Policy for maintenance pharmacotherapy for opioid dependence (addendum)

Long-acting injectable buprenorphine

VICTORIA State Government | Department of Health

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Contents

Note

This summary should be read in conjunction with the Victorian Department of Health's existing *Policy for maintenance pharmacotherapy for opioid dependence, updated 2016,* and also the *Long-acting injectable buprenorphine: Brief clinical guidelines for use in the treatment of opioid dependence*, December 2020.

This summary outlines the changes to the current *Policy for maintenance pharmacotherapy for opioid dependence* (for sublingual buprenorphine or buprenorphine/naloxone treatment) to include the requirements for using long-acting injectable buprenorphine.

Warning

These preparations should never be dispensed directly to or handled by the patient or their carer(s).

Both long-acting injectable buprenorphine formulations (Buvidal® (Weekly/Monthly) and Sublocade®) are for subcutaneous use only.

There is a risk of serious harm or death if long-acting injectable buprenorphine is administered intravenously, intra-arterially, intramuscularly or intradermally (for example: pulmonary thrombosis, tissue necrosis, rhabdomyolysis).

Buvidal® absorbs water and transforms into a highly viscous gel that remains in situ. Sublocade® will form a solid mass upon contact with body fluids.

If not injected subcutaneously, they may cause occlusion, local tissue damage and thrombo-embolic events, including life-threatening pulmonary emboli.

Introduction

In 2019, buprenorphine became available on the Pharmaceutical Benefits Scheme in Australia as a subcutaneous long-acting injection with access initially restricted to specialist settings. In April 2020, the Therapeutic Goods Administration (TGA) approved the availability of these products to a broader group of healthcare professionals.

Currently, two long-acting injectable buprenorphine (LAIB) products are available for the Australian market. They differ in their formulations, administration and pharmacology. Differences are highlighted in the Brief clinical guidelines for use of long-acting injectable buprenorphine in the treatment of opioid dependence.

- Buvidal® (Camurus Pty Ltd, Sweden, TGA lifting of restricted access 3 April 2020)
- Sublocade® (Indivior Pty Ltd, USA, TGA lifting of restricted access 21 April 2020).

Buvidal® formulations allow for weekly or monthly dosing frequency. Sublocade® formulations allow for monthly dosing only.

Weekly or monthly administration of LAIB negates the need for daily dosing and takeaways, and therefore reduces the frequency of supervised dosing to weekly or monthly intervals.

In turn, this potentially reduces travel, stigma and out of pocket expenses for patients. Eliminating takeaway doses also reduces the scope for diversion and improves child safety.

For reference, the main features of the two products are shown in Table 1.

Table 1: Main features of Buvidal® and Sublocade®

Formulation	Buvidal®	Sublocade®
Product of description	Buprenorphine long-acting injectable preparation for subcutaneous injection	Buprenorphine long-acting injectable preparation for subcutaneous injection
Dosage strengths	Buvidal® Weekly strengths: 8 mg, 16 mg, 24 mg, 32 mg Buvidal® Monthly strengths: 64 mg, 96 mg, 128 mg	100 mg 300 mg
Subcutaneous injection site	Buttocks, thigh, abdomen or upper arm	Abdomen only
Frequency of dosing	Weekly Monthly	Monthly
Transport and storage	Usual Schedule 8 requirements (including Schedule 8 compliant safe) Store at room temperature (below 25ºC) Do not refrigerate	Usual Schedule 8 requirements (including Schedule 8 refrigeration requirements) Requires refrigeration (2-8ºC) Can be stored at room temperature (below 25ºC) for up to either 7 or 28 days prior to administration (see individual packaging for details).
Schedule 8 treatment permit requirements	Must hold Schedule 8 permit that includes LAIB prior to prescribing/administering	Must hold Schedule 8 permit that includes LAIB prior to prescribing/administering

Risks and countermeasures specific to long-acting injectable buprenorphine

As well as the established countermeasures designed to reduce the risks of opioid agonist therapies, specific considerations when using LAIB include the following:

