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Australian Capital Territory

Medicines, Poisons and Therapeutic Goods Controlled Medicines Prescribing Standards 2023 (No 1)

Notifiable instrument – NI2023-495

made under the

Medicines, Poisons and Therapeutic Goods Regulation 2008, section 575 (Controlled medicines prescribing standards)

1 Name of instrument

This instrument is the *Medicines, Poisons and Therapeutic Goods Controlled Medicines Prescribing Standards 2023 (No 1).*

2 Commencement

This instrument commences on the day after its notification day.

3 Revocation

This instrument revokes the *Medicines, Poisons and Therapeutic Goods Controlled Medicines Prescribing Standards 2021 (No 1*) – NI2021-161.

4 Approval

In accordance with the *Medicines, Poisons and Therapeutic Goods Regulation 2008*, section 575 (Controlled medicines prescribing standards), the Chief Health Officer may determine circumstances in which category approval to prescribe a controlled medicine may be given. The Controlled Medicines Prescribing Standard determination is set out in Schedule 1.

Dr Kerryn Coleman

Chief Health Officer

9 August 2023

Controlled Medicines Prescribing Standards

These Controlled Medicines Prescribing Standards (Prescribing Standards) are made under the Medicines, Poisons and Therapeutic Goods Regulation 2008 for the purposes of establishing the conditions and criteria under which a prescriber may prescribe a controlled medicine under a Chief Health Officer (CHO) Category Approval or Approval by Drug.

These Prescribing Standards should be read in conjunction with the *Medicines, Poisons and Therapeutic Goods Act 2008* and the Medicines and Poisons and Therapeutic Goods Regulation 2008 (www.legislation.act.gov.au) to ensure prescribers are fully aware of their obligations for prescribing a controlled medicine and applying for CHO controlled medicines approval.

For further information regarding these prescribing standards please contact the Health Protection Service on 5124 9700 or at HPS@act.gov.au.

The Medicines, Poisons and Therapeutic Goods Regulation 2008 (the Regulation) requires prescribers to apply to the CHO for approval prior to prescribing a controlled medicine for a drug dependent person or for ongoing treatment, or treatment of longer than two months in the ACT.

A prescriber **does not** need to apply for Chief Health Officer (CHO) approval **if all** of the following are met:

- the prescriber believes on reasonable grounds that the person is **not a drug dependent person**;
- the prescriber believes on reasonable grounds that the person has not been prescribed **the same controlled medicines within the previous 2 months**; and
- the prescriber expects that the person will only need to use the prescribed controlled medicine for **less than 2 months**.

If any of the above criteria are **not met**, the prescriber **must apply** for CHO approval.

Prescribers can apply for either a Category Approval or Approval by Drug.

Category Approvals

A Category Approval authorises the prescribing of a medicine or medicines within a therapeutic class up to a maximum dose to treat a certain condition(s). A prescriber may request a Category Approval where they meet the eligibility criteria outlined in these Prescribing Standards.

Approvals by Drug

An Approval by Drug authorises the prescribing of a particular dose, form, strength and quantity of a medicine for a person's medical condition. A prescriber may request an Approval by Drug due to their preference, or when the requested treatment does not meet the requirements of a Category Approval.

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Contents

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Chapter 1 - Controlled medicine to treat a person with chronic (non-cancer) pain

CATEGORY 1 APPROVAL

Controlled medicine to treat a person with chronic (non-cancer) pain

Approval under this category allows a prescriber to prescribe a controlled medicine to a non-drug dependent person with chronic (non-cancer) pain, for a maximum of 12 months if:

- The person's total daily oral morphine equivalent dose (MEqD) [as measured in milligrams (mg)] of prescribed opioids is **equal to, or less than 100mg MEqD^**.

This category approval does not include:

- injectable opioid controlled medicines; or
- any methadone formulation; or
- fast acting fentanyl oral dose formulations.

Opioid Dose Equivalence

Calculation of oral Morphine Equivalent Daily Dose (oMEDD)

oMEDD (mg) = Current Opioid Dose x Conversion factor

Drug	Formulations	Conversion Ratio	MEqD 100mg (daily)
Morphine	oral mg/day	1:1	100mg
Hydromorphone	oral mg/day	1:5	20mg
Tapentadol	oral mg/day	1:0.3	333mg
Buprenorphine	transdermal mcg/hr	1:2	50mcg/hr
Fentanyl	transdermal mcg/hr	1:3	33mcg/hr
Oxycodone	oral mg/day	1:1.5	66mg
ADAPTED FROM THE FACULTY OF PAIN MEDICINE ANZCA, MARCH 2019			

~ *Source: http://fpm.anzca.edu.au/documents/opioid-dose-equivalence.pdf*

A MEqD calculator can be found on the Australian and New Zealand College of Anaesthetists Faculty of Pain Medicine website at http://www.opioidcalculator.com.au/index.html.

