

OPIOID USE DISORDER: DIAGNOSIS, EVALUATION, AND TREATMENT

Federal Bureau of Prisons Clinical Guidance

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1. PURPOSE AND BACKGROUND

The Federal Bureau of Prisons (BOP) Clinical Guidance for *Opioid Use Disorder: Diagnosis, Evaluation and Treatment* provides recommendations for the use of medications in treating federal inmates with Opioid Use Disorder (OUD).

OPIOIDS AND OPIOID USE DISORDER (OUD)

Opioids are natural or synthetic chemicals that interact with opioid receptors on the nerve cells in the body and in the brain to reduce feelings of pain. Historically, *opiates* referred to drugs derived from the opium poppy (e.g. oxycodone, hydrocodone, codeine, and morphine), while *opioids* referred to synthetic drugs active at the mu receptor (e.g. tramadol, fentanyl, and methadone). Today, the term opioid is used for the entire class of mu-agonist drugs, regardless of origin (natural, synthetic, and semi-synthetic; legal and illegal). Prescription opioid medications include oxycodone, hydrocodone, codeine, morphine and synthetic opioids, which are designed to mimic naturally occurring opioids, such as tramadol, fentanyl, and methadone.

Opioid Use Disorder (OUD) is a chronic, relapsing disease, with significant economic, personal, and public health consequences. In 2018, 2 million people in the U.S. had OUD. In 2019, 70,630 Americans died from drug overdoses and over 70% (49,860) of those deaths involved opioids. Since 2013, the largest increase in overdose deaths has involved synthetic opioids (other than methadone), primarily fentanyl and fentanyl analogs, resulting in over 36,000 overdose deaths in 2019. Provisional data from December 2020 show that the rate of overdose deaths has increased by 29.4% since December 2019 and the number of opioid-related overdose deaths has continued to climb through July 2021.

OUD in the Prison Population: Studies show that up to 65% of incarcerated individuals meet the criteria for a substance use disorder and up to one-quarter of these inmates have OUD. Also, studies have found that individuals with OUD have a much higher risk of death from drug overdose in the first 2 weeks after release from prison compared to the general population.

Medication for Opioid Use Disorder (MOUD) vs. Medication Assisted Treatment (MAT): Treatment for OUD includes both medications and behavioral therapy. The term, Medication Assisted Treatment (MAT), is used to describe the addition of medication to counseling and behavioral therapy. Another common term for medications for opioid use disorder is MOUD.

Current scientific evidence and trends in the treatment of OUD recognize that medications have a primary role and benefit that is independent of behavioral treatments. As an example, one large study found that treatment with methadone or buprenorphine following a non-fatal opioid overdose reduced subsequent opioid overdose deaths by 59%. The preferred terms for treatment of OUD with medications continues to evolve and to avoid confusion of one term over another, this document will refer to medications or treatment of OUD rather than MAT or MOUD when appropriate.

Medications for OUD are appropriate, first-line treatment for many patients, especially those with moderate to severe OUD. Current FDA-approved medications for OUD include methadone (full opioid agonist), buprenorphine (partial opioid agonist), and naltrexone (opioid antagonist). Both methadone and buprenorphine can reduce the symptoms of withdrawal and cravings—without producing euphoria when taken as directed. Alternatively, naltrexone is useful to prevent relapse to opioid use and helps reduce the risk of fatal overdose after release from the criminal justice system.

Two Treatment Program Types: Naltrexone may be prescribed in any provider setting, however, in the community, DEA-scheduled medications for OUD are generally utilized in **one of two** different settings:

- Opioid Treatment Program (OTP)
- Office-based Opioid Treatment (OBOT)

An **OTP** is a highly regulated stand-alone multidisciplinary clinic where practitioners dispense buprenorphine or methadone to patients in a closely supervised manner. Methadone may only be dispensed or administered through an OTP when used for OUD. In the BOP, medication is dispensed by a certified OTP either in the community or in the BOP, and the medication is administered via directly observed therapy (pill line).

An **OBOT** utilizes buprenorphine only. In this setting, a prescriber provides the patient a buprenorphine prescription which the patient can fill at the pharmacy and take at home. In the BOP, any authorized provider with a DATA 2000 waiver may prescribe buprenorphine and the medication is administered via directly observed therapy (pill line).

Naltrexone can be prescribed in any setting including an OTP or an OBOT.

Benefits of Medications for OUD: Studies show that medications for OUD reduce drug use, disease rates, and overdose events and increases retention in treatment programs while promoting recovery among individuals with OUD, according to studies. Benefits of treatment include:

- Reduced risk of overdose-related deaths
- Reduced risk of HIV and viral hepatitis infections in injection drug users
- Lower rates of cellulitis for injection drug users
- Reduced criminal behavior in the community
- Reduced rates of psychiatric complications in the community

Benefits of Behavioral Therapy with or without Medications for OUD: Behavioral therapy (psychosocial treatment or non-medication treatment by psychology staff or a licensed clinical social worker) can be an effective treatment alone or in combination with medications for OUD. Behavioral therapy includes motivational interviewing, cognitive behavioral therapy, family therapy, 12-step programs, addiction counseling, and group therapy.

Comparative studies in the community show a lower efficacy rate for abstinence/reduced opioid use and retention in treatment outcomes for behavioral therapy alone compared to treatment with medications for OUD alone. Studies examining outcomes of combined behavioral and medication treatment modalities have shown superiority to behavioral health therapy by itself. The use of combined behavioral therapy and medications for OUD is the generally accepted standard of care. The BOP recommends individualized treatment plans for inmates receiving medications for OUD, but does not require one or more forms of behavioral therapy. As a stand-alone treatment, behavioral therapy may be most appropriate for individuals with mild OUD, a past history of successful behavioral therapy, and/or ineligibility for, or a strong preference against medications for OUD.

2. AVOIDING STIGMATIZING TERMINOLOGY

Stigma remains one of the biggest barriers to treatment for people with substance use disorders, and the terminology used to describe substance use disorders has contributed to a stigmatizing culture that may discourage people from seeking help.

Language acknowledging substance use disorders as a brain disorder reduces stigma and improves treatment outcomes. Staff are encouraged to use objective, descriptive, and respectful language when working with offenders with substance use disorders, such as those explained in **TABLE 1** below.

TABLE 1. PREFERRED TERMINOLOGY VS. STIGMATIZING TERMINOLOGY

PREFERRED LANGUAGE	STIGMATIZING LANGUAGE	REASONING
Substance use disorder; substance misuse	Abuse, addiction, habit, problem	Avoids negative/punitive attitudes, even among treatment professionals. Habit inaccurately implies that a person is choosing to use substances and can simply stop whenever.
Person with a substance use disorder	Addict, alcoholic, crackhead, junkie, abuser, user	Avoids demeaning language that labels a person by his/her illness
Drug monitoring, drug screen, drug test, positive/negative drug test	Dirty drug test, clean drug test	Utilizes more neutral, professional, and accurate terms
Actively using. In recovery, Not actively using	Dirty, clean, sober	Utilizes more neutral, professional, and accurate terms
Medications for Opioid Use Disorder (methadone, buprenorphine, naltrexone)	Drug replacement substitution therapy	Medications for opioid use disorder are life-saving and effective treatments, yet these medications are frequently referred to as replacements . This contributes to the mistaken notion that they are simply a way to substitute a legal opioid for an illicit opioid, rather than being a legitimate medical treatment.

3. DIAGNOSIS AND ASSESSMENTS

DIAGNOSIS

The **DSM-5 criteria for opioid use disorder** are based on identifying **at least two out of 11** manifestations of “clinically significant impairment or distress” resulting from opioid use. The criteria also address severity of the condition (mild, moderate, or severe) and status of treatment (early remission, sustained remission, and/or the use of maintenance therapy).

- ➔ Refer to the following link for specific DSM-5 criteria and guidance:
<https://www.aoaam.org/resources/Documents/Clinical%20Tools/DSM-V%20Criteria%20for%20opioid%20use%20disorder%20.pdf>

Determining Severity: Severity of OUD is based on the number of symptoms described in the DSM-5 criteria provided in the link on the previous page:

- Mild: presence of 2 to 3 symptoms
- Moderate: presence of 4 to 5 symptoms
- Severe: presence of 6 or more symptoms

Note that these criteria must have occurred “within a 12-month period” meaning that the symptoms persisted for at least 12 months, but occurred within any 12-month period. It is not necessarily based on the patient’s previous 12 months or current presentation.

Determining Status: The status of the patient is then determined based on his or her **current** presentation:

- **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 of “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 of “craving, or a strong desire or urge to use opioids,” may be met).

The DSM-5 also provides additional specifiers based on the following:

- On maintenance therapy (agonist or antagonist)
- In a controlled environment (includes the correctional environment)

For example, a patient who has been incarcerated for 8 years and who has been completely abstinent from opioid use but reports a history of 8 out of the 11 criteria listed in the DSM-5 ten years ago for 2 years, could be diagnosed as having a **severe opioid use disorder in sustained remission in a controlled environment**.

Following this example, if the patient were to be initiated on long-acting injectable naltrexone, the patient’s new diagnosis would be **severe opioid use disorder in sustained remission on maintenance therapy in a controlled environment**.

An appropriate OUD diagnosis should be listed in the Inmate Health Summary. It is recommended for behavioral health care providers (e.g., clinical social workers, psychologists, psychiatrists) to use the DSM-5 criteria for diagnosis of OUD and for medication providers to use the ICD-10 code of F11.20 with qualifier of *a, *b or *c, based on severity of OUD described in the following table:

TABLE 2. ICD-10 DIAGNOSTIC CODES FOR OUD

ICD-10 CODE	QUALIFIER	ICD-10 DESCRIPTOR	COMMENTS
F11.20	*a	Opioid dependence	Mild OUD (2-3 symptoms)
F11.20	*b	Opioid dependence	Moderate OUD (4-5 symptoms)
F11.20	*c	Opioid dependence	Severe (6 or more symptoms) OUD

INITIAL ASSESSMENT PRIOR TO INITIATION OF MEDICATIONS FOR OUD

Treatment selection is guided by the results of the following assessment. When determining a treatment plan for initiation of medications for OUD, refer to [Section 6, Medications for OUD](#) and [Table 8. Considerations for Treatment Selection](#), as a guide. The recommended dosing schedules for initiation are reviewed in Section 6.

In addition to the regular prescribing considerations (i.e., current and past medication use, side effects, drug-drug interactions, etc.), providers utilizing medications for OUD should document and conduct the following:

A comprehensive medical history and focused physical exam.

Substance use history including drug of choice, last use, frequency, amount, route of administration, age of onset, periods of abstinence, treatment with medications for OUD, and/or administration. Other drugs used together or separately, including alcohol and tobacco. Past experience of withdrawal symptoms or overdose. Consider obtaining incident report history involving drug use.

Behavioral health history including history of behavioral health disorders and treatment for the following: depression, anxiety, personality disorders, post-traumatic stress disorder, bipolar disorder, and psychotic disorders. Consider obtaining any additional prior criminal history.

Education, motivation, and community access including level of education, treatment goals, and future community access to treatment, if known or relevant.

Documentation should include Clinical Opioid Withdrawal Scale (COWS) (See [Section 5](#)) assessments, behavioral health evaluation referral placed in BEMR, and signed Informed Consent and Agreement for Treatment (forms available through BEMR).

- ➔ *The treatment of OUD may include both medications and counseling/behavioral therapies. Therefore, the patient should be referred to a qualified behavioral health provider for concomitant behavioral health treatment. An evaluation of the patient by a qualified behavioral health provider is recommended prior to initiating medications for OUD, but should not delay initiation if the risk of relapse, or severe withdrawal is a concern.*

Baseline Tests including urine drug screen (See [Section 4](#)), CMP, CBC, TSH, urinalysis, screening for HIV, hepatitis (A, B, and C), and clinically relevant STIs, ECG (for patients considered for methadone), and pregnancy test for women of child bearing potential prior to treatment initiation.

