NEW YORK STATE | Office of Addiction Services and Supports

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Guidance on Long-Acting (XR) Buprenorphine Injection

What is long-acting (XR) buprenorphine injection?

Long-acting buprenorphine injection (XR-buprenorphine, currently available brand name: Sublocade) is an injectable formulation of buprenorphine that is given once a month to assist people in obtaining and sustaining long-term recovery from opioid use disorder (OUD). There may be additional XR-buprenorphine brands approved in the future and this guidance will be updated accordingly. 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 with a transmucosal buprenorphine-containing product delivering the equivalent of 8 to 24mg of buprenorphine daily. The patient may be transitioned to XR-buprenorphine only 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 medication daily on a consistent basis;
- Patient concern that resuming use may be easier or more tempting if relying on the need to take a medication daily;
- Patient preference;
- Inability to tolerate transmucosal formulations because of side effects such as nausea;
- Current living environment impedes safe storage of controlled substances.
    - For example, living in a shelter that is unable to store medications safely, living on the street, or having minors in the home where there is a concern about medication access/safety.

Who can prescribe XR-buprenorphine?

Buprenorphine is a Schedule III substance under the Controlled Substances Act. The Consolidated Appropriations Act of 2023 removed all limitations on prescribing buprenorphine, such as having a Drug Enforcement Agency (DEA) X-waiver, and allows all healthcare providers, as permissible under state law, with a valid state license and a current DEA registration that includes Schedule III authority to prescribe all buprenorphine formulations for the treatment of OUD.

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 upon injection, there are increased risks associated with diversion, specifically that the medication could solidify in a vein if injected intravenously, which could be fatal. To mitigate the risk associated with patient possession of this medication, the manufacturer of XR-buprenorphine developed a Risk Evaluation and Mitigation Strategy (REMS) program that 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/#Main.**

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

A healthcare provider who has received federal authority to prescribe a controlled substance can obtain medication under their DEA registration through bulk purchasing or by using a specialty pharmacy identified through the REMS program when the 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/#Main.**

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 a controlled substance (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 or 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 healthcare provider. The Class 3 license is not applicable to the dispensing of controlled substance for OUD treatment unless the facility has an on-site registered pharmacy.

When an entity does not meet the requirements for a Class 3 Facility license, meaning 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.

Facilities that 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 (OTPs) – Article 28/32 or Article 32 only.

To obtain a Class 3A Institutional Dispenser Limited License, a *License Application to Engage in a Controlled Activity* (https://www.health.ny.gov/forms/doh-4330.pdf) must be submitted to the NY DOH Bureau of Narcotics Enforcement (BNE). The application must include a copy of the current OASAS Operating Certificate.

Provider agencies/facilities that are not eligible for a Class 3A Institutional Dispenser Limited License may have the pharmacy deliver the controlled substance to the registered location of either the prescribing healthcare provider or the administering healthcare provider in limited circumstances (Buprenorphine (MOUD) Q&A (usdoj.gov)). The medication must be administered by injection only to the patient named on the prescription within 45 (forty-five) days after the date of receipt of the controlled substance by the healthcare provider.

All provider agencies/facilities must establish a procedure whereby trained medical and nursing staff administer medications. The medical or nursing staff administering medications may be a physician, physician assistant (PA), nurse practitioner (NP), other advanced practice registered nurse (APRN), registered nurse (RN), or licensed practical nurse (LPN) working under the supervision of an RN.

Medications such as XR-buprenorphine must be administered to patients pursuant to a prescription issued by an authorized healthcare provider 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 that 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 locked by a separate key. Both cabinets must have key-locked doors with separate keys.

For more information about and best practices related to the secure storage, administration, and disposal of controlled substances used for the treatment of OUD, refer to the relevant sections of the Substance Abuse and Mental Health Services Administration (SAMSHA) Treatment Improvement Protocol (TIP) 63: Medications for Opioid Use Disorder (PEP20-02-01-006.pdf (samhsa.gov)).

How should XR-buprenorphine be stored?*

The medication should be stored refrigerated at 2-8˚C (35.6-46.4˚F). Once outside the refrigerator, XR-buprenorphine may be stored in its original packaging at room temperature, 15-30˚C (59-86˚F), for up to 7 days prior to administration. XR-buprenorphine that has been left at room temperature longer than 7 days should be discarded.

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

*This information is from the package label for the brand, Sublocade. If using a different brand, review the package label carefully and follow the instructions for that brand.

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 on the package insert. Record the location of each injection in the patient's medical record. Each of the first two monthly doses (with at least 26 days between doses) should be 300mg. Subsequent monthly

doses should be 100mg. Some patients may benefit from increasing the monthly maintenance dose to 300mg if they have tolerated the 100mg dose but continue to use opioids or experience intra-dose cravings or withdrawal symptoms.

