Space for Practice logo

Opioid Policy and Protocol

Opioid Policy template

Resource adapted from Woonona Medical Practice

COORDINARE

phn SOUTH EASTERN NSW

An Australian Government Initiative

Contents

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Opioid policy

This policy is based on the RACGP document: *Prescribing drugs of dependence in general practice, Prescribing drugs of dependence in general practice, Part C1 (1).* It includes many of the elements recommended by the *RACGP clinical indicator 2: Practice policy on prescribing addictive medication (2)* and also considers *safeguards advised by Avant (3).*

The policy and accompanying procedures include recommended management of patients being treated for acute or chronic, non-cancer (or non-malignant) pain when opioids are considered or are prescribed.

It does not include the management of pallaitive care or treatment of patients at the end-of-life.

General statement

General Practitioners (GPs) do not prescribe to support drug dependence or for the purpose of self-medication, regardless of whether the treatment was initiated by another medical practitioner. The exception is for individual GPs who are endorsed prescribers of medication assisted treatments (MAT) for opioid use disorder.

Our GPs understand that it is illegal to supply medications:

- to Australian citizens not within the country at the time the prescription is written;
- for use other than the designated purpose for which it was prescribed;
- for anyone other than the person named on the prescription.

GPs will not:

- initiate opioids without giving the patient an **Opioid patient handout** and considering an **Opioid medicine: doctor-patient agreement – trial**
- provide repeat prescriptions without discussing the risks of long-term opioids (see **Opioid medicine: doctor-patient agreement - continuing.**
- continue opioids after a trial period has demonstrated no functional improvement
- provide drugs of dependence, specifically opioids, on the patient's first practice name appointment
- prescribe opioids to patients who are cared for by other GPs, external to XX.

GPs will:

- prescribe long-term opioids as part of an overall pain management strategy with input from psychologists, behavioural or physical therapists, and specialists, if appropriate;
- routinely engage patients in reviewing and tapering or reducing their long-term opioids.

See Appendix 1: Opioid Patient Handout

Opioid oral and transdermal formulations

Table 1: Available opioid oral, transdermal, sub-lingual and preparations for medication assisted treatment, October 2020

Opioid name	Brand name and formulation oral unless otherwise noted; not all brands may be included
tramadol	Tramal, Tramedo, Zydol, Durotram
codeine	in Panadeine Forte, Codalgin Forte, Codapane Forte, Comfarol Forte, Prodeine Fortea, Panamax Co, Panafen Plus, Nurofen Plus, Aspalgin
tapentadol	Palexia
morphine	MS Contin, Kapanol, MS Mono, Momex, Ordine
oxycodone	OxyContin, Endone, in Targin
buprenorphine	patches: Norspan, Bupredermal sublingual (analgesia): Temgesic sublingual (MAT) Subutex; Suboxone injection (MAT): Buvidal; Sublocade
methadone	Physeptone
hydromorphone	Jurnista, Dilaudid
fentanyl	patches: Durogesic, Denpax, Dutran, Fenpatch sublingual/buccal: Abstral, Fentora, Actiq

Starting an opioid

Before prescribing or continuing potential long-term opioids, discuss with the patient the potential risks, minimal benefits and the aims of treatment.

Provide an **'Opioid patient handout'**.

The discussion should be fomalised, using an **Opioid medicine: doctor-patient agreement – trial** and this should be saved in the patient's clinical notes.

There are best practice expectations which should be considered when starting an opioid, potentially for long-term use.

1. Set goals with patient.
   - » The goals can be general, such as pain reduction and improved function, but must provide a specific aim for an improvement in function.
2. Discuss the short-term benefits, weighed up against the potential side effects and risks.
   - » Risks include the potential loss of efficacy over time, worsening of pain and risk of dependence (see Table 4)
   - » outline the short-term and long-term potential adverse effects (see Table 4)
3. Consider using the **'Opioid-risk assessment tool'** when discussing risk of dependence with the patient
4. Avoid opioid prescriptions with sedatives and hypnotic medicines.
   - » Reduce, withhold or cease other drugs with sedative action when starting an opioid, or reconsider the use of opioid.
5. Warn the patient of the concomitant use of alcohol and cannabis
6. Agree on the duration of an opioid trial
   - » This is typically for two weeks at optimal dose
   - » ongoing review of long-term opioids is recommended every THREE months
7. Before starting opioids, discuss an "exit strategy"
   - » How will the opioid will be discontinued if it does not produce the hoped-for benefit?
8. Set expectations of the patient's behaviour
   - » document what is expected of the patient with respect to supply and repeat prescriptions for an opioid. Use the agreement to discuss these points with the patient.
9. Consider NSW legislation and comply, if appropriate, and prescribe according to PBS restrictions.
   - » Supplying private prescriptions for opioids is discouraged
   - » Consider factors that can increase a patient's **risk of opioid-related adverse effects**
   - » start at very low doses and monitor the response more frequently

Continuing supply of an opioid after surgery

Policy for reviewing a patient's analgesia after discharge from hospital after surgery or an acute injury

For patients who have been discharged from hospital and supplied an opioid:

- only supply a prescription for ongoing opioid if there is a demonstrated degree of pain severe enough to warrant an opioid, unrelieved by other analgesics and non-pharmacological methods
- consider a step-down to a lower dose or frequency
- provide an **Opioid patient handout.**
  - » This can be populated from the patient's file using the template
- consider the use of the **opioid-risk assessment tool** and/or the **opioid doctor-patient agreement – trial** to outline concerns with ongoing use with the patient
- prescribe only prn short-acting (immediate-release) opioids* and not for regular use
- prescribe or recommend other, non-opioid medicines:
  - » regular paracetamol (1000mg qid or 650mg slow release, two tablets three times daily)
  - » regular or prn NSAID or a COX-2 inhibitor for short-term use only, after checking for contra-indications and precautions.

    Consider short-term use of a PPI, if appropriate.
  - » regular laxatives until the patient is no longer taking an opioid (see Table 4.)
- do not continue to supply pregabalin (Lyrica®) if it has been started in hospital for post-operative pain
  - » it should only be used short-term and is associated with adverse effects, abuse, persistence of use and overdose.

Exceptions to prescribing only short-acting or immediate release opioids

1. Short-term use of buprenorphine (Norspan®) patches, post-operatively for a defined duration.
   - » This should only be continued on specific advice from the surgical team with a plan for cessation; for instance, if the patient has been recruited to a **Rehabilitation in the Home project (see next point)**
2. The patient has been recruited to a **Rehabilitation in the Home project** after joint replacement surgery or hip fracture.
   - » For these patients, the aim is to reduce and completely wean long-acting (sustained release) opioids by 6 weeks, but may be sooner (4).
   - » An opioid is used in conjunction with regular paracetamol and short-term NSAID or COX-2 inhibitor, if there are no contra-indications.
   - » Consider short-term use of a PPI, if appropriate.
3. The patient will be reviewed regularly and weaning planned.

Background – supply of opioids after surgery

Persistence of opioid use after surgery

Australian and international studies have provided evidence that persistence of opioid use after surgery can become chronic in people who were previously opioid-naïve. Persistence of opioid use can occur after both low-risk or short-stay surgery and high-risk surgery (5,6). Ongoing or persistent use of opioids has been demonstrated to depend on:

- any supply post-operatively to previously opioid-naïve patients
  - » patients receiving an opioid prescription within 7 days of low-risk surgery were approximately 1.5 times more likely to become long-term opioid users within 1 year, compared with those who received no such prescription (5)
- the duration of initial supply
- the total amount supplied at discharge; that is, the **oral morphine equivalent**
- orthopaedic and spinal surgery (7)
- comorbidities, such as mental health diagnoses, back-pain, myalgia (8) as well as younger age, female gender, lower income and tobacco dependence or abuse (9)
- supply of sustained release formulations.

Reasons for persistent use of opioids

Interviews with people using long-term opioids in one pain medicine centre (10) revealed that patients receiving long-term opioid therapy often transitioned to chronic use after starting opioids for the short-term treatment of postoperative or injury-related pain. Chronic use was described as longer than 90 days of regular use. The results of the study demonstrated:

- 27% started after a surgical procedure and an original prescription from a surgical team
- a further 27% had an opioid commenced for the treatment of an acute injury
- 25% were taking for a different reason than originally started; eg, surgery but now back-ache
  - » Continuous re-evaluation of pain therapy and consideration of alternatives is critical to avoid reliance on opioids for conditions that may be suitable for treatment with non-opioid therapies or interventions
- 44% had concurrent depression, 24%, anxiety and 53%, sleep disorders
- 33% had a history of aberrant drug-related behaviour
- 33% self-reported addiction
- only 40% of patients recalled signing an opioid agreement when opioid therapy was initiated.

The finding that a quarter of patients on long-term opioids were using these for a different indication that originally prescribed is concerning. Continuous re-evaluation of pain therapy and consideration of alternatives is critical to avoid reliance on opioids for conditions that may be suitable for treatment with non-opioid therapies or interventions.

Harm from opioids

Harm from opioids can occur during the course of their intended use, or from deliberate misuse and diversion.

Adverse effects are mainly predictable and can be prevented or minimised, with exceptions being pruritus and in rare cases, allergy.

There are well-documented long-term effects from the chronic use of opioids. Patients must be made aware of these.

For adverse effects, refer to **Table 4.**

Cognitive impairment, risk of falls and respiratory impairment can be minimised by starting on the lowest doses and if necessary ceasing, withholding or reducing the dose of other medicines prescribed (see Table 6) and the patient's kidney function.

Risk of misuse or diversion

To reduce the risks of misuse and diversion, outline the expectations of the patient, using the relevant **'opioid doctor-patient agreement'** (either trial, or continuing), available as a templates in medical software. The ***opioid-risk assessment tool*** might be useful when having the conversation with the patient about ongoing supplies of opioids and the risk of dependence.

Medicare doctor-shopping advice provides limited details of a patient's recent use of PBS and MBS.

An additional strategy is to ask the patient for consent to view all past PBS dispensing and MBS items for the previous 12 months by signing the Medicare release document, this document is accessible through Australian Government Service Australia and is form number MS040 (see appendix 4 below).

See

Appendix 2: Opioid doctor-patient agreement – trial

Appendix 3: Opioid doctor-patient agreement – continuing

Appendix 4: Authority to release personal Medicare and Pharmaceutical Benefits Scheme claims information to a third party.

Laws and regulations

Before prescribing an opioid, GPs must confirm there is a therapeutic need. Once this is established, GPs are required to consider NSW legislation and comply, if appropriate.

NSW legislation is separate from the Pharmaceutical Benefits Scheme (PBS) and Department of Veterans' Affairs (DVA).

NSW legislative requirements

The NSW legislative requirements depend on

- the person's drug dependency status,
- the duration of opioid prescribing, and
- the opioid prescribed.

Table 2: Opioid prescribing – NSW legislative requirements

Statutory definition of **'drug-dependent'**	Prescribing for drug-dependent person	For **non-drug-dependent** patient	Rules for interstate prescriptions
A person who has acquired an overpowering desire for the continued administration of a drug of addiction or a prohibited drug listed in Schedule 1 of the *Drug Misuse and Trafficking Act 1985 (NSW)**	A **NSW health authority**[a] is required for all S8 drugs	A **NSW Health authority**[a] is required when prescribing the following drugs for **more than two months**: • any injectable form of any S8 drug • alprazolam • buprenorphine (except transdermal preparations) • flunitrazepam • hydromorphone • methadone	Interstate prescriptions require prior authorisation

**this list includes heroin, fentanyl derivatives, amphetamines, cannabis, LSD*
[a]*Applications for authority from NSW Ministry of Health*

How to apply

The application can be found on-line at:
https://www.health.nsw.gov.au/pharmaceutical/doctors/Pages/prescribe-S8-opioid.aspx

See **Appendix 5:** Select Application for Authority to Prescribe a S8 Drug of Addiction - Pain Management. For assistance or further information contact the Monitoring and Compliance Section, Pharmaceutical Regulatory Unit on (02) 9424 5923 during business hours.

Send the application

Fax the completed form and supporting documentation to NSW Ministry of Health Pharmaceutical Regulatory Unit on (02) 9424 5889, OR

Post forms and supporting documentation to Pharmaceutical Regulatory Unit, NSW Ministry of Health, Locked Mail Bag 961, North Sydney NSW 2059

Opioids: TGA indications and PBS availability

This information is adapted from that available from the TGA and the PBS.

(https://www.tga.gov.au/hubs/prescription-opioids) **(https://www.pbs.gov.au/info/news/2020/09/revised-opioids-pbs-listings-from-1-october-2020**)

Following a national review into the safety and availability of opioids in Australia, in 2019 and 2020 there were several changes made to indications for opioids and PBS listings.

