AdvancedHealth
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Buprenorphine/Naloxone or Buprenorphine for Opioid Use Disorder Drug Use Criteria

Created: 06/2015
Updated: 02/2017, 05/2017, 08/2017, 10/23/17, 08/23/2018, 02/18/2019, 4/22/19, 05/21/2021

Includes:

Suboxone© Sublingual Tablet, Sublingual film	*Buprenorphine/naloxone*
Zubsolv© Sublingual Tablet	*Buprenorphine/naloxone*
Bunavail© Buccal Film	*Buprenorphine/naloxone*
Subutex© Sublingual Tablet	*Buprenorphine*

**All formulations of buprenorphine and buprenorphine/naloxone will require a prior authorization after the initial 30 days for consideration of coverage by Advanced Health. Preference will be given to the least costly formulation of buprenorphine/naloxone or buprenorphine.*

GUIDELINE FOR USE:

1. Does the prescriber have a 'X' waivered DEA license to prescribe buprenorphine products for opioid use disorder?
    a. If yes, continue to 2.
    b. If no, deny as not meeting criteria. An 'X' waiver is required for legal prescribing of buprenorphine products for opioid use disorder.

2. Does the patient have a documented diagnosis of moderate to severe opioid use disorder (defined as ≥4 use disorder criteria by DSM-V)? See the attached DSM-5 Opioid Use Disorder Checklist on page 5.
    a. If yes, continue to 3.
    b. If no, send for MD review.
        i. Is the buprenorphine product being prescribed for documented diagnosis of mild opioid disorder (defined as ≤3 use disorder criteria by DSM-V)?
            1. If yes, is there rationale to why naltrexone (either long-acting injection or oral) or psychosocial treatment alone cannot be used?
                a. If yes, continue to 3.
                b. If no, deny as not meeting criteria. Per UpToDate first-line medication for mild opioid use disorder is long-acting naltrexone rather than an opioid agonist. Psychosocial treatment alone is a reasonable alternative for highly motivated patients who prefer nonmedication treatment, but since naltrexone is a generally safe and well-tolerated medication, working with such patients to encourage its use is advisable. Per the American Society of Addictive Medicine, pharmacologic treatment may not be appropriate for all patients along the entire opioid use disorder continuum (i.e., for individuals with new onset, mild opioid use disorder).
            2. If no, deny as not meeting criteria. Off-label use of buprenorphine is not a covered benefit under the Oregon Health Plan.

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ii. Is the buprenorphine product being prescribed for a painful condition?
    1. If yes, deny as not meeting criteria. Coverage of buprenorphine products for painful conditions is not a covered benefit for Advanced Health members. Refer to Advanced Health formulary for covered alternatives.
    2. If no, continue to 4.

3. Does the patient have any of the following:
    - Currently taking naltrexone
    - Currently taking opioid analgesics
    - Currently experiencing acute opioid withdrawal
    - Known previous allergic response to buprenorphine or naloxone
    - Under the age of 16 years
    - Currently prescribed other controlled substances (stimulants, benzodiazepines, hypnotic sedatives)

    a. If no, continue to 5.
    b. If yes, submit for MD review.
        i. Has a controlled substance taper plan, other than opioid analgesics, been submitted and honored with PA request?
            1. If yes, continue to 5.
            2. If no, deny as not meeting criteria.
        ii. If concurrent use of opioid and buprenorphine containing product is requested, has referral been made to ADAPT/OTP?
            1. If yes, approve up to 4 weeks, dependent on patient enrollment in program.
            2. If no, deny as not meeting criteria.

4. Is the dose of buprenorphine prescribed less than 24 mg/day and quantity limited to no more than 3 tablets/films per day?
    a. If yes, continue to 5.
    b. If no, and request if for more than 24mg/day, submit for MD review. FDA approved prescribing information supports a maximum dose of 24mg/day. Doses higher than buprenorphine 24mg/naloxone 6mg have not been demonstrated to provide clinical advantage.
    c. If no, and request is for more than quantity limit of 3 per day, deny as not meeting criteria. Request the provider to change to another covered dosage that would be less than 3 tablets/film per day.

5. Has a current urine drug screen (within 90 days) been submitted with the request?
    a. If yes, continue to 6.
    b. If no, deny as not meeting criteria. A current urine drug screen is required.

6. Is there documentation of the Oregon Prescription Drug Monitoring Program being queried to ensure no concurrent dispensing other controlled substances (stimulants, opioids, benzodiazepines, hypnotic sedatives)?
    a. If yes, continue to 7.
    b. If no, deny as not meeting criteria and recommend provider check the Oregon Prescription Drug Monitoring Program.

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7. Is the patient enrolled in the ADAPT Motivational Stepped Care Model or comparable behavioral health support for opioid use disorder?
    a. If yes, continue to 8.
    b. If no, deny as not meeting criteria and provide contact information to enroll member with ADAPT services or comparable behavioral health support.

8. Is the patient filling prescriptions at more than one pharmacy?
    a. If yes, deny as not meeting criteria and request provider and member determine single pharmacy for prescription dispensing.
    b. If no, continue to 9.

