A brief guide to prescribing buprenorphine/naloxone

Advice for prescribers who have not undertaken the accredited one-day opioid pharmacotherapy prescriber training

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This document has been prepared by the Department of Health and Human Services to assist prescribers who have not undertaken the accredited one-day opioid pharmacotherapy prescriber training*, with general information on the key regulatory and policy requirements associated with the safe, appropriate and lawful prescribing of buprenorphine/naloxone. This document should be used in conjunction with the *Policy for Maintenance Pharmacotherapy for Opioid Dependence (2016)*.

*** Further information about this training is available on page 4**

1. Be familiar with the pharmacology of buprenorphine combined with naloxone
2. Assess the patient for evidence of opioid dependence and suitability for treatment
3. Arrange a pharmacy for the patient to receive supervised dosing
4. Obtain a permit from the Department of Health and Human Services before writing the prescription
5. Write a prescription to start treatment, taking into account the risk of precipitated withdrawal
6. Review the patient within the first few days to adjust the dose if necessary
7. Establish the maintenance dose and arrange ongoing consultation
8. Arrange collaborative treatment and counselling with other health professionals

Introduction

The Policy for Maintenance Pharmacotherapy for Opioid Dependence (the Policy) enables all medical practitioners and nurse practitioners with a notation for a category in which the prescribing of buprenorphine/naloxone is authorised, to prescribe buprenorphine/naloxone for up to five patients without the need to undergo additional training and assessment to prescribe pharmacotherapy for opioid dependence.

This may provide better access to treatment for opioid dependent patients, and encourage integration of treatment of addiction with general health care.

Buprenorphine has similar effectiveness as methadone in reducing problematic pharmaceutical opioid use or heroin use, decreasing injecting drug use, reducing risk of needle sharing and transmission of blood borne viruses, and reducing criminal activity where this is driven by drug-seeking behaviour.

Maintenance pharmacotherapy for opioid dependence enables patients to stabilise and control their opioid use, stabilise their social circumstances, and obtain other benefits from treatment.

If you require advice on the clinical management of a patient, advice should be sought from a colleague familiar with the use of buprenorphine in the treatment of opioid dependence. Advice from an addiction medicine specialist may be obtained by contacting the Drug and Alcohol Clinical Advisory Service (DACAS) (tel: 1800 812 804).

General steps in prescribing buprenorphine/naloxone

1. Be familiar with the pharmacology of buprenorphine combined with naloxone

Buprenorphine, like methadone, is used to treat opioid dependence and is a substitute for either pharmaceutical opioid analgesics or heroin, whether such opioids are prescribed, obtained over the counter without a prescription (e.g. over the counter codeine-containing analgesics) or obtained without prescription on the street.

Unlike full opioid agonists such as morphine and methadone, buprenorphine is a partial opioid agonist. This results in a 'ceiling' effect where even with increasing dose there is little increase in respiratory or central nervous system depression, making it less risky than methadone. Nevertheless some deaths are associated with buprenorphine when it is injected and/or combined with benzodiazepines, alcohol or other sedatives, so care is required in patient selection and prescribing. Buprenorphine is an opioid subject to development of tolerance and dependence, and ceasing use abruptly may cause an opioid withdrawal syndrome.

Suboxone® is a combination of buprenorphine and naloxone developed to deter injection of formulations intended for sublingual use. The product is administered sublingually because buprenorphine absorption from the gut is poor. Naloxone is very poorly absorbed via the oral or sublingual route, but is active if the product is injected, so if injected it will delay the onset of opioid effect in those who

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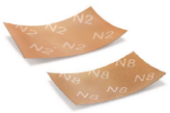
are not opioid dependent, or it will precipitate withdrawal in those who are opioid dependent.

Buprenorphine/naloxone is available as a ***sublingual film*** (in 2 mg and 8 mg dose formulations). The film adheres to the sublingual mucosa within seconds once administered and is difficult to remove after 30 to 60 seconds, making it difficult to divert the dose from the mouth. Under normal circumstances, supervision of a dose does not need to exceed 1 minute.

The onset of effect is between 30 to 60 minutes, and peak effect occurs at 1 to 4 hours. Duration of effect to control craving can be from 24 to 72 hours, depending on dose and individual patient response.

Figure 1: Buprenorphine/naloxone film



Actual size of each film:
2.2 cm x 1.3 cm

2. Assess the patient for evidence of opioid dependence and suitability for treatment

Establishing opioid dependence. Inquire about history of opioid use and past attempts at withdrawal, examine the patient, and arrange investigations. A drug screen of a supervised collection of urine is recommended.

