NSW Health

Long-acting injectable buprenorphine (LAIB) for opioid dependence treatment

Brief Guide

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NSW Health acknowledges the work of

Authors: Professor Nicholas Lintzeris (BMedSci MBBS PhD FAChAM), Professor Adrian Dunlop (MBBS, PhD, GdipEpiBiotat, FAChAM), and Michelle Schulz MPH (BA (Hons), DipGov). First Edition co-authored by Debbie Masters.

Expert advisory group members: Energize Health, NSW Users and AIDS Association, Northwest Health, National Drug and Alcohol Research Centre, Alcohol and other drugs clinical experts from NSW local health districts, and Justice Health and Forensic Mental Health Network, NSW Health staff across the Centre for Alcohol and Other Drugs and the Pharmaceutical Services Unit.

Disclaimers: This document is a guide to recommended practice, to be used as a resource alongside clinician judgement and patient choice. The document is designed to provide information to assist decision-making and is based on the best available evidence at the time of development of this publication.

Contents

Introduction

This Brief Guide is an abbreviated version of the *Long-acting injectable buprenorphine (LAIB) for opioid dependence treatment: Guidance document*.

The guides were developed to inform clinicians prescribing and administering LAIB preparations; they are designed to be used as an adjunct to the *NSW Clinical Guidelines: Treatment of Opioid Dependence – 2018.*

LAIB products currently registered in Australia are: Buvidal Weekly and Buvidal Monthly manufactured by Camurus; and Sublocade, manufactured by Indivior. These products are available on the Pharmaceutical Benefits Scheme (PBS) under an s100 opioid dependence listing.

This guidance:

1. assumes that clinicians are experienced in the management of patients with opioid dependence, and in the use of sublingual (SL) BPN (BPN) formulations in the treatment of opioid dependence
2. is to be used in conjunction with the
    - Long-acting injectable buprenorphine (LAIB) for opioid dependence treatment: Practice Guide (full version)
    - NSW Clinical Guidelines: Treatment of Opioid Dependence – 2018[1] (NSW OTP Guidelines hereafter)
    - National Guidelines for Medication-Assisted Treatment of Opioid Dependence 2014[2]
3. complements other guides and guidelines from the specialist alcohol and other drugs (AOD) treatment sector, including but not limited to:
    - NSW Health Alcohol and Other Drugs Psychosocial Interventions: Practice Guide[3]
    - NADA Practice Guide: Providing Alcohol and Other Drug Treatment in a Residential Setting[4]
    - NSW Health Management of Withdrawal from Alcohol and other Drugs[5]
    - NSW Health Clinical Care Standards for Alcohol and Other Drug Treatment[6]
4. has been informed by a synthesis of:
    - published evidence for Buvidal Weekly, Buvidal Monthly (CAM 2038) and Sublocade (RBP-6000)
    - updated Product Information for Buvidal Weekly, Buvidal Monthly and Sublocade (formulations registered in Australia with the Therapeutic Goods Association [TGA])
    - treatment conditions and regulatory frameworks for the use of BPN in opioid dependence treatment (ODT) in NSW
    - clinical and consumer experience in using LAIB formulations in Australian clinical trials and practice
    - consensus expert opinion of clinicians and consumers with experience of LAIB treatment, including the guidance working group formed by NSW Health

Note: Some recommendations in this document are not included in the TGA Buvidal or Sublocade product registration and can be considered 'off-label' use. Healthcare professionals are encouraged to use their judgement and consider the most recent evidence in addition to referenced information. Updates to the NSW Clinical Guidelines: Treatment of Opioid Dependence are anticipated. Wherever guidance is provided that is not directly informed by research evidence, the document will highlight these sections as Consensus Statements (CS).

[1] https://www.health.nsw.gov.au/aod/Pages/nsw-clinical-guidelines-opioid.aspx
[2] https://www.health.gov.au/resources/publications/national-guidelines-for-medication-assisted-treatment-of-opioid-dependence
[3] www.health.nsw.gov.au/aod/resources/Pages/psychosocial-interventions.aspx
[4] https://nada.org.au/resources/providing-alcohol-and-other-drug-treatment-in-a-residential-setting/
[5] www.health.nsw.gov.au/aod/professionals/Pages/clinical-guidance.aspx
[6] www.health.nsw.gov.au/aod/Pages/clinical-care-standards-AOD

Language

Language should be used in ways that demonstrate respect for the agency, dignity and worth of all people. The terms person and people are used throughout this publication, alongside the term patient – denoting when a person becomes engaged by a treatment service.

