Effective Date: 08/01/2018
Last P&T Approval/Version: 01/26/2021
Next Review Due By: 01/2022
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

A. OPIOID USEDISORDER:
   1. Documented diagnosis of opioid use disorder or opioid dependence
      AND
      (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

2. Prescriber attestation of counseling member regarding a comprehensive substance use disorder treatment plan that includes biopsychosocial support and resource referral
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. Member has been on a transmucosal buprenorphine-containing product delivering the equivalent of8to 24 mg of buprenorphine daily for a minimum of 7 days
AND
5. 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

CONTINUATION OF THERAPY:

A. MODERATE TO SEVERE OPIOID USE DISORDER:

1. Prescriber attestation of monitoring that member has adhered to any recommendations regarding comprehensive rehabilitation program that includes psychosocial support providedby a program counselor qualified by education, training, or experience to assess the psychological and sociological background of individuals receiving treatment
AND
2. Prescriber agrees to administer random clinical drug testing a minimum of twice per year(*or more frequently as appropriate for member)
AND
3. 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).

DURATION OF APPROVAL:

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

PRESCRIBER REQUIREMENTS:

Prescribed by an opioid use disorder specialist with a X DEA number

AGE RESTRICTIONS:

18 years of age and older

QUANTITY:

Up to 300 mg per month in the first two months of Sublocade therapy AND 100 mg per month for doses thereafter

* per FDA product label- Initial: 300 mg monthly for the first 2 months, after treatment has been inducted and adjusted with 8 to 24 mg of a transmucosal buprenorphine-containing product for minimum of 7 days. Maintenance: 100 mg monthly, increasing to 300 mg monthly for patients who tolerate the 100 mg dose butdo not demonstrate a satisfactory clinical response (as evidenced by self-reported illicit opioid use or urine drug screens positive for illicit opioid use).

Note: Administer doses at least 26 days apart

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 isa non-hospital facility-based location.

DRUG INFORMATION

ROUTE OF ADMINISTRATION:
Subcutaneous injection

DRUG CLASS:
Opioid Partial Agonists

FDA-APPROVED USES:
Moderate to severe opioid use disorder

COMPENDIAL APPROVED OFF-LABELED USES:
None

APPENDIX

APPENDIX:
None

BACKGROUND AND OTHER CONSIDERATIONS

BACKGROUND:
None

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. Use in members with moderate to severe hepatic Impairment is not recommended
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

OTHER SPECIAL CONSIDERATIONS:
Administer monthly with a minimum of 26 days between doses
The recommended dose is 300 mg monthly for the first two months followed by a maintenance dose of 100 mgmonthly. Some patients may need 300 mg per month maintenance.

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 to100mg
Q9992	injection, buprenorphine extended release (sublocade), greater than100mg

AVAILABLE DOSAGE FORMS:
SUBLOCADE SYN 100/0.5, SUBLOCADE SYN 300/1.5

REFERENCES

1. Sublocade (prescribing information). North Chesterfield, VA, Indivior Inc., June 2021.
2. Haight BR, Learned SM, Laffont CM, et al. Efficacy and safety of a monthly buprenorphine depot injection for opioid use disorder: a multicentre, randomised, double-blind, placebo-controlled, phase3 trial. Lancet. 2019 Feb 23;393(10173):778- 790