
Sublocade (Extended-Release Buprenorphine) Information

July 17, 2020

1. Overview of Sublocade

Sublocade® has a Health Canada indication for the treatment of moderate to severe opioid use disorder in adult patients who have been inducted and stabilized on sublingual buprenorphine/naloxone. In June 2020, the Newfoundland and Labrador Prescription Drug Program made Sublocade® coverage available under the Special Authorization Request process.

Sublocade® is to be used as part of a treatment plan that includes counselling and psychosocial supports. Sublocade® is administered as a monthly subcutaneous injection in the abdominal region and must not be injected intravenously or intramuscularly. There are two dose strengths of Sublocade®: 100mg/0.5ml and 300mg/1.5ml, both of which are provided in a prefilled syringe with a 19 gauge 5/8-inch (16mm) needle to be administered by a physician, nurse practitioner, registered nurse, or licenced practical nurse.¹ For a full list of contraindications, warnings, and precautions, consult the Sublocade [product monograph](#).

This Bulletin provides information on Sublocade® for prescribers, pharmacists, and nurses, including:

- available education and training;
- guidance on how to prescribe, order, and dispense; and
- instructions for submitting a special authorization request to the NL Prescription Drug Program (NLPDP).

2. Information for Prescribers

Prescribers must be competent in the treatment of opioid use disorder and must complete the manufacturer's training certificate prior to prescribing Sublocade®. Nurse Practitioners must be authorized by CRNPL to prescribe buprenorphine/naloxone (Suboxone®) in order to prescribe Sublocade®. Registered nurses and licenced practical nurses administering Sublocade® should also receive education and practical training before treating patients.

Available Training and Education

The manufacturer of Sublocade® (Indivior) requires that all prescribers interested in prescribing Sublocade® complete training through <http://www.sublocadecertification.ca/>. The manufacturer's [website](#) also provides additional drug information.

Transitioning Patients to Sublocade

Sublocade® should be considered when clinical judgment determines the patient would benefit significantly from this form of buprenorphine; this may include, for example, people who have benefitted

¹ Indivior UK Limited and Pharma Importing Inc. Product monograph: Sublocade. Toronto, ON2018.
https://pdf.hres.ca/dpd_pm/00048406.PDF.

from sublingual buprenorphine/naloxone but have challenges with treatment retention, or people who may not be able to access a pharmacy regularly.

Before transitioning patients to Sublocade[®], discuss the potential benefits and risks of the transition with the patient. If a shared decision is made to switch to Sublocade[®], document the discussion, decision, and clinical rationale carefully in the patient's medical record. If the patient has medication coverage through an insurer, assess whether or not Sublocade[®] may be considered as a benefit and if special authorization is required. If applicable, special authorization approval should be confirmed prior to writing a prescription for Sublocade[®]. In addition, the NL Prescription Monitoring Program (PMP) requirements apply to the prescribing of Sublocade[®]. Prescribers must consult with the patient's medication profile in the electronic health record immediately prior to prescribing.

Prior to receiving Sublocade[®], patients must be inducted and stabilized on sublingual buprenorphine/naloxone (8–24mg/day) for a minimum of 7 days. Following induction and stabilization, patients can be transitioned to Sublocade[®]. Patients should be prescribed a starting dose of 300mg/month for two months, followed by a maintenance dose of 100mg/month.¹ At the discretion of the treating prescriber, the maintenance dose may be increased to 300mg/month^b if the patient experiences ongoing opioid cravings or illicit opioid use.¹ Sublocade[®] doses must be administered monthly at a minimum of every 26 days.¹

Sublocade[®] must be written on a Tamper Resistant Prescription Pad (TRPP). The patient's pharmacy should be contacted in advance to discuss the patient's planned change in treatment, to confirm the pharmacy can dispense Sublocade[®], to provide adequate time for the pharmacy to order and receive the product from the manufacturer, and to confirm the arrangement for medication delivery/pick-up. It is important that patients are given realistic timelines for when they can expect to start their new treatment.

Like other substances subject to the federal Controlled Drugs and Substances Act, Sublocade[®] must be safely and securely stored and monitored. In addition, Sublocade[®] must be stored under refrigeration between 2 to 8°C (35.6 to 46.4°F). Once outside the refrigerator, it may be stored in its original packaging at room temperature for up to 7 days prior to administration. If left at room temperature for longer than 7 days, Sublocade[®] should be discarded. For detailed information on storing Sublocade[®], please consult the manufacturer's [website](#).