Smaller pack sizes for acute severe pain

Smaller pack sizes are listed for immediate-release prescription opioid products, for use for ACUTE SEVERE PAIN. This change was made to reduce unused opioids circulating in the community which may be used in harmful or hazardous ways, either inadvertently or deliberately, or become targets for theft.

The PBS listings are Restricted Benefit for:

- half pack sizes (10 tablets/capsules); no repeats
- no increases in the maximum quantity or number of units.

Full pack sizes remain available for immediate release preparations, for SEVERE PAIN, with restrictions.

Modified-release opioid preparations

The indications and PBS availability are to reinforce that these should only be used where the pain is opioid-responsive and the patient requires daily, continuous, long-term treatment.

- Modified release opioids are not indicated to treat chronic non-cancer pain (other than in exceptional circumstances), or to be used for 'as-needed' pain relief.
- Hydromorphone and fentanyl modified release products should also **not be used in opioid naïve patients**
- Fentanyl is one of the strongest opioids available in Australia. In recognition of the increased potential for harmful and hazardous use, the indication for fentanyl patches is updated to state they should only be prescribed to treat pain in:
  - patients with cancer,
  - patients in palliative care, and
  - those with exceptional circumstances.
- Fentanyl should also only be used where other analgesics are not suitable or have proven not to be effective, and where the pain has been found to be opioid-responsive. The pain should be severe enough to require daily, continuous, long-term opioid treatment. The patches are not for use in patients who are opioid naïve (not already tolerant to opioids).

Boxed warnings in product information and changes to Consumer Medicines Information

- All sponsors of opioids are now required to include boxed warnings and class statements in the Product Information (PI) documents for all prescription opioids in relation to their potential for harmful and hazardous use.
- Safety information, including the relevant warnings, will be prominently displayed in the Consumer Medicines Information (CMI) to ensure consistency of language and information across all classes of prescription opioids.

Review by a second medical practitioner

To ensure appropriate use of opioid medicines for the management of chronic non-cancer pain, patients must be referred to a second medical practitioner for clinical review if opioid use exceeds or is expected to exceed 12 months.

- Patients being treated in the palliative care setting may undergo the secondary annual review with a palliative care nurse practitioner or a medical practitioner.
- However, to ensure further access is not impeded for those who are unable to attend a consultation, a patient may be exempt from requiring an annual secondary review if their condition doesn't allow them to.

Opioid-risk assessment tool

The “opioid-risk tool” has been developed from recognised risk factors and has been validated in predicting patient populations at increased risk of aberrant behaviour, or “opioid use disorder”. The Opioid Risk Assessment Tool considered easiest to use was devised from a combination of outcome studies that analysed patient risk factors, alone or in combination, and the development of an opioid use disorder.

When it can be used

- When considering commencing opioids for a person without a long association with the practice or prescriber.
- If there are concerns about opioid misuse for the current regimen.
- To “objectify” any concerns with initiating or continuing opioids, to use in discussions with the patient.

How it can be used

- Scores > 3 indicate a moderate risk for aberrant behaviour.
  - » Implement an opioid contract (agreemeent) if the patient is assessed at high-risk of aberrant behaviours (11).

Feedback from use of the tool

- Many of the factors appear obvious, without the need for a tool to highlight.
- Pain specialists use this for referred patients for whom there is no detailed history available, and use the results as a mechanism for discussion of risks with the patient.
- The scoring system is based on the evidence obtained from a collation of studies. Experienced clinicians are aware of the risks of misuse of alcohol and other drugs, including opioids, for pre-adolescent males with a history of sexual abuse, as well as for females
- It is not universally accepted in use, although increasing in favour to minimise the risk of persistence of opioid use.
- The NSW Agency of Clinical Innovation Pain Management Network recommends the use of the tool (https://www.aci.health.nsw.gov.au/chronic-pain/health-professionals/assessment) as does the Victorian State Government (11). **See next page, or Appendix 6: Opioid Risk Tool**
- An additional factor that predicts prolonged use is smoking (11).

Opioid Risk Assessment

PREDICTING ABERRANT BEHAVIOURS IN OPIOID TREATED PATIENTS

Opioid Risk Tool (ORT)

Mark each box that applies:	Female (Score)	Male (Score)
1. Family history of substance abuse		
• Alcohol	☐ 1	☐ 3
• Illegal drugs	☐ 2	☐ 3
• Prescription drugs	☐ 4	☐ 4
2. Personal history of substance abuse		
• Alcohol	☐ 3	☐ 3
• Illegal drugs	☐ 4	☐ 4
• Prescription drugs	☐ 5	☐ 5
3. Age (mark box if between 16-45 years)	☐ 1	☐ 1
4. History of preadolescent sexual abuse	☐ 3	☐ 0
5. Psychological disease		
• Attention deficit disorder, obsessive compulsive disorder, bipolar, schizophrenia	☐ 2	☐ 2
• Depression	☐ 1	☐ 1
Scoring Totals	_____	_____

ORT Scoring and risk of aberrant behaviour

0-3:	low risk	estimated 6% risk of aberrant behaviour
4-7:	moderate	estimated 28% risk of aberrant behaviour
8 or >8 :	high risk	estimated 91% risk of aberrant behaviour

Reference: Webster LR. Predicting aberrant behaviours in opioid-treated patients: Preliminary validation of the opioid risk tool.Pain Medicine. 2005;6(6):432-442

The patient-doctor 'Opioid agreement'

An 'agreement' or 'contract 'between a GP and patient regarding the prescribing and ongoing arrangements for opioids has been advocated in many instances, but not universally. It can be considered:

- when commencing a trial of an opioid for chronic, non-cancer pain,
- for a new patient,
- for a patient who is continuing opioids after treatment for acute pain (eg, after surgery),
- if there is a high score on any Opioid Risk Assessment tool **(see Appendix 6).**
- or if there are concerns of aberrant behaviours.

There are mixed views as to the benefits or otherwise of engaging in contracts with patients. The agreements do not have to be written and signed, but documentation of a discussion of aims and risks of opioids in the patient's clinical notes is advised (3,12).

Assessment of functional improvement is advised at 1 – 4 weeks.

Views in favour of contracts/agreements

- The patient can provide written consent that the limitations, potential adverse effects of opioids as well as conditions of supply have been explained.
- The contract can be used as a method of containment with the patient given responsibilities for ongoing supply (13).
- It confirms the clinician and patient agreement that the overriding goal is improvement in function
- It can reduce the risk of medico-legal complications, by having patients with complex pain management needs and requiring opioids agree to the stated goals of treatment and expected behaviours (3).
- It sets agreed boundaries (14), which can help in discussing manipulative or coercive behaviours.

Views against contracts

- Any "contract" is not legal.
- The evidence is weak that the treatment agreements prevent misuse (14)
- Instances have occurred where failure by the patient to follow the "terms" of the contract has led to termination of the relationship with the prescriber, with adverse outcomes for the patient (severe withdrawals, suicides and use of illicit opioids).

Recommended content of an opioid contract

- why the opioid is commenced – it must only be used for this indication
- what the agreed aims of treatment with opioids is – i.e., improvement in function
- what is acceptable patient behaviour – this could include:
  - only obtaining scripts from one doctor
  - having dispensed from one pharmacy
  - receiving a staged supply through the pharmacy (if necessary)
  - attending appointments regularly
  - engaging with psychological and physical supports
- agreement that there will be no early or replacement scripts provided
- how long the therapeutic trial of treatment will last before ceasing (or tapering)
- the possible adverse effects from a long-term opioid
- the risks of withdrawal reactions
- what the consequences are of inappropriate patient behaviour; for instance, referral and/or cessation of clinical relationship
- if there is concern about potential other prescribers and sources, that the Prescription Shopping Programme (PSP) will be contacted

Opioid doctor-patient agreements

The policy is for all patients who request more than a second supply of opioids to be engaged in an opioid agreement. The agreement is to be scanned and uploaded into the patient's clinical record.

See

Appendix 2: Opioid doctor-patient agreement – trial

Appendix 3: Opioid doctor-patient agreement – continuing

Accessing patient details if doctor-shopping is suspected

Medicare Prescription Shopping Information Service (PSIS)

Doctors can register for access to Medicare's Prescription Shopping Information Service under the Commonwealth's Prescription Shopping Programme (PSP). This service is available 24 hours a day, seven days a week on 1800 631 181. Patients meet the PSP criteria if, in any 3 month period, they received:

- any PBS items prescribed by 6 or more different prescribers
- a total of 25 or more PBS target items
- a total of 50 or more items. This includes PBS items both target and non-target, supplied to the patient.

Information up to the previous 24 hours can be obtained on PBS dispensings, provided the patient meets the PIS criteria. If not, no information can be released. A patient summary report can be provided, which includes all PBS dispensings for the previous 3 months.

To register for the PIS:

- complete the Prescription Shopping Information Service registration form PB131 https://www.humanservices.gov.au/organisations/health-professionals/forms/pb131
- call PSIS: 1800 631 181 (24 hours, 7days)

Prescription Shopping Alert Service

The PSP also has a Prescription Shopping Alert Service, accessible by prescribers and approved suppliers such as pharmacists or hospitals. The Alert Service writes to patients and their prescribers if there are concerns that the patient is obtaining more PBS medications than clinically indicated.

There is a list of medicines that the Prescription Shopping Alert Service is concerned with. This list includes benzodiazepines and other sedatives, opioids, antidepressants, stimulants, and medicines used for substance use disorders.

Additional information about a patient's use of PBS and MBS

A patient can be requested to sign a Medicare document which enables their access to PBS and MBS items utilised to be released to a third party; i.e., their XX GP. This can be used when engaging a patient in a contract and to help monitor use.

This document is accessible through Australian Government Service Australia and is form number MS040 (see appendix 4 below).

See Appendix 4.

Opioid-related adverse effects

Table 4: Most common opioid-related adverse effects and management

OPIOID ADVERSE EFFECT	ONSET AND MECHANISM	OPTIONS FOR MANAGEMENT
NAUSEA AND VOMITING	• Commonly occur in the first few days and after an increase in dose.	• Short-term use of an anti-emetic, if warranted • Avoid sedating anti-emetics; e.g., prochlorperazine *(Stemetil),* promethazine *(Phenergan)*.
DROWSINESS	• Commonly occur in the first few days; may subside with ongoing use • Occurs with dosage increases • depends also on dose, context, other drugs	• low dosage increases. • Reduce dose if persistent • Cease, suspend or reduce other medicines that can contribute (see table)
CONSTIPATION	• The onset can be quite quick with continuous use. • Approximately 20% of older patients reported moderate or severe constipation in their first week of treatment with opioids (15) • Diet and fluids alone are **not** sufficient to avoid constipation.	• **Use prophylactic laxative**s routinely with opioids. • **Avoid** bulk-forming laxatives, Metamucil® or Fybogel®, as these can contribute to bowel obstruction • **Do not rely on the naloxone component of Targin®**. This can reduce the overall incidence of constipation in a population, but may not for the individual patient. The Targin® formulation takes ≥2 weeks to have any noticeable benefit over oxycodone alone. • **Use a stimulant** (senna or bisacodyl) and stool softener docusate (Coloxyl®).e.g., when commencing opioids use Coloxyl and Senna®, two tablets regularly twice daily. • **Intensify treatment** with the osmotic laxative macrogol (Movicol®), or use instead of docusate.
COGNITIVE IMPAIRMENT	• May occur when commencing or increasing the dose of the opioid or of other medicines; or with intercurrent illness. • The risk of impairment is greater: » for older patients » with polypharmacy » when used with other CNS depressants See Table 6 » in kidney impairment – see Opioids in presence of impaired kidney function	• Patients should not drive during periods of dose escalation or when they feel cognitively impaired. This generally occurs for a few days after each dose increase. See section on driving. • Review other medicines before commencing and if impaired cognition becomes a problem. See Table 6.
ITCHING	• Can become intolerable and force discontinuation of the opioid. • Once it occurs, it tends to occur with all opioids. • See “allergy”	• Reduce dose or cease altogether • Another opioid MAY be tried but is unlikely to be successful. • Avoid sedating antihistamines if the opioid is continued (eg promethazine, dexchlorpheniramine, pheniramine)
URINARY RETENTION	• The mechanism behind opioid-induced retention is debated. • Is painful and distressing to the patient.	• Catheterisation • Reduce opioid dose • Review other drugs that can contribute; e.g., drugs with anticholinergic activity; (some antipsychotics), calcium channel blockers.
RESPIRATORY DEPRESSION	Possible when: • too-rapid dose increase, • taking other drugs that can also cause respiratory depression see Table 6 • patient has existing respiratory illness • morbidly obese/ sleep apnoea	• start with reduced doses • review or reduce other medicines • if known user of other drugs; eg, benzodiazepines, alcohol, cannabis, consider a **co-prescription of naloxone** (e.g., intranasal spray, Nyxoid®)

Table 5: Most common opioid-related adverse effects and management (continued)

OPIOID ADVERSE EFFECT	ONSET AND MECHANISM	OPTIONS FOR MANAGEMENT
DENTITION	• There is an increased risk of dental caries in those taking opioids, at least partly due to reduced excretion of saliva.	• Patients on long-term opioids should be warned to be meticulous in their dental care
HORMONAL and ENDOCRINE FRACTURE RISK	Effects are well recognised and include: • reduced adrenal function, • reduced sexual function • infertility • fracture risk (hypogonadism and increased risk of falls) They occur in about 50% of those taking long-term potent opioids.	• warn patients about these possibilities when commencing or continuing opioids (see the Opioid patient handout; and the XX Opioid doctor-patient agreement (trial or continuing) • regularly review thyroid function, testosterone (in males) and adrenal function for patients who have received long-term opioids • seek specialist input if these adverse effects arise • review other medicines that may also increase the risk of falls and fractures
HYPERALGAESIA ("Opioid-induced" hyperalgesia)	An opioid may worsen the pain it was initiated to treat.	• tapering of opioid (acknowledging pain may get worse before it improves) • rotation to different opioid (not often recommended) • strengthening of non-pharmacological and non-opioid therapy recommended (with tapering of opioid dose).