9. Is the patient pregnant?
    a. If yes, approve buprenorphine with a maximum dose of 24 mg/day for 3 fills of 30 days (total of 90 days of therapy then a renewal PA will be required. If provider requests smaller day supply prescriptions the number of fills may be adjusted to allow for continuous filling for the 90-day period)
    b. If no, and request is for buprenorphine/naloxone, approve buprenorphine/naloxone with a maximum dose of 24 mg/day for 3 fills of 30 days (total of 90 days of therapy then a renewal PA will be required. If provider requests smaller day supply prescriptions the number of fills may be adjusted to allow for continuous filling for the 90-day period.)
    c. If no, and request is for buprenorphine then request change to buprenorphine/naloxone and approve as stated in 9b.

    **Renewal PA required after 90 days to ensure continued engagement with the ADAPT Motivational Stepped Care Model or comparable behavioral health support for opioid use disorder and that member continues to meet criteria for coverage. There is no duration of therapy limit on buprenorphine/naloxone therapy. Buprenorphine therapy will be allowed for pregnant patients and a request to transition to buprenorphine/naloxone will be made when patient is no longer pregnant.*

Renewals:

1. Does the patient still meet all the criteria stated above?
    a. If yes, continue to 2.
    b. If no, deny as not meeting criteria.

2. Has a current urine drug screen (within 90 days) been submitted to ensure member is abstaining from other controlled substances and to support continued use of buprenorphine?
    a. If yes, continue to 3.
    b. If no, deny as not meeting criteria. Current urine drug screen is required.

3. Is the patient pregnant?
    a. If yes, approve buprenorphine with a maximum dose of 24 mg/day for 90 days.
    b. If no, approve buprenorphine/naloxone with a maximum dose of 24 mg/day of buprenorphine for 90 days.

Approved by Advanced Health Pharmacy and Therapeutics Committee on 08/28/2017, 10/23/17, 08/27/2018, 02/18/19, 4/22/19, 6/9/2021

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**Renewal PA required after each 90 days of therapy to ensure continued engagement with the ADAPT Motivational Stepped Care Model or comparable behavioral health support for opioid use disorder and that member continues to meet criteria for coverage. There is no duration of therapy limit on buprenorphine/naloxone therapy. Buprenorphine therapy will be allowed for pregnant patients and a request to transition to buprenorphine/naloxone will be made when patient is no longer pregnant.*

Rationale:

Due to the potential for diversion, misuse, and prescribing restriction for buprenorphine products, drug use criteria was developed to promote safe, evidence-based prescribing of buprenorphine and buprenorphine/naloxone for opioid use disorder and to align treatment with Clinical Guidelines for the Use of Buprenorphine in the Treatment of Opioid Addiction and ADAPT Medication Assisted Treatment Protocol.

FDA Approved Indications:

The FDA approved indication of buprenorphine sublingual tablet is for the treatment of opioid use disorder.

The FDA approved indication of buprenorphine/naloxone sublingual tablet is for the maintenance treatment of opioid use disorder.

The FDA approved indication of buprenorphine/naloxone sublingual film is for the treatment of opioid use disorder.

**Of note, the FDA approved prescribing information for buprenorphine/naloxone and buprenorphine supports use as part of a complete treatment plan to include counseling and psychosocial support.*

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DSM-5 Opioid Use Disorder Checklist[102]

Patient's Name: _____ Date of Birth: _____

Worksheet for DSM-5 Criteria for Diagnosis of Opioid Use Disorder

DIAGNOSTIC CRITERIA (Opioid use disorder requires that at least 2 criteria be met within a 12-month period.)	MEETS CRITERIA? Yes OR No	NOTES/SUPPORTING INFORMATION
1. Opioids are often taken in larger amounts or over a longer period of time than intended.		
2. There is a persistent desire or unsuccessful efforts to cut down or control opioid use.		
3. A lot 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 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 use despite knowledge of having a persistent or recurrent physical or psychological problem that is likely to have been caused or exacerbated by opioids.		
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) markedly diminished effect with continued use of the same amount of an opioid		
11. Withdrawal,* as manifested by either of the following: (a) the characteristic opioid withdrawal syndrome (b) the same (or a closely related) substance is taken to relieve or avoid withdrawal symptoms		

*This criterion is not met for individuals taking opioids solely under appropriate medical supervision.

Severity: mild = 2–3 symptoms; moderate = 4–5 symptoms; severe = 6 or more symptoms

Signed: _____ Date: _____

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2. Zubsolv© Prescribing Information
3. Suboxone© Prescribing Information
4. Bunavail© Prescribing Information
5. Clinical Guidelines for the Use of Buprenorphine in the Treatment of Opioid Addiction. 2004
6. Brooner, R. K. and M. Kidorf (2002). "Using behavioral reinforcement to improve methadone treatment participation." Sci Pract Perspect **1**(1): 38-47.
7. ADAPT Motivation Stepped Care (MSC): A protocol for office based buprenorphine assisted recovery from opioid use disorder.
8. ADAPT Motivational Stepped Care graphic
9. The American Society of Addiction Medicine (ASAM) National Practice Guideline for the Treatment of Opioid Use Disorder. https://www.asam.org/Quality-Science/quality/2020-national-practice-guideline
10. Substance Abuse and Mental Health Services Administration (SAMHSA) Medications for Opioid Use Disorder for Healthcare and Addiction Professionals, Policymakers, Patients, and Families Updated 2020 Treatment Improvement Protocol (TIP) 62. https://store.samhsa.gov/sites/default/files/SAMHSA_Digital_Download/PEP20-02-01-006_508.pdf
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Approved by Advanced Health Pharmacy and Therapeutics Committee on 08/28/2017, 10/23/17, 08/27/2018, 02/18/19, 4/22/19, 6/9/2021