Original Effective Date: 08/01/2018
Current Effective Date: 03/07/2024
Last P&T Approval/Version: 01/31/2024
Next Review Due By: 01/2025
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
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. Member has been on a transmucosal buprenorphine-containing product delivering the equivalent of 8 to 24 mg of buprenorphine daily for a minimum of 7 days
   AND
6. Documented trial and failure or FDA labeled contraindication to buprenorphine/naloxone tablets for 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:

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 buprenorphine-containing product, followed by dose adjustment for a minimum of 7 days. Sublocade should be used as part of a complete treatment program 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.

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.
Administer monthly doses no less than 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

Note: 1) This list of codes may not be all-inclusive. 2) Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement

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

1. Sublocade (prescribing information). Albany, NY: Curia Global Inc.; December 2023.
2. Haight BR, Learned SM, Laffont CM, et al. Efficacy and safety of a monthly buprenorphine depot injection for opioid use disorder: a multicentre, 32ldactone32, double-blind, placebo-controlled, phase3 trial. Lancet. 2019 Feb 23;393(10173):778- 790
3. Dowell D, Ragan KR, Jones CM, Baldwin GT, Chou R. CDC Clinical Practice Guideline for Prescribing Opioids for Pain — United States, 2022. MMWR Recomm Rep 2022;71(No. RR-3):1–95. DOI: http://dx.doi.org/10.15585/mmwr.rr7103a1
4. The Asam National Practice Guideline for the treatment of opioid use disorder: 2020 focused update. (2020). Journal of Addiction Medicine, 14(2S), 1-91. Doi:10.1097/adm.0000000000000633

SUMMARY OF REVIEW/REVISIONS	DATE
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