

Australian Capital Territory

# Medicines, Poisons and Therapeutic Goods (Category Approval) Determination 2016 (No 1)\*

Notifiable instrument NI2016–522

made under the

**Medicines, Poisons and Therapeutic Goods Regulation, section 575 (Category approval determination)**

---

## **1 Name of instrument**

This instrument is the *Medicines, Poisons and Therapeutic Goods (Category Approval) Determination 2016 (No 1)*.

## **2 Commencement**

This instrument commences on the day after its notification day.

## **4 Revocation**

This instrument revokes NI2014-375, being the Medicines, Poisons and Therapeutic Goods (CHO decisions on applications) Guidelines 2014 (No 1), dated 31 July 2014.

## **5 Approval**

In accordance with section 575 of the Medicines, Poisons and Therapeutic Goods Regulation 2008 (Category approval determination), 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 Paul Kelly  
Chief Health Officer

1 August 2016

\*Name amended under Legislation Act, s 60

## 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 drug approval.

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 (from [www.legislation.act.gov.au](http://www.legislation.act.gov.au)) to ensure prescribers are fully aware of their obligations in 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 6205 1700 or at [HPS@act.gov.au](mailto:HPS@act.gov.au).**

A key regulatory control under the [Medicines, Poisons and Therapeutic Goods Regulation 2008](#) (the Regulation) relates to CHO approvals. 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 therapy of longer than two months.

A prescriber **does not** need to apply for Chief Health Officer (CHO) approval **if all** of the following criteria 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 **any 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.

Following a regulatory change, and in line with current best practice and expert local opinion, prescribers now have the flexibility to apply for either:

### 1. Controlled medicine approval by category (new)

#### **CATEGORY 1** ([page 2](#))

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

#### **CATEGORY 2** ([page 4](#))

- 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.

#### **CATEGORY 3** ([page 7](#))

- Controlled medicine to treat a person with drug-dependency.

#### **CATEGORY 4** ([page 8](#))

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

#### **CATEGORY 5** ([page 9](#))

- Controlled medicine to treat a person with Attention Deficit Hyperactivity Disorder.

### 2. Controlled medicine approval by drug (already in place)

This is where the requested drug's dose, form and strength and the person's condition must be specified. For example, due to prescriber preference; or seeking to treat a person with a controlled medicine at a dosage or for a condition not covered under *controlled medicine approval by category*.

## Controlled medicine approval by category

### CATEGORY 1

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

Under this category approval a prescriber may prescribe a controlled medicine to a non drug dependent person with chronic (non-cancer) pain, up to 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<sup>^</sup>**.

This category approval does not include injectable opioid controlled medicines, methadone or fentanyl lozenges.

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

Oral morphine equivalent dose (MEqD)			
Drug	Formulations	Conversion ratio <sup>~</sup>	MEqD 100mg (daily)
Morphine	oral (mg/day)	1 : 1	100mg
Hydromorphone	oral (mg/day)	1 : 5	20mg
Buprenorphine	transdermal (microg/hr)	1 : 2	50mcg/hr
Fentanyl	transdermal (microg/hr)	1 : 3.6	28mcg/hr
Oxycodone	oral (mg/day)	1 : 1.5	66mg
Tapentadol	oral (mg/day)	1 : 0.4	250mg

<sup>~</sup> Source: Australian Medicines Handbook 2016

A MEqD calculator can be found on the ACT Health, Pharmaceutical Services website <http://www.health.act.gov.au/public-information/businesses/pharmaceutical-services>

#### 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, provided that the person's total dosage is equal to, or less than 100mg MEqD<sup>^</sup>.

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.

When considering an application the CHO may choose not to approve an application if the CHO believes that it is in the best interests of the person or the public to do so.

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

- NPS. (2015). *Best Practice Opioid Analgesic Prescribing for Chronic Pain*. Retrieved from <http://www.nps.org.au/conditions/nervous-system-problems/pain/for-individuals/pain-conditions/chronic-pain/for-health-professionals/opioid-medicines/best-practice-prescribing>
- 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 <http://www.cdc.gov/mmwr/volumes/65/rr/rr6501e1.htm>.

