

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

Created: 06/2015

Updated: 02/17, 05/17, 08/17, 10/23/17, 08/23/18, 02/18/19, 4/22/19, 05/21/21, 10/7/21

Includes:

Suboxone® Sublingual Tablet, Sublingual film	<i>Buprenorphine/naloxone</i>
Zubsolv® Sublingual Tablet	<i>Buprenorphine/naloxone (nonformulary)</i>
Bunavail® Buccal Film	<i>Buprenorphine/naloxone (nonformulary)</i>
Subutex® Sublingual Tablet	<i>Buprenorphine</i>
Sublocade® Injection	<i>Buprenorphine</i>

**All formulations of buprenorphine and buprenorphine/naloxone will require a prior authorization after the initial 30 days for consideration of coverage by Advanced Health.*

GUIDELINE FOR USE:

1. Does the prescriber have a 'X' waived 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)? ***Chart notes from initial diagnosis must support diagnosis of opioid use disorder.** See the attached DSM-5 Opioid Use Disorder Checklist on page 5.
 - a. If yes, continue to 6.
 - b. If no, continue to 3.
3. Is the buprenorphine product being prescribed for documented diagnosis of mild opioid disorder (defined as 2-3 use disorder criteria by DSM-V)?
 - a. If yes, continue to 4.
 - b. If no, continue to 5.
4. Is there rationale to why naltrexone (either long-acting injection or oral) or psychosocial treatment alone cannot be used?
 - a. If yes, continue to 6.
 - b. If no, approve for up to 30 days Request a taper plan of buprenorphine product and recommend change to naltrexone and/or psychosocial treatment. 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).

5. Is the buprenorphine product being prescribed for a painful condition?
 - a. If yes, and there is a well-documented opioid tapering plan failure for a patient that was previously on opioids with an MED \geq 90, send for MD review. (OMB Policy State on chronic pain management).
 - b. If yes, and the patient is not at MED \geq 90, may approve for up to 30 days. Please provide a taper plan. Without a taper plan in place with the next prior authorization request, we will be unable to continue coverage of this medication. The buprenorphine products in this drug use are not FDA approved for chronic pain and opiates for chronic low back pain are not a covered benefit under the Oregon Health Plan. Please see Guideline Note 56 Non-Interventional Treatments for Conditions of the Back and Spine and Guideline Note 60 Opioids for Conditions of the Back and Spine.
 - c. If no, deny as not meeting criteria. The buprenorphine products listed in this drug use criteria are only FDA-approved for opioid use disorder. Off-label use of medication is not a covered benefit under the Oregon Health Plan.

6. Is the patient currently taking opioid analgesics or other controlled substances or illicit drugs?
 - a. If yes, continue to 7.
 - b. If no, continue to 8.

7. Has a controlled substance taper plan, other than opioid analgesics, been submitted and honored with PA request or is there clinical rationale and/or behavioral health involvement that supports the benefit of concurrent therapy outweighing the risk?
 - a. If yes, continue to 8.
 - b. If yes, concurrent use of opioid and buprenorphine containing product is requested, has referral been made to ADAPT/OTP?
 - i. If yes, approve up to 30 days, dependent on patient enrollment in program. *Note: enrollment may be problematic in areas of our network.
 - ii. If no, approve for up to 14 days. Request a referral be made to ADAPT/OTP. Referral will be required for consideration of ongoing coverage.
 - c. If no, approve for up to 30 days. Request a taper plan and/or behavioral health consult/assessment for consideration of ongoing coverage.

8. Is the patient 16 years old or younger?
 - a. If yes, send for MD review.
 - b. If no, continue to 9.

9. Is the requested medication Sublocade (buprenorphine injection)?
 - a. If yes, continue to 10.
 - b. If no, continue to 12.

10. Is the prescribed signed up for the Sublocade REMS program and has provided attestation that they will follow proper storage and administration?
 - a. If yes, continue to 11.

-
- b. If no, deny as not meeting criteria. The prescriber must be signed up for the Sublocade REMS program. Storage requirements include refrigeration that is locked and only accessible by the prescriber. There needs to be policies and procedures in place to ensure medication is only dispensed to the healthcare provider.
- 11.** Has the patient had at least 7-days of a transmucosal buprenorphine product?
- If yes, continue to 14.
 - If no, is there a plan to ensure patient has had the minimum 7-days of transmucosal buprenorphine product?
 - If yes, continue to 14.
 - If no, deny as not meeting criteria. FDA labeling states Sublocade is indicated to treat moderate to severe OUD in patients who have initiated treatment with a buprenorphine containing product, followed by dose adjustment for a minimum of 7 days.
- 12.** Is the dose of transmucosal buprenorphine prescribed ≤ 24 mg/day?
- If yes, continue to 13.
 - 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.
- 13.** Is the quantity limited to no more than 3 tablets/films per day?
- If yes, continue to 14.
 - If no, is the patient stable on therapy?
 - If yes, continue to 14.
 - If no, approve up to 30 days and request change to different dosage form to be less than 3 tablets/films per day.
- 14.** Has a current urine drug screen (within 90 days) been submitted with the request and are the results consistent to prescription medication? *If positive for illicit drugs, will require UDS looking for buprenorphine.
- If yes, are there any positive results that are not explained by a prescription?
 - If yes, approve for up to 30 days and request detailed urine drug screen looking for buprenorphine (and naloxone, if applicable).
 - If no, continue to 15.
 - If no, approve for up to 30 days and request a current urine drug screen.
- 15.** 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)?
- If yes, continue to 16.
 - If no, approve for up to 30 days. PDMP check is a requirement for consideration of ongoing coverage.
- 16.** Is the patient enrolled in the ADAPT Motivational Stepped Care Model or comparable behavioral health support for opioid use disorder?
- If yes, continue to 17.

