Information for prescribers and dispensers

Long-Acting Injectable formulations of buprenorphine (LAI-BPN) will soon be available in Queensland for the treatment of opioid dependence under the provisions of the Queensland Opioid Treatment Program (QOTP). Two products Buvidal® and Sublocade® will have current Therapeutic Goods Administration (TGA) access restrictions removed in April 2020.

There are important safety and regulatory restrictions that prescribers and pharmacists need to be aware of before supplying these products.

Key information

- The Therapeutic Goods Administration (TGA) has approved two long acting injectable buprenorphine (LAI-BPN) products - Buvidal® and Sublocade®.
- The products are administered by subcutaneous injection in weekly or monthly increments, depending on product and strength.
- Buvidal® (from 4 April 2020) and Sublocade® (from 21 April 2020) will have TGA access restrictions removed. Both products are Section 100 Opiate Dependency Treatment PBS medicines for treatment of opioid dependence within a framework of medical, social and psychological support under the auspices of the Queensland Opioid Treatment Program (QOTP) to approved prescribers.
- LAI BPN preparations are controlled (Schedule 8) medicines and subject to all the provisions for controlled drugs under the Health (Drugs & Poisons) Regulation, 1996.
- LAI-BPN preparations must NEVER be supplied by a pharmacist directly to a patient, carer or patient’s agent.
- LAI-BPN products MUST only be supplied directly to the prescriber or clinic from the dispensing or sale point.
- Intravenous injection presents significant risk of serious harm or death as the long-acting injection preparation forms a gel upon contact with body fluids. Occlusion, local tissue damage and thromboembolic events, including life threatening pulmonary emboli, may occur if administered intravenously.
- In Queensland QOTP prescribers, including those that become approved for LAI BPN, are medical officers or nurse practitioners.
- A self-paced online training module for prescribers is available at the Insight Centre for Alcohol and Other Drug Training and Workforce Development: https://insight.qld.edu.au/toolkits/qotp/detail
Prescribers: how to prescribe LAI BPN

- **Current QOTP prescribers require particular further approval** under the *Health (Drugs & Poisons) Regulation, 1996* by Queensland Health prior to prescribing. A current QOTP prescriber does not have approval to prescribe LAI-BPN, unless they have previously received specific approval for LAI-BPN (for prescribers who had restricted access approval).
- Existing QOTP Prescribers are required to undertake and complete the Insight online training module before submitting their approval application to prescribe LAI-BPN under the QOTP. All new QOTP prescribers from this point on will complete this training module as a standard part of their training.
- Prescribers should **not use the current QOTP written instructions** for prescribing LAI BPN.
- Prescribers can write a prescription for dispensing from a pharmacy, or a purchase order to buy LAI BPN from a pharmacy or a wholesaler.
- A prescription for LAI BPN must comply with all the requirement of a standard controlled (Schedule 8) drug prescription.

Pharmacists: how to dispense or supply LAI BPN

- A pharmacist can dispense LAI BPN on a prescription from an approved prescriber, or sell LAI BPN on compliant purchase order to an approved prescriber.
- Pharmacists should only dispense or sell LAI BPN on the basis of an arrangement with the prescriber or clinic to ensure supply of the product directly to the prescriber or clinic.
- Dispensing of LAI BPN should be entered into the pharmacy dispensing system and submitted with all other weekly submissions of controlled (Schedule 8) drugs dispensing to Queensland Health.
- Dispensing of LAI BPN should be recorded in the pharmacy controlled drug register along with any other controlled drug dispensing.
- A controlled drug administration facility (dosing centre) cannot be involved in the dispensing or sale of LAI BPN.
- **Long-acting injection buprenorphine preparations must NEVER be dispensed by a pharmacist directly to a patient, carer or patient’s agent. Supply of these products MUST be directly from the dispensing point to the clinic administering the injections.**

Further information

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