**Recommendation:**

When the person's total daily dose is between **40 – 50mg MEqD**, the prescriber should consider additional precautionary measures. For example, referring the person to an appropriate specialist (that is, a pain or addiction specialist or addiction psychiatrist) for review. 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.**

## **When to apply for *controlled medicine approval by drug***

Prescribers are advised that a **Category 1** approval is not available when:

1. a person's total daily dose is **above 100mg MEqD**;
2. treating a **drug dependant** person with chronic (non-cancer) pain;  
*For the circumstances outlined in points 1,2 and 3 if the prescriber is not a pain or addiction specialist or an addiction psychiatrist the application must include documented support from one of the afore mentioned specialists.*
3. treating a non-drug dependent person for chronic (non-cancer) pain with any **methadone formulation**;
4. treating a non-drug dependent person for chronic (non-cancer) pain with **Fentanyl Lozenges**; or
5. treating a non-drug dependent person for chronic (non-cancer) pain with **injectable opioid controlled medicines**.

*For the circumstances outlined in points 4 and 5 if the total daily dose is above 100mg MEqD and the prescriber is not a pain or addiction specialist or an addiction psychiatrist the application must include documented support from a pain or addiction specialist or an addiction psychiatrist.*

**In these circumstances the prescriber must apply for *controlled medicine approval by drug*.**

## CATEGORY 2

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.

Prescriber (other than those specified in Category 2C)

Under this category approval a prescriber may prescribe a controlled medicine to a non drug dependent person, up to a maximum of 12 months if:

### Category 2A

The person's total daily oral morphine equivalent dose (MEqD) [as measured in milligrams (mg)] of prescribed opioids is **equal to, or less than 160mg MEqD**<sup>◊</sup> (injectable controlled medicines and fentanyl lozenges included) and provide evidence of the person's active malignancy or life limiting disease state.

### Category 2B

The person's total daily oral MEqD of prescribed opioids is **equal to, or less than 300mg MEqD**<sup>◊</sup> (injectable controlled medicines and fentanyl lozenges included) with appropriate specialist support<sup>^^^</sup> (that is, a pain or addiction or palliative care specialist or oncologist or other specialist as considered appropriate or Credentialed General Practitioner# or palliative care nurse practitioner) for the requested dosing regimen and provide evidence of the person's active malignancy or life limiting disease state.

Concurrent approvals for a prescriber and appropriate specialist are permitted to treat a person with pain directly attributable to active malignancy or life limiting disease states.

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

Oral morphine equivalent dose (MED)				
Drug	Formulations	Conversion ratio <sup>~</sup>	MED 160mg (daily)	MED 300mg (daily)
Morphine	oral (mg/day)	1 : 1	160mg	300mg
Hydromorphone	oral (mg/day)	1 : 5	32mg	60mg
Buprenorphine	transdermal (microg/hr)	1 : 2	80mcg/hr	150mcg/hr
Fentanyl	transdermal (microg/hr)	1 : 3.6	45mg/hr	84mcg/hr
Oxycodone	oral (mg/day)	1 : 1.5	107mg	200mg
Tapentadol	oral (mg/day)	1 : 0.4	400mg	750mg

<sup>~</sup>Source: Australian Medicines Handbook 2016

A MEqD calculator can be found on the ACT Health, Pharmaceutical Services website <http://www.health.act.gov.au/public-information/businesses/pharmaceutical-services>

<sup>^^^</sup> When completing an application under Category 2B prescribers must declare that they have consulted with an appropriate specialist via telephone or email.

# A Credentialed General Practitioner is a general practitioner whose palliative care experience and training is recognised via endorsement by ACT Health

<sup>◊</sup>Based on expert advice from palliative care specialists at Clare Holland House.

### Other Information

The above categories are inclusive of any controlled medicine approval given by category or drug. That is, the above categories will not be approved on top of an existing *controlled medicine by drug 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 relevant *controlled medicine by category* provisions.

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 not to approve an application if the CHO believes that it is in the best interests of the person or the public to do so.

### When to apply for *controlled medicine approval by drug*

Prescribers are advised that a **Category 2A or 2B** approval is not available when:

1. prescriber who is not included in the following list is treating a person with pain directly attributable to active malignancy or life limiting disease state **with any methadone formulation**:
  - pain specialist;
  - addiction specialist/psychiatrist;
  - palliative care specialist;
  - oncologist;
  - other specialist as considered appropriate;
  - Credentialed General Practitioner#; or
  - palliative care nurse practitioner.

**In this circumstance, prescribers must apply for *controlled medicine approval by drug*.** This application must include documented support from an appropriate specialist (that is, a pain or addiction or palliative care specialist or oncologist or other specialist as considered appropriate or Credentialed General Practitioner# or palliative care nurse practitioner) that clearly supports the requested dosing regimen and provide evidence of the person's active malignancy or life limiting disease state.

