

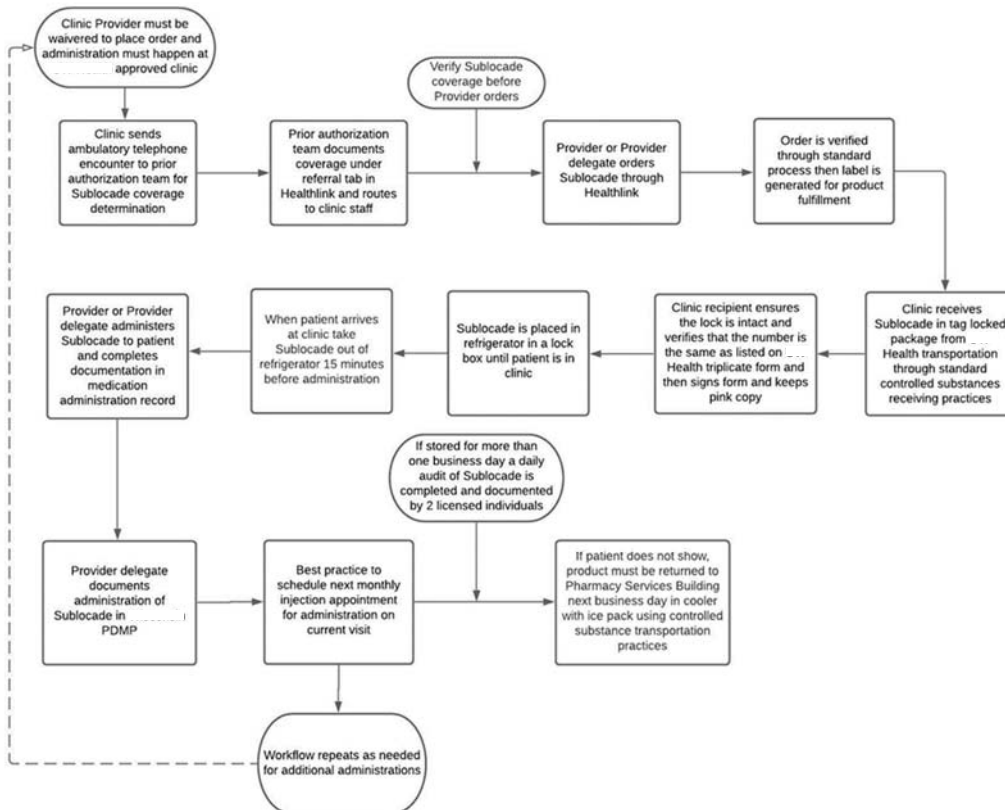
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I. PURPOSE: Establish process for clinics to order, procure, store, and document administration of Sublocade at approved [Clinic Name] locations.

II. Definitions:

1. Sublocade: Once-monthly buprenorphine extended-release subcutaneous injection designed to deliver therapeutic plasma concentrations for the treatment of moderate to severe opioid use disorder (OUD).
2. Sublocade REMS Program: The Food and Drug Administration Sublocade risk evaluation and mitigation strategy program to ensure benefits of Sublocade outweigh its risks. Primary components of the REMS program include:
  - a. All healthcare settings and pharmacies that dispense SUBLOCADE must be certified in the SUBLOCADE REMS program
  - b. Healthcare providers, healthcare settings, and pharmacies must obtain SUBLOCADE through a restricted distribution program
  - c. SUBLOCADE should never be dispensed directly to a patient.
3. Authorized Representative: Provider or healthcare institution registered with Sublocade REMS Program who ensures clinic adherence to REMS requirements

III. Executive Workflow Summary:

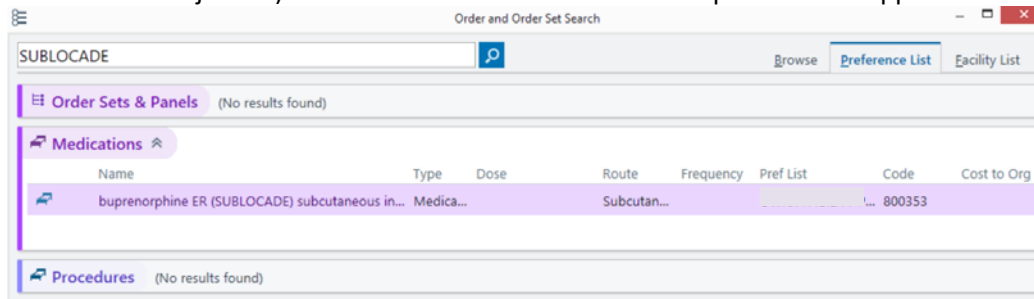


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IV. PROCEDURE:

