

## **Clinical Guidelines and Coverage Limitations for Medication Assisted Treatment (MAT)**

For Apple Health clients served Fee-for-Service and through contracted Medicaid Managed Care Organizations

Updated 09/11/2015 and effective for dates of service on and after 10/01/2015

**UPDATE:** Effective October 1, 2015, Health Care Authority and its contracted Managed Care Organizations will no longer require authorization for buprenorphine/naloxone at dose equal to or less than 24mg per day.

**UPDATE:** Effective October 1, 2015, Health Care Authority will require that prescribers must complete form HCA 13-333 Medication Assisted Treatment Patient Status for all MAT which continues beyond six months of therapy. If treatment continues for longer than six months, prescribers must complete form HCA 13-333 Medication Assisted Treatment Patient Status every six months and maintain it in the patient's records for later audit and review by Health Care Authority.

- *The requirement to complete and maintain 13-333 Medication Assisted Treatment Patient Status applies to all MAT, including those not requiring prior authorization.*
- *The requirement to complete and maintain 13-333 Medication Assisted Treatment Patient Status applies for all Apple Health clients regardless of managed care enrollment.*

### **Policy Intent**

It is the goal of the Washington State Health Care Authority (HCA) to maximize opportunities for clients to receive effective and successful treatment for Substance Use Disorders. Substance Use Disorders are chronic remitting and relapsing diseases. Medicaid coverage of MAT prescribed outside of traditional substance use disorder treatment programs increases the number of access points for treatment and provides patients with additional flexibility in managing their illness. Improving access to medication assisted treatment for opioid use disorder is also important given what appears to be a transition from the high rates of prescription opioid use in Washington State to increasing rates of heroin use. In order to provide HCA clients with the widest range of treatment options, and with the recognition that substance use disorders are chronic conditions, HCA and its contracted Managed Care Organizations (MCO) will cover MAT products for the treatment of substance use disorders as an office based therapy, and allow indefinite continuation as maintenance treatment under the following conditions and recommended treatment protocols.

**Ongoing Treatment beyond six months:**

For all MAT products listed below, if treatment extends beyond six months, HCA requires prescribers to complete form 13-333 Medication Assisted Therapy Patient Status and keep it in the patient's record. Every six months thereafter, a new copy of the form should be completed.

This requirement applies to ALL medications listed in this document and/or HCA published clinical guidelines for Medication Assisted Therapy, even if the product does not require authorization.

HCA may request copies of Medication Assisted Therapy Patient Status forms and other patient records as needed to monitor quality of care and the success of treatment expansion at any time.

This form can be found on [FFS Drug Coverage Criteria](http://www.hca.wa.gov/billers-providers/programs-and-services/apple-health-medicaid-drug-coverage-criteria) at <http://www.hca.wa.gov/billers-providers/programs-and-services/apple-health-medicaid-drug-coverage-criteria>

**Coverage for acamprosate:**

Covered without limitations or authorization. Prescribers are encouraged to use caution in prescribing and ensure that their patients can clear the drug (creatinine clearance greater than 30ml/min).

**Coverage for disulfiram**

Covered without limitations or authorization.

**Coverage for oral naltrexone:**

Covered without authorization for clients 18 years of age and older. Naltrexone should not be prescribed for clients who have used or have shown signs of acute opioid withdrawal in the last three days. Naltrexone should not be prescribed for clients who are pregnant or have decompensated liver disease.

**Coverage for IM naltrexone:**

Requires prior authorization.

**For Apple Health Fee-for-Service patients:** Providers must complete form 13-331 Medication Assisted Treatment Request for IM Naltrexone when initiating therapy for a patient with IM naltrexone (Vivitrol® IM). This form can be found on [FFS Drug Coverage Criteria](http://www.hca.wa.gov/billers-providers/programs-and-services/apple-health-medicaid-drug-coverage-criteria) at <http://www.hca.wa.gov/billers-providers/programs-and-services/apple-health-medicaid-drug-coverage-criteria>

[coverage-criteria](#) Directions for submitting request forms via the patient's pharmacy can be found on the back of the form.

**For Managed Care enrollees:**

Please consult the patient's MCO's website for appropriate forms and submission requirements. Prior Authorization requirements are the same regardless of enrollment, and forms used for requesting authorization will be similar, but prescribers must adhere to authorization processes as defined by the client's MCO.

