Long Acting Injectable Buprenorphine

Prescribing and dispensing issues for consideration
March 2020

Issues for consideration, related to broad availability of LAIB

Long Acting Injectable Buprenorphine (LAIB) has been approved for release by the Australian Therapeutic Goods Administration (TGA). Buvidal® will be available from April 3 2020; Sublocade® from 21 April 2020. These pharmaceuticals exist in multiple subcutaneous formulations, to be injected either weekly or monthly, depending on the clinical assessment of patient need.

The release of LAIB - how it is prescribed and administered to patients – needs to be considered in the context of Victorian policy and regulation of Schedule 8 medicines. These considerations and other issues are discussed below.

In considering LAIB, clinicians should also be aware of the range of supports which exist for them to assist in this workspace. Assistance available for GPs to better understand opioid dependence, to improve skills to conduct difficult conversations with patients about transition between medications, opioid dependence, and pain management. Such support mechanisms include **Drug and Alcohol Clinical Advisory Service** (**DACAS**) and/or **GP Clinical Advisors Service (GPCAS)** on 1800 812 804.

1. Launch of SafeScript

From 1 April 2020, SafeScript is mandatory for all General Practitioners and Pharmacists. This allows for the monitoring of many drugs of dependence, including all Schedule 8 medicines such as Buprenorphine. LAIB can be delivered directly to General Practitioners in their clinics; this means the requirement for pharmacists to enter the dispensing of LAIB onto SafeScript can be circumvented.

Once General Practitioners take delivery of the medications, they may have few mechanisms for ensuring the prescription and administration event is entered into the SafeScript system. Consequently, the SafeScript system will be “blind” to this prescription and the fact an individual patient has had LAIB administered to them by a doctor.

A permit under the *Drugs, Poisons and Controlled Substances Regulations 2017* specifically for LAIB will need to be applied for by the prescribing clinician – even in circumstances where prescribers may already have an active ORT permit in place for Buprenorphine or Buprenorphine - Naloxone. The ORT LAIB permit will prompt DHHS regulations officers to enter this information onto SafeScript, capturing the prescribing/dispensing event. Whilst the permit for this medicine will be noted on SafeScript, permit data is static and will not capture or alert other clinicians to dose variations, transition to other ORT medications, or cessation in the program.

2. Safety issues

Patients with Buprenorphine implants will be at increased clinical risk under certain circumstances. For example, if they are involved in a critical accident or became acutely unwell and are hospitalised, their medication management and safety could be compromised because clinicians may be unable to ascertain whether they have Long Acting Injectable Buprenorphine in their system without checking SafeScript. Further, as referred above, dosing or transitions to other pharmacotherapies may not be up to date in SafeScript. This risk would become critical in situations where clinicians are unable to see recent prescriptions and administration events and where their clinical judgement and management is based on a less than compete clinical history.

Whilst ORT permits can act as a flag that a patient may be using ORT medications (including LAIB), this cannot be taken as a given, and doses noted on a permit should not be taken as current. In all cases where there is any

doubt, clinicians should be aware of their responsibility to verify medicines prescribed and current doses. Currently, where an acute medical event occurs and clinicians are unable to verify medication used and dosing, a conservative clinical approach is taken until details can be verified. This approach is recommended in clinical guidance developed for LAIB and accords with current custom and practice.

When assessing clients for treatment with LAIB, clinicians should note their responsibility to assess for those likely to continue to use drugs recreationally or sporadically, and for whom abstinence is not a realistic treatment goal. In cases where patients are assessed as likely to continue to use other drugs, this may foreshadow risks related to central nervous depression and potentially toxicity or overdose.

3. Financial considerations

Concerns about costs to the patient of administering ORT- as allowed for s100 pharmaceuticals under the PBS - have been broadly expressed. The out-of-pocket cost of daily administration of ORT has been identified as a barrier to access for some vulnerable patient groups in Victoria. A medicine which can be delivered directly to a clinic, and administered to the patient there, may remove this barrier to access for many patients. Pharmacy administration fees for s100 medications, including ORT, remain beyond the remit of the state government.

As these new products are introduced to the Victorian market the application and financial impost of administration fees will likely impact on the choices made by clients. Accepting this reality, it is likely that market forces will provide some regulation of these costs as building viable business models will predicate finding a balance between covering delivery and dispensing costs and setting prices at a level likely to attract patients for treatment.

There are risks associated with patients who are already stable on ORT, who may choose to deliberately destabilise in order to access a perceived cheaper therapeutic model of care. It is important that clinicians are aware of these incentives when having discussions around transitioning patients between medications. Supports exist for clinicians to have difficult conversations, and to consider appropriate medications for ORT. See above.

4. Skills requirements

LAIB is an additional pharmaceutical for ORT. The current skills requirements for GPs before prescribing ORT remain in place, that is clinicians are required to complete *95513 - Medication Assisted Treatment for Opioid Dependence (MATOD) Module 1 - Safer Opioid Prescribing* and *179438 - Medication Assisted Treatment for Opioid Dependence (MATOD) - Module 2*.

