

Medication Treatment Guidelines for Substance Use Disorders (SUDs) - Transmucosal Buprenorphine

Medical policy no. 65.20.00.10-3

Effective: TBD

Related medical policies:

- Sublocade (65.20.00.E5)

Note: New-to-market drugs included in this class based on the Apple Health Preferred Drug List are non-preferred and subject to this prior authorization (PA) criteria. Non-preferred agents in this class require an inadequate response or documented intolerance due to severe adverse reaction or contraindication to at least TWO preferred agents. If there is only one preferred agent in the class documentation of inadequate response to ONE preferred agent is needed. If a drug within this policy receives a new indication approved by the Food and Drug Administration (FDA), medical necessity for the new indication will be determined on a case-by-case basis following FDA labeling.

Background:

Substance use disorders (SUDs) impacts the lives of millions of Americans in the general population, including individuals who are enrolled in the Medicaid program. The use of medications in combination with behavioral therapies to treat SUDs can help reestablish normal brain functioning, reduce cravings and prevent relapse. Multiple studies demonstrate that medications, opioid agonists in particular, are the most effective treatment for opioid use disorders (OUD). The medications used can manage the symptoms of substance use withdrawal that often prompt relapse and allow individuals to utilize other treatments, such as behavior therapy.

It is the goal of the Washington State Health Care Authority (HCA) to maximize opportunities for patients to receive effective and successful treatment for SUDs. Coverage of FDA approved medications, or those with a compendia-approved indication for the treatment of SUDs increases access and provides patients with additional flexibility in managing their recovery.

HCA and its contracted Managed Care Organizations (MCO) will consider medications for the treatment of SUDs medically necessary whether prescribed in an outpatient, emergency room or hospital setting. (The medications may also be started in a hospital).

Medical necessity

Drug	Medical Necessity
<p><u>Preferred</u> buprenorphine-naloxone sublingual tablet (generic) Suboxone sublingual film</p>	<p>Preferred buprenorphine-naloxone combination products do not require authorization and are considered medically necessary when used for the treatment of:</p> <ul style="list-style-type: none"> • Moderate to severe opioid use disorder
<p><u>Non-Preferred</u> buprenorphine sublingual tablet (generic) buprenorphine-naloxone sublingual film (generic) Zubsolv sublingual tablet</p>	<p>Buprenorphine sublingual tablets are considered medically necessary when used for the treatment of</p> <ul style="list-style-type: none"> • Moderate to severe opioid use disorder in the setting of pregnancy or intolerance to buprenorphine-naloxone

Bunavail buccal film

Clinical guidelines:

Transmucosal Buprenorphine	Clinical Criteria
<p>buprenorphine (monotherapy)</p>	<p>Buprenorphine monotherapy may be considered medically necessary when ONE of the following are met:</p> <ol style="list-style-type: none"> 1. Patient is currently pregnant or recently gave birth and plans to breast feed for up to 12 months after delivery <ol style="list-style-type: none"> a. Confirmation of pregnancy by lab test and expected delivery date are required for authorization. Lab test is not required for providers who are managing the pregnancy. <ol style="list-style-type: none"> i. For pregnant patients, pharmacies may submit an expedited authorization (EA) code (85000000077) to allow a 28-day supply, max 32 mg/day for up to 12 months b. For patients who are not breastfeeding after delivery, patients should be transitioned to a buprenorphine-naloxone combination product; OR 2. Patient has experienced a documented serious allergic reaction (e.g., urticaria, angioedema, or anaphylaxis) or serious idiosyncratic reaction to the buprenorphine-naloxone combination product; OR 3. Patient continues to experience nausea or daily headache after a 7-day trial of BOTH of the following: <ol style="list-style-type: none"> a. Buprenorphine-naloxone sublingual tablet or film; AND b. Buprenorphine-naloxone buccal film (Bunavail) <p>Buprenorphine as a monotherapy will initially be approved for a seven (7) day supply until the patient demonstrates evidence of stability.</p> <ul style="list-style-type: none"> • Up to 14 days can be prescribed after the first month if clinically stable. Up to 30 days can be prescribed after the second month if clinically stable. • If travel burden or other circumstances limit the patient’s ability to receive the prescription every 2 weeks, an exception requesting a longer duration can be made to the patient’s health plan. • If previously stable on buprenorphine-naloxone and transitioning to buprenorphine monotherapy, the client can receive up to the standard day supply limit (e.g., if the patient was receiving a 30-day supply of buprenorphine/naloxone, they can begin with a 30-day supply of buprenorphine).
<p>Medication for OUD (MOUD): <i>Guidelines:</i></p> <ul style="list-style-type: none"> • Any provider with a SAMHSA approved waiver may prescribe a buprenorphine-containing product. Providers should evaluate the risks and benefits of prescribing buprenorphine to patients less than 16 	

years of age with an OUD. Guidelines from the American Academy of Pediatrics support the use of medication for opioid use disorder in children and adolescents.