Other Information

This category approval is inclusive of any controlled medicine approval given by category or drug for chronic (non-cancer) pain. That is, this category approval will not be approved in addition to a separate approval for *controlled medicine by drug approval* to treat a person with chronic (non-cancer) pain.

This category approval permits more than one opioid controlled medicine being prescribed at a time and allows for opioid rotation and titration of dose, provided that the person's total dosage is equal to, or less than 100mg MEqD^.

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The CHO may ask for further information when considering this application, including but not limited to seeking evidence of appropriate specialist (that is, a pain or addiction specialist or addiction psychiatrist) support. The specialist review must have occurred within the previous 2 years.

When considering an application the CHO may choose to refuse, amend or place a condition on an application if the CHO believes that it is in the best interests of the patient or the public to do so.

^ 100mg MEqD has been selected based upon current best practice outlined in reference below:

- Royal Australian College of General Practitioners. (2015). *Prescribing drugs of dependence in general practice, Part A Clinical governance framework, D. 9 Practice Policy – Opioid dosing thresholds.* Retrieved from http://www.racgp.org.au/your-practice/guidelines/drugs-of-dependence-a/appendix-d-example-practice-policies/d9-practice-policy-%E2%80%93-opioid-dosing-thresholds/
- Faculty of Pain Medicine ANZCA. (2015). *Recommendations regarding the use of Opioid Analgesics in patients with chronic Non-Cancer Pain.* Retrieved from http://fpm.anzca.edu.au/documents/pm1-2010.pdf
- Currow, D.C., Phillips, J., Clark, K. (2016) Using opioids in general practice for chronic non-cancer pain: an overview of current evidence. *Medical Journal of Australia*, *204* (8): 305-309.

In addition, this opioid threshold is reasonably comparable to the 90mg MEqD limit contained within the Centre for Disease Control and Prevention. (2016). *CDC Guideline for Prescribing Opioids for Chronic Pain — United States, 2016.* Retrieved from https://www.cdc.gov/mmwr/volumes/71/rr/rr7103a1.htm?s_cid=rr7103a1.htm_w.

Recommendation

When the person's total daily dose is between **40 – 50mg MEqD**, the prescriber should consider additional precautionary measures. For example, the prescriber could consider referring the person to an appropriate specialist (that is, a pain or addiction specialist or addiction psychiatrist) for consultation. Other precautionary measures could also include staged supply arrangements and/or a Voluntary Undertaking .

Note: 40 – 50 mg MEqD has been selected based upon current best practice outlined in the Faculty of Pain Medicines ANZCA Recommendations regarding the use of Opioid Analgesics in persons with chronic Non-Cancer Pain which suggests caution at total daily doses > 40mg MEqD and the CDC Guideline for Prescribing Opioids for Chronic Pain — United States, 2016 which suggests a re-assessment of individual benefits and risks for total daily doses ≥ 50mg MEqD.

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APPROVAL BY DRUG

The below section describes circumstances where a **Category 1** approval will not be granted. Under these circumstances prescribers must apply for Approval by Drug. The CHO may issue a controlled medicine approval by drug for up to 12 months.

1. a person's total daily dose is **above 100mg MEqD**;

   Applications to prescribe opioids in doses greater than 100mg MEqD will not be approved unless made by, or include documented support from a pain or addiction specialist; geriatrician; or addiction psychiatrist.

   The need for support from a specialist mentioned above does not apply for applications submitted for any of following patient groups:

   a) In-patients of residential care facilities for all indications, for doses less than 300mg MEqD, where it is not practical for the prescriber to obtain a specialist review.
   b) Patients who are experiencing acute on chronic exacerbation(s) of pain. Approvals may be issued for up to 8 weeks, following which specialist support would be required if dose reduction was unsuccessful.
   c) Patients who have a comprehensive pain management plan in place and where the plan proposes to reduce the patient's use of opioids to below 100mg MEqD.

   Approvals may be issued for up to three months, following which support from a specialist mentioned above will be required if the dose reduction is unsuccessful. Subsequent approvals may be granted (up to a maximum of 6 months from commencement of a reduction plan) if dose reduction is successful but not yet less than 100mg MEqD.

2. treating a **drug dependant** person with chronic (non-cancer) pain; treating a non-drug dependent person for chronic (non-cancer) pain with any methadone formulation;

   Applications to prescribe opioids to a drug-dependent person will not be approved unless made by, or include documented support from a pain or addiction specialist; or addiction psychiatrist.

3. treating a non-drug dependent person for chronic (non-cancer) pain with fast acting fentanyl oral dose formulations;

   Applications to prescribe a fast acting fentanyl oral dose formulation will not be approved unless made by, or include documented support from a pain or addiction specialist; or addiction psychiatrist.

4. treating a non-drug dependent person for chronic (non-cancer) pain with injectable opioid controlled medicines;

   Applications to prescribe an injectable opioid controlled medicine will not be approved unless made by, or include documented support from a pain or addiction specialist; or addiction psychiatrist.