Prescribers and nurses should also refer to manufacturer's training materials, [website](#), and the [product monograph](#) for detailed instructions on how to properly administer Sublocade[®]. As with initiating any treatment, prescribers should discuss potential side effects and other relevant facets of care, such as depot removal and follow-up care, with their patient.

3. Summary of Prescription Requirements

- The NL Prescription Monitoring Program and the Tamper Resistant Drug Pad Program apply to the prescribing and dispensing of Sublocade[®]. Prescribers and dispensers should be familiar with the requirements of these provincial programs.
- Administration of Sublocade[®] can be performed by a prescriber (MD or NP), registered nurse (RN), or licenced practical nurse (LPN).
- Prescribers should indicate the date of administration/clinic appointment on the prescription (after consultation with the pharmacist to ensure the medication can be received by the appointment date).

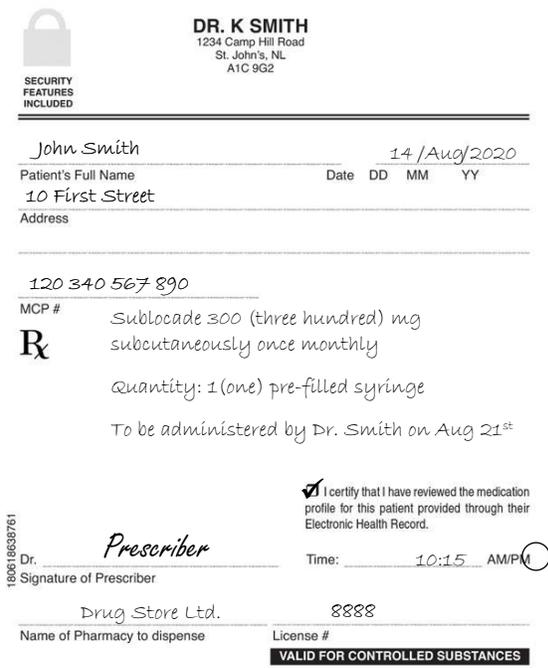
^b In clinical trials, the 300 mg/month maintenance dose did not provide additional efficacy as compared to the 100 mg/month dose, and was associated with a higher incidence of adverse events and study discontinuations.

- To avoid errors, best practice is to write 'subcutaneously' on the prescription.
- An example of a first prescription:
Sublocade® 300 (three hundred) mg subcutaneously once monthly
Quantity: 1 (one) pre-filled syringe
To be administered by {clinician} on {SPECIFIC DATE}

(The second 300 mg dose for month two would then be written as a separate prescription upon re-assessment)

- The initial prescription may also be written for both doses to be dispensed as a part-fill, for example:
Sublocade® 300 (three hundred) mg subcutaneously once monthly
Quantity: 2 (two) pre-filled syringes total, dispense 1 (one) syringe to administering clinician every 26-30 days starting on {SPECIFIC DATE}
- To avoid errors, the reduction in dose to 100mg after two months should be written as a separate prescription, ideally after reassessment, for example:
Sublocade® 100 (one hundred) mg subcutaneously once monthly
Quantity: 3 (three) pre-filled syringes total, dispense 1(one) syringe to {administering clinician} every 26-30 days after the previous injection

An initial and maintenance Sublocade prescription may look like:



DR. K SMITH
1234 Camp Hill Road
St. John's, NL
A1C 9G2

SECURITY FEATURES INCLUDED

John Smith
Patient's Full Name
10 First Street
Address

14 / Aug / 2020
Date DD MM YY

120 340 567 890
MCP #

Rx Sublocade 300 (three hundred) mg subcutaneously once monthly
Quantity: 1 (one) pre-filled syringe
To be administered by Dr. Smith on Aug 21st

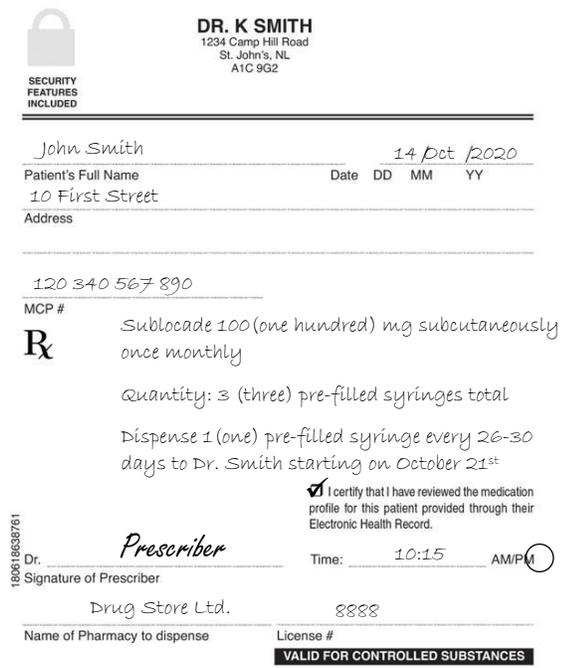
I certify that I have reviewed the medication profile for this patient provided through their Electronic Health Record.

