



**November 1, 2021**

**What is long-acting (XR) buprenorphine injection?**

Long-acting buprenorphine injection (XR-buprenorphine, current available brand name: Sublocade) is a long-acting injectable formulation of buprenorphine that is given once monthly to assist people in obtaining and sustaining long-term recovery from opioid use disorder (OUD). There may be additional formulations and/or brands of XR-buprenorphine approved in the future. XR-buprenorphine is one of several options for medication for addiction treatment (MAT) for OUD.

**Who is most appropriate for XR-buprenorphine?**

Patients appropriate for XR-buprenorphine are adults who have initiated treatment on a transmucosal buprenorphine-containing product delivering the equivalent of 8 to 24 mg of buprenorphine daily. The patient may only be transitioned to XR-buprenorphine after a minimum of 7 days on transmucosal buprenorphine. Patients and providers may opt for XR-buprenorphine for a variety of reasons, including but not limited to:

- Convenience of not having to carry and self-administer a medication daily;
- Difficulty taking a daily medication on a consistent basis;
- Patient concern that resuming use may be easier or more tempting if relying on the need to take a daily medication;
- No risk of diversion compared with transmucosal medications;
- Patient preference;
- Unable to tolerate transmucosal medications because of side effects such as nausea;
- Current living environment impeding safe storage of controlled substances. For example, living in a homeless shelter that is unable to store medications safely, living on the street, or having minors in the home where there is concern about medication access/safety.

**Who can prescribe XR-buprenorphine?**

Buprenorphine is a controlled substance used for the treatment of OUD. Under the Drug Addiction Treatment Act (DATA) (21 U.S.C. 823(g)) a prescriber, including physicians, physician assistants, nurse practitioners, and other advanced practice nurses must obtain a special registration known as a DATA 2000 waiver or X-waiver to prescribe any narcotic drug (Schedule III-V), including all buprenorphine formulations, to an individual with a substance use disorder.

To obtain a DATA 2000 waiver, or learn more about it, visit: <https://www.samhsa.gov/medication-assisted-treatment/training-materials-resources/apply-for-practitioner-waiver>

### **How can a prescriber obtain XR-buprenorphine?**

XR-buprenorphine is a long-acting formulation of buprenorphine that is injected subcutaneously in the abdomen. Given that XR-buprenorphine could solidify on injection, there are increased risks associated with diversion, specifically that it could solidify in a vein if injected intravenously, which could be fatal. To mitigate the risks associated with patient possession of this medication, the manufacturer of XR-buprenorphine developed a Risk Evaluation and Mitigation Strategy (REMS) Program. This REMS provides for a restricted distribution of the product. Information on obtaining XR-buprenorphine from the manufacturer of Sublocade (Indivior) through the REMS program can be found at: <https://www.sublocaderems.com/>.

If/when additional formulations of XR-buprenorphine become available, information about obtaining the medication including any REMS programs should be obtained from the manufacturer.

A provider who has received federal authority to prescribe a controlled substance and currently holds a DATA 2000 waiver to prescribe buprenorphine can obtain medication under their Drug Enforcement Administration (DEA) registration through bulk purchasing or using a specialty pharmacy identified through the REMS program when a medication is prescribed to a specific patient. The process to obtain Sublocade through bulk purchase or a specialty pharmacy is described on the Indivior website: <https://www.sublocaderems.com/>.

### **What are the facility licensing and anti-diversion requirements?**

Article 33 of the New York State (NYS) Public Health Law and the associated regulations contained in Part 80 require any facility acting as an institutional dispenser of controlled substances (i.e., dispenses from an on-site registered pharmacy) to obtain a Class 3 Institutional Dispenser license from the NYS Department of Health (DOH). An example of this type of provider would be a hospital with an on-site pharmacy. Class 3 license holders also must register with the federal DEA. Class 3 facilities may purchase stocks of controlled substances from a licensed manufacturer or distributor for inpatient and outpatient use through an appropriately registered pharmacy. Controlled substances are distributed within the facility from the registered pharmacy. Administration of all controlled substances within a Class 3 facility is authorized only by a written order of an authorized practitioner. The Class 3 license is not applicable to the dispensing of controlled substances for opioid use disorder treatment unless the facility has an on-site registered pharmacy.