Table 6: Other drugs that can contribute to cognitive or respiratory depression when used with opioids

Benzodiazepines	• alprazolam • clobazam • clonazepam • diazepam • midazolam • nitrazepam • oxazepam • temazepam *(Normison, Temaze, Temtab)*	**Antihistamines**	• dexchlorpheniramine *(Polaramine)* • diphenhydramine *(Snuzaid, Unisom)* • doxylamine *(Dozile, Restamine,* • *Restavit)* • pheniramine *(Avil)* • alimemazine *(trimeprazine) (Vallergan)* • cyproheptadine *(Periactin)*
Other sedatives	• mirtazapine *(Avanza, Mirtanzon, Milivin, Remeron)* • prochlorperazine *(Nausetil, Nausrelief, Procalm, Stemetil, Stemzine)* • pregabalin *(Lyrica)* • zopiclone *(Stilnox, Stilden, Zomiden, Dormizol)* • zolpidem *(Imovane, Imoclone, Imrest)*	**SSRIs SNRIs and other antidepressants**	• citalopram • escitalopram • fluoxetine • fluvoxamine • paroxetine • sertraline • desvenlafaxine • duloxetine • milnacipran *(Joncia)* • venlafaxine • agomelatine *(Valdoxan)* • mianserin • mirtazapine • moclobemide • reboxetine *(Edronax)* • vortioxetine *(Brintellix)*
Antipsychotics	• amisulpride *(Amipride, Solian, Sulprix)* • aripiprazole *(Abilify, Abyra)* • asenapine *(Saphris)* • brexpiprazole *(Rexulti)* • clozapine *(Clopine, Clozaril)* • haloperidol *(Serenace)* • lurasidone *(Latuda)* • olanzapine *(Ozin, Pryzex, Zypine, Zyprexa, Zydis)* • paliperidone *(Invega)* • periciazine *(Neulactil)* • quetiapine *(Kaptan, Quetia, Seroquel, Syquet)* • risperidone *(Ozidal, Rispa, Risperdal, Rispericor, Rispernia, Rixadone)* • ziprasidone *(Zeldox, Ziprox)*	**Antiepileptics**	• acetazolamide • brivaracetam • carbamazepine • ethosuximide • gabapentin • lacosamide • lamotrigine • levetiracetam • oxcarbazepine • perampanel • phenytoin • sulthiame • tiagabine • topiramate • valproate • vigabatrin • zonisamide
Antidepressants	• amitriptyline • clomipramine • dosulepin *(dothiepin)* • doxepin • imipramine • nortriptyline • mirtazapine • mianserin *(Avanza, Mirtanzon, Milivin, Remeron)*	**Drugs for parkinsonian disorders**	• benztropine *(Benztrop)* • trihexyphenidyl *(benzhexol) (Artane)* • levodopa with benserazide, carbidopa • ± entacapone *(Madipar, Sinemet, Stalevo)*
H2-receptor antagonists	• cimetidine • famotidine • nizatidine • ranitidine	**Anticholinergics for urinary incontinence**	• darifenacin *(Enablex)* • oxybutynin *(Ditropan, Oxytrol)* • propantheline *(Pro-banthine)* • solifenacin *(Vesicare)* • tolterodine *(Detrusitol)*

Patient factors that increase the risk from an opioid

Certain factors put a patient at risk of opioid-related harm. These include:

- **sleep apnoea** or sleep disorder diagnosis
- morbid obesity
- snoring
- smoker
- older age: the risk is
  - » 2.8 times higher for individuals aged 61-70
  - » 5.4 times higher for age 71-80
  - » 8.7 times higher for those over age 80 (16)
- no recent opioid use (or opioid-naivety)
- escalating opioid doses, or a previous opioid dependence
- use with other **sedating medicines**. See Table 6.
- pre-existing **respiratory or cardiac disease** or dysfunction or **major organ failure**; eg liver or kidney impairment (See Opioids in presence of impaired kidney function)

The patient has an "allergy" documented to an opioid

Patients may refer to opioid side effects as "allergies", for instance, nausea or vomiting, dizziness, pruritus.

- Most adverse effects are not associated with an immunologic response.
- **"Pseudoallergic"** reactions include mild itching, urticaria, pruritus, bronchospasm and hypotension.
  - » These symptoms are often caused by mast cell activation and subsequent histamine release but are not true immunologic reactions.
  - » Histamine release is commonly seen with morphine and other natural opioids.
  - » These reactions may be idiosyncratic and may or may not recur with re-challenge of the same opioid.
- **Hypotension** can occur due to vasodilation, negative inotropic effects and/or vagal-mediated bradycardia.
- **Immunologic reactions** may present as an allergic dermatitis (erythroderma, eczema or exudative vesicular eruptions) related to a type IV (delayed) hypersensitivity reaction.
  - » Patients can undergo diagnostic patch testing for confirmation.
- Immediate, **anaphylactic** reactions are systemic immunoglobulin E (IgE)-mediated reactions with release of potent mediators, and associated with contraction of smooth muscle, vasodilation, increased mucous secretion, and enhanced vessel permeability and can lead to bronchospasm, hypotension and death.
- Non IgE-mediated reactions include nasal congestion, flushing, pruritus and angioedema

Recommended management – patient has an allergy to an opioid

1. Ask what the reaction was and in what context did it occur (e.g, post-operatively)
2. If a patient has a history of true anaphylactic reaction to an opioid, an opioid from a different structural class should be prescribed with caution and the patient assessed carefully after administration.
   See table below for different opioid structural classes

Opioid structural classes	Opioids in class (32)(33)(34)
Phenanthrenes	codeine, hydromorphone, morphine, oxycodone
Phenylpiperadines	alfentanil, fentanyl, pethidine, sufentanil, remifentanil
Diphenylheptanes	methadone, propoxyphene
Other	tapentadol, tramadol (severe anaphylactic reactions have been recorded)

Prescribing opioids to patients who drive

- Opioids can interfere with driving due to sedation; diminished reaction times, reflexes and coordination; reduced peripheral vision due to the persistent miotic effects, and decreased ability to concentrate.
- The risk of accidents appears to increase in the first weeks of starting or after increasing the dose.
- There does not appear to be evidence that any one opioid has less impact than another.
- However, stable doses of sustained-release opioids do not appear to impair driving activity.
- A person is not fit to hold an unconditional licence if they have an alcohol disorder or other substance dependence, or other substance use that is likely to impair safe driving.

For more information, refer to Assessing Fitness to Drive for commercial and private vehicle drivers (updated 2017) at https://austroads.com.au/__data/assets/pdf_file/0022/104197/AP-G56-17_Assessing_fitness_to_drive_2016_amended_Aug2017.pdf (35)

See austroads.com.au and search for "assessing fitness to drive'.

In practice

- consider each patient individually
- it is ultimately the prescriber's judgement that determines opioid prescription
- where there are concerns about a patient's ability to drive (e.g. high doses of opioids or opioids plus other sedative medication), a formal driving assessment may be considered
- patients should be advised that they are likely to be impaired and should not drive until a stable regime has been obtained for at least two weeks.
- Driving at night may be a problem due to the persistent miotic effects of opioid drugs reducing peripheral vision.

Driver advice from NSW Centre for Road Safety

- Refer to the NSW Centre for Road safety website, search prescription drugs https://roadsafety.transport.nsw.gov.au/stayingsafe/alcoholdrugs/drugdriving/prescriptiondrugs.html

Opioid tapering, reduction or weaning

See also Therapeutic Goods Administration information sheets for opioid tapering, for health professionals: https://www.tga.gov.au/opioid-resources. (See **Appendix 8** and **Appendix 9**)

Reasons to taper a patient's opioid

The patient:

- requests a dosage reduction.
- has not had any clinically meaningful improvement in pain and function; e.g., at least 30% improvement on the 3-item PEG (pain/enjoyment/general activity) assessment scale after commencing or increasing the opioid dose (See below or **Appendix 7**)
- is taking opioid dosages greater than 50mg oral morphine equivalent per day without benefit; or a patient has less than this but is also taking a benzodiazepine, other CNS depressant, is frail or has substantial comorbidities.
- shows signs of any substance use disorder; for instance, work or family problems related to opioid use, difficulty controlling use
- experiences overdose or other serious adverse event; or shows early warning signs for overdose risk, such as confusion, sedation, or slurred speech.

Elective surgery:

Tapering may also be suggested or requested by a surgeon for a patient who is planning elective surgery. Patients receiving long-term opioids have worse surgical outcomes and longer lengths of hospital stay after surgery, compared to patients previously opioid-naïve.

The 3-item PEG scale

The 3-item PEG (pain/enjoyment/general activity) scale is a modified quick pain assessment tool based on the Brief Pain Inventory. It can be used as a tool to assess and evaluate any functional improvement from opioids, after commencing or increasing the dose.

A writable version is available:
https://www.aci.health.nsw.gov.au/__data/assets/pdf_file/0008/257417/PEG_Pain_Screening_Tool.pdf
See **Appendix 7**, for a copy for printing.

Aims of tapering

- Tapering can be undertaken with the aim of complete cessation due to unwanted or adverse effects, or if the opioid is ineffective in achieving the aims
- for a measured dosage reduction; eg prior to surgery, or due to ongoing concerns.

SEE TGA Information sheets for opioid tapering, for health professionals: https://www.tga.gov.au/opioid-resources. (See **Appendix 8** and **Appendix 9**)

Prepare the patient

Explain the benefits of tapering but also the expected unwanted effects. See Table 7. Patients need to understand an individual reason for their tapering, beyond the general, population-level concerns such as “addiction potential”.

The long-term goal is improved pain control and quality of life while reducing potential harms of opioid treatment. Having the patient engaged in any withdrawal plan may be more successful than following a specific or dogmatic protocol:

- encourage the patient to let their family and other healthcare provide know and be involved
- having a reduction plan may help set boundaries and goals for certain patients
- acknowledge the patient’s concerns and reassure them that the process will not be undertaken too quickly
- acknowledge as well that they may have originally been prescribed an opioid and be taking this on the doctor’s advice
- explain that practice has changed since they may have been originally prescribed an opioid, and that the evidence now is that overall, long-term opioids contribute to more harm than benefit.