Medical or nursing staff giving the injection should review the video with instructions for subcutaneous injection of XR-buprenorphine (Dosing & Administration | SUBLOCADE® (buprenorphine extended-release) injection, for subcutaneous (abdominal) use (CIII) (sublocadehcp.com)).* Additionally, the manufacturers of XR-buprenorphine products may be able to make in-person injection administration trainings available to provider agencies. If interested, provider agencies should contact the manufacturers directly.

*This information is summarized from materials from Indivior, the manufacturer of Sublocade. When using Sublocade, review the full package label prior to administration. If using a different brand, review the package label carefully and follow the instructions for that brand.

What laboratory monitoring is necessary with XR-buprenorphine?

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

What are the common adverse effects of XR-buprenorphine?

The most 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 that the long-term use of medications for OUD, including buprenorphine, results in improved patient outcomes, including decreased opioid-related (overdose) mortality and all-cause mortality. However, if a patient wishes to stop XR-buprenorphine, the steady-state buprenorphine plasma concentrations decrease slowly over time following the last injection and remain therapeutic for 2-to-5 months on average, depending on the dose administered and the 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 medication and should be disposed of properly, per facility procedure for a Schedule III medication, 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 the DEA guidance documents below:

Drug Disposal Information (usdoj.gov)

eCFR :: 21 CFR Part 1317 -- Disposal

2014-20926.pdf (govinfo.gov)

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

https://www.health.ny.gov/professionals/narcotic/safe_disposal/

https://www.health.ny.gov/forms/instructions/doh-2340_instructions.pdf

https://www.health.ny.gov/professionals/narcotic/licensing_and_certification/destruction.htm

https://www.health.ny.gov/professionals/narcotic/licensing_and_certification/docs/reverse_distributor.pdf

https://www.health.ny.gov/professionals/narcotic/docs/rhcf_disposal_guidance.pdf

How does a provider bill for XR-buprenorphine injections?

A guidance about billing for medication services jointly issued by OASAS and the NYS Office of Mental Health (OMH) in 2019 addresses billing for long-acting injectable medications: Guidance Memo on Opioid Use Disorder Billing (ny.gov). Rather than J codes, Q codes are used to bill for XR-buprenorphine and are specific to the product used as follows:

Sublocade Subcutaneous Injections* code Q9991 (100mg or less) and Q9992 (more than 100mg)

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

How does someone obtain coverage for XR-buprenorphine?

NYRx the NYS Medicaid Pharmacy Program

Effective April 1, 2023, NYRx, the NYS Medicaid Pharmacy Program, became the NYS Medicaid pharmacy benefit for most Medicaid members, including those enrolled in Medicaid Managed Care (MC) plans, Health and Recovery Plans (HARPs), HIV-Special Needs Plans (SNPs), and Medicaid Fee for Service Plans (FFS).

New York State had implemented a Single Statewide Medication Assisted Treatment (MAT) formulary for Medicaid MC and FSS on October 1, 2021, in accordance with §367-a (7)(e) of Social Services Law. Since this change, Medicaid MC and FFS members follow a single MAT formulary, and coverage parameters were made consistent across the Medicaid Program.

Additionally, on December 22, 2021, Governor Kathy Hochul signed Chapter 720 of the Laws of 2021. This law amended Social Services Law and Public Health Law to require coverage without prior authorization for all medications used for the treatment of substance use disorder when prescribed according to generally accepted national professional guidelines for the treatment of a substance use disorder, effective March 22, 2022.

With these changes to the statewide formulary, Medicaid MC and FFS – whose medications are covered by NYRx as of April 1, 2023 -- follow a single formulary where coverage parameters are consistent across the Medicaid Program, and all products are available without prior authorization when they are prescribed according to generally accepted national professional guidelines for the treatment of substance use disorder. The NYRx MAT formulary can be found in the section "Medication Assisted Treatment Formulary" at https://newyork.fhsc.com/downloads/providers/NYRx_PDP_PDL.pdf.

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. OASAS acknowledges 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*

As of February 28, 2020, NYS Insurance Law required coverage without prior authorization for buprenorphine, among other medications for the treatment of OUD. However, because formularies can change, and it can be difficult to determine if a policy is covered by NYS law, it is a best practice that a practitioner confirm that the medication being prescribed for a 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:

For commercial policies:

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

Non-formulary medications may be covered if the provider or member requests coverage. A response to a coverage request for non-formulary medications must be made within 72 hours. For urgent cases, the decision must be made within 24 hours.

For questions about and/or assistance with insurance coverage, please contact the NYS Community Health Access to Addition & Mental Healthcare Project (CHAMP) at **ombuds@oasas.ny.gov** or 888-614-5400.

Updated April 18, 2023