A brief guide to prescribing buprenorphine/naloxone

health

Advice for medical practitioners who have not undertaken the one-day Pharmacotherapy GP Training Program

April 2013

Note: This document has been prepared by the Department of Health to assist medical practitioners who have not undertaken the one-day Pharmacotherapy GP Training Program with general information on the key regulatory and policy requirements associated with the safe, appropriate and lawful prescribing of buprenorphine/naloxone. Refer to the *Policy for Maintenance Pharmacotherapy for Opioid Dependence* for more detailed information.

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. **Obtain a permit from the Department of Health before writing the prescription**
4. **Arrange a pharmacy for the patient to receive supervised dosing**
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 as appropriate**

Introduction

The *Policy for Maintenance Pharmacotherapy for Opioid Dependence* (the Policy) enables all medical practitioners 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 heroin or problematic prescription opioid use, decreasing injecting drug use, reducing risk of needle sharing and transmission of blood borne viruses, reducing risk of overdose death, 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 substitute for either heroin or pharmaceutical opioid analgesics, whether such opioids are prescribed, obtained without prescription on the street, or available over the counter without a prescription (e.g. OTC codeine-containing analgesics).

Unlike full agonist opioids 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 CNS 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 oral 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 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.

Figure 2: Opioid dependence criteria

Diagnostic Definition of Opioid Dependence (DSM IV)

'A maladaptive pattern of substance use leading to clinically significant impairment or distress as manifested by three or more of the following occurring at any time in the same 12 month period.'

- *Tolerance* as defined by either of the following:

– A need for markedly increased amounts of opioids to achieve intoxication or desired effect;

– Markedly diminished effect with continued use of the same amount of opioids.

- *Withdrawal* as manifested by either of the following:

– The characteristic withdrawal syndrome for opioids;

– Opioids, or a closely related substance, being taken to relieve or avoid withdrawal symptoms.

- *Impaired control over use:* Opioids often taken in larger amounts or over longer period than intended.
- *Wish to quit:* A persistent desire or unsuccessful attempts to cut down or control opioid use.
- *Time factor:* A great deal of time regularly spent in activities necessary to obtain opioids, use opioids, or recover from their effects.
- *Life-style changes:* Important social, occupational, or recreational activities given up or reduced because of opioid use.
- *Continued use despite awareness it is causing harm:* The opioid use continued, despite knowledge of having a persistent or recurrent physical or psychological problem that is likely to have been caused or exacerbated by opioids.

3. Obtain a permit from the Department of Health before writing the prescription

A permit must be obtained from Drugs and Poisons Regulation, Department of Health (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 bupenorphine"* may be submitted online via at: www.health.vic.gov.au/dpcs/smartforms.htm.

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).

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

Doses of buprenorphine/naloxone are taken under the supervision of a pharmacist at a nominated 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 the patient 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 treatment 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.

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 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 dose according to side effects, and symptoms of withdrawal (dose too low), or intoxication or over-sedation (dose too high). Take use of other CNS depressants into account in assessing intoxication or sedation.

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:

- date of the first dose
- date of the last dose (to encourage the patient to attend for review at an appropriate interval)
- number of take-away doses per week authorised (**nil during commencement of treatment**; refer to "Take-away doses" (pp. 21-28) section of the Policy for further information))
- name of the dispensing pharmacy.

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 and address
01/02/2013	Date of prescription written
Rx Suboxone® Film	
8 (eight) mg daily	Dose in words and figures
from: 1 Feb 2013	Date of first dose
last dose: 14 Feb 2013	Date of last dose
nil take-away doses (daily supervised dosing)	Take-away doses (if authorised)
Rx Suboxone® Film *8 (eight) mg daily* *from: 1 Feb 2013* *last dose: 14 Feb 2013* *nil take-away doses* *(daily supervised dosing)*	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 dispensed
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 CNS 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 "Review of patient's progress" (pp. 28-29) 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" (pp. 21-28) section 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 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.

Medical practitioners who are confidently managing up to five (5) patients with buprenorphine/naloxone, are highly encouraged to undertake the one-day Pharmacotherapy GP Training Program. 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 or buprenorphine/naloxone to more than five (5) patients. Contact Harm Reduction and Pharmacotherapy Services on (03) 9096 5057 for further information.

Useful resources and contacts

Medical 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.

- Policy for Maintenance Pharmacotherapy for Opioid Dependence
- National clinical guidelines and procedures for the use of buprenorphine in the maintenance treatment of opioid dependence

Drugs and Poisons Regulation

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, clinical guidelines, permit application forms, and the Pharmacotherapy Newsletter is available at: www.health.vic.gov.au/dpcs/pharm.htm

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-hour service)

Web: www.dacas.org.au

DirectLine

For the general public and health and welfare professionals, the service provides counselling, information and referral, 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 hour service)

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

Additional useful contacts are listed in Appendix 2 (pp. 47-49) of the Policy.