Acronyms

AHPRA	Australian Health Practitioner Regulation Agency	**NUAA**	NSW Users and AIDS Association
AOD	alcohol and other drugs	**NSAID**	Non-steroidal anti-inflammatory drug
BPN	Buprenorphine	**NTX**	Naltrexone
BNX	Buprenorphine-naloxone film	**NX**	Naloxone
CAOD	Centre for Alcohol and Other Drugs	**ODT**	Opioid dependence treatment
CMI	Consumer Medicines Information	**OTAC**	Opioid Treatment Accreditation Course
CS	Consensus statement	**OTP**	Opioid treatment program (NSW)
DDI	Drug-drug interaction	**PBS**	Pharmaceutical Benefits Scheme
EN	Enrolled nurse	**PSU**	Pharmaceutical Services Unit
IM	Intra-muscular	**RN**	Registered nurse
IV	Intra-venous	**SC**	Subcutaneous (injection)
LAIB	Long-acting injectable buprenorphine	**SL**	Sublingual
LHD	Local health district	**TGA**	Therapeutic Goods Administration (Australia)
MoH	NSW Ministry of Health		

LAIB formulations: Buvidal and Sublocade

Buvidal is a modified release formulation of BPN, registered in Australia for 'maintenance treatment of opioid dependence within a framework of medical, social and psychological support'.

Buvidal is designed to be administered by subcutaneous injection (SC) once a week (Buvidal Weekly) or once a month (Buvidal Monthly). The formulation is provided in prefilled syringes with a ½-inch 23-gauge needle, BPN as the active ingredient.

Buvidal Weekly is available in four dose strengths:

8 mg/0.16 mL

16 mg/0.32 mL

24 mg/0.48 mL

32 mg/0.64 mL

Buvidal Monthly is available in four dose strengths:

64 mg/0.18 mL

96 mg/0.27 mL

128 mg/0.36 mL

160 mg/0.45 mL

Sublocade is available in two dose strengths:

100 mg/0.5 mL and

300 mg/1.5 mL

provided in a prefilled syringe with a 5/8-inch 19 Gauge needle.

Product and consumer information

Product and consumer information is available on the TGA website at www.ebs.tga.gov.au

Framework for treatment

The key elements of safe and effective BPN treatment for opioid dependence are:

safe and effective use of medicine

regular clinical reviews and monitoring

participation in psychosocial interventions and

addressing medical, mental health and social comorbidities.

LAIB may be the preferred medication for many, however it may not suit all patients. Some patients will prefer SL BPN or methadone treatment, and these options should generally be made available, where possible. It is essential that patients are provided accurate information and options regarding their treatment, as part of informed decision making and consent. Patients should be given a choice (where possible) of the type of LAIB they are prescribed.

Potential Benefits of LAIB

Once-a-week and once-a-month depot injections can reduce the need for daily supervised and/or 'takeaway' doses of Sublingual (SL) BPN formulations.

Potential benefits of LAIB treatment include:

Greater convenience for clients with less frequent attendance at dosing sites (pharmacies, clinics) compared to methadone or SL BPN.

Reduced travel costs with less frequent attendance for dosing.

Greater medication adherence and enhanced treatment outcomes for clients who struggle to attend regularly for dosing with SL BPN or methadone.

Improved client experience of treatment, and increased treatment options. Many clients report less stigma with LAIB treatment.

Less risk of diversion and non-medical use of the medication, enhancing community safety.

Withdrawal off LAIB appears to be associated with less severe opioid withdrawal symptoms than cessation of SL BPN or methadone.

Administration

LAIB medications must not be handled by, or dispensed to, clients or carers.

LAIB should never be administered intramuscularly, intradermally, intravenously, or intra-arterially. Serious health risks (including pulmonary thrombosis, infections, tissue necrosis) may occur if LAIB is not injected as advised.

Practical training to administer LAIB injection is advised, as LAIB formulations have higher viscosity than many other medicines delivered subcutaneously. This could mean that the injection takes longer to administer, and that the patient may feel some discomfort or pain when the injection is administered. Refer to the PIs for formulation specific advice about administration techniques to reduce patient pain and discomfort.

LAIB Injections should only be administered by an Australian Health Practitioner Regulation Agency (AHPRA) registered healthcare professional who has injection of Schedule 8 medications within their scope of practice. This includes:

Medical professionals

Registered nurses, or enrolled nurses under the supervision of a medical practitioner or registered nurse

Pharmacists - with vaccination accreditation, a suitable consultation room, and where the administration area and equipment comply with the NSW Pharmacist Vaccination Standards

Finding a community pharmacy to administer LAIB

A map of some of the NSW community pharmacies that supply LAIB is available on the NSW Health website. Contact the pharmacy to confirm before proceeding.