5. treating a person for intestinal conditions with codeine; or

   Applications to prescribe codeine for intestinal conditions may be approved up to doses of 240mg daily. Applications for higher doses will not be approved unless made by, or include documented support from a gastroenterologist.

6. treating an indication not listed on the Australian Register of Therapeutic Goods.
   Applications to prescribe a controlled medicine for an indication not listed on the Australian Register of Therapeutic Goods will not be approved unless a signed patient consent form is attached to acknowledge the treatment is for a non-licensed condition.

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Chapter 2 - Controlled medicine to treat a person with active malignancy or life limiting disease

CATEGORY 2 APPROVAL

Controlled medicine to treat a person with pain directly attributable to:

- **active malignancy or life limiting disease state; or**
- **considered on a case by case basis; and**
- **where the prognosis might reasonably be expected to be 12 months or less.**

Concurrent category 2 approvals are permitted for more than one practitioner (e.g. general practitioner and an appropriate specialist) to treat a person due to active malignancy or life limiting disease state.

CATEGORIES 2A and 2B

Categories 2A and **2B** are for any prescriber (other than a pain, addiction or palliative care specialist, oncologist, palliative care registrar, palliative care nurse practitioner or other specialist as considered appropriate).

Under a **Category 2A** or **2B** approval a prescriber may prescribe a controlled medicine to a non-drug (opioid) dependent person, for a maximum of 12 months if:

- **CATEGORY 2A** - The person's total daily oral morphine equivalent dose (MEqD) mg of prescribed opioids is equal to, or less than 160mg MEqD ◊ (including injectable controlled medicines and fast acting fentanyl oral dose formulations) and written confirmation of the patients' active malignancy or life limiting disease state is provided.
- **CATEGORY 2B** - The person's total daily oral MEqD of prescribed opioids is equal to, or less than 300mg MEqD ◊ (including injectable controlled medicines and fast acting oral dose formulation fentanyl) with appropriate specialist support^^^ (that is, a pain, addiction or palliative care specialist, oncologist, advanced training palliative care registrar, palliative care nurse practitioner or other specialist as considered appropriate) for the requested dosing regimen and written confirmation of the patients' active malignancy or life limiting disease state is provided.

CATEGORY 2C

Category 2C is for the following prescribers:

- pain, addiction or palliative care specialist;
- oncologists;
- general practitioners#;
- advanced training palliative care registrars;
- palliative care nurse practitioners; or
- other specialist as considered appropriate.

Approval under this category allows any of the above prescribers to prescribe a controlled opioid medicine (including injectable controlled medicines, methadone and fast acting oral dose formulation fentanyl) to a non-opioid dependent person, for a maximum of 12 months.

The prescriber must have formed the reasonable belief that a controlled medicine is needed to treat a person with pain directly attributable to active malignancy or life limiting disease state. The prescriber will need to provide written confirmation of the person's active malignancy or life limiting disease state, including any relevant details e.g. nature of malignancy or disease state.

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CATEGORY 2D

A **Category 2D** approval enables the treatment of drug (opioid) dependent patients by a prescriber in either Groups A or B as listed below.

Treatment@ of a patient who is opioid-dependent for active malignancy or life limiting disease should be undertaken collaboratively between practitioners of different disciplines:

- Active malignancy or life limiting disease (Group A), and
- Pain and addiction (Group B).

Group A	Group B
Palliative Medicine Specialist	Pain Medicine Specialist
Palliative Medicine Registrar	Addiction Medicine Specialist
Palliative Care Nurse Practitioner	Prescriber endorsed to treat drug dependency*
Oncologist	Drug and Alcohol Nurse Practitioner
General practitioner#	

Approval under this category permits a prescriber in either Group A or B to prescribe a controlled opioid medicine (including injectable controlled medicines, methadone and fast acting oral dose formulation fentanyl) to an opioid-dependent person, for a maximum of 12 months, if:

- A prescriber in Group A provides support& from a practitioner listed in Group B; or
- A prescriber in Group B provides support& from a practitioner in Group A.

The prescriber must have formed the reasonable belief that a controlled medicine is needed to treat a person with pain directly attributable to active malignancy or life limiting disease state, or to treat their opioid dependency. The prescriber will need to provide written confirmation of the person's active malignancy or life limiting disease state, including any relevant details e.g. nature of malignancy or disease state.

