OBAT TTA +

OFFICE BASED ADDICTION TREATMENT
TRAINING AND TECHNICAL ASSISTANCE +

MASSACHUSETTS NURSE CARE MANAGER MODEL OF OFFICE BASED ADDICTION TREATMENT: CLINICAL GUIDELINES

A COLLABORATIVE CARE APPROACH

Updated: April 2021

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Disclaimer

Boston Medical Center is pleased to share its Office Based Addiction Treatment clinical guidelines with other providers. Although Boston Medical Center has attempted to confirm the accuracy of the information contained in these documents, this information is not a substitute for informed medical decision making by an appropriate, licensed provider. Clinicians must confirm the appropriateness of all treatment that they provide to a patient and are responsible for the health care decisions they make when caring for patients. If clinicians believe that any information included in these guidelines should be revised or clarified, please contact Boston Medical Center at 617-414-7453.

The contents of these guidelines are solely the responsibility of the authors and do not necessarily represent the official views of BSAS or any other part of the Massachusetts Department of Public Health.

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INTRODUCTION TO OFFICE-BASED ADDICTION TREATMENT (OBAT) PROGRAM

Purpose

The purpose of this document is to provide detailed guidelines of the Nurse Care Manager Model of Office Based Addiction Treatment program for management of substance use disorders, with particular emphasis on treatment of opioid use disorder with buprenorphine (alone and in combination with naloxone) and naltrexone (oral and extended-release injectable formulations).

Target Audience

The target audience for the Office Based Addiction Treatment (OBAT) clinical guidelines is nurses and other health care providers practicing in addiction specialty care settings or multidisciplinary care teams in search of integrated models of addiction care to implement within primary or ambulatory care, behavioral health, corrections, or other practice settings with a team motivated to treat substance use disorder.

Treatment Philosophy

A substance use disorder is a chronic medical condition that responds best when treated with comprehensive care that is both evidence-based and patient-centered. Patients engaged in OBAT deserve to be treated with dignity and respect. We strive to remove any unnecessary obstacles to accessing addiction treatment in the OBAT program. The goal of OBAT is a cessation or reduction in harmful substance cravings and use, active participation and engagement in treatment, restoration of normal physiologic functions, and an improvement in one's quality of life.

Introduction to Substance Use Disorders

Substance use disorders (SUD) are a significant public health crisis in the United States (US). In 2018, the National Survey on Drug Use and Health (NSDUH) estimated that 9.9 million people aged 12 or older in the US reported non-medical use of prescription pain medication in the past year, and 808,000 reported use of heroin in the past year (SAMHSA, 2019). Largely driven by opioids, drug overdose persists as the leading cause of personal injury-related death in the US (NCIPC, CDC using WISQARS, 2021). Though heroin-involved overdose death rates have stabilized in recent years, deaths related to synthetic opioids other than methadone—specifically, illicitly manufactured fentanyl— are steadily increasing, along with cocaine and psychostimulant-related overdose deaths (CDC, 2020b).

A SUD is a chronic, treatable condition characterized by physiologic changes in the brain with anticipated periods of recurrent use. Despite the availability of safe and effective medications to treat SUD, a dire gap in treatment persists. In 2018, approximately 21.2 million people in the US aged 12 and over (about 1 in 13) needed treatment for a substance use disorder, but only 3.7 million received any treatment (SAMHSA, 2019). There are additional care disparities in terms of accessing both appropriate treatment and overdose reversal among racial/ethnic minority populations and women, when compared to white males (Lagisetty et al., 2019; Hadland et al.,

2017). This treatment gap can be attributed to numerous barriers, including lack of patient and provider knowledge of evidence-based treatments; limited treatment capacity; stigma; racial disparities; and financial, legislative, political, and geographic obstacles (Appel et al., 2004; Appel & Oldak, 2007; Jordan et al., 2020; Priester et al., 2016; Walley et al., 2008; Yarborough et al., 2016). In addition to a reduction in fatal overdoses, appropriate and timely treatment can reduce the societal, economic, and infectious disease impacts associated with substance use disorders (SAMHSA, 2020d).

Substance Use Disorders

The *Diagnostic and Statistical Manual of Mental Disorders*, fifth edition (DSM-5), defines SUD as a maladaptive pattern of use causing impairment to one's health or functioning over a 12-month period (APA, 2013). Patients with SUDs should be offered medication treatment for addiction and psychosocial therapies as part of a comprehensive treatment plan. Like other chronic diseases, SUDs can be effectively managed in a primary care or community clinic incorporating models of care such as BMC OBAT's Nurse Care Manager model. Additionally, polysubstance use is common; aside from opioid and alcohol use disorders, an estimated 48 million people over the age of twelve disclosed use of other illicit substances use including cannabis, methamphetamines, cocaine, and benzodiazepines in 2019 (SAMHSA, 2020d). While FDA-approved medications for addiction treatment may not be available to treat all substance use disorders, it is imperative that therapeutic modalities and clinical interventions be implemented to support the recovery process and long-term health outcomes of patients experiencing polysubstance use.

OPIOID USE DISORDER

Opioid use disorder (OUD) currently has three FDA-approved medications for treatment:

I. Oral methadone
II. Transmucosal buprenorphine products, formulated both with and without naloxone, and long-acting injectable buprenorphine (implantable product removed from market 10/2020)
III. Oral formulation and long-acting injectable naltrexone

Methadone, buprenorphine, and naltrexone each block the effects of illicit opioids and reduce opioid cravings to varying degrees; at sufficient doses, both methadone and buprenorphine reduce opioid withdrawal symptoms. Numerous clinical trials and meta-analyses have demonstrated that methadone, a full agonist at the μ-opioid receptor, retains patients in treatment and reduces the risks of fatal overdose, HIV and Hepatitis C infection, and criminal behavior (SAMHSA, 2020e). Buprenorphine, a partial agonist at the μ-opioid receptor, has also been shown to retain patients in treatment and reduce illicit opioid use more effectively than placebo and to reduce behaviors associated with HIV transmission (Hedden et al., 2014). There is evidence that injectable naltrexone, an antagonist at the μ-opioid receptor, reduces illicit opioid use and retains people in treatment longer than placebo and no medication; however, treatment outcomes have generally been inferior to those attained with methadone and buprenorphine maintenance (Marchand et al., 2019; Wakeman, Larochelle & Ameli, 2020).

The landmark legislation of the Drug Addiction Treatment Act of 2000 (DATA 2000) and the FDA approval of buprenorphine in 2002 paved the way for clinicians to treat OUD with agonist

medications in an outpatient setting, greatly expanding access to this life-saving treatment (H.R.2634 - 106th Congress (1999-2000), 2000). Prior to this, methadone was the only FDA-approved agonist medication for the treatment of OUD, receiving approval in 1972. However, it can only be dispensed under the federal regulations of an opioid treatment program. Medications for the treatment of OUD (MOUD) are severely underutilized despite the more than two million people in the US who have an opioid use disorder (SAMHSA, 2019). The most effective treatment for OUD involves treatment with maintenance medications sustained over time supported with behavioral health interventions.

ALCOHOL USE DISORDER

Alcohol is now the third leading cause of preventable death in the US, with an estimated 88,000 deaths annually (Connery, 2015). In 2018, over half of individuals aged 12 and older in the US reported drinking alcohol in the past 30 days; approximately one in three of this group reported heavy episodic alcohol use (SAMHSA, 2019). An estimated 14.8 million people had an alcohol use disorder, encompassing almost 75% of all those with any substance use disorder.

Alcohol use exists on a spectrum, from abstinence and lower-risk drinking to severe alcohol use disorder and addiction. Typically, the severity of consequences positively correlates with alcohol consumption. Unhealthy alcohol use is associated with risk for serious chronic health conditions (e.g., liver cirrhosis) and risks related to acute intoxication and alcohol withdrawal such as accidental injury and death (NIAAA, 2021). There are three FDA approved medications for the treatment of alcohol use disorder: naltrexone, acamprosate, and disulfiram. These medications are not indicated for use in the treatment of alcohol withdrawal, which when untreated can be severe and life threatening.

Naltrexone, in addition to being FDA-approved for treatment of opioid use disorder, is also FDA-approved for treatment of alcohol use disorder. Naltrexone is available as an oral tablet taken daily and an extended-release injectable formulation administered into the gluteal muscle every 28 days. Naltrexone is a competitive μ-, κ-, and δ-opioid receptor antagonist that blocks the effects of opioids through highly competitive binding. Naltrexone reduces the reward or pleasure associated with consuming alcohol by blocking the dopaminergic endorphins (which act on the μ- and δ-opioid receptors) released following alcohol consumption, in addition to reducing cravings for alcohol (Méndez & Morales-Mulia, 2008; Swift & Aston, 2015).

Disulfiram, approved by the FDA in 1951, causes an aversive effect when any amount of alcohol is consumed by irreversibly blocking the enzyme aldehyde dehydrogenase (CSAT, 2009). This results in a buildup of aldehyde dehydrogenase in the body, causing a dose-dependent alcohol-disulfiram reaction. Symptoms range from mild nausea, sweating, and thirst, to severe reactions such as respiratory failure, heart failure, unconsciousness, seizure, and death. Patients on disulfiram should be motivated for abstinence from alcohol and be educated to avoid alcohol and alcohol-containing products while on the medication and for two weeks post discontinuation.

Acamprosate may decrease cravings for alcohol use and aid in the treatment of protracted withdrawal symptoms from alcohol use such as insomnia, anxiety, restlessness, and dysphoria (CSAT, 2009). The exact mechanism of acamprosate is unknown, but it is thought to act on the glutamate and GABA neurotransmitter pathways. Both acamprosate and naltrexone may be initiated while a patient is still consuming alcohol.

As with OUD, medication treatment for alcohol use disorder is severely underutilized. The most effective treatment for alcohol use disorder is comprehensive and is supported with behavioral health interventions.

Introduction to the Nurse Care Manager Model of OBAT

In 2003, Boston Medical Center's Office Based Addiction Treatment (OBAT) program was created to address a key barrier to the integration of buprenorphine treatment identified by many office-based settings: the lack of structured clinical support for providers. Nationally recognized and replicated, the BMC OBAT program utilizes a collaborative care model that relies on nurse care managers (NCM) to ensure delivery of high-quality addiction treatment while effectively and efficiently utilizing the time of providers waivered to prescribe buprenorphine. Within three years of its creation, BMC's OBAT model expanded to 14 community health centers, and the number of physicians waivered to prescribe buprenorphine in Massachusetts increased by 375%. The model's success has since led to its expansion to over 40 community health centers across Massachusetts and many health care organizations nationwide, including a NIDA-funded clinical trial in six health systems, the PRimary Care Opioid Use Disorders Treatment (PROUD) trial (Kaiser Permanente, 2021).

Dubbed the "Massachusetts Model," BMC's OBAT program serves as a model of service delivery for facilitating access to life-saving treatment and improving treatment outcomes in patients with OUD. It has been expanded to include treatment and care provision for other SUDs. Key to this model is the interprofessional collaboration between the nurse, prescriber, and other members of the care team to provide comprehensive care during all phases of treatment. By integrating SUD treatment within primary care, SUDs can be treated similarly to other chronic medical conditions. The registered nurse's scope of license and expertise in chronic disease management and patient education make NCMs ideally suited to deliver ongoing care for substance use disorders. Additionally, nurse care management enables physicians and advanced practice providers (APPs) to safely prescribe medications for addiction treatment to a greater number of patients, increasing overall access to these lifesaving medications.

BMC's OBAT program in adult primary care, our flagship clinic, is the largest office based opioid treatment program of its kind in New England, currently serving over 900 patients. The BMC OBAT NCM model is effective at increasing access to evidence-based treatment for addiction as well as improving the quality of care provided to patients with substance use disorders (LaBelle et al., 2016). Expansion and replication of innovative, evidence-based models, such as ours, are key to increasing access to addiction treatment across the US.

CARE TEAM COMPONENTS

Providers

Provider qualifications and training are different for those prescribing buprenorphine (both alone and in combination with naloxone) and naltrexone.

BUPRENORPHINE AND BUPRENORPHINE/NALOXONE

Qualifications: Qualified providers must obtain a waiver of authority to prescribe any medication that is a schedule III, IV, or V and FDA approved for the treatment of OUD for the purpose of detoxification or maintenance treatment. With DATA 2000, physicians became legally qualified to apply for a waiver. In July 2016, the Comprehensive Addiction and Recovery Act (CARA) was signed into law, extending buprenorphine prescription authority to include physician assistants and nurse practitioners. The 2018 Substance Use Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act (SUPPORT) extended prescribing privileges to include Clinical Nurse Specialists, Certified Registered Nurse Anesthetists, and Certified Nurse Midwives (CNSs, CRNAs, and CNMs) (H.R.6 - 115th Congress (2017-2018), 2018). In 2021, the Department of Health and Human Services released an exemption to training requirements to obtain a waiver for all physicians and APPs treating up to 30 patients with buprenorphine (DHHS, 2021).

Physician Waiver Eligibility: To be eligible for a waiver, physicians must have a current state medical license, a valid registration number from the US Drug Enforcement Agency (DEA), and completion of an eight-hour approved waiver training course.

Advanced Practice Provider Waiver Eligibility: To be eligible for a waiver, Advanced Practice Providers (APPs) (e.g., Nurse Practitioners, Physician Assistants, Nurse Midwives, or Clinical Nurse Specialists) must have a current nursing/medical license and a valid DEA registration number, in addition to completing a total of 24 hours of approved training (the eight-hour approved waiver course mentioned above plus 16 additional hours of federally approved MAT training). APPs approved to prescribe buprenorphine must be supervised by or work in collaboration with a qualifying physician if required by law in their state.

Resources for completing the additional 16 hours of training are available at no cost from:

- PCSS: https://pcssnow.org/medication-assisted-treatment/waiver-training-for-nps/
- ASAM: https://elearning.asam.org/buprenorphine-waiver-course
- OBAT TTA: https://www.bmcobat.org/training/register/index.php?category=124

Referrals: Providers must be able to refer patients to counseling and other services.

Patient Limits: The number of patients that a provider is allowed to treat at any one time is dependent upon the provider's practice setting, field of discipline, and waiver status. It is

imperative that a provider does not prescribe to more patients than identified on their waiver (either 30, 100, or 275).

To Become A Waivered Provider or Request a Patient Limit Increase:

- Providers must complete a notification of intent through SAMHSA's Center for Substance Abuse Treatment (CSAT) at: https://buprenorphine.samhsa.gov/forms/select-practitioner-type.php
- Providers must then send training certificates to infobuprenorphine@samhsa.hhs.gov
- SAMHSA reviews applications within 45 days of receipt.
- Once the application process is complete and the application is approved, SAMHSA will email an approval letter that contains the certification date and maximum number of prescriptions.
- If it has been more than 45 days since a provider has submitted an application or if a provider submitted an application and did not receive an acknowledgement of receipt, then contact CSAT's Buprenorphine Information Center at 866- BUP-CSAT (866-287-2728) or send CSAT an email: infobuprenorphine@samhsa.hhs.gov

The regulations concerning buprenorphine prescriptions are often updated, and it is therefore recommended to review the current guidelines to ensure practice within the federal regulations: www.buprenorphine.samhsa.gov (Saia et al., 2019).

NALTREXONE

Naltrexone is not a scheduled medication and therefore does not require a special licensure, certification, or waiver to prescribe. Any individual who is licensed to prescribe medication may prescribe and/or administer naltrexone. There is no limit to the number of patients that a provider can legally treat with naltrexone. However, when treating patients with substance use disorders, it is important that providers understand the nature of the underlying disorder, the pharmacological properties of available medications, and the importance of monitoring and treatment plan revision.

OBAT Nurse Care Managers

Nurse Care Managers (NCMs) are registered nurses who must, at a minimum, have passed the National Council Licensure Examination for registered nurses (NCLEX-RN) and hold an active license in the state in which they are practicing.
Though not required, ideally NCMs will have achieved or be working toward a certification in addiction nursing (Certified Addiction Registered Nurse [CARN]), offered through the Addiction Nursing Certification Board (www.ancbonline.org). To be eligible to sit for the certification examination, candidates must meet the following requirements:

- Provide evidence of a current, full, and unrestricted license as a registered nurse (RN) in the United States, its territories, or Canada.

- Complete documentation verifying a minimum of 2,000 hours within the last three years of current nursing experience related to addictions as an RN in a staff, administrative, teaching, private practice, consultation, counseling, or research capacity.

- Acquire a total of 30 hours of continuing education related to addictions nursing within three years of application submission.

More information about the CARN, and CARN-AP for advanced practice nurses, can be found on the Center for Nursing Education and Testing website:
https://www.cnetnurse.com/certifiedaddictions-registered-nurse/

Additional recommendations include:

- Complete an initial training curriculum covering OBAT and/or medications for addiction treatment with buprenorphine and naltrexone, in-person or online.

- Attend ongoing professional education on topics relevant to treatment for SUD (e.g., HIV and HCV screening, treatment and prevention, urine toxicology screening, overdose education, motivational interviewing, retention in care, harm reduction, compassion fatigue, case discussions, materials development, and networking).

- Meet and maintain OBAT nursing competencies related to the 10 domains of nursing practice: safety, quality improvement, evidence-based practice, patient-centered care, professionalism, leadership, systems-based practice, informatics and technology, teamwork, and collaboration.

NURSE CARE MANAGER RESPONSIBILITIES

- Provide patient-centered care within the nursing license scope of practice, including the initial assessment and intake, medication initiation, stabilization, and maintenance phases of treatment.

- Collaborate with OBAT providers, social workers/counselors, psychiatrists, pharmacies, primary care providers, recovery support persons, and specialty care providers to whom the patient has been referred.

- Coordinate between the OBAT provider and the pharmacy by assisting with prescription processing and refills, prior authorizations, and insurance issues.

- Complete appropriate documentation in medical records and comply with the scope of practice and federal, state, and departmental policies when sharing and/or documenting patient care.

Medical Assistants

Medical assistants are allied health professionals that support the work of nurses, APPs, and physicians. Medical assistants may perform routine administration and clinical duties under the direct supervision of licensed healthcare professionals or the organization that employs them (Taché & Chapman, 2005).

Education requirements and certifications vary widely for medical assistants depending on the state in which they practice. Completion of an accredited medical assistant certification or diploma program is typically required.

Medical assistants should have a basic understanding of the disease model of addiction, the role of medications for addiction treatment, confidentiality, and provision of trauma-informed care. Medical assistants should therefore be encouraged and supported to attend educational opportunities related to the care of persons with substance use disorders.

MEDICAL ASSISTANT RESPONSIBILITIES

- Perform patient-centered and trauma-informed clinical and administrative duties within the medical assistant scope of practice, including:
    - Clinical tasks such as collecting and preparing laboratory specimens (e.g., toxicology screens and pregnancy tests), recording vital signs, rooming patients, performing ECGs, changing dressings, and documenting care in the electronic medical record.
    - Administrative tasks such as greeting patients, scheduling appointments, communicating via telephone, filing medical charts, and functioning as a liaison between the patient and other care team members.

Recovery Support Providers: Recovery Coaches/Peer Supports

Persons with lived experience in addiction who are in stable recovery are considered peers. Not all recovery support providers are peers, but all should have training in addiction and understand the best approach to connecting with people in all stages of recovery (CSAT, 2009).

Generally, there are no educational requirements for recovery support providers, although a high school diploma or GED is preferred.

- Training for recovery support staff will vary based on the role expectations in a given care team or medical setting. Such role expectations should prioritize the supportive relationship between peer recovery staff and patients.
- It is imperative that recovery support providers in the OBAT setting are educated regarding the use of medications for addiction treatment and employ the harm reduction-inspired philosophy of OBAT to engage and maintain relationships with patients.

Licensure and certification for Recovery Support Providers varies by state. There are national certifications offered for peer recovery support specialists, but typically, these team members must obtain state certification and meet certain training requirements to be eligible ((NAADAC, the Association for Addiction Professionals, n.d.; *National Certified Peer Specialist (NCPS) Certification-- Get Certified!,* n.d.). There is a certification process for peer specialists in 48 states and the District of Columbia, and, in 2018, an extensive list of certification programs was compiled by the University of Massachusetts Medical School (London et al., 2018). For more information, visit these websites:

- https://www.mhanational.org/national-certified-peer-specialist-ncps-certification-get-certified#WhatAreTheRequirements
- https://www.naadac.org/ncprss

Recovery Support Responsibilities

- Recovery peer support staff may begin working with patients not yet ready to engage in formal treatment in settings by providing active outreach.

- Recovery peer support staff may participate in wellness planning, service navigation, resource sharing/linkage, engagement in treatment, community outreach and advocacy, and social/emotional support.

- Recovery peer support staff should be nonjudgmental and caring individuals that can offer support and assistance in achieving and maintaining recovery. They must recognize all pathways to recovery and be able to address the stigma related to pathways utilizing medications for addiction treatment.

Clear role delineation and adequate support and supervision for this role is key to recruitment, retention, and successful collaboration; these must be determined before a care team hires peers and other recovery support providers.

Behavioral Health Partners

Behavioral health services are an important part of treatment for substance use disorders for patients at all stages of the recovery process. Counseling and other psychotherapies seek to change behaviors, thoughts, emotions, and how people see and understand problematic situations (SAMHSA, 2020b). Connections to behavioral health teams for counseling and increased support should be readily accessible to patients. However, medication treatment should be considered or continued even if patients are not actively engaging in these services. The DATA 2000 highlights that providers are required to have the ability to refer patients to behavioral health and other recovery support services, but not that patients are required to attend or engage with these services.

Many programs utilize the NCM model of OBAT integrated with behavioral health providers, while others coordinate behavioral health services with local community and/or remote partners. Behavioral health clinicians involved in the care of patients with substance use disorders should be comfortable caring for patients in various stages of recovery and have a basic knowledge of medications for addiction treatment.

Training for behavioral health partners is largely dictated by their licensing body, and there can be significant variation in the types of licensing pathways for different behavioral health partners.

- Behavioral health partners should have a basic understanding of addiction as a chronic medical condition and the importance of medications for addiction treatment, employ a harm reduction philosophy, and engage patients with a trauma-informed approach for behavioral health care.

- It is recommended that behavioral health partners also complete an initial training curriculum covering the NCM model of OBAT with buprenorphine and naltrexone, in-person or online.

Behavioral Health Partners Responsibilities

- Behavioral health partners are responsible for helping coordinate and/or employing the patient's behavioral health treatment. Goals of behavioral health treatment may include identifying and maintaining motivation for recovery, developing insight into triggers for recurrent use, developing safe and effective coping strategies, and building a connection to a patient's community.