**For all Apple Health clients:**

Health Care Authority and its contracted Managed Care Organizations will authorize IM naltrexone for clients who have a diagnosis of moderate to severe opioid or alcohol use disorder and meet one of the following criteria:

- The patient has a co-occurring mental or behavioral health condition which impairs their ability to be compliant; or
- The patient has had unsuccessful treatment attempts with oral naltrexone; or
- In the past year, the patient has had three or more of the following:
  - Emergency room visits
  - Hospital admissions
  - Services for alcohol or drug related illness, injury or detoxification

For treatment of alcohol dependence, patients must have abstained from alcohol for 4 days prior to initiation of treatment. The efficacy of IM naltrexone in promoting abstinence has not been demonstrated in patients who have not completed detoxification and achieved abstinence prior to beginning treatment.

For qualifying patients, all of the following must be true:

- Must not be using opioid narcotics concurrently with IM naltrexone because of the potential to cause immediate and severe opioid withdrawal.
- Is receiving adequate psychosocial support for substance use disorder either directly from the prescriber, or as determined by the prescriber to be adequate to meet the client's needs through other available resources.

Dosage and Administration:

- Each IM injection (no more than 380mg/injection) is given no sooner than every 4 weeks.
- Injections are administered by a licensed healthcare professional in a medical facility.
- Treatment is limited to 6 doses in 24 weeks
- Extensions to be determined on case by case basis.

### **Coverage for oral products containing buprenorphine:**

Studies demonstrate that treatment with buprenorphine is comparable to methadone in reducing illicit opioid use<sup>1</sup>. At fixed doses at or above 8mg, retention rates approach those found with methadone maintenance, and for Medicaid patients, there is no evidence of increased costs or safety problems compared with methadone<sup>2</sup>.

### **Authorization and prescribing requirements:**

- Buprenorphine monotherapy requires prior authorization and is covered only for women who are pregnant and meet DSM-IV criteria for opioid dependence or DSM 5 criteria for moderate or severe opioid use disorder. After delivery, patients must be transitioned to a buprenorphine/naloxone combination product.
- Buprenorphine/naloxone is covered up to 24mg per day without authorization for all individuals aged 16 years or older, who meet DSM-IV criteria for opioid dependence or DSM 5 criteria for moderate or severe opioid use disorder.

Although authorization is not required for buprenorphine/naloxone at dose at or under 24mg per day, HCA requires prescribers to follow all of the following guidelines. Failure of the prescribing community to voluntarily apply all standards to ensure the quality of care for Washington Apple Health clients may result in reinstatement of authorization requirements.

### **Initiation of MAT:**

- Physicians with a waiver may prescribe oral buprenorphine or buprenorphine/naloxone to anyone 16 years or older that meets the DSM criteria noted above.
- 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 assisted 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 use and improve their functional status without engaging in a formal treatment program should be referred to an Addiction Medicine or Chemical Dependency professional

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<sup>1</sup>Mattick RP, Breen C, Kimber J, Davoli M. Buprenorphine maintenance versus placebo or methadone maintenance for opioid dependence. Cochrane Database of Systematic Reviews 2014, Issue 2. Art. No.: CD002207. DOI: 10.1002/14651858.CD002207.pub4.

<sup>2</sup>Clark, RE, Samnaliev, M, Baxter, JD and Leung, GY. The Evidence Doesn't Justify Steps By State Medicaid Programs To Restrict Opioid Addiction Treatment With Buprenorphine. Health Aff August 2011 30:81425-1433

- The WA Prescription Monitoring Program must be accessed and reviewed for each patient before or at the time of induction.

### **Documentation:**

- 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 diagnoses and treatment is required.
- A physical exam appropriate to the patient's clinical presentation and method of use should be documented.

### **Initial prescription requirements:**

- Patients may not receive more than a 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 urine drug screens must be performed during the first month of treatment.
- Patients with significant untreated psychiatric comorbidity or those with a comorbid dependence on high doses of 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.
- When prescribing buprenorphine monotherapy or doses in excess of 24mg per day, providers are required to obtain prior authorization by submitting form 13-330 Medication Assisted Treatment Request for Buprenorphine Monotherapy or form 13-332 Medication Assisted Treatment Request for Buprenorphine > 24mg Per. These forms can be found on [FFS Drug Coverage Criteria](http://www.hca.wa.gov/billers-providers/programs-and-services/apple-health-medicare-drug-coverage-criteria) at <http://www.hca.wa.gov/billers-providers/programs-and-services/apple-health-medicare-drug-coverage-criteria> Directions for submitting request forms via the patient's pharmacy can be found on the back of the form.

### **Follow-up Visits in the First Six Months:**

- Patients are required to be seen within one week of starting buprenorphine and then weekly for the first 4 weeks of treatment.\*
- A urine drug screen documenting the buprenorphine is being taken (either a GCMS or LCMS for buprenorphine and norbuprenorphine) should be collected twice during the 1<sup>st</sup> month of treatment.
- Because there are a number of variables influencing what is in a particular patient's best interest, the frequency of follow up visits after the first month should be a shared decision between the patient and provider, but must occur at least monthly.