INITIAL ASSESSMENT FOR CONTINUING MEDICATIONS FOR OUD ON INTAKE

When an inmate arrives to an institution on medications for OUD, it should be continued unless contraindicated. BOP institutions should seek to gather all collateral information and conduct an independent initial assessment as described above in a timely fashion. Confirmation of medication dose should be obtained whenever possible, either through outside medical records or contact with the provider. If such confirmation is not available at the time of intake, providers should conduct an initial assessment as described above and the decision to continue medications for OUD should be individualized and based on available information, patient presentation, and clinical judgment.

For patients who are continuing buprenorphine or methadone, the institution should ensure all provider/facility regulatory criteria are met. (See [Section 6](#)). If criteria are not met, refer to the *BOP Medication Treatment for Opioid Use Disorder Technical Guidance* on how to refer patients to properly credentialed facilities/providers or how to meet proper criteria.

ONGOING ASSESSMENTS FOR PATIENTS NOT ON MEDICATIONS FOR OUD

Inmates should be screened and assessed for OUD and treatment throughout their incarceration as clinically appropriate. Indications that an inmate may require assessment for OUD include:

- BOP staff referral of an inmate
- Inmate requests for evaluation
- Positive opioid urine drug test
- Naloxone administration for opioid overdose reversal
- Any opioid-related misconduct

FOLLOW-UP ASSESSMENTS

Follow-up assessments and dosage adjustments may be necessary during early stabilization, and frequent contact with patients increases the likelihood of adherence. Follow-up assessments should continue to cover the relevant topics covered in the initial assessment including treatment goals, addressing cravings, progress with behavioral health counseling (as appropriate), and continued review of relevant laboratory findings.

Because OUD is a chronic, relapsing disease, the duration of treatment will need to be individualized. Some patients may choose or require treatment for a few months to a few years, and some may require lifelong treatment. In general, medications for OUD should be continued for as long as the patient is willing to consent fully with their treatment plan and the treatment provider finds the patient continues to derive benefit from the medication.

Regular ongoing assessments of patient response to treatment and adherence to their treatment plan should be conducted as outlined under each individual medication (See [Section 6](#)).

MULTIDISCIPLINARY DELIVERY OF MEDICATIONS FOR OPIOID USE DISORDER

The effective delivery of medications for OUD requires a multidisciplinary approach. As such, the *BOP Medication Treatment for Opioid Use Disorder Technical Guidance* recommends each institution conduct a **monthly (or more frequent) OUD treatment multidisciplinary meeting**. These meetings are recommended to include, at the least, the institution OUD Treatment Point of Contact (POC), social worker (if available), nurse, psychologist, pharmacist, medical provider, a unit team representative, and Captain, or designee.

The purpose of these meetings is to foster communication between departments and keep everyone informed about individual patient progress. Additionally, these meetings provide an opportunity to ensure aftercare needs are being addressed, provide feedback and assist with decisions regard treatment planning in difficult cases, and review current processes for possible changes or further expansion. The POC is appointed at each institution as described in the *BOP Medication Treatment for Opioid Use Disorder Technical Guidance*. This POC will develop the agenda and facilitate the meetings.

4. URINE DRUG TESTING

Drug testing is a tool that provides information about an individual's substance use. Urine drug testing (UDT) detects the presence or absence of specific drug(s) and drug metabolites in a urine sample within a specific timeframe.

There are two types of UDT, **presumptive testing** by immunoassay and **definitive testing** by chromatography. Presumptive testing serves as an initial screening tool. Definitive testing is a confirmatory test that can identify and quantify specific drugs and/or drug metabolites. Information about the different types of drug monitoring technologies is listed in **Table 3**.

TABLE 3. TYPES OF URINE DRUG TESTING

PRESUMPTIVE	DEFINITIVE
Preliminary	Confirmatory
Qualitative (positive or negative)	Quantitative
Immunoassay	GC-MS/LC-MS*
Results indicate a class or category	Results identify specific drugs or drug metabolites and concentration detected may be reported
* gas chromatography-mass spectrometry/liquid chromatography-mass spectrometry	

The BOP has both presumptive and definitive testing available for drug monitoring. Several tests available are presumptive with the ability to provide confirmation only if the preliminary test is positive. Others are quantitative only, as specified in the test name. **Table 4** below lists the current tests available, their type, and the drugs they screen.

TABLE 4. URINE DRUG TESTING IN THE BOP

BEMR TEST NAME	DRUGS SCREENED	PRESUMPTIVE AND/OR DEFINITIVE
Drug Monitoring Opiates Screen	Opiates; codeine, hydrocodone, hydromorphone, morphine, norhydrocodone	Presumptive Only
Drug Monitoring Oxycodone Screen	Oxycodone, noroxycodone, oxymorphone	Presumptive Only
Drug Monitoring Buprenorphine & Naloxone Qnt	Buprenorphine, norbuprenorphine	Definitive
Drug Monitoring Fentanyl w/Conf	Fentanyl, norfentanyl	Definitive
Drug Monitoring Heroin Metab w/Conf	6-Acetylmorphine	Definitive
Drug Monitoring MDMA/MDA w/Conf	MDMA, MDA	Definitive
Drug Monitoring Methylphenidate	Ritalinic acid	Definitive
Drug Monitoring Panel 3 w/Conf	Amphetamines, benzodiazepines, marijuana, cocaine, opiates, oxycodone	Presumptive + Definitive
<i>(Table 4 continues on the next page)</i>		

BEMR TEST NAME	DRUGS SCREENED	PRESUMPTIVE AND/OR DEFINITIVE
Drug Monitoring Panel 4 w/Conf	Amphetamines, barbiturates, benzodiazepines, cocaine, methadone, opiates, oxycodone, phencyclidine	Presumptive + Definitive
Drug Monitoring Panel 5 Screen	Amphetamines, Barbiturates, Benzodiazepines, Marijuana, Cocaine, Methadone, Opiates, Oxycodone	Presumptive Only
Drug Monitoring Panel 5 w/Conf	Same as Drug Monitoring Panel 5	Presumptive + Definitive
Drug Monitoring Buprenorphine & Naloxone QntPanel 8 w/Conf	6-Acetylmorphine, Alcohol, Amphetamines, Benzodiazepines, Buprenorphine, Marijuana, Cocaine, MDMA, Opiates, Oxycodone	Presumptive + Definitive

Use of urine drug testing in clinical practice is determined by the provider. Patients will likely require more drug testing early in treatment or during periods of relapse. More frequent testing may also be indicated when there is suspicion of illicit substance use, non-adherence to prescribed medication for OUD, or for patients with a high vulnerability to relapse. If patients or providers are suspicious of false negative or false positive lab results from presumptive forms of UDT, it may be appropriate to conduct definitive forms of testing in order to allow patients to confirm that they are compliant with their treatment contract.

A UDT should confirm the presence of the prescribed DEA-scheduled medications for OUD (methadone or buprenorphine) when these medications are part of the treatment plan.

- When testing for buprenorphine, a positive test should reflect BOTH buprenorphine and the metabolite norbuprenorphine. If buprenorphine alone is in the sample, this would indicate that the sample is most likely adulterated. (See [Section 7. Discontinuation of Medications for Opioid Use Disorder](#)).
- Absence of a prescribed medication in a UDT suggests non-adherence to the treatment regimen and possible diversion.

Drug monitoring should be used as a therapeutic tool to improve care. Providers can use drug monitoring to provide motivation and reinforcement for abstinence, as well as confirm adherence to medications for OUD. Patients should be educated on the therapeutic purpose of drug testing. All BOP treatment agreements include the expectation for inmates to comply with drug testing. Patients who will not comply with this expectation should be considered for discontinuation of buprenorphine or methadone. (See [Section 7. Discontinuation of Medications for Opioid Use Disorder](#).)

FREQUENCY OF URINE DRUG TESTING

For institutions operating as an OTP: the Code of Federal Regulations requires **eight urine drug tests per year** for patients on maintenance treatment with methadone or buprenorphine. The eight required urine drug tests for an OTP can be presumptive and/or definitive. Although eight UDTs are required per year for patients in an OTP, additional testing can be done on a case-by-case basis.

For OBOT settings: Patients being treated with buprenorphine as prescribed under an individual provider's DATA 2000 waiver in an OBOT setting do not have a mandatory UDT requirement. Ongoing clinical monitoring that includes urine drug testing is part of a good practice in order to acquire objective evidence of any ongoing illicit substance use and confirm buprenorphine adherence. Frequency of UDT should be clinically determined but should occur not less than at the time of initial evaluation and regularly during initiation of treatment with buprenorphine. For patients prescribed ongoing maintenance treatment with buprenorphine in an OBOT setting, the BOP suggests **at least quarterly UDTs** with more frequent testing as clinically indicated.

URINE DRUG TESTING DURING INITIAL DIAGNOSTIC EVALUATION

Urine drug testing during initial assessment for treatment with medications for OUD can be used as a component of assessment and treatment planning. Urine drug screens can:

- Provide baseline, objective information to compare with the patient's subjective self-report. For example, when there is a discrepancy between a subjective patient report and objective drug testing, the inconsistency provides an opportunity for dialogue between the provider and patient to discuss the discrepancy. This dialogue will enhance accuracy of diagnosis and appropriateness of the treatment plan.
- Serve as a tool to estimate the risk of acute withdrawal and help guide the treatment of opioid withdrawal.
- Urine drug testing alone is not a diagnostic test for OUD or severity of OUD and should be used with other pertinent clinical information in generating a treatment plan for a patient.

Use of a broader panel of definitive tests, such as Drug Monitoring Panel 8 w/confirmation from the previous table, can be helpful for initial evaluation and in early treatment to rule out polysubstance use or continued use of illicit substances.

During initial assessment, **consider obtaining multiple random drug tests over a 2-week period** to assist in determining if the patient is actively taking opioid substances and to what degree or frequency.

URINE DRUG TESTING DURING INITIATION AND MAINTENANCE PHASE

There are two main reasons for continued drug testing throughout the course of treatment: 1) assessing use of methadone or buprenorphine, and 2) misuse of other drugs not prescribed to the patient.

After initial diagnostic evaluation, narrower drug monitoring panels than those used during initial evaluation could be more cost effective if the use of other illicit substances is no longer suspected.

- **Unexpected positive results** for other drugs not prescribed to the patient should be acknowledged – ignoring positive test results undermines treatment goals. Unexpected positive results can indicate the need to intensify or change current treatment strategies.
- **Negative results** for methadone or buprenorphine in patients prescribed these medications may indicate non-adherence to treatment and may indicate suspicion of diversion. It should be noted that unexpected positive test results (continued illicit drug use despite treatment) is not unexpected early in treatment. However, repeated unexplained negative test results for prescribed medications could justify discharging the patient from treatment. ([Section 7. Discontinuation of Medications for Opioid Use Disorder.](#))

COMPARISON OF MEDICAL AND CORRECTIONAL UDT

Inmates may receive drug testing for medical reasons or for correctional reasons. These two programs are managed independently of one another. Urine drug testing conducted by correctional services should not be relied upon to meet the requirements for monitoring patients on medications for OUD. However, if available, the data from urine drug testing completed by correctional services can be reviewed by a medical provider in guiding a patient’s treatment. See **TABLE 5** for a comparison of medical and correctional UDTs.