# A Credentialed General Practitioner is a general practitioner whose palliative care experience and training is recognised via endorsement by ACT Health

## CATEGORY 2

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.

Pain or addiction or palliative care specialist or oncologist or other specialist as considered appropriate or Credentialed General Practitioner# or palliative care nurse practitioner

Under this category approval a pain or addiction or palliative care specialist or oncologist or other specialist as considered appropriate or Credentialed General Practitioner# or palliative care nurse practitioner may prescribe a controlled opioid medicine (including injectable controlled medicines, methadone and fentanyl lozenges) to a non drug dependent person, up to a maximum of 12 months if:

### Category 2C

The prescriber has 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 evidence (that is, 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.

Concurrent approvals for a prescriber or appropriate specialist are permitted to treat a person with pain due to active malignancy or life limiting disease state.

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

### Other Information

This category approval permits more than one opioid controlled medicine being prescribed at a time and does not specify a maximum dosage.

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 not to approve an application if the CHO believes that it is in the best interests of the person or the public to do so.

# A Credentialed General Practitioner is a general practitioner whose palliative care experience and training is recognised by the ACT Palliative Care Network.

## CATEGORY 3

### Controlled medicine to treat a person with drug-dependency

Under this category approval an endorsed prescriber<sup>Δ</sup> may prescribe methadone, buprenorphine or buprenorphine/naloxone to a drug dependent person for treatment of drug dependency, up to a maximum of 2 years if:

#### CATEGORY 3A

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

#### CATEGORY 3B

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

### Other Information

*Controlled medicine approval* applications will be considered in accordance with the [ACT Opioid Maintenance Treatment Guidelines](#) and prescribers must prescribe in accordance with these Guidelines, including applications for takeaway dose approval.

While this category permits transfer between methadone and buprenorphine (and vice versa), 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 not to approve an application if the CHO believes that it is in the best interests of the person or the public to do so.

### When to apply for *controlled medicine approval by drug*

Prescribers are advised that an application for **Category 3A or 3B** is not available when:

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

3. 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).

**In these circumstances the prescriber must apply for *controlled medicine approval by drug*.**

<sup>Δ</sup> An endorsed prescriber is a prescriber who has completed designated as outlined in the *ACT Opioid Maintenance Treatment Guidelines* and applied to ACT Health for endorsement.



## CATEGORY 4

### Controlled medicine to treat a person with a licensed indication or severe insomnia

Under this category 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 [licensed 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~.

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

~ 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 not to approve an application if the CHO believes that it is in the best interests of the person or the public to do so.

### When to apply for *controlled medicine approval by drug*

Prescribers are advised that an application for **Category 4A or 4B** is not available:

1. for a prescriber (other than a psychiatrist) to prescribe alprazolam to treat a person for a [licensed 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 [licensed ARTG indication](#) with a daily dosage in excess of 10mg daily;
4. for a specialist prescriber (psychiatrist, neurologist or sleep medicine specialist) must apply for *controlled medicine approval by drug* to treat a person with flunitrazepam for severe insomnia with a daily dosage in excess of 2mg at night; or
5. for a prescriber, including a psychiatrist, neurologist or sleep medicine specialist to treat for a non-licensed ARTG indication.

**In these circumstances the prescriber must apply for *controlled medicine approval by drug*.**

## CATEGORY 5

### Controlled medicine to treat a person with Attention Deficit Hyperactivity Disorder

Prescriber (other than those specified in Category 5C and 5D)

Under this category approval a prescriber may prescribe a controlled medicine to a non drug dependent person with Attention Deficit Hyperactivity Disorder (ADHD), up to a maximum of 2 years if:

#### CATEGORY 5A

**Persons aged between 4 and 19 years** have been initiated or reviewed by a paediatrician, psychiatrist or neurologist within the previous two years.

#### CATEGORY 5B

**Persons aged 19 years or older** have been initiated or reviewed by a psychiatrist or neurologist within the previous three years.

This category approval is only inclusive of the total daily dosage as specified below:

- 40mg daily of dexamphetamine (dexamfetamine)
- 70mg daily of lisdexamphetamine
- 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 regimen and ADHD diagnosis.

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 provided that the maximum daily dose does not exceed the above and that this dosing regimen is supported by an appropriate specialist.

