Government of **Western Australia**
Department of **Health**

Depot buprenorphine long-acting subcutaneous injections (Buvidal® and Sublocade®)

Guidance note for pharmacists and medical practices

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health.wa.gov.au

Depot buprenorphine long-acting injections (depot BPN)

Important Note

Intravenous injection of the product can be fatal.

The pharmacist with overall responsibility must implement procedures to ensure that **under no circumstances** are these formulations handed to the patient.

Key information

- Two products have been approved by the Therapeutic Goods Administration (TGA):
  - Buvidal® (weekly or monthly administration)
  - Sublocade® (monthly administration)
  - Both products are for subcutaneous administration.
- **Depot BPN must NEVER be dispensed by a pharmacist directly to a patient – supply MUST always be directly from the pharmacy to the clinic for administration.**

Approval and Training

- All pharmacists dispensing depot BPN for treating patients under the Community Program for Opioid Pharmacotherapy (CPOP) must have undertaken additional training provided by the Community Pharmacotherapy Program (CPP).
- Pharmacies supplying depot BPN must have received additional written authorisation from the Department prior to ordering from the relevant wholesaler.
- Medical practitioners prescribing depot BPN must have undertaken additional training via CPP and received endorsement from the Director of Clinical Services at Next Step.
- Medical practitioners must also have received written approval to prescribe depot BPN formulations from the Department in order to apply for individual patient authorisations.
- Other health professionals involved in the prescribing, dispensing or administration of these products must complete additional training modules via the CPP.

General requirements

- The product must be delivered to the prescriber's medical practice for administration.
- Patients should be stabilised on Suboxone® or Subutex® treatment for at least seven days prior to transferring to depot BPN.
- Once depot BPN is administered, treatment with Suboxone® or Subutex® must be ceased.

Interruptions to treatment

- Interruptions to treatment of greater than 2 months (for monthly formulations) or 3 weeks (for Buvidal Weekly) will require re-induction to a sublingual formulation.
- WA Department of Health prescribing authorisations will be considered invalid in the circumstances described above.
- Pharmacists and medical practitioners are advised to contact CPOP Advice and Support (CAS) for advice prior to dispensing or administering doses of any depot formulation following treatment interruption.

Ordering procedure

- Pharmacy
    - Sublocade® may be ordered directly from Indivior.
    - Buvidal® may be ordered from Symbion wholesale.
- Medical practice
    - The medical practice provides a patient order list to the pharmacy, allowing sufficient time to obtain stock, dispense and deliver to the medical practice.
    - The prescriber is to attach a copy of all prescriptions required to the order list, noting the WA Department of Health authorisation number on each prescription.

Delivery

- Cold chain storage must be maintained when transporting Sublocade® from the dispensing pharmacy to a medical practice.
- Deliveries of depot BPN must be handed directly to an authorised health professional (pharmacist, medical practitioner or registered nurse) with appropriate recording of date and name and signature of receiver on the delivery receipt.
- Original CPOP prescriptions must be provided to the pharmacist or their agent upon delivery to a medical centre.

Drugs of Addiction (Schedule 8 (S8) medicine) Register

- The dispensing, delivery, administration and any other movement of depot BPN must be recorded in an approved Drugs of Addiction Register, available from the preferred wholesaler.
    - Pharmacies are required to use HA176 or other approved electronic register.
    - Medical practices are required to use HA14.
- Entries in the register must be completed and countersigned (when required) by an authorised health professional (pharmacist, medical practitioner or registered nurse).
- All other record keeping requirements apply in full, including retention of signed delivery receipts at the pharmacy in addition to CPOP prescriptions.
- Please note that pharmacy assistants, intern pharmacists and other administrative staff do not have authority to sign or countersign entries in the Drugs of Addiction Register.

Storage at pharmacies

- Sublocade®: S8 medicine requiring refrigerated storage
    - There are currently no known manufacturers of refrigerators with specifications that meet those of a S8 safe, therefore an approval to store this product other than in a compliant S8 safe must be granted by the Department. An example of storage that may be considered suitable as alternate storage is the Enlake Schedule 8 Drug Refrigerator http://www.enlake.com.au/schedule-8-drug-refrigerator/
    - To apply for alternative S8 storage approval, an application must be made to the WA Department of Health. The application must detail any additional security measures considered to prevent unauthorised access and theft of S8 medicines. An application form is available from the Medicines and Poisons Regulation Branch (email MPRB@health.wa.gov.au to request a copy).
- Buvidal®: S8 medicine requiring storage in a large drug safe, as defined in the Medicines and Poisons Regulations 2016.