TABLE 5. COMPARISON OF URINE DRUG TESTING FOR INMATES

	MEDICAL URINE DRUG TESTING	CORRECTIONAL URINE DRUG TESTING
Scheduled¹	OTP: 8 times per year or more frequently as clinically indicated ^{2,3} OBOT: Suggested quarterly or more frequently as clinically indicated	As determined by correctional services policies and procedures
Random	As indicated for suspicion	As indicated for suspicion
Staff Completing	Medical Staff	Custody Staff
Follow-up for Positive Findings	<ul style="list-style-type: none"> • Documentation of finding and patient follow-up in BEMR. • Cannot be used for the inmate disciplinary process 	<ul style="list-style-type: none"> • A positive result may only be confirmed by a clinician, qualified within their scope of practice, to review of UDT laboratory results. • May be used for disciplinary action if positive for anything other than prescribed medication(s).
¹ Scheduled UDTs should not be done on a regularly occurring basis (i.e. same time each month) ² If data from custodial UDT is available, it may be counted as part of this requirement. ³ UDT can be presumptive or definitive to count towards the required 8 UDTs per year and should include at least opioids as well as the selected medications for OUD (methadone or buprenorphine).		

5. OPIOID WITHDRAWAL

All patients on medication for OUD may experience symptoms of withdrawal, regardless of the medication. Physical symptoms of withdrawal can include:

- Restlessness, irritability, anxiety
- Increased tearing
- Insomnia
- Muscle aches and muscle twitching
- Yawning
- Runny nose
- Abdominal cramps, nausea, diarrhea, vomiting
- Dilated pupils
- Sweating
- Piloerection
- Mild hypertension and/or tachycardia

TABLE 6. AVERAGE TIME TO OPIOID WITHDRAWAL SYMPTOMS

	EARLY WITHDRAWAL	FULLY DEVELOPED WITHDRAWAL	TOTAL DURATION OF WITHDRAWAL
Short-acting opioids	8 to 24 hours	1 to 3 days	7 to 10 days
Long-acting opioids	Up to 36 hours	72 to 96 hours	14 days or more

DETERMINING SEVERITY OF WITHDRAWAL

The **Clinical Opiate Withdrawal Scale (COWS)** is an 11-item scale designed to be administered by a clinician. This tool can be used in both inpatient and outpatient settings to reproducibly rate common signs and symptoms of opioid withdrawal, and monitor these symptoms over time. The summed score for the complete scale can be used to help clinicians determine the stage or severity of opioid withdrawal and assess the level of physical dependence to opioids.

Practitioners sometimes express concern about the objectivity of some of the items in the COWS. However, the symptoms of opioid withdrawal have been likened to a severe influenza infection (e.g., nausea, vomiting, sweating, joint aches, agitation, tremor). Patients should not exceed the lowest score in most categories without exhibiting some observable signs or symptoms of withdrawal. It is unlikely that a patient will have moderate to severe symptoms without exhibiting objective signs of withdrawal.

Throughout initiation of medications for OUD, providers should assess for signs and symptoms of withdrawal using the COWS. The COWS scores are totaled to determine the severity of opioid withdrawal and the next plan of action for treatment:

- **5–12:** mild opioid withdrawal
- **13–24:** moderate opioid withdrawal
- **25–36:** moderately severe opioid withdrawal
- **>36:** severe opioid withdrawal

➔ The COWS form appears in [Appendix 1](#) and is available in the flow sheets section of the electronic health record.

SUPPORTIVE THERAPY DURING WITHDRAWAL

Patients experiencing symptoms of withdrawal may require short-term supportive therapy, including non-opioid medication to manage their symptoms. Refer to the [BOP Clinical Guidance for Medically Supervised Withdrawal of Inmates with Substance Use Disorders](#) for treatment options.

6. MEDICATIONS FOR OUD

Although all of the listed medications are FDA approved for the treatment of OUD, these medications vary in their prescribing criteria, dosage forms, and mechanism of action. (See [Table 7](#))

As with any drug treatment, the most up-to-date clinical resources should be referenced when considering side effects, drug interactions, and contraindications to therapy. Determining which

medication to use is based on past treatment history, current state of illness, and patient preference including a discussion of risks versus benefits between the clinician and the patient.

TABLE 7. COMPARISON OF MEDICATIONS FOR OUD

DRUG NAME	FORMULATIONS AVAILABLE	MECHANISM OF ACTION	ORDERING RESTRICTIONS	SPECIAL CONSIDERATIONS
Buprenorphine	Long-acting injection (<i>Sublocade®</i>) Sublingual tablet (<i>various generics</i>)	Partial opioid-receptor agonist	Prescriber must have DATA 2000 (“X” waiver) DEA license or must be dispensed or administered in an OTP REMS registration required for Sublocade	<ul style="list-style-type: none"> • Less potential for respiratory depression or overdose than methadone if taken at doses greater than prescribed • Buprenorphine can precipitate opioid withdrawal in opioid dependent patients (including patients on methadone). • The tablet formulation of this medication can be altered and injected as a form of substance misuse.
Buprenorphine/ Naloxone	Sublingual film (<i>Suboxone®</i>) Sublingual tablet (<i>Zubsolv®</i>)	Partial opioid-receptor agonist/ opioid-receptor antagonist	Prescriber must have DATA 2000 (“X” waiver) DEA license or must be dispensed or administered in an OTP	<ul style="list-style-type: none"> • Naloxone in this formulation has little effect if taken orally. However, if the medication is altered and injected, it will blunt the agonist effects of buprenorphine.
Methadone	Tablet or liquid concentrate	Full opioid receptor agonist	Can only be dispensed or administered for treatment of OUD in an OTP	<ul style="list-style-type: none"> • Most widely studied • Blunts or blocks effects of other illicit opioid substances
Naltrexone	Long-acting injection (<i>Vivitrol®</i>) Tablet (<i>various generics</i>)	Opioid-receptor antagonist	No restrictions	<ul style="list-style-type: none"> • Also indicated for alcohol dependence • No misuse potential • Tablets are low cost • Opioid withdrawal may occur if started soon after last opioid use.

MEDICATION TREATMENT GOALS

There are no data to help predict which patient will respond best to methadone, buprenorphine, or naltrexone. The goals of treatment for all medications for OUD include:

- Minimizing harm from ongoing illicit opioid use.
- Sustained recovery with abstinence from other illicit substances.
- Reduce cravings or urge for illicit opioids.
- Promote engagement in recovery-oriented activities.

There is no “one size fits all” approach to OUD treatment. BOP providers for patients with OUD should develop an individualized treatment plan for each patient based on that patient’s needs, goals, the availability of treatment (including aftercare planning, see [Section 9](#)), and the patient’s willingness to comply with the expectations of treatment with medications for OUD. The following table can be used as a guide to suggest what medication may be best to accomplish treatment goals for a patient with OUD. When considering the best treatment, the provider should also review the inmate’s medical history and baseline labs for contraindications to therapy.

TABLE 8. CONSIDERATIONS FOR TREATMENT SELECTION

PATIENT CHARACTERISTICS	TREATMENT TO CONSIDER	ADDITIONAL CONSIDERATIONS
Actively taking medications for OUD	Continue current medication if stable	<ul style="list-style-type: none"> In collaboration with the patient, consider converting to medication that is most appropriate for the patient in an institutional setting. Consider conversion to long-acting injection when patient is stable.
Mild OUD	Long-acting injectable naltrexone ¹	<ul style="list-style-type: none"> Buprenorphine or methadone can be considered depending on patient factors including patient willingness to follow expectations for treatment. Examples could include patients with a history of success on prior medications for OUD, or contraindications to taking naltrexone.
Moderate to Severe OUD, post-withdrawal / in remission, and not currently using opioids	<p>Consider long-acting injectable naltrexone¹ in shared decision making with the patient.</p> <p>If previously treated successfully, consider restarting the same medication.</p>	<ul style="list-style-type: none"> Buprenorphine or methadone can be considered depending on patient factors including patient willingness to follow expectations for treatment. Examples could include patients with a history of success on prior medications for OUD, or contraindications to taking naltrexone.
Moderate to Severe OUD, currently using opioids	Naltrexone, buprenorphine, buprenorphine/naloxone, methadone ²	<ul style="list-style-type: none"> Consider initiating medications for OUD as part of a treatment plan that is most appropriate for the institutional setting. Consider conversion to long-acting injection when patient stable and if medication available.
Pregnant with OUD	See Section 8. Special Populations	

¹Supervised (directly observed therapy) daily oral naltrexone is a reasonable alternative to long-acting injectable naltrexone in highly motivated patients who do not wish to receive injections.
²Methadone for OUD can be used in BOP OTPs only. Methadone is a reasonable alternative in patients with a history of a poor response to buprenorphine, previous misuse or diversion of buprenorphine, have higher levels of opioid physical dependence, or who have had previously successful treatment with methadone.

BUPRENORPHINE AND BUPRENORPHINE/NALOXONE

Use and formulation: Buprenorphine is a partial opioid agonist, available with and without naloxone, in the following formulations:

- **Buprenorphine/naloxone sublingual tablets or strips**
 - ▶ Naloxone is given in combination with buprenorphine to decrease potential for misuse as it decreases the euphoria produced by the opioid drug and is more likely to precipitate withdrawal if injected.
- **Buprenorphine-only long-acting injections and implants**
- **Buprenorphine-only sublingual tablets or buccal films**
 - ▶ Given the lower risk of misuse with buprenorphine/naloxone and buprenorphine-only injections and implants, the buprenorphine-only sublingual tablet is only recommended in the BOP for the following patients:
 - Documented or observed allergic reaction to naloxone
 - Moderate to severe hepatic impairment (See [Appendix 3](#))

Prescribing Restrictions: Only providers that have a DATA 2000 waiver can prescribe buprenorphine. Providers may refer to the *BOP Medication Treatment for Opioid Use Disorder Technical Guidance* for further instructions on how to acquire a DATA 2000 waiver and/or how to properly utilize outside providers to continue therapy if there is no DATA-waived provider on site.

INITIATION PHASE

The goal of the initiation phase is to **determine the minimum dose of buprenorphine** at which the patient markedly diminishes or discontinues use of all other opioids, experiences minimal withdrawal symptoms, minimal or no side effects, and no uncontrollable cravings.

Precipitated Withdrawal: Buprenorphine has a high affinity for the opioid receptor, which can displace full agonists and cause an acute—and potentially severe— precipitated opioid withdrawal. The likelihood of precipitating withdrawal upon starting buprenorphine is reduced as the interval between the last dose of the opioid and the first dose of buprenorphine increases.

Conditions to reduce the risk of precipitated withdrawal: Prior to initiation of buprenorphine (with or without naloxone) patients who have been actively or recently using opioids should be exhibiting symptoms of mild to moderate opioid withdrawal. The American Society of Addiction Medicine (ASAM) recommends using a COWS score or ≥ 11 as an appropriate level of withdrawal for starting buprenorphine in patients who are current opioid users. Patients are likely to achieve this level of withdrawal after a period of time has elapsed from the last opioid dose, depending on the duration of action of the opioid, as follows:

- 6-12 hours for short-acting opioids (immediate-release morphine, heroin)
 - 24 hours for sustained-release opioid medications
 - 24-72 hours for methadone (For methadone doses ≥ 30 mg, more time may be required before buprenorphine can be initiated.)
- ➔ *For patients previously using fentanyl, consider initiating buprenorphine (with or without naloxone) with COWS score ≥ 13 .*
- ➔ *For patients not currently dependent on opioids, conditions to avoid precipitated withdrawal are not required to initiate buprenorphine. Instead, patients with little to no tolerance to opioids due to prolonged abstinence are at risk for over-sedation and possible overdose. Therefore, the initial dose should be started lower and increased slower than in tolerant patients. See **INITIATION FOR OPIOID-ABSTINENT PATIENTS**.*

INITIATION FOR OPIOID-DEPENDENT PATIENTS - DAY 1

STEP 1. Ensure conditions to reduce the risk of precipitated withdrawal have been met.