- Behavioral health partners may employ counseling techniques including cognitive behavioral therapy, dialectical behavioral therapy, mindfulness, motivational interviewing, eye-movement desensitization and reprocessing, and many others.

Support Staff

Support staff may include front desk staff, patient care navigators, administrators, and other team members within the healthcare setting. Every person that comes in contact with a person seeking care for a substance use disorder affects that individual's experience and recovery journey.

Training for support staff should include an overview of addiction and recovery and the importance of recognizing and addressing stigma of patients with a substance use disorder. Support staff should also have a clear understanding of all services offered at their clinical site.

Support Staff Responsibilities

- Perform the necessary functions of the job which may include greeting patients, scheduling appointments, administrative responsibilities, how to identify and respond to an overdose, and/or telephonic communications.

- All interactions with patients should be empathetic and nonjudgmental.

PROGRAM COMPONENTS

Administrative Requirements

Buprenorphine is a Schedule III medication. Programs utilizing buprenorphine must therefore follow federal, state, and institutional requirements for the management of Schedule III substances (e.g., those regarding prescribing practices, storage, and dispensation of the substances).

Records on prescription and dispensation of medications for the detoxification and maintenance treatment of OUD must be kept in accordance with DEA regulations 21 CFR 1304.03(c). The most up-to-date information on this regulation is available through SAMHSA's Center for Substance Abuse Treatment (CSAT):

SAMHSA's Center for Substance Abuse Treatment
https://www.samhsa.gov/about-us/who-we-are/offices-centers/csat
SAMHSAInfo@samhsa.hhs.gov 877-SAMHSA-7 (726-4727), TTY: 800-487-488

Candidates for OBAT

- Have a *DSM-V* diagnosis of a substance use disorder.
- Be able to present to visits during the program's hours of operation.
- If seeking treatment with buprenorphine, not have chronic pain requiring full μ-agonist opioid therapy.
- If seeking treatment with naltrexone, not have chronic pain requiring ongoing opioid therapy
- Be able to be treated in an office-based setting safely without harm to themselves or others.

Goals of OBAT Treatment

- Reduce symptoms of a person's substance use disorder.
- Reduce risk for adverse health outcomes through harm reduction and overdose education.
- Reduce illicit or problematic substance use.
- Reduce or eliminate withdrawal symptoms and cravings for substances.
- Restore physiological functions that may have been disrupted by substance use.
- Enhance connection to a person's community and inspire hope for recovery.
- Improve the patient's overall quality of life.

Consents

In addition to the Health Insurance Portability and Accountability Act (HIPAA), federal regulations mandate strict confidentiality for information about patients being treated for substance use disorders (42 CFR Part 2). This regulation also requires written patient consent before information about their substance use disorder can be disclosed to any other party. For OBAT, this may include communications with other providers, treatment centers, social service organization, officers of the court, family, or significant others.

For the most up to date information of 42 CFR Part 2, please visit the following resources:

SAMHSA
https://www.samhsa.gov/national-center-excellence-protected-health-information
https://www.samhsa.gov/about-us/who-we-are/laws-regulations/confidentiality-regulation

FOCUS: PHI
https://www.coephi.org/

Legal Action Center
https://lac.org/resources/substance-use-resources/confidentiality-resources/

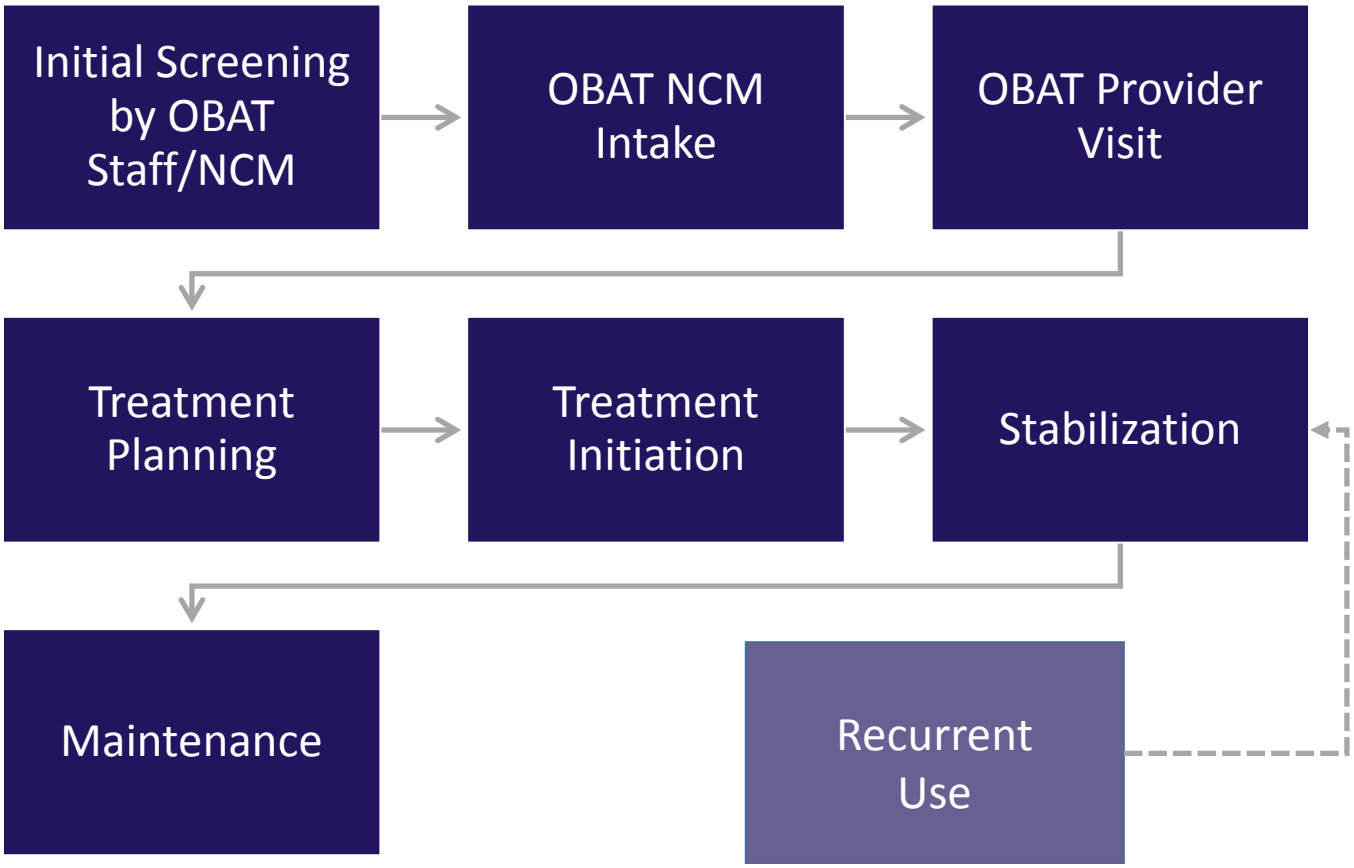
Center of Excellence for Protected Health Information
https://caiglobal.org/index.php?option=com_content&view=article&id=1149&Itemid=1953

For examples of OBAT note templates and consent forms, see *Essential Documents and Tools*.

GETTING STARTED

Patient Initiation Roadmap

The following steps are key to a patient's successful engagement in the OBAT program:



Initial Screening

PHONE OR IN PERSON SCREENING BY OBAT STAFF

- Screener includes: Review of medical, social, and substance use history as well as current use. Demographics, living situation, insurance, safety, and treatment goals are also reviewed.

- *See Essential Documents and Tools: Initial Screening.*

The OBAT team reviews initial screening information and decides if a given patient is an appropriate candidate to receive medication for addiction treatment in an office-based setting. Appropriate candidates proceed to OBAT intake. This review process should occur in a timely manner as to not delay patient care. For all patients seeking treatment within the OBAT program, treatment on demand defined as low-barrier, same day access to treatment is the goal.

OBAT NCM Intake

INTAKE PERFORMED BY NURSE CARE MANAGER

See Essential Documents and Tools: OBAT Nurse Intake Form

The OBAT NCM intake includes:

- Information to lay the groundwork for a therapeutic relationship with the patient. Assess patient goals for treatment, strengths for obtaining recovery, and risks to treatment success.
    - The OBAT NCM values the uniqueness of each individual and helps each person define their own goals for treatment.
    - Building rapport with the patient during initial visits can help in caring for the patient longitudinally and engaging them within the healthcare system.
- Assess the patient's substance use including substance use history, current use status, prior treatment history, overdose history, and recovery history.
- Assessment/review the patient's medical, mental health, and social history.
- Obtain appropriate signed consent forms to assist with collaboration of care with outside providers and supports.
- Educate the patient on medication for addiction treatment what it is, how it works, medication administration, interactions, side-effects, potential adverse reactions, and medication initiation and maintenance processes.
    - The OBAT NCM reinforces that a substance use disorder is a chronic medical condition that affects numerous aspects of a person's wellbeing. The OBAT team will support the patient throughout the recovery process, even in the event of recurrent use. The patient's treatment plan and medication will be revised as necessary to assist the patient in achieving recovery and meeting their identified treatment goals.
- Educate the patient on harm reduction, including overdose prevention, identification, and reversal; safer injection techniques, when appropriate; safer consumption techniques as appropriate; and access to safer consumption supplies.
- Obtain laboratory testing. Laboratory screening at intake generally includes:
    - Toxicology screening
    - Pregnancy testing (if applicable)
    - HIV/HBV/HCV/syphilis testing
    - Tuberculosis screening (per institutional protocol)

- Obtain additional laboratory tests as clinically indicated.
    - Consider: complete blood count, comprehensive metabolic panel, hepatic function, hepatitis A serology, and/or three-site chlamydia and gonorrhea testing.

      Review the treatment agreement and clinic policies. Patient signs treatment agreement and consents for treatment. *See Essential Documents and Tools: OBAT Treatment Agreement and Clinic Policies*.

- Discuss responsibilities for safe medication storage.
- Review clinic hours and times available for scheduling visits, including after-hours emergency contact information and process for the on-call coverage.
    - If unable to meet the patient's needs and the program requirements, site will provide a warm hand-off to another treatment setting that may be better able to meet the needs of the patient (e.g., distance, insurance restrictions, transfer to methadone, etc.).

OBAT Provider Visit

The OBAT provider visit includes:

- Provider assessment of the patient including collecting or reviewing a previously completed substance use history
- Assessment of comorbid mental health or medical issues
- Physical examination if needed
- Collection or review of laboratory test results.
- Confirmation of *DSM-5* diagnosis of SUD and assessment of appropriateness for medication treatment for addiction.
- Education regarding medication options and initiation; behavioral health services; peer support meetings and recovery coaching; residential treatment; acute treatment centers; and complementary treatment modalities such as acupuncture, reiki, meditation, etc.
- Counseling about harm reduction interventions and overdose prevention and response.

The OBAT NCM will manage the patient under the guidance of the provider with close clinical follow-up and ongoing communication with the waivered provider via telephone, electronic medical record, in-person communications, and team meetings.

Follow-up visits with the waivered provider occur at a minimum of once every four months. Programs utilizing the NCM model often include frequent nurse-patient visits, and therefore provider visits are less frequent. The frequency of provider visits is based on provider preference, practice setting, etc. Additional follow-up with primary care provider (PCP) is as warranted by medical need. Often the PCP and the OBAT provider are the same; if so, this will not apply.

Treatment Planning

Treatment On Demand

Ambivalence about recovery, poor support systems, co-morbid medical and mental health conditions, and unstable lifestyle are some of the many reasons why low-barrier, rapid access to treatment for substance use disorders is essential. Treatment-on-demand models have been shown to enhance rates of engagement in treatment and reduce substance use (Wiercigroch et al., 2020). In 2015, a study found that among patients who initiated same-day treatment in the emergency department with buprenorphine, alongside a brief negotiated interview, 80% were engaged in OUD treatment at 30 days (D'Onofrio et al., 2015).

Providing access to same-day treatment with life-saving medications and access to OBAT programming facilitates a patient-centered model of care that allows the treatment team to adapt to the patient rather than the reverse.

Due to the importance of starting treatment during the first visit, providers often need to prioritize collection of the most important patient information and completing further assessment at subsequent visits.

All patients coming into care for treatment are at risk for opioid overdose and should be prescribed naloxone and educated on how to recognize overdose and administer the medication.

For information on same day prescribing of buprenorphine, see Treatment Initiation, Stabilization, and Maintenance (pp.27).

Treatment Agreement

The goals of the treatment agreement are to:

- Engage patients, and the OBAT team, in the treatment plan
- Individualize treatment to meet the needs of the patient
- Encourage patient involvement with their treatment.
- Outline what the patient can expect from the team and what the team expects from the patient.

See Essential Documents and Tools: OBAT Treatment Agreement and Clinic Policies.

During the OBAT intake, the NCM will explain the treatment agreement verbally and provide it in written form, which patients will sign and date. This form is to be kept in the patient's record. Review each line of the agreement, encouraging the patient to ask questions, and give them a copy to keep for their review.

Review this agreement again with the patient intermittently during the course of treatment and as needed. Provide reassurance about common issues including:

- Initiation of treatment (provide education around options and support).
- The challenges of transferring care from one form of medication treatment to another, and/or patients' ambivalence about such changes.

The agreement reinforces that a substance use disorder is a chronic medical condition that affects numerous aspects of a person's well-being. The OBAT team will support the patient throughout the recovery process, even in the event of recurrence of use. The patient's treatment plan will be modified as necessary to assist the patient in obtaining recovery, achieving identified treatment goals, and decreasing risk for harm.

To provide the optimum treatment environment for all, patients, visitors and staff are expected to maintain appropriate behaviors in the clinic setting. The patient can expect:

- To be treated with dignity and respect.
- To be notified if the office is closed and how to seek urgent assistance if the office is closed, including for the ability to contact a member of the OBAT team for urgent issues at night and weekends.
- That confidentiality will be maintained in compliance with 42 CFR Part 2 within the confines of the electronic medical record.
- That medication refills will be sent electronically to the pharmacy in a timely manner.

The OBAT team can expect:

- To be treated with dignity and respect.
- That patients will make their best effort to attend all appointments as scheduled with their primary care providers, OBAT providers, and OBAT NCMs. If an appointment cannot be kept, patients should be encouraged to notify the clinic and to reschedule the appointment.

Patients in need of a higher level of care will be assisted in this seamless transition and provided with medically appropriate treatment until the transfer is complete.

BUPRENORPHINE/NALOXONE PRESCRIPTION POLICIES

The roles of the provider, OBAT NCM, office staff, and the patient in the handling of prescriptions/medications are listed below:

- Prescriptions are sent to the designated pharmacy within 24 hours of a scheduled visit.
- If a patient is without medication, the prescription will be filled that day.
- Patients should communicate with the NCM regarding any prescription issues, refill, etc.
- Prescriptions will be queued up by the OBAT NCM after reviewing the medication record, consulting with provider, and checking the Prescription Drug Monitoring Program (PDMP) to confirm dosage, refill amounts, and timing of refill.
- The OBAT NCM will check insurance coverage, preferred covered medication formulary, and need for prior authorization.
- Following confirmation, the OBAT NCM will follow the institution workflow for queuing up the prescription to the OBAT provider and to the patient's preferred pharmacy.
- Prescription records will be maintained in the electronic medical record required under DATA 2000 and for DEA regulatory purposes.

PRESCRIPTION QUANTITY AND REFILL FREQUENCY

At treatment initiation, prescriptions are typically written for a one-week supply with no refills. The prescription length is typically increased when the patient moves into the maintenance phase of treatment, meaning without illicit substance use, at the discretion of the OBAT team based on recovery capital, adequate support structures, and adherence to follow up. After **four to six weeks of treatment,** prescription refills may increase to **two-week prescriptions.** After **eight weeks of treatment**, prescriptions may increase to **four-week prescriptions**. These parameters may be adjusted due to other factors such as housing, program requirements, support structure, medical issues, etc.

If a patient begins to struggle in their recovery process or the staff are concerned about giving the patient longer-interval prescriptions, the OBAT team will make the decision to continue with shorter-interval prescriptions as long as necessary.

If a patient is experiencing homelessness, or is living in an unsafe or unstable setting, the OBAT team, along with the patient, will develop a plan that promotes the security of their treatment. Examples of modified treatment plans include:

- Weekly prescriptions with refills.
- Collaboration with shelter staff in an effort to find feasible methods to support the patient and secure their medication if possible.

- Offer monthly injectable buprenorphine (where available).

Lost, Stolen, or Destroyed Buprenorphine/Naloxone

At intake, patients are informed that buprenorphine/naloxone prescriptions are generally not replaced. However, cases will be reviewed by the team on an individual bases in the event of lost, stolen, or destroyed medication. If a decision is made to replace medication, the OBAT team will return to weekly prescriptions until they feel it is safe for the patient to be given a larger quantity of medication.

Prior to receiving a replacement prescription, the patient will be asked to complete a follow-up with the OBAT clinic within 24 hours for assessment. At this time, patients will receive additional education about safe handling and storage of buprenorphine/naloxone by the OBAT NCMs and/or providers to prevent these events from recurring. A patient safety assessment should also be completed. The treatment plan should be reviewed, along with length of prescription and frequency of visits to further assess and ensure that there are not additional concerns or needs.

If the patient continues to experience lost, stolen, damaged, or destroyed medications, the team will meet to address this and the potential need to refer the patient to a more structured treatment setting or transition them to the injectable formulation of the medication to better safeguard their treatment and recovery.

Safe and Proper Storage of Medication

- ✓ Keep medication out of sight/reach of children.
- ✓ Use a locked box, bag, or cabinet for safe storage.
- ✓ Do not put tablets/films down on counters, sinks, dresser, and/or nightstands or in any public unsecure space.
- ✓ It is easy for children to put small pieces and crumbs in their mouth, which could result in a life-threatening situation. Poison control should be notified after removal of the medication from the child's mouth.
- ✓ To prevent damage to the tablet form of the medication, keeping cotton or tissue in the bottle may be indicated.
- ✓ Always keep medication in a labeled prescription bottle with child-proof cap.
- ✓ Patient's prescribed buprenorphine/naloxone films/tablets should be stored with an official pharmacy label at all times. Patients may request a second label from the pharmacy if they plan to carry medication on their person.
- ✓ Avoid carrying medication in your pocket, wallet, bag, purse, or backpack.

- ✓ Avoid leaving the medication in the bathroom, car, or any public space**.**
- ✓ **Call 911** if an accidental exposure occurs and/or go to the nearest emergency department.

TREATMENT INITIATION, STABILIZATION, AND MAINTENANCE

Checklist: Prior to Buprenorphine Initiation

- ✓ Treatment agreement and consents are reviewed and signed.

- ✓ Reinforce the need for frequent appointments and establish whether this is realistic. If the patient states it is not manageable, this needs to be addressed with the team prior to initiating treatment.

- ✓ Offer the patient a connection to counseling services as part of the treatment plan. A lack of counseling engagement should not prohibit the start of medication treatment. Counseling may be group-based or individual.

- ✓ Complete and review toxicology screen, when possible.

    - Ideally, toxicology screen and other laboratory testing would occur at time of initial OBAT encounter. However, in events such as the COVID-19 pandemic, many onsite encounters and laboratory workups may be deferred if risk of coming to the clinic is greater than the benefit of obtaining such screening.

- ✓ Obtain a pregnancy test for patients with uterine reproductive capabilities.

    - In cases of a suspected or confirmed pregnancy, the OBAT team will assist with connecting patient to appropriate OB providers and will manage the patient in OBAT until a warm handoff occurs.

    - A positive HCG should not defer the start of treatment with buprenorphine. For details on further management of pregnant and parenting women, please refer to the BMC Project RESPECT Guidelines for Treating Opioid Use Disorder in Pregnant and Parenting Patients: https://www.bmcobat.org/resources/index.php?filename=109_BMC_Pregnancy_OBAT_Manual_vTF.pdf

    - As above, in events such as the COVID-19 pandemic, many onsite encounters and laboratory workups may be deferred if risk is greater than benefit. If pregnancy is suspected, then appropriate measures should be taken to screen.

- ✓ If patient presents from detoxification/medically supervised withdrawal, then the OBAT team should attempt to obtain discharge paperwork or coordinate with treatment facility to determine medications administered (i.e., if methadone was administered, this may delay initiation with partial-agonist or antagonist medication due to risk of precipitated withdrawal). This documentation should be reviewed by the treatment team.

- ✓ NCM consults with waivered provider after initial NCM and provider visits. After OBAT team review of patient case, buprenorphine initiation should occur as soon as possible to support the patient and prevent further risk from opioid use.

    - Whenever possible, same-day initiations are encouraged.

    - The standard of care regarding the location of buprenorphine initiation has evolved from the office to the community setting. This change has occurred for many reasons, including efforts to reduce barriers to starting care, an expedited treatment start, ubiquitous familiarity with buprenorphine for patients entering OBAT treatment, increased availability of clinical tools to help guide buprenorphine initiation, uncertainty of initiation time due to illicit drug supply, and the rise in the use of telemedicine across outpatient clinics.

  See section titled: Essential Documents and Tools: A Guide for Patients Beginning Buprenorphine Treatment

- ✓ NCM reviews medication initiation plan with the patient

Timing Between Full Agonist Opioid Use and Starting Buprenorphine

Traditionally, to avoid precipitated opioid withdrawal during buprenorphine initiations, full agonist opioids should be discontinued for enough time to allow the patient to enter mild to moderate opioid withdrawal. The exception to traditional initiation of buprenorphine is micro-dosing, which is covered elsewhere in this manual, pp. 35.

TIMELINE FOR OPIOID DISCONTINUATION

The timeline for full agonist discontinuation should be determined as part of initiation treatment plan and based on patient's current opioid use and risk for medical complications from withdrawal.

- *Short-acting opioids, other than fentanyl:* discontinue 8-12 hours prior to scheduled initiation.

- *Fentanyl:* discontinue at least 16-24 hours prior to scheduled initiation.

- *Long-acting opioids:* discontinue at least 12-24 hours prior to scheduled initiation.

- *Methadone:* when possible, discontinue at a dose of 30 mg or less at least 36-96 hours prior to scheduled buprenorphine initiation.

Methadone-to-buprenorphine transfers are especially complex due to the long half-life of methadone and its unpredictable metabolic clearance. Please refer to the section on methadone to buprenorphine transfers in this manual, pp 32.

Buprenorphine/Naloxone Initiation: Opioid-Dependent Patients

INITIATION: PREPARATION

- Buprenorphine/naloxone prescription is sent to the pharmacy.

