



SUBLOCADE (EXTENDED-RELEASE BUPRENORPHINE) INFORMATION

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1. OVERVIEW OF SUBLOCADE

Sublocade is an extended-release formulation of buprenorphine that is administered monthly via abdominal subcutaneous injection for the management of moderate to severe opioid use disorder.¹ Sublocade was made available in British Columbia on April 30, 2020, through Pharmacare Special Authority. This bulletin provides information for prescribers and pharmacists on Sublocade, including guidance on how to prescribe, order, and dispense; instructions for submitting a Special Authority request form to PharmaCare; and available education and training.

The evidence base regarding which patients will benefit from transitioning to Sublocade is limited and continues to evolve. Sublocade is associated with significantly higher treatment retention (almost double; $p < 0.0001$) and mean abstinence percentages (over 40%) compared to placebo (5%; $p < 0.0001$) in individuals with moderate to severe opioid use disorder.² A longitudinal study of extended-release buprenorphine found that 75% of participants who were retained in extended-release buprenorphine treatment for 12 months were abstinent at 12 months compared to 24% of those who were retained in extended-release buprenorphine treatment for 0–2 months ($p < 0.001$). Overall, 51% of all participants remained abstinent for 12 months.³

¹ Indivior UK Limited and Pharma Importing Inc. Product monograph: Sublocade. Toronto, ON 2018. https://pdf.hres.ca/dpd_pm/00048406.PDF.

² Haight BR, Learned SM, Laffont CM, et al. Efficacy and safety of a monthly buprenorphine depot injection for opioid use disorder: A multicentre, randomised, double-blind, placebo-controlled, phase 3 trial. *Lancet*. 2019; 393(10173):778-790.

³ Ling W, Vijay R, Nadipelli V, et al. Recovery from opioid use disorder (OUD) after monthly long-acting buprenorphine treatment: 12-month longitudinal outcomes from RECOVER, an observational study. *J Addict Med*. 2020; online ahead of print.

2. INFORMATION FOR PRESCRIBERS

Sublocade is indicated for adult patients who have been inducted and stabilized on sublingual buprenorphine/naloxone for a minimum of 7 days.^a Sublocade is administered as a monthly subcutaneous injection in the abdominal region and must not be injected intravenously or intramuscularly. It is to be used as part of a treatment plan that includes counselling and psychosocial supports. For a full list of contraindications, warnings, and precautions, consult the Sublocade [product monograph](#). 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 registered psychiatric nurse.¹ Prescribers must complete Indivior's training certificate prior to prescribing Sublocade; nurses should receive training on administering Sublocade prior to treating patients (see below).

How to Submit a Coverage Request

Sublocade should be considered when clinical judgment determines the patient would benefit significantly from Sublocade; for example, people who have benefitted from sublingual buprenorphine/naloxone but have challenges with treatment retention, or people who may not be able to regularly access a pharmacy. Prescribers interested in prescribing Sublocade to a patient must complete a [General Special Authority Request Form](#) for each patient.

| Information that must be included in the request |
|---|
| <ul style="list-style-type: none">• 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 |
| Information that does not need to be included |
| <ul style="list-style-type: none">• A copy of the prescription• Pharmacy information |
| <i>Note: Additional information may be requested by PharmaCare, on a case-by-case basis, in order to adjudicate the request.</i> |

Special Authority coverage request forms can be faxed to 1-800-609-4884(toll free) (preferred) OR mailed to: PharmaCare, Box 9652 Stn Prov Govt, Victoria, BC V8W 9P4

After the Request is Submitted

Special Authority requests for Sublocade are prioritized by date received and will be classified as "urgent." Once the request is processed, PharmaCare will notify the prescriber of the decision.

Prescribers are advised to wait to write the prescription for Sublocade until after they have been notified of approval.

Estimated Turnaround Times

Sublocade Special Authority requests will be processed as urgent requests. Urgent requests are usually processed within 1–2 business days.

^a Patients may also be inducted and stabilized on transmucosal buprenorphine; however, individuals who receive opioid agonist treatment in BC generally receive sublingual buprenorphine/naloxone as first-line treatment unless naloxone component is contraindicated.

Duration of coverage

Sublocade coverage is valid from the date that approval is entered into a patient's record on PharmaNet, which links all of the province's community pharmacies and other authorized health care providers.

The duration of initial approval and all subsequent renewals of coverage for Sublocade will be for 1 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 2 weeks prior to the expiry date, if required.

Level of Coverage Provided to a Patient

An approved request normally grants full coverage of a drug that would otherwise not be covered or be only partially covered. Note that full coverage differs from actual reimbursement. Actual reimbursement depends on a patient's PharmaCare plan rules, including any annual deductible and co-payment requirements, and is subject to pricing policies such as the Maximum Pricing Policy, the Low-Cost Alternative (LCA) Program, or the Reference Drug Program (RDP). Individuals on PharmaCare Plans C, G, and W are eligible for coverage of Sublocade.

Transitioning Patients on to Sublocade

Before transitioning patients to Sublocade, discuss the potential benefits and risks of the transition. If a shared decision is made to switch to Sublocade, document the discussion, decision, and clinical rationale carefully in the patient's medical record. Once Special Authority coverage has been confirmed through PharmaCare, the prescription for Sublocade should be written using the Controlled Prescription Program prescription pad and the patient's pharmacy should be contacted to discuss the switch, to ensure the pharmacy is aware of the planned transition and is knowledgeable on how to obtain the product from the manufacturer.

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

Refer to the manufacturer's [website](#) or the [product monograph](#) for detailed instructions on administering 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.

Available Training and Education

The manufacturer of Sublocade requires that all prescribers interested in prescribing Sublocade complete training through www.sublocadecertification.ca. The manufacturer's [website](#) provides additional information on Sublocade.