- b. If no, approve for up to 30 days and recommend patient engage with behavioral health and/or ADAPT.

17. Is the patient filling prescriptions at more than one pharmacy?

- a. If yes, approve for up to 30 days and request provider and member determine single pharmacy for prescription dispensing.
- b. If no, approve for up to 90 days.

**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 for patients that continue to meet criteria.*

Renewals:

1. Does the patient still meet all the criteria stated above?
 - a. If yes, continue to 2.
 - b. If no, approve for up to 30 days and request a taper plan.
2. Has a current urine drug screen (within the past year) been submitted to ensure member is abstaining from other controlled/illicit substances and to support continued use of buprenorphine?
 - a. If yes, may approve up to 12 months on a case-by-case basis.
 - b. If no, approve for up to 30 days. Current urine drug screen is required.

**There is no duration of therapy limit on buprenorphine/naloxone therapy for patients that continue to meet criteria.*

Rationale:

Due to the potential for diversion, misuse, and prescribing restriction for buprenorphine products, drug use criterion 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.
- The FDA approved indication of Sublocade is for the treatment of moderate to severe 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.*



DSM-5 Opioid Use Disorder Checklist¹⁰²

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: _____

Opioid Use Disorder

Diagnostic Criteria

- A. A problematic pattern of opioid use leading to clinically significant impairment or distress, as manifested by at least two of the following, occurring within a 12-month period:
1. Opioids are 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 a 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 caused 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 an opioid.
 - c. **Note:** 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 (refer to Criteria A and B of the criteria set for opioid withdrawal, pp. 547–548).
 - b. Opioids (or a closely related substance) are taken to relieve or avoid withdrawal symptoms.
 - c. **Note:** This criterion is not considered to be met for those individuals taking opioids solely under appropriate medical supervision.

Specify if:

- **In early remission:** After full criteria for opioid use disorder were previously met, none of the criteria for opioid use disorder have been met for at least 3

months but for less than 12 months (with the exception that Criterion A4, “Craving, or a strong desire or urge to use opioids,” may be met).

- **In sustained remission:** After full criteria for opioid use disorder were previously met, none of the criteria for opioid use disorder have been met at any time during a period of 12 months or longer (with the exception that Criterion A4, “Craving, or a strong desire or urge to use opioids,” may be met).

Specify if:

- **On maintenance therapy:** This additional specifier is used if the individual is taking a prescribed agonist medication such as methadone or buprenorphine and none of the criteria for opioid use disorder have been met for that class of medication (except tolerance to, or withdrawal from, the agonist). This category also applies to those individuals being maintained on a partial agonist, an agonist/antagonist, or a full antagonist such as oral naltrexone or depot naltrexone.
- **In a controlled environment:** This additional specifier is used if the individual is in an environment where access to opioids is restricted.

Coding based on current severity /remission : Note for ICD-10-CM codes: If an opioid intoxication, opioid withdrawal, or another opioid-induced mental disorder is also present, do not use the codes below for opioid use disorder. Instead, the comorbid opioid use disorder is indicated in the 4th character of the opioid-induced disorder code (see the coding note for opioid intoxication, opioid withdrawal, or a specific opioid-induced mental disorder). For example, if there is comorbid opioid-induced depressive disorder and opioid use disorder, only the opioid-induced depressive disorder code is given, with the 4th character indicating whether the comorbid opioid use disorder is mild, moderate, or severe: F11.14 for mild opioid use disorder with opioid-induced depressive disorder or F11.24 for a moderate or severe opioid use disorder with opioid-induced depressive disorder.

Specify current severity /remission :

- **305.50 (F11.10) Mild:** Presence of 2–3 symptoms.
- **(F11.11) Mild, In early remission**
- **(F11.11) Mild, In sustained remission**
- **304.00 (F11.20) Moderate:** Presence of 4–5 symptoms.
- **(F11.21) Moderate, In early remission**
- **(F11.21) Moderate, In sustained remission**
- **304.00 (F11.20) Severe:** Presence of 6 or more symptoms.
- **(F11.21) Severe, In early remission**
- **(F11.21) Severe, In sustained remission**

References:

1. Subutex© Prescribing Information. Updated 2/2018
2. Zubsolv© Prescribing Information. Updated 3/2021
3. Suboxone© Prescribing Information. Updated 3/2021
4. Bunavail© Prescribing Information. Updated 2/2018
5. Sublocade© Prescribing Information. Updated 6/2021
6. Clinical Guidelines for the Use of Buprenorphine in the Treatment of Opioid Addiction. 2004
7. Brooner, R. K. and M. Kidorf (2002). "Using behavioral reinforcement to improve methadone treatment participation." Sci Pract Perspect 1(1): 38-47.
8. ADAPT Motivation Stepped Care (MSC): A protocol for office based buprenorphine assisted recovery from opioid use disorder.
9. ADAPT Motivational Stepped Care graphic
10. 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>
11. 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
12. UpToDate Approach to treating opioid use disorder. Literature current through April 2021. Topic last updated May 5, 2021. Accessed 5/21/21.
13. Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition. Section II: Diagnostic Criteria and Codes. Substance-Related and Addictive Disorders. Opioid Use Disorder. Accessed 9/16/2021.
14. Oregon Medical Board: Pain Management. <https://www.oregon.gov/omb/board/Philosophy/Pages/Pain-Management.aspx> Accessed 9/28/21.