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Policy Number: C10899-A

Buprenorphine-Naloxone and Buprenorphine for Opioid Dependence

PRODUCTS AFFECTED

Bunavail FILM (buprenorphine/naloxone buccal film), buprenorphine, buprenorphine/naloxone, Suboxone FILM (buprenorphine/naloxone SL film), Zubsolv SUBL (buprenorphine/naloxone SL tab)

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:
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. 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 of the buprenorphine/naloxone or buprenorphine
   AND
3. Prescriber attestation of counseling member regarding a 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
4. Prescriber agrees to administer random clinical drug testing a minimum of twice per year (*or more frequently as appropriate for member)
   AND
5. Prescriber attests member has no more than TWO failures of buprenorphine/naloxone or buprenorphine treatment requiring a restart within the previous 12 months. EXCEPTIONS: Exceptions may be made on a case-by-case basis by a Molina Pharmacy/Medical Reviewer. NOTE: After TWO or more treatment failures warrant further assessment of the member. A higher-level care, such as a methadone treatment program, may be recommended by Molina Pharmacy/Medical Reviewer. Molina Healthcare may contact the Prescriber for further discussion of treatment plan and review on a case-by-case basis.
   AND
6. Members with co-existent Behavioral Health Disorders ONLY: Prescriber agrees to coordinate or oversee ongoing behavioral health care for co-existing behavioral health disorders
   AND
7. FOR BUPRENORPHINE REQUESTS ONLY: Member is unable to take buprenorphine/naloxone as documented by ONE of the following:
   (a) Pregnancy or breastfeeding. Document anticipated date of delivery. NOTE: Member may initiate or continue on buprenorphine monotherapy for the duration of the pregnancy and while breastfeeding.
   OR
   (b) Moderate to severe hepatic impairment (Child-Pugh B to C)
   OR
   (c) Maintenance therapy: Unable to take naloxone-containing products due to a documented hypersensitivity to naloxone or naltrexone, FDA-labeled contraindication, drug- drug interaction, or history of toxic side effects that caused immediate or long-term damage
   AND
8. IF THIS IS A NON-FORMULARY/NON-PREFERRED PRODUCT: Documentation of trial/failure of or serious side effects to a majority (not more than 3) of the preferred formulary/PDL alternatives for the given diagnosis. Submit documentation including medication(s) tried, dates of trial(s) and reason for treatment failure(s).

CONTINUATION OF THERAPY:

A. OPIOID USE DISORDER:

1. Adherence to Buprenorphine/Naloxone or buprenorphine therapy since previous authorization 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. Prescriber attests substance abuse disorders, untreated or unstable psychiatric conditions, or co-morbid conditions that may interfere with buprenorphine or buprenorphine/naloxone compliance are being evaluated/monitored
AND
5. (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
6. FOR BUPRENORPHINE REQUESTS ONLY: Member continues to be unable to take buprenorphine/naloxone as documented by ONE of the following:
(a) Pregnancy or breastfeeding. Document anticipated date of delivery. NOTE: Member may initiate or continue on buprenorphine monotherapy for the duration of the pregnancy and while breastfeeding.
OR
(b) Moderate to severe hepatic impairment (Child-Pugh B to C)
OR
(c) Maintenance therapy: Unable to take naloxone-containing products due to a documented hypersensitivity to naloxone or naltrexone, FDA-labeled contraindication, drug-drug interaction, or history of toxic side effects that caused immediate or long-term damage
AND
7. Prescriber attests to or clinical reviewer has found no evidence of intolerable adverse effects or drug toxicity

DURATION OF APPROVAL:
Initial authorization: 6 months, Continuation of Therapy: 6 months

PRESCRIBER REQUIREMENTS:
Prescribed by an opioid use disorder specialist

AGE RESTRICTIONS:
16 years of age and older

QUANTITY:
buprenorphine sublingual tab: maximum daily dose 24 mg
Suboxone (buprenorphine/naloxone sublingual film/tablet): maximum daily dose 24/6 mg
Bunavail (buprenorphine/naloxone buccal film): maximum daily dose 12.6mg/2.1mg
Zubsolv (buprenorphine/naloxone) sublingual tablet: maximum daily dose 17.1mg/4.2mg

PLACE OF ADMINISTRATION:
The recommendation is that oral medications in this policy will be for pharmacy benefit coverage and patient self-administered.

