specialist support

Where specialist support is required, it must be in writing, be current, and agree with the proposed medicinal cannabis product regimen requested on the application. Specialist opinion is valid for a maximum period of three years, after which a review and renewed support is required. In certain circumstances, the CEO may require endorsement from a specific specialist class (for example pain specialist).

Where treatment will require specialist support, prescribers should organise specialist review in advance. This includes patients already established on medicinal cannabis product treatment, who may require dose increases or treatment modification that will require authorisation from the CEO.

Where there are conflicting specialist opinions, the CEO may request that a patient is referred for further opinion or multidisciplinary review, as necessary, to inform any decision.

4.6.3 Terminal illness exemption to specialist support

Where treatment of a patient with terminal illness requires authorisation due to the total daily dose exceeding the dose limit outlined in Section 4.5.3, practitioners may supply clinical documentation confirming life expectancy of less than 12 months, in lieu of specialist support for a specific medicinal cannabis product regimen.

Authorisations may be issued to support dose titration and flexible dosing when required.

Prescribing practitioners from the same practice or team (for example Silver Chain) who meet the Prescriber criteria (see Section 4.5.1) and any TGA requirements can apply for group authorisation in the group to allow all palliative care prescribers in the group to prescribe for a patient that is terminally ill.

4.6.4 Standard conditions of an authorisation from the CEO

Authorisations are specific for the medicine(s), form(s) and dose(s) requested. Treatment may not be varied without authority and all prescribing must match the approved therapy. Where it is necessary to vary the product or nature of treatment or a new SAS Category B approval is required, a new application for authorisation is required.

Authorisation will only be granted to one prescriber at a time. Where a new authorisation is requested and granted, all prior authorisations are cancelled. The Department will notify any previously authorised prescriber.

An authorisation granted for an individual patient will ordinarily extend to other practitioners meeting the Prescriber criteria (see Section 4.5.1) and any TGA requirements at that same place of practice, unless otherwise indicated. Other practitioners meeting the Prescriber criteria (see Section 4.5.1) at the same place of practice may prescribe, in cases of emergency or absence of the authorised practitioner, in accordance with the conditions of the authorisation.

Where an authorisation is in place, except as outlined above, other prescribers may not prescribe medicinal cannabis products, irrespective of the type of practitioner, patient, or medicinal cannabis product.

4.7 Summary of when authorisation from the CEO is and is not required

Figure 7 summarises when authorisation from the CEO to prescribe an S8 medicinal cannabis product is and is not required.

If the Prescriber criteria **and/or any** of the Patient **or** Product criteria are **not** met,
written authorisation of the CEO is required before prescribing.

If the Prescriber criteria **and** all the Patient **and** Product criteria are **met**,
a practitioner may prescribe an S8 medicine, as specified in Part 4, **without authorisation of the CEO**

Prescriber criteria (see 4.5.1)

*To be able to prescribe without authorisation, the prescriber must meet and comply with **one** of these*

The prescriber is a:

- ❑ TGA Authorised Prescriber prescribing medicinal cannabis products in accordance with their Human Research Ethics Committee (HREC) approval **or** in line with the products on the established history of use list ;

  OR
- ❑ medical practitioner or nurse practitioner accessing medicinal cannabis products through the SAS prescribing medicinal cannabis products in accordance with their SAS notification/approved application;

  OR
- ❑ medical practitioner or nurse practitioner prescribing a medicinal cannabis product on the ARTG in accordance with the Product Information.

AND

Patient criteria (see 4.5.2)

To be able to prescribe without authorisation, the patient/situation must meet the following conditions

The S8 medicinal cannabis product is being prescribed to a patient to treat a diagnosis consistent with either the:

- ❑ ARTG approved indication of a product (e.g., Multiple Sclerosis); **OR**
- ❑ treatment indications specified on the prescriber's approval as an TGA Authorised Prescriber; **OR**
- ❑ treatment indications specified on the prescriber's SAS notification/approved application.

AND

The patient

- ❑ is 18 years-of-age or older;

AND

- ❑ has no history of psychosis (including stimulant induced psychosis, see Section 1.6) or bipolar disorder;

AND

- ❑ has no history of substance abuse, diversion, or misuse of drugs of addiction or Schedule 9 poisons within the previous five years;

AND

- ❑ has no record of Drug Dependence or Oversupply (see Section 1.5.1);

AND

- ❑ is not a current CPOP patient.

AND

Product criteria (see 4.5.3)

*To be able to prescribe without authorisation, the prescribed S8 opioid product(s) must meet **all** of these*

The total daily prescribed dose of S8 medicinal cannabis products in any combination **does not exceed:**

- ❑ 40 mg of THC per day orally across all Categories;

AND

- ❑ 300 mg of THC per day across all products for inhalation/vaporisation

Figure 7: Summary of when authorisation from the CEO is and is not required for S8 medicinal cannabis products

Part 5: Esketamine, MDMA, and psilocybine

5.1 Overview

Part 5 outlines the prescribing conditions and requirements for esketamine, including:

- when prescribers may prescribe it without authorisation of the CEO;
- when prescribers require written authorisation from the CEO before prescribing it.