- OBAT NCM ensures that the prescription is processed by the pharmacy and available for pick-up in accordance with buprenorphine initiation.

  Patient discontinues use of illicit opioids to avoid risk of precipitated withdrawal.

OFFICE INITIATION: DAY ONE

- ✓ The patient arrives at clinic with prescription medication in hand.

- ✓ For patients actively using opioids other than buprenorphine, the NCM assesses withdrawal symptoms using the Clinical Opioid Withdrawal Scale (COWS). If the timeline from most recent use is appropriate and the COWS score is > 8-15, with the target COWS for fentanyl transition being at least 13-15, then the OBAT NCM instructs the patient to self-administer buprenorphine/naloxone as prescribed and per clinic protocol and prescription (sublingually or in the buccal mucosa).

- ✓ If the patient does not present in mild to moderate withdrawal, the OBAT team and patient have a few options:

  - Patient receives education and guidance to complete community initiation of buprenorphine. This option may be the preferred choice for high-risk patients and those with a history of taking buprenorphine.

  - Patient remains in the clinic or office setting to wait and complete an assessment to mitigate the risk of precipitated withdrawal (guided by the COWS). Once the target withdrawal score is achieved, it is safe to start buprenorphine.

  - Offer the patient an inpatient admission to provide a supportive transition from full agonist use.

  - Offer to reschedule the office initiation to a later date or time. Due to the risks of continued use or loss to follow-up, this is generally considered a less desirable option.

- ✓ OBAT NCM educates the patient on appropriate technique for sublingual/buccal administration. Counsels that appropriate self-administration requires the medication to be kept in the mouth for 10-15 minutes for appropriate absorption. Additional instructions should be given to avoid eating, drinking, smoking cigarettes, or using smokeless nicotine products for at least 15 minutes before and after administration.

- ✓ Buprenorphine/naloxone 2-4 mg initial dose is removed by the patient from their medication container and self-administered, while the OBAT NCM observes and guides

the process.

- ✓ OBAT NCM reassesses patient after 30-60 minutes, utilizing the COWS, and instructs the patient to take their second dose of 4 mg if needed, observed and supervised by the OBAT NCM to ensure proper administration.

- ✓ Patients may remain on-site for additional support and observed dosing or may leave the clinic setting at this time.

- ✓ Prior to leaving the clinic, the patient should be provided with *"A Guide for Patients Beginning Buprenorphine Treatment,"* and the NCM should review this document with the patient, with specific attention to subsequent dosing.

- ✓ Establish a follow-up plan, including telephone or video check-in and follow-up clinic visits. *See Essential Documents and Tools: OBAT Nursing Follow-Up Note Template*

    - The patient's dose will continue to be titrated per prescription instructions and/or until signs and symptoms of withdrawal subside.

    - Typically, patients will titrate their dose to 12-16 mg by the end of the first day; this may vary according to a patient's level of opioid dependence at the onset of treatment.

    - A growing body of evidence is supporting "macro-dosing" or "rapid start" of buprenorphine for patients with higher opioid tolerance such as those using fentanyl analogues (CA Bridge, 2020; Herring et al. 2019). With macro-dosing, typical Day 1 dosing of buprenorphine may total 16-24 mg or more. This increased initial dosing has been found to help patients safely and rapidly achieve a therapeutic dose of buprenorphine, thus more easily stabilizing patients with a high level of physical opioid dependence resulting from the high potency and lipophilic properties of fentanyl (Ahmadi et al., 2018).

    - For patients with higher opioid tolerance, consider providing withdrawal management medications such as small amounts of anxiolytics (hydroxyzine, clonidine), antispasmodics (dicyclomine), sleep medications (trazodone), and acetaminophen/NSAIDs; these may be used to manage distressing withdrawal symptoms. *See section titled: Essential Documents and Tools: Pharmacotherapy for Managing Opioid Withdrawal*

- ✓ Advise patient to contact clinic to update NCM or clinical supervisor by the end of the day in case of off-hours calls or concerns.

COMMUNITY INITIATION: DAY ONE

- ✓ For patients actively using opioids other than buprenorphine, the NCM provides education about rationale for ideal timing between full-agonist use and taking their first

dose of buprenorphine. The OBAT NCM also educates the patient about the clinical signs and symptoms of opioid withdrawal.

- ✓ "A Guide for Patients Beginning Buprenorphine Treatment" is provided and reviewed with the patient. *See section titled: Essential Documents and Tools: A Guide for Patients Beginning Buprenorphine Treatment*

- ✓ OBAT NCM educates the patient on the appropriate technique for sublingual/buccal administration and that appropriate self-administration requires the medication be kept in the mouth for 10-15 minutes for appropriate absorption. Additional instructions should be given to avoid eating, drinking, smoking cigarettes, or using smokeless nicotine products for at least 15 minutes before and after administration.

- ✓ OBAT NCM educates the patient on how to correctly self-administer buprenorphine/naloxone and reviews dosing limits of the medication.

    - The patient's dose will be titrated per prescription instructions and/or until signs and symptoms of withdrawal subside.

    - Most patients will titrate to 12-16 mg by the end of the first day; this dose will vary according to a patient's level of physical opioid dependence at the onset of treatment.

    - For patients using fentanyl analogues, macro-dosing of buprenorphine may be beneficial. As described above, with macro-dosing, the dosage of buprenorphine may reach 16-24 mg by the end of day one. This increased initial dosing helps patients more rapidly achieve a therapeutic dose of buprenorphine, which is helpful to stabilize those with a high level of physical opioid dependency resulting from the potency and lipophilic properties of fentanyl.

    - For patients with higher opioid tolerance, consider providing withdrawal management medications such as small amounts of anxiolytics (hydroxyzine, clonidine), antispasmodics (dicyclomine), sleep medications (trazodone), and acetaminophen/NSAIDs; these may be used to manage distressing withdrawal symptoms. *See section titled: Essential Documents and Tools: Pharmacotherapy for Managing Opioid Withdrawal*

- ✓ Patients are provided with contact information for the OBAT team, including emergency contact information. Patients are encouraged to reach out to the OBAT team for support.

- ✓ OBAT NCMs should review the follow-up plan with the patient, including telephone or video check-in and clinic visits. For patients starting treatment through a community initiation, a follow-up visit within 24 hours is recommended.

OFFICE OR COMMUNITY INITIATION: DAYS 2-7

- All patients who require 8 mg or more of buprenorphine on day one are instructed to take 8 mg upon awakening on day two. Patients who require less than 8 mg of buprenorphine on day 1 are instructed to take their total day one dose on the morning of day two (e.g., someone who stabilized at 4 mg on day one would take 4 mg upon awakening on day two). All patients are encouraged to check in with the OBAT NCM team via phone, video, or in-person encounter on day two.

- If symptoms of opioid withdrawal or cravings occur throughout the day, patients may take up to a total of 16 mg of buprenorphine daily for days 2-7 of treatment.

    - Patients who require up to 24 mg of buprenorphine on day one are advised to reduce their dose to a daily maximum of 16 mg buprenorphine for days 2-7 of treatment.

- After one week of treatment at the 16 mg dose, patients may be reassessed for a dose change.

    - In certain circumstances, some patients may require higher dosing on days 2-7 of treatment (e.g., those with severe uncontrolled OUD, those with prior experience on a maintenance dose of buprenorphine more than 16 mg daily, those transitioning from methadone, or those with co-morbid pain). These patients should be carefully assessed and monitored by OBAT staff.

The patient should complete weekly visits with the OBAT NCM until they are stable, defined as having achieved a steady dose of the medication resulting in minimal to no withdrawal symptoms or cravings and made progress towards treatment goals. Once stable, their clinic visits progress to every other week and eventually to monthly as clinically indicated. If a patient requires more support (e.g., they are struggling with continued use, polysubstance use, multiple issues related to social determinants of health, or medical needs related to their SUD), then they may continue having weekly or more frequent visits.

Methadone to Buprenorphine Transfers

CONSIDERATIONS WHEN TRANSITIONING FROM METHADONE TO BUPRENORPHINE

The transitional period from methadone to buprenorphine is a challenging time for both the patient and care team due to the risk of discomfort, destabilization, and recurrent use. Transitions must be carefully planned with close monitoring of patients for both comfort and safety.

It is highly recommended to a sign 42 CFR Part 2 release and collaborate with the patient's opioid treatment program (OTP), for close communication with the patient and their OTP is essential to coordinate the plan of care. Establish with both the patient and methadone team that if the transition to buprenorphine is unsuccessful (e.g., patient begins to experience withdrawal that interferes with functioning or leads to return to use or does not tolerate the medication), the patient may return to methadone treatment without a gap in care.

Information on the process of transitioning from methadone to other medications for the treatment of opioid use disorder can be found in the American Society for Addiction Medicine National Practice Guidelines at https://www.asam.org/docs/default-source/quality-science/npg-jam-supplement.pdf?sfvrsn=a00a52c2_2

- Close follow-up and support of the patient throughout the transition process, with the ability to reach the OBAT team emergently to address symptoms, provide support, and readjust plan as needed for safety, is optimal.

- Timing of the patient's last methadone dose and first buprenorphine dose is difficult to determine due to the unpredictable clearance of methadone caused by its long elimination half-life, hepatic metabolism, and storage in body tissues (Kharasch, 2017).

    - To decrease the level of physical opioid dependence and minimize the risk for precipitated withdrawal, patients have been shown to benefit from reducing their methadone dose to 30 mg before beginning buprenorphine treatment. (2020 Focused Update Guideline Committee, 2020, p.42)

    - Initiation of buprenorphine should ultimately be guided by withdrawal symptoms, objectively documented with COWS score of 13-15, rather than by the time since last methadone dose. Often, patients will reach this level of withdrawal within 36-48 hours after last methadone dose. Utilization of clinical judgment is essential in this process.

    - The tapering and transitioning period will include discomfort and increased risk for recurrent use.

    - Access to the OBAT team is critical in helping patients make this transition during the taper and immediately prior to the planned transition. Intensive stabilization and support may be needed (e.g., telephone contact up to three times daily until they are free of withdrawal signs/symptoms and are stable). Frequent visits, adequate supports, and a supportive environment to assist in the transition are recommended. Alternatively, an inpatient withdrawal management program (i.e., detox or acute treatment services) may be beneficial.

    - Advise the patient to arrange for time off work during the transition and family support with childcare and other responsibilities, etc., for their discomfort may last several days.

    - Consider providing withdrawal management medications such as anxiolytics (hydroxyzine, clonidine), antispasmodics (dicyclomine), sleep medications (trazodone), and acetaminophen/NSAIDs; these may be used to manage distressing withdrawal symptoms. *See section titled: Essential Documents and Tools: Pharmacotherapy for Managing Opioid Withdrawal*

    - If a patient were to discontinue methadone suddenly without effectively completing the taper schedule, they are at an increased risk of relapse and

overdose due to the discomfort of withdrawal symptoms. Continue to manage withdrawal symptoms and initiate buprenorphine as described above. Reinforcing overdose education and ensuring patient access to naloxone is critical in this case.

- Patients transitioning from methadone may require higher initial buprenorphine dosing. For example, they may require up to 24 mg of buprenorphine daily for the first seven days with close monitoring and assessment.

- Given that the transitional period from methadone to buprenorphine can be a challenging time, close collaboration with an experienced addiction provider is recommended. To connect with a national network of trained clinicians and receive free mentoring and clinical advice, consider utilizing the PCSS mentoring program (pcssnow.org/mentoring) or discussion board (https://pcss.invisionzone.com).

- Having the patient attend an inpatient program for supervised withdrawal management (i.e., detox or acute treatment services) can be a safer and more effective way to transition the patient from methadone maintenance to buprenorphine, but this is not required.

Suggested Methadone to Buprenorphine Protocol

- When the patient first expresses an interest in transitioning from their methadone maintenance program to buprenorphine, obtain a signed consent for release of information (42 CFR Part 2) to help coordinate care. It is also recommended to introduce the patient to the OBAT care team and ensure access to naloxone at this time. Educate patients regarding the anticipated treatment plan, including withdrawal symptoms and transition to buprenorphine, during this initial discussion.

- Educate patients regarding recommended methadone dose levels when transitioning to buprenorphine.

- Coordinate the last dose of methadone and initiation of buprenorphine with the methadone treatment team and patient.

- A methadone dose of 30 mg or less daily for one to two weeks prior to transition to buprenorphine is optimal but not required.

    - Alternatively, taper the methadone dose to the point of patient discomfort; buprenorphine can be initiated with objective withdrawal symptom documentation via COWS.

- If possible, the last dose of methadone should decrease to 15 mg daily. The following day, the patient should not take any methadone.

- After the day of no methadone, initiate buprenorphine.

- Adjuvant medications for symptom management are prescribed for the week of transition.

- Maintain close follow-up with OBAT team, including daily check-ins, for at least the first three days of transition.

- Again, when possible, transition through an inpatient program for withdrawal management is recommended to ensure a safe transition from methadone maintenance to buprenorphine.

Micro-dosing with Buprenorphine

Rationale of Micro-dosing

Small amounts of buprenorphine should not precipitate opioid withdrawal; due to its relatively long half-life, buprenorphine may accumulate at the receptor site gradually, thus slowly replacing a full μ-agonist without precipitating withdrawal if given in small enough doses (Rozylo et al., 2020).

Background

Standard buprenorphine initiation is a barrier for some patients and providers as it requires patients to experience moderate withdrawal and reduced analgesia, may be time consuming, and carries a risk of precipitated withdrawal.

The rising prevalence of fentanyl in the illicit drug supply carries additional concerns for precipitated withdrawal (Randhawa et al., 2019). Fentanyl has a rapid onset and short duration of action, which many agree is part of the reason for its increased risk of overdose mortality. However, fentanyl is also lipophilic, resulting in tissue distribution that is not necessarily dose-dependent. Consequently, continuous, and prolonged use of fentanyl not only increases a person's risk for fatal overdose but can result in slow and unpredictable clearance of the drug. These qualities appear to be increasing the incidence of precipitated withdrawal during transition from full-agonist use to buprenorphine products, despite patients being in moderate to severe opioid withdrawal at time of initiation as measured by the COWS scale.

With micro-dosing, patients may continue to use full agonist opioids (e.g., fentanyl, methadone, and oxycodone) until a therapeutic dose of buprenorphine has been achieved, at which point full-agonist opioids are generally discontinued. A growing body of research shows that micro-dosing methods of buprenorphine initiation may reduce the time to start treatment, remove the experience of withdrawal and reduced analgesia, and ease the transition to buprenorphine treatment.

The research on buprenorphine micro-dosing is limited, and further data is needed for an evidence base regarding viability, safety, and efficacy in order to safely develop protocols for treatment. It is recommended to consult addiction treatment and institutional pharmacy specialists before initiating micro-dosing protocols utilizing buprenorphine products.

Bernese Method

Very small initial doses of transmucosal buprenorphine (e.g., 0.125 mg to 0.5 mg) are followed by daily incremental increases in both dose and frequency over seven to ten days.

Benefits specific to the Bernese method include that transmucosal buprenorphine formulations are approved for treatment of OUD and available in traditional medical and pharmacy settings.

Drawbacks specific to the Bernese method, as observed by Rozylo et al. (2020) include:

- Optimum dosing schedules have yet to be defined.
- Ongoing illicit opioid use at treatment start continues to place the patient at risk for fatal opioid overdose, for initial doses of buprenorphine are not sufficient for opioid blockade to occur.
- Complex dosing regimens may require pharmacy assistance, and some patients using fentanyl will require even lower initiation doses of buprenorphine.
- The dose of buprenorphine is not always consistent across a buprenorphine film, and the film is not scored. Therefore, cutting a 2 mg buprenorphine film in half may not result in two equal 1 mg doses.

TRANSDERMAL PATCH METHOD

The transdermal buprenorphine patch is a schedule III medication that is FDA approved for treatment of severe chronic pain. Use of the currently available buprenorphine transdermal patches for treatment of OUD, including micro-dosing, is therefore considered off-label use and is NOT compliant with DATA 2000 in an outpatient setting. **For that reason, this medication cannot be used in outpatient settings for initiation of buprenorphine treatment for opioid use disorder as it does not fall within the guidelines outlined with DATA 2000 and would therefore be a violation of this federal law.** Currently, this method may only be facilitated in inpatient settings.

The transdermal buprenorphine patch is applied once weekly to the upper outer arm, upper chest, upper back, or the side of the chest. There are five different strengths: 5, 7.5, 10, 15, and 20 mcg/hour patches.

Benefits specific to the transdermal patch method of micro-dosing includes a similar safety profile to other buprenorphine products, and the strength of patch is consistent and allows for very low dosing of buprenorphine (doses in mcg vs. mg). Additionally, weekly application of the patch permits ease of administration and improved adherence.

The largest concern with this method is that the medication is not approved for treatment of OUD; **use in outpatient settings for initiation of buprenorphine would not fall within the guidelines outlined with DATA 2000 and would therefore be a violation of this federal law**. Additionally, the medication is expensive and often requires prior authorization for insurance coverage.

Existing protocols that utilize transdermal buprenorphine patches should only be conducted within inpatient settings, which allow for buprenorphine to be administered without a waiver, rather than prescribed or dispensed.

As micro-dosing is a new method in initiating buprenorphine, the information and protocols regarding initiation continue to evolve. Please visit bmcobat.org or contact the authors of this guideline directly for more information.

Managing Precipitated Withdrawal

Precipitated withdrawal occurs when an individual uses a partial agonist (buprenorphine) or antagonist (naltrexone or naloxone) too soon after using a full agonist opioid (such as fentanyl, heroin, oxycodone, morphine, methadone, etc.), causing rapid and often severe withdrawal symptoms. This occurs because buprenorphine, naltrexone, and naloxone all have a stronger affinity for the opioid receptors in the body, resulting in the displacement of the full opioid agonist molecules previously occupying that receptor site and thus triggering acute symptoms of withdrawal (SAMHSA, 2018).

Symptoms of precipitated withdrawal are consistent with those of opioid withdrawal, including diaphoresis, restlessness, anxiety, stomach cramping, diarrhea, vomiting, tachycardia, muscle aches and cramping, yawning, rhinorrhea, lacrimation, and tremors (Wesson and Ling, 2003).

The increased prevalence of fentanyl in the illicit drug supply carries specific concerns for precipitated withdrawal due to its pharmacokinetic properties (Randhawa et al., 2019). Fentanyl has a rapid onset and short duration of action; it is also lipophilic, resulting in tissue distribution that is not necessarily dose-dependent. Consequently, the drug's clearance from the body can be slow and unpredictable. These qualities appear to be increasing the incidence of precipitated withdrawal during the transition from full-agonist use to buprenorphine products despite patients objectively being in moderate to severe opioid withdrawal at time of buprenorphine initiation.

Having a plan for treatment of precipitated withdrawal is essential in case it occurs during buprenorphine initiation to prevent illicit substance use and issues with retention.

TREATMENT IMPLICATIONS

- Patients with an anticipated risk of precipitated withdrawal should be educated regarding this risk and its management prior to initiation of buprenorphine; this is important for retention and establishing trust. Please see our section "Treatment, Initiation, Stabilization and Maintenance" (pp. 27) for specific instructions regarding initiation.

- Reassure patients that if precipitated withdrawal occurs, symptoms are limited and will resolve relatively quickly (symptoms peak within 1-4 hours).

- Historically, management of precipitated withdrawal has involved two options: 1) stopping initiation and having the patient return the following day to retry initiation or 2) giving additional doses of buprenorphine to suppress the withdrawal symptoms.

    - By stopping initiation, the patient is at an increased risk of being lost to follow up and, more importantly, of ongoing illicit substance use and overdose-related death. Additionally, due to the uncomfortable physical experience and a lack of partnership between the healthcare team and the patient, stopping and deferring treatment initiation may decrease a patient's trust in the treatment and thus a decreased willingness to engage in treatment with the OBAT team and/or buprenorphine in the future.

- Administering additional buprenorphine to provide enough partial-agonist effect to mitigate withdrawal is the preferred method for managing precipitated withdrawal. This option also enables the patient to reach the goal of achieving opioid blockade with buprenorphine more quickly, decreasing their overdose risk.

- Medications may be prescribed/offered to assist with targeted withdrawal symptoms. Consider clonidine for anxiety and elevated blood pressure, hot packs or NSAIDs/acetaminophen for body aches, dicyclomine for intestinal spasms, and antihistamines for rhinorrhea or epiphoria, among other medication options. *See section titled: Essential Documents and Tools: Pharmacology for Managing Opioid Withdrawal*

- Following management of precipitated withdrawal, patients should continue maintenance and stabilization on buprenorphine as planned.

Buprenorphine/Naloxone Initiation: Opioid-Naïve Patients

Examples of Non-Opioid Dependent Candidates for Buprenorphine

- Persons transferring from naltrexone.

- Those with intermittent use not (yet) resulting in opioid dependence.

- Persons with a history of OUD who are not currently using opioids but may be at risk for recurrent use.

For more information on this topic, watch a short video: "Initiation of Buprenorphine in Patients who are NOT Opioid Dependent" here: https://bmcobat.org/resources/videos.php?category=8

Prior to Initiation

- ✓ Patient status of most recent opioid use should be carefully reviewed by the OBAT NCM.

- ✓ For patients who are not using opioids or for those with inconsistent opioid use who have no signs of physical dependence, it is still recommended to provide education about precipitated withdrawal and review the timing of their last use of full-agonist opioids and first dose of buprenorphine.

- ✓ OBAT NCM reviews with the patient that regular use of buprenorphine will result in opioid dependence.

- ✓ OBAT NCM and patient engage in shared decision-making for in-office versus community initiation plan.

OFFICE INITIATION: DAY ONE

- ✓ The patient arrives with prescription buprenorphine medication in hand.
- ✓ OBAT NCM assesses for recent use and utilizes the COWS to assess for presence of withdrawal. A very low or negligible COWS score is anticipated.
- ✓ NCM educates the patient on the appropriate technique for sublingual/buccal administration, including counseling that the medication be kept in the mouth for 10-15 minutes for appropriate absorption. Additional instructions should be given to avoid eating, drinking, smoking cigarettes, or using smokeless nicotine products for at least 15 minutes before and after administration.
- ✓ The initial buprenorphine/naloxone dose of 2-4 mg is taken from the patient's medication container and administered transmucosally while the OBAT NCM observes and guides the process.
- ✓ OBAT NCM reassesses patient after 30-60 minutes for tolerance of medication and any signs or symptoms of sedation. A second dose of medication may not be indicated due to absence of opioid tolerance and dependence.
- ✓ Patients should receive instructions about subsequent dosing and establish a follow-up plan, including telephone or video check-ins and clinic visits.

