

Guidance on the Administration of Sublocade® by a Pharmacist

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 physician, nurse, or pharmacist. A pharmacist may administer this drug if they meet the requirements outlined below and are authorized to administer the injection by the Sublocade® prescriber.

Ideally, the first two Sublocade® injections should be administered by the approved prescriber or a nurse who works in the clinic the patient attends for their opioid agonist therapy (OAT) care. A pharmacist can administer further doses as authorized by the Sublocade® prescriber. A pharmacist should only administer the first dose of Sublocade® if the prescriber or a nurse is not able to administer the medication in a timely manner and the pharmacist is comfortable and competent in doing so. Prescriber obligations in terms of counselling, ruling out pregnancy, ensuring reliable fertility control, informed consent, and all standards of care would still apply.

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. Please see the following for further information on the expectations and requirements of the pharmacist and the prescriber.

Expectations of the Pharmacist

Section 18 of the Pharmaceutical Regulation states that a member may only engage in aspects of pharmacy practice that they have the requisite knowledge, skill, and judgement to provide or perform and that are appropriate for their area of practice. Pharmacists who hold current authorization from the College of Pharmacists of Manitoba (CPhM) may administer a drug or vaccine by an advanced method, but only if the pharmacist is comfortable, knowledgeable, and competent to administer the injection. The pharmacist must also have the ability to appropriately handle any adverse reactions that may occur due to the administration.

Training Requirements

At a minimum, pharmacists who want to administer Sublocade®, in addition to holding certification of authorization to administer drugs and vaccines by injection from CPhM, along with maintaining the required CPR/First Aid certification, must complete the following training:

1. Sublocade® Certification

Each pharmacist wanting to administer Sublocade must successfully complete the non-accredited certification program, which can be found here:

www.sublocadecertification.ca.

2. Sublocade® product monograph

The product monograph must be reviewed and can be found here: <https://health-products.canada.ca/dpd-bdpp/index-eng.jsp>.

3. Approved OAT training program

A good understanding of OAT is imperative. Please review the recommended training for dispensing buprenorphine/naloxone (different from injectable buprenorphine) as listed in the [Opioid Agonist Therapy Guidelines for Manitoba Pharmacists](#). These guidelines and the College of Physicians and Surgeons of Manitoba (CPSM) [Manitoba Opioid Agonist Therapy Recommended Practice Manual](#) must be reviewed in detail.

It is also strongly recommended that pharmacists participate in the following:

- Sublocade® Webinar

Indivior (the manufacturer of Sublocade®) offers non-accredited live webinars on the administration of the injection. The pharmacist should contact the representative, Anna Magnan, by email Anna.Magnan@indivior.com for scheduling and to register.

Pharmacists may wish to seek additional training/shadowing from a prescriber or health care provider who has experience administering Sublocade®.

Pharmacy managers must ensure that all pharmacists, including new or casual staff, are aware of the requirements around administration of Sublocade®. Information must be included in the pharmacy policy and procedures manual.

Additional Requirements

- Pharmacists, when administering Sublocade®, must meet all the requirements outlined in the Practice Direction, [Standard of Practice #5: Administration of Drugs including Vaccines](#). Although the prescriber is responsible for obtaining the patient's consent to start treatment with Sublocade®, the pharmacist must obtain consent from the patient or from the person authorized to consent on the patient's behalf to administer the drug.
- It is recommended that Sublocade® be administered to patients in the supine position, in both clinic and pharmacy settings. To ensure appropriate administration, a prescriber, nurse, or pharmacist should administer the injection where the patient is able to lie down, face up. **A private area with an exam table is required.** Occasionally, in patients who are very slim with minimal subcutaneous fat, it may be beneficial for the patient to sit in a chair during administration, as this may help to manipulate the site to gather enough subcutaneous fat for appropriate injection. This must still occur in a private area.