It also details how to apply for authorisation from the CEO.

Part 5 also outlines the method of application and requirements to be met when applying for authorisation to prescribe MDMA [*N, α* -dimethyl-3,4-(methylenedioxy) phenylethylamine] and psilocybine, which are listed as S8 medicines for specific uses only (post-traumatic stress disorder [PTSD] and treatment-resistant depression [TRD], respectively).

5.2 Scope

Part 5 applies to all formulations of esketamine. Part 5 also applies to all formulations of MDMA and psilocybine where being prescribed for the purposes of treating PTSD and TRD respectively.

Part 5 does not apply to MDMA or psilocybine for any other purposes or uses. For all other purposes, MDMA and psilocybine are a Schedule 9 substance.

5.3 Authority

Part 5 is issued under the provisions of Medicines and Poisons Regulations 2016, Part 11, Division 2.

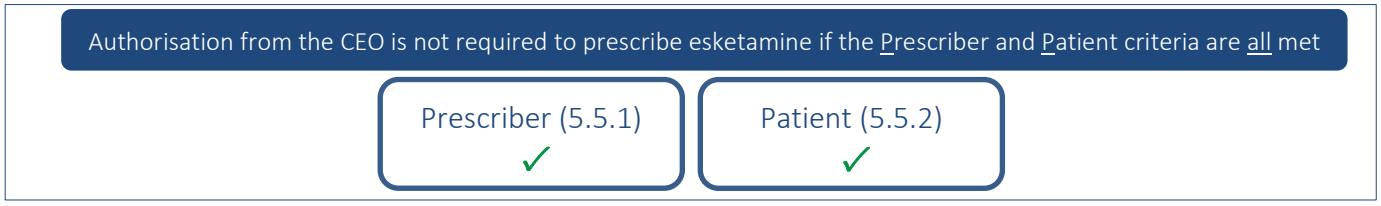
5.4 General conditions for prescribing Esketamine, MDMA, and psilocybine

All prescribing must conform to the criteria and conditions outlined within Part 1 and Part 5 of this Code.

Esketamine, MDMA, and psilocybine must be administered in a clinic by an authorised health professional.

5.5 Eligibility to prescribe esketamine without authorisation from the CEO

Esketamine for TRD is restricted by the Australian sponsor to psychiatrists treating patients in particular clinics. If **all** the Prescriber criteria **and** Patient Criteria outlined in Section 5.5 are **met**, a practitioner may prescribe esketamine, as specified, without authorisation of the CEO.



If the Prescriber criteria **and/or any** of the Patient criteria are **not** met, written authorisation from the CEO is required before prescribing (for process, see Section 5.6).

MDMA and psilocybine **always require written authorisation** from the CEO prior to prescribing (see 5.6).

5.5.1 Prescriber criteria

A medical practitioner who holds specialist registration on the AHPRA register of practitioners in the Speciality of 'Psychiatry', is eligible to prescribe esketamine without authorisation of the CEO if:

- their professional registration does not have conditions or undertakings relevant to the prescribing of S8 medicines;

- the prescriber and clinic is sourcing from a community pharmacy by prescription (for each patient) and the dispensed product is delivered to the clinic address (prescriptions must be endorsed with supply to the clinic only); and
- they are prescribing in accordance with the Patient criteria outlined in Section 5.5.2.

5.5.2 Patient criteria

i. Age criteria

The patient is 18-years-age or older.

ii. Diagnosis criteria

Esketamine is being prescribed for the purposes of treating TRD.

iii. Co-morbidity

The patient:

- does not have a history of substance abuse, diversion, or misuse of drugs of addiction or Schedule 9 poisons within the previous five years;
- does not have a record of Drug Dependence or Oversupply (see Section 1.5.1); and
- is not a current CPOP (opioid pharmacotherapy) patient.

5.6 Authorisation from the CEO to prescribe a Part 5 S8 required

As there are no products on the ARTG, written authorisation of the CEO is required before prescribing or administering S8 MDMA or psilocybine.

Where prescribing of esketamine is not in accordance with Section 5.5, written authorisation of the CEO is required before prescribing.

5.6.1 Applying for authorisation

Applications must be on the approved form, which must be completed in full and, where required, be accompanied by supporting documentation as specified on the form.

5.6.1.1 Applying to prescribe esketamine

Where authorisation of the CEO is required to prescribe esketamine, applications need to be submitted by a medical practitioner who holds specialist registration on the AHPRA register of practitioners in the Speciality of 'Psychiatry'.