OFFICE OR COMMUNITY INITIATION: DAYS 2-7

- Patients are instructed to take 2 mg buprenorphine daily for the first three days of treatment.
- Buprenorphine doses are typically increased by 2-4 mg every three to five days until a maintenance dose is achieved that effectively manages the patient's cravings and provides opioid blockade.
- Close monitoring via phone, video, or in-person visits are recommended during the first week of treatment.

Buprenorphine Stabilization

Goal: Stabilization of medication dose. The target buprenorphine/naloxone dose is 8-24 mg/day with the goals of opioid blockade, cessation of withdrawal symptoms, cessation of cravings, and improved functioning and quality of life. Total daily dose may be taken in divided doses.

- Opioid blockade is typically reached at 16 mg of buprenorphine daily. Achieving a dose that will provide opioid blockade is recommended, particularly in the early stages of recovery.

- Divided dosing is especially helpful for patients with co-morbid chronic pain for improved analgesic effect, helping to avoid the need for additional pain medications.

- Buprenorphine has a long half-life. The majority of patients take buprenorphine/naloxone twice daily. The prescription may need to be specifically written as twice daily dosing to allow some patients to receive it as such while engaged in settings where medications are administered or managed by staff (e.g., residential treatment for substance use disorders or post-acute rehabilitation facilities).

- Within one week of starting buprenorphine, the patient should present remotely or on-site for an assessment, prescription renewal, education, support, evaluation of mental health, and other needs.

- Generally, prescriptions lasting longer than one week are not given during the stabilization phase.

- Refills are permitted, but the patient must provide pharmacy information as all prescriptions are electronically sent to the pharmacies.

Patient sees NCM weekly for 4-6 weeks or until stable. If the patient is adherent to the treatment plan, illicit substance use has decreased, and buprenorphine dose is stable, then patient may then progress to the maintenance phase of treatment.

Buprenorphine Maintenance

Regardless of buprenorphine initiation pathway, once stable, patients will visit the clinic every two to four weeks, with refills that coincide with visits.

Goal: Monthly visits for a few months; ultimately, random visits, if appropriate for patient; random visits are more effective in managing patients (ASAM Expert Panel and Quality Improvement Council, 2017).

- Many patients will remain on a higher visit frequency than monthly as patients find these visits important to their recovery process.
- Each decrease in visit frequency requires treatment team review.

Maintenance phase clinic visits should include (*See Essential Documents and Tools: OBAT Nursing Follow-Up Note Template):*

- Urine or oral toxicology testing, as indicated for treatment planning.

- Patient assessment: review of medication dose, medication adherence, medication side effects, continued cravings and/or withdrawal symptoms, safe storage of medication, recovery capital evaluation (e.g., engagement in counseling, peer support meetings,

recovery groups, etc.), any concerns regarding recurrence of use, medical concerns, and other psychosocial factors that could affect the patient's health and wellness.

- Review of treatment plan: visit frequency, counseling, and need for additional support.

- Indicated lab testing: for example, if LFTs were elevated at treatment initiation, consider re-checking within one to two months, or sooner depending on degree of elevation, and regularly monitor thereafter. Elevations are more common in patients with hepatitis C, alcohol use disorder, and HIV infection.

- If there is a history of risky alcohol use, address these concerns with the patient. Consider use of a breathalyzer at each visit or assessment with a urine EtG when appropriate.

    - Acamprosate (Campral®) and disulfiram (Antabuse®) may be offered to patients with alcohol cravings or unhealthy use with provider input and agreement.

    - Patients managed on buprenorphine cannot be treated with any naltrexone formulation; these medications are contraindicated due to their interaction at the μ-receptor.

- OBAT NCM notes should be documented in the medical record and available to the entire clinical team.

- Visits with waivered OBAT provider should occur at least every three to four months.

- Review and confirm contact information, including pharmacy of choice, at each visit.

- Refills for up to six months may be provided once the patient is stable, and these prescriptions are sent to a pharmacy with information kept on file.

- In addition to office visits, OBAT NCM contacts patient via phone for support as needed.

Injectable Buprenorphine (Sublocade®)

Sublocade® is the first, and at time of publication, only injectable buprenorphine product for the treatment of moderate-to-severe opioid use disorder in adult patients who have initiated treatment with a transmucosal buprenorphine-containing product (FDA, 2017). It is a once-monthly subcutaneous injection that is indicated for patients who have been on a stable dose of buprenorphine treatment at a minimum dose of 8 mg and for a minimum of seven days.

For the most up to date information regarding Sublocade®:
Full Prescribing Information: https://www.sublocade.com/Content/pdf/prescribing-information.pdf

FDA Medication Guide: https://www.sublocade.com/Content/pdf/medication-guide.pdf

For information about ordering Sublocade®: https://www.insupport.com/specialty-product

For guidance on administering Sublocade®: https://www.youtube.com/watch?v=10C_ju7uD6o

SUBLOCADE® DOSING

There are currently two available dosage strengths of Sublocade®: 100 mg/0.5 mL and 300 mg/0.5 mL. The recommended dose of injectable buprenorphine is 300 mg monthly for the first two months, followed by a monthly maintenance dose of 100 mg.

While the majority of patients will be adequately maintained on 100 mg maintenance doses, certain individuals may benefit from continued 300 mg maintenance doses. These may include patients with a high daily opioid requirement, persistent toxicology screens positive for opioids, persistent opioid cravings, or other unsatisfactory clinical response.

- Doses should be given no less than 26 days apart.
- A patient who misses a dose of injectable buprenorphine should receive the next dose as soon as possible.
    - During clinical trials, delays in dosing by up to two weeks did not have clinically significant changes in treatment outcomes.
- For patients who have missed an injection by more than two weeks, consider restarting treatment with transmucosal buprenorphine or with the 300 mg loading dose regimen, with a plan to transition back to a maintenance dose of 100 mg.

SAFETY

Sublocade® forms a solid mass upon contact with body fluids, and therefore, must be administered into subcutaneous tissue (Indivior, 2018). Intravenous use of Sublocade® poses significant risks including occlusion, local tissue damage, thromboembolic events, and death.

Sublocade® is available only through the SUBLOCADE® Risk Evaluation and Mitigation Strategy (REMS) Program due to the risk of serious harm that could result from intravenous self-administration (Indivior, 2018). Notable requirements of the SUBLOCADE® REMS Program include:

- Certified healthcare settings and pharmacies must establish processes and procedures to verify that Sublocade® is provided directly to healthcare providers for administration by a healthcare provider and that the drug is never dispensed to or handled by the patient.
- Certified Healthcare Settings and Pharmacies must not distribute, transfer, or sell Sublocade®.
- For more information, visit www.SublocadeREMS.com or call 1-866-258-3905.

STORAGE AND HANDLING

Injectable buprenorphine is a Schedule III medication (Indivior, 2018). Handle with adequate security and accountability per federal and state regulations and institutional protocols.

- Medication must be stored behind two locks.
- A logbook of injectable buprenorphine inventory and dispensing must be kept with the medication.
- The receipt and administration of injectable buprenorphine will be documented in the logbook by two licensed providers.
- The inventory of the logbook will be audited on a regular (e.g., weekly) basis to verify completion of entries and appropriate stock of medication.
- All records related to controlled substances must be maintained and be available for inspection for a minimum of two years.
- It is highly recommended to contact your institutional legal and pharmacy teams to assist with establishing protocols for storing, dispensing, and documenting the use of injectable buprenorphine.
- Unrefrigerated, injectable buprenorphine can be stored at temperatures not exceeding 30 °C (86 °F) for no more than seven days prior to administration.
    - Should the medication experience an excursion in temperature, the medication may be marked once and returned to refrigeration to be used until the expiration date.
    - Discard Sublocade® if left at room temperature for longer than seven days. Follow the protocol of your institution or pharmacy for appropriate disposal.

MEDICATION DISPOSAL

A practitioner may dispose of out-of-date, damaged, or otherwise unusable or unwanted controlled substances by transferring them to a registrant who is authorized to receive such materials (FDA, 2017). These registrants are referred to as "Reverse Distributors." The practitioner should contact the local DEA field office for a list of authorized Reverse Distributors. Copies of the records documenting the transfer and disposal of controlled substances must be maintained for two years.

Injectable Buprenorphine: Patient Selection

Candidates for treatment with injectable buprenorphine include patients who:

- Have been diagnosed with a moderate to severe opioid use disorder.
- Have begun treatment on a transmucosal formulation of buprenorphine at a dose equivalent of 8 to 24 mg of buprenorphine daily for seven days.

- This is to mitigate risk of precipitated withdrawal, allergic reactions, over-sedation, side effects, adverse reactions, or any other intolerance of the medication.

- 8 mg equivalents include: one 8-2 mg SUBOXONE® (buprenorphine/naloxone) film, one 8-2 mg sublingual buprenorphine-naloxone tablet, one 8 mg buprenorphine-mono tablet, or one 5.7-1.4 mg Zubsolv® (buprenorphine/naloxone) tablet.

- Have a history of non-adherence to daily formulations of buprenorphine.

OR

- Are in sustained recovery utilizing a transmucosal formulation of buprenorphine between 8 and 24 mg daily, who would like to transition to a monthly injectable medication.

Contraindications for treatment with injectable buprenorphine:

- ✗ Patients who are opioid naïve.

- ✗ Patients with advanced liver disease or acute hepatitis (LFTs > 5x upper limits of normal).

- ✗ Patients with moderate to severe renal impairment.

- ✗ Patients who have been shown to be hypersensitive to buprenorphine of any component of the ATRIGEL® delivery system.

Checklist: Prior to Monthly Buprenorphine Injection

- ✓ Treatment agreement and consents are reviewed and signed.

- ✓ Reinforce to patient the need for frequent appointment adherence and establish whether this is realistic. If patient states it is not manageable, this needs to be addressed with the team prior to initiating treatment.

- ✓ Toxicology screen completed and reviewed by OBAT team.

- ✓ Pregnancy test for individuals biologically capable of childbearing as injectable buprenorphine (specifically Sublocade®) is not approved during pregnancy.

    - If positive HCG, OBAT team will assist patient engagement with appropriate OB providers and will manage the patient in OBAT until a warm handoff occurs.

    - Pregnant patients may be safely maintained on transmucosal buprenorphine products.

- For more information about management of peripartum patients on medications for addiction treatment, visit American College of Obstetrics and Gynecology (ACOG) (https://www.acog.org/clinical/clinical-guidance/committee-opinion/articles/2017/08/opioid-use-and-opioid-use-disorder-in-pregnancy or BMC Project RESPECT (https://www.bmcobat.org/resources/index.php?filename=109_BMC_Pregnancy_OBAT_Manual_vTF.pdf)

✓ If patient presents from detoxification/medically supervised withdrawal in a facility such as an acute treatment setting, then the OBAT team should attempt to obtain discharge paperwork that includes medications administered (i.e., methadone administered in detox may delay induction with partial-agonist or antagonist due to risk of precipitated withdrawal). This paperwork must be reviewed by the treatment team.

✓ Patient is approved for treatment with injectable buprenorphine by OBAT provider.

✓ NCM consults with OBAT provider, obtains the medication order from the OBAT provider, and reviews the injection plan.

✓ Sublocade® is ordered one of two ways:

- Through a REMS-certified pharmacy that will deliver the medication directly to healthcare provider's office.

OR

- By ordering directly through a specialty distributor, also known as "buy-and-bill". In this situation, the healthcare setting ordering the medication must be REMS certified.

✓ NCM coordinates with the pharmacy or specialty distributor the delivery of injectable buprenorphine to be stored behind two locks.

✓ NCM confirms with the provider prior to visit to confirm medication order.

✓ NCM reviews the details of injection appointment with the patient including date, time, location, and expectations.

Injectable Buprenorphine Administration

- Obtain injectable buprenorphine from the pharmacy per written prescriber order. As stated above, the recommended dose of injectable buprenorphine is 300 mg monthly for the first two months followed by a monthly maintenance dose of 100 mg.

- Injectable buprenorphine should be stored in the locked refrigerator at 2-8 °C (35.6 - 46.4 °F. The medication should be removed from the refrigerator at least 15 minutes prior to administration so it can reach room temperature.
    - When removing the medication from the locked refrigerator, the healthcare provider must appropriately document its removal in the designated medication log. This must be signed by two healthcare providers.
    - Each dose is provided in a prefilled syringe with a 19-gauge 0.625 in. needle.
    - Do not open the foil pouch or prepare the medication until the patient has arrived for the office visit and agreed to receive the injection.
- The foil package containing the medication should be kept intact until just prior to administration.

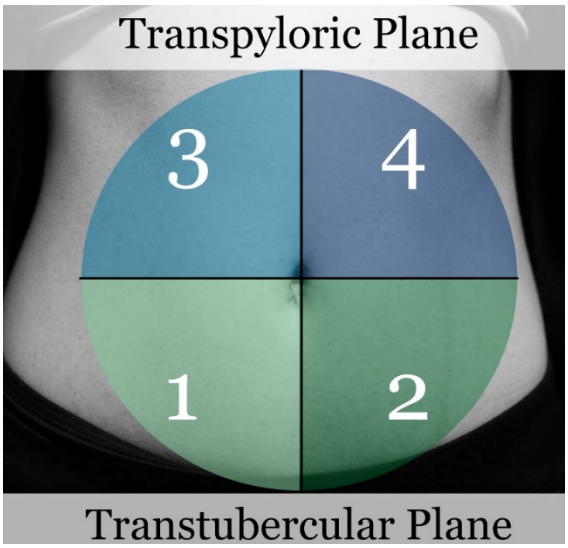


Fig. 1: Transpyloric and transtubercular planes.

- After meeting with the patient and ensuring appropriateness for receipt of injectable buprenorphine and confirmation of dosage, the healthcare provider then prepares and administers medication, following the specific detailed directions contained in the injectable buprenorphine medication package insert.
- Injectable buprenorphine should be administered as a subcutaneous injection between the transpyloric and transtubercular planes of the abdomen (Fig. 1) monthly with a minimum of 26 days between doses. Do not substitute any components of the carton.
- After administration, properly dispose of all syringe components into a secure sharps disposal and per institutional protocol.
- Injectable buprenorphine should never be handled by the patient and should always be administered by a healthcare provider.
- Advise patient to contact the OBAT clinic, or go to the Emergency Department, in the event of suspected injection site or other adverse reaction.

Special Considerations for Injectable Buprenorphine

- Sublocade® ranges in color from clear, to yellow, to amber. Variations within this range do not affect the safety or potency of the medication.

- Administer each injection only using the syringe and safety needle included with the product.
- It is recommended that the patient lie in the supine position during administration.
- Many patients report a burning sensation during injection that resolves shortly after administration.
    - Consider measures to reduce the discomfort of administration such as an application of ice, lidocaine, aromatherapy, etc.
- Advise the patient that they may have a lump for several weeks that will decrease in size over time.
- Do not rub the injection area after administering the injection. If there is bleeding, lightly apply a gauze pad or bandage, using minimal pressure.
- Instruct the patient not to rub or massage the injection site and to be aware of placement of belts or clothing waistbands.
- To avoid irritation, rotate injection sites. Record the location of the injection to ensure that a different site is used at the time of the next injection.

Removal of Depot: In the event the depot must be removed, it can be surgically excised under local anesthetic within 14 days of injection. Only the most recent depot can be removed. The removed depot should be handled with adequate care as this is a biohazardous material as well as a Schedule III substance.

Injectable Buprenorphine (Sublocade®) Maintenance

Once stable, patients should continue clinic visits every two to four weeks in person or remotely. The goal is to have the patient visit the clinic every 26-28 days—on the date of their buprenorphine injection. A decrease in visit frequency requires review by the treatment team.

Clinic visits should include the following (*See Essential Documents and Tools: OBAT Nursing Follow-Up Note Template):*

- Collect specimens for toxicology screening, as clinically indicated.
- Check injection site for signs or irritation or attempts of tampering to remove the depot.
- Assess patient recovery status; recurrence; and medical, social, and psychiatric issues should be addressed as indicated.

- Monitor and assess for potential medication side-effects or adverse reactions (e.g., injection site reaction, hepatic complications, gastrointestinal distress, etc.).

- Review treatment plan: visit frequency, counseling, need for additional support.

- If there is a history of risky alcohol use, address concerns with patient, then consider use of breathalyzer or urine metabolite screening.

    - Acamprosate (Campral®) and disulfiram (Antabuse®) may also be offered to patients with problematic alcohol use with provider input and agreement.

    - Patients with concurrent alcohol use may benefit from increased frequency of visits and additional recovery supports.

- Lab testing: if liver function tests were elevated at initiation, consider re-checking within one to two months, or sooner depending on the degree of elevation. Continue to regularly monitoring LFTs thereafter.

- Coordinate care with other OBAT team members as needed, including OBAT provider and PCP.

- Review contact information at each visit.

- Conduct OBAT provider visits at least every three to four months.

- In addition to office visits, OBAT NCM performs telephone and/or video contact for support as needed.

Buprenorphine Discontinuation

Substance use disorder are chronic and complex health conditions; therefore, enforcing a predefined treatment duration is not recommended. Some patients may choose to taper off of or discontinue buprenorphine treatment. These patients will continue to be supported by the OBAT team and receive assistance with ongoing recovery supports, dose adjustments and management of withdrawal symptoms. The taper duration is individualized to the patient and should be continually adjusted to meet the patient's needs. If a patient tapers off buprenorphine, the clinical team should continue regular check-ins via phone to assess the patient and provide support as needed.

If injectable buprenorphine (Sublocade®) is discontinued, its extended-release qualities should be considered, and the patient should be monitored for several months for signs and symptoms of withdrawal and treated appropriately. Ongoing follow-up is advised given the long-term outcomes post-taper have not been well-studied.

Of note, after a steady-state has been achieved (per clinical trial data, following 4-6 months of treatment), patients who discontinue Sublocade® may have detectable plasma levels of buprenorphine for twelve months or longer. The correlation between plasma levels and urine levels is not known. Patient education surrounding this information should be provided.

Buprenorphine to Naltrexone Transfers

CONSIDERATIONS

When transitioning from buprenorphine to naltrexone, work with the current buprenorphine clinic staff to coordinate the buprenorphine taper with the transition to naltrexone.

- Establish with both patient and buprenorphine clinic that, if the transition to naltrexone is unsuccessful (e.g., patient begins to experience withdrawal or cravings that interferes with functioning or leads to return to use or the patient does not tolerate the medication), the patient may return to buprenorphine treatment without a gap in care.

- Long half-life of buprenorphine and slow dissociation for μ-opioid receptor causes unpredictable clearance.

    - Timing between the last buprenorphine dose and the first naltrexone dose is difficult to predict. The limited data suggests that patients may do best when tapered to 2-4 mg of buprenorphine/naloxone daily for one week, waiting 5-7 days between last dose of buprenorphine/naloxone and the first dose of naltrexone, and then starting with low-dose oral naltrexone (Mannelli et al, 2012).

    - The taper and transition periods will include discomfort and increased risk for recurrent use. Support patients during this process.

    - Educate patients regarding appropriate buprenorphine dose levels for a transition to naltrexone. To decrease the level of physical opioid dependence and minimize the chance for severe precipitated withdrawal, most patients will benefit from a dose taper to 2 mg, and again waiting 5-7 days, before beginning naltrexone treatment (Sigmon et al., 2009).

    - Advise patient to arrange for time off work during the transition and family support with childcare and other responsibilities, for the discomfort may last several days.

    - Close monitoring and support of the patient is highly recommended to guide the process and provide assistance including treatment adjustments as needed. This transition is a critical time. Ensure the patient has an overdose plan and access to naloxone.

- Initiation of naltrexone should be guided by patient motivation, clinical judgment, and toxicology screening results negative for all opioids rather than by most recent buprenorphine dose, family pressure, or law enforcement desire for patient to be on antagonist treatment.

- Withdrawal signs and symptoms will occur, causing patient discomfort.

    - Intensive stabilization and support may be needed (e.g., telephone contact up to three times daily until free of withdrawal signs/symptoms and patient stable). Frequent visits, adequate supports, supportive environment to assist in the transition are recommended. Conversely, an inpatient withdrawal management program (i.e., detox or acute treatment services) may be beneficial.

    - Clonidine, anxiolytics (including benzodiazepines), and NSAIDs may be used to manage distressing withdrawal symptoms and continued during initiation if prescribed by provider and closely monitored.

- Begin with naltrexone tablets before administering extended-release injectable naltrexone.

SUGGESTED BUPRENORPHINE TO NALTREXONE PROTOCOL

- Patient to reduce daily buprenorphine dose to 2 mg for one week.

- Establish last dose date with patient. Five to seven days after final buprenorphine dose, patient to present to clinic with naltrexone tablet prescription bottle for naltrexone initiation appointment with OBAT nurse.

- Toxicology screening negative for all opioids.

- Negative naloxone/naltrexone challenge.

    - It is recommended to initiate naltrexone treatment with oral naltrexone formulation versus extended-release injectable formulation to mitigate allergic reactions, side-effects and adverse reactions.

- Symptom management with adjunctive medications, as appropriate, with provider input.

- Support and access to OBAT team is critical in helping patients to make this transition and not jeopardize recurrent use.

Implantable Buprenorphine

On October 16, 2020, Titan Pharmaceuticals, Inc., announced the discontinuation of sales of the only implantable buprenorphine product (Probuphine®) approved for use in the U.S (Titan Pharmaceuticals, Inc., 2020). Titan stated that this decision was made as part of its restructuring plan.

Implantable buprenorphine (Probuphine®) was approved for use of treating moderate to severe opioid use disorder in individuals who have been stable on a dose of buprenorphine no greater than 8 mg equivalent daily (Titan Pharmaceuticals, Inc., 2020). Probuphine® was designed to provide a constant, low-level of buprenorphine for six months. This medication consisted of four rods, inserted sub-dermally on the inside of the upper arm.

For more information regarding Probuphine®:
FDA Medication Guide: https://probuphine.com/wp-content/uploads/2019/09/Probuphine-MedGuide-Jul2018.pdf:

Naltrexone Initiation: Patient Selection

Candidates for treatment with naltrexone include patients who:

- Are not currently using opioids, but have a history of opioid use disorder and are at risk for recurrent use.
- Have a high degree of motivation for abstinence from opioids.
- Wish to discontinue agonist or partial-agonist therapy.
- Are not interested in agonist/partial agonist therapy to treat their opioid use disorder.
- Have a history of alcohol use disorder.
- Have a history of OUD and cannot be on agonist medication due to work, program etc.