Dr. Prescriber
Signature of Prescriber

Time: 10:15 AM/PM

Drug Store Ltd. 8888
Name of Pharmacy to dispense License #

VALID FOR CONTROLLED SUBSTANCES



DR. K SMITH
1234 Camp Hill Road
St. John's, NL
A1C 9G2

SECURITY FEATURES INCLUDED

John Smith
Patient's Full Name
10 First Street
Address

14 Oct 2020
Date DD MM YY

120 340 567 890
MCP #

Rx Sublocade 100 (one hundred) mg subcutaneously once monthly
Quantity: 3 (three) pre-filled syringes total
Dispense 1 (one) pre-filled syringe every 26-30 days to Dr. Smith starting on October 21st

I certify that I have reviewed the medication profile for this patient provided through their Electronic Health Record.

Dr. Prescriber
Signature of Prescriber

Time: 10:15 AM/PM

Drug Store Ltd. 8888
Name of Pharmacy to dispense License #

VALID FOR CONTROLLED SUBSTANCES

4. Coverage for Newfoundland and Labrador Prescription Drug Program (NLPDP) Beneficiaries

Sublocade® (100MG/0.5ML, 300MG/1.5ML) may be considered as a benefit under the NLPDP for the management of moderate to severe opioid use disorder in adult patients who meet **all** of the following criteria:

- The patient has been inducted and is stabilized on an equivalent of 8mg to 24mg per day of transmucosal buprenorphine for a minimum of seven (7) days;
- The patient is under the care of a health care provider with experience and competence in the diagnosis and management of opioid use disorder; and
- Each dose is administered subcutaneously in the abdominal region by a healthcare provider under the Sublocade Certification Program.

Dose: 300mg/month for two months, followed by a maintenance dose of 100mg/month. The maintenance dose may be increased to 300mg/month only if the patient does not demonstrate satisfactory clinical response.

Prescribers interested in prescribing Sublocade® to a patient with NLPDP coverage, for new requests and dosage adjustments, must complete a [Special Authorization Request Form](#) for each patient.

<p>Information that must be included in the request:</p> <ul style="list-style-type: none">• Patient name, address, date of birth and MCP number• Confirmed diagnosis of moderate to severe opioid use disorder• Clinically stable on 8mg to 24mg of buprenorphine/naloxone for a minimum of 7 days (current dose must be provided)• Any additional clinical rationale
<p>Information that <u>does not</u> need to be included:</p> <ul style="list-style-type: none">• A copy of the prescription• Pharmacy information
<p>Note: Additional information may be requested by Pharmaceutical Services, on a case-by-case basis, in order to adjudicate the request.</p>

Special Authorization Request Forms can be faxed to (709)729-2851 (**preferred**) OR mailed to Pharmaceutical Services, Department of Health and Community Services, P.O. Box 8700, St. John's, NL, A1B 4J6.

After the Request is Submitted

- Special Authorization requests are reviewed in the order they are received.
- Once the request is processed, the NLPDP will notify the prescriber and the beneficiary of the decision by mail.
- Prescribers are advised to wait to write the prescription for Sublocade® until after they have been notified of approval.

Estimated Turnaround Times

- Special Authorization requests will be processed in 7-10 business days.

Duration of coverage

- Sublocade® coverage is valid from the date that approval is entered into a patient's record in the NLPDP patient profile, which is linked to all of the province's community pharmacies.
- The duration of initial approval and all subsequent renewals of coverage for Sublocade® will be for one year. Renewal will be considered upon submission of a written request, which should indicate the patient's current dose and provide information to demonstrate that the patient is stable on and benefiting from Sublocade®.
- To ensure continuity of coverage, prescribers may wish to schedule an appointment with their patient for re-evaluation several weeks in advance of the expiry date to ensure that a request for renewal can be submitted at least 30 days prior to the expiry date if required.