5.6.1.2 Applying to prescribe MDMA or psilocybine

Applications for authorisation of the CEO to prescribe and administer MDMA or psilocybine, must be submitted by a medical practitioner who:

- holds specialist registration on the AHPRA register of practitioners in the Speciality of 'Psychiatry' **and** is approved as an Authorised Prescriber of the product by the TGA[27]; **or**
- is prescribing MDMA or psilocybine, for the indications specified in the Poisons Standard, within clinical trials that have been approved by or notified to the TGA.

5.6.2 Standard conditions of an authorisation from the CEO

Authorisations are specific for the medicine(s), form(s) and dose(s) requested. Treatment may not be varied without authority and all prescribing must be consistent with the details of the authorisation. Where it is clinically necessary to vary treatment, a new application for authorisation is required.

Authorisation for a drug group (e.g., esketamine, MDMA, or psilocybine), will only be granted to one prescriber at a time. Where a new authorisation is granted for a particular drug group, all prior

[27] Australian Government Department of Health and Aged Care Therapeutics Goods Administration. MDMA and psilocybin hub [2023]. https://www.tga.gov.au/products/unapproved-therapeutic-goods/mdma-and-psilocybin-hub

authorisations issued for that drug group will be cancelled. The Department will notify the previously authorised prescriber or practice.

Where an authorisation is in place for a drug group, other prescribers may not prescribe medicines from that drug group, irrespective of the type of practitioner, patient, or medicine.

Part 6: S8 benzodiazepines, sodium oxybate, and all other S8s not captured elsewhere in this Code

6.1 Overview

Part 6 outlines the method of application and requirements to be met when applying for authorisation to prescribe S8 benzodiazepines, sodium oxybate, and all other S8s not captured elsewhere in this Code.

6.2 Scope

Part 6 applies to all formulations of S8 benzodiazepines (alprazolam and flunitrazepam), sodium oxybate, and any other S8 medicine not covered in other Parts of this Code.

Part 6 does not apply to:

- the administration of the above S8 medicines to an inpatient in hospital; or
- the prescribing of a 14-day supply of the above S8 medicines from emergency departments or on discharge from hospital where
    - the treatment with the S8 medicine is associated with that episode of care; and
    - the patient is not recorded as Drug Dependent or Oversupplied.
- S8
    - Opioids and ketamine (see Part 2 of this Code);
    - Stimulant medications (see Part 3 of this Code);
    - Medicinal cannabis products (see Part 4 of this Code);
    - Esketamine, MDMA, and psilocybine (see Part 5 of this Code);
    - Opioid pharmacotherapy (see Part 7 of this Code).

6.3 Authority

Part 6 is issued under the provisions of Medicines and Poisons Regulations 2016, Part 11, Division 2.

6.4 General conditions for prescribing S8 benzodiazepines, Sodium Oxybate and all other S8s not captured elsewhere in this code

All prescribing must conform to the criteria and conditions outlined within Part 1 and Part 6 of this Code.

6.5 Authorisation from the CEO to prescribe required

Written authorisation of the CEO is **always** required before prescribing S8 benzodiazepines, sodium oxybate, and any other S8 medicines not captured elsewhere in this code.

6.5.1 Applying for authorisation

Applications for authorisation must be on the approved form, which must be completed in full and, where required, be accompanied by appropriate supporting documentation (such as support from a Relevant Specialist, see 6.5.2).

6.5.2 Relevant Specialists

Applications for authorisation either need to be submitted by, or the proposed treatment regimen supported by, a medical practitioner who holds specialist registration on the AHPRA register of practitioners in a Speciality, or Speciality Field, relevant to the diagnosed condition the S8 medicine is being prescribed for. For example, a medical practitioner who holds specialist registration on the AHPRA register of practitioners in the Speciality of ‘Psychiatry’ would be considered a Relevant Specialist for the purpose of treating anxiety with alprazolam. Applications will be considered on a case-by-case basis.

If required, specialists should apply and name a general practitioner or nurse practitioner as a co-prescriber at the time of the first prescription. If a co-prescriber is nominated, specialists should provide written advice to the co-prescriber within 30 days, specifying each S8 medicine supported, including dose and frequency, and a management plan.

6.5.2.1 Relevant Specialist support

Where specialist support is required, it must be in writing, be current, and agree with the proposed S8 regimen requested on the application. Specialist opinion is valid for a maximum period of three years, after which a review and renewed support is required. In certain circumstances, the CEO may require endorsement from a specific specialist class (for example psychiatrist).

Where treatment will require specialist support, prescribers should organise specialist review in advance. This includes patients already established on S8 treatment, who may require dose increases or treatment modification that will require authorisation from the CEO.

Where there are conflicting specialist opinions, the CEO may request that a patient is referred for further opinion or multidisciplinary review, as necessary, to inform any decision.