CONTRAINDICATIONS

- × Patients who are unable to remain opioid free for 7-10 days.
- × Patients with chronic or acute pain that requires opioid analgesics.
- × Patients who are currently opioid dependent.
- × Patients who fail the naloxone/naltrexone challenge test.
- × Patients with advanced liver disease or acute hepatitis.
- × Patients with moderate to severe renal impairment.
- × Patients with advanced uncontrolled psychiatric disease or active suicidal/homicidal ideation, especially if symptoms worsen during withdrawal.
- × Patients who have displayed a hypersensitivity to naltrexone, PLG, carboxymethyl cellulose, or any other component of the diluent.

SPECIAL CONSIDERATIONS

Pain: chronic pain must be managed with non-opioids. Severe acute pain may require an anesthesia consult. If a patient has a surgical procedure pending, they may want to consider delaying naltrexone initiation or utilizing an alternative treatment until after the procedure.

Cirrhosis: Naltrexone is extensively metabolized through the liver and should not be administered if AST/ALT are greater than five times normal limits. However, even moderate transaminitis at five times the normal limit is not an absolute contraindication to naltrexone initiation.

Pregnancy: At the time of publication, there has not been sufficient research to assess the safety or efficacy of naltrexone in pregnancy. Naltrexone, both oral and injectable formulations, are Category C medications. The care team needs to evaluate the risks and benefits of naltrexone, and appropriate consent of unknown risk should be utilized.

Breastfeeding: The oral formulation of naltrexone does pass into breast milk. It is not known if extended-release injectable naltrexone passes into breast milk. *In vivo* studies indicate potential tumorigenicity. At the time of publication, the FDA advises against breastfeeding while on both oral and injectable formulations of naltrexone. The manufacturer acknowledges that there are no data on the effects on lactation or to the breastfed child. They advise consideration of the health benefits of breastfeeding, the mother's medical need for naltrexone, and potential adverse effects from naltrexone of the mother's underlying condition on the breastfed child (Alkermes, 2010).

Due to overwhelming evidence regarding the benefits of breastfeeding for both the birthing parent and baby, the knowledge that naltrexone is minimally excreted into breast milk, and insufficient evidence of harms to a breastfeeding infant, many programs support patients who are benefiting from naltrexone treatment to remain on that treatment and supports them breastfeeding their child (Jones et al., 2013).

For details on further management of pregnant and parenting patients with naltrexone, please refer to the BMC Project RESPECT Guidelines for Treating Opioid Use Disorder in Pregnant and Parenting Patients https://www.bmcobat.org/resources/?category=1or American College of Obstetricians and Gynecologists at https://www.acog.org/clinical/clinical-guidance/committee-opinion/articles/2017/08/opioid-use-and-opioid-use-disorder-in-pregnancy.

Anemia/Thrombocytopenia: Administer extended-release injectable naltrexone with caution and observe site for bleeding. Consider the oral formulation.

Obese/large body habitus: Extended-release injectable naltrexone must be administered intramuscularly into the gluteal muscle using the contents of the medication package. Alternate treatment may be considered for patients whose body habitus precludes an intramuscular (IM) gluteal injection with one of the provided needles. Consider the oral formulation.

Checklist: Prior to Naltrexone Initiation

- ✓ Review treatment agreement and consents with patient, and obtain patient signature on both.

- ✓ Reinforce with patient the need for regular appointment adherence, and establish whether this is realistic. If patient states it is not manageable, this needs to be addressed with the team prior to initiating treatment.

- ✓ The patient should consider counseling to augment the treatment plan, but lack of counseling should not preclude initiation of medication treatment. Counseling may be group-based or individual.

- ✓ The patient must be cleared by psychiatry if concern for a history of ongoing depression or a significant history of suicidal ideation.

- ✓ Confirm that labs are appropriate: HCG negative; LFTs < 5x upper limit normal.

    - If positive HCG, OBAT team will assist patient engagement with appropriate OB providers.

    - If LFTs >5 x normal, evaluate etiology and determine if appropriate for naltrexone.

- ✓ Obtain toxicology screening that is negative for opioids.

    - Withdrawal from opioids should be completed prior to the administration of naltrexone to prevent precipitated or spontaneous opioid withdrawal. The patient must not be experiencing withdrawal symptoms at time of initiation. Patients should discontinue short-acting opioids at least three to seven days prior to starting naltrexone. If taking longer-acting opioids such as fentanyl, methadone, or buprenorphine, the patient must discontinue use for at least seven to ten days.

    - Withdrawal from alcohol is not always necessary prior to naltrexone initiation. However, medically supervised withdrawal from alcohol is recommended if a patient has a history of alcohol-related seizures, delirium tremens, longstanding daily use, presence of alcohol withdrawal signs or symptoms, or other clinical indications as naltrexone does not treat symptoms of alcohol withdrawal. Consider a referral for a patient to receive medically supervised withdrawal from alcohol if clinically indicated.

    - If patient presents from medically supervised withdrawal in a facility, such as an acute treatment setting, the OBAT team should attempt to obtain discharge paperwork that includes medications administered (i.e., methadone or buprenorphine administered during this inpatient level of care may delay initiation with antagonist due to risk of precipitated withdrawal). This paperwork must be reviewed by the treatment team.

- ✓ The NCM consults with the OBAT provider and clinical team after the initial visit. After OBAT team review, the patient is scheduled for medication initiation per protocol in collaboration with patient and team.

- ✓ The NCM reviews the medication initiation plan with the patient and forwards the prescription to the provider for review and signature. A prescription for the oral naltrexone tablet may be electronically delivered to the pharmacy for patient to pick up. Extended-release injectable naltrexone often requires insurance prior authorization and ordering through a specialty pharmacy; this process may take several days and requires thoughtful planning.

Naltrexone Initiation

- Patients should be started on the oral naltrexone at 50 mg daily prior to receiving the extended-release IM injection to assess for tolerability. This is to mitigate allergic reactions, side effects, adverse reactions, or any other intolerance of the medication.
    - Typically, patients will remain on the oral formulation for a few days before receiving their first extended-release naltrexone injection to assess for side effects and any contraindications.
- Give patient an emergency card, bracelet, and/or medical alert identification indicating they have received the long-acting injectable naltrexone.
- A "naloxone challenge" or "naltrexone challenge" should be performed for patients who are at risk for precipitated or spontaneous withdrawal.

Naloxone Challenge

- Toxicology screening negative for all opioids.
- The patient must discontinue use of short-acting opioids for at least three to seven days. If they are taking long-acting opioids such as methadone or buprenorphine, the patient must discontinue use for seven to ten days or longer.
- Obtain baseline BP and pulse.
- Obtain baseline Clinical Opiate Withdrawal Score (COWS).
    - If the patient is still having signs of opioid withdrawal even if the toxicology screen is negative, do not perform a naloxone challenge. It will be positive.
- A total of 2-4 mg naloxone hydrochloride should be administered intramuscularly or intranasally. This may be divided into two doses to minimize risk of severe withdrawal.
    - Complete COWS at 15 min and again at 30 min following naloxone administration.

Negative Naloxone Challenge: No change in subjective or objective signs of withdrawal. Proceed with administering full dose naltrexone or extended-release injectable naltrexone.

Positive Naloxone Challenge: **Stop** the naloxone challenge if the patient experiences any symptoms of withdrawal. Do not give additional naloxone. In dependent individuals, naloxone

will precipitate withdrawal that usually emerges within five to ten minutes and dissipates within 80 minutes. The most common early signs of a positive challenge are an increase in anxiety and an elevated heart rate.

Naltrexone Challenge with Oral Formulation

- The patient must discontinue short-acting opioids at least three to seven days; long-acting opioids require at least seven to ten days.
- Toxicology screening negative for all opioids.
- Obtain baseline BP and pulse.
- Obtain baseline COWS.
    - If the patient is still having signs of opioid withdrawal, even if the drug screen is negative, do not perform a naltrexone challenge. It will be positive.
- Observe patient self-administering 25 mg naltrexone by mouth. Advise patient to remain in the clinic for 60 minutes to monitor for the presence/absence of withdrawal symptoms.

Negative Naltrexone Challenge: No change in subjective or objective signs of withdrawal. Proceed with extended-release naltrexone injection per protocol.

Positive Naltrexone Challenge: **Stop** the naltrexone challenge if the patient experiences any symptoms of withdrawal. Do not give any more naltrexone. The most common early signs of a positive challenge are increased anxiety and an increase in heart rate. Symptom management with adjuvant medications to occur as appropriate with provider input. Have the patient come back to the clinic in one to two days for a repeat naltrexone challenge.

Extended-Release Injectable Naltrexone Administration

- Obtain extended-release injectable naltrexone from the pharmacy per written prescriber order. Standard dose is 380 mg IM. Do not prepare suspension prior to patient arrival.
- Extended-release injectable naltrexone should be stored in the refrigerator. Prior to preparation, allow the drug to reach room temperature which takes about one hour.
- **Manufacturer medication guide must be reviewed prior to each administration of injectable naltrexone.** *See Appendix 9: Patient Medication Guide for Injectable Naltrexone (Vivitrol).* For copies of the Medication Guide you may also visit: http://www.vivitrolrems.com or call 1-800-848-4876
- After meeting with the patient and ensuring continued opioid abstinence, reconstitute and immediately administer medication, following the specific detailed directions contained in the extended-release injectable naltrexone medication package insert.

- Extended-release injectable naltrexone should be administered as an IM gluteal injection every 28 days.

- Administer the suspension by deep IM injection into a gluteal muscle, alternating buttocks per monthly injection. Aspirate for blood before injecting.

- If the needle clogs during administration, the needle must be withdrawn from the patient, capped with the attached needle protection device, and replaced with the provided spare administration needle. Gently push on the plunger until a bead of the suspension appears at the tip of the needle. The remainder of the suspension should then be administered into an adjacent site in the same gluteal region.

- Document administration of extended-release injectable naltrexone and note right or left gluteal injection site.

- Advise patient to contact the OBAT clinic or go to the Emergency Department in the event of suspected injection site or other adverse reaction.

Special Considerations

- Unrefrigerated extended-release injectable naltrexone can be stored at temperatures not exceeding 25 °C (77 °F) for no more than seven days prior to administration. Do not expose the unrefrigerated product to temperatures above 25 °C (77 °F). This medication should never be frozen.

    - Mark the medication each time it is removed and returned to the refrigerator.

- A properly mixed suspension will be milky white, free of clumps, and move freely down the walls of the vial.

- Use only the needles specifically designed for administration of extended-release injectable naltrexone. Select the appropriate needle based on patient's body habitus. Do not make any substitutions for components in the medication carton.

- Extended-release injectable naltrexone is administered as an intramuscular gluteal injection and must **not** be given subcutaneously or intravenously. A subcutaneous injection may increase the likelihood of severe injection site reactions.

Adverse Effects and Patient Education:

Injection Site Reactions: Providers should be trained in proper techniques for IM injections to prevent problems (SAMHSA, 2015). Extended-release injectable naltrexone injections may cause pain or tenderness at the injection site, which usually resolves in a few days. More serious reactions such as swelling, erythema, bruising, and pruritus have been reported. Generally, inadvertent subcutaneous injections result in the most significant injection site reactions.

Vulnerability to Opioid Overdose: Following injection with extended-release naltrexone, a patient's opioid tolerance is reduced markedly from when they were actively using opioids prior to treatment (SAMHSA, 2015). As such, patients are vulnerable to potentially fatal overdose when approaching the end of the dosing interval. If a dose is missed, active outreach should occur to reengage the patient in treatment. All patients that discontinue naltrexone should be educated on the risks of fatal opioid overdose. Additionally, attempting to break through the opioid blockade can also result in fatal overdose due to the high dose of opioids required to overcome blockade.

Depression and Suicide: In pre-market clinical trials of extended-release injectable naltrexone, reports of depression were infrequent but more common in the group that received injectable naltrexone than the placebo group (Alkermes, 2021). Patients should be evaluated, monitored, and treated appropriately, and families and caregivers should be alerted to the need to monitor patients for depression and suicidality.

Naltrexone (Oral or Injectable) Stabilization

- Patient presents for OBAT follow-up appointment (telemedicine or onsite) after one week for assessment, education, support, and evaluation of mental health, medical, and other psychosocial support needs.

- If a patient misses an extended-release naltrexone injection, they should be instructed to receive the next injection as soon as possible. Reassess the patient status prior to administering medication. Consider a naloxone/naltrexone challenge if opioid use is suspected or if injection has lapsed for an extended period of time. Augment treatment plan as needed.

- Patient sees NCM weekly for four to six weeks until stable. If the toxicology and breathalyzer screens are as expected and the patient is adherent to the treatment plan, then they should progress to the maintenance phase.

Naltrexone Maintenance

- Once stable, patients should have clinic visits every two to four weeks.

- **Goal:** Clinic visits every 28 days, occurring on the date of the patient's extended-release naltrexone injection are preferable.

    - Each decrease in visit frequency requires treatment team review.

Clinic visits should include (*see Essential Documents and Tools: OBAT Nursing Follow-Up Note Template*):

- Urine or oral toxicology screening as clinically indicated.

- Patient assessment: review of medication adherence, medication side effects including site reaction, continued cravings and/or withdrawal symptoms, safe storage of medication,

recovery capital evaluation, concerns regarding recurrence of use, medical concerns, and other psychosocial factors that could affect the patient's health and wellness.

- Review treatment plan: visit frequency, counseling, need for additional support.
- If there is a history of risky alcohol use, address concerns with patient and consider the use of breathalyzer or urine EtG at each visit.
    - Acamprosate (Campral®) and disulfiram (Antabuse®) may be offered to patients with alcohol cravings with provider input and agreement.
- Lab testing: if liver function tests were elevated at induction, consider re-checking within one to two months, or sooner depending on degree of elevation. Continue to regularly monitor LFTs thereafter as indicated.
- Contact other OBAT team members as needed, including OBAT provider and PCP if different and warranted.
- Review contact information, including specialty pharmacy, at each visit.
- Schedule OBAT provider visits at least every three to four months.

In addition to clinic visits, the OBAT NCM should perform telephone contact to support the patient as needed.

MONITORING, RETENTION, AND TREATMENT CONSIDERATIONS

Toxicology Screening

Toxicology screens are tools for monitoring the effectiveness of addiction treatment that involve collecting a biological specimen which is tested for the presence of specific substance(s) over a narrow window of time. This is an objective measure meant to be used in combination with a patient's self-report about substance use to assist in identifying threats to progress and patient safety concerns. This is particularly important when unexpected positive or negative results appear on screening, as they may not accurately depict a patient's substance use over time or their absence of use of a prescribed substance. Discrepancy between self-report and toxicology screen results can be a point of engagement for the provider, as the substances of known use may have been contaminated by other substances (ASAM Expert Panel and Quality Improvement Council, 2017).

While DATA 2000 does not establish a required number of toxicology screens needed prior to initiating or continuing buprenorphine or naltrexone treatment, monitoring and assessing substance use disorder with objective diagnostics including toxicology screening is important (H.R.2634 - 106th Congress (1999-2000), 2000.). Providers should order the right test, for the right patient, at the right time, with the goal of conducting toxicology screening only as often as needed to create an appropriate treatment plan that supports patient safety and recovery goals. As with visit frequency, toxicology screens are often conducted more frequently early in treatment and decrease as the patient progresses in recovery (ASAM Expert Panel and Quality Improvement Council, 2017).

The guidance for OBAT programs in Massachusetts is to conduct baseline laboratory data, including urine toxicology screening, within one week of initiating treatment. Urine is the standard medium for toxicology screening, although oral swabs may also be utilized.

In all cases of toxicology screening, a trauma-informed approach to specimen collection should be utilized to avoid re-traumatizing the patient or harming the therapeutic provider-patient relationship. Organizations should re-evaluate policies that inadvertently create stressful environments that interfere with the recovery of patients and jeopardize the well-being of staff and fulfillment of the organizational mission (SAMHSA's Trauma and Justice Strategic Initiative, 2014).

URINE TOXICOLOGY SCREENING POLICY

- Extraneous belongings (e.g., coats, bags, etc.) are not permitted in the bathroom.
- Patients enter the bathroom on their own with a sealed and labeled urine cup and bio-hazardous bag. The medical attendant collecting the sample may wait outside the bathroom.
- After providing a sample, patients may place the cup within the bio-hazardous bag. Patients are asked to avoid washing of hands or flushing the toilet until the labeled urine sample is handed to the gloved medical attendant.

- The medical attendant should check the sample for color, clarity, and temperature.
    - Concerning specimens are to be reported to OBAT NCM seeing the patient and/or ordering provider.

Urine Sample Adulteration/Tampering

If the urine sample is suspected to be adulterated:

- A discussion will take place between the patient and OBAT NCM and/or OBAT provider regarding the sample in an effort to better support the patient.

- The patient may be asked to repeat the urine screen.

- The patient will be counseled by the OBAT NCM about the importance of accurate UTS monitoring to promote safety and disclosure of substance use to allow the team to provide appropriate treatment. Reinforce that the role of the OBAT team is to help the patient if they are struggling.

- The patient is educated that unexpected urine results require additional care or a revision of the treatment plan and not discharge from treatment.

- Urine samples that are suspected of adulteration should not be sent to the laboratory for screening.

Telehealth

Addiction treatment has historically involved regularly scheduled in-person visits, but it has become apparent that telehealth management is an important tool that should be utilized to expand access to treatment, particularly in times of public health crisis such as the COVID-19 pandemic. The goals of telehealth management are to expand and expedite access to treatment, improve appointment adherence, and keep patients safe if they are unable to physically come into the clinic.

Telehealth management may be appropriate for new or follow-up visits and may be conducted utilizing either telephone or video/voice technology. Refer to your facility's policy regarding the use of telecommunication tools and patient privacy. For support regarding confidentiality with telehealth, visit https://www.healthit.gov/ for specific guidelines and technical assistance related to telehealth, and consult your organization's specific policies.

Considerations:

- Always identify the patient using at least two personal identifiers before beginning any assessments, education, or discussions (Laughlin & Witwer, 2019).

- Ensure that you, as the healthcare provider, are in a space that is confidential and protects the patient's privacy.

- Ask if the patient is in a location in which they have privacy to discuss sensitive health information.

- Seek collateral information from pharmacies, PDMP, or other agencies, which may be helpful in evaluating the patient treatment plan.

- As with in-person visits, telehealth management of patients should continue to comprehensively assess the health status of patients including: adherence to treatment, side effects, symptoms of withdrawal, cravings, use of substances, and other psychosocial stressors important to treatment of substance use disorders.

- In the setting of extensive telehealth management of patients in substance use disorder treatment it is important to establish the clinical need for urine toxicology screening that may change the course of a patient's plan of care. Limiting urine toxicology screens during public health crises may be necessary to address concerns of patient safety and wellbeing (Rights (OCR), 2020).

Contingency Management

Contingency Management (CM) is a treatment strategy which employs operant conditioning as a strategy to elicit behavior change among people with SUD (NIDA, 2020A). There is robust literature to support its use in stimulant use disorders (Drug Commissioner of the German Federal Government et al., 2016). At its core, CM is a treatment care plan based in celebrating patients' accomplishments and strengths in recovery (Petry & Bohn, 2003). In addition, to provide incentives to patients' continued participation in treatment, CM promotes engagement in activities that help to build recovery capital, such as participating in individual and group therapy, exercising, adhering to scheduled appointments, building sober social support networks, and finding meaningful activities to do throughout their recovery.

CONTINGENCY MANAGEMENT IN PRACTICE

- CM should not replace the use of other evidence-based treatments for other SUD, like medications for addiction treatment; it should be used in combination with other therapeutic modalities like motivational interviewing, cognitive behavioral therapy, community reinforcement approach, or relapse prevention counseling (De Crescenzo et al., 2018).

- CM treatment is typically 8-12 weeks in length with the ability for reenrollment.

- It is not necessary to hire additional staff to have a CM program. It is important to establish staffing roles within your organization to help patients in navigating the treatment program and how to be successful. Staffing considerations for CM programs may include:

- Peer recovery coach staff to support accomplishment of the tasks/goals of the patient's treatment program.

- Nursing staff to support the medical recovery process, group visits, and prescriptions.

- Behavioral health staff to support individual and group therapy, which may be beneficial for patients.

- Providers to manage additional medication concerns and the overall treatment plan of the patient.

- Administrative support to manage and coordinate the incentives associated with patients' accomplishment of tasks/goals.

Funding for CM can be complicated as it is currently not reimbursed by insurance and may require outside funds. The Centers for Medicare and Medicaid Services (CMS) have annual limits on CM funds to a maximum value of $75 per patient. In some states, health plans have laws restricting CM; therefore, one needs to know the rules/regulations of their states and health plans. Research funded by the National Institute on Drug Abuse (NIDA) has shown great efficacy in using CM; however, incentives typically range $400-$500 per patient, and lower incentives were found to be less effective (Glass et al., 2020).

Consider getting creative with prizes including donated items, clinic benefits such as special appointment times, specific waiting room chairs, waived co-pays, designated coat hooks, or vouchers for the clinic/hospital cafeteria. Length of buprenorphine/naloxone prescription, refills, or other medication prescriptions can also be increased to reward expected behavior.

IDENTIFIED METHODS OF CONTINGENCY MANAGEMENT

Fishbowl Method: patients earn a chance to win a prize of varying value by drawing a token at random out of a fishbowl in exchange for completing/accomplishing a specific task. Steps to utilizing the fishbowl method include:

- Establish a set list of tasks/goals for the program that result in the chance to draw from the fishbowl.

- For each task/goal, establish what kinds of activities would constitute completion and identify how the program will verify completion of the task/goal.

- In a fishbowl, place varying tokens—some with prizes, words of encouragement, or privileges that may be viewed as a prize.

- As patients accomplish more of the tasks or goals, they will be able to draw from the fishbowl a greater number of times. Additionally, patients who continue to accomplish tasks weekly, or in an otherwise scheduled fashion, may earn additional changes through

the longitudinal accomplishment of one particular task (e.g., an expected urine toxicology screen).

Voucher-Based Reinforcement Therapy: provides patients with a voucher for a desired behavior like a negative or expected urine toxicology screen. Voucher-based reinforcement should increase the intensity of the reward for each consecutive week of accomplishing a task/goal. Consider having a non-clinical staff member manage the voucher reinforcement. Steps to utilizing the voucher-based method:

- Establish a set of tasks/goals for the program that result in a specific reward.
- For each task/goal, identify what would constitute completion of that goal and how the program will verify its completion.
- Should patients not complete the task/goal one week, they can either stay at the level of reward they were at the previous week, or the process of increasing reward intensity can restart from the baseline level. This should be established at the beginning of the treatment to avoid any concerns that staff may create different rules for different patients.
- Visual presentation of the incentives, the accomplished tasks, and the growing intensity of the incentive may be helpful in promoting the patient's interest in continuing treatment and successful accomplishment of subsequent goals/tasks.