For more information, please see the full version of this Guide (link on page 1), product information for Buvidal and Sublocade (search ebs.tga.gov.au), and details for telephone and online support (at end of this document

Dosing recommendations

Buvidal

Commencing BPN treatment with Buvidal

Clients dependent on heroin or other short acting opioids (e.g. oxycodone, morphine, hydromorphone, tapentadol) can commence Buvidal Weekly directly without the need for SL BPN treatment.

Delay the first dose of Buvidal if the client has recently used opioids and is showing features of intoxication, however there is no need to defer initiation until the client is in moderate or severe opioid withdrawal (unlike recommendations for initiating SL BPN).

Avoid a 'test dose' of SL BPN unless (a) the client has never previously had buprenorphine and uncertain of side effect profile or (b) safety concerns are present such as severe liver disease or drug-drug interactions, in which case the client should stabilise on SL BPN and transfer to LAIB later.

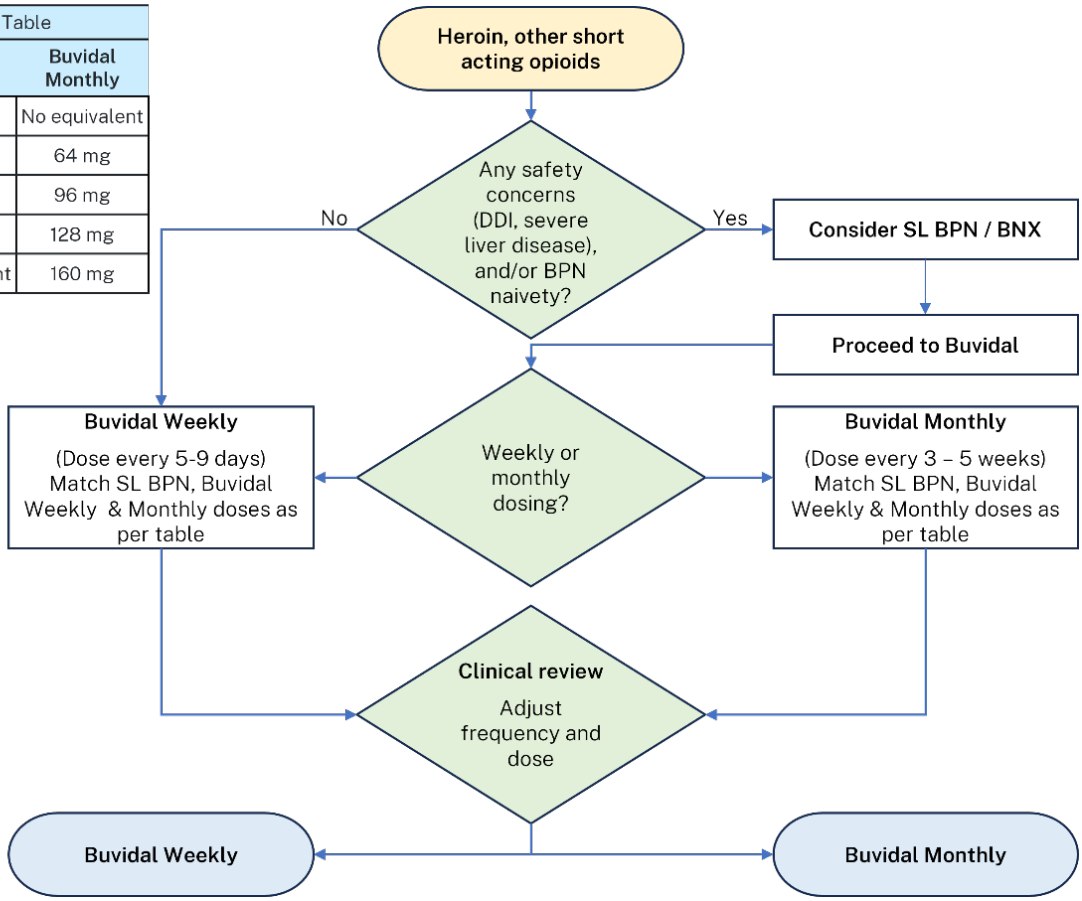
Commence with Buvidal Weekly 16 mg, or Buvidal Weekly 24 mg for clients with severe opioid use disorder.

Review the client regularly in coming days, with the option of 8 mg Buvidal Weekly 'top up' doses if experiencing cravings or withdrawal symptoms.

Titrate subsequent Buvidal Weekly doses or convert to Buvidal Monthly doses (Table 1 below).