A recent hospital discharge summary (no more than three months old) may qualify as specialist support. This will be valid for a period of three months from the application date, after which time independent specialist review is required. Prescribers are strongly advised to validate patient claims made on outdated or unfamiliar hospital discharge summaries.

6.5.3 Standard conditions of an authorisation from the CEO

Authorisations granted are issued to a named prescriber at their practice address. An authorisation allows other prescribers at the same place of practice to prescribe in accordance with the conditions of the authorisation.

Where a new authorisation is granted for a particular drug group (e.g., benzodiazepine or sodium oxybate), all prior authorisations issued for that drug group under Part 6 of the Code will be cancelled. The Department will notify the previously authorised prescriber or practice.

Authorisations are specific for the medicine(s), form(s) and dose(s) requested. Treatment may not be varied without authority and all prescribing must be consistent with the details of the authorisation. Where it is clinically necessary to vary treatment, a new application for authorisation is required.

PART 7: Opioid pharmacotherapy

7.1 Overview

Part 7 outlines when S8 medicines, as pharmacotherapy, may be prescribed and administered to a patient for the purposes of treating opioid dependence. It details how to apply for authorisation to prescribe pharmacotherapy for opioid dependence and administer opioid pharmacotherapy for detoxification.

It also details general conditions and requirements for the prescribing and administration of pharmacotherapy for opioid dependence.

7.2 Scope

This Part applies to methadone and buprenorphine, in any formulation approved for the treatment of opioid dependence (addiction).

It does not apply to the use of methadone and buprenorphine for the treatment of pain, which is contained in Part 2.

7.3 Authority

Part 7 is issued under provisions of the Medicines and Poisons Regulations 2016, Part 11, Division 5.

7.4 Opioid substitution therapy

A health practitioner cannot prescribe or administer an S8 medicine to a person for the treatment of dependence, without the prior permission of the CEO.

In WA, Opioid Substitution Therapy (OST) for the treatment of drug dependence is managed through the Community Program for Opioid Pharmacotherapy (CPOP) framework, established under the Medicines and Poisons Regulations 2016. S8 medicines can only be prescribed and dispensed to treat opioid dependence within the CPOP. Treatment must be by an authorised prescriber, from an authorised dispenser, and to an authorised patient.

Approved treatments in the CPOP include:

- methadone syrup/solution;
- Subutex® tablets;
- Suboxone® film;
- Buvidal® Depot injection; and
- Sublocade® Depot injection.

OST supplied under the CPOP is funded via the Commonwealth Section 100 Opiate Dependence Treatment Program. This program is open to those pharmacies approved by the WA Department of Health. Treatments funded under this program may not be used or supplied for other purposes.

Depot formulations must never be supplied directly to the patient. They must always be provided to the authorised health professional to administer.

7.4.1 Prescriber authorisation

7.4.1.1 Prescriber requirements

Registered medical practitioners and nurse practitioners (within their nominated scope of practice) are eligible to be authorised as CPOP prescribers. Professional registration must not have conditions or undertakings relevant to the prescribing of S8 medicines.

Practitioners must have first successfully completed the approved training and assessment package delivered by the Community Pharmacotherapy Program (CPP). A practitioner may be authorised to prescribe all formulations, or may be authorised for specific formulations only.

CPOP Prescriber accreditation is valid for a 3 year period. After this time, a re-accreditation process must be completed, involving participation in approved online professional development activities delivered by the CPP. Upon successful completion, prescribers may be reapproved for a further 3 years.

Prescribers who are prescribing and administering Buprenorphine Depot formulations must store the prescribed S8 medicine in a compliant safe. Alternatively, delivery must coincide with administration and any unused product must be promptly returned to the pharmacy if not administered.

7.4.1.2 Applying to become authorised as a CPOP Prescriber

Prescribers must apply for authorisation, in writing, using the approved form.

Prescribers must ordinarily be practising in WA. The CEO may recognise prescribers who are authorised in corresponding programs in other States or Territories. Authorisations to prescribe for individual patients issued to interstate prescribers will be:

- no more than one month in duration; and
- only issued for patients travelling within, or moving permanently to, WA.

To maintain authorisation, prescribers must treat a minimum of two CPOP clients annually. The CEO may request refresher training or relevant continuing development activities to maintain authorisation.

The CEO may amend, cancel, or suspend an authorisation, in writing, at any time. The CEO may apply conditions to any authorisation.

At any time, a prescriber may, request cancellation of their authorisation by writing to the CEO. In this case, active patients will need to be safely transferred to other prescribers.

7.4.1.3 Treatment limited to a maximum number of clients

Prescribers authorised for methadone and buprenorphine are limited to treatment of a standard maximum number of clients at any one time. This includes:

- sole metropolitan prescriber: 50 CPOP clients; or
- sole regional prescriber: 25 CPOP clients.

These client numbers may not be exceeded without written authorisation of the CEO. Applications to exceed the standard maximum client number, must be in writing and in the approved form.