Opioid dependence can be diagnosed by considering well-established criteria (see Figure 2).

Patients who are pregnant, breast-feeding or are allergic to buprenorphine or naloxone are not suitable for treatment with buprenorphine/naloxone.

3. Arrange a pharmacy for the patient to receive supervised dosing

Doses of buprenorphine/naloxone are taken under the supervision of a pharmacist at an approved pharmacy that provides pharmacotherapy services.

Daily supervised dosing is required during the commencement of treatment. Dosing arrangements must be made with a pharmacy **before** applying for a permit and before the patient is given a prescription. DirectLine (tel: 1800 888 236) may assist with details of pharmacies that provide supervised dosing of buprenorphine/naloxone.

The supply of buprenorphine/naloxone by the pharmacy to the patient is not subsided under the Pharmaceutical Benefits Scheme (PBS). Advise the patient to check with the pharmacy on the cost of daily dosing fees, the opening hours and arrange to meet the pharmacist, if possible.

These details should be confirmed by the prescriber with the nominated pharmacy, to ensure all parties are in agreement.

Certify a photograph of the patient for the patient to provide to the pharmacy to ensure that the patient who presents at the pharmacy is the same person who consulted you.

Figure 2: Diagnostic Criteria for Opioid Use Disorder

Diagnostic criteria

A problematic pattern of opioid use leading to clinically significant impairment or distress, as manifested by at least two of the following, occurring within a 12-month period:

- opioids are often taken in larger amounts or over a longer period than was intended
- there is a persistent desire or unsuccessful efforts to cut down or control opioid use
- a great deal of time is spent in activities necessary to obtain the opioid, use the opioid or recover from its effects
- craving, or a strong desire or urge to use opioids
- recurrent opioid use resulting in a failure to fulfil major role obligations at work, school or home.
- Continued opioid use despite having persistent or recurrent social or interpersonal problems cause or exacerbated by the effects of opioids
- Important social, occupational, or recreational activities are given up or reduced because of opioid use
- Recurrent opioid use in situations in which it is physically hazardous
- Continued opioid use despite knowledge of having a persistent or recurrent physical or psychological problem that is likely to have been cause or exacerbated by the substance.
- Tolerance*, as defined by either of the following:
  - A need for markedly increased amounts of opioids to achieve intoxication or desired effect
  - A markedly diminished effect with continued use of the same amount of an opioid
- Withdrawal* as manifested by either of the following:
  - the characteristic opioid withdrawal syndrome (refer to Criteria A and B or the criteria set for opioid withdrawal, pp 547-548 of the Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition)
  - Opioids (or a closely related substance) are taken to relieve or avoid withdrawal symptoms

* Note: this criterion is not considered to be met for those individuals taking opioids solely under appropriate medical supervision).

4. Obtain a permit from the Department of Health and Human Services before writing the prescription

A permit must be obtained from Drugs and Poisons Regulation, Department of Health and Human Services (tel: 1300 364 545) **before** prescribing buprenorphine/naloxone (a Schedule 8 poison) to an opioid dependent person. The *Application for a permit to treat an opioid dependent person with methadone or buprenorphine* can be completed and submitted online via an online form at https://www2.health.vic.gov.au/public-health/drugs-and-poisons/smart-forms-drugs-and-poisons.

Prescribers with no internet access may contact Drugs and Poisons Regulation, however the online form is the preferred method.

Your local Area-Based Pharmacotherapy Network is available to assist you with completing this form. See below for contacts.

Individual permits must be obtained for each patient. Before applying for a permit, ensure that the limit of five (5) patients has not been exceeded.

Drugs and Poisons Regulation may also be contacted for information on a patient's previous prescriber to ascertain previous treatment details.

To prevent inadvertent double dosing do not commence treatment until a permit has been issued (usually within one working day after submitting the application).

5. Write a prescription to start treatment, taking into account the risk of precipitated withdrawal

Precipitated withdrawal. This is the main risk of beginning treatment for opioid dependence with buprenorphine, and may be so unpleasant that the patient will avoid further involvement in treatment. Buprenorphine has a strong affinity for opioid receptors, and will replace other opioids and precipitate a withdrawal syndrome if treatment initiation is not carefully managed. To avoid precipitated withdrawal it is best to commence treatment after a suitable time to allow early opioid withdrawal symptoms to be observed, and start with a low dose.