- Buprenorphine monotherapy for pregnant clients is limited to a maximum of a seven-day supply throughout the course of treatment, with a minimum follow-up visit frequency as detailed below.
- For non-pregnant patients reporting allergies 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. Buprenorphine as a monotherapy will only be approved for dispense in seven-day supplies.
- For buprenorphine/ naloxone treatment after induction and stabilization, no sooner than 3 months, up to a 30-day supply of buprenorphine may be prescribed at the physician’s discretion if patients are doing well. Visits after month 1 may occur at 2-4 week intervals. The minimum required visit frequency and dosing limits for the first 3 months are as follows:

Visit type	Follow-up Interval	Medications dispensed (maximum of 24mg/ day without authorization)
Induction	Within 7 days	Maximum 7 days
Weeks 2 through 4	Weekly visits	Maximum 7* days
Weeks 5 through 8	Visits every 2-4 weeks	Maximum 14 days
Week 9 and beyond	Visits <sup>3</sup> at provider discretion	14 – 30 day supply

In addition to buprenorphine treatment, prescribing providers should provide brief intervention and motivational interviewing techniques to help the patient identify and set self-management goals that promote their stabilization. Visits in the primary care setting with the provider, mental health professional or case/care team coordinator if available, are all acceptable types of follow up. If follow-up visits are not with the prescribing practitioner, the prescriber must assure visits and who they are with are documented in the patient’s chart.

\*For physicians and patients in rural areas where there is not ready access to transportation, the week 3 and week 4 visits may be conducted by phone. A fourteen day supply of medication may be prescribed in these instances. These phone visits must 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, and telephone visits are not a reimbursable service.

**Documentation:**

First six months:

- Urine drug screens **and/or** random call backs of patients requesting they return to the clinic within a specified time frame with their remaining medications for a pill count

must be conducted at least every month during the first 6 months for patients new to buprenorphine or more often at the discretion of the provider.

- Urine drug screens must include testing for buprenorphine, methadone, oxycodone, benzodiazepines, amphetamine/methamphetamine, cocaine, and other opiates. 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.
- The Prescription Monitoring Program database must be checked at three-month intervals for the first six months and then at the provider's discretion but no less frequently than every six months for clients receiving ongoing maintenance treatment.

### **MAT after the First Six months:**

After the first six months of treatment and every six months thereafter:

- Urine drug screens and/or pill counts can be performed at the discretion of the provider but must occur no less often than every six months.
- After six months, if the patient is stable, the PMP must be checked at a minimum of every 6 months.
- Screens for depression and anxiety must be performed twice a year and documented in the health record, unless the patient is receiving treatment for either of these conditions in which case they should be repeated at the discretion of the provider.
- HCA requires prescribers to complete form 13-333 Medication Assisted Therapy Patient Status and keep it in the patient's record. Every six months thereafter, a new copy of the form should be completed. This form can be found on [FFS Drug Coverage Criteria](http://www.hca.wa.gov/billers-providers/programs-and-services/apple-health-medicaid-drug-coverage-criteria) at <http://www.hca.wa.gov/billers-providers/programs-and-services/apple-health-medicaid-drug-coverage-criteria>

### **Additional Information:**

- Patients may remain on medication assisted treatment with buprenorphine for as long as they are stable and evidence abstinence or reduced use from their baseline. As patients will differ in terms of their preferences and ability to manage their substance use disorder with time limited or continuous treatment, the length of treatment should be determined by the patient and their provider.
- Patients who discontinue or reduce their opioid use but demonstrate continued use of other illicit drugs after stabilization on buprenorphine, usually one to two months, must receive 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.

- Patients should be maintained on the lowest 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 24mg require prior authorization.
- Use of other opioids or controlled substances while being treated with buprenorphine should be closely monitored by the prescribing physician. Patients must 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.
- Individual patients may not go through more than 3 buprenorphine inductions in a calendar year, without consultation from an addiction medicine provider.
- 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.

Payment for buprenorphine will be stopped if:

- Patient is found to be diverting some or all of their buprenorphine
- Patient is found to be selling their buprenorphine to others

Forms for requesting authorization and an electronic copy of this document can be found on [FFS Drug Coverage Criteria](http://www.hca.wa.gov/billers-providers/programs-and-services/apple-health-medicaid-drug-coverage-criteria) at <http://www.hca.wa.gov/billers-providers/programs-and-services/apple-health-medicaid-drug-coverage-criteria>

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