1. Ordering and Obtaining Sublocade:

- a. Approved clinics must identify clinic representative to ensure required training and workflows for Sublocade to comply with FDA REMS requirements at clinic location
- b. Clinic staff must send ambulatory telephone encounter to prior authorization (PA) team for coverage determination prior to sending any order for Sublocade
  - i. Requests routed to the PA Team [Pharmacy Name] PRIOR AUTHORIZATION REQUEST
    1. Refer to Appendix 1 for detailed workflow
    - ii. PA team documents coverage in referral tab
      1. Will route coverage determination to clinic staff
- c. Provider or Provider delegate orders Sublocade through Healthlink if patient has verified coverage
- d. Waivered provider or provider delegate places a patient specific order for clinic administration in Healthlink utilizing order 800353 (buprenorphine ER (Sublocade) subcutaneous injection) at least 48 to 72 hours in advance of patient clinic appointment



- e. Pharmacy purchasing places order through wholesaler in accordance with standard pharmacy procurement practices
  - i. Pharmacy centralized services will follow standard product fulfillment practices upon delivery from wholesaler
  - ii. It will take 48-72 business hours to transport Sublocade to approved clinic location
- f. [Clinic Name] transportation will courier Sublocade from Pharmacy Services Building (PSB) to approved clinic location using standard controlled substance delivery practices
- g. Clinic approved delegate receives Sublocade in tag locked package from [Clinic Name] transportation through standard controlled substances receiving practices
- h. Clinic recipient will ensure that the lock is intact and verifies that the number is the same as listed on [Clinic Name] triplicate form
- i. The clinic recipient will sign triplicate form and keep the pink copy on file at clinic location
- j. Sublocade is placed inside lock box in refrigerator until the patient arrives for appointment
  - i. If Sublocade is stored more than one business day, two licensed clinic staff members must conduct daily audit and document inventory count in controlled substance inventory audit book
  - ii. If any discrepancy is found during the daily audit, auditing individuals must notify clinic management immediately according to controlled substance policies

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- k. If patient does not show for appointment, the product must be returned to the Pharmacy Services Building by next business day in a cooler with an ice pack using controlled substance transportation practices
- 2. Administering Sublocade
  - a. Ordering provider or provider delegate verifies all criteria outlined in order instructions is met for the patient specific Sublocade order
    - i. Must be ordered by waived provider
    - ii. Product is not dispensed directly to the patient
    - iii. Use is compliant with [Clinic Name] Policies #6.1.9 and #6.1.5 including fiscal screening as described
    - iv. Buprenorphine extended-release subcutaneous injection should only be ordered for patients who have initiated treatment with a transmucosal buprenorphine-containing product followed by a dose adjustment for a minimum of 7 days
  - b. Ordering provider or provider delegate selects appropriate administration dose, route, frequency, and time of administration

Dose:  mg

Administer Dose: 100 mg  
Administer Amount: 100 mg

Route:

Frequency:

Starting:  Today  At:

First Dose: **Tomorrow 1000** Number of doses: **1**  
[Scheduled Times ^](#)

- c. Ordering provider or provider delegate signs medication order via standard order mode

Providers ✖

**Ordering Information** Filter:  Treatment team  
 Nearby

Order mode 🔍  
Standard

Ordering provider  
 🔍

**Authorizing Providers**  
For medications  
 🔍

**Cosigners**  
For medications

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- d. Clinic approved staff obtains Sublocade dose from locked refrigerator box when patient arrives for appointment
- e. Sublocade must be removed from refrigerator for 15 minutes prior to administration
- f. Provider or provider delegate administers Sublocade during patient clinic appointment per clinic injection administration standard practice
- g. Administering provider or provider delegate documents administration via Sublocade smart set in the medication administration record
  - i. Local lidocaine can be given upon patient request to mitigate injection site pain
- h. Provider delegate documents the administration of Sublocade in the PDMP
- i. Clinic staff schedules next monthly Sublocade injection appointment during current visit

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Appendix 1:

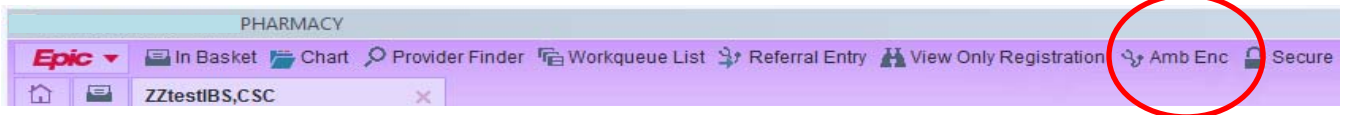
**Requesting prior authorizations from the PA Teams**

PA requests should be sent to the [Clinic Name] Prior Authorization Teams via Healthlink as a telephone encounter.