Commencing treatment. Treatment should not be started until you or the pharmacist observe the physical signs of opioid withdrawal (including one or more of the following: dilated pupils, pulse > 90/min, BP > 140/90, sweatiness, sniffing, yawning, watery eyes, anxiety, piloerection (goose bumps)).

The onset of withdrawal is usually 8 to 12 hours after the last use of a short-acting opioid and may be delayed for longer acting opioids.

Patients exhibiting signs of opioid withdrawal may start on 4 mg buprenorphine (2 x 2 mg films) on the first day and may be and provided with a further 4 mg after 1 to 2 hours if necessary and if the first dose did not precipitate a withdrawal syndrome. This 'split dosing' reduces the risk of a severe precipitated withdrawal. If 'split dosing' may be required, contact the nominated pharmacy to make this arrangement.

Over subsequent days, doses may be increased by 2, 4 or 8 mg increments, with upper limits of 16 mg on day 2 and 24 mg on day 3.

Adjust the dose according to whether the patient is experiencing opiate withdrawal symptoms prior to their dose of Suboxone, craving for opiates or ongoing illicit opiate use (Suboxone dose is too low); or whether the patient is experiencing symptoms of intoxication, sedation or nausea (Suboxone dose is too high). Take use of other central nervous system depressants into account in assessing intoxication or sedation. Refer to *Multiple missed doses* section of the Policy (pp 57).

Consider contacting the DACAS (tel: 1800 812 804) if unsure about dosing.

Writing a prescription. The prescription must comply with all legislative requirements for writing a prescription for a Schedule 8 poison (including the dose to be written in words and figures).

In addition, the prescription should include:

- the date the first dose is to be supplied
- the date the authorisation to supply will end (to encourage the pharmacotherapy patient to attend for review at an appropriate interval)
- the precise dose in words and figures
- number of take-away doses per week authorised (**nil during commencement of treatment**; refer to Take-away doses section (starting pp 28) of the Policy for further information)) and
- the name of the pharmacy at which the pharmacotherapy dose it to be supplied.

Figure 3: Example of a prescription

Dr William Pacemaker 123 Medical Street Ash Park VIC 3999 Tel: (03) 1234 5678	< Prescriber's name, address, contact details
Mr Barry Patient 88 Luck Street Forktown VIC 3131	< Patient's name
01/07/2015	< Date of prescription written
Rx Methadone Syrup	< Prescription written is legible and durable
60 (sixty) mg daily	< Dose in words and figures
from: 1 July 2015	< Date of first dose on this prescription
last dose: 31 July 2015	< Date of last dose on this prescription
take-away doses for Saturdays and Sundays	< Take-away doses (if authorised)
Rx Methadone Syrup 60 (sixty) mg daily from: 1 July 2015 last dose: 31 July 2015 take-away doses for Saturdays and Sundays	< For computer-generated prescription, particulars of prescription also handwritten
To be dispensed at: Mortarpestles Pharmacy 125 Fourth Street, Splotswood	< Pharmacy at which pharmacotherapy is to be supplied
William Pacemaker	< Signature

As with prescribing other opioids, ensure the patient is advised not to drive or operate machinery if the patient feels sedated at any time during the course of treatment. Also warn the patient to avoid the use of other central nervous system depressants such as benzodiazepines or alcohol. Advise about the risk of overdose and symptoms and signs suggesting a need to seek help (refer to patient leaflet *Starting methadone or buprenorphine*).

6. Review the patient within the first few days to adjust the dose if necessary

Review the patient on days 2 and 3 of dosing to assess adverse effects and effectiveness of treatment, and adjust dose as necessary. Review again by the next week to check progress, and liaise with the pharmacy to inquire about attendance and progress they may have observed.

Refer to *Frequency of review* (pp 39) section of the Policy for further information.

7. Establish the maintenance dose and arrange ongoing consultation

The typical maintenance dose range for treating opioid dependence is 12 to 16 mg buprenorphine daily. Most patients become stable on 12 to 24 mg, and the maximum dose is 32 mg per day. Following a period of continuous treatment and stability in treatment, patients may be considered suitable for take-away doses to reduce the demands of daily supervised dosing.

Refer to *Take-away doses* section (starting pp 28) of the Policy for further information.

8. Arrange collaborative treatment and counselling with other health professionals as appropriate

Opioid dependent individuals may engage in chaotic drug taking, and pharmacotherapy can help to stabilise their lives and their drug use, providing an opportunity to enable them to address any underlying problems that have led to opioid dependence or problematic opioid use.