- The preparation should never be dispensed directly to or handled by the patient or their carer(s).
- Given the reduced frequency of supervised doses (reduced interaction with the pharmacist), additional clinical supervision and management may be required for some patients. Frequency of review should be considered in this context and individualised care plans made accordingly.
- The prescribing and administration of LAIB should only be undertaken by registered health professionals who meet the requirements under the 'Permission to prescribe and administer long-acting injectable buprenorphine' section of this document. Patient safety and the correct administration of LAIB must be fully understood.
- When doses are missed by a patient, there is greater flexibility in the time before which re-induction is required due to missed doses.
- **If a dose is missed**, the next dose should be administered as soon as practicable. If more than 10 to 14 days have elapsed between doses of Buvidal® Weekly, re-induction may be required. If more than eight weeks have elapsed since the last dose of Buvidal® Monthly or Sublocade®, then re-induction may be required.

Who is eligible to prescribe and administer long-acting injectable buprenorphine

1. For **medical[1] and nurse practitioners** to prescribe and administer LAIB;

   It is *expected* that:

   (a) They are familiar with and understand Victorian pharmacotherapy guidelines, including:
      i. Policy for maintenance pharmacotherapy for opioid dependence
      ii. Brief clinical guidelines for use of LAIB

   (b) They are familiar with injection technique for specific LAIB formulations:
      i. Buvidal administration
      ii. Sublocade administration

   It is *strongly recommended* that:

   (a) Training developed by the Royal Australian College of General Practitioners is completed:
      i. Medication Assisted Treatment of Opioid Dependence (MATOD) - Module 1
      ii. Medication Assisted Treatment of Opioid Dependence (MATOD) - Module 2
      iii. Long-Acting Injectable Buprenorphine - MATOD Module 3

   (b) Practitioners new to prescribing LAIB, who are managing a complex patient, should seek addiction medicine specialist advice for support https://www.dacas.org.au/ or 1800 812 804.

2. For **registered nurses** to administer LAIB on the order of a prescriber it is *expected* that:
   (a) They are familiar with the product information for Buvidal® and/or Sublocade®
   (b) They are familiar with injection technique for specific LAIB formulations
      i. Buvidal administration
      ii. Sublocade administration

3. For **pharmacists** to administer LAIB on the order of a prescriber it is *expected* that:
   (a) They are familiar with and understand requirements for pharmacotherapy program delivery by:
      i. Completing Victorian Opioid Pharmacotherapy Program training developed by the Pharmaceutical Society of Australia (PSA); or
      ii. Working as a registered pharmacist in opioid replacement therapy delivery for at least five years
   (b) They understand requirements for injection administration by completing an immunisation course approved by the Department of Health (see PSA or The Pharmacy Guild of Australia)
   (c) They understand requirements specific to LAIB by completing LAIB Administration by Pharmacists training developed by PSA

   Further detail around policy requirements for pharmacist administration of LAIB can be found in the section ‘Pharmacist administration practice standards’

It is the responsibility of the relevant healthcare professional to complete the expected training and product familiarisation to ensure they are practicing within their scope of competency.

[1] Training requirements for Addiction Medicine Specialists are beyond the scope of this guideline. Eligibility to prescribe/administer pharmacotherapy is established through completion of a speciality training program.

Pharmacist administration practice standards

A pharmacist may administer a Schedule 8 medication on the order of a prescriber under the Drugs, Poisons and Controlled Substances Regulations 2017.

Pharmacists should adhere to the following practice standards to ensure patients receive safe and quality service delivery for LAIB administration within a community pharmacy or health service setting.

Accreditation and training

Pharmacists are required to meet the competencies related to pharmacotherapy program delivery, injection administration and LAIB as listed under the section 'Who is able to prescribe or administer long-acting injectable buprenorphine'.

In addition, after completing the required competencies, pharmacists are ***required*** to consolidate this knowledge by administering an initial LAIB injection under the supervision of a medical or nurse practitioner. It is recommended that initial mentorship or supervision for LAIB administration is sought from their regular LAIB prescriber to consolidate collaborative practice. If this is not possible pharmacists can contact aod.enquiries@dhhs.vic.gov.au for assistance in locating a suitable prescriber.