Storage at medical practices

- All depot BPN products, such as doses awaiting administration to patients, must be stored in a small safe, as defined in the Medicines and Poisons Regulations 2016
- Sublocade® is approved for storage at room temperature for up to 7 days and can therefore be stored in a safe at medical practices.
- Information about safes is available on the Department website: https://ww2.health.wa.gov.au/Articles/S_T/Storage-of-Schedule-8-medicines

Stock control

- In the interests of public safety, stock levels should be kept to a minimum at all times.

Dispensing requirements

- Prescriptions for depot BPN require a valid CPOP prescription including WA Department of Health authorisation number.
- The WA Department of Health authorisation number must be sighted before dispensing a depot BPN preparation.

Labelling

- All **dispensed** depot BPN formulations must have a dispensing label attached and be labelled in accordance with the Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP).
- In addition to the standard labelling requirements, labels must also include the warning statement:

  "WARNING: FOR SUBCUTANEOUS INJECTION ONLY.
  Risk of serious harm or death if given by other routes."

- Attach Cautionary & Advisory Labels "1" (both formulations) and "6" (Sublocade® only) as per the *Australian Pharmaceutical Formulary and Handbook* (APF).
- Dispensed products not used due to patient non-attendance or re-scheduling of appointments must NOT be used for anyone other than the named patient.

Remuneration:

- Patient charges are at the discretion of the dispensing pharmacy.

Pharmacy Monthly CPOP reports

- Pharmacies are required to submit Monthly CPOP reporting information to the Department using the standard CPOP Monthly report form.
- Please note that take-away doses should be reported as zero (0), **as these products must never be handed to the patient.** Stock is to be transported directly to the prescriber.

Returns

- Any stock kept at the medical practice when authorised staff are not at the premises must be stored in a small safe, as defined in the Medicines and Poisons Regulations 2016.
- Any unused stock must be returned to the pharmacy.
- If stock is returned, the pharmacy dispensing record is to be adjusted to ensure that the CPOP monthly report reflects the actual dose the patient received that month.
- All returns must be recorded in the Drugs of Addiction Register at each location.

Destruction

- Dispensed items that are not used must be destroyed using an approved destruction method and recorded in an approved Drugs of Addiction Register.
- Information regarding destruction and disposal of medicines is available on the Department website: https://ww2.health.wa.gov.au/Articles/A_E/Disposal-of-medicines

Adverse drug reaction reporting

- All adverse drug reactions must be reported to the Therapeutic Goods Administration (TGA) using the *Blue Card Adverse Reaction Reporting* form available from:

  https://www.tga.gov.au/form/blue-card-adverse-reaction-reporting-form

- A copy of the completed form must also be forwarded to:
  - Department of Health:
    - Email cpop@health.wa.gov.au or fax (08) 9222 2463

Resources:

For health professionals:

- Guidelines for depot buprenorphine developed by NSW Ministry of Health: https://www.health.nsw.gov.au/aod/Pages/depot-bupe-guidelines.aspx
- Sublocade® product information: https://www.ebs.tga.gov.au/ebs/picmi/picmirepository.nsf/pdf?OpenAgent&id=CP-2019-PI-01756-1&d=202002281016933
- Buvidal® product information: https://www.ebs.tga.gov.au/ebs/picmi/picmirepository.nsf/pdf?OpenAgent&id=CP-2018-PI-02611-1 (Buvidal® monthly)
- https://www.ebs.tga.gov.au/ebs/picmi/picmirepository.nsf/pdf?OpenAgent&id=CP-2018-PI-02610-1 (Buvidal® Weekly)
- Guidance about storage of S8 medicines: https://ww2.health.wa.gov.au/Articles/S_T/Storage-of-Schedule-8-medicines

For consumers:

- Sublocade® consumer information: https://www.ebs.tga.gov.au/ebs/picmi/picmirepository.nsf/pdf?OpenAgent&id=CP-2020-CMI-01182-1
- Buvidal® consumer information: https://www.ebs.tga.gov.au/ebs/picmi/picmirepository.nsf/pdf?OpenAgent&id=CP-2019-CMI-01178-1 (Buvidal® monthly)
- https://www.ebs.tga.gov.au/ebs/picmi/picmirepository.nsf/pdf?OpenAgent&id=CP-2019-CMI-01177-1 (Buvidal® Weekly)

Questions or advice:

- For regulatory matters, contact the Department of Health on (08) 9222 6812.
- For clinical advice or questions about the application process, contact the CPOP Advice and Support Service (CAS) on (08) 9442 5042 or the Community Pharmacotherapy Program on (08) 9219 1913.

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