Routine Health Maintenance

Individuals with an SUD, particularly those with an OUD, have mortality risks six to twenty times higher than those of the general population. Many individuals with an SUD do not access health care due to barriers such as stigma, mistreatment from medical community, and lack of access. A 2015 study examining all-cause mortality among individuals accessing treatment for OUD found that although the leading cause of death was overdose (38%), 14% of individuals died of cardiovascular disease, 8% of cancer, and 5% of unintentional injury or respiratory illness; these findings reinforce the value of routine health maintenance for this high-risk population (Evans et al., 2015).

- As deaths from associated from HIV and liver-related diseases are high, it is imperative to link patients to primary care and offer routine testing for infectious disease for early diagnosis, linkage to care and treatment.
- Patients should be offered preventative health maintenance measures such as vaccinations recommended by ACIP and preventative screenings as recommended by USPSTF.
- Family planning and sexual health should be addressed regularly throughout a patient's engagement in OBAT.

Sexual Health

Individuals who inject drugs and those who use stimulants are more likely to engage in unprotected sex and sex with multiple partners (Nerlander et al., 2017; Novoa et al., 2005; Semple et al., 2004). In addition, those who inject substances report receptive sharing of syringes and other injection equipment. These actions place people who use substances at higher risk for infectious diseases such as HIV and hepatitis B and C. Furthermore, chronic stimulant use has been linked to a weakened immune response, increased predisposition to infection, and retroviral replication (Ellis et al., 2003; SAMHSA, 2020c). Many patients with sexually transmitted infections (STI) are asymptomatic, and their infections might be identified while receiving screening services in the primary care setting. Early identification and treatment of an infected patient can decrease further transmission (Barrow, 2020).

TREATMENT IMPLICATIONS

- When asking about sexual history, do not assume sexual practices or genders of partners.
- Relationship status, age, and gender do not define a patient's sexual practices.
- Create a space of confidentiality and safety.
- Obtain a comprehensive sexual history utilizing the five P's approach: Partners, Practices, Past history of STI's, Protection from STIs and Pregnancy Plans (if applicable).
- Comprehensive screening for gonorrhea and chlamydia includes three site testing: oral, rectal, and urethral.
    - Patient-collected samples are just as accurate as samples collected by the health care provider (Lunny et al., 2015).
- Offer routine testing for HIV.
    - For patients with an HIV exposure in the last 72 hours, offer Post-Exposure Prophylaxis (PEP).
        - For more information visit: https://www.cdc.gov/hiv/clinicians/prevention/pep.html
        - PEP may be obtained at no cost if not covered by a patient's insurance or if the patient encounters financial barriers. For more information visit: https://www.justice.gov/ovw/local-resources
    - For individuals at high risk of HIV exposure, offer Pre-Exposure Prophylaxis (PrEP). Studies have shown that PrEP can provide up to a 48.9% reduction in the incidence of HIV infection amongst PWID (Choopanya et al., 2013).
        - For more information visit: https://www.cdc.gov/hiv/clinicians/prevention/prep.html

        - PrEP may be obtained at no cost if not covered by the patient's insurance or if they encounter financial barriers. For more information about the "Ready Set PrEP" program, visit https://www.hiv.gov/federal-response/ending-the-hiv-epidemic/prep-program

- Make expedited partner therapy available: Assuring timely treatment of the partners of persons diagnosed with STIs has proven to be pivotal in the prevention of further bacterial STI transmission. Expedited partner therapy provides medications (or prescriptions) to the partners of those found to be infected with an STI without clinical assessment of the partner (CDC, 2020a). Parameters of treatment are dictated by local and state laws. For more information about the limitations of EPT in your state of practice, please consult your local health department. For more information about EPT please visit: https://www.cdc.gov/std/ept/legal/default.htm

- Integrate Family Planning: Up to 86% of pregnancies among patients with OUD are unintended (Heil et al., 2011). Many patients who did not want to get pregnant reported not using contraception (or using less effective methods, such as condoms) and expressed wanting greater access to contraception (Heil et al., 2019). Offering contraception services alongside substance use treatment can bridge this gap and reduce unintended pregnancy (Terplan et al., 2015).

    - All patients who can get pregnant should receive counseling regarding family planning and linkage to preconception care, peri-partum care, or access to contraception.

    - Ensure patients have all the information needed to make an informed choice.

    - Do not assume patients in recovery want to avoid pregnancy. For those planning or wanting conception, refer early to preconception counseling.

    - Offer family planning services in a non-coercive manner.

    - If patients are ambivalent about family planning, offer emergency contraception.

For more information, visit: https://www.guttmacher.org/united-states/contraception

Intimate Partner Violence

Unfortunately, many patients of all genders with an SUD will experience intimate partner violence (Soper, 2014). Intimate partner violence (IPV) is a violent or abusive situation occurring in the setting of power imbalance between intimate partners. Among women experiencing IPV, SUD can occur at rates two to six times higher than that of the general population (Warshaw, 2017).

TREATMENT IMPLICATIONS

- Maintain a list of local referral sources for domestic violence advocates, hotlines, and emergency shelters. Consider offering this list to all patients during intake to avoid the need for disclosure of violence.

- During the initial intake and regularly throughout treatment, screen all patients for safety with their partners.

- Particularly in the peri-partum period, consider increasing frequency of IPV screening as patients in this period are at a heightened risk for being victims of violence.

- Help support and create safety plans for individuals that report experiencing IPV.

- Evaluate for intersectional violence including drug coercion, sexual trafficking, and partner-mediated substance administration (Warshaw, 2017).

- Consider promoting autonomy in this group through education on harm reduction and strategies to use substances safely.

- Should patient report being perpetrators of IPV, have referrals for programs and counselors that specialize in treating and caring for perpetrators of IPV.

Mental Health

People with SUDs are more likely than those without SUDs to have co-occurring mental disorders (SAMHSA, 2020a). Approximately 40% of adults with substance use disorders have a co-occurring psychiatric condition independent of their substance use (SAMHSA, 2020d). At treatment entry, mood instability and anxiety are common. Substance-induced psychiatric disorders generally resolve within a few days of treatment initiation and cessation of substance use. Psychiatric symptoms that persist beyond acute use and withdrawal of substances suggest the presence of an independent mental health condition.

Psychiatric conditions most likely to co-occur with addiction include depression and anxiety disorders, bipolar disorder, posttraumatic stress disorder (PTSD), schizophrenia, attention deficit hyperactivity disorder (ADHD), and eating disorders (SAMHSA, 2020a). Care for persons with co-occurring mental health and SUDs should be person-centered, trauma-informed, culturally responsive, and recovery-oriented. These services should be continuously offered to patients.

TREATMENT IMPLICATIONS

- All patients are assessed for psychiatric disorders as a part of standard OBAT screening procedures.

- Reassure patients that the use of buprenorphine or naltrexone formulations for treatment of substance use should not be a barrier for treatment of a psychiatric condition.

- Treatment of a patient's mental health and SUD should occur concurrently. The combination of psychotherapeutic and pharmacologic management has been shown to be most effective (SAMHSA, 2020a).

- For patients engaged in psychiatry services, obtain a signed 42 CFR 42 Part 2 consent for release of information to facilitate care coordination with their mental health providers.

- For patients with anxiety and depressive disorders, first-line treatments include selective-serotonin reuptake inhibitors and psychotherapy.

- Benzodiazepines should be used cautiously with patients receiving buprenorphine/naloxone because of the potential for increased central nervous system (CNS) depression. Patient history of benzodiazepine misuse should also be explored prior to prescribing with the weighing risk/benefit and an agreed upon plan.

- If there is concern for ADHD: obtain collateral information from PDMP, and consider referral to psychiatry for diagnostic clarification. Continue stimulants if legitimately prescribed by prior prescribers.

Brain Injury and Cognitive Impairment

Approximately 5.3 million people are living with disabilities related to brain injury (BI) in the United States (CDC, 2015). Many patients with BI and/or SUD are likely to have or develop co-occurring mental illness, resulting in a trifecta of conditions that compound the challenges of treatment. Generally, the effects of BI fade over time, but the effects can be long lasting in some cases. If a patient has suffered multiple brain injuries, regardless of severity, the effects can be cumulative and therefore lead to severe brain damage. Approximately 75% of traumatic brain injuries (TBI) are categorized as mild, leading to missed diagnosis as patients can appear "normal" with vague symptoms. The effects of brain injury can be difficult to distinguish from those characteristics of psychiatric disorders, SUD, or withdrawal, particularly early in recovery. It is important to consider the type of BI, severity and location of the injury, time elapsed since injury, age of first injury, pre-injury cognitive status, rehabilitation provided (if any), and substance use history (Faul et al., 2010; Taylor et al., 2017). The risk of death from unintentional poisoning from substances is 11 times greater among patients following TBI and with co-occurring disorders than in the general population (Harrison-Felix et al., 2014). A significant percentage of patients suffer from chronic pain, further complicating treatment planning and outcomes (Corrigan and Adams, 2018).

TREATMENT IMPLICATIONS

- Screen for brain injury during an OBAT initial assessment or early on in treatment.
    - Collect an overdose history as part of the initial OBAT assessment. Consider the link between BI and non-fatal overdoses as a patient may be affected in several ways during an overdose: not enough oxygen to the brain (hypoxia), no oxygen

flow to the brain (anoxia) and/or BI sustained during the fall during the overdose event (TBI) (Corrigan & Sayko Adams, 2018).

  - The HELPS tool is a validated screener that can be used to determine whether a patient has a possible BI; a score of 3 or more indicates the presence of BI (Picard et al., 1991); *See* *Appendix 1a: HELPS Brain Injury Screening Tool*

  - If a patient scores positively with the HELPS screener, assist with referral to or consult with neurology. For moderate to severe brain injuries, neurology specialty care, neuropsychological testing, and rehabilitations programs are particularly helpful to improve daily functioning.

- Initiate medication for addiction treatment.

  - In most cases, the benefits of treating with medications for addiction treatment outweighs the risk of contributing to cognitive impairment.

  - It is best to start low and go slow with close monitoring.

- Build upon patient strengths and provide immediate positive feedback; consider incentives.

- Provide harm reduction, injury prevention, and overdose prevention counseling, which can help prevent future BI (Bartolomei-Hill et al., n.d.; Corrigan & Sayko Adams, 2018).Consider advocating for post-acute rehabilitation, especially within 3-12 months after injury, in the case of moderate to severe BI(though some patients may need lifelong services).

- Advocate for accommodations in various settings (e.g., home, groups, treatment programs, etc.) *See* *Appendix 1b: Accommodations and Compensatory Strategies for Cognitive Deficits Resulting from a Brain Injury*.

For more information on neurocognitive dysfunction and brain injury:

- National Association of State Head Injury Administrators: https://www.nashia.org/

- Brain Injury Association of America. "Non-lethal Opioid Overdose & Acquired Brain Injury". Available at: https://www.biausa.org/public-affairs/media/non-lethal-opioid-overdose-acquired-brain-injury

Adolescents and Young Adults (AYA)

The risk of OUD begins in adolescence and young adulthood, defined as the ages of 13-25. (Bagley et al., 2019). In fact, 67% of individuals in treatment for OUD report that their first use of opioids was before the age of 25, and 33% report use before the age of 18 (Hadland et al., 2017). Intervening early in the development of OUD is critical. The prefrontal cortex, responsible for impulse control, planning, and judgement, is the last part of the brain to develop; it does not fully develop until well into a person's twenties. This increase a youth's risk for

development of substance use disorder(s) and vulnerability to long-term consequences (NIDA, 2015). However only 1 in 12 adolescents or young adults (AYA) who need care for any type of addiction receive treatment (Hedden et al., 2014). In 2016, the American Academy of Pediatrics released a policy statement calling for the use of medication for addiction treatment for youth (Committee on Substance Use and Prevention, 2016).

There are three FDA-approved medications for the treatment of opioid use disorder in youth. Buprenorphine is FDA-approved for AYA 16 years of age and up, and naltrexone is approved for ages 18 and up. Methadone is FDA-approved for AYA ages 18 and up and is available to adolescents younger than age 18 with strict regulations. Federal regulations (42 CFR 8.12) allow for methadone as a treatment modality for patients under the age of 18 who have parental consent and at least two prior unsuccessful withdrawal management attempts (2020 Focused Update Guideline Committee, 2020). Methadone may also be difficult for AYA to access due to the early morning hours of methadone programs, transportation barriers, and interference with obligations such as attending school. Additionally, many methadone programs do not accept adolescents.

TREATMENT IMPLICATIONS

Adolescence and young adulthood encompass many significant social and developmental changes in an individual's lifespan. It is a transitional age at which youth develop a sense of autonomy.

- Recognize that motivation for engaging in treatment may not come fully from within. Many AYA may be encouraged to engage in treatment by concerned family members or because of criminal-legal involvement.

- Treatment on demand should be available to AYAs as motivation for treatment and recovery may fluctuate.

- Advocate for evidence-based treatment. Less than half of U.S. states do not allow adolescents to consent for their own substance use treatment; in such cases, permission must be obtained from a parent or guardian. A parent or guardian who refuses to consent to treatment that a health care professional believes is necessary for the adolescent's well-being may face charges of child neglect (SAMHSA, 1999).

- Engage support persons and caregivers whenever possible. Parents and other caregivers can be key allies in supporting an adolescent with a substance use disorder. AYAs who have an involved family tend to do better in SUD treatment than those who do not. Family members and caregivers may need their own support as well through mutual support groups or therapy.

VOCATIONAL/ PEER SUPPORT

- Provide developmentally appropriate supports for treatment. The AYA time period is a transitional period where individuals feel "in between" as they become emerging adults gaining autonomy and exploring their identity, possibilities of what they can accomplish, becoming self-focused as they become independent from parental and society driven routines (Munsey, 2006).

- Make an effort to connect AYAs to peer support groups to help meet their recovery needs and build a foundation for their development of self-identity and autonomy. AYA with SUDs may need to leave friendships with their existing peer group, which may leave them with only older adults who may not be able to help them achieve milestones that help to promote recovery capital such as employment/vocational training, education or pursuit of romantic relationships (Bagley, 2019).

MULTIDISCIPLINARY APPROACH

Research supports the effectiveness of the following treatment approaches in caring for the AYA. The treatment team should select the approach that is best suited to the patient and their family.

- Behavioral Treatment

    - The aim of behavioral treatment is to modify attitudes and actions related to substance use in AYA and assist families and caregivers to improve communication and interactions to handle stressful situations and cues, which may trigger cravings for recurrence of use. Some examples include cognitive-behavioral therapy, Adolescent Community Reinforcement Approach, and Motivational Enhancement Therapy (NIDA, 2020a).

- Family-Based Approach

    - As many AYA live with at least one parent, family-based approaches help to promote communication, reduce conflict, and address other co-occurring behavioral or learning disorders can be utilized (NIDA, 2020b).

- Recovery Support Services

    - These services help to reinforce progress, build recovery capital and provide a group setting where peers can share their experience and offer mutual support.
    - Examples include: mutual support groups (e.g., 12 step, AA, SMART recovery, etc.), recovery high schools, and recovery community centers (NIDA, 2020c).

Criminal-Legal Involved

Reasons for a person's involvement with the criminal-legal system may or may not be related to a SUD. In 2016, among incarcerated individuals in the U.S., 50% to 85% were identified as having a history of substance use disorder; of these individuals, over 80% with a diagnosis of an OUD did not receive treatment (Aronowitz and Laurent, 2016). In addition, state prisons report that alcohol was involved when the convicting crime was committed for one-third of their population. According to the Centers for Disease Control and Prevention (CDC), 75% of all federal drug offenses are related to stimulant use (2019). Studies indicate that the most common cause of incarceration is criminal activity related to the procurement of substances, rather than criminal activity due to violent or aggressive behaviors (McKetin et al., 2020).

Post-release opioid-related overdose mortality has been identified as the leading cause of death among people released from jails or prisons; in fact, rates of increased fatal overdose can be as high as 129 times that of the general population in the first two weeks following release (Binswanger et al., 2007; Joudrey et al., 2019). People who use drugs involved in the criminal-legal system are often affected by a multitude of intersectional issues including stigma, racism, poverty, trauma, mental health co-morbidities, disrupted social networks, racism, and disrupted and/or insufficient access to evidence-based addiction treatment (Joudrey et al., 2019). Each of these factors contribute involvement with the criminal-legal system—both one-time and recurrent—as well as overdose death.

Further advocacy is needed to address many of these disparities and to reduce post-release overdose deaths. To best care for patients with criminal-legal involvement, it is vital to provide care that considers the issues described above.

TREATMENT IMPLICATIONS

- Build relationships with correctional facilities, drug courts, and related systems to help support patients' access to evidence-based treatment while involved in criminal-legal settings.

- Educate and empower patients in states and criminal-legal facilities where treatment is available to inform the medical staff of their disease in order to facilitate seamless access to treatment.

- Collaborate with local correctional facilities to facilitate fast and easy access to treatment post-release.

- Whenever possible, provide treatment on demand.

- Advocate for patients involved with the criminal-legal system to access, or remain on, medication for addiction treatment. This often requires signing releases of information that comply with 42 CFR Part 2 to facilitate communication with probation/parole officers and/or courts.

- Some patients who are newly released from the correctional system may present with very low or no opioid tolerance. These patients should still be offered a range of

treatment options including medication treatment with methadone, buprenorphine, or naltrexone.

  - For those choosing agonist or partial-agonist therapy, an initiation that starts with low doses and includes graduation titration is recommended. See section on Buprenorphine/Naloxone Initiation: Opioid-Naïve Patients (pp. 38).

- To best engage patients with criminal-legal involvement, ensuring fast and easy access to treatment may greatly affect mortality and morbidity associated with release.

Older Adults and Medically Complex Patients

Over one million adults aged 65 and older have a substance use disorder, and the number of older patients with SUDs is growing as a result of several factors (NIDA, 2020d). Patients successfully engaged in treatment and long-term recovery are living longer, healthier lives. Those who were using substances and did not seek treatment previously are doing so later in life as their bodies become more vulnerable to the harmful effects of substance use or prescription medication use, due to the development of comorbidities or to the natural process of aging.

The classification of an individual as an "older adult" with substance use disorder is a controversial issue, for many patients younger than 65 years of age may have similar vulnerabilities due to the effects from substance use such as liver or kidney disease. For these individuals, we use the term "medically complex".

TREATMENT IMPLICATIONS

- Initiate or continue medications for addiction treatment with the following considerations:

  - Start low and go slow. Dose adjustments should be carefully conducted with time for the body to adjust.

  - Consider use of tools to support safe storage and administration of medications (e.g., collaboration with supportive family member, VNA, lock boxes, pill packs, etc.).

- Assess and adjust treatment regimen to account for potential polypharmacy.

  - A functional and interactive tool to assist in reviewing medications is ARMOR (Assess, Review, Minimize, Optimize, Reassess). Use of ARMOR was documented to result in a significant reduction in polypharmacy in a long-term care facility (Haque, 2009). The ARMOR is available here: https://www.cse.msu.edu/~cse435/Handouts/EMR/Polypharmacy-ARMOR.pdf

- Evaluate cognitive function.

  - If available, consider a referral for neuropsychological testing for severely cognitively impaired patients.

- Consider oral swabs for monitoring. Urine toxicology screening for patients who are homebound or with end-stage renal disease can be challenging.

- Ensure that behavioral health and pain management needs are met. Include consideration of the challenges related to social isolation and regular assessment of suicide risk.

- Provide safety and injury prevention counseling (including harm reduction and overdose prevention).

- Advocate for accommodations in various settings (e.g., home, groups, treatment programs, etc.)

- If a patient requires placement at a skilled nursing facility or long-term care facility, make sure to collaborate closely with care teams.

For more information on neurocognitive dysfunction and brain injury:

- National Institute on Aging: Assessing Cognitive Impairment in Older Patients: https://www.nia.nih.gov/health/assessing-cognitive-impairment-older-patients

- NIDA's Drug Facts: Substance Use in Older Adults: https://www.drugabuse.gov/sites/default/files/df-subabuse-older-adults.pdf.

Persons Experiencing Homelessness

Persons struggling with both an SUD and homelessness are a particularly vulnerable population with complex needs. The intersection of these two conditions is increasingly common, with up to two thirds of those experiencing homelessness having a lifetime history of SUD (Polcin, 2016). Adapting clinical practices when caring for people who both have an SUD and are experiencing homelessness can strengthen the therapeutic relationship. In addition to substance use, other contributors of homelessness include physical and mental health problems, trauma, unemployment, lack of affordable housing, lack of affordable healthcare, incarceration, and eviction (National Alliance to End Homelessness, 2020). Minority groups, including Black and Indigenous people, are disproportionately impacted by homelessness (US Department of Housing and Urban Development, 2020).

In addition to homelessness, patients may encounter complications related to their housing instability. These include lack of a safe and clean place to recover after an illness, chronic pain, fragmented care, functional impairments, traumatic brain injuries, chronic stress, lack of adequate sleep, loss of child custody, lack of transportation, lack of social supports, and the criminalization of homelessness (Meges et al., 2014).

TREATMENT IMPLICATIONS

- When gathering a patient's history, asses for living conditions, prior homelessness, nutrition and hydration, history of trauma, mental health, and legal problems.

- In addition to assessing for physical signs of substance use, assess for signs and symptoms of skin and soft tissue infections.

- Screen for sexually transmitted infections including syphilis, HBV, HAV, HCV, HIV, and tuberculosis. Administer appropriate vaccinations.

- Offering flexible office hours, drop-in appointments, multiple points of service, and a multidisciplinary team allows for a comprehensive model of care (Meges et al., 2014). Use of non-conventional treatment models, such as mobile health vans or street outreach, allows for engagement of patients who may not access a traditional clinic setting.

- Patients experiencing homelessness should be offered medication treatment for their substance use. A simple medication regimen—a low pill count, once-daily dosing, or longer-acting formulations—works best in terms of promoting treatment adherence and maintaining a safe supply of medication and should therefore be utilized when possible.

- If a patient is staying in a shelter or on the streets, consider where and how they will store their medications safely. Prescriptions with a smaller supply may decrease the risk of loss or theft, particularly for medications with a risk of diversion. Consider cost of co-pays when providing patients with smaller prescriptions, and work with payers to waive co-pays in an effort to support medication safety.