In the future, it may be appropriate for pharmacists experienced in LAIB administration to provide peer mentorship for newly trained pharmacists.

Pharmacists administering LAIB should also be familiar with the Victorian *Policy for maintenance pharmacotherapy for opioid dependence* and *Brief clinical guidelines for use of long-acting injectable buprenorphine in the treatment of opioid dependence.*

Premises

A pharmacy providing LAIB administration services must have already been granted permission to operate as a pharmacotherapy supplier. Additional requirements to operate as a LAIB administration pharmacy include:

Equipment

Appropriate equipment for an injection administration service must be available, including:

- injection administration consumables i.e. hand hygiene products, gloves and alcohol swabs;
- appropriately sized sharps container to dispose of clinical waste, including used syringes and needles;
- anaphylaxis response kit[2] and emergency protocol[3];
- secure records system for documentation and storage of patient information; and
- schedule 8 medication storage facilities (see 'Regulatory requirements' for details)

Consultation space

Availability of a dedicated room or private consultation area. The room is not used as a storeroom or staffroom. The dispensary is not to be used for LAIB administration services.

[2] Example kit https://immunisationhandbook.health.gov.au/resources/publications/preparing-an-anaphylaxis-response-kit

[3] Example protocol https://www.nps.org.au/australian-prescriber/articles/anaphylaxis-emergency-management-for-health-professionals

The room or private consultation area is to contain:

- handwashing facilities;
- a room design such that the procedure is not visible or audible to other persons in the pharmacy;
- a floor area, clear of equipment and furniture, to accommodate the patient and an accompanying person, and to allow the pharmacist room to manoeuvre;
- a workbench of an adequate area
- a chair and/or bed for the patient to sit or lie during LAIB administration; and
- An area within line of sight of the pharmacist for the patient to remain post injection as required.

The consultation space and service delivery must also consider individual patient needs including disability and cultural safety.

Staffing

The pharmacist must be able to leave the dispensary for the time taken to assess the patient, administer the injection and conduct appropriate record keeping.

When pharmacists are conducting pre-injection assessment, they must not engage in any other activity including dispensing.

Certificate of training completion

A copy of the *Long-acting injectable buprenorphine administration by pharmacists* training certificate should be retained and made available, if requested.

Service delivery

The most appropriate time for a patient to transition to pharmacist administration should be decided by the prescriber on an individual patient basis. Factors to be considered include patient complexity, concerns with dosing stability and potential barriers to access. The patient should be fully informed about consideration and included in decision making.

If there is a need for the patient to revert to prescriber administration, clear communication of this plan is essential between the pharmacist, prescriber and patient for safe coordination of care.

An agreed frequency and method of communication should be established between the prescriber and pharmacist. The agreed communication plan may vary based on clinical need (e.g. regular reporting on treatment progress versus communication on an as needed basis).

Pre-injection assessment

Prior to injection administration, the pharmacist should provide a holistic review considering factors including confirmation of injection due date, review of previous dose adequacy, any previous adverse events and general patient health and wellbeing. Pre-injection observations should be documented, and any concerns escalated to the prescriber as appropriate.

Circumstances requiring escalation to the prescriber:

- Immediate concerns with dosing (including signs of intoxication, opioid withdrawal, presentation for dosing outside of eligible date range)
- Significant change in mental or physical health (including pregnancy)
- Significant change in social circumstances

A valid prescription must also be confirmed prior to injection administration.

LAIB administration

After pre-injection assessment is complete, the dose should be aseptically administered using subcutaneous injection technique specific for the LAIB formulation prescribed.

LAIB administration will require the patient to expose skin and/or remove clothing. The pharmacist should ensure patient privacy is considered and provide the option to either sit or lie down to receive the injection.

Post administration

Brief clinical notes should be documented including site of administration to ensure this is rotated each visit. Any adverse events to be reported as soon as practical www.tga.gov.au/reporting-problems.

The pharmacist should keep clinical records and communicate these with the prescriber as required based on the agreed communication plan.

