

# **Newfoundland and Labrador Pharmacy Board Guidelines for Pharmacy Practice**



**Guidance for the Dispensing and Administration of  
Buprenorphine Extended-Release Injection (Sublocade®)**

**October 2020**

## 1) Introduction

Sublocade® (buprenorphine extended-release injection) is a partial opioid agonist for the management of moderate to severe opioid use disorder that must be administered subcutaneously in the abdominal region by a trained health care professional. A pharmacist may dispense and/or administer this injection provided that they meet the requirements outlined in the guidance document below.

This guidance document is supplementary to the *Standards for Safe and Effective Provision of Opioid Agonist Maintenance Treatment* and the *Standards for Safe and Effective Administration of Drug Therapy by Injection or Inhalation*<sup>1</sup>.

## 2) Pharmacist Requirements

### 2.1 Requirements for Dispensing Sublocade®

In order to dispense Sublocade®, pharmacists must:

- a) be authorized by NLPB to participate in opioid agonist maintenance treatment (OAMT) services and maintain competence in such as per section 5. of the *Standards for Safe and Effective Provision of Opioid Agonist Maintenance Treatment*; and
- b) complete additional education specific to Sublocade®; including the Sublocade® Certification program provided by the manufacturer, Indivior, available at [www.Sublocadecertification.ca](http://www.Sublocadecertification.ca).

### 2.2 Requirements for Administering Sublocade® Injection

In order to administer Sublocade® injection, pharmacists must:

- a) meet all of the requirements for dispensing Sublocade® outlined in section 2.1 above;
- b) be authorized by NLPB to administer injections and maintain competence in such as per section 2. of the *Standards for Safe and Effective Administration of Drug Therapy by Injection or Inhalation*; and
- c) complete additional training to be competent to administer Sublocade®, considering that this is an abdominal injection with specific associated risks if administered incorrectly. This additional education could include self-education, completion of manufacturer-supplied education specific to administration, or shadowing another clinician experienced in Sublocade® administration (if available).

## 3) Operational Requirements

### 3.1 Pharmacy Requirements for Dispensing Sublocade®

In order for the pharmacy to be a site from which Sublocade® is dispensed, pharmacists-in-charge must ensure that:

- a) all operational requirements outlined in section 6. of the *Standards for Safe and Effective Provision of Opioid Agonist Maintenance Treatment* are met; and
- b) any additional requirements for the safe and effective provision of Sublocade® are considered and met, including but not limited to:

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<sup>1</sup> Both available on the [Standards, Guidelines, Policies & Positions page](#) of the NLPB website.

- i) confirming that any pharmacist involved in the provision of Sublocade® has completed additional training to support safe practice;
- ii) ensuring that staff pharmacists have access to additional reference materials specific to Sublocade®;
- iii) making necessary arrangements with the manufacturer to order Sublocade® (contact the manufacturer by email at [indivior@lynden.com](mailto:indivior@lynden.com) to obtain and account opening form package); and
- iv) developing an appropriate procedure and obtain any necessary supplies for packaging Sublocade for transport, considering that it is a cold chain product with unique specifications.

### 3.2 Pharmacy Requirements for Sublocade® Injection Services

In order for a pharmacy to offer Sublocade® injection services, pharmacists-in-charge must ensure that:

- a) all operational requirements outlined in section 6. of the *Standards for Safe and Effective Administration of Drug Therapy by Injection or Inhalation* are met; and
- b) any additional requirements for the safe and effective administration of Sublocade® are considered and met, including but not limited to:
  - i) confirming that any pharmacist administering Sublocade® has completed additional training to support safe practice; and
  - ii) equipping the private consultation room with an examination table as the product monograph recommends that Sublocade® be administered to patients in the supine position.

## 4) **Practice Standards Specific to the Provision of Sublocade®**

### 4.1 Collaboration with Prescribers

Communication and collaboration between the pharmacist and prescriber throughout the patient's treatment are of utmost importance to ensure that the patient receives safe and optimal care. Prescribers are encouraged to contact pharmacies in advance of prescribing Sublocade® to confirm the pharmacy is able to provide the medication, to allow time for pharmacies to order and receive the medication, and to share information about the patient's care plan. Pharmacists are expected to consult with the prescriber to clarify the prescription and care plan, and to confirm arrangements for the administration of the injection before proceeding.

### 4.2 Establishing the Pharmacist-Patient Relationship

As per section 7.2 of the *Standards for the Safe and Effective Provision of Opioid Agonist Maintenance Treatment*, prior to providing OAMT services to a patient, pharmacists should discuss the services that they will provide, along with the obligations and expectations of both the pharmacy staff and the patient within this relationship. The patient should be given the opportunity to ask questions and relevant written information should be made available to supplement the discussion.

### 4.3 Assessing the Prescription

- a) *Prescriber Eligibility*. Prescribers are expected to be competent in the treatment of opioid use disorder and are expected to complete the manufacturer's training certificate prior to prescribing

Sublocade®. Any prescriber involved in provision of Sublocade® should be able to provide a copy of their training certificate upon request.

Specifically, nurse practitioners must be authorized by the College of Registered Nurses NL (CRNNL) to prescribe buprenorphine/naloxone before prescribing Sublocade®. Pharmacists can confirm a nurse practitioner's eligibility to prescribe buprenorphine/naloxone for OAMT on the [member search page of the CRNNL website](#).

