



Clinical Guidelines for the Pharmacologic Treatment of Opioid Use Disorder

Community Behavioral Health (CBH) is committed to working with our provider partners to continuously improve the quality of behavioral healthcare for our shared population. Whenever possible, this is best accomplished by the implementation of evidence-based practices, as well as those informed by nationally recognized treatment guidelines, while respecting the need for individualized treatment and recovery planning.

The following are medication prescribing standards, adapted for the CBH network from national treatment guidelines; they are intended to guide providers in aligning their practices with the best available scientific evidence to help members with opioid use disorder (OUD) access state-of-the-art care.

To assess the quality of care CBH is helping to provide, several standardized metrics will be collected in relation to these guidelines. These metrics come either from the Healthcare Effectiveness Data and Information Set (HEDIS) set of measures used by most major healthcare organizations for quality improvement, or are measures of clear clinical priority in our network. While CBH will initially be collecting specific data related only to these guidelines, the use of empirical guidelines and practice parameters is encouraged in all prescribing.

CBH expects providers to follow these guidelines in addition to all other relevant CBH, state, and federal regulations and standards, including CBH prescribing bulletins (e.g. *Bulletin 07-07 Screening for and Treatment of the Components of Metabolic Syndrome*¹, *Bulletin 18-07 Requirement for All Crisis Response Centers (CRCs) and Drug and Alcohol Licensed Providers to Establish Protocols to Assist Individuals in Accessing Evidence-Based Treatment*², *Including Medication-Assisted Treatment*), the Network Inclusion Criteria (NIC) Standards of Excellence,³ and the DBHIDS Practice Guidelines for Resiliency and Recovery-oriented Treatment.⁴

¹ Department of Behavioral Health and Intellectual Disability Services (DBHIDS), *Bulletin 07-07 Screening for and Treatment of the Components of Metabolic Syndrome*

² Department of Behavioral Health and Intellectual Disability Services (DBHIDS), *Bulletin 18-07 Requirement for All Crisis Response Centers (CRCs) and Drug and Alcohol Licensed Providers to Establish Protocols to Assist Individuals in Accessing Evidence-Based Treatment*

³ Department of Behavioral Health and Intellectual Disability Services (DBHIDS), *Philadelphia Behavioral Health Practice Guidelines*, 2013, or latest version

⁴ Department of Behavioral Health and Intellectual Disability Services (DBHIDS), *Network Inclusion Criteria*, 2013, or latest version

Note further that the following are guidelines for the pharmacologic treatment of OUD. CBH and DBHIDS encourage a biopsychosocial and recovery-based approach to treatment; in each case these guidelines for medication treatment should be but one part of a robust, multidisciplinary treatment approach that involves high-quality psychosocial treatment, collaboration with physical health providers, and inclusion of families and other supports.

Introduction

CBH has updated its guidelines for the treatment of opioid use disorder (OUD) to reflect the most recently published evidence-based practice parameters available: *The American Society of Addiction Medicine (ASAM) National Practice Guideline for the Use of Medications in the Treatment of Addiction Involving Opioid Use*.⁵

Treatment of OUD with the following forms of medication-assisted treatment (MAT) leads to better outcomes than “drug free” treatment.⁶

CBH encourages its network providers to remain current with the state of evidence-based practice parameters and to incorporate these into the clinical care offered. These guidelines reflect the best scientific evidence available to guide treatment delivery, and should be considered the standard of care in the CBH network. Resources related to these guidelines for providers may be accessed at:

<https://www.asam.org/resources/guidelines-and-consensus-documents/npg>.

Note that the guidelines below are in addition to any extant local, state, or federal requirements related to the prescribing or dispensing of medications, including those used in medication-assisted treatment.