Table 7: Tapering or ceasing opioids – patient information

BENEFITS of reducing opioid dose or ceasing	Possible **ADVERSE EFFECTS** of opioid tapering
Overall, studies have shown improvement of function without worsening pain • some patients report improvement of pain	Transient increase in pain is possible, but this is short-lived and often more severe in the days immediately following a taper: • the pain is due to the withdrawal and should not be long-term. It may be similar to the pain being treated but also include total body and joint pains • non-pharmacological therapies should be used as much as possible • non-opioid analgesics should be used if appropriate and not contra-indicated • slowing the withdrawal or weaning can reduce the pain experienced
Withdrawing from opioids is not harmful • unless pregnant	Withdrawal symptoms can be unpleasant Early symptoms may be: • anxiety and restlessness • sweating • rapid short respirations • runny nose, tearing eyes • dilated, reactive pupils • brief increase in pain Later symptoms: • runny nose, tearing eyes • rapid breathing, yawning • tremor, diffuse muscle spasms/aches • pilo-erection (goose bumps) • nausea and vomiting; diarrhoea • muscle and joint aches • abdominal pain • fever, chills • craving; restlessness, insomnia
There is a risk of overdose if the opioid dose continues to rise, or at times of other illness or with other drugs	There is a risk of overdose if the previous dose is resumed after period of tapering • tolerance is lost to previous dose after 1-2 weeks • consider Rx for take-home naloxone (Nyxoid®) if concerned
Better outcomes after surgery or illness • people taking chronic opioids before surgery require up to 3 times more opioid after surgery than opioid-naive patients	
Long-term opioids have negative effects on mood and sleep, sometimes described as a "brain fog" • reducing opioids increases alertness and pleasurable experiences	Insomnia, anxiety and depression may be experienced during the taper period • encourage the patient to be see a psychologist, or increase involvement if already engaged
Any dosage reduction reduces the risk of harm from long-term opioids	Adverse effects may be difficult to cope with • the rate of tapering can be slowed (but do not reverse once it has begun)

How to taper

- There is no single strategy that can be applied to all patients, and each situation must be handled on an individual basis, although a particular patient may benefit from the structure or a plan at the outset.
- Dose reductions range from reducing the daily dose by 5% to 20%, with the dose reduction occurring weekly or up to 4-weekly intervals. The actual amount will depend on available strengths of the opioid used.
- For patients who have been on opioids long-term, the anticipated tapering will be longer than if the tapering is for a patient who has only had a recent trial of 1-3 months, without benefit.
- Slower, more gradual tapers are often the most tolerable and can be completed over several months, or longer, depending on the dose
  - » More rapid tapers may be required if there is drug diversion, or adverse effects and the risks of continuing the opioid outweigh the risks of a rapid taper.
- for a patient taking several formulations of opioids:
  - » **calculate the oral morphine equivalent daily dose (mg) OMEDD**
  - » for 2 different opioids, use 50% of one of the calculated OMEDD and add this to the other daily dose. This may be required if the patient is using a patch formulation plus other opioid.
  - » use only one formulation for withdrawal and prescribe the daily dose at the appropriate frequency for the chosen formulation

Stopping or slowing the taper

Holding or discontinuing a taper may be necessary for a specific patient, due to events such as severe withdrawal, pain crisis, worsening of mood, or impairment of physical function.

- Adjust the rate and duration of the taper according to the patient's response.
- Don't reverse the taper; instead, slow down the rate or pause the process while monitoring and managing withdrawal symptoms
- as the dose gets lower, the rate of reduction can be halved (ie, to 50% of the previous reduction)
- Once the smallest available dose is reached, the interval between doses can be extended and the opioid may be stopped when taken less than once a day.

Tapering in the patient with comorbidities

Discontinuing opioids is more difficult with:

- comorbid psychiatric conditions
- patients with poor coping skills, depression, high pain scores and high opioid doses

If a previous attempt at opioid weaning has proven unsuccessful, then the rate of tapering can be slowed.

- reduce the size of the dose reduction and/or
- increase the time spent at each dose level (eg two or three months between reductions)

Slower tapering is required for patients with cardiac or respiratory conditions and in psychiatric comorbidities

- monitor BP and adjust antihypertensive medicines briefly, if needed.

Medication assisted treatments (MAT)

Consider referral for Drug and Alcohol specialty advice or services. Treatment options for Medication Assisted Treatment are: sublingual (Subutex; Suboxone), and injection (Buvidal; Sublocade). Buprenorphine may be an option for people having difficulty in weaning.

Using tapentadol for tapering

Tapentadol is a mu-opioid receptor (MOR) agonist and inhibitor of noradrenaline re-uptake. These two mechanisms act centrally at the spinal cord and brain to produce analgesia individually and synergistically. Although it has 18 times less binding affinity than morphine to the mu-opioid receptor, is only 2-3 times less potent in producing analgesia due to its noradrenaline re-uptake inhibition (NRI). Both MOR and NRI contribute to the analgesic effect.

Care must be taken if using tapentadol for weaning, as "equivalent" doses can cause acute and profound opioid withdrawal reactions. To avoid; slowly reduce the original opioid as the tapentadol is introduced.

If appropriate, slowly withdraw tapentadol, using techniques described above.

Managing withdrawal symptoms

- avoid introducing new immediate-release opioids or sedatives to manage the symptoms
- diarrhoea – can use short-term loperamide, emphasising the maximum dose of 16mg/day
  - » there are cases of large doses of loperamide taken for abuse purposes
- short-term anti-emetics may be required, if nausea is severe
- if not already using, ensure regular paracetamol and prn NSAIDs, if not contra-indicated
- encourage non-pharmacological methods; eg hot packs, baths, gentle and paced exercise
- severe autonomic withdrawal symptoms have been managed by clonidine (hypertension, cramps, diaphoresis, tachycardia)
  - » in the outpatient setting this requires careful monitoring due to hypotension, dizziness and drowsiness and the risk of depression.
  - » It may be useful for some patients but causes side effects that people find very troublesome. It should only be used prn and only for a very limited period (eg a day or 2 after dose reduction).

It is important at the outset to have the patient visit a psychologist if possible, or engage a psychologist in the planned process.

Oral morphine equivalent daily dose (OMEDD) and safe limits

- All opioid doses and formulations can be estimated as approximate equivalences with oral morphine. These are known as **oral morphine equivalent daily dose, or OMEDD, or just OME.**
- OMEDD should not be used for directly swapping one opioid over to another without other considerations and for **opioid tapering.**
- OMEDD is used to assess the equivalent daily dose a person is using of an opioid and is a method of combining different formulations.
- There is an upper limit of OMEDD considered safer to prescribe, although this has changed over time and been reduced in light of accumulating evidence of long-term harm at high doses.

Opioid doses with an OMEDD less than 50mg are considered lower doses; 50 to 100mg are MODERATE doses; and above 100mg, HIGH doses.

- OMEDD ranges are not absolute and depend on the patient's comorbid conditions and other medicines; eg, 50mg OME is still a moderate dose for an older, frail person using other sedatives.
- Other OMEDDs are used as targets to reduce opioid doses; eg, 60mg is often quoted.
- OMEDDs are not routinely considered in the management of cancer-related pain.

To estimate the Oral Morphine Equivalent Daily Dose (OMEDD) of a patient's regimen

This should be considered when:

- a patient's dose for long-term pain has been escalating;
- there is a question of benefit of the opioid/s;
- there is evidence of harm or intentional misuse;
- recommending a second opinion or referral;
- discussing the potential for harm with the patient.

Use the on-line app

The Australian Faculty of Pain Management (FPM) /Australian and NZ College of Anaesthetists (ANZCA) app is free, downloadable and becoming widely used and recommended in Australian guidelines http://www.opioidcalculator.com.au/

This app provides useful guidelines as well and recommended dosage reductions if it is necessary to switch opioids. It also has embedded a "traffic light" system, with the dosage ranges above built in as:

- **GREEN** (up to 50mg and described as low risk of dose-related effects),
- **AMBER** (50 – 100mg: CAUTION: increased risk of dose-related harm; and
- **RED** (greater than 100mg: ALERT: High risk of harm due to predictable adverse effects, dependence and inadvertent overdose).

The equivalences are also available printed. See Appendix 10: FPM Opioid Dose Equivalence. Care should be taken with using the conversion factor correctly; eg, multiply the oxycodone dose by 1.5 to get the Oral Morphine Equivalent Dose. This multiplication has been incorrectly interpreted on some occasions.

High oral morphine daily equivalent doses – safe limits

For OMEDDs greater than 50mg/day, 'name of the practice' recommends:

- a thorough review of the benefits of the opioid for the patient and consider a second opinion
- discussing tapering the dose with the patient
- to consider prescribing Take Home Naloxone.

Take Home Naloxone

- From February 2019, there has been a federal initiative to have take-home doses of naloxone widely available.
- An intranasal formulation (Nyxoid®) is available to buy over the counter for approximately $80. It is available as a twin-pack of 2 x 1.8mg/0.1mL preloaded intranasal solutions.
- Intranasal naloxone is now available without restriction, on the PBS. It is also provided in some circumstances, at no cost via some local health services through state funding.
- It has been recommended that Nyxoid® be prescribed to patients receiving high-doses of prescription opioids, due to the risk of overdose.
  - » consider prescribing when OMEDD > 50mg; if doses are increasing; if there are multiple opioid formulations or if the patient is tapering from a high-dose, due to the risk of loss of tolerance.
- Other indications for THN are:
  - » for patients with a history of overdose,
  - » for patients with a history of substance use disorder,
  - » for patients taking benzodiazepines or other sedatives (including cannabis or alcohol) with opioids.

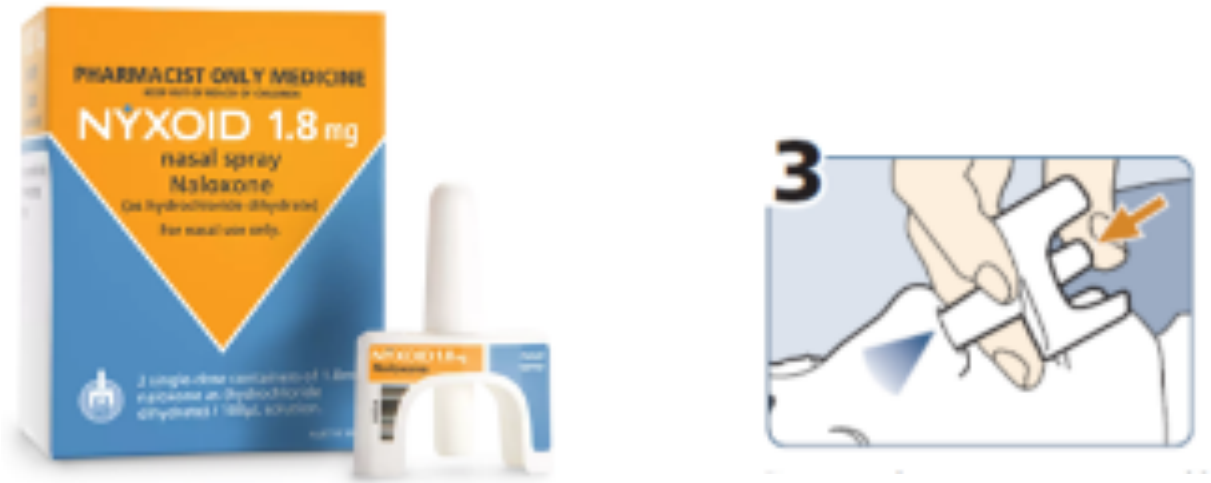

Figure 1: Intranasal naloxone formulation Nyxoid® and method of administration

Resource adapted from Woonona Medical Practice

Return of patient's Schedule 8 medicines

The policy is not to accept a patient's Schedule 8 medicines that are no longer needed, either from a family member after a death, or from a patient due to a change in circumstance or condition. This especially pertains to opioids. The patient or family are to be advised to return them to their community pharmacy for storage and eventual disposal via the Return of Unwanted Medicines program (RUM), an Australian government funded program.

The only exception to this is when it is considered dangerous for the medicine to remain in the patient's or family's possession.

If a schedule 8 medicine is accepted into the practice, it is the responsibility of the receiving GP to:

1. Record the return into the XX's S8 register and lock the medicines. The medicines are to be locked in the S8 key-locked box, secured to the floor of the locked drug cupboard (when not in immediate use) in the clinical area. They are not to be kept in the doctors' rooms.

2. Take the register and the medicines for disposal to a local community pharmacy, for return via RUM, when convenient. This should occur within 48 hours.

Background:

NSW Pharmaceutical Services mandates:

- S8s can only be destroyed on-site by a retail community pharmacist and GP.
- RNs or non-retail pharmacists are not permitted to destroy S8s.

https://www.health.nsw.gov.au/pharmaceutical/doctors/Pages/faq-medical-practitioners.aspx

Opioids in presence of impaired kidney function

General advice – opioids in kidney impairment

- Guidelines have been developed with recommendations for opioid use in kidney impairment
  - these have been based on known opioid pharmacokinetics and expert opinion, rather than a strong evidence base (17).
- The choice of opioid and adjuvant analgesics in kidney impairment depends on:
  - the extent of kidney impairment, and
  - active metabolites that are dependent on the kidney for excretion (18)
- Analgesics that are the safest in patients with kidney impairment are **buprenorphine, fentanyl, ketamine and paracetamol** (except with compound analgesics).
  - None of these medicines has a high level of active metabolite or has a significantly prolonged clearance in kidney impairment.
- Gabapentin, pregabalin, codeine, hydromorphone, methadone, morphine and tramadol have all been used in patients with kidney disease, depending on the degree of impairment (18).
  - Adjust doses and extend dosage intervals
- Although there are mixed opinions about **oxycodone**, Australian guidelines support the use of oxycodone and **fentanyl** as opioids of choice in the presence of kidney impairment (18)(19).
  - commence at lower doses and monitor for adverse effects
- Use **hydromorphone and morphine** with caution in mild to moderate kidney impairment (20) and avoid in severe kidney impairment.