- Given the importance of opioid substitution therapy to treatment success, and the need to reduce the risk of opioid overdose, enrollment in a Department of Social and Health Services (DSHS) approved treatment facility is not a requirement for initiating treatment with buprenorphine.
- Recognizing the chronic nature of opioid addiction, additional interventions that address the mental health and social needs of the patient should be addressed. Patients who are unable to achieve a reduction in their use of illicit opioids and improve their functional status without engaging in a formal treatment program should be referred to an opioid treatment program, if available.
- The Washington Prescription Monitoring Program (PMP) must be accessed and reviewed for each patient before and at the time of buprenorphine induction.

Documentation Requirements:

Initiation of MOUD:

- A complete medical history, including drug and alcohol use, and mental health history (including overdose or suicide attempts) should be obtained in a reasonable time frame.
- Similarly, a physical exam should be performed and documented when practical given the patient's circumstances.
- Patients with a history of a prior overdose or suicide attempt are at increased risk for recurrence. Care for these patients should include discussing suicide and overdose safety plans and the danger of opioids. This group of patients should also be prescribed naloxone and given information about the National Suicide Prevention Lifeline 1-800-273-8255 or the 24-hour crisis line number 1-866-427-4747.

First Six (6) Months:

- Point of care (POC) urine drug screens, or random call backs of patients requesting they return to the clinic within a specified time frame for a pill count or urine drug screen should be considered at least every month during the first six (6) months for patients.
- POC urine drug screens should include testing for buprenorphine, methadone, oxycodone benzodiazepines, amphetamine/methamphetamine, cocaine and others. (It is recognized that most POC urine drug screens do not test for all of the most commonly used benzodiazepines.) Testing for barbiturates, THC and other substances should be guided by medical necessity. Documentation should support the request for testing of additional substances. Serial quantitative testing is not considered medically necessary and will not be covered. For limits on urine drug screen testing, see the fee-for-service (FFS) [Physician-related services/health care billing guide](#) or contact patient's Apple Health managed care plan(s).
- The PMP database must be checked at three (3) month intervals for the first six (6) months and then at the provider's discretion but no less frequently than every six (6) months for patients receiving ongoing maintenance treatment.

After Six (6) Months:

After the first six (6) months of treatment and every six (6) months thereafter:

- POC urine drug screens or pill counts can be performed at the discretion of the provider but no less often than every six (6) months
- After six (6) months, if the patient is stable, the PMP must be checked at a minimum of every six (6) months.

- Screenings for depression and anxiety must be performed twice a year and documented in the patient’s chart, unless the patient is receiving treatment for either of these conditions in which case they should be repeated at the discretion of the provider.

Initial Prescription Requirements:

- Patients may not receive more than a seven (7) day supply of medication at the time of induction.
- An order for a urine drug screen is not required with the initial request for buprenorphine, but should be performed during the first month of treatment.
- Patients with significant untreated psychiatric comorbidity or those with a comorbid dependence on high dose benzodiazepines or other CNS depressants should be co-managed with an addiction medicine physician or a prescribing mental health provider if available. Concurrent use of benzodiazepines is not a contraindication to therapy with buprenorphine.