Guidelines (Summarized and adapted from the ASAM guidelines)

Assessment

1. First clinical priority should be given to identifying and making appropriate referral for any urgent or emergent medical or psychiatric problem(s), including drug-related impairment or overdose.
2. Completion of the individual’s medical history should include screening for concomitant medical conditions, including infectious diseases (hepatitis, HIV, and tuberculosis[TB]), acute trauma, and pregnancy.
3. A physical examination should be completed as a component of the comprehensive assessment process. The prescriber (the clinician authorizing the use of a medication for the treatment of opioid use disorder) may conduct this physical examination him/herself, or, in accordance with the ASAM Standards, ensure that a current physical examination is contained within the treatment record before a member is started on a new medication for the treatment of his/her addiction.

⁵Kampman K. and Jarvis M. American Society of Addiction Medicine (ASAM) National Practice Guideline for the Use of Medications in the Treatment of Addiction Involving Opioid Use. *J Addict Med* 2015;9: 1–10.

⁶ Cochrane Database Syst Rev. 2014 Feb 6;(2):CD002207. doi: 10.1002/14651858.CD002207.pub4.

4. Initial laboratory testing should include a complete blood count, liver function tests, and tests for hepatitis C and HIV. Testing for TB and sexually transmitted infections should also be considered. Hepatitis B vaccination should be offered, if appropriate.
5. The assessment of women presents special considerations regarding their reproductive health. Women of childbearing age should be tested for pregnancy, and all women of childbearing potential and age should be queried regarding methods of contraception, given the increase in fertility that results from effective opioid use disorder treatment.
6. Individuals being evaluated for addiction involving opioid use, and/or for possible medication use in the treatment of opioid use disorder, should undergo (or have completed) an assessment of mental health status and possible psychiatric disorders.
7. Opioid use is often co-occurring with other substance-related disorders. An evaluation of past and current substance use and a determination of the totality of substances that surround the addiction should be conducted.
8. The use of marijuana, stimulants, or other addictive drugs should not be a reason to suspend opioid use disorder treatment. However, evidence demonstrates that individuals who are actively using substances during opioid use disorder treatment have a poorer prognosis. The use of benzodiazepines and other sedative hypnotics, or the heavy use of alcohol, may be a reason to suspend agonist treatment because of safety concerns related to respiratory depression (refer to DBHIDS guidelines on the use of benzodiazepines and those related to MAT).⁷
9. A tobacco use query and counseling on cessation of tobacco products and electronic nicotine delivery devices should be completed routinely for all individuals, including those who present for evaluation and treatment of opioid use disorder.
10. An assessment of social and environmental factors should be conducted (as outlined in the ASAM Standards) to identify facilitators and barriers to addiction treatment, and specifically to pharmacotherapy. Before a decision is made to initiate a course of pharmacotherapy for the individual with opioid use disorder, the individual should receive a multidimensional assessment in fidelity with The ASAM Criteria: Treatment Criteria for Addictive, Substance Related, and Co-occurring Conditions (the “ASAM Criteria”)⁸. Addiction should be considered a bio-psycho-social-spiritual illness, for which the use of medication is but only one component of overall treatment.

⁷https://hip.phila.gov/Portals/default/HIP/EmergentHealthTopics/Opioids/Opioid_PrescribingGuidlinesFlyer_082017.pdf (also look for more complete BZD)

⁸ Once formally adopted by the network

Diagnosis

1. Other clinicians may diagnose opioid use disorder, but confirmation of the diagnosis by the provider with prescribing authority, and who recommends medication use, must be obtained before pharmacotherapy for opioid use disorder commences. Please refer to state and federal regulations, which are mandatory and detail requirements for documentation of diagnosis.^{9,10}
2. Opioid use disorder is primarily diagnosed based on the history provided by the individual and a comprehensive assessment that includes a physical examination.
3. Validated clinical scales that measure withdrawal symptoms, for example, the Objective Opioid Withdrawal Scale (OOWS), the Subjective Opioid Withdrawal Scale (SOWS), and the Clinical Opioid Withdrawal Scale (COWS), may be used to assist in the evaluation of individuals with opioid use disorder.
4. Urine drug testing during the comprehensive assessment process, and frequently during treatment, is recommended. The frequency of drug testing is determined by a number of factors including the stability of the individual, the type of treatment, and the treatment setting.