Figure 1 Overview Buvidal dosing

Dose Conversion Table		
Daily SL BPN dose	**Buvidal Weekly**	**Buvidal Monthly**
2- 6 mg	8 mg	No equivalent
8-10 mg	16 mg	64 mg
12-16 mg	24 mg	96 mg
18-24 mg	32 mg	128 mg
26-32 mg	No equivalent	160 mg



Transferring from SL BPN to Buvidal

Clients can transfer from existing treatment with SL BPN using the dose conversion Table 1. Clients should be reviewed prior to the next scheduled dose and assessed for adverse events, withdrawal, cravings, substance use and client's rating of dose adequacy. Titrate doses upwards or downwards accordingly. Steady-state equilibrium is usually achieved after three to four doses.

Table 1. Dose conversion: SL BPN to Buvidal Weekly and Buvidal Monthly

Daily SL BPN	Buvidal Weekly	Buvidal Monthly
2–6 mg	8 mg	No equivalent
8–10 mg	16 mg	64 mg
12–16 mg	24 mg	96 mg
18–24 mg	32 mg	128 mg
26–32 mg	No equivalent	160 mg

Transferring from methadone to Buvidal

From stable low dose methadone (30 mg or less)

Transfers from stable low dose methadone (30 mg or less) can be accomplished by ceasing methadone treatment, waiting until the client experiences early mild-to-moderate opioid withdrawal symptoms (e.g. COWS score ≥6) usually after 24–72 hours. Initiate with Buvidal Weekly 16 mg or 24 mg dose (with Buvidal Weekly 8 mg top up doses on subsequent days as required). Avoid test doses with SL BPN when transferring from methadone to Buvidal. Titrate the Buvidal Weekly dose on subsequent doses, or transfer to Buvidal Monthly.

From methadone doses higher than 30 mg

Transfers from methadone doses higher than 30 mg can be achieved:

By transferring to SL BPN as per routine clinical practice (see 2018 OTP Guidance), and then transferring to LAIB after client has stabilised on SL BPN (e.g. after seven days).

Bridging technique: ceasing methadone, transferring to a short acting opioid agonist medication for several days (e.g. oxycodone, morphine), and then transferring to Buvidal Weekly as though initiating from a short acting opioid.

Microdose technique: commencing gradually increasing doses of SL BPN over seven to 10 days whilst continuing methadone treatment. Once the daily SL BPN dose of 8 mg has been achieved, cease methadone altogether and rapidly increase BPN dose on subsequent days. LAIB can be initiated at this time.

Both Microdose and Bridging techniques should only be undertaken by specialist addiction services, or in consultation with a specialist.

Flexible dosing schedule

Clients may switch between Buvidal Weekly and Buvidal Monthly (see Table 1). Individual dose adjustment may be required.

Buvidal Weekly doses may be given up to two days before or after the weekly time point (days five to nine).

Buvidal Monthly may be given up to one week before or after the monthly time point (weeks three to five).

Missed doses

If a dose is missed, the next dose should be administered as soon as possible. Re-induction may be required if >14 days has elapsed between Buvidal Weekly doses, or >8 weeks between Monthly doses, based on a clinical assessment.

Supplemental or 'top up' BPN doses for patients on Buvidal

Supplemental Buvidal injections may be used if clinically indicated (client experiencing opioid withdrawal, cravings or persistent unprescribed opioid use). Clients may receive additional 8 mg Buvidal Weekly injections at least 24 hours apart, to a maximum total weekly dose of 32 mg, and maximum total monthly dose of 160 mg. If supplemental Buvidal Weekly doses cannot be administered, supplemental doses of SL BPN (≤8 mg daily) may be used for a limited period, until the next LAIB injection can be organised.

For more information, please see the full version of this Guide (link on page 1), product information for Buvidal and Sublocade (search ebs.tga.gov.au), and details for telephone and online support (at end of this document)

Sublocade

Commencing BPN treatment with Sublocade

Sublocade treatment requires preceding treatment with SL BPN for at least seven days, preferably achieving SL doses ≥8 mg daily. Sublocade is generally not recommended for clients on daily SL BPN doses <8 mg.

The first Sublocade dose should usually be administered approximately 24 hours after the last SL BPN dose but may be administered on the same day. For most clients, commence 300 mg doses for the first two months (2 x monthly doses), reflecting 'loading' doses that elevate plasma BPN levels more rapidly during the initial treatment period. Sublocade may be initiated with 100 mg doses where there may be safety concerns of high BPN plasma levels (e.g. severe hepatic disease, drug-drug interactions [DDI]).