Follow-Up Requirements in the First Six (6) Months:

- Patients are required to be seen within one (1) week of starting buprenorphine and then weekly for the first four (4) weeks of treatment unless this poses an undue hardship on the patient. For physicians and patients in rural areas where there is not ready access to transportation, the week 3 and week 4 visit may be conducted by phone. A fourteen (14) day supply of medication may be prescribed in these instances. These phone visits should be scheduled at the time of the 2-week visit. The need and indication for conducting phone visits to replace in person visits must be clearly documented in the medical record. Telephone visits are not a reimbursable service.
- A POC urine drug screen documenting the buprenorphine is being taken should be collected during the first month of treatment.
- In addition to buprenorphine treatment, prescribing providers should provide brief intervention and motivational interviewing techniques to help the patient set self-management goals that promote recovery. Visiting in the primary care setting with the provider, mental health professional or care team coordinator are all acceptable types of follow up. If follow up visits are not with the prescribing practitioner, the prescriber must assure visits occurred and are clearly documented in the patient’s chart.
- The frequency of follow up visits after the first month should occur at least monthly for the 1st 6 months and then at the discretion of the provider.
- For non-pregnant patients requesting buprenorphine monotherapy, clinical documentation of witnessed hives, angioedema or anaphylaxis must be provided. Alternatively, documentation of nausea or headache with at least 2 formulations of buprenorphine-naloxone (at least one buccal film) is required.
- Buprenorphine as a monotherapy will only be approved for dispensing in 28 day supplies for up to 12 months with a maximum dose of 32 mg/day.
- See table below for minimum required visit frequency and dosing limits for the first three (3) months:

Visit Type	Follow-Up Interval	Medications dispensed (maximum of 32mg/day without authorization)
Induction	Within 7 days	Maximum 7 days
Weeks 2 through 4	Weekly visits	Maximum 7 days (see note above regarding rural areas)
Weeks 5 through 8	Visits every 2 to 4 weeks	Maximum 14 days

Week 9 and beyond	Visits at providers discretion (see note above regarding rural areas)	14-30-day supply
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ADDITIONAL INFORMATION:

- Patients may remain on MOUD for as long as they are stable and demonstrate clinical improvement.
- Patients who remain unstable and demonstrate continued use of other illicit drugs after stabilization on buprenorphine, should receive additional or increased intensity of services to achieve abstinence from illicit drugs. If on site services do not exist to meet the need for higher intensity services, patients should be referred to a licensed Opioid Treatment Program (OTP), a chemical dependency professional or to an addiction medicine physician to determine appropriate level of care.
- Patients should be maintained on the dose necessary to achieve a reduction of their symptoms and abstinence or a reduction in their use of opioids. It is recognized that some patients may require doses above 16 mg to achieve this state. Requests for doses greater than dose limits require prior authorization.
- Recognizing that certain groups of patients are at a higher risk of overdose than others (e.g. people who have co-existing serious mental illness or those who may be homeless) clinical strategies that allow same day or near same day access to buprenorphine induction with minimal barriers for patients are encouraged.
- The prescribing physician should closely monitor use of other opioids or controlled substances while being treated with buprenorphine. Unless prescribed as the result of an emergency, patients should consult with and receive approval from their buprenorphine prescriber for any medically necessary use of other opioids during the course of their treatment.
- There is no lifetime limit on the duration of buprenorphine treatment.
- It is also recognized that patients with severe OUD may need to be seen daily or several times a week during induction and stabilization. Pharmacies are allowed to bill multiple fills for the 1st month of treatment.
- For questions regarding this clinical policy, please contact:
Apple Health Pharmacy Policy Mailbox at applehealthpharmacypolicy@hca.wa.gov

Monitoring for Compliance:

- Full record reviews may be requested by HCA or MCO staff if there are concerns regarding the appropriateness of continued buprenorphine treatment in a particular patient.
- Representatives of HCA or the patient’s MCO will also periodically review records of patients in the Prescription Monitoring Program to assure they are not receiving additional opioids or other types of controlled substances from other providers.

Dosage and quantity limits

Drug Name	Dose Limits
Buprenorphine Hcl sublingual tablet	32 mg per day
buprenorphine/naloxone sublingual film (generic, Suboxone) sublingual tablet	32 mg/8 mg per day
buprenorphine/naloxone sublingual tablet	32 mg/ 8mg per day
Bunavail® buccal film	16.8 mg/2.8 mg per day

Zubsolv® sublingual tablet	22.8 mg/5.6mg per day
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References