Treatment Options

1. The choice of available treatment options for addiction involving opioid use should be a shared decision between the clinician and individual that includes all currently available options, not only those available at a provider. If a person elects to have a treatment modality not offered at the provider in question, an appropriate referral should be made.
2. Clinicians should consider the individual's preferences, past treatment history, and treatment setting when deciding between the use of methadone, buprenorphine, and naltrexone in the treatment of addiction involving opioid use. Generally, providers and individuals should be prepared for a one-two year period on MAT as an initial target.
3. The venue in which treatment is provided is as important as the specific medication selected. Opioid treatment programs (OTPs) offer daily supervised dosing of methadone, and increasingly of buprenorphine. In accordance with the federal law (21 CFR §1306.07), office-based opioid treatment (OBOT), which provides medication on a prescribed weekly or monthly basis, is limited to buprenorphine. Naltrexone can be prescribed in any setting by any clinician with the authority to prescribe any medication. Clinicians should consider an individual's psychosocial situation, co-occurring disorders, and risk of diversion when determining whether OTP or OBOT is most appropriate.

⁹ <https://store.samhsa.gov/shin/content/PEP15-FEDGUIDEOTP/PEP15-FEDGUIDEOTP.pdf>

¹⁰ https://www.pacode.com/secure/data/028/chapter715/028_0715.pdf

4. OBOT may not be suitable for individuals with active alcohol use disorder or sedative, hypnotic, or anxiolytic use disorder (or who are in the treatment of addiction involving the use of alcohol or other sedative drugs, including benzodiazepines or benzodiazepine receptor agonists). It may also be unsuitable for persons who are regularly using alcohol or other sedatives, but do not have addiction or a specific substance use disorder related to that class of drugs. The prescribing of benzodiazepines or other sedative-hypnotics should be used with extreme caution in individuals who are prescribed methadone or buprenorphine for the treatment of an opioid use disorder.
5. Methadone is recommended for individuals who may benefit from daily dosing and supervision in an OTP, or for individuals for whom buprenorphine for the treatment of opioid use disorder has been used unsuccessfully in an OTP or OBOT setting.
6. Oral naltrexone for the treatment of opioid use disorder is often adversely affected by poor medication adherence. Clinicians should reserve its use for individuals who would be able to comply with special techniques to enhance their adherence, for example, observed dosing. Extended release injectable naltrexone reduces, but does not eliminate, issues with medication adherence.

Treating Opioid Withdrawal

1. Using medications for opioid withdrawal management is recommended over abrupt cessation of opioids. Abrupt cessation of opioids may lead to strong cravings, which can lead to continued use.
2. Individuals should be advised about risk of relapse and other safety concerns from using opioid withdrawal management as standalone treatment for opioid use disorder. Opioid withdrawal management on its own is not a treatment method, and tapering has poorer outcomes than does transition to maintenance treatment.
3. Assessment of an individual undergoing opioid withdrawal management should include a thorough medical history and physical examination, focusing on signs and symptoms associated with opioid withdrawal.
4. Opioid withdrawal management in cases in which methadone is used to manage withdrawal symptoms must be done in an inpatient setting or in an OTP. For short-acting opioids, tapering schedules that decrease in daily doses of prescribed methadone should begin with doses between 20 and 30 mg per day, and should be completed within 6–10 days. The maximum total dose of methadone for the first day of such treatment is not to exceed 40mg.
5. Opioid withdrawal management in cases in which buprenorphine is used to manage withdrawal symptoms should not be initiated until 12–18 hours after the last dose of a short-acting agonist such as heroin or oxycodone, and 24–48 hours after the last dose of a long-acting agonist such as methadone. A dose of buprenorphine sufficient to suppress withdrawal symptoms is titrated (starting with a maximum of 8mg on the first treatment day and typically reaching a maximum of

16mg total) and then the dose is tapered in cases where transition to maintenance treatment is not desired. The duration of the tapering schedule can be as brief as 3–5 days or as long as 30 days or more. In general, longer tapers are preferred to shorter tapers.