After the initial two monthly Sublocade doses, select between 100 mg or 300 mg four-weekly doses. For many clients, 100 mg four-weekly Sublocade doses will be adequate, maintaining plasma levels (at steady state equilibrium) achieved with the first two 300 mg 'loading' doses. A 300 mg dose should be considered for those clients who had previously stabilised on high dose SL BPN (e.g. 24 to 32mg daily), or continue to experience cravings, withdrawal or unprescribed opioid use during the first two months of Sublocade dosing or with 100 mg Sublocade doses.

Flexible dosing schedule with Sublocade

Sublocade doses can be administered up to two days ahead of a scheduled dose (i.e. 26 days since the last injection), or up to 14 days after the 28-day interval (i.e. 42 days since the last injection) without dose adjustments.

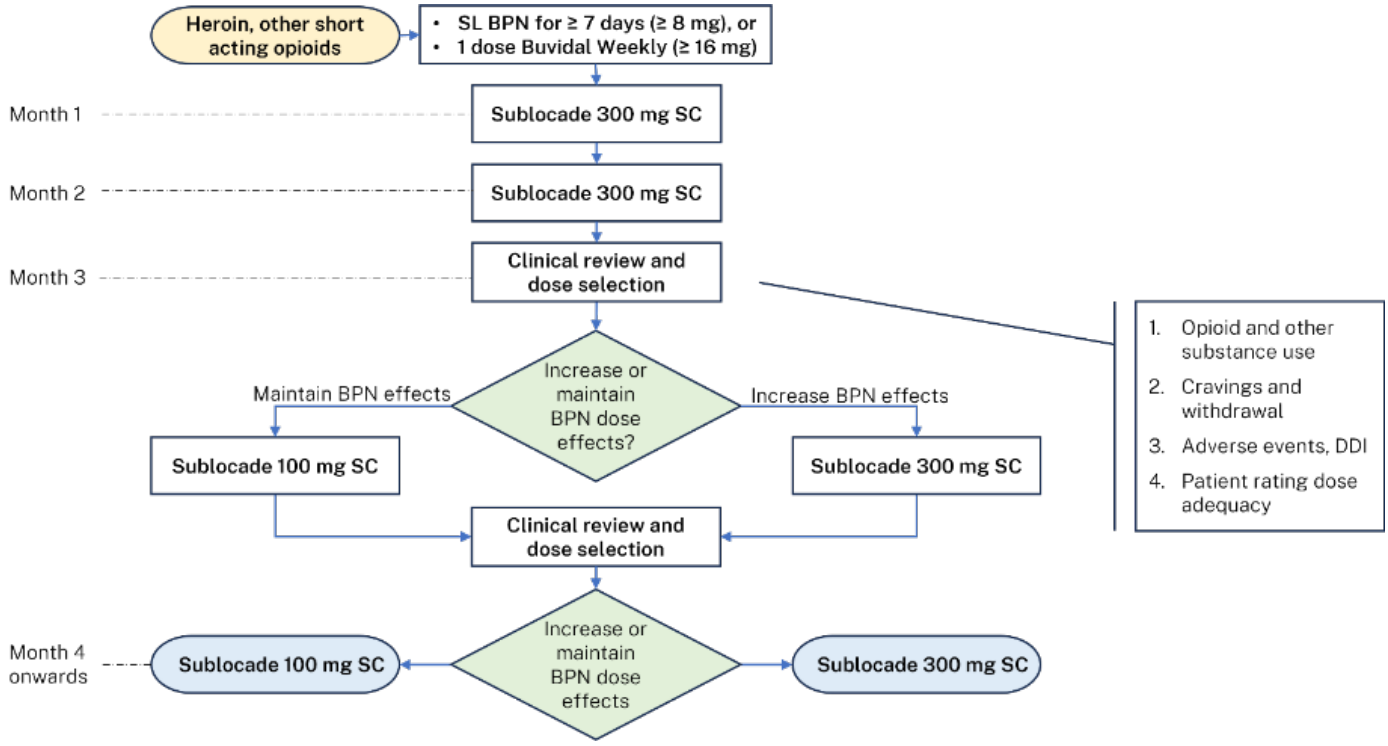
Missed doses

If a dose is missed, the next Sublocade dose should be administered as soon as practically possible. Re-induction may be required if more than eight weeks between Sublocade doses has elapsed.

Supplemental or 'top up' BPN doses with Sublocade

Supplemental SL BPN doses may be given if clinically indicated (client experiencing opioid withdrawal, cravings or persistent unprescribed opioid use). Additional SL BPN (≤8 mg daily) may be used for a limited period of time until the next depot injection can be organised.