- ▶ If a patient never experiences COWS score ≥ 11 , consider utilizing *INITIATION FOR OPIOID-ABSTINENT PATIENTS* below.

STEP 2. Administer initial dose of 2 to 4 mg of oral buprenorphine/naloxone.

- ▶ Relief of withdrawal symptoms should begin 30–45 minutes after the first dose. The patient should be monitored for two hours and reassessed.
- ▶ If symptoms of precipitated withdrawal occur, treat symptoms, and attempt initiation again in 24 hours.

STEP 3. Two hours after administering the first dose of buprenorphine/naloxone, assess the patient for signs and symptoms of withdrawal using COWS.

STEP 4. If withdrawal symptoms persist or return (COWS score >8), administer an additional 4 mg of buprenorphine/naloxone.

- ▶ Do **not** exceed a total daily dose of 8 mg of buprenorphine on Day 1.

STEP 5. Proceed to Initiation Day 2

- ▶ If withdrawal symptoms were relieved after Step 3, skip additional dose (Step 4) and proceed to Initiation Day 2.

INITIATION FOR OPIOID-ABSTINENT PATIENTS – DAY 1

STEP 1. Administer an initial dose of 2 mg of oral buprenorphine/naloxone.

- ▶ A lower dose of 1mg may be used, but requires additional accountability and documentation of the unused portion.

STEP 2. Two hours after administering the first dose of buprenorphine/naloxone, assess the patient for signs and symptoms of sedation and precipitated withdrawal.

STEP 3. If the patient tolerates the dose well (no signs of sedation or precipitated withdrawal), proceed to Initiation Day 2.

- ▶ If the patient shows signs of sedation, do not proceed forward with initiation phase. Reassess the patient's indications for treatment or consider naltrexone.
- ▶ If the patient shows signs of precipitated withdrawal, treat symptoms according to clinical guidance and assess patient conditions to reduce precipitated withdrawal. Attempt Day 1 again at least 24 hours later if indicated.

INITIATION DAY 2

STEP 1. Administer the previous day's total dose as one dose in the morning.

STEP 2. Two hours after administering the dose of buprenorphine/naloxone, assess the patient for signs and symptoms of withdrawal using COWS.

- ▶ To avoid over sedation in opioid-abstinent patients, it is recommended to increase the dose more slowly, up to once weekly.

STEP 3. If withdrawal symptoms persist or return (COWS score >8), administer an additional 4 mg of buprenorphine/naloxone and repeat Step 2.

- ▶ If withdrawal symptoms were relieved or never occurred, skip additional doses (step 3) and proceed to Stabilization Phase. The patient's total dose received on Day 2 is the starting dose for the patients Stabilization Phase.
- ▶ Do **not** exceed a total daily dose of 16 mg of buprenorphine.

FIGURE 1. INITIATION OF BUPRENORPHINE FOR OPIOID-DEPENDENT PATIENTS – DAY 1:

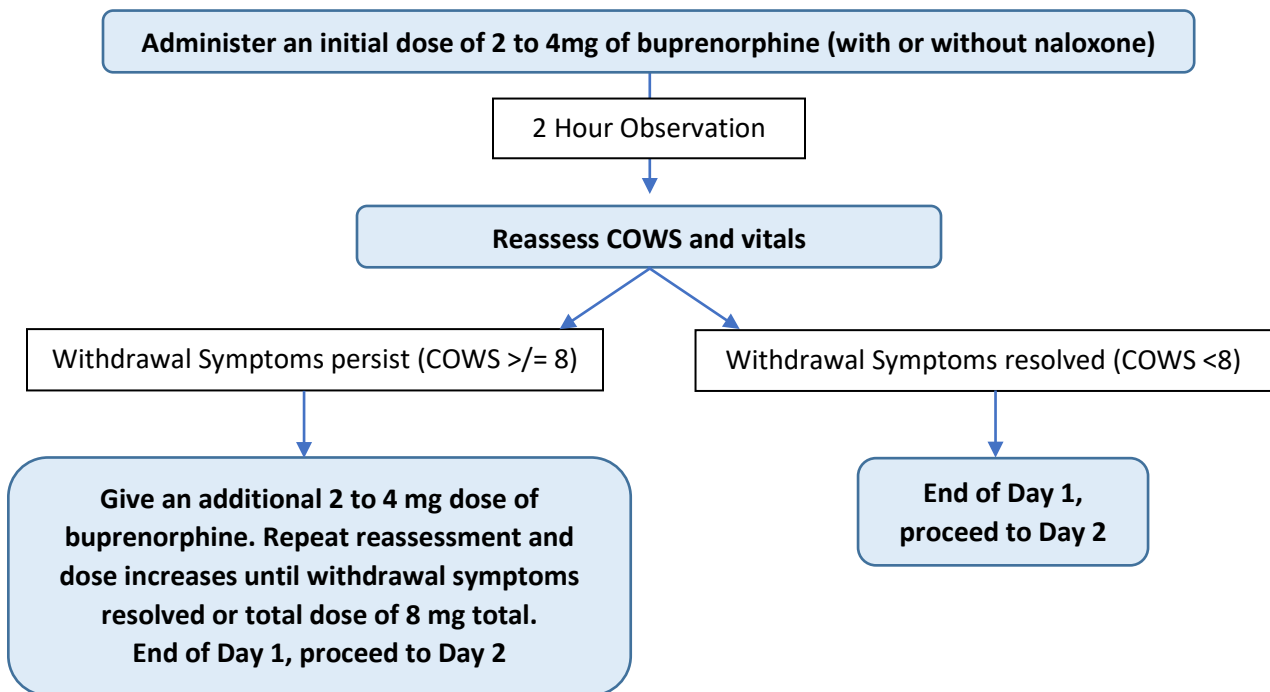


FIGURE 2. INITIATION OF BUPRENORPHINE FOR OPIOID-ABSTINENT PATIENTS – DAY 1:

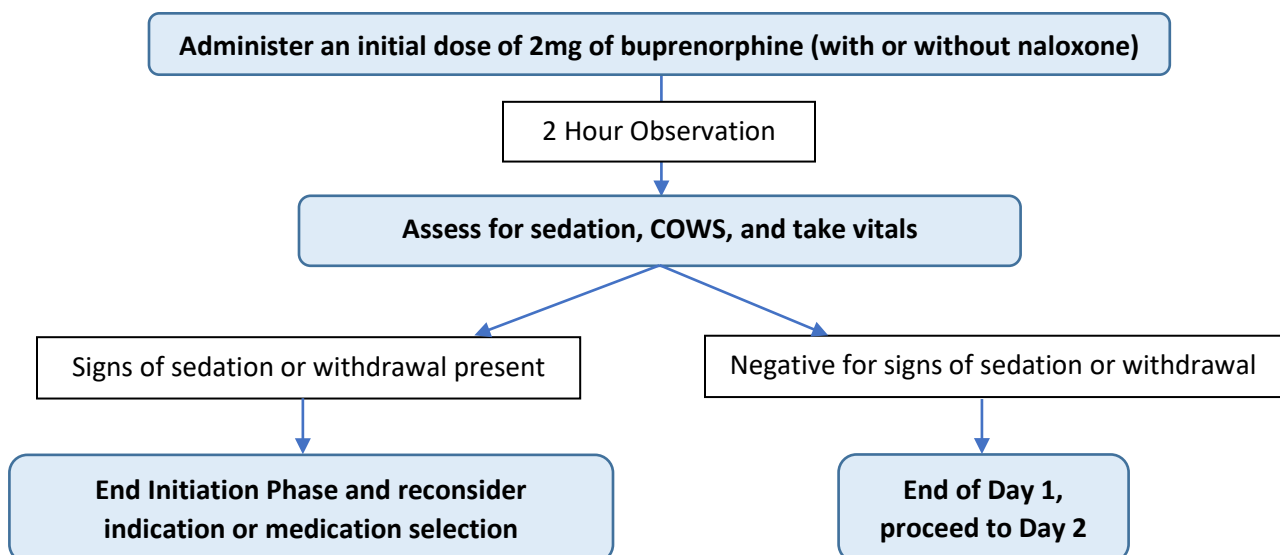
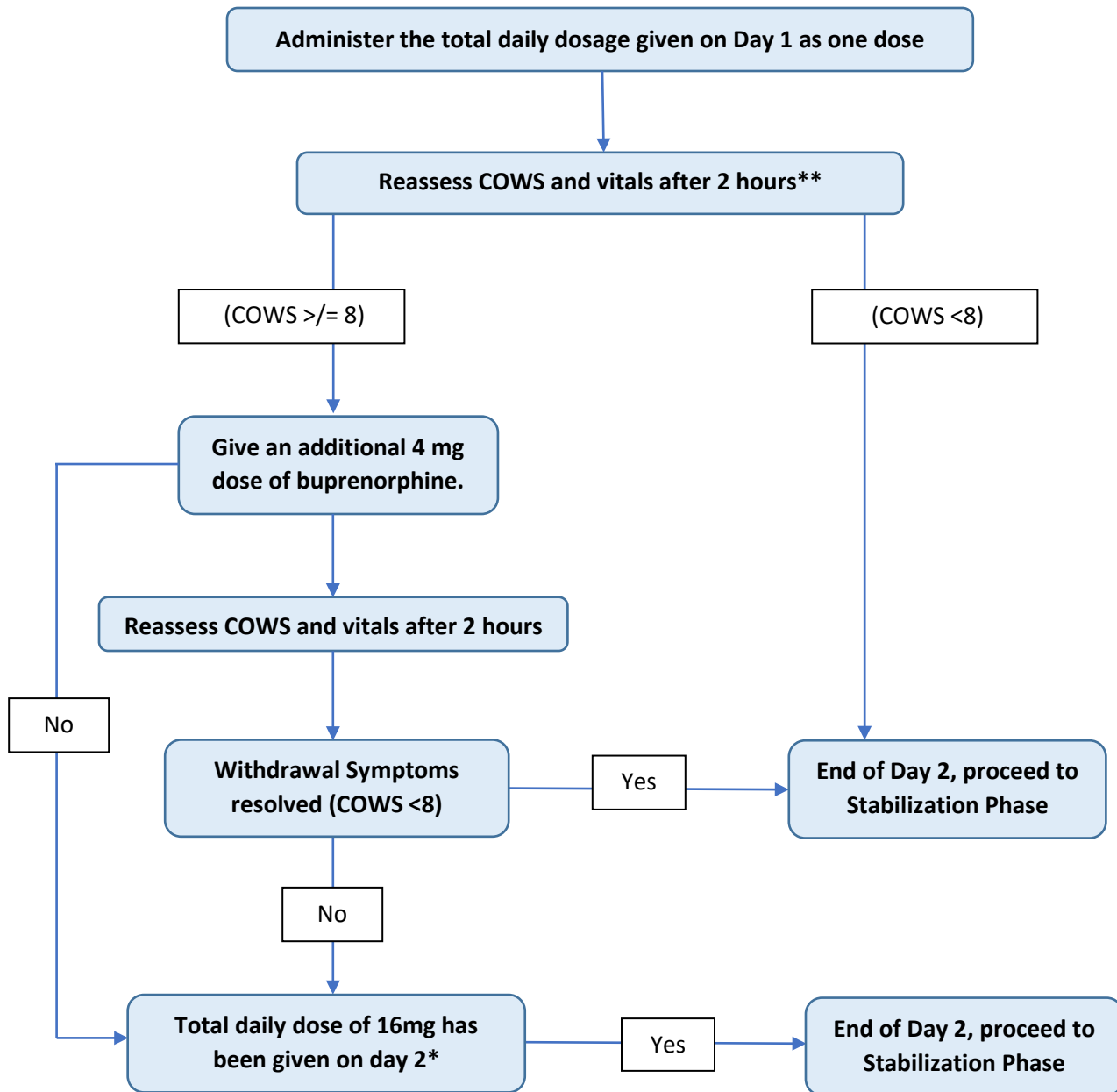


FIGURE 3. INITIATION OF BUPRENORPHINE DAY 2



**The recommended target dosage of buprenorphine is 12 to 16 mg per day. Nearly all patients stabilize on daily doses of 4-24 mg per day. There is limited data to show additional benefits of doses higher than the FDA label's recommended maximum dose of 24mg/6mg per day.*

*** To avoid over sedation in opioid-abstinent patients, it is recommended to increase the dose more slowly, up to once weekly.*

STABILIZATION PHASE

Stabilization is achieved when the patient experiences mild or no withdrawal symptoms, has minimal or no side effects, and has less cravings for opioid agonists. During the stabilization phase, providers can continue to adjust the daily dose if the patient experiences continued symptoms of withdrawal and cravings and continues to tolerate their current dose.