1. AAP COMMITTEE ON SUBSTANCE USE AND PREVENTION.
2. Medication-Assisted Treatment of Adolescents with Opioid Use Disorders. *Pediatrics*. 2016; 138(3):e20161893
3. Medications for Opioid Use Disorder. Treatment Improvement Protocol (TIP) Series 63. HHS Publication No. (SMA) 18-5063. Rockville, MD: Substance Abuse and Mental Health Services Administration, 2018. <https://store.samhsa.gov/product/SMA18-5063FULLDOC>
4. Centers for Disease Control and Prevention. Drug Overdose in the United States: Fact Sheet, Home and Recreational Safety, accessed on January 9, 2018 from <http://www.cdc.gov/homeandrecreationalafety/overdose/facts.html>
5. American Society of Addiction Medicine (for buprenorphine information). <http://www.asam.org/>
6. https://www-micromedexsolutions-com.offcampus.lib.washington.edu/micromedex2/librarian/CS/318013/ND_PR/evidencexpert/ND_P/evidencexpert/DUPLICATIONSHIELDSYNC/C02129/ND_PG/evidencexpert/ND_B/evidencexpert/ND_AppProduct/evidencexpert/ND_T/evidencexpert/PFActionId/evidencexpert.IntermediateToDocumentLink?docId=2299&contentSetId=31&title=BUPRENORPHINE%2FNALOXONE&servicesTitle=BUPRENORPHINE%2FNALOXONE#

History

Date	Action and Summary of Changes
9.29.2020	Restructure to clarify buprenorphine monotherapy requires a PA, while buprenorphine-naloxone does not
10.14.2019	Updated clinical criteria for buprenorphine (monotherapy) to include criteria for confirmation of pregnancy.
09.18.2019	Updated to match other opioid policies
07.01.2019	Added breastfeeding criteria to clinical criteria; Updated days supply limits;
10.03.2018	Updated allergic reaction criteria and added intolerance criteria to clinical criteria
09.20.2018	New Policy

Transmucosal Buprenorphine

Please provide the information below, please print your answer, attach supporting documentation, sign, date, and return to our office as soon as possible to expedite this request. **Without this information, we may deny the request in seven (7) working days.**

Patient	Date of birth	ProviderOne ID	
Pharmacy name	Pharmacy NPI	Telephone number	Fax number
Prescriber	Prescriber NPI	Telephone number	Fax number
Medication and strength		Directions for use	Qty/Days supply

1. Is this request for a continuation of therapy? Yes No
 If yes, is there documentation of a positive clinical benefit? Yes No

2. Indicate patient's diagnosis:
 Moderate to severe opioid use disorder
 Other. Specify: _____

3. Select from the following for your patient and complete associated question(s):

Patient is pregnant. Estimated delivery date (EDD): _____
 Was pregnancy confirmed with a lab test by the provider? Yes No
 Is buprenorphine prescriber managing patient's pregnancy? Yes No
 Has patient been stable on buprenorphine/naloxone for at least 8 weeks? Yes No

Patient is breastfeeding. Delivery date: _____

Patients approved based on breastfeeding, will be approved for 12 months following delivery. Transition to a buprenorphine/naloxone combination product is required for ongoing treatment thereafter.

Patient has experienced a documented serious allergic or idiosyncratic reaction to the buprenorphine/naloxone combination product. **Chart notes documenting reaction are required.**

Patient has continued to experience severe nausea or daily headache after 7day trial of buprenorphine/naloxone sublingual tablet and buccal film formulations.
 Indicate formulations tried for at least 7 days (check all that apply):
 Buccal film
 Sublingual tab or film

4. **Best practice is to limit patients to a 7-day supply at a time for the first month of treatment.**
 Indicate the intended day supply per fill for your patient: 7 day 14 day 28 day

If over a 7 day supply is indicated:

- Is the reason due to transportation complications? Yes No
 If no, provide reason: _____
- Has patient demonstrated evidence of stability (8 weeks of treatment) taking buprenorphine monotherapy and/or buprenorphine/naloxone? Yes No
 If yes, how long has patient been clinically stable? _____

Prescriber signature	Prescriber specialty	Date
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Notice Prohibiting Rediscovery of Alcohol or Drug Treatment Information

This information has been disclosed to you from records protected by Federal confidentiality rules (42 CFR part 2). The Federal rules prohibit you from making any further disclosure of this information unless further disclosure is expressly permitted by the written consent of the person to whom it pertains or as otherwise permitted by 42 CFR part 2. A general authorization for the release of medial or other information is NOT sufficient for this purpose. The Federal rules restrict any use of the information to criminally investigate or prosecute any alcohol or drug abuse patient.