Where an entity does not meet the requirements for a Class 3 Facility license, meaning that they do not have an on-site pharmacy, Section 80.47 of Part 80 applies. Facilities not qualifying as institutional dispensers may apply for a Class 3A Institutional Dispenser Limited license, which authorizes an eligible facility to obtain and hold medications on behalf of a patient.

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**Facilities which are eligible to obtain a 3A license do not include residential part 819 programs or Part 820 reintegration programs. Also not included are:** Section 822 – Outpatient Clinics – Article 28/32 or 32 Only, Section 822 – Outpatient Rehabilitation Programs – Article 28/32 or Article 32 Only and Section 822 – Opioid Treatment Programs (OTP) – Article 28/32 or Article 32 Only.

To obtain a Class 3A Institutional Dispenser Limited License, a *License Application to Engage in a Controlled Substance Activity* ([DOH-4330](#)) must be submitted to the NY DOH Bureau of Narcotics Enforcement (BNE). The application must include a copy of the current OASAS Operating Certificate.

All provider agencies/facilities must establish a procedure whereby trained medical and nursing staff [administer medications and/or oversee self-administration of medications](#). The medical or nursing staff may be a physician, physician assistant, nurse practitioner, other advanced practice nurse, an RN, or an LPN (under the supervision of an RN).

Medications such as XR-buprenorphine, must be administered to patients pursuant to a prescription issued by an authorized prescriber and filled by a registered pharmacy. An order for the administration of XR-buprenorphine should be in the patient's medical record. The facility must ensure a Medication Log is maintained for all prescribed controlled substances and a separate record shall be maintained for the administration of prescribed controlled substances, which must be retained for 5 years. Medications must be stored in a steel or otherwise approved metal stationary, locked, double cabinet and/or refrigerator, with each lock requiring a separate key. Both cabinets must have key-locked doors with separate keys.

For more information and best practices related to the secure storage, administration, and disposal of controlled substances used for the treatment of substance use disorders, please refer to relevant sections of the [Substance Abuse and Mental Health Services Administration \(SAMHSA\) Treatment Improvement Protocol \(TIP\) 63: Medications for Opioid Use Disorder](#).

### **How should XR-buprenorphine be stored?\***

Store refrigerated 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 XR-buprenorphine if left at room temperature for longer than 7 days.

XR-buprenorphine is a Schedule III drug product. Handle with adequate security and accountability. After administration, syringes should be properly disposed, per facility procedure for a Schedule III drug product, and per applicable federal, state, and local regulations. See section below on disposal of XR-buprenorphine.

\*This information is from the package labeling for brand, Sublocade. If using a different brand/formulation, please carefully review package labeling and follow it for any differences.

### **How is XR-buprenorphine administered?\***

The medication should be removed from refrigeration 30 minutes before administration and allowed to reach room temperature. Patient scheduling and medical and nursing workflows should reflect this time requirement.

Rotate the abdominal subcutaneous injection site with each injection, following the instructions in the package insert. Record the location of each injection in the medical record. Each of the first two monthly doses (with at least 26 days between doses) should be 300 mg. Subsequent monthly doses should be 100 mg. Some patients may benefit from increasing the maintenance dose to 300 mg monthly if they have tolerated the 100 mg dose but continue to use illicit opioids or experience intra-dosing cravings or withdrawal symptoms.

Please have medical or nursing staff giving the injection review this [video with instruction about subcutaneous injection of XR-buprenorphine](#). \*In addition, manufacturers of XR-buprenorphine products may be able to make in-person injection administration trainings available to provider agencies. If interested, provider agencies should directly contact the manufacturer(s).