The College of Physicians and Surgeons NL (CPSNL) does not maintain a specific list of physicians who prescribe OAMT. Therefore, pharmacists are **not** required to confirm a physician's eligibility to prescribe buprenorphine/naloxone with CPSNL.

- b) *Tamper Resistant Prescription Drug Pad Program Form*. In NL, prescriptions for buprenorphine **MUST** be written on the form required by the Tamper Resistant Prescription Drug Pad Program. This form is required regardless of whether the prescription is written by an in-province or out-of-province prescriber. For more information on this program and its requirements, visit the [Department of Health and Community Services website](#).
- c) *Prescription Requirements*. The [Provincial Opioid Dependence Treatment Centre of Excellence Sublocade Bulletin](#) provides guidance on how to appropriately write prescriptions for Sublocade® (see section 3. above). If the prescriber's intentions are unclear, the pharmacist must consult with the prescriber to clarify, and the outcome of this clarification must be documented and included with the original prescription and noted in the patient's medication profile.
- d) *Buprenorphine/Naloxone Dosing*. Pharmacists must assess each buprenorphine/naloxone prescription to determine whether or not the dose, dosing schedule, and duration of prescription falls within recommendations outlined in the product monograph, clinical practice guidelines and standards of practice. If pharmacists receive prescriptions that are inconsistent with these references, they must consult with the prescriber, document the conversation and the rationale for their decision to dispense in the patient record.

#### 4.4 Dispensing the Prescription

- a) *Formulations*. Sublocade® is available as a 100 mg/0.5 mL and 300 mg/1.5 mL pre-filled syringe for subcutaneous injection into the abdomen by a trained health professional.

**NOTE:** Sublocade® is currently only available through a manufacturer-controlled distribution process. Ensure that the prescriber and the patient are informed of when the medication will be available in the pharmacy so that this can be taken into account when planning treatment initiation.

#### 4.5 Releasing the Prescription / Administration of Sublocade®

- a) As per the manufacturer's requirements and in the interest of patient and public safety, **Sublocade® may not be released directly to a patient or a patient's agent**; it must only be released to the prescriber or administering clinician. For this reason, advance arrangements for delivery or pick-up must be made in consultation with the prescriber.
- b) Prior to releasing Sublocade® to the administering clinician (if not the pharmacist), or administering the injection (if being administered by the pharmacist), the pharmacist must review the patient's local medication profile, the patient medication profile in the electronic health record, the Administration

Log (for buprenorphine/naloxone initiation), and any other applicable information to determine that it is safe and appropriate. It is important to note that the NL Prescription Monitoring Program requirements apply to the prescribing and dispensing of Sublocade®.

If a drug-related problem is detected (for example, another mood-altering or sedating drug has been prescribed) the pharmacist must consult with the relevant prescribers prior to dispensing the prescription and document the outcome of the consultation.

**As per the [product monograph](#), Sublocade® carries risk of reproductive and developmental toxicity and should not be used in women of child-bearing potential who are not using a reliable and effective method of birth control.** Pharmacists are expected to confirm that female patients are using a reliable and effective form of birth control (such as an IUD or contraceptive injection) and that the patient is adherent to the contraceptive schedule. If the patient's medication profile indicates that the patient is not receiving such contraceptive therapy, consult with the patient and the OAMT prescriber, and document the outcome of the consultation.

- c) If administering the injection, pharmacists must:
- i) Positively identify the patient. If uncertain as to the patient's identity, photo identification must be requested.
  - ii) Assess the patient for signs of intoxication or sedation. If it is determined that the patient is intoxicated or sedated, the pharmacist must withhold the injection and consult with the prescriber.
  - iii) If it is safe to provide the Sublocade® injection, follow best practices for administration of the medication.

<p><b>NOTE:</b> To ensure appropriate administration of Sublocade®, a pharmacist must only administer the injection in a suitable location that ensures patient privacy and comfort, and where the patient is able to lie down, facing up.</p>
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- iv) Document the injection as per section 5.3 of the *Standards for Safe and Effective Administration of Drug Therapy by Injection or Inhalation*.
- v) Notify the OAMT prescriber that the injection has been administered as prescribed and confirm the patient's follow-up plan.

#### 4.6 Patient Counselling

Regardless of whether or not the pharmacist administers the Sublocade® injection, the pharmacist is still responsible for counselling the patient on the medication. This includes, but is not limited to:

- side effects and treatment effects of buprenorphine;
- symptoms of opioid withdrawal and overdose;
- the need to contact the pharmacy prior to taking any prescribed or non-prescribed medications in order to prevent potentially harmful drug interactions;
- the risk associated with driving an automobile or operating machinery during the stabilization period or periods of instability due to possible sedation and symptoms of withdrawal;
- the risk associated with the use of alcohol and other sedating substances in combination with buprenorphine;
- the recommendation to have a naloxone kit on-hand; and

- the need for regular use of effective contraception and the risks Sublocade® may pose during pregnancy, if applicable

**NOTE:** In accordance with the *SOPO-Community* and the *SOPO-Hospital*, all counselling activities must be documented. The pharmacist should use professional judgement when determining the information to be contained in the counselling record, but it should include, at a minimum, the name of the pharmacist who delivered the counselling and the date and time the counselling was given.