Figure 2 Overview Dosing with Sublocade



Safety issues

Precautions and contraindications

Depot formulations should not be administered to anyone hypersensitive to BPN or any of the excipients of Buvidal or Sublocade (see Product Information for details). Precautions regarding the use of Buvidal and Sublocade are similar to treatment with SL BPN and include clients with high-risk sedative use (e.g. alcohol, benzodiazepines), severe hepatic disease, cardiac arrhythmias, and respiratory depression. See Product Information for details.

Adverse events (AEs)

Both LAIB formulations can be associated with local injection site AEs – redness, pain, tenderness and swelling in 5–10% clients. These are usually mild, transient and resolve spontaneously. Sublocade doses appear to be more commonly associated with a palpable lump at the injection site, which dissolves with time. Systemic AEs to LAIB are as per SL BPN (e.g. nausea, headache, constipation).

Drug-drug Interactions (DDI)

DDIs are expected to be the same as for SL BPN and are most notable with other sedating medications, and medications metabolised by hepatic CYP450 enzymes. If there are concerns, stabilise on SL BPN and monitor DDI before transferring to LAIB formulations.

Pregnancy and breastfeeding

SL BPN has an acceptable safety profile and is effective in pregnancy. There is a lack of research data on the safety and effectiveness of LAIB formulations in pregnancy and breastfeeding. Babies exposed to opioids during pregnancy may experience a neonatal opioid withdrawal syndrome after delivery. Pregnant women on LAIB should be informed about the risks and benefits of different BPN formulations and may choose to transfer to SL BPN. They may continue on LAIB formulations if the potential benefit justifies the potential risks to the mother and baby.

Driving, operating machinery

BPN may impair the mental or physical abilities required for the performance of potentially dangerous tasks such as driving a car or operating machinery. Clients should be cautioned about driving or operating hazardous machinery.

Withdrawal from LAIB formulations

The prolonged duration of action of the depot formulations means that withdrawal symptoms are likely to emerge long after the last LAIB dose. Withdrawal features may peak six–12 weeks after last Buvidal Monthly dose, or one–three weeks after last Buvidal Weekly dose. Peak withdrawal features may emerge eight–24 weeks after last 300 mg or 100 mg Sublocade dose. Withdrawal symptoms may persist for weeks (or months) and appear to be less severe than withdrawal from other opioids (e.g. SL BPN, methadone). It is generally recommended to taper the depot dose to the lowest possible (e.g. 64mg Buvidal Monthly, 100mg Sublocade) before discontinuing treatment, and to review the client at regular intervals.

Intoxicated presentations

Assess patients who present intoxicated at the time of dose administration to identify any safety concerns regarding dosing.

Peak plasma and clinical effects occur approximately 12–24 hours after Buvidal Weekly depot injections, six–10 hours after Buvidal Monthly and 24 hours after a Sublocade injection. There is usually not a clinical indication to withhold a LAIB injection, as the period of intoxication will have passed before the peak in BPN effects following subcutaneous administration.

Concerns will also be mediated by whether the patient has been on long-acting depot BPN long enough to be at steady state (and therefore have more stable BPN effects). This response differs from intoxicated presentations for SL BPN or methadone dosing, where peak medication effects are likely to occur whilst the patient is still intoxicated.

Consider whether intoxicated patients have capacity to provide informed consent, and to understand warnings regarding risks of sedation and overdose from polysubstance use. If there are concerns that the patient is very intoxicated and unable to understand or follow instructions, the administration of the dose may be deferred and rescheduled.

Consultation with an addiction medicine specialist is advised if there are concerns regarding dosing.

Table 2. Overview of BPN formulations available for treatment of opioid dependence in Australia