The above categories do not permit a prescriber to initiate an increase in dose or change in stimulant controlled medicine without appropriate specialist support.

The above categories exclude persons aged less than four years.

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 not to approve an application if the CHO believes that it is in the best interests of the person or the public to do so.

### When to apply for *controlled medicine approval by drug*

Prescribers are advised that an application for **Category 5A or 5B** is not available:

1. for a prescriber (other than a paediatrician, psychiatrist or neurologist) to treat a person with ADHD at a dosage in excess of any of the total daily dosages listed above or for treatment of a condition other than ADHD.

**In this circumstance the prescriber must apply for *controlled medicine approval by drug*.** This application must be accompanied by documented support from an appropriate specialist (that is, a paediatrician, psychiatrist or neurologist) that clearly supports the requested dosing regimen and condition.

## CATEGORY 5

### Controlled medicine to treat a person with Attention Deficit Hyperactivity Disorder

#### Specialist

Under this category approval a specialist (that is, a paediatrician, psychiatrist or neurologist) may prescribe a controlled medicine to a non drug dependent person with ADHD, up to a maximum of 3 years for:

#### CATEGORY 5C

Persons aged between 4 and 19 years

#### CATEGORY 5D

Persons aged 19 years or older

This category approval is only inclusive of the total daily dosage below:

- 40mg daily of dexamphetamine (dexamfetamine)
- 70mg daily of lisdexamphetamine
- 72mg daily of controlled release methylphenidate
- 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 provided that the maximum daily dose does not exceed the above.

The above categories exclude persons aged less than four years.

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 not to approve an application if the CHO believes that it is in the best interests of the person 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.

### When to apply for *controlled medicine approval by drug*

Prescribers are advised that an application for **Category 5C or 5D** is not available:

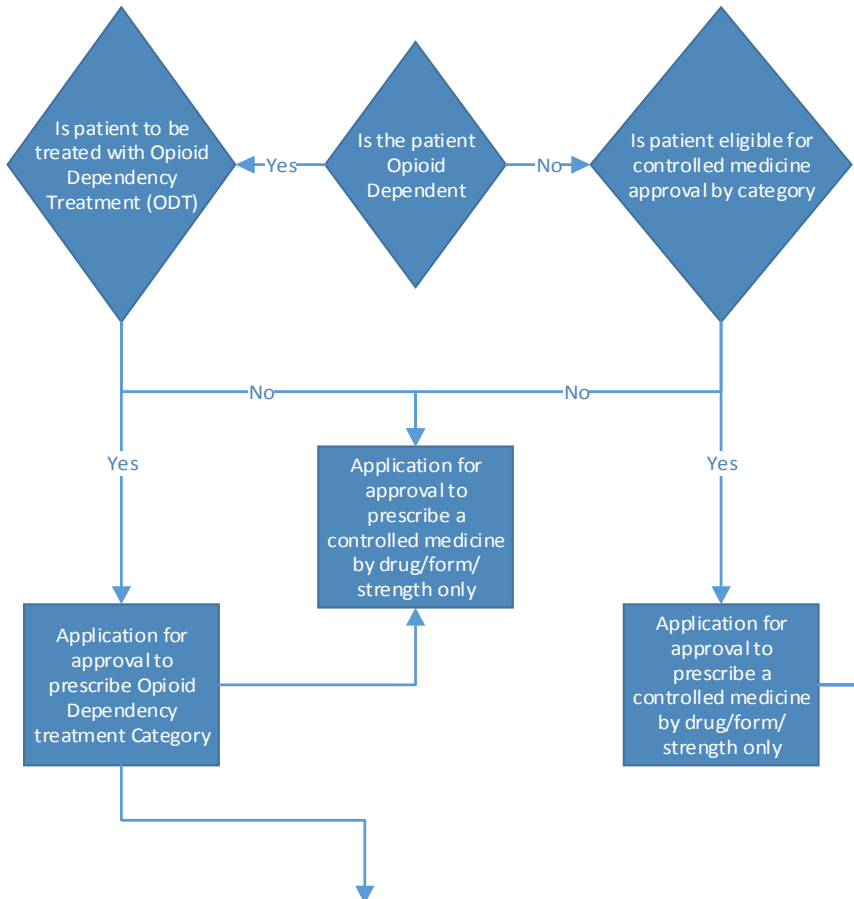
1. for a specialist prescriber (paediatrician, psychiatrist or neurologist) to treat a person with ADHD at a dosage in excess of any of the total daily dosages listed above or for treatment of a condition other than ADHD; or
2. for a specialist prescriber (paediatrician, psychiatrist or neurologist) to treat a person with ADHD aged less than 4 years.