Oral morphine equivalent dose (MEqD)				
Drug	**Formulations**	***Conversion ratio****	***MEqD 160mg** (daily)*	***MEqD 300mg** (daily)*
Morphine	oral (mg/day)	1:1	160mg daily	300mg daily
Morphine	parenteral (mg/day)	1:3	53mg daily	100mg daily
Hydromorphone	oral (mg/day)	1:5	32mg daily	60mg daily
Hydromorphone	Parenteral (mg/day)	1:15	10mg daily	20mg daily
Buprenorphine	transdermal (microg/hr)	1:2	80mcg/hr	150mcg/hr
Fentanyl	transdermal (microg/hr)	1:3	53mg/hr	100mcg/hr
Oxycodone	Oral/rectal (mg/day)	1:1.5	107mg daily	200mg daily
Tapentadol	oral (mg/day)	1:0.3	533mg daily	1000mg daily

~ Source: adapted from Faculty of Pain Medicine ANZCA March 2019 http://fpm.anzca.edu.au/documents/opioid-dose-equivalence.pdf

A MEqD calculator can be found on the Australian and New Zealand College of Anaesthetists Faculty of Pain Medicine website at http://www.opioidcalculator.com.au/index.html.

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^^^ When seeking specialist support under 2B prescribers may choose to consult with an appropriate specialist via telephone or email should a face-to-face review of the patient not be practicable.

A General Practitioner#, for the purpose of 2C and 2D, is a general practitioner whose scope of practice includes palliative care experience providing care within a collaborative team.

◊ Based on expert advice from palliative care specialists at Clare Holland House.

@ When taking over the prescribing of a patient who is established on opioid dependency treatment (ODT), the new prescriber must inform the patient's existing ODT prescriber of the treatment for noting as a minimum.

* A prescriber endorsed to treat drug dependency is a prescriber who holds an endorsement to treat drug dependency, issued by the Chief Health Officer under section 583 of the Medicines Poisons and Therapeutic Goods Regulation 2008.

& This application must include support from an appropriate specialist (that is, a specialist from Group A and/or Group B) that clearly supports the requested dosing regimen and evidence of the person's active malignancy or life limiting disease state. Support may be obtained through verbal consultation between groups where a face-to-face review is not practicable, however it is the responsibility of the applicant to provide a written account of the support with their application.

Other Information

Category 2 approvals are inclusive of any controlled medicine approval given by category or drug. That is, requests for a Category 2 approval will not be approved in addition to an existing Approval by Drug or other Category Approval to treat a person with pain directly attributable to active malignancy or life limiting disease state.

The above categories permit more than one controlled medicine being prescribed at a time, provided that the person's total daily dosage does not exceed the maximum dose stated in the relevant sub-Category.

Concurrent approvals for two practitioners (eg. a general practitioner and an appropriate specialist) are permitted to treat a person with pain directly attributable to active malignancy or life limiting disease state.

The CHO may ask for further information when considering this application, including but not limited to seeking evidence of specialist support (or support from another specialist). Should a face-to-face review not be practicable, prescribers may choose to consult an appropriate specialist via verbal or written conversation and document the conversation appropriately.

When considering an application the CHO may choose to refuse, amend or place a condition on an application if the CHO believes that it is in the best interests of the patient or the public to do so.

A maximum dose for opioids has not been stated in Category 2D in recognition that opioid dependent persons will have a high tolerance to opioids and therefore will generally require high doses to achieve analgesic effect.

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APPROVAL BY DRUG

The below section describes circumstances where a **Category 2** approval will not be granted. Under these circumstances prescribers must apply for Approval by Drug. The CHO may issue a controlled medicine approval by drug for up to 12 months.

1. Treating a patient **with any methadone formulation**, where the prescriber is not a pain, addiction or palliative care specialist, oncologist, advanced training palliative care registrar, general practitioner#, or palliative care nurse practitioner.

Applications to prescribe methadone for treatment of pain directly attributable to active malignancy or life limiting disease will not be approved unless made under Category 2C, or include support from an appropriate specialist (that is, a pain, addiction or palliative care specialist, oncologist, palliative care registrar, credentialed general practitioner#, palliative care nurse practitioner or other specialist as considered appropriate) that clearly supports the requested dosing regimen and evidence of the person's active malignancy or life limiting disease state. If a current review is not available, verbal or written support for the dose regime may be obtained from an appropriate specialist should a face-to-face review not be practicable.

2. Treating an opioid **drug-dependant** person with active malignancy or life limiting disease state by a prescriber who is not listed in either Group A or B below.

Treatment@ of a patient who is opioid-dependent for active malignancy or life limiting disease should be undertaken collaboratively between practitioners of different disciplines, being active malignancy or life limiting disease (Group A), and pain and addiction (Group B).

Group A	Group B
Palliative Medicine Specialist	Pain Medicine Specialist
Palliative Medicine Registrar	Addiction Medicine Specialist
Palliative Care Nurse Practitioner	Prescriber endorsed to treat drug dependency*
Oncologist	Drug and Alcohol Nurse Practitioner
General practitioner#	

Applications to prescribe opioids to an opioid-dependent person with active malignancy or life limiting disease from a prescriber who is not listed in either Group A or Group B will not be approved unless they include support& from a practitioner(s) in Group A (and/or) Group B.

@ When taking over the prescribing of a patient who is established on opioid dependency treatment (ODT), the new prescriber must inform the patient's existing ODT prescriber of the treatment for noting as a minimum.