In certain circumstances, it is appropriate for the patient to remain on the pharmacy premises for a short period of time post administration to allow for monitoring. (i.e. first injection, dosing stability not established or previous adverse events)

Confirm with the patient when they are next due to attend the pharmacy for an injection.

Additional advice on record keeping is provided in the 'Regulatory requirements' section. A suggested record keeping template is available in Appendix 1.

Financial considerations

LAIB is subsidised under the Pharmaceutical Benefits Scheme (PBS). However, pharmacists are not remunerated for administering LAIB under the PBS. Pharmacists may wish to charge an additional service fee for patient consultation and administration of the injection. If they wish to do so, pharmacists must advise the patient of associated costs **prior** to administrating LAIB. Service fees should be set at reasonable price that balances the costs associated with service delivery against potential barriers to treatment access that an additional cost might impose on the patient.

Regulatory requirements

Applying for a Schedule 8 treatment permit

Practitioners must obtain a Schedule 8 permit from the Department of Health before prescribing pharmacotherapy for opioid use disorder (methadone, sublingual buprenorphine or LAIB).

Prescribers wishing to obtain a permit for LAIB should nominate the starting drug as long-acting injectable buprenorphine within the *Application for a permit to treat and opioid dependent person with methadone or buprenorphine* via an *online smartform* available on the Victorian Department of Health website.

Please note it is the responsibility of a practitioner to meet the eligibility criteria (See 'Who is eligible to prescribe or administer long-acting injectable buprenorphine') prior to applying for a Schedule 8 treatment permit to prescribe.

Practitioners who have completed MATOD training (module 1 and 2)

For practitioners who have completed MATOD training, their LAIB permit will include methadone and sublingual buprenorphine as well which authorises the permit holder to prescribe methadone and sublingual buprenorphine so there is no need for the practitioner to reapply if a transition to methadone or sublingual buprenorphine is needed.

There is no limit on the number of Schedule 8 permits a MATOD trained prescriber may hold for LAIB.

Practitioners who have NOT completed MATOD training

For practitioners who have not completed MATOD training, their LAIB permit will include sublingual buprenorphine which authorises the permit holder to prescribe sublingual buprenorphine and LAIB for that patient, so there is no need for the practitioner to reapply to prescribe sublingual buprenorphine.

Up to a total of ten (10) Schedule 8 permits for buprenorphine (sublingual and/or long-acting injectable formulations) may be issued to a practitioner without the requirement to complete MATOD training.

If a patient requires transition to methadone the practitioner must complete MATOD training and apply and hold a permit for methadone or transfer the patient to a practitioner who has completed MATOD training.

Circumstances where a Schedule 8 permit is not required

There are some circumstances where a practitioner does not require a permit to prescribe pharmacotherapy, including LAIB.

A Schedule 8 permit is not required where a practitioner is treating a patient if that patient is:

- an inpatient being treated in a hospital or a patient being treated in an emergency department (ED) of a hospital, for the period in hospital and a period not exceeding seven days after that person's discharge from hospital
- a prisoner being treated in a prison for the period in prison and a period not exceeding seven days after that prisoner's release from custody
- a resident being treated in an aged care service.

If the LAIB treatment duration exceeds seven days after the patient is discharged from hospital or ED, or released from prison, (i.e. patient is administered monthly LAIB whilst in hospital or prison) a Schedule 8 permit is required.

In addition, if LAIB is initiated in hospital or prison **the patient's usual MATOD prescriber should be notified of LAIB administration to ensure the safety of the patient** once discharged into the community.

Note that LAIB will **not** always be captured on SafeScript, as it may not be dispensed by pharmacies. In this case, the Schedule 8 LAIB permit may be the sole means of indicating that the patient may have been administered LAIB.

Record keeping

A practitioner must record in the patient's file a record of prescription, including the patient's name and address, date of prescribing and date of administration, and the drug name (including the brand name), strength and the interval in which the injections are to be administered.

If a LAIB prescription is for pharmacist administration, written instructions must be provided by the prescriber authorising this action (i.e. "to be administered at XX pharmacy") in addition to other usual requirements for pharmacotherapy prescriptions.