Fentanyl in kidney impairment

- Fentanyl has no active metabolites (18). Its inactive metabolites, and approximately 10% of the intact molecule, are mainly excreted by the kidneys (21). It is not removed to any significant degree by dialysis (18).
- The recommendation for transdermal fentanyl **is are to use 50% of the usual dose in severe kidney impairment** (22).
  - This is difficult to practically implement if, for instance, the calculated dose after opioid switching is 12 microgram.
  - fentanyl should never be used in an opioid-naïve patient, especially if there is kidney impairment

Fentanyl is indicated for:

- The management of pain associated with cancer, palliative care, and other conditions in patients where:
  - other treatment options have failed, are contraindicated, not tolerated or are otherwise inappropriate to provide sufficient management of pain, and
  - the pain is opioid-responsive, and
  - severe enough to require daily, continuous, long term opioid treatment. Not for use in opioid-naïve patients

NB: fentanyl is NOT recommended for chronic, non-cancer pain.

Recommendation – fentanyl in kidney impairment

It is recommended in severe kidney impairment that the dose of transdermal fentanyl should be 50% of usual.

Note: there may be other rationale for reducing the dose of fentanyl in a person with reduced kidney function; eg, age, frailty, comorbidities.

Oxycodone in kidney impairment

- The metabolite of oxycodone is oxymorphone which is active but plasma levels are normally negligible and therefore it has an insignificant clinical effect in patients with normal kidney function
- Higher blood concentrations of oxycodone and metabolites occur in patients with moderate to severe kidney impairment.
- The half-life of oxycodone is significantly increased in end-stage kidney disease (18).
- Some references advise that no dosage adjustment is required for most patients with kidney impairment, but to monitor the effect of oxycodone and adjust if necessary (18)
- Others recommend caution in kidney impairment
- when CrCl <60 mL/min, commence with 50% of usual dosage and monitor and adjust if necessary (23)

Most consensus guidelines have oxycodone as preferrred in the presence of kidney impairment (1,3)

Recommendation – oxycodone in kidney impairment

1. Reduce initial dose of oxycodone in severe kidney impairment
2. Monitor efficacy and for adverse effects
3. Oxycodone is a preferred opioid in the presence of kidney impairment.

Morphine in kidney impairment

Morphine and its metabolites in kidney impairment

- Morphine accumulates in the presence of kidney impairment.
- Morphine undergoes metabolism to its 3-glucuronide (M3G), which has no analgesic activity but has significant neuroexcitatory properties.
- The other metabolite, morphine-6-glucuronide (M6G), is a more potent respiratory depressant than morphine itself and in kidney insufficiency can accumulate and cause excessive sedation and respiratory depression (20)
- M6G is an opioid agonist that crosses the blood-brain barrier slowly;
  - » delayed sedation from M6G has been reported in kidney failure.
- Morpine and its metabolites are cleared by most haemodialysis procedures but may not be significantly affected by peritoneal dialysis.
  - » M6G is removed but slow diffusion from CNS delays the response to dialysis (18)

Recommendation – morphine in kidney impairment

1. The initial doses should be 50% of usual dose for patients with moderate kidney impairment, and 25% of the usual dosage for patients with severe kidney impairment (22)
2. The dosage intervals should be extended
3. Morphine is not advised for **ongoing** use in the presence of moderate to severe kidney impairment, due to accumulation of morhphine itself, its opioid-active (M6G) and neurotoxic (M3G) metabolites.

Hydromorphone in kidney impairment

Hydromorphone is excreted through the kidneys. The parent drug and its active metabolites accumulate in the presence of kidney impairment (25)

- Compared with subjects with normal kidney function, (CrCl > 80 mL/min), after oral administration of hydromorphone of a single dose of 4 mg Dilaudid (using 2 x 2 mg IR Tablets), the mean hydromorphone is increased:
  - » by 2-fold in patients with impaired kidney function (CrCl = 40-60 mL/min), and
  - » by 3-fold in severe (CrCl < 30 mL/min) kidney impairment
- In patients with severe kidney impairment hydromorphone is more slowly eliminated with a longer terminal elimination half-life (40 hours) compared to patients with normal kidney function (15 hours) (25)

Hydromorphone metabolites

Hydromorphone is extensively metabolised to hydromorphone-3-glucuronide (H3G) (18)(26)(27)(20) which accumulates in kidney impairment. Hydromorphone administration in the presence of kidney failure has been associated with nausea and delirium (26); both of these effects are postulated to be related to its metabolites.

- Neurotoxicity from accumulation of H3G is possible (18). The effects of can present with a report of increased pain.
- Any report of increased pain in the setting of confusion, myoclonus, or other features of opioid neurotoxicity should prompt a suspicion of neurotoxixity and hyperalgaesia and not an increase in dose. If suspected, consider rotating to a different opioid without an active metabolite (26)
- H3G is a neurotoxic metablite but does no analgesic effects.
- With chronic dosing of oral hydromorphone, blood levels of H3G are about 30 times higher than blood levels of the parent drug, and this ratio rises to 100-fold in the presence of even modest kidney impairment (25)
- There is also a minor amount of hydromorphone 6-glucuronide (6HG). This has no opioid atcivity so there is a lower risk of respiratory depression with hydromorpone in the setting of kidney failure compared to morphine (20), and hence its reputation for being the preferred opioid.
- H3G is effectively removed during dialysis (18)

Recommendation – hydromorphone in kidney impairment

1. Adjust doses and dosing intervals, or use an alternative opioid (1)
2. Start patients with moderate kidney impairment at 50% dose.
3. Avoid in patients with severe kidney impairment.
4. Change to another opioid if there are signs of neurotoxicity.
5. NOTE: Jurnista® 8mg daily is approximately equivalent to MS Contin® 20mg twice daily BOTH can accumulate in kidney impairment.

Tapentadol in kidney impairment

Tapentadol and its metabolite in kidney impairment (18,20)(28)

- Tapentadol is metabolised by glucuronidation.
- The major metabolite tapentadol-O- glucuronide (TOG) accumulates in kidney impairment. In subjects with mild, moderate, and severe kidney impairment, the metabolite levels are 1.5-, 2.5-, and 5.5-fold higher compared with normal kidney function, respectively. The metabolite however, is inactive.
- The product information advises to avoid use in severe kidney impairment (28); other references advise for CrCl <10 mL/minute, use a lower starting dose and/or increase dosage interval; titrate dose carefully and monitor for adverse effects (29).
- Tapentadol is removed by haemodialysis.

Tramadol in kidney impairment

- Tramadol and its metabolite accumulate with advanced CKD (estimated GFR <30 mL/min/1.73 m^2)
- There is an increase in tramadol-like effects from the active metabolite O-desmethyltramadol (M1), especially for tramadol ultra-metabolisers. Respiratory depression has been reported (18) as well as a reduced seizure threshold and risk of serotonin syndrome (30)
- Dose adjustment or the use of alternative agent is recommended in presence of significant kidney impairment. Reduce the dose if CrCl <30mL/minute and imcrease the frequency. Do not use SR formulations.
- Tramadol is incompetely removed by haemodialysis

Buprenorphine in kidney impairment

- buprenorphine is extensively metabolised through the liver: the metabolite (norbuprenorphine) has a weak analgesic effect
- kidney clearance of both buprenorphine and norbuprenorphine is 30%
- appears safe for advanced chronic kidney disease and dialysis: no dose reduction suggested at this time, but use with caution (30)
- removed by dialysis
- the product information advises that no dosage adjustment is required in patients with kidney impairment and caution in chronic kidney and disease (31).

Methadone in kidney impairment

Methadone has no known active metabolites so it is a good choice for patients with chronic pain and kidney insufficiency. However, due to its complicated pharmacokinetics and risk of accumulation, ongoing therapy is recommended to be by specialists familiar with methadone (20).

- Methadone and its metabolites are excreted in urine and faeces; in anuric patients it may be mostly in faeces
- Dose adjustment may be required in severe kidney impairment

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Opioid Handout

Name: .....

Name and dose of medicine: ..... When commenced: / /

Reason for medicine (source of pain): .....

What is an opioid?

An opioid is a medicine that works by blocking pain signals sent from the body to the brain. Opioid medications can be prescribed to manage severe pain. There is no medicine that can completely relieve all pain.

Opioids are very strong medicines and **severe side effects** can occur if used with other medicines that make you feel drowsy or sleepy, alcohol or cannabis. Opioid overdose may result in death.

How long will I use this for?

Your doctor will talk to you about this in more detail, but it is usually advised that these medicines are for short-term treatment only. There are side effects when taking opioids, and health and lifestyle effects from long-term use.

What side effects can occur?

Some side effects that you may experience are constipation, nausea, drowsiness or confusion and loss of balance.

Your driving may be affected.

Severe side effects can occur especially if used with other sedative medicines, alcohol or cannabis. These include extreme drowsiness, snoring or gurgling, slow or unusual breathing, cold and clammy skin or blue lips. These may be signs of an overdose. **Call an ambulance 000 if an overdose is suspected.**

What are the long-term effects of opioids?

- **Tolerance:** your body will need higher doses and more often.
- **Worsening of pain over time.**
- **Psychological dependence, or "addiction":** a strong desire to take more of the medicine.
- Depression and anxiety.
- Problems sleeping and worsened sleep apnoea.
- Weight gain and change in appetite.
- **Hormone imbalance & changes to sexual function**: impotence, loss of sex drive; change in menstrual periods; osteoporosis.
- Reduced saliva, dry mouth & problems with teeth.
- **If Pregnant:** the baby can become dependent and may experience withdrawal when born.
- **Physical dependence:** if the medicine is stopped suddenly, I may experience diarrhoea, stomach cramps, goose pimples and runny nose.

What do I need to do?

- Continue using other medicines recommended by your doctor, and physical therapies to manage your pain.
- Tell your doctor if you take other medications, drink alcohol or use recreational drugs (especially cannabis).
- While using opioid medication, also take a laxative to prevent constipation.
- Return any unused opioids to your community pharmacy for safe disposal.
- Never give an opioid to a child or share an opioid with anybody else.
- Store out of reach of children, in a locked area.
- Avoid driving or using machinery if you are drowsy.

Call an ambulance 000 if an overdose is suspected.

Resource adapted from Woonona Medical Practice

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Opioid Agreement - Trial

Name: .....

Address: .....

Name and dose of medicine: ..... Date commenced: / /

Reason for medicine (source of pain): .....

This is an agreement between *<insert Doctor's name>* ..... **and me for a trial of starting or for continuing a morphine-like medicine for my pain.**

- ☐ **I agree to this trial for .....weeks.**
- ☐ **At the end of that period, I agree that if the medicine has not provided the benefit that we have aimed for, then it will be slowly withdrawn and ceased.**
- ☐ **I agree that the decision to cease or continue this trial remains with the doctor.**
- ☐ **I understand that I may experience the following SIDE EFFECTS:**

SIDE EFFECTS	
Tolerance: • I may need higher doses and more often	Constipation
My pain may worsen over time	Nausea or vomiting
Physical dependence: • If this medicine is stopped suddenly, I may experience diarrhoea, stomach cramps, goose bumps and runny nose	Drowsiness, confusion, lethargy or clouded thinking • driving may be affected
Psychological Dependence: • I may experience a strong desire to take more of this medicine • I may experience an uncontrollable need to seek out and use this drug, despite harmful consequences	Hormone and sexual function changes: • Cause impotence or lose my sex drive • Changes in my menstrual periods • Osteoporosis
Loss of balance	Depression and anxiety
Slowed breathing	Itchy skin
Problems with my teeth and dry mouth	Problems with sleeping and worsened sleep apnoea
Hallucinations	Weight gain and change in appetite
If pregnant – my baby may become dependent and may experience withdrawal when born	An overdose if too much is taken or used with other medicines, alcohol or cannabis • slowed thinking & breathing • speech slurs • staggering when walking

I agree also:

- ☐ that I will see only *<insert name of primary GP>* ..... for ongoing prescriptions of this medicine,

  or ..... *<insert name of secondary GP>* from ..... *<insert name of medical practice>*

  if this has been arranged in advance by my doctor (an appointment with this doctor may be required);
- ☐ that I will not use any more of the medicine than is prescribed for me;
- ☐ that my own or any other doctor will not be able to give me extra medicine if mine is lost, stolen or runs out early;
- ☐ I will not give my medicine to anybody else;
- ☐ not to use it for any other purpose than why it has been originally prescribed;
- ☐ that if I do not abide by any of these conditions, my doctor may no longer prescribe this medicine for me.

What I am hoping to be able to do by taking this medicine: .....

Signature ..... Date: .....

Resource adapted from Woonona Medical Practice

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Opioid Agreement

Name: .....

Address: .....

Name and dose of medicine: ..... Year commenced: .....

Reason for medicine (source of pain): .....