	Sublingual formulations	Buvidal (weekly and monthly LAIB)	Sublocade (monthly LAIB)
Formulations 	**Suboxone** contains buprenorphine (BPN) and naloxone in 4:1 ratio 2/0.5 mg and 8/2 mg sublingual film **Subutex** contains buprenorphine in 0.4 mg, 2 mg and 8 mg sublingual tablets	Buvidal Weekly and Monthly contain BPN in FluidCrystal injection depot technology. SC injections in prefilled syringes with 23-gauge needle. Administration via upper arm, thigh, abdomen or buttocks. **Buvidal Weekly**: 8 mg/0.16 mL, 16 mg/0.32 mL, 24 mg/0.48 mL, 32 mg/0.64 mL **Buvidal Monthly**: 64 mg/0.18 mL, 96mg/0.27 mL, 128/0.36 mL, 160 mg/0.45 mL	**Sublocade** contains BPN in a proprietary BPN gel depot delivery system (Indivior's delivery system). SC injections in prefilled syringes with 19-gauge needle administered in abdomen. **Monthly doses**: 100 mg/0.5 mL or 300 mg/1.5 mL
Storage requirements 	Store at room temperature (below 30°C)	Store at room temperature (below 25°C) Do not refrigerate or freeze.	Cold storage requirements (2–8°C). Do not freeze. Remove from cold storage for at least 15 minutes prior to SC injection. May be stored at room temperature (below 25°C) for up to 12 weeks before use. [7] [1] Some older stock will have a shorter room temperature shelf life and may only be stored at room temperature for 28 days. Please refer to the information on the pack for the correct storage conditions.
Clinical pharmacology 	**Bioavailability** = 10–30% **Onset effects** within one hour, with peak effects two–four hours after dose **Duration effects** usually 24 hours but dose dependent and can vary from 8 to 72 hours	**Bioavailability** = 100% **Time to peak plasma level (tmax)** Buvidal Weekly = 24 hrs Buvidal Monthly = six to 10 hrs **Half life** • Buvidal Weekly = three to five days • Buvidal Monthly = 19 to 25 days **Steady-state equilibrium** by 4th dose	**Bioavailability** = 100% **Time to peak plasma levels (tmax)** = 24 hrs **Half-life** = 43–60 days **Steady-state equilibrium** by 2nd (300/100 mg) to 6th dose (300/300 mg)

	Sublingual formulations	Buvidal (weekly and monthly LAIB)	Sublocade (monthly LAIB)
Frequency of dosing 	Daily, two-day or three-day doses Takeaways and unsupervised dosing available for patients with low risk	Buvidal Weekly dose can be administered every seven days ±two (five to nine-day schedule) Buvidal Monthly dose can be administered every four weeks ±one (three to five-week schedule)	Sublocade dosed every four weeks (26 to 42-day schedule)
Key Drug – Drug Interactions (DDIs) 	Systemic BPN DDI include **opioids agonists**: can reduce effects other opioids (blockade); BPN may precipitate withdrawal on induction; **sedatives** (e.g. benzodiazepines, alcohol, TCAs, antipsychotics, gabapentinoids): sedation, respiratory depression, overdose. A number of potential DDI can occur but are rarely of clinical significance (e.g. interactions with medications that induce or inhibit CYP450 and can lower or increase BPN plasma levels); or are rare (e.g. serotonergic syndrome in combination with medication such as SSRIs, MAOIs, tramadol; or medications that can cause QT prolongation and increase risk of cardia arrhythmias). Long duration of effects of LAIB formulations precludes timely dose adjustment for DDI. If concerned re: potential DDI – initiate treatment with 'short acting' SL BPN for one–four weeks, monitor DDI and adjust medications accordingly, prior to transfer to LAIB.		
Key adverse events 	Systemic BPN adverse events	○ Systemic BPN adverse events ○ Local injection site AEs: Redness, pain, tenderness, swelling in approximately 5–10% clients. Usually mild and transient and resolves spontaneously.	

Dosing Regimen	Sublingual formulations	Buvidal (weekly and monthly LAIB)	Sublocade (monthly LAIB)
Commencing treatment	**From short acting opioids** (e.g. heroin, oxycodone, morphine): • commence 8 mg day one, when client in early / mild opioid withdrawal (usually at least eight hours after last dose or use) • titrate upwards on daily basis as required	**From short acting opioids** (e.g. heroin, oxycodone, morphine): • Buvidal may be initiated directly (without transition via SL BPN) for people using heroin or other short acting opioids (e.g. morphine, oxycodone) • ensure client not intoxicated at time of first dose and commence either 16 or 24 mg Buvidal Weekly dose • review client frequently, with option of top-up doses (8 mg Buvidal) if required. Subsequent doses can be either Buvidal Weekly or Buvidal Monthly doses	Initiate treatment with SL BPN (at least 8 mg) or Buvidal Weekly for ≥7 days, then transfer to Sublocade. Recommended induction: • 300 mg monthly injections x 2 doses (8 weeks) • then 100 mg monthly doses (if client 'stable' on initial 2 x 300 mg doses) or 300 mg monthly doses if require additional BPN effects (e.g. cravings, withdrawal, continued opioid use)