\*This information is summarized from materials from Indivior, the manufacturer of Sublocade. When using Sublocade, please review the full package label prior to administration. If using a different brand/formulation, please carefully review package labeling and follow it for any differences.

### **What laboratory monitoring is necessary?**

Consider baseline liver function tests for patients with previous moderate-to-severe hepatic impairment. Consider regular monitoring of liver function tests for patients on continuous 300 mg monthly dosing.

### **What are common adverse effects?**

The most common reported adverse effects are gastrointestinal symptoms (nausea, vomiting, and constipation), fatigue, and injection site reactions. Injection site reactions are typically self-limiting and resolve within 2-3 days. Patients might complain of a “bump” at the injection site. This bump may be present for the first several months as the body adjusts to metabolizing XR-buprenorphine.

### **How does someone stop or discontinue XR-buprenorphine?**

Studies indicate the long-term use of medications for OUD, including buprenorphine, results in improved patient outcomes. However, if a patient wishes to stop XR-buprenorphine, the steady-state

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buprenorphine plasma concentrations decrease slowly over time following the last injection and remain at therapeutic levels for 2-to-5 months on average, depending on the dosage administered and duration of treatment. Options for stopping XR-buprenorphine more slowly include decreasing the dose and/or increasing the duration between injections.

### **How does a provider dispose of XR-buprenorphine?**

XR-buprenorphine is a Schedule III drug product. XR-buprenorphine should be properly disposed of, per facility procedure for a Schedule III drug product, and per applicable federal, state, and local regulations. Syringes should be disposed of in sharps containers on site.

For additional information on federal regulations on the disposal of controlled substances, including XR-buprenorphine, see DEA guidance documents below:

[https://www.deadiversion.usdoj.gov/drug\\_disposal/index.html](https://www.deadiversion.usdoj.gov/drug_disposal/index.html), <https://www.ecfr.gov/current/title-21/chapter-II/part-1317?toc=1>,  
[https://www.deadiversion.usdoj.gov/fed\\_regs/rules/2014/2014-20926.pdf](https://www.deadiversion.usdoj.gov/fed_regs/rules/2014/2014-20926.pdf)

For additional information on state regulations on the disposal of controlled substances, including XR-buprenorphine, see NYS DOH guidance documents below:

[https://www.health.ny.gov/professionals/narcotic/safe\\_disposal/docs/class\\_3a\\_guidance.pdf](https://www.health.ny.gov/professionals/narcotic/safe_disposal/docs/class_3a_guidance.pdf)  
[https://www.health.ny.gov/professionals/narcotic/licensing\\_and\\_certification/docs/reverse\\_distributor.pdf](https://www.health.ny.gov/professionals/narcotic/licensing_and_certification/docs/reverse_distributor.pdf)  
[https://www.health.ny.gov/professionals/narcotic/licensing\\_and\\_certification/destruction.htm](https://www.health.ny.gov/professionals/narcotic/licensing_and_certification/destruction.htm)  
[https://www.health.ny.gov/professionals/narcotic/medication\\_drop\\_boxes/](https://www.health.ny.gov/professionals/narcotic/medication_drop_boxes/)  
[https://www.health.ny.gov/professionals/narcotic/safe\\_disposal/docs/guideline\\_for\\_waste\\_disposal\\_system\\_use.pdf](https://www.health.ny.gov/professionals/narcotic/safe_disposal/docs/guideline_for_waste_disposal_system_use.pdf)

### **How does a provider bill for XR-buprenorphine injections?**

Please see [guidance about billing for medication services previously issued jointly by OASAS and the NYS Office of Mental Health \(OMH\)](#), in which billing for long-acting injectable medications is addressed. Rather than J codes, Q codes are used for XR-buprenorphine, which are specific to the product used as follows:

**Sublocade Subcutaneous Injections\***: code Q9991 (100 mg or less), Q9992 (more than 100 mg)

\*As other brands/formulations of XR-buprenorphine are approved, additional Q codes will be available.