6. The use of combinations of buprenorphine and low doses of oral naltrexone to manage withdrawal and facilitate the accelerated introduction of extended-release injectable naltrexone has shown promise. More research will be needed before this can be accepted as standard practice.
7. The Guideline Committee recommends, based on consensus opinion, the inclusion of clonidine as a practice to support opioid withdrawal. Clonidine is not US FDA approved for the treatment of opioid withdrawal, but it has been extensively used off-label for this purpose. Clonidine may be used orally or transdermally at doses of 0.1–0.3 mg every 6–8 hours, with a maximum dose of 1.2 mg daily, to assist in the management of opioid withdrawal symptoms. Its hypotensive effects often limit the amount that can be used. Clonidine can be combined with other non-narcotic medications targeting specific opioid withdrawal symptoms such as benzodiazepines for anxiety (this should be reserved for supervised settings), loperamide for diarrhea, acetaminophen or nonsteroidal anti-inflammatory medications (NSAIDs) for pain, and ondansetron or other agents for nausea.
8. Opioid withdrawal management using anesthesia is not recommended due to high risk for adverse events or death.

Methadone

1. Methadone is a treatment option recommended for individuals who are physiologically dependent on opioids, able to give informed consent, and who have no specific contraindications for agonist treatment when it is prescribed in the context of an appropriate plan that includes psychosocial intervention.
2. The recommended initial dose for methadone ranges from 10 to 30 mg, with reassessment in 3–4 hours, and a second dose not to exceed 10 mg on the first day if withdrawal symptoms are persisting.
3. The usual daily dosage of methadone ranges from 60 to 120 mg. Some individuals may respond to lower doses and some individuals may need higher doses. Dosage increases in 5–10-mg increments applied no more frequently than every 7 days (depending on clinical response) are necessary to avoid oversedation, toxicity, or even iatrogenic overdose deaths.
4. The administration of methadone should be monitored because unsupervised administration can lead to misuse and diversion. OTP regulations require monitored medication administration until the individual's clinical response, and behavior demonstrates that the prescribing of nonmonitored doses is appropriate.

5. Psychosocial treatment should be implemented in conjunction with the use of methadone in the treatment of opioid use disorder.
6. Methadone should be reinstated immediately if relapse occurs, or when an assessment determines that the risk of relapse is high for individuals who previously received methadone in the treatment of opioid use disorder, but who are no longer prescribed such treatment.
7. Strategies directed at relapse prevention are an important part of comprehensive addiction treatment and should be included in any plan of care for an individual receiving active opioid treatment or ongoing monitoring of the status of their addictive disease.
8. Switching from methadone to another medication for the treatment of opioid use disorder may be appropriate if the individual experiences intolerable side effects or is not successful in attaining or maintaining treatment goals through the use of methadone.
9. Individuals switching from methadone to buprenorphine in the treatment of opioid use disorder should be on low doses of methadone before switching medications. Individuals on low doses of methadone (30–40 mg per day or less) generally tolerate transition to buprenorphine with minimal discomfort, whereas individuals on higher doses of methadone may experience significant discomfort in switching medications.
10. Individuals switching from methadone to oral naltrexone or extended-release injectable naltrexone must be completely withdrawn from methadone and other opioids, before they can receive naltrexone. The only exception would apply when an experienced clinician receives consent from the individual to embark on a plan of naltrexone-facilitated opioid withdrawal management.
11. Individuals who discontinue agonist therapy with methadone or buprenorphine and then resume opioid use should be made aware of the risks associated with opioid overdose, and especially the increased risk of death.