*This application must include documented support from the second specialist that is a (paediatrician, psychiatrist or neurologist). The CHO will refer this application to the Medicines Advisory Committee.*

**In these circumstances the prescriber must apply for *controlled medicine approval by drug*.**

**For further information regarding these prescribing standards please contact the Health Protection Service on 6205 1700 or at [HPS@act.gov.au](mailto:HPS@act.gov.au).**

# Decision to Seek Approval to Prescribe Controlled Medicines



**CATEGORY 3**  
**Controlled medicine to treat a person with drug-dependency**  
 Under this category approval a prescriber may prescribe methadone, buprenorphine or buprenorphine/naloxone to a drug-dependent person for treatment of drug dependency, up to a maximum of 2 years if:  
**CATEGORY 3A**  
 The total daily oral dosage of methadone is **equal to, or less than 120mg.**  
**CATEGORY 3B**  
 The total daily oral dosage of buprenorphine is **equal to, or less than 32mg.**

**CATEGORY 1**  
**Controlled medicine to treat a person with chronic (non-cancer) pain**  
 Under this category approval a prescriber may prescribe a controlled medicine to a non drug-dependent person with chronic (non-cancer) pain, up to 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 controlled medicines, methadone or fentanyl lozenges.

**CATEGORY 2**  
**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.  
Prescriber (other than those specified in Category 2C)  
 Under this category approval a prescriber may prescribe a controlled medicine to a non drug-dependent person, up to a maximum of 12 months if:  
**Category 2A**  
 The person's total daily oral morphine equivalent dose (MEqD) [as measured in milligrams (mg)] of prescribed opioids is **equal to, or less than 160mg MEqD** (injectable controlled medicines and fentanyl lozenges included) and provide evidence of the person's active malignancy or life limiting disease state.  
**Category 2B**  
 The person's total daily oral MEqD of prescribed opioids is **equal to, or less than 300mg MEqD** (injectable controlled medicines and fentanyl lozenges included) with appropriate specialist support<sup>^^</sup> (that is, a pain or addiction or palliative care specialist or oncologist or other specialist as considered appropriate or Credentialed General Practitioner# or palliative care nurse practitioner) for the requested dosing regimen and provide evidence of the person's active malignancy or life limiting disease state.  
 Concurrent approvals for a prescriber and appropriate specialist are permitted to treat a person with pain directly attributable to active malignancy or life limiting disease states.  
**Category 2C**  
Pain or addiction or palliative care specialist or oncologist or other specialist as considered appropriate or Credentialed General Practitioner# or palliative care nurse practitioner  
 Under this category approval a pain or addiction or palliative care specialist or oncologist or other specialist as considered appropriate or Credentialed General Practitioner# or palliative care nurse practitioner may prescribe a controlled opioid medicine (including injectable controlled medicines, methadone and fentanyl lozenges) to a non drug-dependent person, up to a maximum of 12 months if the prescriber has 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 evidence (that is, 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.  
 Concurrent approvals for a prescriber or appropriate specialist are permitted to treat a person with pain due to active malignancy or life limiting disease state.

**CATEGORY 4**  
**Controlled medicine to treat a person with a licensed indication or severe insomnia**  
 Under this category 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 [licensed 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.

**CATEGORY 5**  
**Controlled medicine to treat a person with Attention Deficit Hyperactivity Disorder**  
Prescriber (other than those specified in Category 5C and 5D)  
 Under this category approval a prescriber may prescribe a controlled medicine to a non drug-dependent person with Attention Deficit Hyperactivity Disorder (ADHD), up to a maximum of 2 years if:  
**CATEGORY 5A**  
**Persons aged between 4 and 19 years** have been initiated or reviewed by a paediatrician, psychiatrist or neurologist within the previous two years.  
**CATEGORY 5B**  
**Persons aged 19 years or older** have been initiated or reviewed by a psychiatrist or neurologist within the previous three years.  
 This category approval is only inclusive of the total daily dosage as specified below:  
 • 40mg daily of dexamphetamine (dexamfetamine)  
 • 70mg daily of lisdexamphetamine  
 • 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 regimen and ADHD diagnosis.