Stabilization phase for Opioid Dependent Patients:

- For patients that were opioid dependent prior to initiation, providers can continue to make dose adjustments during stabilization of up to 4mg/2mg of buprenorphine/naloxone every 3 days based on continued symptoms of withdrawal and/or cravings for illicit substances.
- When a total daily dose of 16 mg is achieved, no further dose increases are recommended for several days (4-7) to allow the medication to have maximum effect. Additional dose increases may be needed occasionally, up to 24 mg/day.
- Stabilization for patients that were opioid dependent prior to initiation typically occurs within 3 to 7 days after the initiation phase. However, depending on the individual characteristics of the patient, more time may be required to achieve a maintenance dose.

Stabilization phase for Opioid Abstinent Patients:

- For patients that were not opioid dependent prior to initiation, providers can continue to make dose adjustments during stabilization of up to 2mg/0.5mg of buprenorphine/naloxone every 7 days.
- Stabilization doses are expected to be lower in individuals who were not opioid dependent prior to initiation. Although there is no established recommended maintenance dose for previously opioid abstinent patients, the BOP recommends the lowest possible tolerated dose where no signs of sedation, withdrawal, or cravings for illicit substances are present. When a total daily dose of 8mg is achieved, no further dose increases are recommended unless objective findings for withdrawal symptoms or continued illicit substance use is confirmed.

After stabilization, patients can proceed with one of the following treatment choices if appropriate:

- **CONTINUE WITH ORAL BUPRENORPHINE (WITH OR WITHOUT NALOXONE):** When stabilized on a daily dose of oral therapy, proceed to ***MAINTENANCE PHASE***.

OR

- **CONVERSION TO LONG-ACTING INJECTABLE BUPRENORPHINE (SUBLOCADE®):** In order to reduce the risk of diversion, and provide more stable levels of buprenorphine, consider **converting to the long-acting injectable buprenorphine after dose stabilization is achieved with an oral formulation**. It should be discussed early on before initiation of treatment as the plan of care and goal of treatment to utilize injectable dosage forms when appropriate as they may improve adherence and reduce diversion. The following schedule is recommended if converting the patient to monthly subcutaneous injections:
 - ▶ The long-acting injectable form of buprenorphine should NOT be used until patients have completed the stabilization phase with dosages of at least 8mg of buprenorphine daily for a minimum of 7 days.

- ▶ Initiate dose at 300 mg subcutaneous abdominal injection monthly for the first two months followed by 100mg every 28 days thereafter. The oral form of buprenorphine is discontinued on the day of the first injection.
 - ▶ If patient does not demonstrate satisfactory response on 100 mg dose (continued reports of cravings, illicit substance use, or positive urine drug screens), dose may be increased back to 300 mg monthly.
- ➔ *Ordering and administering of Sublocade® requires your institution to enroll in the Sublocade® REMS program. Instructions on how to enroll can be found on the Sublocade® website or with the following link: <https://sublocaderems.com>. Discuss with your institution pharmacist to ensure enrollment in REMS and availability of Sublocade®.*

MAINTENANCE PHASE

When the minimum effective dose of buprenorphine has been established, the dose should be continued based on the agreed upon patient and provider goals. The length of the maintenance phase is a collaborative decision between the patient and provider, and depends on the patient complying with the expectations of their treatment plan.

SWITCHING TREATMENT MEDICATIONS

Buprenorphine and buprenorphine/naloxone are generally well-tolerated. However, switching to other OUD treatment medications may be appropriate in the following cases:

- Patient experiences intolerable side effects.
- Patient has not experienced a successful course of treatment in attaining or maintaining goal through the initially chosen pharmacotherapy option.
- Patient requests a change and is a candidate for an alternative treatment.

➔ See [Appendix 2 Converting to OUD Medications](#)

SWITCHING TO NALTREXONE

Oral buprenorphine (monotherapy or with naloxone) has a long half-life; 10–14 days should elapse between the last dose of buprenorphine and the start of naltrexone to ensure that the patient is not physically dependent on opioids before starting naltrexone.

Due to its long-acting formulation and variable half-life, converting long-acting injectable buprenorphine to naltrexone is difficult and not typically recommended. Patients should be converted back to oral buprenorphine/naloxone and then converted to naltrexone as previously outlined.

SWITCHING TO METHADONE

➔ *Switching to methadone must be done within an OTP.*

Transitioning from buprenorphine (monotherapy or with naloxone) to methadone does not typically result in adverse reactions. There is no time delay required in transitioning a patient from buprenorphine to methadone.

For patients taking long-acting injectable buprenorphine, initiate methadone on the next scheduled injection day instead of the injection.

ADMINISTRATION CONSIDERATIONS

- **Medications for OUD must be administered during a pill line separate from the institution's standard pill lines.**
- **Patients should be instructed not to swallow sublingual films or tablets.** These medications have been formulated to be directly absorbed into the bloodstream through the vessels under the patient's tongue, avoiding first-pass metabolism.
- Buprenorphine sublingual films and tablets require direct observation for 15 to 30 minutes after administration. An initial mouth check should be conducted prior to administration to ensure the oral cavity is cleared of any potential tools for diversion (such as dentures or peanut butter on the roof of the mouth). At the conclusion of the observation period, time a second mouth-check should be completed to ensure no diversion occurs and the tablet/strip has fully dissolved.
- Local procedures may need to be implemented to optimize observation of patients.
- Non-health services staff may be used to help with the observation.
- Refer to the *BOP Medication Treatment for Opioid Use Disorder Technical Guidance* for additional administration considerations.

MISSED DOSES

- **< 5 DAYS MISSED:** Continue next scheduled maintenance dose.
- **5 OR MORE DAYS MISSED:** Repeat initiation phase.

FREQUENCY OF FOLLOW-UP

After a patient has completed the stabilization phase for buprenorphine, it is recommended that they are seen at least once weekly to ensure adherence to medication, assess the patient's clinical needs, medication effectiveness, medication side effects, and ensure adequate therapeutic dosing.

When a patient has demonstrated compliance and is on a therapeutic dose, less frequent visits may be needed. Monthly visits may be reasonable once a patient has gone several weeks of abstinence from opioids, demonstrated compliance with medication, absence of medication side effects, and mental health is stable. Patients on buprenorphine should be seen at least quarterly the first year of treatment and may be seen every 6 months thereafter.

METHADONE

Formulation: Methadone is a full opioid agonist that is available as an oral solution or tablet.

Prescribing restrictions: When methadone is used for the treatment of OUD, the facility must be registered as an Opioid Treatment Program (OTP) or arrange services with a community OTP. Facilities may **NOT** order or stock methadone for OUD unless registered as an OTP.

- ➔ *For patients entering BOP custody on methadone for OUD, institutions without an OTP certification may continue methadone for OUD for no more than 72 hours. Continuation of methadone beyond 72 hours requires management by an OTP.*
- ➔ *Refer to the BOP's Medication Assisted Treatment Technical Guidance for more about prescribing regulations and restrictions.*

OTP admission criteria: To be eligible to receive methadone in an OTP, patients must be currently dependent and have a history of opioid dependence for at least one year before admission for treatment.

- Exceptions to the one-year rule are pregnant patients, patients recently released from correctional facilities, and patients previously treated with methadone and discharged from an OTP within the last two years.

Methadone should be considered for patients who meet OTP admission criteria **AND** meet one of the following criteria:

- Patient has an observed adverse drug reaction, intolerance, or contraindication to buprenorphine.
- Patient has failed to meet treatment goals through buprenorphine-containing therapy.
- Patient has entered BOP custody on methadone.
- Patients who were successfully treated with methadone in an OTP in the community but treatment was discontinued as a result of exposure to the criminal justice system and/or incarceration.
- Through prescriber-patient shared decision-making, methadone may be considered for first-line treatment on a case-by-case basis.

INITIATION PHASE

STEP 1. Administer an initial dose of methadone between 10 to 30 mg as a single dose.

- ▶ Lower initial doses (e.g., 2.5 to 10 mg) and slower dose titration should be considered in patients with low tolerance at initiation (e.g., abstinence from opioids > 5 days) or situations outlined in [Appendix 3](#) under methadone precautions.

STEP 2. Reassess the patient for sedation or relief of withdrawal symptoms in 2 to 4 hours

- ▶ If sedation occurs after the first dose, the patient should stay under observation until symptoms resolve. The patient should be reassessed the following day and the dose should be reduced.
- ▶ If withdrawal symptoms have not been suppressed or if symptoms reappear after 2–4 hours, an additional 5 to 10mg may be provided.

➔ ***The maximum initial dose of methadone is 30 mg. The total daily dose on the first day should not exceed 40 mg.***

STEP 3. When withdrawal symptoms decrease and do not return after 2 to 4 hours and there are no signs of sedation after the initial or additional dose, proceed to the TITRATION AND MAINTENANCE PHASE the following day.

TITRATION AND MAINTENANCE PHASE

Titrate to a dosage that minimizes or prevents opioid withdrawal symptoms and prevents cravings for 24 hours—without excessive sedation.

➔ ***Dose increases should **not** be done daily because methadone levels do not reach steady state until approximately 7-10 days. Even when holding the methadone dose constant over several days, the methadone level will rise each day. Patients are highly variable in how they absorb, metabolize and tolerate this medication.***

- **WEEKS 1-2:** Dose titration should be increased 5 mg or less every 7 or more days.
- **WEEKS 3-4:** Dose titration can be increased in 5 mg increments every 5 days, based on the patient's symptoms of opioid withdrawal or sedation.
- **WEEK 5 AND BEYOND:** When an adequate dose is achieved, continue the same treatment goal of avoiding sedation, eliminating withdrawal and cravings, and blocking the euphoric effects of illicit opioids.
- The usual **MAINTENANCE DOSE RANGE** is 60 to 120 mg/day in a single daily dose.

SWITCHING TREATMENT MEDICATIONS

Switching from methadone to other OUD treatment medications must be done within an OTP and may be appropriate in the following cases:

- The patient experiences intolerable methadone side effects.
- The patient has not experienced a successful course of treatment on methadone.
- The patient wants to change and is a candidate for an alternative treatment.

→ See [Appendix 2](#) for additional guidance regarding switching treatment medications

SWITCHING TO BUPRENORPHINE

- Taper down to a target dose of 30 mg of methadone and remain on 30mg dose for ≥ 7 days, then discontinue methadone.
- As described in the section Conditions to Reduce the Risk of Precipitated Withdrawal under the initiation phase of buprenorphine, symptoms of mild to moderate withdrawal (COWS score ≥ 11 should be present before initiating buprenorphine (usually 24 to 72 hours after the last dose of methadone).
- To minimize the risk of **PRECIPITATED WITHDRAWAL** in switching to buprenorphine, use careful initial dosing of buprenorphine, followed by titration to an appropriate maintenance dose.