- Harm reduction strategies, case management, directly observed therapy, and contingency management can increase medication adherence (Meges et al., 2014).

- Identifying basic survival needs, addressing co-morbidities, and treating patients holistically can improve the care outcomes and engagement with this population (Meges et al., 2014). Utilize integrated case management services and advocacy.

- Treat patients with empathy and respect in a welcoming, supportive, and nonjudgmental environment. Utilize team-based care and leverage all members in supporting the multiple needs of the patient.

Persons with Concurrent Pain

Addressing both acute and chronic pain in patients with SUDs is complex, as the experience of pain is largely subjective, often cannot be visualized, and is commonly co-morbid with psychiatric disorders. More specifically, in patients with opioid use disorder, analgesic requirements are typically greater due to increased pain sensitivity and opioid cross tolerance (Martin, 1965; Ho & Dole 1979; Compton 1994, 2001; Meyer, 2007; Peng, 2005; Alford, 2006).

Additionally, many barriers to adequate pain management exist including: stigma leading to disparities in access, a lack of decision support for chronic pain management, financial pressures favoring the use of medications, and inadequate support for team-based care (Institute of Medicine, 2011). Patients physically dependent on opioids, including buprenorphine, require maintenance of daily opioid equivalence before any pain relief is achieved with opioid analgesics (the "opioid debt"). Moreover, opioid agonist treatment at maintenance doses for the treatment of OUD does not provide analgesia. Recommendations for patients on opioid agonist treatment for OUD who have concurrent pain are generally to remain on their maintenance medication and receive supplemental analgesic therapy.

TREATMENT IMPLICATIONS

- Reassure patients that their substance use disorder will not be an obstacle to pain management.
- Include patients in the decision-making process.
- Establish clear goals for pain management such as: pain reduction rather than elimination and improved functioning.
- Utilize practical, evidence-based tools to assess pain such as the PEG Scale. *See Appendix 2: PEG Scale*

BUPRENORPHINE: ACUTE AND CHRONIC PAIN MANAGEMENT

Maintaining buprenorphine has been shown to increase pain control while allowing a person to remain stabilized on their medication treatment for OUD (Lembke et al., 2019). However, adequate pain control may require higher opioid doses at shorter dosing intervals.

- Support, reassure, implement shared decision-making, communicate and set clear expectations.
- Use a multimodal approach to pain management:
    - Consider splitting the patient's usual buprenorphine/naloxone dose into six to eight-hour dosing intervals (e.g., 24 mg per day changed to 8 mg every 8 hours).
    - Consider a modest increase in patient's buprenorphine/naloxone maintenance dose (e.g., increase from 16 mg per day to 24 mg per day).
    - Try non-opioids and adjuvant therapies. Examples include acupuncture, acupressure, massage, physical therapy, hydrotherapy, mindful meditation, NSAIDs, acetaminophen, topical lidocaine, SSRIs, TCAs, etc.
- If multimodal therapies do not effectively reduce pain, opioid analgesics are an option.

- If opioids are needed during the acute pain process, consider short-acting formulations while continuing MOUD. Anticipate higher than typical dosing due to opioid cross-tolerance and increased pain sensitivity. Follow patients closely during this time.

- If ongoing opioid analgesics are necessary for treatment of chronic pain, the patient may benefit from buprenorphine discontinuation and transfer to methadone maintenance. Ongoing full agonist therapy while on buprenorphine for MOUD is a contraindication to buprenorphine maintenance.

PERI-OPERATIVE MANAGEMENT FOR PATIENTS TAKING BUPRENORPHINE

The appropriate treatment of acute pain in patients on buprenorphine or methadone maintenance includes continuing the patient's baseline opioid requirements to avoid increased pain sensitivity associated with opioid withdrawal (BMC, 2017). All patients on buprenorphine maintenance should be co-managed with procedural team and their buprenorphine provider during the pre- and post-procedure period.

PERIOPERATIVE TREATMENT IMPLICATIONS FOR PATIENTS TAKING BUPRENORPHINE

- Collaboration between the buprenorphine provider/OBAT team and surgical team is strongly recommended to ensure ongoing assessment, support, pain management, and SUD care.

- Efforts should be made to ensure that the patient's maintenance buprenorphine regimen should remain uninterrupted throughout the peri-operative period.

- For patients prescribed transmucosal formulations, consider splitting their usual buprenorphine dose into an eight-hour dosing interval (e.g., 24 mg per day changed to 8 mg every 8 hours).

- As indicated, utilize multimodal pain management with non-opioids (NSAIDs, acetaminophen, lidocaine patches, etc.). Consider the use of local and regional anesthesia as indicated.

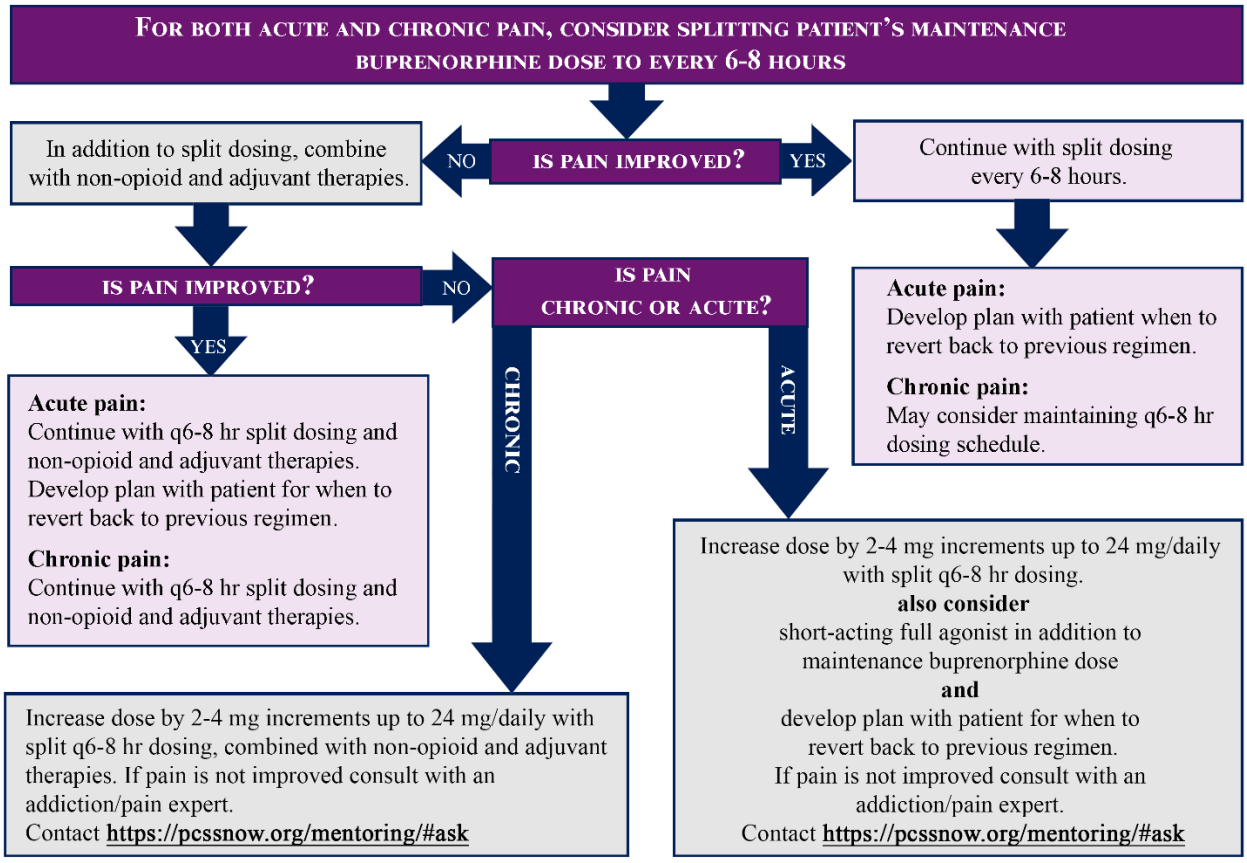
- If opioids are needed for breakthrough pain, standard dosing protocols should initially be utilized with careful monitoring and consideration of higher dosing requirements.

- The OBAT team should follow closely with patients during the immediate post-operative time period (i.e., the patient should be scheduled to see their buprenorphine prescriber within one week after the procedure).

- For further guidance, see Boston Medical Center's clinical guidelines for managing patients maintained on buprenorphine products undergoing invasive procedures. *Appendix 3: Perioperative Management of Non-Pregnant Patients on Maintenance Therapy for Opioid Dependence*. These guidelines were created using expert opinions

and pharmacological principles with the intent to avoid under-treatment of acute pain while also avoiding opioid withdrawal and disruption of opioid use disorder treatment.

Algorithm: Pain Management While on Buprenorphine for Opioid Use Disorder



Naltrexone: Acute and Chronic Pain Management

It should be highlighted that chronic pain necessitating ongoing opioid medication(s) is a contraindication for naltrexone treatment, and therefore be evaluated as part of the OBAT screening process. For patients seeking medication treatment for an opioid use disorder, who also have severe chronic pain, agonist medications should be considered including buprenorphine or methadone maintenance therapy.

- Support, reassure, implement shared decision-making, and establish clear and realistic goals for pain management.

- Use a multimodal approach to pain management:

- Try non-opioids and adjuvant therapies. Examples include acupuncture, acupressure, massage, physical therapy, hydrotherapy, mindful meditation, NSAIDs, acetaminophen, topical treatments, SSRIs, TCAs, etc.

- If multimodal therapies do not effectively reduce pain, discuss with patient transfer to agonist therapy: methadone or buprenorphine.

PERIOPERATIVE TREATMENT IMPLICATIONS FOR PATIENTS TAKING NALTREXONE

- Collaboration between the OBAT team and surgical team is strongly recommended to ensure ongoing assessment, support, pain management, and SUD care.

- Discontinue injectable naltrexone at least 4 weeks prior to scheduled surgery. May bridge with oral naltrexone. Oral naltrexone should be discontinued 72 hours prior to surgery.

- Use a multimodal approach to pain management with non-opioid medications and adjuvant therapies. Examples include: NSAIDs, acetaminophen, topical lidocaine, epidural/spinal analgesia, nerve blocks, etc.

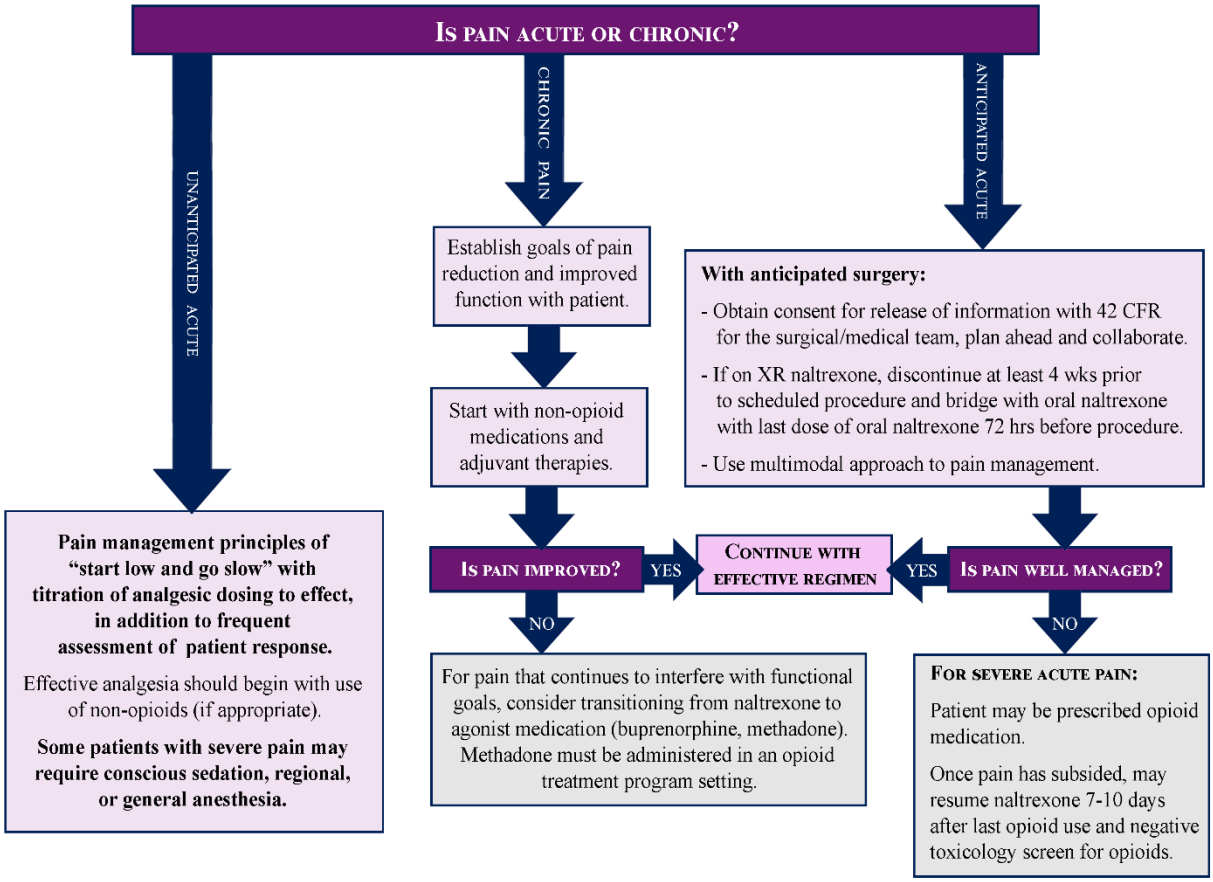
- If surgery is performed emergently or naltrexone was not discontinued prior to surgery, naltrexone should be discontinued post-operatively. If this occurs, higher than usual doses of opioids may be attempted to overcome naltrexone's opioid antagonist effects. This must be done with close observation for respiratory depression.

- Irrespective of the drug chosen to reverse naltrexone blockade, the patient should be monitored closely by appropriately trained personnel in a setting equipped and staffed for cardiopulmonary resuscitation.

- The OBAT team should follow closely with patients during the immediate post-operative time period (i.e., the patient should be scheduled to see their naltrexone prescriber within one week after the procedure).

- For further guidance, see Boston Medical Center's clinical guidelines for managing patients maintained on buprenorphine products undergoing invasive procedures. *Appendix 3: Perioperative Management of Non-Pregnant Patients on Maintenance Therapy for Opioid Dependence*. These guidelines were created using expert opinions and pharmacological principles with the intent to avoid under-treatment of acute pain while also avoiding disruption of opioid use disorder treatment.

ALGORITHM: PAIN MANAGEMENT WHILE ON NALTREXONE FOR OPIOID USE DISORDER



For more information on complex pain management:

- SCOPE of Pain: https://www.scopeofpain.org/
- CDC Guideline for Prescribing Opioids for Chronic Pain: https://www.cdc.gov/drugoverdose/prescribing/guideline.html

EVALUATING AND REVISING THE TREATMENT PLAN

Evaluating and Supporting Long-Term Recovery

As the Nurse Care Manager Model follows a harm reduction model of care, automatic discharge for patients who struggle with continued or recurrent substance use while engaged in medication treatment for addiction is not recommended. Treatment should be evaluated in a way that is supportive of both short- and long-term recovery goals. Monitoring and evaluation are meant to:

- Assess the treatment effectiveness
- Identify and reduce threats to progress
- Encourage self-monitoring
- Facilitate conversation between the care team and patient.

REEVALUATING THE TREATMENT PLAN

In the case of a recurrence and/or concerning medication management, review of the treatment plan(s) is recommended to optimize the benefits of medication, enhance behavioral therapies, and increase recovery supports. This is best accomplished in collaboration between the care team and patient to identify appropriate strategies to intensify treatment.

Revision of the treatment plan may include:

- More frequent visits/check-ins
- Clinical team meeting with patient dose adjustments
- Shortened prescription intervals
- Deferred refills
- Confirmation of counseling and/or team engagement with counselor
- Referral to groups or individual therapy
- Download recovery/support applications on phone if available
- Safety plan and ensure naloxone access
- Referral to intensive outpatient program (IOP) or partial hospitalization program (PHP)
- Residential treatment
- Psychiatric evaluation and treatment per psychiatric assessment

- Referral to community agencies and providers to meet psychosocial needs (e.g., local or state agencies providing services for families, children, and/or older adults)
- Increased collaboration with community providers
- Increased collaboration within the OBAT team among nursing, recovery support persons, providers, and behavioral health colleagues
- Increased engagement with the justice system or law enforcement
- Family/support involvement

PATIENTS PRESENTING IMPAIRED

Any patient who presents to the clinic impaired or intoxicated would benefit from urgent team evaluation, including a safety assessment, along with revisions of their treatment plan. Education and counseling to prevent serious risk of harm to self and others, including injury, illness, and suicidal or homicidal ideation, may be warranted. Of note, situations may arise that require mandated reporting (e.g., concern for the safety of a dependent in the patient's care). Refer to your institutional policies regarding safety concerns and mandated reporting.

CONCERNS FOR DIVERSION

In cases of suspected diversion (e.g., urine toxicology screening negative for buprenorphine, requests for early refills, frequent reports of lost/stolen/destroyed medication, reports from law enforcement that medication was sold or diverted), the OBAT team can request that the patient return to the clinic for an assessment as soon as possible. Recommendations for assessment include a frank discussion of concerns with the patient, toxicology screening, and a medication count. When possible, confirmatory testing (e.g., via GC/MS) would further characterize buprenorphine and its metabolite norbuprenorphine (ASAM Expert Panel and Quality Improvement Council, 2017). High levels of buprenorphine (> 700 ng/mL) coupled with low (or absent) levels of norbuprenorphine may indicate that the patient has tampered with the sample. Interpretation of GC/MS results can be nuanced, so review results with a local laboratory contact if needed.

Any patient known to be diverting buprenorphine will be evaluated by the care team to discuss appropriate next steps. If the patient is being considered for discharge from the OBAT program, efforts should be made to seamlessly transition to another level of care.

REFERRAL TO ANOTHER LEVEL OF CARE

If recurrence or ongoing use occurs, the treatment plan should be reviewed to increase monitoring and supports. In the case of continued use despite an intensified treatment plan *and* when the risk of continuing treatment outweighs the benefit, a patient may benefit from referral to a different level of care.

Clinicians should always carefully weigh the risk of discontinuation medication against the benefit of continuing treatment in an office-based setting prior to referring to another level of

care. Availability and accessibility to a more appropriate level of treatment must also be considered. Treatment termination without a connection to another level of care is rarely, if ever, advised.

Additional levels of care may be more structured, such as a methadone maintenance program, IOP or PHP, residential treatment, or an inpatient treatment setting. Referrals may also be to community programs such as a syringe service program, peer support program, or an engagement center.

To ensure a safe transfer of services, patients should be either physically or remotely connected to the receiving program whenever possible. Examples of this include:

- OBAT NCM calls local methadone clinic with patient and establishes an intake appointment
- Recovery support person walks patient over to the local syringe service program
- Staff from the receiving program join a teleconference call with the patient and OBAT team.

Patients who are referred to a different level of care should always be offered the opportunity to re-engage with OBAT in the future.

Harm Reduction

Harm Reduction is a philosophy and set of strategies that seeks to engage patients where they are at and keep them safe while actively using substances. The following are specific harm reduction strategies to consider for patients who continue to engage in active substance use.

CORE OBAT HARM REDUCTION RECOMMENDATIONS

- Encourage patients to never use substances when physically alone.
- Encourage patients not to lock doors when using substances, as this can prevent or delay access in the event of an emergency.
- In the event that a patient may use alone, recommend services that monitor use (e.g., www.neverusealone.com) or encourage patients to phone a support person prior to injection.
- Educate patients about the importance for testing substance potency prior to administering full dose of a substance (e.g., "warm" or "tester" shots).
- Encourage patients to use new/sterile equipment for every substance administration.
- Ensure access to naloxone.

- Recognize patient engagement and treatment retention as a primary goal of OBAT treatment. This includes acknowledging alterative goals to treatment aside from total abstinence of illicit substance use.

- Become familiar with local agencies that are able to provide harm reduction materials and supplies to current OBAT patients.

- Encourage warm hand-offs between all levels of care.

- Establish relationships and communication with other recovery-oriented agencies in your local area.

SAFER INJECTION RECOMMENDATIONS

- Emphasize the importance of hygiene such as hand washing and skin preparation prior to injection.

- Safe injection supplies may include needles/syringes, cookers, cottons/filters, tourniquets, alcohol pads, triple antibiotic ointment, and sterile water.

- Encourage patients to use new equipment for every injection.

- In areas with limited access to syringes, consider patient education about strategies to bleach needles prior to reuse.

- Review safer injection sites with the patient.

- Review sterile injection techniques with patients.

- If injecting crack cocaine, consider safer acids for dissolving the substance, such as vitamin C, to reduce the base prior to injection.

- Educate the patient on safer supplies of water if sterile water is unavailable.

SAFER SMOKING AND INSUFFLATION RECOMMENDATIONS

- Educate patients on the risks of sharing glass pipes with others.

- Educate on the use of pipe holders to prevent burning lips and keeping lips and nares moist and free of cracks.

- Educate patients on the risks of open flames.

- Educate patients on the risks of sharing snorting equipment and encourage patients to use their own materials.

- Educate patients about toxic drug supplies.

- Teach overdose prevention and reversal.

NALOXONE

Naloxone is a potent and fast-acting μ-opioid receptor antagonist. Naloxone acts as an opioid overdose reversal agent by displacing substances like heroin, fentanyl, morphine, and oxycodone from the receptor sites within 3-5 minutes of administration. Naloxone is most commonly administered as an intranasal spray (4 mg/actuation dose), but it can also be administered subcutaneously or intravenously.

Individuals at a particularly increased risk for fatal overdose include persons who have a history of previous overdose, are using opioids alone, return to use following a period of abstinence (e.g., recent incarceration or recovery period), experience a sudden change in opioid tolerance, engage in polysubstance use (especially with central nervous system depressants), and/or who have co-morbid medical conditions.

- All patients at risk for opioid overdose should be prescribed and/or provided with naloxone and educated on how and when to use this medication at the initial OBAT visit. The risk of overdose and the need for naloxone should be reassessed at each subsequent encounter.

- Due to the importance of naloxone being readily accessible, providers may consider dispensing multiple naloxone intranasal delivery systems (e.g., dispense 4) and indicate a large number of refills on their prescription (e.g., refills 99).