A general practitioner is a general practitioner whose scope of practice includes palliative care experience.

* A prescriber endorsed to treat drug dependency is a prescriber who holds an endorsement to treat drug dependency, issued by the Chief Health Officer under section 583 of the Medicines Poisons and Therapeutic Goods Regulation 2008.

& This application must include support from an appropriate specialist (that is, a specialist form Group A and/or Group B) that clearly supports the requested dosing regimen and evidence of the person's active malignancy or life limiting disease state. Support may be obtained through verbal consultation between groups where a face-to-face review is not practicable, however it is the responsibility of the applicant to provide a written account of the support with their application.

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Chapter 3 - Controlled medicine to treat a person with drug-dependency

CATEGORY 3 APPROVAL

A Category 3 approval allows an endorsed prescriber[Δ] or a non-endorsed prescriber (continuing treatment for 5 patients or less) to prescribe methadone, buprenorphine or buprenorphine/naloxone to a drug dependent person for treatment of drug dependency, for a maximum of 12 months[▫] if:

CATEGORY 3A

The total daily oral dosage of methadone is **equal to, or less than 120mg**.

Unsupervised (take-away) doses of methadone are permitted as outlined in the following table for persons that have been clinically assessed as stable in treatment*. Requests to prescribe additional take-away doses, or to commence unsupervised dosing earlier than permitted in the following table may be considered via an application for Approval by Drug.

Length of time in treatment (months)	Methadone	Comments
0-3	0	Special circumstances may allow one dose
3-5	2 per week	Not consecutively
5-7	2 per week	Maximum 2 consecutive
7-9	3 per week	Methadone – maximum 2 consecutive
>9	4 per week	

CATEGORY 3B

The total daily sublingual dosage of buprenorphine is **equal to, or less than 32mg;** or

The total weekly dosage of depot buprenorphine (Buvidal®) is **equal to, or less than 40 mg** (32 mg Buvidal Weekly plus one supplemental Buvidal Weekly 8 mg) and the regular weekly dose may be administered up to two days before the due date to avoid missed doses; or

The total monthly dosage of depot buprenorphine (Buvidal®) is **equal to, or less than 160mg** and may be administered up to one week before or 1 week after the due date to avoid missed doses; or

The total monthly dosage of depot buprenorphine (Sublocade®) is **equal to, or less than 300mg** and may be administered at a minimum of 26 days.

Unsupervised (take-away) doses of sublingual buprenorphine/naloxone are permitted as outlined in the following table for persons that have been clinically assessed as stable in treatment*. Requests to prescribe additional take-away doses, or to commence unsupervised dosing earlier than permitted in the following table may be considered via an application for Approval by Drug.

Length of time in treatment (months)	Buprenorphine/ naloxone	Comments
0-1	0	Special circumstances may allow one dose
1-3	2 per week	Not consecutively
3-5	4 per week	Maximum 2 consecutive
5-7	6 per week	
7-9	13 per fortnight	2 weeks unsupervised dosing
9-12	27 per 28 days	4 weeks unsupervised dosing

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Supplemental breakthrough doses of sublingual buprenorphine while undergoing depot buprenorphine treatment are not authorised under a Category 3B approval. A prescriber may apply for an Approval by drug to prescribe breakthrough doses of the sublingual formulation.

The prescribing of depot buprenorphine is conditional on the following:

- the patient is NOT given the depot buprenorphine prescription by the prescriber;
- if the product is supplied from a pharmacy, the prescriber arranges collection of the product from the pharmacy to ensure the patient is not in possession of the product prior to administration;
- the prescriber has undertaken depot buprenorphine training; and
- the prescriber ensures the person administering the depot buprenorphine has undertaken training in the administration of the product.

Unsupervised (take-away) dosing – special cases

Additional unsupervised (take-away) doses are permitted under a Category 3A and 3B approval for Easter, Christmas, New Year or other public holidays when supervised dosing is not available at the person's usual dosing pharmacy.

Additional unsupervised (take-away) doses are also permitted in instances where the person is required to travel interstate urgently and is unable to return to their usual pharmacy for supervised dosing for reasons outside their control. Examples include where there is a death in the client's family.

Additional take-away doses should be limited by prescribers and are permitted up to one occasion per month. Additional unsupervised doses should only be prescribed to a person who already receives unsupervised doses unless in special circumstances.

Other Information

Controlled medicine approval applications will be considered in accordance with the *National Guidelines for Medication-Assisted Treatment of Opioid Dependence (2014)* (National Guidelines).Prescribers must prescribe in accordance with the National Guidelines under their approval. Further advice regarding the treatment of a drug-dependent person can also be found in the *Opioid Maintenance Treatment in the ACT: Local Policies and Procedures* available at http://www.health.act.gov.au/our-services/alcohol-and-other-drugs/opioid-maintenance-treatment

Under this Category approval the person must remain on a single controlled opioid medicine in which the total daily oral dosage above is not exceeded.