To administer the long acting injectable depot requires additional skills and knowledge. At the current time, clinicians can build their understanding of how to administer the injectable by viewing the training provided by the pharmaceutical companies and reading the clinical guidance provided by the Department of Health and Human Services on the health.vic website <https://www2.health.vic.gov.au/alcohol-and-drugs/aod-treatment-services/pharmacotherapy-for-aod-treatment>.

5. Schedule 8 storage requirements

Schedule 8 medicines, including Buprenorphine, have restrictions and permit requirements for the possession, storage, use, and recording of transactions. Responsibility for compliance with these regulatory requirements sits with the permit holder. The medicines can be supplied to an individual clinician - who holds an individual permit - or to the health service – holding a health services permit (HSP). Both permit types are issued under the *Drugs, Poisons and Controlled Substances Act (1981) (Vic)*.

Health Services Permit holders (HSP)

Where an HSP is applicable (e.g. hospitals, larger primary health clinics, or clinics with changing staff), possession, storage, use, recording of transactions and compliance with other requirements are primarily the responsibility of the HSP holder with the manner in which compliance is to be achieved detailed within the conditions of the HSP and in the online form most recently completed by the permit holder when obtaining, reviewing or amending the HSP for that health service.

Whilst these requirements will be similar to those contained in the regulations, the most recently completed online form might contain requirements that are more specific or additional to regulatory requirements. The most recently

completed online form, which is commonly controlled by the Director of Nursing or Director of Pharmacy, should be available for perusal by relevant staff. In some cases, it may be available on a hospital's intranet.

Health practitioner's in private practice

Where a registered health practitioner is not practising under the auspices of an HSP, compliance of the manner in which scheduled poisons are obtained, possessed, used, recorded and destroyed will be the sole responsibility of the health practitioner to whom the scheduled poisons were supplied.

6. LAIB Delivery system(s)

The delivery systems described below should be read in conjunction with two documents which have been uploaded to the Victorian Heath Website:

i. *Policy for maintenance Pharmacotherapy for Opioid Dependence – Summary of changes related to the use of long acting injectable buprenorphine for opioid dependence*, and

ii. *Brief clinical guidelines for use of depot Buprenorphine (Buvidal® and Sublocade®) in the treatment of opioid dependence*

Both documents are uploaded to: https://www2.health.vic.gov.au/public-health/drugs-and-poisons

Pharmacy based delivery

- Pharmacies can order LAIB via the appropriate wholesaler
- Pharmacies can make arrangements to deliver (to clinic or individual clinicians) LAIB dispensed for individual patients
- Individual prescribers/clinicians can receive LAIB medicine deliveries for patients scheduled for administration, by arrangement with the pharmacy.
- In order to facilitate a pharmacy delivering (dispensing these medications) patients will need to present a valid script to the pharmacy and pay any dispensing fee to the pharmacy as agreed (these fees are often much less that the daily $5 dispensing fee associated with other pharmacotherapy)
- The pharmacy will, subsequent to payment, arrange for the LAIB to be delivered to or picked up by the clinician
- If the dose is not administered as planned to the named patient, this medication will need to be returned or arrangement made for the pharmacy to pick up the medication for the pharmacy to manage according to Schedule 8 medication storage and record keeping processes.

  NB. This medication must not be dispensed to patients under any circumstance; significant clinical risks exists if the medication were to be self-administered (see brief clinical guidance documents for details on this warning)

Individual prescribers

- Accredited Opioid Replacement Therapy (ORT) prescribers, that is, General Practitioners (GP) and Nurse Prescribers (NP) who have undertaken the accredited ORT training program in Victoria are able to order, store and administer LAIB.
- To be able to order LAIB, prescribers will need to open an account with the appropriate distributor for each medication
- Compliant Schedule 8 record keeping processes and storage must be implemented and maintained, by the individual prescriber

  NB The need for a compliant safe fridge only refers to Sublocade® and is required only when the product is likely to be stored longer the seven days after being dispatched from the wholesaler. This can be avoided by management of stock, ordering only stock likely to be used within a seven-day window.

Clinic based or Specialist AoD service prescribers

- Services hosting accredited ORT prescribers and who hold a health services permit that authorises them to possess Schedule 8 drugs are able to order and store LAIB onsite in a compliant safe
- Entities must open an account with the appropriate wholesaler.
- Compliant Schedule 8 record keeping processes must be implemented and maintained
- Entities (services and clinics) that do not have a permit to possess Schedule 8 drugs need to apply to DHHS (Medicines Poisons and Regulation) for a Health Services Permit
- Entities will also need to install a Schedule 8 medicines compliant safe if they do not already have one

NB Nurse Practitioners in clinics of Hospital Health care networks covered by a Health Services Permit may prescribe and administer LAIB.

Registered nurses can administer LAIB if they are employed by an entity / medical practice that has prescribers, medical or nurse practitioners that can prescribe and supply.

Other methods of accessing LAIB

In time, other health practitioners working within their scope of practice and existing regulations may potentially be part of the patient journey for accessing long acting injectable buprenorphine depot.