Buprenorphine

1. Opioid-dependent individuals should wait until they are experiencing mild to moderate opioid withdrawal before taking the first dose of buprenorphine to reduce the risk of precipitated withdrawal. Generally, buprenorphine initiation should occur at least 6–12 hours after the last use of heroin or other short-acting opioids, or 24–72 hours after their last use of long-acting opioids such as methadone.
2. Induction of buprenorphine should start with a dose of 2–4 mg. Dosages may be increased in increments of 2–4 mg, and clinicians should observe individuals in their offices during induction. Dose should not exceed 8mg on the first treatment day.

3. Buprenorphine doses after induction and titration should be, on average, at least 8 mg per day. However, if individuals are continuing to use opioids, consideration should be given to increasing the dose by 4–8 mg (daily doses of 12–16 mg or higher). The US FDA approves dosing to a limit of 24 mg per day, and there is limited evidence regarding the relative efficacy of higher doses. In addition, the use of higher doses may increase the risk of diversion.
4. Psychosocial treatment should be implemented in conjunction with the use of buprenorphine in the treatment of opioid use disorder.
5. Clinicians should take steps to reduce the chance of buprenorphine diversion. Recommended strategies include frequent office visits (weekly in early treatment), urine drug testing, including testing for buprenorphine and metabolites, and recall visits for pill counts. Accessing Prescription Drug Monitoring Program (PDMP) data may be useful for monitoring.
6. Individuals should be seen frequently at the beginning of their treatment. Weekly visits (at least) are recommended until individuals are determined to be stable. There is no recommended time limit for treatment.
7. Buprenorphine taper and discontinuation is a slow process and close monitoring is recommended. Buprenorphine tapering is generally accomplished over several months. Individuals should be encouraged to remain in treatment for ongoing monitoring past the point of discontinuation.
8. When considering a switch from buprenorphine to naltrexone, 7–14 days should elapse between the last dose of buprenorphine and the start of naltrexone to ensure that the individual is not physically dependent on opioids before starting naltrexone.
9. When considering a switch from buprenorphine to methadone, there is no required time delay because the addition of a full opioid agonist to a partial agonist does not typically result in any type of adverse reaction.
10. Individuals who discontinue agonist therapy and resume opioid use should be made aware of the risks associated with an opioid overdose, and especially the increased risk of death.

Naltrexone

1. Naltrexone is a recommended treatment in preventing relapse in opioid use disorder. Oral formula naltrexone may be considered for individuals in whom adherence can be supervised or enforced. Extended-release injectable naltrexone may be more suitable for individuals who have issues with adherence.
2. Oral naltrexone should be taken daily in 50-mg doses, or 3 times weekly in two 100-mg doses followed by one 150-mg dose.

3. Extended-release injectable naltrexone should be administered every 4 weeks by deep IM injection in the gluteal muscle at a set dosage of 380 mg per injection.
4. Psychosocial treatment is recommended in conjunction with treatment with naltrexone. The efficacy of naltrexone use in conjunction with psychosocial treatment has been established, whereas the efficacy of extended release injectable naltrexone without psychosocial treatment has not been established.
5. There is no recommended length of treatment with oral naltrexone or extended-release injectable naltrexone. Duration depends on clinical judgment and the individual's circumstances. Because there is no physical dependence associated with naltrexone, it can be stopped abruptly without withdrawal symptoms.
6. Switching from naltrexone to methadone or buprenorphine should be planned, considered, and monitored. Switching from an antagonist such as naltrexone to a full agonist (methadone) or a partial agonist (buprenorphine) is generally less complicated than switching from a full or partial agonist to an antagonist because there is no physical dependence associated with antagonist treatment and thus no possibility of precipitated withdrawal. Individuals being switched from naltrexone to buprenorphine or methadone will not have physical dependence on opioids and thus the initial doses of methadone or buprenorphine used should be low. Individuals should not be switched until a significant amount of the naltrexone is no longer in their system, about 1 day for oral naltrexone or 30 days for extended-release injectable naltrexone.
7. Individuals who discontinue antagonist therapy and resume opioid use should be made aware of the increased risks associated with an opioid overdose, and especially the increased risk of death.