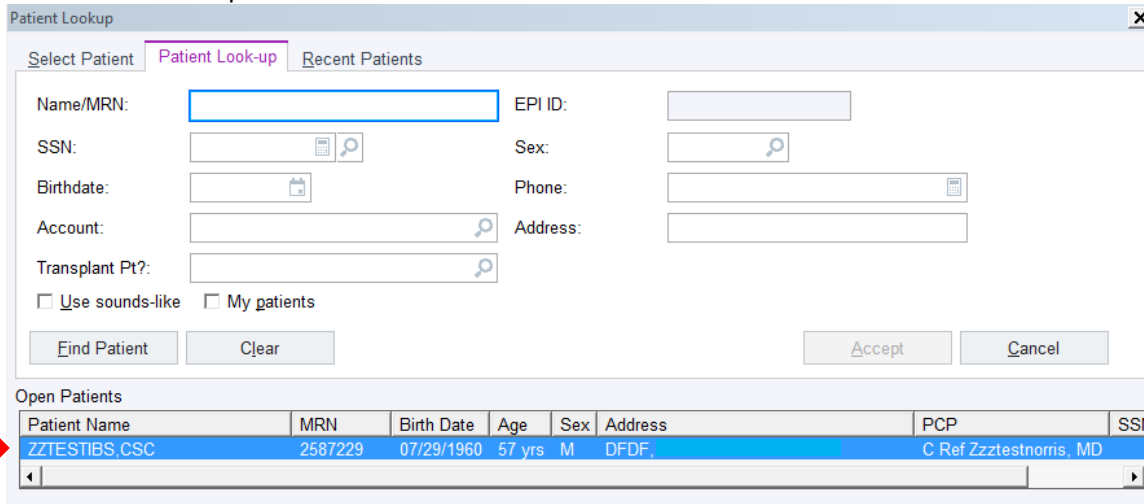
- Standard/Routine prior authorization requests will be addressed within 48-72 hours of receiving request.
- Urgent/High priority requests will be addressed within 24 hours of receiving request. Urgent requests must meet the following criteria:
  - Life or limb threatening
  - Patient risks hospitalization without medication
  - Lapse of current therapy (same medication)

Telephone Encounter for a PA request:

i. Amb Enc



ii. Select patient



iii. If there is already an existing telephone encounter started for this patient, please double check to ensure the PA has not already been requested. If there is not an existing telephone encounter, select "New"

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Encounter Selection for ZZtestIBS,CSC

Selected record: ZZTESTIBS,CSC

Contact Date	Contact Type	Provider	Department	Status
10/25/2017	Clinical Info Note	P Op Zzzdissanayake, MD, ...	NORTHEAST FAM MED	
10/23/2017	Telephone	P Provider Zzzdissanayake	NORTHEAST FAM MED	
10/17/2017	Telephone	P Op Zzzdissanayake, MD, ...	TAC CARDIOVASC MED_NEW	
08/14/2017	Info Note	P Op Zzzdissanayake, MD, ...	NORTHEAST FAM MED	
01/09/2017	Orders Only	P Provider Zzzdissanayake	TAC ED	
01/06/2017	Refill	P Op Zzzdissanayake, MD, ...	TAC GEN SURG	
11/30/2016	Orders Only	P Op Zzzdissanayake, MD, ...	TAC GEN SURG	
11/30/2016	Telephone	P Op Zzzdissanayake, MD, ...	TAC GEN SURG	

Encounter Information: 10 loaded so far, press More to see more.

- iv. **Type:** Telephone  
**Provider:** Prescribing Physician  
**Department:** Clinic Requesting

New Encounter for ZZtestIBS,CSC

**Date:** 11/7/2017

**Type:** Telephone

**Provider:** MCKOWN, KEVIN M **PCP**

**Department:** EAST CLINIC RHEUM

- v. Once within the telephone encounter there are 3 fields that will always need to be completed.
- Reason for Call
  - Notes
  - Routing
- **Reason for call:** Chief Complaint should be Prior Authorization. Please indicate which drug, strength, and device (pen vs syringe if applicable) into the comment section.

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Reason for Call

Establish Care Medication Man... Medication Prob... Pre-Op Exam Pro

Well Child Exam

Chief Complaint Comment

Prior Authorization Humira 40mg Pen

- **Notes:** Please create a dotparse or use .parequest for your clinic with the below minimum requirements to initiate PA.