This is an agreement between *<insert Doctor's name>* **..... and me to continue a morphine-like medicine for my pain.**

☐ **I agree to this contract for 12 months.**

☐ **I agree that the decision to cease or continue this medication remains with the doctor.**

☐ **I understand that I may experience the following SIDE EFFECTS:**

SIDE EFFECTS	
Tolerance: • I may need higher doses and more often	Constipation
My pain may worsen over time	Nausea or vomiting
Physical dependence: • If this medicine is stopped suddenly, I may experience diarrhoea, stomach cramps, goose bumps and runny nose	Drowsiness, confusion, lethargy or clouded thinking • driving may be affected
Psychological Dependence: • I may experience a strong desire to take more of this medicine • I may experience an uncontrollable need to seek out and use this drug, despite harmful consequences	Hormone and sexual function changes: • Cause impotence or lose my sex drive • Changes in my menstrual periods • Osteoporosis
Loss of balance	Depression and anxiety
Slowed breathing	Itchy skin
Problems with my teeth and dry mouth	Problems with sleeping and worsened sleep apnoea
Hallucinations	Weight gain and change in appetite
If pregnant – my baby may become dependent and may experience withdrawal when born	An overdose if too much is taken or used with other medicines, alcohol or cannabis • slowed thinking & breathing • speech slurs • staggering when walking

I agree also:

☐ that I will see only *<insert name of primary GP>* ..... for ongoing prescriptions of this medicine,

or ..... *<insert name of secondary GP>* ..... from ..... *<insert name of medical practice>* .....

if this has been arranged in advance by my doctor (an appointment with this doctor may be required);

☐ that I will not use any more of the medicine than is prescribed for me;

☐ that my own or any other doctor will not be able to give me extra medicine if mine is lost, stolen or runs out early;

☐ I will not give my medicine to anybody else;

☐ to a regular review of this medicine for its benefits and unwanted effects.

☐ not to use it for any other purpose than why it has been originally prescribed;

☐ that if I do not abide by any of these conditions, my doctor may no longer prescribe this medicine for me

What I am hoping to be able to do by taking this medicine: .....

Signature ..... Date: .....

Resource adapted from Woonona Medical Practice

Australian Government
Medicare Australia

Authority to release personal Medicare and Pharmaceutical Benefits Scheme claims information to a third party

Important information

Complete this form to authorise the release of personal Medicare or Pharmaceutical Benefits Scheme (PBS) claims information to a third party.

Your request will not be actioned unless this form is complete. If the form is incomplete it will be returned to you.

Information will only be released for the dates authorised on this form. This authority will remain valid for 12 months from the date signed unless the authority is expressly withdrawn.

Information will not be included about services provided after the date on which the form is signed.

Medicare and PBS records are available for the past five years.

Assistance

If you need assistance completing this form call **132 011** (call charges may apply). For more information about releasing personal Medicare or PBS claims information to a third party go to **www.medicareaustralia.gov.au > About Medicare Australia > Your information and rights > How to request your personal information**

Lodgement

Applicants must return the complete form to their nominated third party (as per question 6) who will then forward it to:

NSW, ACT and VIC residents:

Information Release
Medicare Australia
GPO Box 9822
Sydney NSW 2001

NT, QLD, TAS, SA and WA residents:

Information Release
Medicare Australia
GPO Box 9822
Brisbane Qld 4001

or visit your local Medicare office.

Print in **BLOCK LETTERS**

Tick where applicable ☑

Applicant's details

1 Medicare card number

[ ][ ][ ][ ] – [ ][ ][ ][ ][ ] – [ ] Ref no. [ ]

2 Dr ☐ Mr ☐ Mrs ☐ Miss ☐ Ms ☐ Other [ ]

Family name

First given name

Other given name(s)

3 Date of birth

[/ /]

4 Address

Postcode

Postal address (if different to above)

Postcode

5 Phone number

( )

Mobile phone number

Authorisation

Tick all that apply

6 I authorise Medicare Australia to provide my:

Medicare claims history for the period ☐

from [/ /] to [/ /]

(insert full date range e.g. 01/05/2006 to 31/05/2007)

and/or

PBS claims history for the period ☐

from [/ /] to [/ /]

(insert full date range e.g. 01/05/2006 to 31/05/2007)

to the following organisation or person

Declaration

7 I declare that:

- the information on this form is correct.

Applicant's signature

Date

[/ /]

Privacy note

The information on this form will be used to provide Medicare Australia with the authority to release your Medicare or PBS claims information to a third party. The collection of this information is authorised by the *Health Insurance Act 1973* and *National Health Act 1953*. The information collected may be disclosed to the Department of Health and Ageing, Department of Veterans' Affairs or as authorised or required by law.

Sample Medicare claims history

The information in your Medicare claims history may include details that are not directly related to the purpose for which it is being requested.

A sample of the information that may be included in your Medicare claims history:

Date of service	Item	Item description	Benefit	Provider charge	Payment method	Date of lodgement	Date of processing	Rendering provider location and name	Ordering provider location and name
15 June 2007	00023	VR Level B Cons	$32.10	$32.10	Bulk Bill	08 July 2007	10 July 2007	Dr J Black 104 Smith Rd, Smithville	
06 July 2007	11700	ECG	$23.50	$32.50	Bulk Bill	02 Aug 2007	04 Aug 2007	Dr Smith, Suite 2b 8 Johns St, Melbourne	
15 Aug 2007	56807H	CT chest/ abd/pelv	$420.00	$680.00	Cash	16 Aug 2007	16 Aug 2007	Dr Smith, Suite 2b 8 Johns St, Melbourne	Dr W Brown 17 Hope Pl, Melbourne

Sample PBS claims history

The information in your PBS claims history may include details that are not directly related to the purpose for which it is being requested.

A sample of the information that may be included in your PBS claims history:

Prescribing date	Supply date	Item Code	Item Description	QTY Repeats	Prescriber Name	Pharmacy name	Pharmacy address
29 July 2007	1 Sept 2007	03133X	OXAZEPAM (UNREST) TABLET 30MG (NO Q/R) 20	2	Dr S Smith	One Stop Pharmacy	5 Smith St Melbourne
29 July 2007	1 Sept 2007	01215Y	CODEINE PHOSPH " PAR TABLET 30MG-500MG 60	0	Dr B Brown	Sth Melbourne Pharmacy	100 Brown Road South Melbourne
06 Sept 2007	20 Sept 2007	01746X	PARACETAMOL TABLET 500MG 100	5	Dr K Kelly	Day Night Pharmacy	18 Black Street Melbourne

Clear Form

NSW GOVERNMENT

PN10/19

Application for Authority to Prescribe a Schedule 8 Drug – Pain Management

This form is available online in PDF format (http://www.health.nsw.gov.au/pharmaceutical) and should be filled in electronically using a computer. If completing the form by hand, please use BLOCK LETTERS and ensure that all details are legible.

Eligible applications are generally processed within 7 business days.

Section A: Prescriber details

Prescriber Name:

(first names) *(family name)*

Name of Practice:

Address:

Suburb/Town: **Postcode:**

Telephone:	**Fax:**	**Email:**

AHPRA Registration No:	**PBS Prescriber No:**

AHPRA Specialty/Field: ☐ General Practice ☐ Pain Medicine ☐ Addiction Medicine ☐ Palliative Medicine

☐ Other specialty, *please specify* .....

Section B: Patient details

Patient Name:

(first names) *(family name)*

Also known as *(if applicable)*:

(first names) *(family name)*

Patient Residential Address:

Suburb/Town: **Postcode:**

Patient Date of Birth: __ __ __ __ __ __ __ __ **Sex:** ☐ M ☐ F

Do you consider this patient to be drug dependent? ☐ Y ☐ N

A 'drug dependent person' means a person who has acquired, as a result of repeated administration of a drug of addiction or a prohibited drug within the meaning of the Drug Misuse and Trafficking Act 1985, an overpowering desire for the continued administration of such a drug (Section 27 of the Poisons and Therapeutic Goods Act 1966).

Do you have any of the following concerns?

☐ past/current IV drug use ☐ drug seeking ☐ unsanctioned dosage escalation
☐ illicit drug use ☐ doctor shopping ☐ medical dependence
☐ diversion ☐ drug misuse ☐ lost prescriptions/medication
☐ longer period of use than intended or appropriate

☐ no concerns

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Section C: Drug authorisation details

oral Morphine Equivalent Daily Dose (oMEDD) is the opioid dosage as compared to oral morphine.
Opioid prescribing recommendations in general practice (published by ACI Pain Management Network) are as follows:

- *≤40mg daily oMEDD for non-cancer pain for a maximum 90 days*
- *≤300mg daily oMEDD for cancer pain*

For opioid doses ≥100mg daily oMEDD, a specialist review is recommended.
To calculate the oMEDD go to http://fpm.anzca.edu.au/documents/opioid-dose-equivalence or http://www.opioidcalculator.com.au/
More information about the role of opioids in chronic non-cancer pain and further resources go to http://www.aci.health.nsw.gov.au/chronic-pain
Note: For non-opioid drugs, 'Total oMEDD' details are to be left blank.

Drug (1): ..... **Form:** ..... **Maximum Daily Dose:** ..... mg **If unable to specify a maximum daily dose, indicate the dosage and frequency:** ..... *Note: If dosage P.R.N. indicate maximum per week/month*	Total oMEDD
Drug (2): ..... **Form:** ..... **Maximum Daily Dose:** ..... mg **If unable to specify a maximum daily dose, indicate the dosage and frequency:** ..... *Note: If dosage P.R.N. indicate maximum per week/month*	Total oMEDD
Drug (3) : ..... **Form:** ..... **Maximum Daily Dose:** ..... mg **If unable to specify a maximum daily dose, indicate the dosage and frequency:** ..... *Note: If dosage P.R.N. indicate maximum per week/month*	Total oMEDD

Section D: Diagnostic criteria and other management information

1. Diagnosis

☐ Cancer

☐ Other, *please specify* ..... ⇢ *Go to Q3*

2. Prognosis: What is the prognosis for this patient? ..... (months)

3. Is the patient currently enrolled on the Opioid Treatment Program (OTP)?

☐ No, the patient is NOT currently on the OTP ⇢ *Go to Q5*

☐ Yes, the patient is currently on the OTP and I am the authorised OTP prescriber

Note: If you are not the authorised OTP prescriber, you must contact the authorised OTP prescriber and obtain a letter of support

☐ Yes, the patient is currently on the OTP and I have a letter of support from the authorised OTP prescriber

⇢ *The letter of support must be attached*

4. Is there a report from an addiction medicine specialist supporting concurrent OTP treatment?

☐ Y ⇢ *The report must be attached*

☐ N ⇢ *A report from an addiction medicine specialist may be requested*

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5. If you are a palliative medicine or pain medicine specialist ····▶ *Go to Q6*

If you are not a palliative medicine or pain medicine specialist:

Indicate below the circumstances of your application and provide specialist review dates as applicable (tick one box only):

☐ I have a recent report from a palliative medicine or pain medicine specialist ····▶ *The report must be attached.*

Note: A report older than 12 months is not considered to be recent

☐ The patient will be reviewed by *(please specify name and address of specialist)* .....

.....

on *(please specify)* ___ ___ ___ ___ ___ ___

☐ Other, *please specify why you are applying to prescribe for this patient*

.....

.....

Section E: Injectable opioids

6. Are you applying to prescribe an injectable opioid?

☐ N ····▶ *Go to Q9*

☐ Y ····▶ *A report from a pain medicine or palliative medicine specialist supporting the drug and dose must be attached*

7. How often will injections be administered? .....

Note: If frequency P.R.N. indicate the average per day/week/month

8. Who will administer the injections?

Note: The Ministry does not endorse self-administration or administration by family members

☐ I as the prescriber ☐ Other medical practitioner ☐ Nurse

☐ Other, *please specify* .....

····▶ ***Go to Q10***

Section F: Pain Management details

9. Are you applying to prescribe a total oMEDD > 400mg?

☐ N ····▶ *Go to Q12*

☐ Y

10. What analgesic medications is the patient currently taking (including opioids and non-opioids)?

Drug	Dose	Frequency	Rate effectiveness *(1 = low, 5 = high)*

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11. What other medications have been trialled?

Drug	Route of administration	Brand name	Rate effectiveness *(1 = low, 5 = high)*	Reasons for discontinuing *e.g. ineffective, allergy, adverse effects such as vomiting*

12. What other non-pharmacological pain relief treatments have been trialled?

- ☐ None
- ☐ Cognitive behaviour therapy (CBT)
- ☐ Relaxation techniques
- ☐ Counselling
- ☐ Physiotherapy
- ☐ Hydrotherapy
- ☐ Massage therapy
- ☐ Exercise therapy
- ☐ Acupuncture
- ☐ Other, *please specify* .....

13. Is there a written management plan for the patient?

- ☐ Y
- ☐ N

14. What is the expected duration of treatment with the requested drug(s)? ..... months

Section G: Declaration

I confirm that the information I have provided in this application is true and complete to the best of my knowledge.

