

Oregon Jail MOUD Technical Assistance Team

EXTENDED-RELEASE BUPRENORPHINE (ER-BUP) IN JAILS

IMPLEMENTATION GUIDE

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OHSU Jail MOUD Technical Assistance Team

The Oregon Health & Science University (OHSU) Jail Medication for Opioid Use Disorder (MOUD) Technical Assistance Team is funded by Oregon's Opioid Settlement Prevention, Treatment and Recovery Board. This document informs jails on the steps to obtain and store Extended-Release Buprenorphine injectable medications (ER-BUP). This document is not meant as clinical advice. As your jail is developing plans to obtain MOUD, including ER-BUP, we recommend engaging in individual technical assistance (TA) with our team. TA meetings can be utilized to help your team decide on evidence-based clinical protocols and dosing of products for your facility. Please contact Dan Hoover with interest in TA at hooverda@ohsu.edu.



Injectable Extended-Release Buprenorphine in Jails

Extended-release buprenorphine (ER-BUP) is a novel formulation available as a weekly or monthly injectable medication to treat opioid use disorder (OUD).

There are currently two different formulations of ER-BUP available for consideration in jails.

Brand	Formulations	Administration	Storage
Sublocade	Monthly	Subcutaneous (under the skin injection)	Refrigeration required; may be stored for 12 weeks at room temperature.
Brixadi	Monthly & Weekly	Subcutaneous (under the skin injection)	No refrigeration required

What are the benefits of extended-release buprenorphine?

- Not treating opioid use disorder in incarcerated individuals causes people to have a reduced opioid tolerance and increases risk of overdose death upon release.
- Buprenorphine is an evidence-based medication for opioid use disorder that treats opioid withdrawal, opioid cravings, and reduces overdose death.
- Extended-release versions of buprenorphine reduces logistical barriers faced with daily medication dosing, reduces medical/security staff time, and improves the rate of follow-up into community treatment after release.
- In clinical trials, ER-BUP increased treatment retention in the community after release from jail when compared to sublingual (SL) buprenorphine:

- New York City jail releases: **69% of patients started on ER-BUP were still on treatment at 8 weeks** compared to **35%** retained in treatment at 8 weeks who were on sublingual (SL) buprenorphine.

Lee, J.D., Malone, M., McDonald, R., Cheng, A., Vasudevan, K., Tofighi, B., Garment, A., Porter, B., Goldfeld, K.S., Matteo, M., Mangat, J., Katyal, M., Giftos, J., Macdonald, R., 2021. Comparison of Treatment Retention of Adults With Opioid Addiction Managed With Extended-Release Buprenorphine vs Daily Sublingual Buprenorphine-Naloxone at Time of Release From Jail. *JAMA Network Open* 4, e2123032..

- Maine rural jail releases: Patients were approximately **3 times as likely to continue buprenorphine treatment** if started on ER-BUP while incarcerated compared to those started on SL buprenorphine.

O'Connor, A. B., et al. (2024). "Community buprenorphine continuation post-release following extended release vs. sublingual buprenorphine during incarceration: a pilot project in Maine." *Health & Justice* 12(1).

ER-BUP Implementation Checklist

- Plan the brand and formulation(s) of ER-BUP that you wish to stock at the jail.
- Obtain or verify that the appropriate DEA licensure is in place.
- Enroll in the pertinent REMS program. Work with the Indivior/Braeburn contact for REMS assistance needs.
- Enroll in MMCAP purchasing program. Work with the MMCAP contact to set up the specialty distributor account for ordering.
- Develop a system to store ER-BUP at your jail
- Develop a system for records and inventories of ER-BUP
- Create a policy and internal destruction log for on-site destruction of ER-BUP

Formulation Selection and Industry Contacts

Sublocade	Formulations	Dose
Sublocade manufacturer (Indivior) contact Rachael Fisher , Access Director Criminal Justice Systems, Pacific Northwest OR/ID Phone: 503-200-9456 Rachael.Fisher@indivior.com	Monthly	300 mg
		100 mg
Brixadi	Formulations	Dose
Brixadi manufacturer (Braeburn) contact Kali Gesser Regional Business Specialist, Northwest Phone: 425-221-3994 kgesser@braeburnrx.com	Monthly	64 mg
		96 mg
		128 mg
	Weekly	8 mg
		16 mg
		24 mg
		32 mg

MMCAP Discount Program

MMCAP is a free voluntary group purchasing organization that your jail can access to purchase reduce price injectable ER-BUP. The State of Oregon, Department of Administrative Services has both agreements (pharmacy wholesaler – Cardinal Health, and medical supplies – Henry Schein) in place, so no additional procurement is needed.

Kim Hankins can help your facility complete the necessary paperwork for an expedited and smooth implementation.