This Call Notes

+ Create Note

My Note

Details

Medication Name: \*\*\*  
Dose and Frequency: \*\*\*  
Diagnosis (ICD 10 or specific diagnosis): \*\*\*  
Any additional info: \*\*\*

- **Routing:** Please route all request to the [Clinic Name] PA team pool.  
**Pool:** [Clinic Name] Pharmacy Prior Authorization Request Pool #
  - **For any urgent requests please ensure they meet urgent criteria and change the priority to high.**

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**Routing**

Patient Call messages will be sent when the workspace closes.

Route as:  Priority:

Recipient	Message
	MEDICATION PRIOR AUTHORIZATION REQUEST [6000200116]

vi. Sign and close workspace.

Routing comment (not saved to notes):

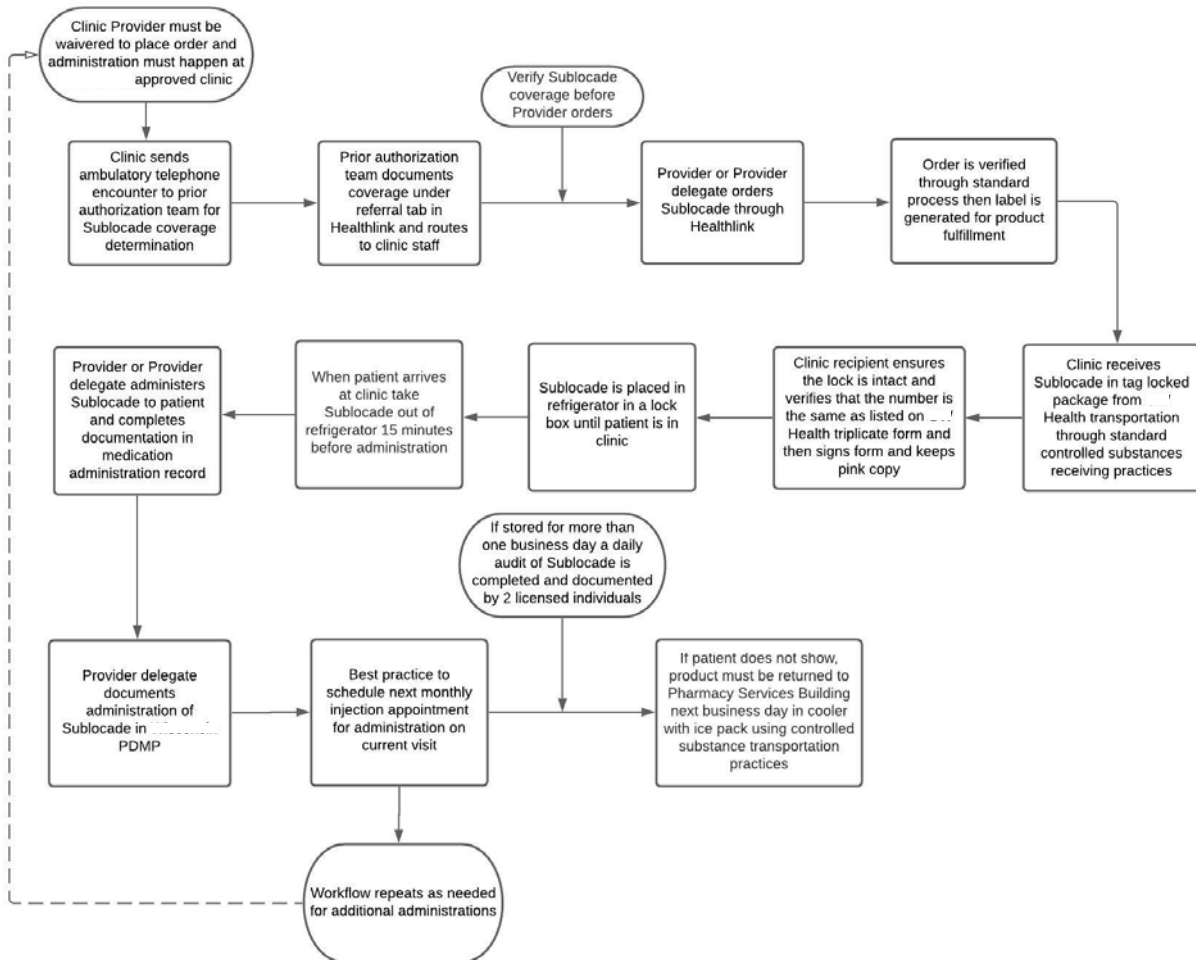
[View Routing History](#)



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Appendix 2:

**Executive Workflow Summary of Sublocade**



Approved By: _____ Director of Pharmacy Services	Date: _____
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