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

WA.PHAR.62 MAT Buprenorphine Products

Effective: November 1, 2019

Related medical policies:

- **Medication Treatment Guidelines for Substance Use Disorders (SUDs) – Naltrexone Containing Products**

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.

Medical necessity

Medication Treatment for Substance Use Disorder
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 medications FDA approved or those that are listed as an approved indication in a pharmacologic compendia to treat SUDs increases the number of access points for treatment 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).

Clinical guidelines:

Buprenorphine Containing Products	
Buprenorphine containing products reduce or eliminate opioid withdrawal symptoms and opioid cravings. Because buprenorphine is a partial agonist, a partial receptor activator, the risk of overdose is less than with a full agonist like methadone. It is available for sublingual, buccal, subcutaneous injection and as an intradermal implant. Many formulations are combined with naloxone in an effort to deter diversion or abuse of the medication by causing a withdrawal reaction if it is intravenously injected by individuals dependent on opioids.	
buprenorphine (monotherapy)	Buprenorphine monotherapy for clients, who meet DSM 5 criteria for moderate or severe opioid use disorder, requires authorization and may be considered medically necessary in the following circumstances:

	• for clients who are pregnant or are breastfeeding for up to 12 months after delivery;
	  ○ for pregnant clients only: 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 or for clients who have been stable on buprenorphine/naloxone for more than 8 weeks;
	  ○ for pregnant clients only: to allow a 7-day supply while the prior authorization is being processed an expedited authorization code 85000000077 may be used one time
	  ○ for clients who are not breastfeeding after delivery, patients should be transitioned to a buprenorphine/naloxone combination product; **OR**
	• for clients who have experienced a documented serious allergic reaction (e.g., urticaria, angioedema, or anaphylaxis) or serious idiosyncratic reaction to the buprenorphine/naloxone combination product; **OR**
	• for clients who continue to experience severe nausea or daily headache after trying at least 2 different formulations of the buprenorphine/naloxone combination products, one of which should be a buccal film, for at least 7 days each.
	
	Buprenorphine as a monotherapy will only be approved for dispensing in seven (7) day supplies until the patient demonstrates evidence of stability.
	• Up to 14 days can be prescribed after the 1st month if clinically stable. Up to 30 days can be prescribed after the 2nd 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 client'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 30 days supply of buprenorphine/naloxone, they can begin with 30 days supply of buprenorphine).

buprenorphine/naloxone	Buprenorphine/naloxone is covered up to dosing limits (see below) without authorization for all individuals who meet DSM-IV criteria for opioid dependence or DSM 5 criteria for moderate or severe opioid use disorder. • Authorization is not required for buprenorphine/naloxone at a dose at or under dosing limits (see below). HCA requires prescribers to follow evidence based practice guidelines when prescribing buprenorphine. Acceptable guidelines include but are not limited to the most current edition of those published by the American Society of Addiction medicine, https://www.asam.org/docs/default-source/practice-support/guidelines-and-consensus-docs/asam-national-practice-guideline-supplement.pdf?sfvrsn=24 or those produced or the Substance Abuse and Mental Health Services Administration,

	https://store.samhsa.gov/shin/content//SMA18-5063FULLDOC/SMA18-5063FULLDOC.pdf.
	• If significant deviations from these guidelines occur, documentation in the patient record must support the medical necessity of the differences.
	• Dose limits for buprenorphine/naloxone products
	  ○ Bunavail: 16.8 mg/2.8 mg per day
	  ○ Cassipa: 32 mg/8 mg per day
	  ○ Suboxone/generic: 32 mg/8 mg per day
	  ○ Zubsolv: 22.8 mg/5.6 mg per day

Medication Treatment for OUD:

Guidelines:

- Any provider with a SAMHSA approved waiver may prescribe a buprenorphine-containing product to anyone that meets the DSM criteria as listed above. Recognizing that there are children and adolescents with OUDs whose age is below that listed in the FDA product labelling, providers are encouraged to determine the risks and benefits of providing buprenorphine vs the risks and benefits of not providing medication treatment to persons less than 16 years of age with an OUD. Guidelines from the American Academy of Pediatrics support the use of medication for the treatment of 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 DSHS approved treatment facility is not a requirement for initiating medication 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 a higher level of care, opioid treatment program, if available.
- The Washington Prescription Monitoring Program must be accessed and reviewed for each patient before and at the time of induction.