7.4.1.4 Specialist Prescribers

A medical practitioner employed at the Next Step Drug and Alcohol Service may be authorised as a Specialist Prescriber. Specialist Prescribers may write interim prescriptions to continue therapy, without individual patient authorisation, provided:

- the patient is currently participating in CPOP;
- there is a current and valid authorisation;
- OST is prescribed in accordance with the details of the authorisation;
- the specialist is satisfied that it is not practical to obtain a prescription from the authorised prescriber; and
- the prescription is for no more than one month.

7.4.1.5 Co-prescribers

Upon application from a Specialist Prescriber, the CEO may appoint a medical practitioner to be a Co-prescriber, who is not an authorised CPOP prescriber, to prescribe OST provided:

- the Specialist Prescriber has a valid authorisation for the patient;
- the Co-prescriber has completed relevant training provided by CPP;
- OST is prescribed in accordance with the details of the authorisation; and
- prescriptions are for no more than 3 months supply.

7.4.1.6 Custodial settings and hospitals

A medical practitioner who is not an authorised CPOP prescriber may prescribe continuing OST for a person in custody or while an inpatient in hospital, provided:

- the patient is currently participating in CPOP;
- there is a current patient authorisation on admission;
- the OST is being prescribed in compliance with the details of the authorisation;
- the practitioner is satisfied it is safe to prescribe OST; and
- treatment is for no more than one month.

Outside these conditions authorisation is required.

For OST supplied in a hospital to an inpatient, refer to Section 7.6. Authorised health professionals are to refer to relevant hospital protocols for the management of CPOP patients in the hospital setting.

7.4.2 Pharmacy requirements

Authorised CPOP prescribers must nominate a pharmacy dosing site on all applications for authorisation.

Pharmacies must be authorised by the CEO to dispense and dose OST under the CPOP. Authorisation is limited to 50 patients receiving treatment when the pharmacy is accredited unless authorised by the CEO for increased patients.

To participate in the CPOP, pharmacists who are dispensing and/or administering CPOP treatment must complete pharmacist approved training provided by the CPP every three years.

If a dosing site is open less than 7 days per week, and the patient is not eligible for unsupervised dosing, the prescriber must make alternative arrangements to cover the days the pharmacy is not open.

7.4.3 Patient authorisation

OST may not be prescribed or dispensed for a person unless authorised by the CEO.

S8 and CPOP prescribing and dispensing history can be obtained by checking in ScriptCheckWA[28] or contacting the Department's S8 Prescriber Information Service.[29]

7.4.3.1 Record of drug dependence

A patient may only be authorised to receive OST for treatment of opioid dependence. It is a condition of authorisation that patients are recorded as Drug Dependent Persons.

7.4.3.2 Applying for patient authorisation

Patient applications must be in the approved form, completed in full, and include any clinical information required for a decision. Applications submitted by community CPOP prescribers are reviewed by the CPP prior to authorisation being considered by the CEO.

[28] ScriptCheckWA is Western Australia's Real Time Prescription Monitoring System; further information is available via: https://www.health.wa.gov.au/Articles/N_R/Prescription-monitoring-in-Western-Australia/About-ScriptCheckWA

[29] The S8 Prescriber Information Service is available 8.30 am to 4.30 pm Monday to Friday on 08 9222 4424.

Patient authorisation is generally issued for a maximum of five years duration. Different authorisation periods may be considered at the discretion of the CEO. The CEO may place specific conditions on an authorisation, or amend, cancel, or suspend any authorisation. Applications for Subutex® are ordinarily for 6 months when issued to enable low dose tapering for withdrawal from treatment.

Patient authorisation is specific to the authorised prescriber, the patient, and the type of OST. A new application is required whenever the following is altered:

- OST type – transfer to or from methadone, Suboxone®, Subutex®, or depot buprenorphine
- treating medical practice (including address); or
- patient details (e.g., name).

The Department will issue renewal reminders as a courtesy prior to the date of expiry. Where a time limited authorisation is approaching expiry, but treatment is to continue unchanged, a renewal form may be submitted, rather than a full application. A new application is required for any expired authorisation.

7.4.3.3 Authorised dose

The CEO will ordinarily authorise a person to receive up to a maximum dose of:

- 120 mg daily of methadone syrup/solution;
- 24 mg daily of buprenorphine sublingual as Subutex® or Suboxone®;
- 160 mg of Buprenorphine (Buvidal®) Depot per month; or
- 300 mg of buprenorphine (Sublocade®) Depot per month.

Buprenorphine may be dosed at longer daily intervals, where the standard maximum authorised dose is 32 mg every second or third day. Higher doses require application using the approved excess dose form. Applications must be reviewed by the CPOP Clinical Review Committee prior to authorisation being considered by the CEO. Specific conditions may be applied, such as ECG monitoring for high dose methadone.