The CHO may ask for further information when considering this application, including but not limited to seeking evidence of specialist support (or support from another specialist).

When considering an application the CHO may choose to refuse, amend or place a condition on an application if the CHO believes that it is in the best interests of the person or the public to do so.

To receive unsupervised (take-away) doses, a person needs to be assessed by their medical practitioner as meeting stability criteria. A Client Stability Assessment Form and information to guide the assessment of a person's stability is provided in the *Opioid Maintenance Treatment in the ACT: Local Policies and Procedures* available at http://www.health.act.gov.au/our-services/alcohol-and-other-drugs/opioid-maintenance-

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treatment. A completed Client Stability Assessment Form is to be submitted with the application where a prescriber needs to apply for Approval by Drug to authorise the take-away doses.

Special case provisions for declared public health emergency

Up to three additional unsupervised (take-away) doses are permitted under a Category 3A or 3B approval or an Approval by Drug during a declared public health emergency to enable rapid commencement or continuation of unsupervised doses for a person unable to attend their usual pharmacy for supervised dosing for reasons outside their control. An example is compulsory isolation during the COVID- 19 public health emergency.

The limit of three additional take-aways is intended to authorise the commencement or continuation of take-aways over a weekend. The prescriber will be required to seek Approval by Drug (or an amendment to their existing Approval by Drug) for any additional take-away doses required over the public health emergency period.

APPROVAL BY DRUG

The below section describes circumstances where a **Category 3A or 3B** approval will not be granted. Under these circumstances prescribers must apply for Approval by Drug. The CHO may issue a controlled medicine approval by drug for up to 12 months if:

1. the person's total daily dose is **above 120mg for methadone or 32mg for sublingual buprenorphine**;

   For an endorsed prescriber this application must include documented support from a second endorsed prescriber that clearly supports the requested dosing regime.

   A non-endorsed prescriber must include documented support from an addiction specialist or addiction psychiatrist or endorsed prescriber with the application that clearly supports the requested dosing regime.

2. the person's total monthly dose for **Buvidal® depot buprenorphine is above 160mg or for Sublocade® depot buprenorphine is above 300mg.**

   For an endorsed prescriber this application must include documented support from a second endorsed prescriber that clearly supports the requested dosing regime.

   A non-endorsed prescriber must include documented support from an addiction specialist or addiction psychiatrist or endorsed prescriber with the application that clearly supports the requested dosing regime.

3. applying to prescribe outside the *National Guidelines for Medication-Assisted Treatment of Opioid Dependence (2014)*;

4. a person with drug-dependency requires treatment for an acute pain condition with another controlled medicine;

   A non-endorsed prescriber must include documented support from an addiction specialist or addiction psychiatrist or endorsed prescriber with the application that clearly supports the requested dosing regime.

5. a person with drug dependency requires **methadone tablets or additional supply of buprenorphine** due to the person being away from the ACT (e.g. interstate or overseas and where the patient cannot reasonably be dosed at an appropriate healthcare setting);

6. a person requires a greater number of unsupervised (take-away) doses than provided for in Category 3A or 3B or

   In this circumstance the prescriber must provide details of the person's stability assessment of the client being sufficiently stable using the Client Stability Assessment Form available in the Opioid Maintenance Treatment in the ACT: Local Policies and Procedures *available at http://www.health.act.gov.au/our-services/alcohol-and-other-drugs/opioid-maintenance-treatment*.

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7. a person requires buprenorphine for unsupervised (take-away) dosing; or

   In this circumstance the prescriber must provide details of the person's confirmed allergy to naloxone or the pregnancy.

8. a person requires breakthrough sublingual buprenorphine while undergoing depot buprenorphine therapy; or

9. treating an indication not listed on the Australian Register of Therapeutic Goods.

   In this circumstance patients must sign a consent form acknowledging treatment for a non-licensed condition.

▫ Based on expert advice from alcohol and drug specialists at the ACT Alcohol and Drug Service

Δ An endorsed prescriber is a prescriber who has completed designated training as outlined in the Medicines, Poisons and Therapeutic Goods (Guidelines for treatment of opioid dependency) Approval 2018 (No 1) and been granted endorsement to treat drug-dependency by the Chief Health Officer under section 581 of the Medicines, Poisons and Therapeutic Goods Regulation 2008.

*These unsupervised (take-away) limits are based on long held principles determined in close consultation with local stakeholders within the alcohol, tobacco and other drug sector.

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Chapter 4 - Controlled medicine to treat a person with a licensed indication or severe insomnia

CATEGORY 4 APPROVAL

Under a Category 4 approval a specialist may prescribe a controlled medicine to a non-drug dependent person, up to a maximum of 12 months if:

CATEGORY 4A

The specialist (that is, a psychiatrist) is treating a person with panic disorder or short term symptomatic treatment of anxiety (that is, a licenced ARTG indication) with **alprazolam** up to 10mg daily~.

