Buprenorphine & Buprenorphine-Naloxone for Opioid Dependence
Policy Number: C10899-A

CRITERIA EFFECTIVE DATES:

ORIGINAL EFFECTIVE DATE	LAST REVIEWED DATE	NEXT REVIEW DATE
9/1/2014	2/1/2019	2/1/2020
J CODE	**TYPE OF CRITERIA**	**LAST P&T APPROVAL**
	RxPA	Q2 2019

PRODUCTS AFFECTED:
Zubsolv SUBL (buprenorphine/nalxone SL tab), Suboxone FILM (buprenorphine/naloxone SL film), Bunavail FILM (buprenorphine/naloxone buccal film), buprenorhpine

DRUG CLASS:
Opioid Agonist-Antagonist Analgesics

ROUTE OF ADMINISTRATION:
Buccal, Sublingual,

PLACE OF SERVICE:
Retail Pharmacy

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

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

For all buprenorphine products: Under the Drug Addiction Treatment Act (DATA) codified at 21 U.S.C. 823(g), prescription use of this product in the treatment of opioid dependence is limited to physicians who meet certain qualifying requirements, and who have notified the Secretary of Health and Human Services (HHS) of their intent to prescribe this product for the treatment of opioid dependence and have been assigned a unique identification number that must be included on every prescription.

COMPENDIAL APPROVED OFF-LABELED USES: None

COVERAGE CRITERIA: INITIAL AUTHORIZATION

DIAGNOSIS: opioid use disorder

REQUIRED MEDICAL INFORMATION:

A. OPIOID USE DISORDER:
1. Diagnosis clinically based on history and physical exam findings that support Diagnostic and Statistical Manual of Mental Disorders, 5th ed. DSM-V-TR criteria for Opiate Abuse and Dependence and/or DSM-IV-TR criteria for opioid dependence
   AND
2. (a) FOR STATES WITH PRESCRIPTION DRUG MONITORING PROGRAMS (PDMPs): Prescriber utilized (and will continue to utilize) the applicable State PDMP prior to issuance of a prescription or continuation of therapy request to ensure the member is not concurrently utilizing opioids, benzodiazepines or sedative/hypnotic agents. NOTE: PDMP check is required on date of request and completed within the last 48 hours.
   OR
   (b) FOR STATES WITHOUT PDMPs: Prescriber agrees to review member's records AND/OR perform drug screens on a periodic basis or as necessary to ensure no abuse or diversion of the buprenorphine/naloxone or buprenorphine
   AND
3. Documentation prescriber recommends 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 eight times per year (*or more frequently as appropriate for member) EXCEPTION: If drug screen is POSITIVE for ANY non-prescribed drug of abuse, prescriber must submit an acknowledgement and rationale for requesting continued therapy despite a positive drug screen. Continuation of therapy will not be authorized unless written documentation is submitted for Molina Pharmacy/Medical Director Review
   AND
5. No more than TWO (2) 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 (2) 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 Behavioral Health Disorders ONLY: Prescriber agrees to coordinate or oversee ongoing behavioral health care for co-existing behavioral health disorders
   AND
7. FOR BUPRENORHPINE REQUESTS ONLY: Member is unable to take buprenorphine/naloxone as documented by ONE (1) of the following: (a) Pregnancy or Breastfeeding: Anticipated date of delivery. NOTE: Member may initiate or continue on buprenorphine monotherapy for the duration of the pregnancy OR may transfer to methadone maintenance therapy at the discretion of the Prescriber and/or Molina Medical Director, (b) Moderate to severe hepatic impairment (Child-Pugh B to C), (c) Maintenance therapy: Unable to take naloxone-containing products due to a documented hypersensitivity to naloxone or naltrexone; intolerance, FDA-labeled contraindication, drug-drug interaction, history of toxic side effects that caused immediate or long-term damage
   AND