Signed: ..... Date: __ __ __ __ __ __ __ __

Privacy Statement: The information set out in this form is required by the Ministry of Health for the issuance of an authority to prescribe a Schedule 8 drug as required under the law. The collection, use and disclosure of the information provided will be in accordance with privacy laws. The information collected may be disclosed to health practitioners when necessary to facilitate coordination of treatment and patient safety. Personal information will not be disclosed for any other purpose without prior consent, except where required by law or where otherwise lawfully authorised to do so. The application may not be processed if all information requested on the form is not completed. For further information on privacy visit http://www.health.nsw.gov.au/patients/privacy.

Fax completed form and supporting documentation to the Pharmaceutical Regulatory Unit: 02 9424 5889
Enquiries: Tel 02 9424 5923 or email MOH-S8Auth@health.nsw.gov.au
Allow up to 7 business days for the processing of applications.

Pain Management Network

Opioid Risk Assessment

PREDICTING ABERRANT BEHAVIOURS IN OPIOID TREATED PATIENTS

Opioid Risk Tool (ORT)

Mark each box that applies:	Female (Score)	Male (Score)
1. Family history of substance abuse		
• Alcohol	☐ 1	☐ 3
• Illegal drugs	☐ 2	☐ 3
• Prescription drugs	☐ 4	☐ 4
2. Personal history of substance abuse		
• Alcohol	☐ 3	☐ 3
• Illegal drugs	☐ 4	☐ 4
• Prescription drugs	☐ 5	☐ 5
3. Age (mark box if between 16-45 years)	☐ 1	☐ 1
4. History of preadolescent sexual abuse	☐ 3	☐ 0
5. Psychological disease		
• Attention deficit disorder, obsessive compulsive disorder, bipolar, schizophrenia	☐ 2	☐ 2
• Depression	☐ 1	☐ 1
Scoring Totals	_____	_____

ORT Scoring and risk of aberrant behaviour

0-3:	low risk	estimated 6% risk of aberrant behaviour
4-7:	moderate	estimated 28% risk of aberrant behaviour
8 or >8 :	high risk	estimated 91% risk of aberrant behaviour

Reference: Webster LR. Predicting aberrant behaviours in opioid-treated patients: Preliminary validation of the opioid risk tool.Pain Medicine. 2005;6(6):432-442

PEG Pain Screening Tool

1. What number best describes your pain on average in the past week:

0 1 2 3 4 5 6 7 8 9 10

No pain — Pain as bad as you can imagine

2. What number best describes how, during the past week, pain has interfered with your enjoyment of life?

0 1 2 3 4 5 6 7 8 9 10

Does not interfere — Completely interferes

3. What number best describes how, during the past week, pain has interfered with your general activity?

0 1 2 3 4 5 6 7 8 9 10

Does not interfere — Completely interferes

To compute the PEG score, add the three responses to the questions above, then divide by three to get a final score out of 10.

The final PEG score can mean very different things to different patients. The PEG score, like most other screening instruments, is most useful in tracking changes over time. The PEG score should decrease over time after therapy has begun.

0 Save Print

Clinician information sheet on opioid analgesic tapering

This information sheet aims to:

- Summarise agreed principles and highlight some key points of, and signpost to, a number of Australian guidelines
- Recommend language that guides and supports patients
- Support opioid analgesic tapering for patients with complex problems, noting that in these cases referral to a specialist service may be required, but there will likely be a waiting period before these services can be accessed
- Support taper in situations where the patient may not fully cooperate, but the prescriber feels the current dose is causing harm thus is unable to continue current prescribing
- Emphasise that every practitioner attempting a taper must create a patient-specific plan to ensure ongoing monitoring and support to avoid serious withdrawal symptoms, worsening of pain or psychological distress

Treatment indication: opioid analgesics and Chronic Non Cancer Pain (CNCP)

Opioid analgesics are no longer indicated for CNCP other than in exceptional circumstances following changes to the TGA registered indications and PBS reimbursement criteria in 2020.

Goals of intervention and target patient groups

- **Chronic Non-Cancer Pain patients on opioid analgesics**, for whom the prescriber considers does not meet the criterion of exceptional circumstances, and where the prescriber and patient believe they can collaborate to achieve a reduction in opioid analgesic dose.
- **Indications for opioid analgesic tapering include** suspected lack of efficacy of opioid analgesic in pain management (including increased pain sensitivity), hazardous/harmful use of opioid analgesics, other adverse events (respiratory depression, tiredness, constipation, difficulty in concentrating, difficult to treat depression and/or sexual dysfunction).
- The **oMEDD** (**oral morphine** equivalent daily dose) is a measure of how potent the opioid analgesic dose is. The Faculty of Pain Medicine have a simple dose calculator www.opioidcalculator.com.au that is free to download, including as an app. The 'traffic light' system on the app is also a useful, visual tool when discussing concerns with patients taking high doses of opioid analgesics. (Note the ratios for conversion of morphine and other full agonist opioids to buprenorphine do not apply at high doses).
- **In particular, CNCP patients taking more than 60mg oMEDD** should aim to taper to below this dose to improve safety outcomes. While the 60 mg oMEDD figure is based on expert opinion only, use of 60 mg or higher likely indicates pain that is poorly responsive to opioid analgesics and that the analgesic response is not justified by the potential for harm. **For frail or older patients and those prescribed other sedative medicines** such as benzodiazepines, gabapentinoids or antipsychotics, a better oMEDD threshold is lower, at 30 to 40 mg.
- **Patients with CNCP taking less than 60 mg oMEDD** should have an opioid analgesic tapering plan developed after discussion of possible tapering.

Having the opioid analgesic tapering discussion

The patient may have commenced, maintained and increased opioid analgesics on advice from their doctor. A number of patients may not be aware that the analgesics they have been taking are opioids, and that little benefit may be expected from long term opioids. It may be helpful to explain to the patient that evidence shows taking opioid analgesics for long periods may not be safe or beneficial. Outline the potential side effects of long-term opioid analgesic use, relating this to the patient, and the benefits of reducing their dose.

Discussions about future opioid analgesic prescribing with patients who have been on opioids for a significant period are challenging. The discussion should not always start from the view that a lower dose of opioid analgesic is preferable for each patient who is on less than 60 mg oMEDD. Noting a lower threshold oMEDD of 30 mg in older, frail patients and those prescribed other sedating medicines. It is important to reassure the patient that opioid analgesic tapering does not mean that you will abandon them, and that you will continue to support them to take up more efficient strategies they can use in the longer term. The transition from opioid analgesic treatment to supported self-management and other pain management strategies is strongly supported by scientific evidence.

Successful opioid analgesic tapering can take time with multiple facilitators, most importantly the patient. Tapering is supported by policy and regulation, clinician expertise including holding therapeutic boundaries with empathy and patient empowerment, opportunity and motivation. Opioid analgesic tapering is more likely to succeed when there is a shared decision between the prescriber and patient. In particular, be clear when the patient has made an active decision to taper their opioid analgesic, and document and agree on the tapering plan. Also, recognise there is variability in the level of opioid analgesic tapering and discomfort patients can or will accept that will guide the approach.

Some resources to support GPs in opioid analgesic tapering discussions with patients

Communication techniques for tapering conversations (University of Sydney, Aug 2020)

NPS MedicineWise: www.nps.org.au/professionals/opioids-chronic-pain/starting-a-conversation and www.nps.org.au/cpd/activities/real-time-prescription-monitoring-safe-script

Internal Medicine Society of Australia/ NZ:
https://www.imsanz.org.au/sb_cache/associationnews/id/643/f/PSA%20Opioid%20Medicine%20Fact%20Sheet%20_FINAL.pdf

www.researchgate.net/publication/51070630_The_Behaviour_Change_Wheel_a_new_method_for_characterising_and_designing_behaviour_change_interventions

Opioid analgesic tapering protocols

Whether a faster or gradual opioid analgesic tapering is best will depend on the level of patient engagement, and how the patient progresses during tapering (e.g. withdrawal symptoms). In general, switching between different opioid analgesics during tapering may be unsettling to the patient. However, switching from opioid analgesics, such as oxycodone to buprenorphine (a partial agonist), may be appropriate for those patients who may be at risk of overdose through seeking illicit opioids during tapering. Pain management services are usually willing to provide telephone advice to prescribers to support replacement of poorly performing treatments such as opioid analgesics with better or safer alternatives for particular patients. In general:

- At every consultation, give the patient a written opioid analgesic tapering plan. With the patient's agreement, communicate the plans with the patient's nominated pharmacy to reinforce the plan. Prescribe only enough of the opioid analgesic until the agreed review date and emphasise that "bridging" prescriptions will not be provided.
- Consider implementing a staged supply arrangement with the patient's nominated pharmacy.

- In the case of unequal split daily dosing, have the patient participate in deciding which opioid analgesic doses are reduced first.

Gradual taper

- Rationalise the patient's regimen to a single modified release opioid analgesic. However, in patients on higher doses of an immediate release opioid analgesic, taper on the same product.
- When stabilised, the opioid analgesic dose should be reduced slowly by 5 to 20% oMEDD **each month**. Note that some symptoms of withdrawal and transient rebound pain may last several weeks.
- In the case of persisting or recurrent withdrawal symptoms, consider reverting to the previous lowest tolerated dose. Then slow the process by recommencing weaning after 6 to 12 weeks at lower weaning rate (e.g. by 5 to 10% oMEDD every 2 to 3 months).

Faster taper

- If tapering after a short (< 3 month) period of opioid analgesic treatment or opioid analgesic trial, reduce dose by 10 to 25% oMEDD **every week**.
- If significant adverse events or significant risk of harm is likely if current opioid analgesic dose is maintained, reduce dose by 10 to 25% oMEDD **daily** (this may require hospital admission).

Specialist services should be considered for some patients. This includes patients where opioid analgesic withdrawal management with short-term clonidine may be required to limit opioid tolerance and hyperalgesia.

Some resources to support GPs in choosing tapering protocols

NPS MedicineWise: www.nps.org.au/news/5-steps-to-tapering-opioids

NSW Therapeutic Advisory Group: http://www.nswtag.org.au/wp-content/uploads/2018/06/1.8-Deprescribing-Guide-for-Regular-Long-Term-Opioid-Analgesic-Use-in-Older-Adults.pdf

NSW Government guidelines on deprescribing in general practice: http://www.aci.health.nsw.gov.au/chronic-pain/health-professionals

Note, an Australian Clinical Practice guideline is under development with an anticipated completion date of 2022: www.clinicalguidelines.gov.au/register/development-evidence-based-opioid-deprescribing-guidelines

End points for opioid analgesic tapering

The end point for opioid analgesic tapering will depend on the overall aim for the particular patient. The timing and rate of opioid analgesic reduction should always be negotiated. In some cases, it may be appropriate to taper to the lowest tolerated opioid analgesic dose rather than de-prescribing, as some patients will report reduced function and increased distress and pain with opioid analgesic de-prescribing.

In other patients it is appropriate to cease opioid analgesics altogether. These patients may continue non-pharmacological pain management approaches and use other analgesics, such as NSAIDs, if tolerated, and not contraindicated. It is vital that patients are closely monitored and supported during opioid analgesic tapering to increase the chance of success.

Other points

- **Only prescribe enough opioid analgesic** during the tapering period until you can see the patient again. Set up a series of regular appointments with the patient and stage dispensing from the patients pharmacy.

- The opioid analgesic tapering plan should **take into account the available formulations** for the chosen opioid analgesic, and ensure the patient understands the percentage reduction that is practical at each stage. If opioid analgesics are prescribed twice a day, agree with the patient which dose is reduced first. If three times a day, it might be the midday dose. When weaning controlled release oxycodone there is no formulation for less than 10mg, but the oxycodone/naloxone combination can usually be substituted.
- **Other support for the patient** may be needed throughout opioid analgesic tapering, including:
  - agreement on the goals of therapy, and access to self-management services and helplines
  - information on adverse effects of opioid analgesics and of withdrawal symptoms, and acknowledgement that the patient has been alerted to these
  - setting an opioid analgesic treatment agreement with the patient, including conditions such as the patient using only a single pharmacy, single prescriber (or a nominated second prescriber from the same practice if the patient's main GP is not available), staged supply, regular review, real time prescription monitoring services (where available) and Urine Drug Screen check, and agreement to engage with specialist services
  - for those patients who may not fully cooperate during the taper, "nudge" approaches may be appropriate
  - take home naloxone should be used to support all high and co-morbid use of opioids (see www.health.gov.au/initiatives-and-programs/take-home-naloxone-pilot; www.penington.org.au/wp-content/uploads/2019/04/COPE-overdoseresponse-nyxoid.pdf)
- For some patients, if on the advice of an addiction medicine specialist opioid use disorder is the primary problem, conversion to opioid substitution treatment (for example, buprenorphine) may be appropriate. This can be undertaken either in outpatient or inpatient settings.
- **Opioid analgesic tapering requires special care with pregnant patients** on high doses, and should be carried out in conjunction with an obstetrician/neonatologist as it is important to avoid precipitating withdrawal—perinatal risk or risk of miscarriage or premature labour.