Kim Hankins

Oregon MMCAP Representative,
 Cell: 503-999-5013
 kim.hankins@state.mn.us

For entities outside of Alaska, Hawaii, Idaho, Montana, Oregon, Washington and Wyoming, please see the MMCAP Resources page to find the Senior Healthcare Consultant assigned to your State. [MMCAP Contact Information / Minnesota.gov](#)

The MMCAP application is free here: <https://infuse-mn.gov/membership-application/index.jsp>.

- If you are in the process of obtaining a DEA license, you can still begin a MMCAP application.
- Once in the application check “pharmaceutical wholesaler services”

The OHSU Jail MOUD TA team recommends you work directly with the highlighted contacts for correct and efficient medication procurement setup. If you are participating in one-one-one TA with our team, we can include these contacts in recurring meetings with you for efficiency.

What regulatory steps do I need to complete before ordering ER buprenorphine?

Requirement	Additional Information	Resources
<p>DEA Licensing</p> <p>□ Jail providers must have a separate DEA license with the jail address practice site listed. The jail facility also has the option to obtain a hospital/clinic DEA license.</p>	<ul style="list-style-type: none"> Each jail provider must have a separate DEA license with the address of the jail practice location where they are working. This will allow the provider to order schedule III-controlled substances (buprenorphine) to be delivered to the jail. The updated 42 CFR Part 8 rule now allows a jail to apply for a hospital/clinic type of DEA license. 	<p>DEA license application: DEA form 224</p> <ul style="list-style-type: none"> Select your license type. <p>Helpful contacts</p> <p>National DEA Policy Office (for policy and regulation questions) dpy@dea.gov</p> <p>Regional DEA NW Seattle Office (for application questions) 571-387-3028</p> <p>Oregon State Opioid Treatment Authority Office (can assist with DEA regulation interpretation, particularly for methadone) John McIlveen, PhD JOHN.W.MCILVEEN@oha.oregon.gov Dana Bowman Dana.C.Bowman@oha.oregon.gov</p>

Requirement	Additional Information	Resources
<p>REMS</p> <p>□ Enroll in REMS program by submitting REMS Form. (Must have 1 per jail)</p>	<ul style="list-style-type: none"> Risk Evaluation and Mitigation Strategy (REMS) is a drug safety program that is required for certain high-risk medications. ER-BUP REMS is to ensure that the medication is not directly dispensed to the patient but instead, administered by a healthcare provider. Any jail that intends to order Sublocade or Brixadi directly from a specialty distributor, and therefore keep a stock of non-patient-labeled ER-BUP, <i>must be certified</i> in the Sublocade or Brixadi REMS prior to purchasing. Note, this “specialty distributor” pathway is different than ordering through a “specialty pharmacy.” You must complete a separate REMS certification for each brand that you store on site. The Indivior / Braeburn contacts highlighted above are recommended for REMS advising. 	<p>Designate an authorized representative to oversee implementation and compliance with REMS program (lead provider, nurse, or healthcare staff)</p> <p>The forms can be submitted online, faxed, or emailed.</p> <p>Sublocade:</p> <ul style="list-style-type: none"> REMS Webpage Fax- 1-866-823-9549 certify@SublocadeREMS.com <p>Brixadi:</p> <ul style="list-style-type: none"> REMS Webpage Fax- 1-833-274-8597 BRIXADIREMS@braeburnrx.com

Requirement	Additional Information	Resources
<p>Storage System</p> <p>□ Develop a system to store ER-BUP.</p>	<ul style="list-style-type: none"> • Sublocade and Brixadi are a federal DEA schedule III-controlled substance and require special handling and storage. • ER-BUP should be kept in a locked cabinet within a locked medication room or locked refrigerator (Sublocade). DEA security requirements state “in a securely locked, substantially constructed cabinet” with limited access by office staff. (see next column) • Controlled substance medications require storage under two sets of locking mechanisms (double locked). – See examples in next column • The medication room is to remain locked at all time. 	<ul style="list-style-type: none"> • Security Requirements (Part 1301.72 section b) • Examples of two sets of locking mechanisms (double locked) <ul style="list-style-type: none"> ○ A locked box within a locked drawer or locked cabinet ○ A locked fridge behind a locked door ○ A locked cabinet behind a locked door
	<p>Sublocade requires refrigeration, but can be stored for up to 12 weeks unrefrigerated.</p> <ul style="list-style-type: none"> ○ Sublocade should be stored in a refrigerator maintained between 2 to 8 degrees Celsius (36 to 46 degrees Fahrenheit) ○ Temperatures shall be monitored and logged on the Medication Refrigerator and Room Temperature Record maintained by your jail. ○ Temperatures should be checked on a business daily basis. 	<p>Locking Fridge Example Products</p> <p>Large: https://www.follettice.com/flexlock-ready-follett-refrigerators</p> <p>Compact \$350-1,200 (low to high):</p> <ul style="list-style-type: none"> • accucold All-Refrigerator, Compact, Front Lock, 1.7 Cu.Ft. • Summit FFAR25L7, 1.7 CuFt Commercial All-refrigerator • ConServCompact 24in COMMERCIAL/PHARMACEUTICAL Refrigerator 3.9cf WIFI 110V • Accucold 24 Inch Wide 5.5 Cu. Ft. General Purpose Medical Refrigerator with Copper Handle and Keyed Lock • ACCUCOLD ACR45LCAL Pharmacy 20" Wide Built-in Undercounter All-refrigerator with NIST Calibrated Alarm/Thermometer • Summit FF6LWTBC FF6LTBC, 2.65 Cu. Ft. locking, alarm
	<p><u>Brixadi does not require refrigeration</u></p>	