### **How does someone obtain coverage for XR-buprenorphine?**

**NYS Medicaid Fee for Service (FFS) and Medicaid Managed Care (MMC):**

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Effective October 1, 2021, per the enacted New York State Executive Budget for State Fiscal Year 2020-2021 and in accordance with § 367-a (7) (e) of Social Services Law, the Department of Health (DOH) implemented a single statewide formulary for Opioid Antagonists and Medications for Opioid Use Disorders (MOUD) for Medicaid Managed Care (MMC) Plans and Medicaid Fee for Service (FFS). Under this statewide formulary (listed below), Medicaid FFS and Medicaid Managed Care (MMC) will:

- follow a single formulary, where coverage parameters are consistent across the Medicaid Program, preferred products are available without prior authorization (PA) when prescribed consistent with FDA package labeling and non-preferred products require PA; and,
- use standard clinical criteria for approval of a non-preferred drug in accordance § 273 (3) (a) of Public Health Law.

See the NYS Medicaid MOUD formulary [here](#).

Current laws support access to all formulations of MAT at a reasonable cost, while also allowing for members and providers to exercise preferences for certain formulations. We do acknowledge the challenge providers may face when navigating utilization review limitations, versus frequency, quantity or duration (f/q/d) limits that are based on Federal guidelines.

### **Commercial Coverage:\***

Effective February 28, 2020, New York State Insurance law requires coverage without prior authorization for buprenorphine, among other medications for the treatment of OUD, without prior authorization. However, because formularies can change, and it can be difficult to determine if a policy is covered by New York State law, it is a best practice to confirm that the medication you are prescribing for your patient is covered by their insurance.

\*Only applicable for commercial insurance plans subject to NYS regulations.

### **Requests for coverage of non-preferred or non-formulary medications:**

#### Medicaid Managed Care Billing:

- MMC members will continue to access these medications by presenting their plan card to the pharmacy.
- PA is required for all non-preferred agents. Providers should contact the MMC plan to obtain authorization when necessary. Contact and billing information may be found here: <https://mmcdruginformation.nysdoh.suny.edu/>
- Managed Care Plans will message pharmacy providers about utilizing the brand product Suboxone instead of the generic alternative, consistent with FFS or Managed Care Plans will provide guidance on DAW (dispense as written) Code requirements
  - o Managed Care Plans will reimburse claims consistent with brand drug reimbursement for Suboxone

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o If a pharmacy is out of stock of brand name Suboxone and the member needs the medication, the pharmacist should contact the MMC plan for a one-time override to allow for the generic equivalent to be dispensed until the brand is restocked.

FFS Billing:

- FFS members will continue to access these medications by presenting their Medicaid benefit card to the pharmacy.
- PA is required for all non-preferred agents. Providers should contact Magellan plan to obtain authorization when necessary. Contact and billing information may be found here: <https://newyork.fhsc.com/>
- Pursuant to the Brand Less Than Generic (BLTG) program prescription claims submitted to the Medicaid program:
  - o Message pharmacy providers about utilizing the brand product Suboxone instead of the generic alternative
  - o Reimburses claims consistent with FFS approved drug reimbursement for brand name drugs

For commercial policies:

- NYS law allows for prescribers to seek an exception to the formulary. Drugs that are not listed on the commercial formulary may be either non-formulary or covered as a medical benefit, which is especially relevant with XR-buprenorphine, as it is an injectable medication administered in an office setting.

Non-formulary drugs may be covered if the provider or member requests coverage. A response to a request for coverage for non-formulary medications must be made within 72 hours. For urgent cases, the decision must be made within 24 hours. For Medicaid, the patient is also able to access a 72-hour emergency supply of medication without prior authorization while waiting for the prior authorization process to be completed.

For questions about and/or assistance with coverage, please contact the NYS [Community Health Access to Addiction & Mental Healthcare Project \(CHAMP\)](#) at [ombuds@oasas.ny.gov](mailto:ombuds@oasas.ny.gov) or 888-614-5400.