→ Refer to the buprenorphine discussion for more information on avoiding [precipitated withdrawal](#).

SWITCHING TO NALTREXONE

Patients switching from methadone to naltrexone (oral or extended-release injectable) should be completely withdrawn from methadone before initiating naltrexone, which can usually be achieved within seven days but may require as long as 14 days. Medically supervised withdrawal of methadone should occur within an OTP prior to initiating naltrexone. A naloxone challenge may be used to confirm withdrawal is complete.

MISSED DOSES

- **< 3 DAYS MISSED:** Resume regular scheduled dose.
- **3 DAYS MISSED:** Restart at 75% of the patient's confirmed maintenance dose. The dose should be increased by 5 mg per day until reaching the previous maintenance dose.
- **4 DAYS MISSED:** Restart at 50% of the patient's confirmed maintenance dose. The dose should be increased by 5 mg per day until reaching the previous maintenance dose.
- **5 OR MORE DAYS MISSED:** Restart according to [initiation dosing](#), as described above.

FREQUENCY OF FOLLOW UP

After a patient has been initiated on methadone, it is recommended that they are seen at least once weekly to ensure adherence to medication, assess the patient's clinical needs, medication effectiveness, medication side effects, and ensure adequate therapeutic dosing.

When a patient has demonstrated compliance and is on a therapeutic dose, less frequent visits may be needed. Monthly visits may be reasonable once a patient has gone several weeks with abstinence from opioids, demonstrated compliance with medication, absence of medication side effects, and mental health is stable. Patients on methadone should be seen at least quarterly the first year of treatment and may be seen every 6 months thereafter.

NALTREXONE

Use and Formulation: Naltrexone, an opioid antagonist, has been shown to be useful for preventing positive reinforcement (euphoria) if a relapse in opioid use should occur and may reduce cravings for opioid use. Naltrexone is available in the following formulation:

- **Oral naltrexone**
 - ▶ Administered daily on pill line as a 50 mg dose.
 - ▶ Can precipitate opioid withdrawal syndrome; ensure patient is opioid free for at least 7-10 days from last use of short-acting opioids and 10-14 days from last use of long-acting opioids prior to first dose (confirm with UDT).
 - ▶ Data shows oral naltrexone to be no more effective than placebo except in limited situations:
 - Highly motivated and compliant patients
 - Individuals with high levels of monitoring and/or negative consequences for non-adherence
 - Patients who wish to take antagonist treatment but cannot or will not take the long-acting injection
- **Long-acting injectable naltrexone (Vivitrol®)**
 - ▶ Preferred over oral naltrexone; however, oral naltrexone may still be considered in highly motivated patients under directly observed therapy.
 - ▶ Administered every 28 days by a health care provider as a 380 mg gluteal IM injection. Alternate buttocks for each subsequent injection.
 - ▶ The inmate should be issued an identification (ID) card stating that he/she is taking long-acting naltrexone. The purpose of the ID card is to alert healthcare providers in the event of an emergency requiring treatment of pain with opioids. The ID card and a copy of the FDA Medication Guide should be given to the patient by a healthcare provider at the institution.
 - A copy of the Vivitrol® ID card can be obtained at:
<https://www.vivitrol.com/content/pdfs/emergency-pain-management-card.pdf>
 - The FDA Medication guide is available at:
<https://www.fda.gov/downloads/Drugs/DrugSafety/UCM206669.pdf>
 - ▶ Because of the risk of severe injection site reactions, refer to the Vivitrol REMS website for patient counseling tools, and visual aids to reinforce proper injection technique:
<https://www.vivitrolrems.com/>

Prescribing Restrictions: Naltrexone does **NOT** have any prescribing restrictions and can be prescribed by any provider licensed to prescribe medications.

INITIATION OF LONG-ACTING INJECTION NALTREXONE (VIVITROL®)

To reduce the risk of precipitated withdrawal, prior to the first injection, providers should ensure that the patient has **not** taken a short-acting opioid (including tramadol) for at least 6 to 10 days **OR** a long-acting opioid (including buprenorphine or methadone) for at least 7 to 14 days confirmed by UDT. Providers should also conduct a **NALTREXONE OR NALOXONE CHALLENGE DOSE** described below:

- **NALTREXONE CHALLENGE DOSE:** To reduce the risk of precipitated withdrawal and rule out hypersensitivity to naltrexone, an **ORAL CHALLENGE DOSE** of 50 mg naltrexone is administered one day prior to the first injection.
 - ▶ Prior to administering the naltrexone challenge test, confirm there are no signs or symptoms of opioid withdrawal and perform baseline vital signs.
 - ▶ After the oral challenge dose is administered, the patient is observed for 60-90 minutes for signs of withdrawal by conducting a COWS assessment. (See [Section 5](#)).
 - ▶ After a successful challenge dose, the long-acting injectable naltrexone may be administered the following day and monthly thereafter.
- **NALOXONE CHALLENGE DOSE:** An alternative to giving an oral naltrexone dose is to give 0.4-0.8 mg of naloxone subcutaneously.
 - ▶ Monitor the patient for 20 minutes for signs of withdrawal. If no withdrawal symptoms are present, administer injectable naltrexone the same day.
 - ▶ If withdrawal symptoms are present, wait 24 hours and repeat the test.
 - ▶ An advantage of using naloxone rather than naltrexone for a challenge dose is the shorter half-life of naloxone and the shorter duration of symptoms if precipitated withdrawal occurs.

➔ **LOOK-ALIKE/SOUND-ALIKE ALERT:** *Naloxone is a subcutaneous challenge dose and naltrexone is an oral challenge dose.*

➔ **Naltrexone is not recommended for use in pregnant patients.** *Baseline pregnancy test should be conducted prior to naltrexone initiation. See [Section 8. Medications for treatment of OUD in special populations](#).*

SWITCHING TREATMENT MEDICATIONS

Naltrexone is generally well-tolerated. However, switching to other OUD treatment medications may be appropriate in the following cases:

- Patient experiences intolerable side effects.
- Patient has not experienced a successful course of treatment in attaining or maintaining goal through the initially chosen pharmacotherapy option.
- Patient requests a change and is a candidate for an alternative treatment.

➔ See [Appendix 2. Converting to OUD Medications](#)

Switching to buprenorphine or methadone

- Wait one day before starting buprenorphine or methadone after stopping oral naltrexone tablets
- Wait 28 days before starting buprenorphine or methadone from last long-acting injection.
- Initial doses of methadone or buprenorphine should be started low and doses should be slowly titrated since the patient will not have physical dependence on opioids.

FREQUENCY OF FOLLOW UP

After a patient has been initiated on naltrexone, it is recommended that they are seen at least once weekly to ensure adherence to medication, assess the patient's clinical needs, medication effectiveness, medication side effects, and ensure adequate therapeutic dosing.

When a patient has demonstrated compliance and is on a therapeutic dose, less frequent visits may be needed. Monthly visits may be reasonable once a patient has been abstinent from opioids for several weeks, demonstrated compliance with medication, absence of medication side effects, and mental health is stable. Patients on naltrexone should be seen at least yearly, once stable.

7. DISCONTINUATION OF MEDICATIONS FOR OUD

Similar to other conditions such as diabetes and hypertension, OUD is a chronic, relapsing disease. As with other chronic conditions, failure to maintain adherence to all requirements of treatment is NOT normally an adequate reason for discontinuation. Throughout treatment, patients should be encouraged to engage in behavioral therapy and maintain adherence to medications for OUD.

When patients are less adherent to the treatment plan, the primary goals should be to keep the patient on medication and work towards greater adherence. At times, a patient's failure to meet treatment expectations may warrant a pause or decrease in medication. However, discontinuation should only be considered after discussion with the behavioral health team, the medical team, and the patient. The monthly OUD treatment multidisciplinary meeting (See [Section 3](#)) can be a setting to discuss the potential for discontinuing of medications for OUD. If possible, medications should be tapered to avoid withdrawal symptoms.

If medications for treatment of OUD are being discontinued (voluntarily or involuntarily), patients should continue to be monitored for indications to restart treatment during incarceration or in preparation for release (See [Section 9](#)). Patients should be encouraged to attend behavioral health counseling and/or health care providers should use motivational interviewing strategies to address stages of change or barriers to adherence.

The following instances may warrant discontinuation of medications for OUD:

- Patient desires to discontinue or reduce medications for OUD
- Diversion of medications prescribed for OUD.
- Non-compliance with directly observed therapy.
- Disruptive, violent or threatening conduct.
- Failure to report for behavioral health or medical appointments.
- Failure to comply with treatment agreements outlined in Informed Consent.

TABLE 9. RECOMMENDED TAPERS FOR DISCONTINUATION OF MEDICATIONS FOR OUD

DRUG NAME	DISCONTINUATION
Methadone	<ul style="list-style-type: none"> • Abrupt discontinuation should be avoided unless clinically necessary. • Decrease dose by 5-10% of the maintenance dose every 1 to 2 weeks^{1, 2}
Buprenorphine oral	<ul style="list-style-type: none"> • Abrupt discontinuation should be avoided unless clinically necessary. • Daily doses >8mg, reduce dose by 4mg every 2 weeks • Daily dose <8mg, reduce by 2mg every 2 weeks.
Buprenorphine long-acting injection	<ul style="list-style-type: none"> • Due to the long-acting formulation, tapering is not required for long-acting injectable buprenorphine.
Naltrexone oral	<ul style="list-style-type: none"> • Discontinuation can occur anytime without any risk of developing physical withdrawal symptoms
Naltrexone long-acting injection	<ul style="list-style-type: none"> • Discontinuation can occur at any time without any risk of developing physical withdrawal symptoms; however, it may take 28 days since receiving the injection for the effects to wear off.
<p>¹ Even with a slow taper, physical withdrawal symptoms may still occur. The patient may be prescribed short-term use of medications to reduce withdrawal symptoms (see the BOP Clinical Guidance on Medically Supervised Withdrawal of Inmates with Substance Use Disorders).</p> <p>² Consider naltrexone after discontinuation (tablets or long-acting injection) to aid in the reduction of cravings and to help avoid any positive reinforcement (or euphoria) if a relapse should occur.</p>	

MONITORING THE PATIENT DURING DISCONTINUATION

In addition to addressing the physical symptoms of withdrawal that may emerge during discontinuation, medical and behavioral health staff should continue to monitor and educate the patient on the following issues:

- Psychiatric comorbidities, especially anxiety and depression.
- Return and/or worsening of chronic physical pain.
- Somatic consequences of drug use including the risk of overdose death
- Risk of acquiring infectious diseases (HIV/hepatitis) from illicit IV drug use.
- Family education and support issues.
- Structuring time in pro-social activities.

8. MEDICATIONS FOR TREATMENT OF OUD IN SPECIAL POPULATIONS

PREGNANT WOMEN

Both the American Society of Addiction Medicine (ASAM) and the American College of Obstetrics and Gynecology (ACOG) recommend continuation of medication for OUD over medically supervised opioid withdrawal during pregnancy because of the high rate of relapse among those not placed on medications for OUD. All pregnant inmates with recent opioid use and at risk for withdrawal, as well as pregnant inmates entering custody already on medications for OUD, should receive a **prompt referral** to an OTP or a DATA-waived provider who treats pregnant patients.