Level of Coverage Provided to a Patient

- Following Special Authorization approval, the level of coverage is dependent on the plan for which the beneficiary has qualified. Actual reimbursement depends on a patient's NLPDP plan rules, including co-payment requirements, and is subject to NLPDP pricing.
- Individuals who have qualified for coverage on the Foundation, Access, Assurance, and 65Plus Plans are eligible for funding of Sublocade®.

Dispensing and Reimbursement Permissions

- **Approvals will be for one prefilled syringe per month. A minimum of 26 days is required between claims.**

5. Additional Information for Pharmacists

In order to provide Sublocade®, pharmacists must have an authorization to participate in Opioid Agonist Maintenance Treatment (OAMT) under the Newfoundland and Labrador Pharmacy Board (NLPB). In addition, pharmacies are required to register for OAMT services with NLPB prior to offering this service. Pharmacists, other health care professionals, and the public are encouraged to contact NLPB if they have questions about the pharmacy regulatory standards related to the provision of Sublocade®.

Available Training and Education

In addition to the education requirements for a general OAMT authorization, pharmacists are expected to complete the manufacturer-provided training <http://www.sublocadecertification.ca/> as well as any other education deemed necessary to feel competent in the handling and dispensing of Sublocade and to keep up-to-date on opioid use disorder and Sublocade® education. The manufacturer's [website](#) provides additional information on Sublocade®.

Ordering Sublocade®

Pharmacists must email Indivior@lynden.com to obtain an account opening form package from Indivior. The completed form must be emailed (Indivior@lynden.com) or faxed (905-879-0123) to Indivior. The requesting pharmacist will receive an email with a username and a separate email with a password within 2 business days. Both are required to access the Controlled Substances e-Ordering form. To order Sublocade, download, complete, sign, and mail an original copy of the Controlled Substance e-Ordering form to:

**CPDN Controlled Substances e-Ordering Program
9-2798 Thamesgate Drive, Mississauga, ON L4T 4E8**

Indivior will validate the requesting pharmacist's license, who will then receive an email containing a private key, which is required to complete the order. The order must be finalized at <https://www.cpdnweboms.ca>.

Dispensing Information

For detailed information on storing Sublocade®, please consult the manufacturer's [website](#). It is important to note that Sublocade® is both a controlled substance and a cold chain product, and therefore there are special considerations when storing or transporting the medication. Pharmacists are reminded that in accordance with NLPB requirements, the medication must be safely and securely stored, and there must be appropriate cold chain management when handling the medication at the pharmacy and when delivering the medication to an administering clinician. Pharmacies are advised to stock only the amount of Sublocade needed to avoid overstocking.

As per the manufacturer's requirements, pharmacists may not release Sublocade® directly to a patient or patient's agent. Currently, in NL, Sublocade® must be administered by a prescriber (MD or NP), registered nurse, or licenced practical nurse. Sublocade® is to be either picked up by an authorized nurse or prescriber or delivered to the clinic, keeping in mind proper storage. Given the unique dispensing pathway necessary for Sublocade®, prescribers and pharmacists should create a plan in advance for each prescription- including, what day the prescription will be dispensed and delivered or picked-up, who will pick-up the prescription, and any additional information necessary.

Even though Sublocade® is delivered directly to the administering clinician, pharmacists are still responsible for counseling patients on their new medication, either in-person, by phone, or another appropriate means, and must document the counselling accordingly. Pharmacists should follow-up with patients as necessary and encourage patients to call with any questions/concerns or when starting another new medication to ensure there are no safety concerns such as drug interactions.

6. Resources

1. [CADTH Common Drug Review: Clinical Review Report Buprenorphine extended-release injection \(Sublocade\)](#)
2. [Sublocade Product Monograph](#)
3. [Manufacturer-Provided Training](#)
4. [Manufacturer-Provided SUBLOCADE® Distribution FAQ \(see below\)](#)
5. [Regulatory Decision Summary - Sublocade - Health Canada](#)
6. [Sublocade Patient Medication Guide](#)
7. [CRISM National Guideline for the Clinical Management of Opioid Use](#)
8. [British Columbia Centre on Substance Use: A Guideline for the Clinical Management of Opioid Use Disorder](#)
9. [Transportation of Controlled Substances in Canada](#)
10. [CPSNL: Standards and Guidelines](#)
11. [CRNNL Scope Practice for NPs](#)
12. [CRNNL Standards of Practice for Registered Nurses and Nurse Practitioners](#)
13. [NLPB Standards, Guidelines, Policies, and Positions](#)
14. [CLPNNL Scope of Practice for Licensed Practical Nurses](#)

7. Acknowledgments

This bulletin was adapted (with permission) from the British Columbia Centre on Substance Use (BCCSU) Bulletin [*Sublocade \(Extended-Release Buprenorphine\) Information \(May 29, 2020\)*](#). Thank you to the BCCSU for providing this support.