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

3. INFORMATION FOR PHARMACISTS

Ordering Sublocade

Indivior has launched a new registration process for pharmacies to open an account for Sublocade. The requesting pharmacist must complete the [online form](#), which includes providing the requesting pharmacist's license and the pharmacy's license. Once approved, the requesting pharmacist will become the primary pharmacist for the Sublocade account at that pharmacy.

Indivior will validate the requesting pharmacist's license. If the pharmacist's license is not valid upon review, account set-up will be suspended. Indivior will notify the pharmacist and provide the opportunity to submit valid license information and complete the validation and registration process.

More [information](#) on ordering Sublocade can be found through the registration form.

Dispensing Information

For detailed information on storing Sublocade, please consult the manufacturer's [website](#).

Given the unique dispensing pathway necessary for Sublocade, prescribers and pharmacists should create a plan in advance for each prescription (e.g., what day the prescription will be dispensed and picked-up, who will pick-up the prescription, and any additional information necessary to meet the College of Pharmacists of British Columbia's [CPBC] requirements). Pharmacists are reminded that in accordance with CPBC requirements the medication must be safely and securely stored and maintained following appropriate cold chain management. Additionally, CPBC counseling requirements must be met. Sublocade is to be either picked up by a nurse or prescriber on behalf of the patient, or delivered to the clinic, keeping in mind proper storage and delivery of the prescription. Pharmacies are advised to stock only the amount of Sublocade needed to avoid overstocking. Currently in BC, Sublocade must be administered by a prescriber (MD or NP) or nurse (RN, RPN, or LPN[°]).

Available Training and Education

Pharmacists are encouraged to complete the manufacturer-provided training available at: www.sublocadecertification.ca

Pharmacists are also encouraged to keep up to date on Sublocade education, such as through attendance of webinars hosted by the BC Pharmacy Association and BC Centre on Substance Use. The manufacturer's [website](#) provides additional information on Sublocade.

[°] It is within the [Scope of Practice for LPNs](#) to administer Sublocade with a client-specific order. Licensed Practical Nurses must meet all of the BC College of Nurses and Midwives' [LPN standards, limits, and conditions](#) and possess the individual competency to perform this activity.

4. ADDITIONAL RESOURCES

Example Prescription

-----BC CONTROLLED PRESCRIPTION FORM-----

| | | | | |
|--|-----------------------------|---|--|-----------------------------|
| PERSONAL HEALTH NO. 1234 567 890 | | PRESCRIBING DATE 02 DAY 07 MONTH 21 YEAR | | |
| PATIENT NAME | FIRST (GIVEN) Generic | MIDDLE / INITIAL A | LAST (SURNAME) Name | |
| PATIENT ADDRESS | STREET 123 Main Street | | | |
| | CITY Victoria | PROVINCE BC | DATE OF BIRTH 26 DAY 12 MONTH 82 YEAR | |
| Rx: DRUG NAME AND STRENGTH Sublocade 300mg | | ONLY ONE DRUG PER FORM VOID IF ALTERED | | |
| QUANTITY (IN UNITS) | | | | |
| 300mg <small>NUMERIC</small> | | Three hundred mg <small>ALPHA</small> | | |
| THIS AREA MUST BE COMPLETED IN FULL FOR OPIOID AGONIST TREATMENT (OAT) | | | | |
| START DATE: 05 DAY 07 MONTH 21 YEAR | | | END DATE: 05 DAY 07 MONTH 21 YEAR | |
| TOTAL DAILY DOSE | | NUMBER OF DAYS PER WEEK OF DAILY WITNESSED INGESTION | | |
| 1 <small>NUMERIC</small> | One <small>ALPHA</small> | mg/day | nil <small>NUMERIC</small> | nil <small>ALPHA</small> |
| <input type="checkbox"/> NOT AUTHORIZED FOR DELIVERY | | | | |
| DIRECTION FOR USE, INDICATION FOR THERAPY, OR SPECIAL INSTRUCTIONS Sublocade 300mg subcutaneously as a single dose. Deliver to Evergreen OAT Clinic (123 Main Street). To be administered by MD on July 5, 2021 | | | | |
| NO REFILLS PERMITTED | | PRESCRIBER'S SIGNATURE Generic Prescriber | | |
| VOID AFTER 5 DAYS <small>UNLESS PRESCRIPTION IS FOR OAT</small> | | | | |
| PRESCRIBER'S CONTACT INFORMATION Generic Prescriber Tel: 250-999-9911 123 Health Street Fax: 250-999-9119 Victoria BC V8Z 4H4 | | 91-09898 PRESCRIBER ID | | |
| | | FOLIO | | |
| PHARMACY USE ONLY | | | | |
| RECEIVED BY: PATIENT OR AGENT SIGNATURE | | SIGNATURE OF DISPENSING PHARMACIST | | |
| PHARMACY COPY - PRESS HARD YOU ARE MAKING 2 COPIES PRINTED IN BRITISH COLUMBIA | | | | |

Note:

- Administration of Sublocade can be performed by an MD, NP, or nurse (RN, RPN, or LPN)
- Prescribers can consider indicating the date of administration/clinic appointment on the prescription
- To avoid errors, best practice is to write "subcut" or "subcutaneously" on the prescription
- Prescription may be written as a part-fill, for example:
"600mg six hundred, inject 300mg subcut once a month as a single dose by MD x 2 months (May, June), dispense 300mg in 25- to 30-day intervals."
- To avoid errors, the reduction in dose to 100mg after two months should be written as a separate prescription, ideally after reassessment
- An example of this second prescription would be:
"100mg, one hundred, inject 100mg subcut as a single dose by MD starting in July, may release 25 to 30 days after previous injection."