



Original Effective Date: 08/01/2018
 Current Effective Date: 06/28/2025
 Last P&T Approval/Version: 04/30/2025
 Next Review Due By: 01/2026
 Policy Number: C15161-A

Sublocade (buprenorphine extended-release inj.)

PRODUCTS AFFECTED

Sublocade (buprenorphine extended-release inj)

COVERAGE POLICY

Coverage for services, procedures, medical devices and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Coverage Guideline must be read in its entirety to determine coverage eligibility, if any. This Coverage Guideline provides information related to coverage determinations only and does not imply that a service or treatment is clinically appropriate or inappropriate. The provider and the member are responsible for all decisions regarding the appropriateness of care. Providers should provide Molina Healthcare complete medical rationale when requesting any exceptions to these guidelines.

Documentation Requirements:

Molina Healthcare reserves the right to require that additional documentation be made available as part of its coverage determination; quality improvement; and fraud; waste and abuse prevention processes. Documentation required may include, but is not limited to, patient records, test results and credentials of the provider ordering or performing a drug or service. Molina Healthcare may deny reimbursement or take additional appropriate action if the documentation provided does not support the initial determination that the drugs or services were medically necessary, not investigational or experimental, and otherwise within the scope of benefits afforded to the member, and/or the documentation demonstrates a pattern of billing or other practice that is inappropriate or excessive.

DIAGNOSIS:

Moderate to severe opioid use disorder

REQUIRED MEDICAL INFORMATION:

This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. If a drug within this policy receives an updated FDA label within the last 180 days, medical necessity for the member will be reviewed using the updated FDA label information along with state and federal requirements, benefit being administered and formulary preferencing. Coverage will be determined on a case-by case basis until the criteria can be updated through Molina Healthcare, Inc. clinical governance. Additional information may be required on a case-by-case basis to allow for adequate review. When the requested drug product for coverage is dosed by weight, body surface area or other member specific measurement, this data element is required as part of the medical necessity review. The Pharmacy and Therapeutics Committee has determined that the drug benefit shall be a mandatory generic and that generic drugs will be dispensed whenever available.

A. MODERATE TO SEVERE OPIOID USE DISORDER:

1. Documented diagnosis of opioid use disorder or opioid dependence
AND
2. (a) FOR STATES WITH PRESCRIPTION DRUG MONITORING PROGRAMS (PDMPs):
Prescriber attestation that they utilized (and will continue to utilize) the applicable State PDMP prior to issuance of a prescription or continuation of therapy request

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Drug and Biologic Coverage Criteria

OR

(b) FOR STATES WITHOUT PDMPs: Prescriber attestation that they will review member's records on a periodic basis or as necessary to ensure no abuse or diversion

AND

3. Prescriber attestation of counseling member regarding a comprehensive substance use disorder treatment plan that includes biopsychosocial support and resource referral
AND
4. Prescriber agrees to administer random clinical drug testing a minimum of twice per year (*or more frequently as appropriate for member)
AND
5. Documentation member is currently being treated with a transmucosal buprenorphine-containing product OR Member has tolerated a single initial dose (e.g., 4 mg) of transmucosal buprenorphine
AND
6. Documented trial and failure or FDA labeled contraindication to buprenorphine/naloxone tablets for at least 3 months OR rationale for medical necessity of non-preferred injectable form over preferred generic tablets
AND
7. Members with co-existent Behavioral Health Disorders ONLY: Prescriber agrees to coordinate or oversee ongoing behavioral health care for co-existing behavioral health disorders

CONTINUATION OF THERAPY:

A. MODERATE TO SEVERE OPIOID USE DISORDER:

1. Adherence to therapy as verified by the prescriber or member medication fill history
AND
2. Prescriber attestation of monitoring that member has adhered to any recommendations regarding comprehensive rehabilitation program that includes psychosocial support provided by a program counselor qualified by education, training, or experience to assess the psychological and sociological background of individuals receiving treatment
AND
3. Prescriber agrees to administer random clinical drug testing a minimum of twice per year (*or more frequently as appropriate for member)
AND
4. (a) FOR STATES WITH PRESCRIPTION DRUG MONITORING PROGRAMS (PDMPs): Prescriber attestation that they utilized (and will continue to utilize) the applicable State PDMP prior to issuance of a prescription or continuation of therapy request
OR
(b) FOR STATES WITHOUT PDMPs: Prescriber attestation that they will review member's records on a periodic basis or as necessary to ensure no abuse or diversion
AND
5. FOR DOSE REQUESTS FOR 300MG PER MONTH AFTER THE INITIAL 2 MONTHS: Prescriber attests that patient does not demonstrate a satisfactory clinical response using the 100mg strength (as evidenced by self-reported illicit opioid use or urine drug screens positive for illicit opioid use).
AND
6. Prescriber attests to or clinical reviewer has found no evidence of intolerable adverse effects or drug toxicity

DURATION OF APPROVAL:

Initial authorization: 2 months, Continuation of Therapy: 6 months

PRESCRIBER REQUIREMENTS:

Prescribed by an opioid use disorder specialist

AGE RESTRICTIONS:

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QUANTITY:

300 mg monthly for the first two months followed by a maintenance dose of 100 mg monthly
Per FDA product label: The maintenance dose may be increased to 300 mg monthly for patients who tolerate the 100 mg dose, but do not demonstrate a satisfactory clinical response, as evidenced by self-reported illicit opioid use or urine drug screens positive for illicit opioid use.