Assessing dependence and options for opioid substitution programs

www.racp.edu.au/docs/default-source/news-and-events/covid-19/interim-guidance-delivery-of-medication-assisted-treatment-of-opiod-dependence-covid-19.pdf?sfvrsn=e36eeb1a_4

www.health.nsw.gov.au/aod/Publications/nsw-clinical-guidelines-opioid.pdf

www2.health.vic.gov.au/public-health/drugs-and-poisons/pharmacotherapy/pharmacotherapy-training

www.health.qld.gov.au/__data/assets/pdf_file/0022/444613/qotp-clinical-guidelines.pdf

www.mhc.wa.gov.au/media/1614/wa-clinical-policies-and-procedures-for-the-use-of-methadone.pdf

www.sahealth.sa.gov.au/wps/wcm/connect/public+content/sa+health+internet/clinical+resources/clinical+programs+and+practice+guidelines/substance+misuse+and+dependence/drug+and+alcohol+programs/gp+program+medication+assisted+treatment+for+opioid+dependence

www.dhhs.tas.gov.au/__data/assets/pdf_file/0018/112527/2012_TOPP_Document.pdf

www.health.act.gov.au/services-and-programs/alcohol-and-drug-services/opioid-maintenance-treatment

Opioid analgesic tapering is a personal experience and should be guided by the prescriber as agreed with the patient. Additional information on support services is available from the **National Pain Services Directory** which is an online directory to provide people living with chronic pain—and their health practitioners—with a comprehensive list of available services to help manage their conditions: www.painaustralia.org.au/getting-help/pain-directory.

Appendix 8

The table below describes approaches to opioid tapering for those requiring different levels of support. If it emerges that the primary problem is opioid use disorder then a change of approach is required and advice from an addiction medicine specialist considered. This may be required if significant aberrant behaviour emerges, risk of overdose through polysubstance abuse or emergence of serious cravings during taper.

Opioid tapering guide (for those prescribed opioids for pain)

Patient characteristics		
Low prescribing support	**Moderate prescribing support**	**High prescribing support**
No misuse of opioid medication **No polydrug use** **Patient agrees or volunteers** with opioid analgesic tapering and takes as prescribed Stable mental and physical health.	**Harmful use** with infrequent misuse of opioid medication; no intoxicated presentation Use of atypical opioids (buprenorphine, tapentadol, tramadol) **Polypharmacy** but not high risk; no intoxicated presentations Patient contemplative or disagrees with opioid analgesic tapering after feedback on hazardous use Maladaptive pain cognitions and/or limited pain coping skills Unstable mental or physical health	**High dose** (over 100 mg oMEDD daily) **Harmful use**, with frequent misuse of opioid analgesic medication **Significant aberrant behaviour** (e.g. doctor shopping, forging script/street drug, use for sleep/anxiety, diversion) **High risk polydrug use** (e.g. sedatives) with intoxicated presentation Patient disagrees with opioid analgesic tapering despite feedback on harmful use Unstable social conditions and unstable prescriber engagement Serious unstable mental (e.g. risk of harm to self or others health) or physical health concern, that requires specialist input
Potential tapering intervention for pain		
Low prescribing support	**Moderate prescribing support**	**High prescribing support**
Determine whether opioid analgesic tapering is appropriate Psychoeducation Gradual opioid analgesic tapering under medical supervision Consider rotation to atypical opioid Pain self-management program	Brief intervention Gradual opioid analgesic tapering under medical supervision Or Containment if unable to further reduce, until specialist review, e.g. weekly staged supply Harm reduction strategy Referral for pain clinic and pain self-management program	Brief intervention, behaviour management Containment until specialist review, e.g. daily supervised dosing Or Partial opioid analgesic tapering to safer dose in conjunction with referral to specialist services Harm reduction strategy Specialist referral for urgent review, e.g. drug and alcohol and/or pain management clinic and/or psychiatry

Some opioid tapering resources

www.racgp.org.au/getmedia/33c608d7-e336-41ea-920f-fa171eb02885/Opioid-reduction-policy-template.docx.aspx.

Racgp.org.au/FSDEDEV/media/documents/Clinical%20Resources/Guidelines/Drugs%20of%20dependence/Prescribing-drugs-of-dependence-in-general-practice-Part-A.pdf

www.nps.org.au/professionals/opioids-chronic-pain#resources

NSW Ministry of Health

www.aci.health.nsw.gov.au/chronic-pain/health-professionals/quick-steps-to-manage-chronic-pain-in-primary-care/how_to_de-prescribe_and_wean_opioids_in_general_practice

www.nswtag.org.au/wp-content/uploads/2018/06/1.8-Deprescribing-Guide-for-Regular-Long-Term-Opioid-Analgesic-Use-in-Older-Adults.pdf

QLD Health

www.health.qld.gov.au/__data/assets/pdf_file/0021/444432/quick-clinical-guide.pdf

https://insight.qld.edu.au/shop/withdrawal-management-quick-reference-guide-opioids

https://insight.qld.edu.au/training/opioid-related-case-studies/detail

Primary Health Tasmania

www.primaryhealthtas.com.au/wp-content/uploads/2018/09/A-Guide-to-Deprescribing-Opioids.pdf

South Australia

http://nceta.flinders.edu.au/files/8315/4959/9031/Responding_to_pharmaceutical_opioid_related_problems.pdf

https://reachforthefacts.com.au/for-prescribers/

Victoria

www2.health.vic.gov.au/public-health/drugs-and-poisons/safescript/training

www.turningpoint.org.au/

This information sheet was a joint initiative from the following:

- Dr Anne Burke, President - Australian Pain Society
- Dr Michael Vagg, Board Member - ANZCA Faculty of Pain Medicine
- Dr Malcolm Hogg, Head of Pain Services - Royal Melbourne Hospital, and Clinical Advisor - Painaustralia
- Dr Danielle McMullen, NSW President - Australian Medical Association
- Dr Chris Hayes, Specialist Pain Medicine Physician - Hunter New England Health, NSW
- Dr Adrian Reynolds, Clinical Director - Dept of Health and Human Services, Tasmania
- A/Professor Suzanne Nielsen, Deputy Director - Monash Addiction Research Centre, Monash University
- Margaret Jordan, Project Pharmacist - Society of Hospital Pharmacists Australia
- Steve Morris, CEO - NPS MedicineWise
- Rawa Osman, Senior Clinical Program Officer - NPS MedicineWise
- Dr Tim Ho, Rehabilitation and Pain Specialist - Sydney Adventist Hospital
- Dr Carl Schneider, Senior Lecturer - Faculty of Medicine and Health, University of Sydney

Reviewed by the Opioids Regulations Communication Committee and coordinated by the Therapeutic Goods Administration

Clinician information sheet on **opioid analgesic tapering: summary**

Opioids are no longer indicated for Chronic Non Cancer Pain (CNCP) other than in exceptional circumstances. This guide is for cases where the prescriber and patient believe they can collaborate to achieve a reduction in opioid dose.

Goals of intervention

- **Indications for opioid analgesic tapering include** suspected lack of efficacy of opioid in pain management (including increased pain sensitivity), hazardous/harmful use of opioid analgesics, other adverse events (respiratory depression, tiredness, constipation, difficulty in concentrating, difficult to treat depression and/or sexual dysfunction).
- The **oMEDD** (oral morphine equivalent daily dose) is a measure of how potent the opioid analgesic dose is. The Faculty of Pain Medicine have a simple dose calculator www.opioidcalculator.com.au that is free to download, including as an app.
- **In particular, CNCP patients taking more than 60mg oMEDD** should aim to taper to below this dose to improve safety outcomes. Use of 60 mg or higher likely indicates pain that is poorly responsive to opioid analgesics and potential for harm. **Patients with CNCP taking less than 60 mg oMEDD** should have an opioid analgesic tapering plan developed after discussion of possible tapering. **For frail or older patients and those prescribed other sedative medicines** such as benzodiazepines, gabapentinoids or antipsychotics, a better oMEDD threshold is lower, at 30 to 40 mg.

Having the opioid analgesic tapering discussion

Explain to the patient that taking opioid analgesics for long periods may not be safe or beneficial. Outline the potential side effects of long-term opioid analgesic use, relating this to the patient, and the benefits of reducing their dose.

Discussions about future opioid analgesic prescribing with patients who have been on opioids for a significant period are challenging. The discussion should not always start from the view that a lower dose of opioid analgesic is preferable for each patient who is on less than 60 mg oMEDD. Noting a lower threshold oMEDD of 30 mg in older, frail patients and those prescribed other sedating medicines. It is important to reassure the patient that opioid analgesic tapering does not mean that you will abandon them, and that you will continue to support them to take up more efficient strategies they can use in the longer term. Transition from opioid analgesic treatment to supported self-management and other pain management strategies is strongly supported by evidence.

Successful opioid analgesic tapering can take time with multiple facilitators, most importantly the patient. Tapering is supported by policy and regulation, clinician expertise including holding therapeutic boundaries with empathy and patient empowerment, opportunity and motivation. Opioid analgesic tapering is more likely to succeed when there is a shared decision between the prescriber and patient. In particular, be clear when the patient has made an active decision to taper their opioid analgesic, and document and agree on the tapering plan. Recognise there is variability in the level of opioid tapering and discomfort patients can or will accept that will guide the approach.

Opioid analgesic tapering protocols

Whether a faster or gradual opioid analgesic tapering is best will depend on the level of patient engagement, and how the patient progresses during tapering (e.g. withdrawal symptoms). In general, switching between different opioid analgesics during tapering may be unsettling to the patient. However, switching from opioid analgesics, such as oxycodone to buprenorphine (a partial agonist), may be appropriate for those patients who may be at risk of overdose. Pain management services are usually willing to provide telephone advice to prescribers to support replacement of poorly performing treatments such as opioid analgesics with better or safer alternatives for particular patients.

At every consultation, give the patient a written tapering plan. With the patient's agreement, communicate the plans with the patient's nominated pharmacy to reinforce the plan. Prescribe only enough of the opioid analgesic until the agreed review date and emphasise that "bridging" prescriptions will not be provided.

Gradual taper

- Rationalise the patient's regimen to a single modified release opioid analgesic. However, in patients on higher doses of an immediate release opioid, taper on the same product.
- When stabilised, the opioid dose should be reduced slowly by 5 to 20% oMEDD **each month**. Some symptoms of withdrawal and transient rebound pain may last several weeks.
- In the case of persisting or recurrent withdrawal symptoms, consider reverting to the previous lowest tolerated dose. Then slow the process by recommencing weaning after 6 to 12 weeks at lower weaning rate (e.g. by 5 to 10 % oMEDD every 2 to 3 months).

Faster taper

- If tapering after a short (< 3 month) period of opioid analgesic treatment or opioid analgesic trial, reduce dose by 10 to 25% oMEDD **every week**.
- If significant adverse events or significant risk of harm likely if current opioid analgesic dose is maintained, reduce dose by 10 to 25% oMEDD **daily** (may require hospital admission).

End points for opioid analgesic tapering

The timing and rate of opioid analgesic reduction should always be negotiated. In some cases, it may be appropriate to taper to the lowest tolerated opioid analgesic dose rather than de-prescribing, as some patients will report reduced function and increased distress and pain with opioid analgesic de-prescribing. In other patients it is appropriate to cease opioid analgesics altogether. These patients may continue non-pharmacological pain **management approaches and use other analgesics, such as NSAIDs, if tolerated, and not contraindicated. It is vital that patients are closely monitored and supported during opioid analgesic tapering to increase the chance of success.**

Other practice points

- **Only prescribe enough opioid analgesic** during the tapering period until you can see the patient again. Set up a series of regular appointments with the patient and stage dispensing from the patient's pharmacy.
- The opioid analgesic tapering plan should **take into account the available formulations** for the chosen opioid analgesic, and ensure the patient understands the percentage reduction that is practical at each stage.
- **Setting a treatment agreement with the patient**, including conditions such as the patient using only a single pharmacy, single prescriber (or a nominated second prescriber from the same practice if the patient's main GP is not available), staged supply, regular review, real time prescription monitoring services (where available) and Urine Drug Screen check, and agreement to engage with specialist services. For some patients, if on the advice of an addiction medicine specialist opioid use disorder is the primary problem, conversion to opioid substitution treatment (for example, buprenorphine) may be appropriate. This can be undertaken either in outpatient or inpatient settings.
- **Opioid analgesic tapering requires special care with pregnant patients** on high doses, and should be carried out in conjunction with an obstetrician/neonatologist as it is important to avoid precipitating withdrawal - perinatal risk or risk of miscarriage or premature labour.
- An online directory is available to provide people living with chronic pain—and their health practitioners—with a comprehensive list of available services to help manage their conditions: www.painaustralia.org.au/getting-help/pain-directory.