Special Populations

1. Pregnant Women
 - a. The first priority in evaluating pregnant women for opioid use disorder should be to identify emergent or urgent medical conditions that require immediate referral for clinical evaluation.
 - b. Counseling and testing for HIV should be provided in accordance with state law. Tests for hepatitis B and C and liver function are also suggested. Hepatitis A and B vaccination is recommended for those whose hepatitis serology is negative.
 - c. Pregnant women who are physically dependent on opioids should receive treatment using methadone or buprenorphine rather than withdrawal management or abstinence.

Care for pregnant women with OUD should be managed by an obstetrician and an addiction specialist physician. Release of information forms need to be completed to ensure communication among healthcare providers.

- d. Treatment with methadone should be initiated as early as possible during pregnancy.
- e. Hospitalization during initiation of methadone and treatment with buprenorphine may be advisable due to the potential for adverse events, especially in the third trimester.
- f. If a woman becomes pregnant while she is receiving naltrexone, it is appropriate to discontinue the medication if the individual and doctor agree that the risk of relapse is low. If the individual is highly concerned about relapse and wishes to continue naltrexone, she should be informed about the risks of staying on naltrexone and provide her consent for ongoing treatment. If the individual wishes to discontinue naltrexone, but then reports relapse to opioid use, it may be appropriate to consider treatment with methadone or treatment with buprenorphine.
- g. Naloxone is not recommended for use in pregnant women with opioid use disorder except in situations of life-threatening overdose.

2. Adolescents

- a. Clinicians should consider treating adolescents who have opioid use disorder using the full range of treatment options, including pharmacotherapy. Age is a consideration in treatment, and federal laws and US FDA approvals need to be considered for individuals under age 18.

Concurrent practices to reduce infection (e.g. sexual risk reduction interventions) are recommended as components of comprehensive treatment for the prevention of sexually transmitted infections and blood-borne viruses.)

- b. Adolescents may benefit from treatment in specialized treatment facilities that provide multidimensional services.

3. Individuals with Co-occurring Psychiatric Disorders

- a. A comprehensive assessment including determination of mental health status should evaluate whether the individual is stable. Individuals with suicidal or homicidal ideation should be referred immediately for treatment and possibly hospitalization.

Assessment for psychiatric disorder should occur at the onset of agonist or antagonist treatment. Reassessment using a detailed mental status examination should occur after stabilization with methadone, buprenorphine, or naltrexone.

- b. Clinicians should be aware of potential interactions between medications used to treat co-occurring psychiatric conditions and opioid use disorder.

CBH Implementation Review

CBH encourages its providers to maintain robust internal quality management programs that can assure treatment of CBH members is adherent to these and other applicable guidelines. In addition to “as needed” reviews of medical records when quality issues arise, CBH will be tracking and sharing two main performance metrics with providers:

1. The percentage of members with OUD diagnosis receiving medication-assisted treatment (MAT) at each provider of substance use treatment services¹¹
2. Readmission rates for members diagnosed with OUD at each provider of substance use treatment services

In addition to the metrics above, which will help inform discussions about how to best treat members with OUD and how to promote community tenure, CBH will continue to monitor adherence to the above guidelines through its standard quality review processes, and the DBHIDS Network Improvement and Accountability Collaborative (NIAC) will continue to monitor treatment provided to ensure that care is consistent with the DBHIDS Network Inclusion Criteria (NIC) Standards of Excellence.¹²

¹¹ Providers will submit this data quarterly as per requirement in Department of Behavioral Health and Intellectual Disability Services (DBHIDS), *Bulletin 18-07 Requirement for All Crisis Response Centers (CRCs) and Drug and Alcohol Licensed Providers to Establish Protocols to Assist Individuals in Accessing Evidence-Based Treatment*

¹² Department of Behavioral Health and Intellectual Disability Services (DBHIDS), *Network Inclusion Criteria*, 2013, (or most recent version)