Dosing Regimen	Sublingual formulations	Buvidal (weekly and monthly LAIB)	Sublocade (monthly LAIB)
Commencing treatment (continued)	**From methadone:** initiate BPN when client in moderately severe withdrawal (e.g. COWS≥12) (e.g. one–two days after last methadone dose) • day one: 2 mg + 6 mg after one–two hrs, with additional 2–8 mg doses every two–four hrs as required to alleviate opioid withdrawal • day two onwards: titrate BPN dose daily as required	**From SL BPN:** • patients can commence with either Buvidal Weekly or Monthly dosing. Doses determined by client's SL BPN dose (see Conversion Table 1) • Titrate subsequent doses after clinical review	Clients may be initiated with 100 mg Sublocade (after at least seven days SL BPN treatment) doses if there are: • safety concerns (e.g. severe hepatic disease) • DDI concerns: e.g. overdose risk from polysubstance use
		From methadone Options for transfer include: • transfer from methadone to SL BPN and then convert to LAIB • transfer directly to Buvidal Weekly may be considered for clients transferring from methadone ≤30 mg • microdose or bridging techniques may be considered for transfers from methadone >30 mg	There is no published safety data for initiating Sublocade in clients on low dose SL BPN (<8 mg), and Buvidal may be preferred for such clients
Maintenance phase	Adjust dose to achieve treatment goals (reduced use of other opioids, reduced withdrawal and cravings; blockade effects). Range 2–32 mg daily; most clients require 12–24 mg daily.	Titrate dose to achieve treatment goals Adjust doses when transferring between Weekly and Monthly doses	Titrate dose to achieve treatment goals. 100 mg or 300 mg monthly injections
Withdrawal phase	Gradually taper dose over several weeks–months (e.g. 2–4 mg weekly reductions)	Gradually taper doses (reducing dose strengths every one–two injections). Peak withdrawal features may emerge six–12 weeks after last Buvidal Monthly dose, or one–three weeks after last Buvidal Weekly dose (CS)	Reduce dose to 100 mg monthly injections prior to stopping. Peak withdrawal features may emerge 8–24 weeks after last 100 mg or 300 mg dose

For more information, please see the full version of this Guide (link on page 1), product information for Buvidal and Sublocade (search ebs.tga.gov.au), and details for telephone and online support (at end of this document)

Regulatory Requirements

All accredited and non-accredited OTP prescribers can prescribe and administer LAIB medicines, Buvidal and Sublocade.

See the NSW Health OTP website[1] for details about accreditation information, and requirements for notifications (e.g. changes to dosing point, locum arrangements).

Approvals

To prescribe and supply LAIB

As per other ODT medicines, all prescribers of LAIB must obtain approval from NSW Health, which must be granted prior to a patient commencing treatment in an outpatient setting. Prescribers can use SafeScript NSW to submit and manage applications for approval to prescribe.

If you are unable to apply through SafeScript NSW, see the NSW Health website for more information.

To transfer between medication types

Approvals to prescribe BPN are not specific to dosage form. The practitioner may be authorised to use BPN in SL and/or injectable form, together or separately. A new approval is not required to switch a patient from one form of BPN to another, or when using both forms concurrently. However, a switch to methadone from BPN, or vice-versa, will require a new approval

Documentation

File documentation

The prescribing medical practitioner must record in the client's file a record of prescription, including: the name, strength and quantity of the drug prescribed and the date on which it was prescribed; if the drug is intended for the treatment of a person, the name and address of the person to be treated; the maximum number of times the drug may be supplied on the prescription; the intervals at which the substance may be supplied on the prescription; the directions for use, as shown on the prescription.

Prescriptions

Prescribers must ensure that all prescriptions for LAIB are compliant with local jurisdictional regulations for S8 opioid medications and federal legislative requirements. A template is available in the full version of this guide.

Patient Limits

Non-accredited prescribers

Medical practitioners who are not accredited OTP prescribers may manage up to 30 patients on ODT, including:

up to 20 patients treated with SL BPN or BPN-naloxone, or LAIB, and

up to 10 patients treated with methadone who have been inducted and referred by an accredited OTP prescriber.

Accredited OTP prescribers

Any medical practitioner or nurse practitioner who is an accredited OTP prescriber may prescribe LAIB as part of their patient limit of 200. Practitioners working in Public OTP clinics may prescribe for up to 300 patients.

Getting support and more information

Drug and Alcohol Specialist Advisory Service (DASAS) 1800 023 687

For additional specialist support and advice for health professionals

The Opioid Treatment Line (OTL) 1800 642 428

9:30am to 5:00pm, Monday to Friday (except public holidays). Provides opioid pharmacotherapy information, referrals, advice and a forum for pharmacotherapy concerns.

PeerLine 1800 644 413

email peerline@nuaa.org.au A confidential peer-run telephone service providing support to people who use drugs, who are on the opioid treatment program or who are seeking treatment across NSW.

Alcohol & Drug Information Service 1800 250 115

24 hours a day, seven days a week. A free and confidential counselling helpline for those in NSW with concerns around alcohol or drug misuse. WebChat: www.yourroom.health.nsw.gov.au/webchat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