8. FOR SUBOXONE SL FILM: Rationale for inability to use the preferred Buprenorphine-Naloxone (generic SL tablet) due to: Allergic or hypersensitivity reaction to the generic buprenorphine/naloxone tablets OR Adverse reaction that cannot be managed with the generic buprenorphine/naloxone tablets
   AND
9. FOR BUNAVAIL OR ZUBSOLV REQUESTS: Documented trial of the preferred alternative (buprenorphine-naloxone SL tablet) AND Suboxone SL film

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

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

PRESCRIBER REQUIREMENTS:
FOR OPIOID USE DISORDER: Prescriber meets the qualification certification criteria in the Drug Addiction Treatment Act (DATA) of 2000 and has been issued a unique DEA identification number by the DEA, an "X" waivered DEA license to prescribe buprenorphine products [buprenorphine, Bunavail, Suboxone, buprenorphine/naloxone, or Zubsolv]

MOLINA REVIEWER: Verify Prescriber's "X" waivered DEA license number via The Substance Abuse and Mental Health Services Administration (SAMHSA) Buprenorphine Physician Locator Web site: http://www.samhsa.gov/bupe/lookup-form

AGE RESTRICTIONS:
16 years old and older

GENDER:
Male and female

CONTINUATION OF THERAPY:
A. OPIOID USE DISORDER:
   1. Compliance with Buprenorphine/Naloxone therapy since previous authorization [VERIFIED BY PRESCRIBER SUBMITTED DOCUMENTATION OR PHARMACY CLAIMS DATA]
      AND
   2. Documentation prescriber continues to recommend 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
   3. Prescriber agrees to administer random clinical drug testing a minimum of eight times per year (*or more frequently as appropriate for member) EXCEPTION: If drug screen is POSITIVE for ANY non-prescribed drug of abuse, prescriber must submit an acknowledgement and rationale for requesting continued therapy despite a positive drug screen. Continuation of therapy will not be authorized unless written documentation is submitted for Molina Pharmacy/Medical Director Review
      AND
   4. Urine Drug Screen/Test (UDS/UDT) is POSITIVE* for buprenorphine and/or norbuprenorphine [DOCUMENTATION REQUIRED] *Presence of norbuprenorphine

indicated by a POSITIVE result indicates that the member is taking drug as opposed to adulterating urine sample with tablets or films
AND

5. Substance abuse disorders, untreated or unstable psychiatric conditions, or co-morbid conditions that may interfere with buprenorphine/naloxone compliance are being evaluated/monitored
AND
6. Confirmation of abstinence from opioid medications (including tramadol) via ONE (1) of the following as applicable in accordance to State regulations:
(a) FOR STATES WITH PRESCRIPTION DRUG MONITORING PROGRAMS (PDMPs): Prescriber utilized (and will continue to utilize) the applicable State PDMP prior to issuance of a prescription or continuation of therapy request to ensure the member is not concurrently utilizing opioids, benzodiazepines or sedative/hypnotic agents. NOTE: PDMP check is required on date of request. Prescriber to confirm PDMP was checked today. [DOCUMENTATION REQUIRED]
OR
(b) FOR STATES WITHOUT PDMPs: Prescriber agrees to review member's records AND/OR perform drug screens on a periodic basis or as necessary to ensure no abuse or diversion of the buprenorphine/naloxone or buprenorphine [DOCUMENTATION REQUIRED]
AND
7. FOR BUPRENORHPINE REQUESTS ONLY: Member continues to be unable to take buprenorphine/naloxone as documented by ONE (1) of the following: (a) Pregnancy or Breastfeeding: Anticipated date of delivery. NOTE: Member may initiate or continue on buprenorphine monotherapy for the duration of the pregnancy OR may transfer to methadone maintenance therapy at the discretion of the Prescriber and/or Molina Medical Director, (b) Moderate to severe hepatic impairment (Child-Pugh B to C), (c) Maintenance therapy: Unable to take naloxone-containing products due to a documented hypersensitivity to naloxone or naltrexone; intolerance, FDA-labeled contraindication, drug-drug interaction, history of toxic side effects that caused immediate or long-term damage

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

OTHER SPECIAL CONSIDERATIONS: None

BACKGROUND: None

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

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

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