They may benefit from counselling, and social support with accommodation and employment. They may require assessment for issues experienced by this patient group, including but not limited to blood borne viruses (HIV, hepatitis B and hepatitis C) as per Policy (pp 28), smoking cessation, mental health issues, poor diet, dental issues, social supports and integration.

Medical practitioners and nurse practitioners with a notation for a category in which the prescribing of buprenorphine/naloxone is authorised, who are confidently managing up to five (5) patients with buprenorphine/naloxone, are highly encouraged to undertake the one-day Module 2 opioid pharmacotherapy prescriber training, also referred to as *Medication Assisted Treatment of Opioid Dependence (MATOD*) training.

Successful completion of training and assessment enables prescribers to provide a greater range and capacity of pharmacotherapy services to patients; that is, the ability to prescribe methadone and/or manage more than five (5) buprenorphine/naloxone patients.

Module 1 (a two hour online training course called *Safer Opioid Prescribing*) is a pre-requisite to Module 2.

Module 1 and 2 details can be found at http://www.racgp.org.au/education/courses/racgpevents/vic/

Useful resources and contacts

A short video on prescribing buprenorphine/ naloxone is available at https://www.racgp.org.au/education/courses/faculty-webinars/vic/buprenorphine/

Medical and nurse practitioners prescribing buprenorphine/naloxone should be familiar with the current policy framework and clinical guidelines in relation to buprenorphine use in the treatment of opioid dependence.

- Victorian *Policy for Maintenance Pharmacotherapy for Opioid Dependence* (2016)
- *National clinical guidelines and procedures for the use of buprenorphine in the maintenance treatment of opioid dependence (2014)*

Drugs and Poisons Regulation, Department of Health and Human Services

Issues permits to treat a patient with pharmacotherapy.

Tel: 1300 364 545

Fax: 1300 360 830

Email: dpcs@health.vic.gov.au

Further information about pharmacotherapy in Victoria, including links to the Policy and permit application forms are available at www2.health.vic.gov.au/public-health/drugs-and-poisons/pharmacotherapy

Prevention, Population, Primary and Community Health, Department of Health and Human Services

Provides permission and information for individual medical practitioners, nurse practitioners and pharmacies who wish to prescribe or supply pharmacotherapies.

Tel: 9096 5057

Fax: 9096 9170

Email: AOD.enquries@dhhs.vic.gov.au

Drug and Alcohol Clinical Advisory Service (DACAS)

Exclusively for health and welfare professionals, the service provides advice and information on the clinical management of patients with drug and/or alcohol problems, including:

- advice on recognising and managing withdrawal symptoms
- information about drug use complications
- drug and prescribing information
- assistance with cases of acute intoxication.

Tel: 1800 812 804 (24 hours)

Web: www.dacas.org.au

DirectLine

For the general public and health and welfare professionals, the service provides counselling and information including:

- pharmacotherapy prescriber and pharmacy contact details
- details of needle syringe programs and bin locations
- details of drug and alcohol agencies and drug withdrawal beds
- HIV/AIDS information and referral
- drink driving education and assessment referral.

Tel: 1800 888 236 (24 hours)

Pharmacotherapy Advocacy, Mediation and Support (PAMS) Service

PAMS is a service that is available to pharmacotherapy patients, prescribers or pharmacists to help resolve problems with accessing or delivery of pharmacotherapy.

PAMS will assist in mediating outcomes to these problems and service providers are encouraged to attempt mediation before deciding to withdraw service provision to particular patients of the system.

Tel: 1800 443 844

Area-Based Pharmacotherapy Networks

Prescribers are encouraged to make contact with their local Pharmacotherapy Network. The five Networks assist pharmacotherapy providers with implementing a more integrated and cohesive services and can offer support and mentoring to prescribers.

Area 1 (Barwon South West) **Tel: 5222 0809**
ORTicare (Grampians and Loddon Mallee) **Tel: 5338 4500**
Area 3 (Hume) **Tel: 5823 3219**
(Gippsland) **Tel: 1800 242 696**
Area 4 (South East Metropolitan Melbourne) **Tel: 8514 6600**
Area 5 (North West Metropolitan Melbourne) **Tel: 9448 5511**

More information on Pharmacotherapy Networks and full contact details are provided in *Appendix 15* (pp. 79) of the Policy.

Additional useful contacts are listed in *Appendix 2* (pp 62) of the Policy.