DRUG INFORMATION

ROUTE OF ADMINISTRATION:
Buccal, Sublingual,

DRUG CLASS:
Opioid Agonist-Antagonist Analgesics

FDA-APPROVED USES:
Bunavail buccal film is indicated for the maintenance treatment of opioid dependence and should be used as part of a complete treatment plan to include counseling and psychosocial support.

Buprenorphine sublingual tablet is indicated for the treatment of opioid dependence and is preferred for induction and should be used as part of a complete treatment plan that includes counseling and psychosocial support.

Suboxone sublingual film is indicated for the treatment of opioid dependence and should be used as part of a complete treatment plan that includes counseling and psychosocial support.

Suboxone tablet is indicated for the maintenance treatment of opioid dependence and should be used as part of a complete treatment plan that includes counseling and psychosocial support.

Zubsolv sublingual tablet is indicated for treatment of opioid dependence and should be used as part of a complete treatment plan that includes counseling and psychosocial support.

COMPENDIAL APPROVED OFF-LABELED USES:
None

APPENDIX

APPENDIX:

DSM-5 OPIOID USE DISORDER[J]
DSM-5 opioid use disorder is defined as follows:
A problematic pattern of opioid use leading to clinically significant impairment or distress, as manifested by at least two (or more) of the following, occurring within a 12-month period:

1) Substance is often taken in larger amounts or over a longer period than was intended
2) There is a persistent desire or unsuccessful efforts to cut down or control opioid use
3) A great deal of time is spent in activities necessary to obtain the opioid, use the opioid or recover from its effects
4) Craving, or a strong desire or urge to use opioids
5) Recurrent opioid use resulting in failure to fulfill major role obligations at work, school or home
6) Continued opioid use despite having persistent or recurrent social or interpersonal problems caused or exacerbated by the effects of opioids
7) Important social, occupational, or recreational activities are given up or reduced because of opioid use
8) Recurrent opioid use in situations in which it is physically hazardous
9) Continued opioid use despite knowledge of having a persistent or recurrent physical or psychological problem that is likely to have been cause or exacerbated by the substance
10) Tolerance, as defined by either of the following:
    a) a need for markedly increased amounts of opioids to achieve intoxication or desired effect
    b) a markedly diminished effect with continued use of the same amount of the opioid; however, this criterion is not considered to be met for those taking opioids solely under appropriate medical supervision
11) Withdrawal, as manifested by either of the following:
    a) the characteristic opioid withdrawal syndrome
    b) opioids (or closely related substance) is taken to relieve or avoid withdrawal symptoms NOTE: The severity of opioid use disorder at the time of diagnosis can be specified as a subtype based on the number of criteria present

    Mild: Presence of 2-3 symptoms
    Moderate: Presence of 4-5 symptoms

Severe: Presence of 6 or more symptoms

Reference: American Psychiatric Association. Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition

DRUG ADDICTION TREATMENT ACT OF 2000 (DATA 2000)

Background: In 2000 Congress passed DATA-2000, a law that allows physicians, to become eligible to prescribe specially approved opioid-based medications specifically for the treatment of opioid addiction. Buprenorphine/naloxone (Suboxone®) and buprenorphine (Subutex®) became the first medications to be approved and affected by this law. If physicians take and pass an 8-hour course and meet other qualifications, they become eligible to apply for a special waiver which allows them to treat addiction with above mentioned medications in an office-based setting. This same law, void of any supporting science, arbitrarily caps the number of addicted patients a physician can treat at any one time to 30 through the first year following certification, expandable to 100 patients thereafter. No other medications have such restrictions, including the prescription drugs people get addicted to and die from. Like many well-intentioned laws, the unintended consequences are significant. https://www.naabt.org/data2000.cfm