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- **Dr. Steve Darcy** - Family Physician, Assistant Professor, Faculty of Medicine, MUN
- **Dr. Oscar Howell** - College of Physicians and Surgeons Newfoundland and Labrador
- **Jennifer Patrick** - Nurse Practitioner, Eastern Health ODT HUB
- **Ellisa Sinnicks-House** - Nurse Practitioner, Western Health ODT HUB
- **Stephanie Delaney** - Pharmacist, NuCare Pharmacy (Eastern Health ODT HUB)
- **Michelle Carpenter** - College of Registered Nurses Newfoundland and Labrador
- **Debbie Curtis** - Newfoundland and Labrador Department of Health and Community Services
- **Patricia Clark** - Newfoundland and Labrador Department of Health and Community Services
- **Wayne Bishop** - Opioid Dependence Treatment Centre of Excellence



N SUBLOCADE[®] Distribution Questions for Pharmacists

Q1: Who can set up the account?

A: A billing account must first be set up with the pharmacy. Only then can a pharmacist with a narcotics licence be registered on the online ordering portal. After this is complete, this pharmacist will be the primary pharmacist and becomes the administrator. The administrator can then add other pharmacists and techs to the account.

Q2: Can I order manually?

A: Indivior no longer accepts manual orders from Direct Pharmacy Accounts. All orders for SUBLOCADE must go through the online ordering portal.

Q3: Who do I contact if I have an online issue?

A: The portal has an FAQ section AND the portal provider has robust technical support available by email and by phone for any portal support you may need: ecert@cpdn.ca or 1-855-412-CERT(2378) option 1.

Q4: Who do I contact if I have a delivery problem?

A: The pharmacy should contact the Customer Service Associate at Lynden: indivior@lynden.com or 1-800-265-6756 ext. 2908.

Q5: Can I order from a wholesaler?

A: SUBLOCADE will only be available directly from Indivior to pharmacies that have set up accounts.

Q6: How long does account setup and product delivery take?

A1: The billing account will be opened within one to two business days of receiving the Direct Account Opening Form.

A2: The online portal account setup can take from a few days to a few weeks, depending on how quickly the pharmacist sends back the mandatory documentation. We recommend doing it immediately and sending it by courier to expedite the process.

A3: Once the online ordering account is set up, product ordered through the portal will ship no later than the next business day for following day delivery. Please note that we do not ship narcotics on Fridays or statutory holidays.

Q7: How will I know my account is set up?

A: When the billing account is set up, the pharmacist will receive two emails — one containing the username and the other containing the password to begin the online registration. Once the pharmacist's licence has been

validated (meaning they returned the original signed form to the portal provider), they will receive another email with their private key. This means their account setup has been completed, and they may begin ordering.

Q8: What is the minimum order?

A: During the launch phase, the MOQ (minimum order quantity) will be two (2) units of SUBLOCADE, either strength.

Q9: What is the policy on returns?

A: Please see our Terms and Conditions, which details our returns policy.

Q10: Will I be compensated for delivery?

A: Delivery arrangements to physicians' offices are outside of the manufacturer's purview.

Q11: What are the storage requirements for SUBLOCADE?

A1: As per the SUBLOCADE Product Monograph:¹

- Store at 2-8°C (35.6-46.4°F).
- Once outside the refrigerator this product may be stored in its original packaging at room temperature, 15-30°C (59-86°F), for up to 7 days prior to administration.
- Discard SUBLOCADE if left at room temperature for longer than 7 days.
- Handle SUBLOCADE with adequate security and accountability.

A2: As per the Terms and Conditions:

- **SUBLOCADE must never be handled by, or be in the possession of, the patient prior to administration by a qualified healthcare provider (HCP).**

A3: Storage and handling of Controlled Substances is dictated by the Office of Controlled Substances' (OCS) Narcotic Control Regulations, along with each province's College of Pharmacists. As per Indivior's Terms and Conditions, these regulations must be followed.

Q12: Does it need to be a pharmacist who delivers SUBLOCADE, or can it be any delivery company?

A: Storage and handling of Controlled Substances is dictated by the OCS' Narcotic Control Regulations, as well each province's College of Pharmacists. As per Indivior's Terms and Conditions, these regulations must be followed.

REFERENCE: 1. SUBLOCADE Product Monograph, Indivior UK Limited, May 9, 2019.



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