Treatment with either buprenorphine or methadone is indicated for all pregnant inmates who have active OUD as a component of comprehensive prenatal care. Opioid agonist and partial agonist therapies reduce the maternal-fetal risks of untreated opioid use disorder, including the risks of death by overdose and those associated with blood-borne infectious diseases. Additional risks of opioid misuse during pregnancy include preeclampsia, placental abruption, placental insufficiency, fetal growth retardation, miscarriage, and fetal death. Neonatal opioid withdrawal syndrome may also occur with active opioid use during pregnancy, including with the use of agonist and partial agonist medications for the treatment of OUD. Treatment with medications for OUD have been shown to improve maternal and neonatal outcomes by reducing maternal mortality and severe morbidity, improving the infant's birth weight, and reducing the overall frequency of obstetrical complications.

Monitoring specific to medication treatment for OUD during pregnancy is similar to that for the non-pregnant patient, including regular follow-up evaluations and UDTs.

Buprenorphine has several advantages over methadone for pregnant patients starting medications for OUD.

- Can be prescribed by any provider with a DATA 2000 waiver.
- Does not require dose adjustments during pregnancy (methadone typically requires increasing doses during the second or third trimester due to changing maternal metabolism).
- Neonatal opioid withdrawal syndrome is less severe with buprenorphine than with methadone.

Methadone is also a viable choice for treatment of OUD and may be considered for all pregnant patients, but especially in the following circumstances:

- Patient has access to an OTP (community or BOP institution)
- Patients continuing methadone maintenance during pregnancy for those women already stable on methadone.
- Patients who cannot tolerate buprenorphine
- Patient prefers use of methadone after adequate patient counseling of treatment options.
- **Dose adjustments for pregnant patients taking methadone:** Due to increased metabolism and circulating blood volume in the second and third trimester of pregnancy, doses of methadone may need to be increased or considered for split (twice daily) dosing if symptoms of withdrawal or cravings are reported by the patient. During the postpartum period, titration to lower doses of methadone may be needed to avoid sedation.

Naltrexone: It is not recommended to start naltrexone during pregnancy due to insufficient evidence on the safety and efficacy of using naltrexone during pregnancy. Female inmates already taking naltrexone (oral or IM), may continue naltrexone during pregnancy; however, it may also be appropriate to transition to methadone or buprenorphine. If the risk of relapse is low it may be appropriate to discontinue naltrexone if the patient and provider agree. Of note, a pregnant patient maintained on naltrexone will be refractory to narcotic analgesics in her postpartum recovery.

➔ *A naltrexone or naloxone challenge dose is contraindicated in pregnancy because of the risk of precipitating opioid withdrawal.*

PATIENTS REQUIRING PAIN TREATMENT

It is likely that patients with OUD will at some point experience acute and/or chronic pain. It is important to properly identify the etiology of pain in order to treat the patient safely and effectively.

NON-PHARMACOLOGICAL treatments should be considered when available and appropriate for treatment of pain. If **PHARMACOLOGICAL** treatment is considered, nonnarcotic medications such as acetaminophen and NSAIDs should be tried first, if appropriate. Adjunctive medications including anticonvulsants, tricyclic antidepressants, topical analgesics, or norepinephrine-serotonin reuptake inhibitors may also be used.

→ See the [BOP Clinical Guidance on Pain Management of Inmates](#) for more information for both pharmacologic and non-pharmacologic treatment options.

ACUTE AND/OR CHRONIC PAIN REQUIRING OPIOID ANALGESIA

- **Naltrexone:** Patients on naltrexone will not respond to opioid analgesics due to its blockade effect on the opioid receptor. Mild acute pain may be treated with non-opioid analgesics and moderate to severe pain may be treated with high potency NSAIDs (e.g., ketorolac). If opioids are indicated, discontinuation of naltrexone is required prior to initiation of opioid therapy.
- **Buprenorphine:** Temporarily increasing buprenorphine dose and/or dividing doses may be effective for acute pain not controlled with non-opioid analgesics. Analgesic effects of buprenorphine typically last 6 to 8 hours while the effect on cravings lasts up to 24 hours. For severe acute pain, discontinuing buprenorphine and initiating a high-potency opioid may rarely be necessary. Patients should be monitored closely and interventions such as regional anesthesia and/or non-opioid therapy should be considered.
- **Methadone:** For severe acute pain, temporarily increasing the methadone dose or dosing frequency may be effective in patients where pain is not controlled with non-opioid analgesics. Similar to buprenorphine, the analgesic effects of methadone typically last 6 to 8 hours while the effect on cravings may last for 24 to 36 hours. For severe acute pain not responding to an increase in dose or dosing frequency, the addition of short-acting opioids in addition to methadone may be considered. Use of non-opioid therapies is recommended to manage chronic pain if possible.

PERI-OPERATIVE PAIN

- **Naltrexone:** Oral naltrexone should be discontinued 72 hours before surgery and extended-release injectable naltrexone should be discontinued 30 days before an anticipated surgery. When restarting naltrexone postoperatively, a three to seven day period of abstinence from opioids is recommended.
- **Buprenorphine:** Discontinuation of buprenorphine before surgery is not required; however, if the decision to discontinue buprenorphine before an elective surgery is made it should be done in consultation with the attending surgeon, the anesthesiologist, and the addiction treatment provider. If it is decided that buprenorphine should be discontinued before surgery, this should occur about 24 hours in advance of surgery and restarted postoperatively when the need for intravenous full opioid agonist analgesia has passed.
- **Methadone:** Discontinuation of methadone before surgery is not necessary. Patients on methadone for the treatment of OUD and admitted for surgery may require additional short-acting opioid pain relievers in addition to methadone. The dose of opioid analgesics prescribed may be higher due to tolerance.

PATIENTS WITH CO-OCCURRING PSYCHIATRIC DISORDERS

It is common among individuals who have OUD to also have a psychiatric disorder. Studies have shown a higher prevalence of substance use in people with psychiatric disorders compared to the general population. However, co-occurring psychiatric disorders should not prevent patients from being considered for medications for OUD.

Both psychiatric disorders and OUD are associated with increased risk of suicide. In addition to psychiatric disorders, active substance abuse as well as withdrawal are independent risk factors for suicide. It is important to screen all patients being considered for treatment with medications for OUD for any co-occurring psychiatric disorders and suicide risk.

Due to their higher risk, patients with psychiatric disorders on medications for OUD should be closely monitored for suicidal ideation. In addition, prior to initiation, patients should be negative for suicidal and homicidal ideation and stable on current psychiatric therapy. Throughout stabilization and maintenance phases, patients should be closely monitored for any acute changes in their mental health.

AGING AND ELDERLY PATIENTS

As with other chronic disease states, special care should be given towards the aging and elderly inmates when recognizing, considering, and implementing treatment for patients with an OUD. For the purposes of this document, the term aging refers to individuals who are 50 to 64 years old and elderly refers to individuals who are 65 years or older.

DIAGNOSIS AND ASSESSMENT

Aging and elderly patients with OUD may be more difficult to identify due to several factors including:

- Stereotypes of patients with OUD being more often associated with younger age groups.
- Denial by aging and elderly patients towards a SUD's impact on their social environment.
- Age-related changes and/or co-morbid medical conditions can mask signs of OUD.

It is critical to understand that OUD can impact individuals of all ages and life stages. With the aging of the Baby Boomer population (those born between 1946 and 1964) the healthcare system can expect an increased prevalence of aging and elderly patients with chronic conditions, including SUD. Strategies to overcome barriers to identifying aging and elderly patients with OUD include:

- Educating all patients on OUD including risk factors, symptoms, and available treatment
- Educating providers and other members of the healthcare team on how to screen, diagnose, refer, and/or treat patients with OUD.
- Reduce stigma or hesitation associated with seeking OUD treatment by using destigmatizing language and using patient-centered approaches to therapy.

The DSM-5 criteria discussed in [Section 3](#) is used to diagnose all patients despite age group. However, several specific signs and symptoms can help providers recognize possible opioid misuse in aging and elderly patients:

- History of falls; conduct risk assessments and ask about falls regularly.
- GI conditions, especially constipation as it is a common adverse effect to opioid use
- Psychiatric conditions can exacerbate and/or are associated with OUD.
- Irregular sleep; insomnia or somnolence may be a side effect of chronic opioid use.
- Mental status change can be caused by opioid abuse or misuse.

In addition to the symptoms previously mentioned, the Screening Tool of Older Persons' potentially inappropriate Prescriptions (STOPP) is a validated screening tool for use in elderly patients to determine the risk of adverse drug events and the potential of inappropriate prescribing or misuse of opioids. A link to the STOPP tool can be found here: <http://aging.emory.edu/documents/STOPP%20supplementary.pdf>

TREATMENT CONSIDERATIONS

When a patient has been identified as having an OUD and a diagnosis has been made, all treatment options should be considered. However, there are several characteristics and factors unique to the aging and elderly to consider when selecting and initiating treatment for OUD..

Common characteristics of aging or elderly patients that may complicate treatment:

- Higher rates of medical complications including:
 - ▶ Pain
 - ▶ Psychiatric disorders
 - ▶ Renal and/or hepatic dysfunction due to disease and/or aging
 - ▶ Polypharmacy and/or multiple prescribers/specialists providing care leading to drug-drug or drug-disease interactions
- Difficulty understanding the medical system or treatment directions due to natural aging and/or neurocognitive impairment (dementia).

Refer to appendices regarding medication considerations, as well as related BOP Clinical Guidance documents to manage elderly patients with characteristics that may complicate OUD treatment. Treatment selection is a collaborative decision by both the provider and patient that allows the patient to accomplish treatment goals safely and effectively.

While no FDA-approved medication for OUD is contraindicated in elderly patients, providers should consider the following in elderly patients in addition to other unique patient factors and medication information covered in previous sections:

BUPRENORPHINE

- As effective as methadone for patients with moderate opioid use disorder.
- Initiate therapy with a lower dose compared to the general population and titrate even more cautiously, "start low and go slow."
- Half-life is more predictable compared to methadone and less influenced by renal and hepatic impairment.
- Therapeutic effects for OUD can be prolonged in older adults, allowing for the potential of every other day oral dosing.

METHADONE

- Elderly patients managed with methadone maintenance treatment have similar outcomes compared to younger patients regarding treatment success and reduced relapse.
- Initiate therapy with a lower dose compared to the general population and titrate even more cautiously, "start low and go slow".
- Increased risk in elderly for sedation and QTc prolongation leading to torsades de pointes.

NALTREXONE

- Similar to other patient populations who meet criteria for naltrexone, the long-acting injection is preferred. The oral formulation is recommended only if highly motivated and cognitively able to adhere with daily dosing.

9. AFTERCARE PLANNING

Quality care and treatment includes planning for what will happen when an inmate leaves the institution. Aftercare planning should begin with the inmate and the multidisciplinary team during the initial evaluation as the selection of a particular medication for OUD to utilize during incarceration may be influenced by future community access to these medications. If future community resources are unknown, medication selection should continue to be made based on other confirmed patient factors and preferences as discussed in [Section 6](#). Providers should coordinate aftercare planning with Transitional Care Team and/or Social Work as follows:

- Inmates transferring to Residential Reentry Centers (RRC) or Home Confinement (HC) will be referred by the Transitional Care Team to BOP Health Systems Specialists (HSS) and Community Treatment Specialists (CTS) for continuity of care while in the RCC or on HC.
- If an inmate is participating in treatment for OUD and is not transferring to an RRC or HC, an aftercare plan should be established to ensure continuity of care.
- Specific information related to the aftercare planning referral process can be located in the Technical Guidance and on the MAT Resources Sallyport Page, Institution Social Work, if available, will facilitate aftercare for inmates in their respective institutions.
- If there is not a Social Worker at the institution or an institution needs assistance with aftercare planning, staff can request Social Work assistance by completing the Medication Assisted Treatment (MAT) Social Work Referral form found on the MAT Sallyport page and submitting it to BOP-HSD-MATSocialWork@bop.gov at least 90 days prior to the patients release date.
- The aftercare process can be reviewed by visiting the *MAT Clinical Consultant Social Work Roles & Responsibilities* document found under *MAT Resources* on the Sallyport Transitional Care Page.