- To ensure that the patient has been assessed and will receive the appropriate follow up from the prescriber, a pharmacist must receive authorization from the prescriber to administer the medication. **For every dose, the pharmacist must also notify the prescriber when the medication has been administered or if a patient misses their injection.**
- The pharmacist is responsible for ensuring that the medication can be safely administered and must do their own assessment of the patient that includes but is not limited to:
 - Verifying the identity of the patient and requesting a photo ID if necessary.
 - Checking the patient's local and DPIN history for other medications that may interact or be of concern when used concomitantly.
 - Ensure that the timing of the injection is appropriate. This may require additional collaboration with other health care professionals, especially if there has been a transfer of care.
 - Assessing the patient for intoxication or co-ingestion of alcohol, opioids, benzodiazepines, or other sedating or mood-altering drugs.
 - The pharmacist may also need to confirm that the patient is prescribed and adherent to the schedule of a reliable and effective form of birth control, as appropriate and in collaboration with the prescriber when an individualized and alternative approach is taken.
 - In general, pregnancy and breastfeeding have been viewed as relative contraindications to Sublocade®, as one of its excipients, N-methyl-pyrrolidone (NMP), has been identified as potentially teratogenic in animal studies. Human data is extremely limited: two cases of undiagnosed pregnancy treated with Sublocade®, up to 18 weeks gestation, had normal obstetrical and pediatric outcomes.
 - It is the prescriber's responsibility to ensure that a female patient who is of reproductive age has been adequately counselled regarding the potential risks associated with an unplanned pregnancy. If appropriate and acceptable to the patient, a reliable and effective form of birth control (such as an IUD or Depo Provera) should be prescribed and established prior to administering the first Sublocade® injection, and for the duration of treatment with Sublocade®. Two forms of less reliable birth control (such as an oral contraceptive pill combined with a barrier method) may be an alternative.
 - If a patient who understands this information indicates that they do not require birth control for some reason or indicates that they find the use of birth control unacceptable, OAT providers are to use their clinical judgement in **weighing the potential benefits of treatment with Sublocade® (including treatment access and retention) against the risks of an unplanned pregnancy while on Sublocade®**. There is limited evidence surrounding the use of Sublocade® in pregnancy. See the CPSM [Manitoba Opioid Agonist Therapy Recommended Practice Manual](#) for further guidance, specifically the [Sublocade Chapter](#) section on informed consent.

- The pharmacist must counsel the patient on the medication. More information can be found in the [Practice Direction on Patient Counselling](#).

Expectations of the Prescriber

- Physicians must hold a current, active buprenorphine/naloxone prescribing approval from the College of Physicians and Surgeons of Manitoba to prescribe Sublocade®.
- RN (Nurse Practitioners) must hold current, active buprenorphine/naloxone prescribing authority from the College of Registered Nurses of Manitoba to prescribe Sublocade®.
- Sublocade® Certification: Approved prescribers wanting to prescribe and administer Sublocade® must complete the non-accredited certification program, which can be found here: www.sublocadecertification.ca. This is a Health Canada requirement.
- The certificate generated by this certification program must be faxed to the pharmacy along with the M3P prescription for Sublocade® when the prescriber first orders Sublocade® from a particular pharmacy.
- The prescriber must ensure they meet all requirements associated with prescribing and administering Sublocade®, as outlined in the CPSM [Manitoba Opioid Agonist Therapy Recommended Practice Manual](#).
- Prescribers must actively collaborate and communicate with pharmacists when circumstances indicate that Sublocade® administration by a pharmacist would facilitate access to care and support the patient's ability to participate in their care plan.
- As above, prescribers must ensure that a female patient who is of reproductive age has been adequately counselled regarding the potential risks associated with an unplanned pregnancy. If appropriate and acceptable to the patient, a reliable and effective form of birth control (such as an IUD or Depo Provera) should be prescribed and established prior to administering the first Sublocade® injection, and for the duration of treatment with Sublocade®. Two forms of less reliable birth control (such as an oral contraceptive pill combined with a barrier method) may be an alternative.
 - If a patient who understands this information indicates that they do not require birth control for some reason or indicates that they find the use of birth control unacceptable, OAT providers are to use their clinical judgement in **weighing the potential benefits of treatment with Sublocade® (including treatment access and retention) against the risks of an unplanned pregnancy while on Sublocade®**. This conversation and any decisions made should be carefully documented in the patient record. There is limited evidence surrounding the use of Sublocade® in pregnancy. See the CPSM [Manitoba Opioid Agonist Therapy Recommended Practice Manual](#) for further guidance, specifically the [Sublocade Chapter](#) section on informed consent.
 - In addition to the above, in patients of reproductive age, an in-office pregnancy test is strongly recommended before every injection and regardless of the contraceptive option used by the patient. When Sublocade® is administered in pharmacy and a pregnancy test is not available, periodic pregnancy tests in clinic are recommended when the patient presents for follow-up and other reasons.

Additional Resources

British Columbia Centre of Substance Use
Webinars on Sublocade

<https://www.bccsu.ca/blog/event/webinars-sublocade/>

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