Requirement	Additional Information	Resources
<p>Medication Records</p> <ul style="list-style-type: none"> □ Develop a system for records and inventories of all controlled substances dispensed, including buprenorphine. 	<ul style="list-style-type: none"> • Providers must keep records and inventories of all controlled substances dispensed, including buprenorphine <ul style="list-style-type: none"> ○ Track medication received, medication administered, and do regular inventory verification (see example in next column). ○ These protocols must be readily available if requested by the DEA. • Two staff must sign the med log when adding or removing Sublocade or Brixadi doses to/from the locked storage system: ideally two licensed healthcare staff (e.g., 2 nurses or nurse + provider). If your facility has only one licensed healthcare staff on site, you can develop a policy of one licensed healthcare staff + one jail staff when two licensed healthcare staff are not available. Log entries must be kept for ≥ 2 years. • Jails are also required to keep documentation of their protocols, practice guidelines or practice agreements readily available (see example in next column). • The use of a separate medication administration record (MAR) is also strongly recommended when administering doses in your jail if you do not have an Electronic Medical Record (EMR). 	<ul style="list-style-type: none"> • Code of Federal Regulations: Title 21- Chapter II -Part 1304 – Records and Reports of Registrants (National Archives and Records Administration 2023c) • Example protocols, practice guidelines, and practice agreements. (Grayken Center – Page 19) • Example inventory log (Grayken Center – Page 21)

Requirement	Additional Information	Resources
<p>Destruction Protocol</p> <ul style="list-style-type: none"> □ Create a policy for On-Site Destruction of ER-BUP; purchase destruction supplies □ Create an internal destruction of ER-BUP log □ (for destruction events) Record DEA Form 41 	<ul style="list-style-type: none"> • Jails should create a policy for destruction of On-site ER-BUP in the case that it is expired or not given to a patient (e.g., patient declines ER-BUP after it has been removed from packaging). • The U.S. Drug Enforcement Administration requires the completion of DEA Form 41 to record controlled substance destruction. This form is only given to the DEA if they request it. • This form must be kept and available for a minimum of two years in compliance with 21 U.S.C. 827. (see next column). 	<ul style="list-style-type: none"> • Example On-Site Destruction of ER-BUP Policy (Grayken Center – Page 23) • Example ER-BUP Internal Disposal log (Grayken Center- Page 22) • DEA Form 41 • Example medication destroyer: <ul style="list-style-type: none"> • Rx Destroyer All-Purpose Formula - Eco-Friendly Medication Buster Solution, Drug Disposal in a Bottle for Pills, Capsules, Tablets, Liquids - 64 oz. • Purchasable on amazon here. • Manufacture FAQ here.

Where do I purchase the injectable ER buprenorphine?

In community healthcare there are two pathways for ordering ER-BUP. The specialty pharmacy pathway bills patients' health insurance pharmacy benefit, and then an individual medication dose is labeled with the patient's identifiers and shipped to the provider. In the specialty distributor pathway, a facility orders medication from a distributor and then stocks ER-BUP on site. The ER-BUP supply is not labeled for individual patients and is quickly accessible. Healthcare insurance medical benefit provides reimbursement to the facility after a dose is used.

For jails, the recommended pathway is to purchase through a specialty distributor, since the medication doses will not be covered by health insurance, and the specialty distributor pathway will lead to faster access to medication. The regulatory information in this document has assumed use of the specialty distributor pathway to obtain ER-BUP.

	Sublocade	Brixadi
<input type="checkbox"/> Select an authorized specialty distributor and set up an account through MMCAP if you don't have one already	<p>Full list of specialty distributors: https://www.sublocaderems.com/#Main/Resources</p> <ul style="list-style-type: none"> • Cardinal Health • Henry Schein <p>The above retailers qualify for the MMCAP discount for corrections facilities. (see MMCAP discount section above)</p> <p>Note that a specialty distributor is not the same as a specialty pharmacy.</p>	<p>Full list of specialty distributors: https://www.brixadihcp.com/access-and-support/</p> <ul style="list-style-type: none"> • Cardinal Health • Henry Schein <p>The above retailers qualify for the MMCAP discount for corrections facilities. (see MMCAP discount section above)</p> <p>Note that a specialty distributor is not the same as a specialty pharmacy.</p>

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