CATEGORY 4B

The specialist (that is, a psychiatrist, neurologist or sleep medicine specialist) is treating a person with severe insomnia with **flunitrazepam** up to 2mg at night~.

~ Source: Australian Medicines Handbook 2016

Other Information

It is recommended that a person has annual psychiatric reviews with an aim to discontinue alprazolam use.

The CHO may ask for further information when considering this application, including but not limited to seeking evidence of specialist support (or support from another specialist).

When considering an application the CHO may choose to refuse, amend or place a condition on an application if the CHO believes that it is in the best interests of the patient or the public to do so.

APPROVAL BY DRUG

The below section describes circumstances where a **Category 4A or 4B** approval will not be granted. Under these circumstances prescribers must apply for Approval by Drug. The CHO may issue a controlled medicine approval by drug for up to 12 months.

1. for a prescriber (other than a psychiatrist) to prescribe alprazolam to treat a person for a licenced ARTG indication;

   This application must be accompanied by documented support from an appropriate specialist (that is, a psychiatrist) that clearly supports the requested dosing regimen and indication.

2. for a prescriber (other than a psychiatrist) to prescribe flunitrazepam for severe insomnia;

   This application must be accompanied by documented support from an appropriate specialist (that is, a psychiatrist, neurologist or sleep medicine specialist) that clearly supports the requested dosing regimen and condition.

3. for a specialist prescriber (psychiatrist, neurologist or sleep medicine specialist) to treat a person with alprazolam for a licenced ARTG indication with a daily dosage in excess of 10mg daily;

4. for a specialist prescriber (psychiatrist, neurologist or sleep medicine specialist) to treat a person with flunitrazepam for severe insomnia with a daily dosage in excess of 2mg at night; or

5. treating an indication not listed on the Australian Register of Therapeutic Goods.

   In this circumstance patients must sign a consent form acknowledging treatment for a non-licensed condition.

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Chapter 5 - Psychostimulants

CATEGORY 5 APPROVAL

Controlled medicine to treat a person with a psychostimulant

CATEGORY 5A – Attention Deficit Hyperactivity Disorder

For non-drug dependent persons aged 4 to 18 years who have been initiated or reviewed by a paediatrician, psychiatrist or neurologist within the previous two years.

CATEGORY 5B – Attention Deficit Hyperactivity Disorder

For non-drug dependent persons aged 19 years or older who have been initiated or reviewed by a paediatrician, psychiatrist or neurologist within the previous three years.

A **Category 5A or 5B** approval may be issued for up to a maximum of 2 years.

Category 5A or 5B approval is only inclusive of the total daily dosage as specified below:

- 40mg daily of dexamfetamine
- 70mg daily of lisdexamfetamine
- 72mg daily of controlled release methylphenidate
- 60mg daily of conventional methylphenidate.

Applications made by prescribers other than a paediatrician, psychiatrist or neurologist must be accompanied by documented support from an appropriate specialist (that is, a paediatrician, psychiatrist or neurologist) that clearly supports the requested dosing regime and ADHD diagnosis.

CATEGORY 5C – Attention Deficit Hyperactivity Disorder

For non-drug dependent persons aged 4 to 18 years where the applicant is a paediatrician, psychiatrist or neurologist.

CATEGORY 5D – Attention Deficit Hyperactivity Disorder

For non-drug dependent persons aged 19 years or older where the applicant is a psychiatrist or neurologist.

A **Category 5C or 5D** approval may be issued for up to a maximum of 3 years.

Category 5C or 5D approval is only inclusive of the total daily dosage as specified below:

- 40mg daily of dexamfetamine
- 70mg daily of lisdexamfetamine
- 72mg daily of controlled release methylphenidate
- 60mg daily of conventional methylphenidate.

CATEGORY 5E – Binge Eating Disorder

For non-drug dependent persons aged 18 years or older who have been initiated or reviewed by a psychiatrist within the previous two years.

A **Category 5E** approval may be issued for up to a maximum of 2 years.

Category 5E approval is only inclusive of the total daily dosage as specified below:

- 70mg daily of lisdexamfetamine

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CATEGORY 5F – Binge Eating Disorder

For non-drug dependent persons aged 18 years or older where the applicant is a psychiatrist.

A **Category 5F** approval may be issued for up to a maximum of 3 years.

Category 5F approval is only inclusive of the total daily dosage as specified below:

- 70mg daily of lisdexamfetamine

CATEGORY 5G – Narcolepsy

For non-drug dependent persons aged 6 years or older who have been initiated or reviewed by a paediatrician, sleep specialist, respiratory specialist or neurologist within the previous two years.

A **Category 5G** approval may be issued for up to a maximum of 2 years.

Applications made by prescribers other than a paediatrician, sleep specialist, respiratory specialist or neurologist must be accompanied by documented support from an appropriate specialist (that is, a paediatrician, sleep specialist, respiratory specialist or neurologist) that clearly supports the requested dosing regime and narcolepsy diagnosis.