Commencement doses of OST must not exceed those recommended in the current CPOP Clinical Policies and Procedures: *Clinical Policies and Procedures for the Use of Methadone and Buprenorphine in the Treatment of Opioid Dependence*[30] and the *Clinical Guidelines for use of depot buprenorphine (Buvidal and Sublocade) in the treatment of opioid dependence (CPOP Clinical Policies and Procedures)*[31],.

On the grounds of patient safety, or the recommendation of the CPOP Clinical Review Committee, the CEO may instruct that higher doses are not to be used, or specific conditions are to be met, prior to approval.

7.4.3.4 Subutex®

Subutex® is ordinarily only authorised in conditions where Suboxone® is not clinically appropriate including:

- low dose (6 mg or less) for a duration of less than 6 months for withdrawal; or
- significant adverse reaction to Suboxone®.

A copy of the submitted TGA Blue Card Adverse Reaction Reporting form must be supplied in the case of adverse reaction.

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[30] Community Pharmacotherapy Program. Clinical Policies and Procedures for the Use of Methadone and Buprenorphine in the Treatment of Opioid Dependence. Community Pharmacotherapy Program [2014]. https://www.mhc.wa.gov.au/about-us/our-services/community-pharmacotherapy-program/

[31] Community Pharmacotherapy Program. Clinical Guidelines for use of depot buprenorphine (Buvidal and Sublocade) in the treatment of opioid dependence (CPOP Clinical Policies and Procedures) [2023]. https://www.mhc.wa.gov.au/about-us/our-services/community-pharmacotherapy-program/

7.4.3.5 Transferring between opioid substitution therapy agents

Patient authorisation is specific to the OST type specified in the authorisation. A new application is required if the OST agent is to be changed, such as from methadone to buprenorphine.

Transfer from high doses of methadone, of greater than 40 mg per day, to buprenorphine is not recommended.

7.4.3.6 Termination or variation of authorisation

The CEO may at any time, terminate an authorisation, request a new application, vary an authorisation, or modify conditions of an existing authorisation.

The issue of a patient CPOP authorisation cancels any existing opioid pharmacotherapy authorisations in place for that patient. The Department will notify the previous prescriber.

On issuing a CPOP authorisation for a patient who is already under treatment with S8 medicines, the CEO, at their discretion, may cancel existing authorisations and/or issue an instruction not to prescribe or supply to the patient.

A prescriber may terminate an authorisation by notifying the CEO, in writing. This may be done when a person exits the CPOP, is lost to follow up, or for any other reason.

7.4.4 Prescribing

All prescribing must conform to best treatment practices as outlined in the current CPOP Clinical Policies and Procedures. In addition to the elements referenced in Section 1.4 of this Code, CPOP prescriptions must include:

- name of nominated pharmacy dosing or supply site;
- start and end date of the prescription;
- daily dosing schedule;
- precise details of dose increases/decreases and minimum intervals;
- precise details of takeaway doses, if any; and
- HDWA authorisation number.

Depot buprenorphine prescriptions must also include:

- the name of the pharmacy administering the depot formulations or the medical practice the depot is to be supplied to; and
- planned date of administration and interval in which the injections are to be administered.

CPOP prescriptions are intended to authorise and instruct the CPOP pharmacy as to the specific daily dosing requirements of the patient. They must contain enough information so that the precise intentions of the prescriber are clear. This includes prescriptions generated using computer software.

Prescriptions are valid for the period specified and may contain a maximum of two repeats in line with the CPOP Clinical Policies and Procedures. After this period, a new prescription must be provided. A CPOP prescription should match the schedule of clinical review. Duration of prescriptions should be significantly reduced to safe lengths of time during client induction, dose changes, or dosing instability.

7.4.4.1 Take away and modified daily dosing

Prescribing of takeaway doses must comply with the schedules outlined in the current CPOP Clinical Policies and Procedures. Dosing outside the schedule requires written approval from the CPOP Clinical Review Committee. This may include patients that do not meet stability criteria, patients that do not meet the exclusion period criteria, or takeaway frequency in excess of the schedules. Prescribers must apply, in writing, in the approved form.

Prescribing modified daily dosing, such as for periods of interstate or overseas travel, requires written approval from the CPOP Clinical Review Committee. Prescribers must apply, in writing, using the approved form.

7.5 Detoxification therapy

For the purposes of this Code, opioid detoxification treatment is defined as the use of S8 pharmacotherapy during medically supervised withdrawal from opioids. The detoxification period must be short-term and limited to no more than 7 days for any single period.

Outside the CPOP, an opioid pharmacotherapy may be used for treating opioid dependence for the management of withdrawal from opioids. The CEO must be notified at the commencement of any opioid detoxification through completion of the approved form. Treatment must be by a detoxification prescriber (see 7.5.1.1) or under the direction of a detoxification prescriber. An authority to use an S8 medicine for detoxification is limited to methadone and buprenorphine formulations approved for the treatment of opioid dependence, as outlined in Section 7.2. Other S8 treatments for detoxification are not permitted under this Code.

