



POLICY AND PROCEDURE

POLICY NUMBER: *RX.PA.447*

REVISION DATE: *N/A*

PAGE NUMBER: 1 of 4

POLICY TITLE: *Sublocade (buprenorphine injection)*
DEPARTMENT: *Clinical Pharmacy Services- Utilization Management*
ORIGINAL DATE: *May 2018*

Last P & T Committee Approval Date: May 2018

Product Applicability: *mark all applicable products below:*

COMMERCIAL	<input type="checkbox"/> HMO <input type="checkbox"/> PPO <i>Products:</i> <input type="checkbox"/> Small <i>Exchange:</i> <input type="checkbox"/> Shop <input checked="" type="checkbox"/> All <input type="checkbox"/> Indiv. <input type="checkbox"/> Indiv. <input type="checkbox"/> Large
OTHER	<input checked="" type="checkbox"/> Self-funded/ASO

PURPOSE

The purpose of this policy is to define the prior authorization process for Sublocade (buprenorphine injection).

DEFINITIONS

N/A

POLICY

It is the policy of the Health Plan to maintain a prior authorization process that promotes appropriate utilization of specific drugs with potential for misuse or limited indications. This process involves a review using Food and Drug Administration (FDA) criteria to make a determination of Medical Necessity, and approval by the Pharmacy & Therapeutics Committee of the criteria for prior authorization, as described in RX.002 Pharmacy and Therapeutics Committee and RX.003-Prior Authorization Process.

The drug, Sublocade (buprenorphine injection), is subject to the prior authorization



Sublocade

POLICY NUMBER: RX.PA.447

REVISION DATE: N/A

PAGE NUMBER: 2 of 4

process.

PROCEDURE

Initial Authorization Criteria:

Must meet all of the criteria listed below:

- Must have a diagnosis of opioid dependence
- Must have an initial urine drug screen within the last 3 months which is consistent with a diagnosis of opioid dependence. Documentation of the recent drug test must be provided.
- Must have documentation of an initial evaluation or scheduled appointment with a licensed Drug and Alcohol (D&A) provider to determine the recommended level of care
- Must have documentation of referral to, or enrollment in, formal behavioral health counseling and/or substance abuse counseling. Initial treatment must be performed by a licensed D&A or a behavioral health provider that is consistent with the level of care recommended at the initial evaluation
- Must not have attempted to fill any opioid prescriptions during this initial period as indicated by their drug claim history (if available)
- Benzodiazepines are covered for the initial approval period to allow time to taper benzodiazepine therapy
 - Tapering is not required for members that meet the following:
 - Concurrent use of buprenorphine and a benzodiazepine is medically necessary
 - For patients using benzodiazepines for anxiety or insomnia: documentation of a trial of other treatment options or clinical rationale for why other treatment options cannot be used must be provided
 - The patient has been counseled on the risks associated with concurrent use and will be monitored
- Must be prescribed by a prescriber who has a unique identification number issued by the Drug Enforcement Agency (DEA) certifying prescribing authority for buprenorphine
- Provider must provide attestation that oral buprenorphine treatment would not be effective for patient due to adherence barriers after a minimum one-month trial of oral treatment (documentation of trial must be provided) unless clinically inappropriate
- Patient must be stabilized on an oral buprenorphine product for at least 7 days prior to starting treatment with Sublocade



Sublocade

POLICY NUMBER: RX.PA.447

REVISION DATE: N/A

PAGE NUMBER: 3 of 4

- Must be administered by a healthcare provide

Reauthorization Criteria:

All prior authorization renewals are reviewed on a 6-month basis to determine the Medical Necessity for continuation of therapy. Authorization may be extended at 6-month intervals based upon chart documentation from the provider that the member's condition has improved, based upon the prescriber's assessment while on therapy. In addition, for continuation:

- Must have chart documentation of monthly urine drug screens since the last authorization that document all of the following:
 - Positive for buprenorphine
 - Testing for licit and illicit drugs with the potential for abuse and oxycodone that is consistent for prescribed controlled substances
- Must have chart documentation showing participation of at least monthly formal behavioral health counseling, substance abuse counseling, or an addiction recovery program or must be participating in formal behavioral health counseling or an addiction recovery program as indicated in the initial D&A evaluation. After a period of 1 year, less formal programs would be allowed as participation.
- Must not have attempted to fill any opioid prescriptions or benzodiazepines during this authorization period as indicated by the drug claim history (if available)
 - Concurrent benzodiazepine use is allowed if all of the following are met:
 - Concurrent use of buprenorphine and a benzodiazepine is medically necessary
 - For patients using benzodiazepines for anxiety or insomnia: documentation of a trial of other treatment options or clinical rationale for why other treatment options cannot be used must be provided
 - The patient has been counseled on the risks associated with concurrent use and will be monitored

Limitations:

Length of Authorization (if above criteria met)	
Initial Authorization	Up to 6 months
Reauthorization	Same as initial

If the established criteria are not met, the request is referred to a Medical Director for review.



Sublocade

POLICY NUMBER: RX.PA.447

REVISION DATE: N/A

PAGE NUMBER: 4 of 4

REFERENCES

1. Sublocade [prescribing information]. Indivior Inc, North Chesterfield, MA; November 2017.

RECORD RETENTION

Records Retention for Evolent Health documents, regardless of medium, are provided within the Evolent Health records retention policy and as indicated in CORP.028.E Records Retention Policy and Procedure.

REVIEW HISTORY

DESCRIPTION OF REVIEW / REVISION	DATE APPROVED