CATEGORY 5H – Narcolepsy

For non-drug dependent persons aged 6 years or older where the applicant is a paediatrician, sleep specialist, respiratory specialist or neurologist.

A **Category 5H** approval may be issued for up to a maximum of 3 years.

Category 5G or 5H approval is only inclusive of the total daily dosage as specified below:

- 60mg daily of dexamfetamine
- 60mg daily of conventional methylphenidate.

This category approval applies for controlled medicine treatment longer than two months.

Other Information

The above categories permit a prescriber to prescribe **one long acting** and **one short acting** controlled medicine to treat a person with ADHD or narcolepsy provided that the maximum daily dose does not exceed that stated within the subcategory and that this dosing regimen is supported by an appropriate specialist.

Categories 5A, 5B, 5E and 5G do not permit a prescriber to initiate an increase in dose or change in stimulant controlled medicine without appropriate specialist support.

The CHO may ask for further information when considering this application, including but not limited to seeking evidence of specialist support (or support from another specialist).

When considering an application the CHO may choose to refuse, amend or place a condition on an application if the CHO believes that it is in the best interests of the patient or the public to do so.

Note: Diagnosis of ADHD should be considered in conjunction with any ADHD diagnostic criteria as set out in the *Diagnostic and Statistical Manual of Mental Disorders - 4th Edition* (DSM-IV), or *the Diagnostic and Statistical Manual of Mental Disorders - 5th Edition* (DSM-V) or the latest edition.

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APPROVAL BY DRUG

The below section describes circumstances where a **Category 5** approval will not be granted. Under these circumstances, prescribers must apply for Approval by Drug. The CHO may issue a controlled medicine approval by drug for up to 12 months:

1. for a prescriber to treat a person with a dosage or condition otherwise not authorised under a subcategory listed above;
2. to treat a person with ADHD aged less than 4 years;

   An application must be from a paediatrician, psychiatrist or neurologist and include documented support from a second specialist that is a (paediatrician, psychiatrist or neurologist). The CHO may refer an application to the Medicines Advisory Committee.
3. to treat a person with narcolepsy aged less than 6 years*;*

   An application must be made by a paediatrician, sleep specialist, respiratory specialist or neurologist and include documented support from a second specialist that is a (paediatrician, sleep specialist or neurologist). The CHO may refer an application to the Medicines Advisory Committee.
4. to treat a person with Treatment Resistant Depression;

   An application must be submitted by, or include documented support from a psychiatrist or palliative care specialist with accompanying appropriate clinical patient history and justification for use.
6. To prescribe Sodium Oxybate;

   An application must be submitted by, or include documented support from a neurologist, paediatrician or sleep specialist.
5. treating an indication not listed on the Australian Register of Therapeutic Goods.

   In this circumstance patients must sign a consent form acknowledging treatment for a non-licensed condition.

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Chapter 6 – Medicinal Cannabis

Applications will be considered for Approval by Drug and may be approved for up to 24 months.

Applications for controlled medicine cannabis products not included on the Australian Register of Therapeutic Goods (ARTG) will be assessed by the Therapeutic Goods Administration (TGA) in accordance with the *Therapeutic Goods Act 1989*.

The CHO will assess applications for potential patient drug dependency or drug seeking behaviours and may seek additional information from the applicant.

For further information on obtaining approval to prescribe unregistered medicines see the TGA website at TGA website.

Applications for products included on the ARTG will be assessed by the CHO. Practitioners seeking to prescribe an ARTG included product (eg. nabiximols (Sativex®)) should submit an Application for Approval to Prescribe a Controlled Medicine to the Health Protection Service.

Applications to prescribe nabiximols may not be approved unless submitted by a neurologist or rehabilitation specialist.

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Chapter 7 – Psychedelic medicines

Psychiatrists who are Authorised Prescribers under the Therapeutic Goods Administration Authorised Prescriber Scheme, hold human rights ethics committee approval and have completed training in psychedelic-assisted therapy can apply to prescribe the following psychedelic medicines:

CATEGORY 7A - Post-Traumatic Stress Disorder

3,4-methylenedioxy-methamphetamine (MDMA) for the treatment of post-traumatic stress disorder.

CATEGORY 7B - Treatment-Resistant Depression

Psilocybin for treatment-resistant depression.

A Category 7 psychedelic medicine approval may be issued for a maximum of 12 months.

Other Information

There are no standing approvals for psychedelic medications. A Category 7 approval is required for the prescription of all psychedelic medicines.

Psychiatrists who prescribe psychedelic medicines must comply with the Royal Australian and New Zealand College of Psychiatrists clinical guidelines for psychedelic medicines.

The CHO will assess applications for potential patient drug dependency or drug seeking behaviours and may seek additional information from the applicant.

Psychedelic medications must not be supplied directly to patients.

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