A registered nurse or pharmacist who is administering LAIB must record in the patient's file the date of administration, the drug name (including the brand name), strength and dosing interval. A record of the injection site and additional relevant notes should also be made. Any issues arising must be communicated with the prescriber. See Appendix 1 for an example of an administration record keeping template.

Ordering and storage

LAIB can be supplied to an individual pharmacist, medical or nurse practitioner or to the health service, holding a health services permit (HSP). In hospitals, larger primary health clinics, or clinics with changing staff an HSP is the most applicable permit type.

A HSP is issued under the *Drugs, Poisons and Controlled Substances Act (1981)* and can be applied for online via Application for new licence or permit online form

Supply directly to an individual practitioner or health service

Individual practitioners and health services which hold an HSP that authorises them to possess Schedule 8 drugs are able to order and store LAIB onsite in a compliant safe.

- An account must be opened with the appropriate wholesaler.
- Compliant Schedule 8 record keeping processes must be implemented and maintained.
- A Schedule 8 medicines compliant safe must be installed according to requirements under the Drugs, Poisons and Controlled Substances Regulations 2017
- A refrigerated Schedule 8 compliant safe may be required for Sublocade® depending on duration of storage (either > 7 days or >28 days as specified on individual packaging instructions).

Compliance with the possession, storage, use, recording of transactions and other requirements are primarily the responsibility of the permit holder.

Supply via pharmacy-based delivery

Health services without an HSP may make arrangements for supply via pharmacy delivery to coincide with scheduled LAIB administration. This arrangement does not allow for storage onsite at the health service premises.

- Delivery may only occur through pharmacies which are approved pharmacotherapy suppliers
- Pharmacies will need to contact the pharmaceutical company/ies to open an account with the appropriate distributor/wholesaler to order LAIB.
- Pharmacies can make arrangements to deliver LAIB (with health services or an individual practitioner) dispensed for individual patients who are schedule for administration
- To facilitate pharmacy medication delivery (dispensing these medications) the patient or prescriber will need to present or send a valid prescription to the pharmacy and pay any dispensing fee to the pharmacy as agreed.
- The pharmacy will arrange for the LAIB to be delivered to or picked up by the practitioner. LAIB **should never be dispensed directly to or handled by the patient or their carer(s).**

Refer to the Department of Health website for further details on drugs of dependence guidance, including refrigeration storage.

Other considerations

Interstate and international travel by patients

LAIB may not be available in all areas of Australia or in all countries of the world. Patients are advised not to travel interstate or internationally for longer than the duration of the LAIB formulation (see *Clinical guidelines for use of long-acting injectable buprenorphine in the treatment of opioid dependence*) unless prior arrangements can be made with a local practitioner.

If travel is necessary beyond this timeframe, and a local practitioner cannot be found to prescribe and administer LAIB, conversion to sublingual buprenorphine/naloxone will be required.

The preparation should never be dispensed directly to or handled by the patient or their carer(s), even for interstate or international travel.

Frequency of review

For LAIB, the frequency of review will vary between patients.

One option may be to use the weekly formulation of Buvidal® when commencing treatment, for the first two to four weeks until clinicians and patients are familiar with the treatment. For monthly LAIB, prescribers may schedule more frequent reviews at commencement of opioid agonist treatment or during periods of clinical instability.

Prescribers should consider the timing of reviews for patients who are prescribed LAIB. The frequency of review should be in keeping with the general guidelines for reviews of patients participating in a pharmacotherapy program.

Appendix 1

LAIB administration record keeping template

Patient details	
Name:	
Address:	
Date of birth:	Phone number:
Prescriber details	
Name:	
Clinic Address:	
Phone number:	
Administering health professional details	
Name:	
Qualification:	
Signature:	Date:
LAIB administration details	
Brand (circle formulation): Buvidal® / Sublocade®	
Dose strength:	
Dose frequency:	
Injection site:	
Clinical assessment notes:	
Communication with prescriber:	
Next dose due:	