Update 7/2016: In 2016 HHS amended the regulation to allow qualifying physicians to apply for permission to help up to 275 patients concurrently. Physicians must reapply every 3 years. https://www.naabt.org/tl/275_patient_limit_increase_HHS_2016.pdf

Update 7/2016: On 7/22/2016 the Comprehensive Addiction and Recovery Act (CARA) of 2016 was signed into law. One of its provisions is to allow Nurse Practitioners and Physician Assistants to obtain a DATA-2000 waiver and prescribe buprenorphine for the treatment of Opioid Use Disorder. Prescribing was previously limited to physicians; however, in 2016, Congress passed the Comprehensive Addiction and Recovery Act (CARA) to expand office-based treatment to allow nurse practitioners and physician assistants to prescribe buprenorphine for opioid addiction physician assistants and nurse practitioners to prescribe buprenorphine for addiction if they meet training and state-specific requirements. http://www.asam.org/magazine/read/article/2016/07/13/congress- passes-cara!-asam-applauds-passage-of-historic-addiction-legislation

In October 2018, the SUPPORT for Patients and Community Act expanded buprenorphine prescribing privilege to qualifying clinical nurse specialists, certified registered nurse anesthetists, and certified nurse midwives.

Prescription Drug Monitoring Program (PDMP)

A PDMP is a statewide electronic database which collects designated data on substances dispensed in the state. The PDMP is housed by a specified statewide regulatory, administrative or law enforcement agency. The housing agency distributes data from the database to individuals who are authorized under state law to receive the information for purposes of their profession. Each state designates a state agency to oversee its PDMP, which may include health departments, pharmacy boards, or state law enforcement. The Alliance of States with Prescription Monitoring Programs (www.nascsa.org/rxMonitoring.htm) maintains a list of state contacts.

The National Alliance for Model State Drug Laws (www.namsdl.org/prescription-monitoring- programs.cfm) provides links to each state's statutes and regulations regarding PDMPs. http://www.deadiversion.usdoj.gov/faq/rx_monitor.htm

BACKGROUND AND OTHER CONSIDERATIONS

BACKGROUND:

None

CONTRAINDICATIONS/EXCLUSIONS/DISCONTINUATION:

All other uses of Buprenorphine & Buprenorphine-Naloxone products are considered experimental/investigational and therefore, will follow Molina's Off-Label policy. Contraindications to

Bunavail (buprenorphine and naloxone buccal film), buprenorphine and naloxone sublingual tablets, Suboxone (buprenorphine and naloxone sublingual film), Zubsolv (buprenorphine and naloxone sublingual tablets) include: hypersensitivity to buprenorphine or naloxone. Contraindications to buprenorphine sublingual tablet include: hypersensitivity to buprenorphine.

OTHER SPECIAL CONSIDERATIONS:

None

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
NA	

AVAILABLE DOSAGE FORMS:

Bunavail FILM 2.1-0.3MG
Bunavail FILM 4.2-0.7MG
Bunavail FILM 6.3-1MG
Buprenorphine HCl SUBL 2MG
Buprenorphine HCl SUBL 8MG
Buprenorphine HCl-Naloxone HCl FILM 12-3MG
Buprenorphine HCl-Naloxone HCl FILM 2-0.5MG
Buprenorphine HCl-Naloxone HCl FILM 4-1MG
Buprenorphine HCl-Naloxone HCl FILM 8-2MG
Suboxone FILM 12-3MG
Suboxone FILM 2-0.5MG
Suboxone FILM 4-1MG
Suboxone FILM 8-2MG
Zubsolv SUBL 0.7-0.18MG
Zubsolv SUBL 1.4-0.36MG
Zubsolv SUBL 11.4-2.9MG
Zubsolv SUBL 2.9-0.71MG
Zubsolv SUBL 5.7-1.4MG
Zubsolv SUBL 8.6-2.1MG

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