7.5.1 Detoxification Prescriber authorisation

7.5.1.1 Eligible Prescribers of Detoxification Therapy

Provided their professional registration does not have conditions or undertakings relevant to the prescribing of S8 medicines, registered medical practitioners who are Next Step specialist prescribers or hold specialist registration on the AHPRA register of practitioners in one of the following Specialities are eligible to be authorised as detoxification therapy prescribers:

- Addiction Medicine
- Psychiatry.

Other specialists may be considered on a case-by-case basis depending on individual experience in management of acute opioid withdrawal.

Prescriber authorisation is valid until revoked or amended. The CEO may amend, cancel, or suspend an authorisation in writing, at any time. The CEO may apply conditions to any authorisation, including those that relate to the use of specific treatment protocols.

7.5.1.2 Applying to become an authorised prescriber

Eligible Prescribers (as outlined in 7.5.1.1), must apply for authorisation to become a detoxification prescriber using the approved form or, where relevant, submit a “Notification of the use of Suboxone(R) for the treatment of opioid withdrawal within approved detoxification sites” form for a patient to be treated with the approved buprenorphine protocol to the Department.

7.5.1.3 Detoxification site

Approved sites must be medical treatment facilities - a currently licensed private hospital, public hospital or equivalent. The facility must maintain premises, staffing, and equipment suitable for the treatment of opioid dependent persons.

The approved site may obtain and possess OST for detoxification under authority of a health service permit issued in accordance with the *Medicines and Poisons Act 2014*. Regulations for the storage and recording of S8 medicines apply in full, including keeping of an S8 Register of transactions.

7.5.1.4 Standard conditions

A patient may only be treated by one authorised detoxification prescriber at a time. OST must be administered at the detoxification site, under the personal direction of the authorised detoxification prescriber. All Regulations applying to record keeping and administration of S8 medicines apply in full, including making a record in the clinical notes of administration on each occasion OST is administered.

OST must be directly administered or observed by qualified health practitioners. Patients may not be supplied OST to self-administer at a later time, at a different facility, or outside the observation of a health practitioner.

During detoxification, a patient may not be prescribed, supplied, or administered any other S8 medicine, without the permission of the CEO. All reasonable steps must be taken to prevent patient access to other S8 medicines during this period. When detoxification commences, the authorised specialist must inform other S8 prescribers where known.

7.5.2 Patient notification

7.5.2.1 Notification of detoxification treatment

The treating prescriber must notify the CEO, on the approved form, when a person is treated with opioid pharmacotherapy for detoxification. Notification must occur prior to, or at the commencement of, treatment.

Notification of the intent to commence opioids for detoxification is considered a Report of Drug Dependence (as set out in Section 1.5.1 of this Code).

7.5.2.2 Approved protocol

Medical practitioners providing detoxification treatment are required to prescribe in accordance with the standard Next Step Drug and Alcohol Services buprenorphine (Suboxone®) protocol. Any prescriber who is not an authorised detoxification prescriber or not eligible to be one (as outlined in 7.5.1.1), must seek advice from a detoxification prescriber for each patient before commencing detoxification therapy.

If a different detoxification protocol is to be used, an Addiction medicine specialist or Next Step specialist prescriber must be consulted for advice and endorsement. The endorsed protocol must be forwarded to the Department.

7.5.2.3 Termination of authorisation or notification

On receipt of a notification of detoxification, at their discretion the CEO may , cancel any existing authorisations and/or issue an instruction not to prescribe or supply to the patient.

A prescriber may terminate an existing detoxification notification by notifying the CEO, in writing.

7.6 Opioid substitution therapy in hospitals

Patients who are admitted into hospital may require:

- continuation of OST if they are currently receiving OST;
- initiation of OST;
- management of opioid dependency or withdrawals.

7.6.1 Continuation of OST in hospitals

When a patient receiving opioid pharmacotherapy is admitted to hospital, if it is safe and clinically appropriate to do so, methadone or buprenorphine treatment should continue to be provided.

Continuation of previously authorised OST for inpatients in accordance with the Medicines and Poisons Regulations 2016 does not require the hospital-based prescriber to have any additional approval from the Department.