INITIATION OF MEDICATIONS FOR OUD PRIOR TO RELEASE

For patients who decline medications for OUD or were unable to comply with their treatment plan resulting in discontinuation of medications during incarceration, reconsideration to initiate treatment in preparation for release should be considered. The selection of medications for OUD prior to release should be based on factors described in [Section 6](#) and should involve a full evaluation as described in [Section 3](#). Initiation of medications for OUD prior to release should be conducted with enough time to confirm tolerability and effective maintenance dosing.

CONVERSION OF MEDICATIONS FOR OUD PRIOR TO RELEASE

For patients who may have limited community access to continue specific medications for OUD upon release, such as lack of OTP access in geographic proximity to the releasing community, a discussion should be had with the patient as to alternative treatment options in order to provide the highest likelihood of continuity of care. The choice to convert should be based on a combination of clinical

factors as well as patient preference to change treatment prior to release. Conversion prior to release should be conducted as described in [Section 6](#) and [Appendix 2](#) and with enough time to confirm tolerability to effective maintenance dosing.

NALOXONE FOR RELEASING OFFENDERS WITH OUD

Naloxone is recommended for all offenders identified with OUD or at risk for opioid overdose upon release or transfer to an RRC or HC. These inmates should be referred to the provider to prescribe the naloxone for release or transfer to RRC or HC and should be trained to recognize the signs of opioid overdose and how to administer the naloxone.

RESOURCES

SUBSTANCE ABUSE AND MENTAL HEALTH SERVICES ADMINISTRATION (SAMHSA), DHHS

- Medication for Opioid Use Disorder (MOUD) / Medication-Assisted Treatment (MAT): <https://www.samhsa.gov/medication-assisted-treatment>
- Naltrexone: <https://www.samhsa.gov/medication-assisted-treatment/treatment/naltrexone>
- Buprenorphine: <https://www.samhsa.gov/medication-assisted-treatment/treatment/buprenorphine>
- Practitioner waivers to prescribe buprenorphine: <https://www.samhsa.gov/medication-assisted-treatment/training-materials-resources/apply-for-practitioner-waiver>
- Methadone: <https://www.samhsa.gov/medication-assisted-treatment/treatment/methadone>
- Practitioner training: <https://www.samhsa.gov/practitioner-training>
- Practitioner and treatment program locator: <https://www.samhsa.gov/find-treatment>
- Center for Substance Abuse Treatment (CSAT): <https://www.samhsa.gov/about-us/who-we-are/offices-centers/csat>

OTHER ORGANIZATIONS

- American Academy of Addiction Psychiatry (AAAP): <http://www.aaap.org>
- American Society of Addiction Medicine (ASAM): <http://www.asam.org>
- Association for Addition Professionals (NAADC – formerly National Association of Alcoholism and Drug Abuse Counselors): <http://naadac.org>
- California Society of Addiction Medication (CSAM): <https://csam-asam.org/>
- College on Problems of Drug Dependence (CPDD): <https://cpdd.org/>
- National Institute on Alcohol Abuse and Alcoholism (NIAAA): <http://www.niaaa.nih.gov/>
- National Institute on Drug Abuse (NIDA): <http://www.nida.nih.gov/>
- Office of National Drug Control Policy (ONDCP): <http://www.whitehousedrugpolicy.gov>
- Providers Clinical Support System (PCSS) Mentoring Program: <https://pcssnow.org/mentoring/>
- Sublocade REMS Program: <https://www.sublocaderems.com/>

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APPENDIX 1. THE CLINICAL OPIATE WITHDRAWAL SCALE (COWS)

Inmate Name: _____ Register Number: _____

Reason for this assessment: _____

For each item, write the number that best describes the patient's signs or symptom. Rate on just the apparent relationship to opiate withdrawal. For example, if heart rate is increased because the patient was jogging just prior to assessment, the increased pulse rate would not add to the score.

➔ *The COWS assessment is available in the flow sheets section of the electronic health record.*

Resting Pulse Rate - Measured after patient is sitting or lying for one minute.

- Beats/minute = _____
0 pulse rate 80 or below
1 pulse rate 81 – 100
2 pulse rate 101 – 120
4 pulse rate greater than 120

Sweating - Over past ½ hour not accounted for by room temperature or patient activity.

- 0 no report of chills or flushing
1 subjective report of chills or flushing
2 flushed or observable moistness on face
3 beads of sweat on brow or face
4 sweat streaming off face

Restlessness – observation during assessment

- 0 able to sit still
1 reports difficulty sitting still, but is able to do so
3 frequent shifting or extraneous movements of legs/arms
5 unable to sit still for more than a few seconds

Pupil Size

- 0 pupils pinned or normal size for room light
1 pupils possibly larger than normal for room light
2 pupils moderately dilated
5 pupils so dilated that only the rim of the iris is visible

GI Upset – over last ½ hour

- 0 no GI symptoms
1 stomach cramps
2 nausea or loose stool
3 vomiting or diarrhea
5 multiple episodes of diarrhea or vomiting

Tremor - Observation of outstretched hands.

- 0 no tremor
1 tremor can be felt, but not observed
2 slight tremor observable
4 gross tremor or muscle twitching

Yawning – observation during assessment

- 0 no yawning
1 yawning once or twice during assessment
2 yawning three or more time during assessment
4 yawning several times/minute

Anxiety or Irritability

- 0 none
1 patient reports increasing irritability or anxiousness
2 patient obviously irritable or anxious
4 patient so irritable or anxious that participation in the assessment is difficult

Form continues on next page

- Bone or Joint Aches** - If patient was having pain previously, only the additional component attributed to opiates withdrawal is scored.
- 0 not present
 - 1 mild diffuse discomfort
 - 2 patient reports severe diffuse aching of joint/muscles
 - 4 patient is rubbing joints or muscles and is unable to sit still because of discomfort

- Runny Nose or Tearing**
- Not accounted for by cold symptoms or allergies.
- 0 not present
 - 1 nasal stuffiness or unusually moist eyes
 - 2 nose running or tearing
 - 4 nose constantly running or tears streaming down cheeks

- Gooseflesh Skin**
- 0 skin is smooth
 - 3 piloerection of skin can be felt or hairs standing up on arms
 - 5 prominent piloerection

- Total Score**
- Sum of all 11 items.
- 5 – 12 mild
 - 13 – 24 moderate
 - 25 – 36 moderately severe
 - >36 severe withdrawal

Staff signature:

Date:

Printed name and
title:

APPENDIX 2. CONVERTING BETWEEN MEDICATIONS FOR OUD

From ↓	To →	Methadone	Buprenorphine SL tabs or film	Buprenorphine long-acting injection	Naltrexone tablets	Naltrexone long-acting injection
Methadone			Taper down to a target dose of 30 mg of methadone over ≥7 days then discontinue. Start buprenorphine when COWS score ≥ 11.	Not recommended. Should be stabilized on oral buprenorphine prior to giving long-acting injection.	Should be completely withdrawn from methadone before starting naltrexone. This may take up to 14 days.	Should be completely withdrawn from methadone before starting naltrexone. This may take up to 14 days.
Buprenorphine SL tablets or film	There is no time-delay required when switching from buprenorphine to methadone *Must be done within an OTP			Start long-acting injection once the patient is stabilized on dosages of 8 to 24 mg daily for a minimum of 7 days	Should be completely withdrawn from buprenorphine before starting naltrexone. This may take up to 14 days.	Should be completely withdrawn from buprenorphine before starting naltrexone. This may take up to 14 days.
Buprenorphine long-acting injection	Wait at least 28 days since last injection before initiating methadone *Must be done within an OTP		Wait at least 28 days since last injection given before converting to oral buprenorphine		Not recommended. Should convert back to oral buprenorphine prior to converting to naltrexone.	Not recommended. Should convert back to oral buprenorphine prior to converting to naltrexone.
Naltrexone tablets	Wait one day after taking naltrexone before initiating methadone *Must be done within an OTP		Wait one day after taking naltrexone before initiating buprenorphine	Not recommended. Should be stable on oral buprenorphine before initiating long-acting injection.		Can start injection the next day after receiving naltrexone tablet.
Naltrexone long-acting injection	Wait 28 days after receiving naltrexone long-acting injection before initiating methadone *Must be done within an OTP		Wait 28 days after receiving naltrexone long-acting injection before initiating buprenorphine	Not recommended. Should be stable on oral buprenorphine before initiating long-acting injection.	Start oral tablets 28 days after the last injection	

APPENDIX 3. MEDICATIONS FOR OUD: WARNINGS/PRECAUTIONS, CONTRAINDICATIONS, & DOSING ADJUSTMENTS

	Precautions/Warnings	Contraindications	Dose Adjustments
Methadone	<ul style="list-style-type: none"> • CNS depression, constipation, sedation, hypotension • Concurrent benzodiazepine or alcohol use • QTc prolongation and/or cardiac arrhythmia • Potential for misuse/diversion, physical dependence • Adrenal insufficiency • Biliary tract impairment • Head trauma, increased intracranial pressure • Seizure disorders • Drug-drug interactions • Neonatal withdrawal if used during pregnancy 	<ul style="list-style-type: none"> • Hypersensitivity to methadone • Respiratory depression • Severe bronchial asthma or hypercapnia • Paralytic ileus 	<p>Hepatic Impairment: No dose adjustments; however, initiate at lower doses and titrate slowly, monitor for respiratory and CNS depression</p>
			<p>Renal Impairment: CrCl ≥ 10ml/min: No dose adjustment needed CrCl < 10mL/min: administer 50% to 75% of normal dose</p>
Buprenorphine	<ul style="list-style-type: none"> • Respiratory depression and overdose when used with benzodiazepines or CNS depressants • Potential for misuse/diversion, physical dependence • Adrenal insufficiency • Precipitated opioid withdrawal • Hepatitis and liver failure • CNS depression, sedation, hypotension • Bowel obstruction • Addison’s disease 	<ul style="list-style-type: none"> • Hypersensitivity to buprenorphine 	<p>Hepatic Impairment: Mild (Child-Pugh score 5-6): No dose adjustment needed Moderate (Child-Pugh score 7-9): No dosage adjustment needed; use caution and monitor for signs of toxicity. Do not use oral combo product (buprenorphine/naloxone) for initiation and use with caution for maintenance. Do not use long-acting injectable. Severe (Child-Pugh score 10-15): Do not use combo product (buprenorphine/naloxone) or long-acting injectable. For mono product, decrease starting dose and titration dose by 50%</p>
			<p>Renal Impairment: No dose adjustments</p>
<i>Table continues on next page</i>			

	Precautions/Warnings	Contraindications	Dose Adjustments
Naltrexone	<ul style="list-style-type: none"> • Pregnancy • Risk of overdose • Injection site reactions • Precipitated opioid withdrawal • Hepatitis (Vivitrol) • Caution in moderate to severe renal impairment • Hypersensitivity reactions • Monitor for depression and suicidal ideation 	<ul style="list-style-type: none"> • Current treatment for pain with opioids • Physiological opioid dependence • Acute opioid withdrawal • Severe hepatic impairment • Positive urine drug screen for opioids • Hypersensitivity to naltrexone 	<p>Hepatic Impairment: Mild to moderate: No dose adjustment needed</p> <p>Severe impairment: Use is not recommended in acute hepatitis or hepatic failure</p> <hr/> <p>Renal Impairment: Mild impairment: no dose adjustment needed</p> <p>Moderate to Severe impairment: Use caution since it is primarily eliminated through the kidneys</p>