Documentation Requirements*:*

Initiation of Medications to Treat OUD:

- Recognizing the importance of reducing and eliminating barriers to accessing medication for the treatment of opioid use disorder and the need to make same day access available, a complete medical history, including information detailing the patient's current and past history of drug or alcohol dependency and treatment, as well as any current or past history of mental health diagnosis and treatment, overdose or suicide attempt should be obtained in a time frame that is practical given the patient's circumstances.
- Similarly, a physical exam appropriate to the patient's clinical presentation and method of use 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 fentanyl. This group of patients ideally 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 and/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 new to buprenorphine or more or less often at the discretion of the provider.
- POC urine drug screens should include testing for buprenorphine, methadone, oxycodone benzodiazepines, Amphetamine/Methamphetamine, Cocaine and other opiates. (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) for limits on urine drug screen testing.
- The Prescription Monitoring Program 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 and/or pill counts can be performed at the discretion of the provider but should be considered 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 prior to initiating treatment but POC urine drug screens 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 where and if those resources are available. If these resources are not available, the risk of overdose with buprenorphine when combined with sedative-hypnotics is much less than when they are combined with full agonists. Concurrent use of benzodiazepines is not a contra-indication to therapy with buprenorphine. When prescribing buprenorphine monotherapy, a prior authorization is required.

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 ideally should provide brief intervention and motivational interviewing techniques to help the patient identify and set self-management goals that promote their stabilization. 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 be a shared decision between the patient and the provider but should be considered at least monthly for the 1st 6 months and then at the discretion of the provider.
- For non-pregnant patients reporting a serious allergic reaction or severe intolerance to buprenorphine/naloxone and requesting a buprenorphine monotherapy, clinical documentation of witnessed hives, angioedema or anaphylaxis must be provided at the time of the request or documentation of the patient having tried and failed at least 2 formulations of buprenorphine/naloxone, one to be a buccal film, due to severe nausea or daily headache.
- Buprenorphine as a monotherapy will only be approved for dispensing in seven (7) day supplies until the patient demonstrates evidence of stability. Up to 14 days can be prescribed after the 1st month if clinically stable. Up to 30 days can be prescribed after the 2nd month if clinically stable. If travel burden or other circumstances limit the patient's ability to come every 2 weeks, an exception requesting a longer duration can be made to the client's health plan. A buprenorphine/naloxone combination product should be started after delivery unless the client is breastfeeding.
- Patients with a history of a prior overdose or suicide attempt should be screened at regular intervals to assess whether or not suicide or overdose risks are present. For buprenorphine/naloxone treatment after induction and stabilization, no sooner than three (3) months, up to a 30-day supply of buprenorphine with refills may be prescribed at the physician's discretion if patients are doing well. Visits after month 1 may occur at 2-4 week intervals. 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

ADDITIONAL INFORMATION:

- Patients may remain on medication treatments for OUD for as long as they are stable and demonstrate clinical improvement. Because patients differ in terms of their preferences and ability to manage their substance use disorder, the length of treatment should be determined by medical necessity.
- Patients who remain unstable and demonstrate continued use of other illicit drugs after stabilization on buprenorphine, should receive additional and/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 for evaluation and determination of the appropriate ASAM level of treatment placement if these services are available.

- 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.
- Individuals who are unable to maintain periods of continued buprenorphine use and/or achieve stabilization after multiple attempts should be considered for referral to a higher level of care: a licensed Opioid Treatment Program (OTP), a Chemical Dependency Professional or to an Addiction Medicine physician for evaluation and determination of the appropriate ASAM level of treatment placement if these services are available.
- 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 (monotherapy)	32 mg per day
buprenorphine/naloxone	32 mg per day
Bunavail® buccal film	16.8 mg/2.8 mg per day
Cassipa® sublingual film	32 mg/8 mg per day
Suboxone® sublingual film	32 mg per day
Subutex® sublingual tablet	32 mg per day
Zubsolv® sublingual tablet	22.8 mg/5.6mg per day

References

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2. Medication-Assisted Treatment of Adolescents with Opioid Use Disorders. *Pediatrics.* 2016; 138(3):e20161893
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5. American Society of Addiction Medicine (for buprenorphine information). http://www.asam.org/
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History

Date	Action and Summary of Changes
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