Dosing information must be established prior to administering the first dose of OST in hospital to avoid inappropriate ‘double dosing’ and the risk of overdose. This is done by contacting the

dispensing community CPOP pharmacy. Medicines Handling Policy[32] has published guidelines on the continuation of opioid substitution treatment in hospitals.[33]

7.6.2 Management of withdrawals

Patients who are hospitalised may develop signs and symptoms of acute opioid withdrawal during their inpatient admission, whereby use of Suboxone® as the preferred formulation for the treatment of opioid withdrawal may be warranted. Refer to Detoxification Therapy 7.5

7.6.3 Initiation of OST for hospital inpatients

Initiation of OST in a hospital setting must be by an authorised CPOP prescriber, who has completed the CPOP prescriber training provided by the CPP and been authorised by the Department to treat each individual patient. Note:

- Methadone treatment can only be initiatied by an Addiction Medicine Consultant employed within the hospital.
- Buprenorphine treatment may be initiated by an authorised CPOP prescriber within the hospital.

Where a patient is commenced on an opioid substitution treatment whilst in hospital, a CPOP Application to prescribe opioid substitution treatment, is to be submitted to CPP. The CPP team will review the proposed treatment plan before forwarding to the Department. Once approved by the Department, the authorisation number will be provided to the hospital prescriber by CPP, whereafter treatment can be commenced. The authorisation period will generally be six months, or at the discretion of the CEO.

7.6.4 Patient monitoring

All opioid medicines, including those used for OST, are considered to be 'high risk' medicines and clinical monitoring must therefore be consistent with the potential harmful effects of these medicines.

Even though methadone and buprenorphine are being administered for opioid pharmacotherapy rather than for pain management, the patient remains at risk of developing adverse effects. This includes respiratory depression and reduced level of consciousness, overdose and death.

Close monitoring for treatment affect and side effects is essential whilst the patient is in hospital.

7.6.5 Discharge

Hospital prescribers must not prescribe OST for CPOP patients upon discharge from hospital or supply takeaway doses upon transfer or at discharge.

At the end of any period of hospitalisation, the authorised prescriber, the authorised pharmacy and the CPP must be contacted to confirm treatment details to ensure safe transfer of care to the community.

Where a patient who is receiving OST requires discharge with other S8 medicines (such S8 opioids for the purposes of treating pain or S8 benzodiazepines), the treating medical practitioner must apply for, and receive, authorisation from the CEO before prescribing these medicines using the relevant approved form.

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[32] Government of Western Australia Department of Health. Medicines Handling Policy [2021]. https://www.health.wa.gov.au/About-us/Policy-frameworks/Public-Health/Mandatory-requirements/Medicines-and-Poisons-Management/Medicines-Handling-Policy

[33] Government of Western Australia Department of Health. Guideline on continuation of opioid substitution treatment in hospitals [2021]. https://www.health.wa.gov.au/~/media/Corp/Policy-Frameworks/Public-Health/Medicines-Handling-Policy/Supporting/Guideline-on-continuation-of-opioid-substitution-treatment-in-hospitals.pdf

Part 8: Schedule 4 Monitored Medicines

8.1 Overview

Part 8 outlines the requirements for prescribing and management of S4 Monitored Medicines. S4 Monitored Medicines are S4 reportable poisons as defined by Regulation 7A and listed in schedule 6 of the Medicines and Poisons Regulations 2016.

8.2 Scope

Part 8 applies to all formulations of S4 Monitored Medicines.

Part 8 does not apply to the:

- administration of S4 Monitored Medicines to an inpatient in hospital; or
- prescribing of a 14-day supply of S4 Monitored Medicines from emergency departments or on discharge from hospital.

8.3 Authority

Part 8 is issued under the provisions of Medicines and Poisons Regulations 2016, Part 11, Division 2.

8.4 General conditions for prescribing S4 Monitored Medicines

All prescribing must conform to the criteria and conditions outlined within Part 1 and Part 8 of this Code.

8.5 Risk Management approach to treatment with S4 Monitored Medicines

S4 Monitored Medicines by way of their scheduling are considered lower risk than S8 medicines.

Authorisation from the CEO is not required to prescribe S4 Monitored Medicines; however, specific circumstances require prescribers to carefully document a plan to mitigate potential harms associated with these medicines. As part of the assessment when commencing or continuing treatment, it is strongly recommended prescribers review the patient in ScriptCheckWA. ScriptCheckWA provides real time information that may assist in identifying when a risk mitigation plan is required.

A documented plan to mitigate potential harms must be included in the medical records for patients in the following cases:

- patient is recorded as a Drug Dependent Person or Oversupplied Person;
- patient is currently on OST through CPOP;
- patient is taking concurrent opioids with benzodiazepine medicines;
- patient is being prescribed monitored medicines by multiple prescribers;
- the condition being treated is not a ARTG indication for the product;
- the dose taken by the patient is above the recommended dose in the product information for the condition being treated.

Mitigation strategies may include:

- Viewing prescribing and dispensing history prior to prescribing Monitored Medicines
- staged supply or limited quantities;
- Treatment Contract;
- no early prescriptions;
- ensuring the dose is clear including a maximum daily dose on *prn* prescriptions;
- limiting supply from a single pharmacy;
- referring to drug and alcohol services for management of dependence.

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