PLACE OF ADMINISTRATION:

The recommendation is that injectable medications in this policy will be for pharmacy or medical benefit coverage and the subcutaneous injectable products administered in a place of service that is a non-hospital facility-based location.

DRUG INFORMATION

ROUTE OF ADMINISTRATION:

Subcutaneous injection

DRUG CLASS:

Opioid Partial Agonists

FDA-APPROVED USES:

Indicated for the treatment of moderate to severe opioid use disorder in patients who have initiated treatment with a single dose of a transmucosal buprenorphine product or who are already being treated with buprenorphine. Sublocade should be used as part of a complete treatment plan that includes counseling and psychosocial support.

COMPENDIAL APPROVED OFF-LABELED USES:

None

APPENDIX

APPENDIX:

None

BACKGROUND AND OTHER CONSIDERATIONS

BACKGROUND:

Sublocade Risk Evaluation and Mitigation Strategy (REMS) Program

Sublocade is available only through a restricted program called the SUBLOCADE REMS Program because of the risk of serious harm or death that could result from intravenous self-administration. The goal of the REMS is to mitigate serious harm or death that could result from intravenous self-administration by ensuring that healthcare settings and pharmacies are certified and only dispense SUBLOCADE directly to a healthcare provider for administration by a healthcare provider.

Notable requirements of the Sublocade REMS Program include the following:

- Healthcare Settings and Pharmacies that order and dispense SUBLOCADE must be certified in the SUBLOCADE REMS Program.
- Certified Healthcare Settings and Pharmacies must establish processes and procedures to verify SUBLOCADE is provided directly to a healthcare provider for administration by a healthcare provider, and the drug is not dispensed to the patient.
- Certified Healthcare Settings and Pharmacies must not distribute, transfer, loan, or sell SUBLOCADE.

Further information is available at www.SublocadeREMS.com or call 1-866-258-3905.

Drug and Biologic Coverage Criteria

CONTRAINDICATIONS/EXCLUSIONS/DISCONTINUATION:

All other uses of Sublocade (buprenorphine extended-release inj) are considered experimental/investigational and therefore, will follow Molina's Off- Label policy. Contraindications to Sublocade (buprenorphine extended-release inj) include: Hypersensitivity to buprenorphine or any other ingredients in Sublocade.

OTHER SPECIAL CONSIDERATIONS:

Sublocade (buprenorphine extended-release inj) is a schedule III controlled substance.

Sublocade should only be prepared and administered by a healthcare provider.

Occasional delays in dosing up to 2 weeks are not expected to have a clinically significant impact on treatment effect.

The second injection of Sublocade may be administered as early as 1 week and up to 1 month after the initial injection based on patient need.

Administer monthly doses at least 26 days apart.

BLACK BOX WARNING: WARNING: RISK OF SERIOUS HARM OR DEATH WITH INTRAVENOUS ADMINISTRATION; SUBLOCADE RISK EVALUATION AND MITIGATION STRATEGY

Serious harm or death could result if administered intravenously. Sublocade is only available through a restricted program called the Sublocade REMS Program. Healthcare settings and pharmacies that order and dispense Sublocade must be certified in this program and comply with the REMS requirements.

CODING/BILLING INFORMATION

CODING DISCLAIMER. Codes listed in this policy are for reference purposes only and may not be all-inclusive or applicable for every state or line of business. Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement. Listing of a service or device code in this policy does not guarantee coverage. Coverage is determined by the benefit document. Molina adheres to Current Procedural Terminology (CPT®), a registered trademark of the American Medical Association (AMA). All CPT codes and descriptions are copyrighted by the AMA; this information is included for informational purposes only. Providers and facilities are expected to utilize industry-standard coding practices for all submissions. Molina has the right to reject/deny the claim and recover claim payment(s) if it is determined it is not billed appropriately or not a covered benefit. Molina reserves the right to revise this policy as needed.

HCPCS CODE	DESCRIPTION
Q9991	Injection, buprenorphine extended release (sublocade), less than or equal to 100mg
Q9992	Injection, buprenorphine extended release (sublocade), greater than 100mg

AVAILABLE DOSAGE FORMS:

Sublocade SOSY 100MG/0.5ML

Sublocade SOSY 300MG/1.5ML

REFERENCES

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2. Haight BR, Learned SM, Laffont CM, et al. Efficacy and safety of a monthly buprenorphine depot injection for opioid use disorder: a multicentre, 321dactone32, double-blind, placebo-controlled, phase3 trial. Lancet. 2019 Feb 23;393(10173):778- 790

Drug and Biologic Coverage Criteria

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SUMMARY OF REVIEW/REVISIONS	DATE
REVISION- Notable revisions: Required Medical Information FDA-Approved Uses Other Special Considerations References	Q2 2025
REVISION- Notable revisions: References	Q1 2025
REVISION- Notable revisions: Other Special Considerations Available Dosage Forms References	Q1 2024
REVISION- Notable revisions: Required Medical Information Continuation of Therapy Prescriber Requirements Quantity FDA-Approved Uses Background Contraindications/Exclusions/Discontinuation Other Special Considerations References	Q1 2023
Q2 2022 Established tracking in new format	Historical changes on file