OVERDOSE PREVENTION AND REVERSAL EDUCATION

- Important components of overdose education should include opioid overdose recognition. Common signs and symptoms of an opioid overdose are: cyanosis (blue lips and/or finger tips); small pupils; pale skin; shallow, labored, or absent breathing; slowed heartbeat or low blood pressure; and non-responsiveness to voice or sternal rub.

- All patients and any involved support persons should receive education from the OBAT provider or NCM about how to identify an overdose and effectively administer nasal naloxone.

- Patients should receive specific education regarding interventions to prevent an overdose such as never using alone, avoiding polypharmacy, testing the potency of substances, and the importance of having naloxone readily available.

- Whenever possible, family members and other support persons should also receive overdose prevention education. Education for support persons should include tips on how to recognize and reverse an overdose via naloxone administration.

- Individuals should be educated that while naloxone can quickly reverse the symptoms of an overdose, its effects are only temporary, so it is critical for the individual who received naloxone to obtain medical assessment and intervention immediately (i.e., call 911 and/or go to an emergency department setting).

- Naloxone only reverses substances at the μ-opioid receptor, so it will not reverse the effects of patients who overuse other central nervous system depressants such as alcohol, benzodiazepines, or barbiturates. Additionally, naloxone will not reverse the effects of stimulants like cocaine or methamphetamines. Again, the emergency medical services system should be activated any time an overdose is suspected.

- Most importantly, patients can prevent opioid overdose by starting medication for addiction treatment, specifically buprenorphine or methadone.

For more information on safer consumption strategies, overdose prevention, advocacy, and tools for patient education:

National Harm Reduction Coalition: https://harmreduction.org/

Drug Policy Alliance: https://drugpolicy.org/issues/harm-reduction

Never Use Alone: https://neverusealone.com/

Polysubstance Use

A patient's self-report of substance use or a positive toxicology result should be addressed with the patient as soon as possible by the OBAT team. The treatment plan should be intensified accordingly to meet the needs of the patient as outlined above.

If there is significant concern for acute intoxication and/or the need to manage withdrawal from alcohol, benzodiazepines, or other substances, the patient may warrant a safety assessment that includes transportation evaluation, considerations for care of any dependents, and connection to another level of care (e.g., in-patient withdrawal management followed by reconnection to OBAT care).

Many of the substances listed below may be used by patients who have co-occurring mental illness to manage their symptoms. Concurrent treatment will improve treatment outcomes, so treatment or referral to psychiatry should be initiated as soon as possible. See pp. 66 for more information on mental illness and co-occurring disorders.

In many parts of the US, illicit substances available to patients have been found to be adulterated with fentanyl (e.g., manufactured pills, various forms of cocaine). Counsel patients on harm reduction strategies to ensure safety.

Ongoing use of substances, despite the intensification of the treatment plan, may benefit from a referral to a different level of care. Care teams should always carefully weigh the risks and benefits of continuing treatment in an office-based setting prior to referring to another level of care. Patients should always be offered the opportunity to re-engage in care with OBAT in the

future, should they and care team agree that treatment in a different setting would be both beneficial and appropriate.

STIMULANTS: COCAINE/AMPHETAMINES/METHAMPHETAMINES

- There are no FDA-approved medications available for the treatment of stimulant use disorders at the time of this publication.

- Confirmation of prescribed, reported, or unreported medications can be completed by utilizing the PDMP in your state.

- Withdrawal from crystal methamphetamine can be acute (0-10 days), sub-acute (10-21 days), and protracted (21 days – 12 months). Strategies for managing these symptoms include increasing patient safety, regulating sleep, decreasing psychotic symptoms, and normalizing disrupted brain changes (Clark & Featherstone, 2019). Consider a referral to a program with contingency management combined with psychosocial support (e.g., CBT, counseling). This has been shown to be an effective strategy for decreasing stimulant misuse and should be considered when possible (McPherson et al., 2018).

BENZODIAZEPINES

- While the use of benzodiazepines is not currently a contraindication for treatment of opioid use disorder with buprenorphine, providers should attempt to manage anxiety with medications that have less misuse potential (Martin et al., 2018).

- Confirmation of prescribed, reported, or unreported medications can be completed utilizing the PDMP in your state.

- Counsel patients on the additive CNS depressive effects of benzodiazepine withdrawal in addition to the increased risk of overdose with the concurrent use of benzodiazepines and buprenorphine.

- Due to the increased risk of overdose, close monitoring of patients who concurrently use benzodiazepines and buprenorphine is imperative, even when both are provided via prescription.

ALCOHOL

- Encourage self-report of alcohol use. Consider monitoring patients with concerning alcohol use or co-morbid alcohol use disorder with intermittent breathalyzer or urine ethyl glucuronide (EtG) testing.

- Counsel patients about the recommended dietary guidelines for alcohol consumption, which includes two alcoholic drinks or fewer in a day for men or one alcoholic drink or fewer in a day for women (U.S. Department of Agriculture and U.S. Department of Health and Human Services, 2020). More detailed guidance is available here: https://www.cdc.gov/alcohol/fact-sheets/moderate-drinking.htm

- Recall that naltrexone is a first-line medication for the treatment of alcohol use disorder and may be utilized in patients with co-occurring OUD as long as the patient is abstinent from opioids. These patients benefit from closer OBAT monitoring and support.

- FDA-approved medications for treatment of alcohol use disorder, such as acamprosate or disulfiram, may be prescribed concurrently with buprenorphine formulations in cases of co-occurring OUD and AUD.
    - If a patient is being treated with buprenorphine, they cannot be treated with any naltrexone formulation for their alcohol use disorder. Naltrexone will precipitate withdrawal from buprenorphine.

- Counsel patients about how the additive CNS depressive effects occurring with the combined use of alcohol and buprenorphine can increase the risk of overdose.

- Counsel patients on the risk of injury and serious physical harm related to alcohol use.

- Consider assessing for hepatic function more frequently in patients with ongoing or risky alcohol use and supporting hepatic health by prescribing vitamins such as thiamine, folic acid, and B12.

CANNABIS/SYNTHETIC CANNABINOIDS

- Cannabinoid use may be reported via self-report or toxicology screening and may have consequences for patients enrolled in or working with highly regulated settings or agencies. Refer to federal, state, and institutional policies for guidance on monitoring.

- Consider that a positive result for cannabis on a urine toxicology screen may remain positive for approximately four weeks.

- There are no FDA-approved medications available for the treatment of cannabis/synthetic cannabinoid use disorders at the time of publication.

- Recommend behavioral treatments that have shown efficacy including CBT and contingency management (NIDA, 2021).

GABAPENTIN

Gabapentin is an anti-epileptic and analgesic medication that has the ability to potentiate opioid effects and has an increased risk of misuse and diversion (Smith et al., 2016).

- It is particularly important to screen for and encourage self-report of gabapentin use, for this substance is not typically included in standard toxicology screening panels.

- Monitor patients for acute withdrawal symptoms, which can occur within 12-48 hours of last use and include agitation, confusion or disorientation, diaphoresis, and GI discomfort. Consider a gradual outpatient taper or inpatient supervised withdrawal; rapid withdrawal can lead to seizures (Mersfelder & Nichols, 2016).

- Counsel patients on the additive CNS depressive effects on the central nervous system which can contribute to overdose.

KRATOM

Kratom is an herbal supplement with opioid-like activity that is becoming more pervasive in use and is highly addictive. At low doses, it acts as a stimulant; at higher doses, it has been reported to reduce pain and induce euphoria. Kratom is not FDA regulated and is widely available. (NIDA 2019; Singh et al., 2014).

- Limited studies exist on treatment options for Kratom. There have been a few case studies on the use of buprenorphine in patients who have a concurrent opioid use disorder showing successful treatment (Khazeli et al., 2018).

- Screen for and encourage self-report of Kratom use, for this substance is not included in standard toxicology screening panels.

NICOTINE/TOBACCO

Smoking rates are five times higher in individuals with OUD compared to the general population (Weinberger et al., 2018). While many treatment programs focus on illicit and immediately harmful substance use, evidence has found that providing tobacco cessation interventions during substance use disorder treatment can be successful in achieving tobacco cessation (Apollonio, Philipps, & Bero, 2016). Additionally, it has been found that cessation of cigarette use may be associated with improved recovery from illicit substance use (Thurgood et al., 2016).

- Assess for all forms of nicotine use, including smoke (i.e., cigarettes and cigars), vapor (i.e., e-cigarettes) and smokeless (e.g., chew or dip) use.

- Recommend reduction and/or cessation of nicotine and/or tobacco use. A variety of patient-centered tools and strategies to assist with smoking cessation use may be found at: https://smokefree.gov/.

- Consider FDA-approved medications available for the treatment of nicotine use disorders such as nicotine replacement therapies, varenicline, and buproprion (Prochaska & Benowitz, 2016).

- Offer incentives for successful reduction or cessation of use (Prochaska & Benowitz, 2016).

- Recommend peer networks, text-messaging, or web-based support for those with access as these strategies have been shown to be effective in some populations (Prochaska & Benowitz, 2016).

OTHER CONSIDERATIONS: SEROTONIN SYNDROME/TOXICITY

Serotonin syndrome or toxicity is relatively rare but can occur in patients who have multiple medications that can lead to toxic levels of serotonin (Talton, 2020). Medications commonly

involved include antidepressants, opioids, cold remedies, atypical antipsychotics and antibiotics/antifungals.

Symptoms range in severity and include:

- Mild symptoms: tremors, restlessness, headaches, nausea and diarrhea, clonus of lower extremities
- Moderate symptoms: diaphoresis, hyperreflexia, clonus, myoclonus, ocular clonus, rigors, diaphoresis, tachycardia, dyspnea, dilated pupils
- Severe symptoms: hyperthermia (> 101.3 °F), hyper/hypotension, sustained clonus, confusion, delirium, tonic-clonic seizures, respiratory depression, rhabdomyolysis

Mild symptoms should prompt a medication review by the OBAT provider and medical team, with treatment adjustments implemented as necessary. Moderate to severe symptoms require urgent evaluation through an acute care setting such as an emergency department.

Treatment Duration

A substance use disorder is a chronic and complex condition; therefore, enforcing a predefined treatment duration is not recommended. Some patients may choose to discontinue medication for addiction treatment. These patients may continue to be supported by the OBAT team and receive assistance with their recovery in terms of ongoing support and monitoring. They should also be encouraged to continue building recovery capital through self-care, psychosocial therapies, and mutual-help groups.

BUPRENORPHINE DISCONTINUATION

With patients discontinuing buprenorphine, as part of any taper process, patients will receive assistance with dose decreases and management of withdrawal symptoms. The taper duration is individualized to the patient and should be continually adjusted to meet the patient's needs.

- Common withdrawal symptoms during a buprenorphine taper include restless legs, insomnia, anxiety, abdominal distress, and autonomic signs (e.g., lacrimation, rhinorrhea, tremors, chills, gooseflesh).

- Protracted abstinence syndrome can occur and persist for several months following discontinuation of buprenorphine. It is important to recognize this phenomenon and respond to these withdrawal symptoms such as sleep disturbance, anxiety, and irritability.

- Upon abrupt buprenorphine discontinuation of transmucosal formulations, withdrawal syndrome may occur. Subjective withdrawal symptoms typically begin within the first three days and begin to subside within seven to ten days.

- If injectable buprenorphine (Sublocade®) is discontinued, its extended-release qualities should be considered, and the patient should be monitored for several months for signs and symptoms of withdrawal and treated appropriately.

- Clonidine, anxiolytics (including benzodiazepines), and NSAIDs may be used to manage distressing withdrawal symptoms and continued during induction if prescribed by provider and closely monitored.

NALTREXONE DISCONTINUATION

There is no withdrawal syndrome associated with naltrexone discontinuation. Patients discontinuing naltrexone treatment may continue to be supported by the OBAT team and receive assistance with their recovery in terms of monitoring and clinical management.

Some patients may stop naltrexone due to side effects or adverse reactions. In this case, alternative treatment strategies should be discussed (e.g., psychotherapy, peer support, OBAT NCM support, provider visits, buprenorphine or methadone for those with OUD, and/or acamprosate or disulfiram for those with AUD).

Initial Screening Note

Demographic Info

How did you hear about the clinic?

☐ 1 = Spouse/partner ☐ 2 = Friend ☐ 3 = Healthcare Provider
☐ 4 = Flyer ☐ 5 = Parent/guardian ☐ 6 = Hotline
☐ 7 = Treatment Locator ☐ 8 = Other: _____

What is your preferred name and pronouns? (e.g., he/him/his, she/her/hers, they/their/theirs): _____

Are you currently pregnant?

☐ 1 = Yes
☐ 2 = No
☐ 3 = Don't Know
☐ 4 =Other_____

Current Address_____
Address confirmed/updated within the EMR to be correct ☐

Phone Number _____Is it OK to leave a message? ☐ 1= Yes ☐ 2 =No

Alternative Contact Information: _____ Is it OK to leave a message? ☐ 1= Yes
☐ 2 =No

Emergency Contact _____ Phone Number _____

Is the Emergency Contact aware of your addiction? ☐ 1= Yes ☐ 2 = No

Do you have a valid form of government issued identification? ☐ 1 = Yes ☐ 2 = No

Transportation

How would you get to the OBAT program if you needed to get here?
☐ 1 = I would drive
☐ 2 = I would use public transportation
☐ 3 = I would use a ride share/taxi
☐ 4 = I would walk
☐ 5 = I would get a ride from a family/friend

☐ 6 = I would use medical transportation
☐ 7 = I would need a PT1
☐ 8 = Other _____
☐ 9 = Unable to travel to clinic. Explain: _____

Housing

Have you spent one or more weeks on the street or in a shelter in the last three months?
☐ 1=Yes ☐ 2=No

What type of place are you living in now?
☐ 1 = In a house or apartment I own or rent
☐ 3 = In a house or apartment owned or rented by family or friends
☐ 4 = Hotel
☐ 5 = Alcohol or substance use treatment program
☐ 6 = Shelter
☐ 7 = Street or car
☐ 8 = Sober Home
☐ 9 = Other: _____
☐ 10 = Prefer not to say

Who do you live with at this time?
☐ 1 = I live alone.
☐ 2 = I live with my partner/significant other.
☐ 3 = I live with family members.
☐ 4 = I live with friends/acquaintances.
☐ 5 = Other: _____

Substance Use History

	Age of Initiation	*Date of Most Recent Use*	*Frequency*	*Route of administration*	*Amounts Used*	*Currently Using?*
Opioid ***__Heroin*** ***__Fentanyl*** ***__Oxycodone product*** ***__Buprenorphine*** ***__Methadone*** ***__Other opioid***						
Benzodiazepine						
Alcohol						
Cocaine (including crack cocaine)						
Amphetamines (including methamphetamine)						
Tobacco/nicotine ***Vaping***						
Cannabis						
Other (e.g., Kratom, K2, synthetic cannabinoid, PCP)						

Have you ever shared injection or other substance use supplies? ☐ 1= Yes ☐ 2 = No

Have you ever belonged to a syringe service program? ☐ 1= Yes ☐ 2 = No

Do you have access to clean/new injection supplies? ☐ 1= Yes ☐ 2 = No

Do you have naloxone? ☐ 1= Yes ☐ 2 = No

Are you willing to carry naloxone? ☐ 1= Yes ☐ 2 = No

Have you ever overdosed? ☐ 1= Yes ☐ 2 = No

Number of lifetime overdoses: _____

Was naloxone administered? ☐ 1= Yes ☐ 2 = No

Have you ever been hospitalized due to an overdose? ☐ 1= Yes ☐ 2 = No

Recovery History

What was the longest period of time that you have been in recovery?

_____

When was this? _____

What were you doing at that time for your recovery?

_____

Addiction Treatment History

Have you ever engaged in treatment for a substance use disorder? ☐ 1= Yes ☐ 2 = No

If yes, how many times to each type?

_____ Detoxification Program
_____ Methadone Maintenance
_____ Buprenorphine Maintenance
_____ Naltrexone (oral or injectable)
_____ Injectable Buprenorphine (Sublocade® or Brixadi®)
_____ Residential (e.g., Halfway House)
_____ Section to Treatment
_____ Intensive Outpatient Program
_____ MOUD while incarcerated

Do you attend peer support meetings? (Check all that apply)

☐ 1= AA
☐ 2= NA
☐ 3= Smart Recovery
☐ 4= Other: _____
☐ 5 = None

How many meetings do you attend each week?
☐ 1 = 1-2 week
☐ 2 = 3-4 week
☐ 3 = 5-6 week
☐ 4 = None
☐ 5 = Other: _____

Do you have a sponsor? ☐ 1= Yes ☐ 2 = No

Do you have any history of a process addiction?
☐ 1 = Gambling
☐ 2 = Sex
☐ 3 = Shopping
☐ 4 = Eating disorder (over eating, bulimia, anorexia)
☐ 5 = Other: _____
☐ 6 = No

Comments: _____

Treatment History

Have you ever engaged in a Methadone Maintenance program? ☐ 1= Yes ☐ 2 = No

Where and when did you engage in Methadone Maintenance?

_____

How long were you on Methadone Maintenance? _____

What was your dose? _____

Did you ever earn take-homes? ☐ **1= Yes** ☐ **2 = No**

If you are no longer on methadone treatment, why did you stop?

_____

If currently engaged in methadone treatment, who is the primary contact person?

_____

Are you willing to sign a consent for release of information so that we can communicate with your opioid treatment program about your treatment plan?
☐ 1=Yes ☐ 2=No

Buprenorphine History

Have you ever been prescribed buprenorphine before?
☐ 1= Yes ☐ 2 = No
If yes:

Where and when you prescribed buprenorphine? _____

What was your dose? _____

Did you ever receive an extended-release buprenorphine injection? If yes, please provide details:

_____

Why did you stop taking buprenorphine? _____

Naltrexone History

Have you ever been prescribed naltrexone before?
☐ 1= Yes ☐ 2 = No

If yes:

Where and prescribed naltrexone: _____

Did you ever receive an extended-release naltrexone injection? If yes, please provide details:

_____

Why did you stop naltrexone treatment? _____

Mental Health History

Are you currently seeing a psychiatrist, psychologist, or counselor for a mental health condition?
☐ 1=Yes ☐ 2= No

Where do you see your psychiatrist, psychologist, or counselor? _____

What is their name? _____

How often do you see them? _____

Are you currently taking any medication for this/these conditions(s)?
☐ 1= Yes ☐ 2 = No

If yes, what medications are you taking? _____

Are you willing to sign a consent for release of information so that we can communicate with your psychiatrist, psychologist, or counselor about your treatment plan?
☐ 1=Yes ☐ 2=No

Have you ever been hospitalized for a mental health condition?
☐ 1=Yes ☐ 2=No

Have you ever attempted to end your life or to hurt yourself?
☐ 1=Yes ☐ 2=No

How many times did you try to end your life or to hurt yourself? _____

Do you currently have thoughts about hurting yourself or ending your life?
☐ 1=Yes ☐ 2=No *(If no, skip to homicide question)*

If yes:
Do you currently have a plan for how you would hurt yourself or end your life?
☐ *1=Yes* ☐ *2=No*

Do you have the means to carry out your plan?
☐ *1=Yes* ☐ *2=No*

Have you ever attempted or thought about homicide (killing someone else)?
☐ *1=Yes* ☐ *2=No (If no, skip to health status)*

If yes:
Are you presently thinking about killing someone?
☐ *1=Yes* ☐ *2=No*

Do you have the means to carry this out?
☐ *1=Yes* ☐ *2=No*

****If patient screens positive to any of the above italicized questions, staff member conducting the screener must implement institutional protocols regarding acute suicidal ideation or homicidal ideation.***

Health Status

Have you ever been diagnosed with any of the following medical conditions? Mark all that apply.

☐ 1= Head Trauma/Brain Injury (specify type): _____
☐ 2= HIV ➔ If yes, are you currently in care? ☐ 1= Yes ☐ 2 = No
☐ 3= Hepatitis C ➔ If yes, have you been treated? ☐ 1= Yes ☐ 2 = No
☐ 4= Severe Liver or Kidney Disease ➔ If yes, are you currently in care? ☐ 1= Yes ☐ 2 = No

☐ 5= Chronic Pain Syndrome (specify type):_____
☐ 6= Other (specify type):_____
☐ 7= None

Health Care Provider Information

Where do you access most of your healthcare?
☐ 1= Emergency department
☐ 2= Primary care clinic
☐ 3= Walk-in clinic (e.g., Minute Clinic, urgent care setting)
☐ 4= Shelter-based clinic or street outreach team
☐ 5= Community program (e.g., Engagement center for persons experiencing homelessness)
☐ 6= Criminal-legal setting (e.g., jail or prison)
☐ 7= Other (specify type):_____
☐ 8= None

Do you have a primary care provider? ☐ 1= Yes ☐ 2 = No
If yes, can you tell us their name and where they are located?

_____

Social History

Are you currently employed? ☐ 1= Yes ☐ 2 = No

If yes, what do you do for work? _____

What is a typical work schedule (in terms of days and hours working per week)?

_____

Have you ever spent any time in jail/prison? ☐ 1= Yes ☐ 2 = No

If yes, what is the longest period of time you spent in jail/prison? _____

When was your most recent incarceration? _____

Are you on probation or parole? ☐ 1= Yes ☐ 2 = No

Do you have any outstanding legal issues? ☐ 1= Yes ☐ 2 = No

Social Support

Do you have any support persons in your life? ☐ 1= Yes ☐ 2 = No

If yes, who would you say are you support persons?

☐ 1 = Significant other/partner
☐ 2 = Parent
☐ 3 = Friend/acquaintance
☐ 4 = Employer/supervisor
☐ 4 = Other: _____

If you are in a relationship, do you feel safe (emotionally, physically, and mentally) with your partner?
☐ 1= Yes ☐ 2 = No

Does your support person(s) know about your substance use disorder? ☐ 1= Yes ☐ 2 = No

Do any other family members have a history of substance use disorder?
☐ 1= Yes ☐ 2 = No

Treatment Goals

Can you tell me what your goals are for treatment?

_____

_____

_____

_____

OBAT Nurse Intake

Nursing Summary: review and confirm screener information. Obtain any missing info.

Additional information to include:

Do you use any method to ensure family planning or protective sex?
☐ 1= Yes ☐ 2 = No

If yes, which method are you currently utilizing? (Check all that apply)
☐ Condoms
☐ Oral contraceptives
☐ Injection (e.g., Depo-Provera)
☐ Hormonal implant
☐ Intrauterine device/contraception (IUD or IUC)
☐ Vaginal ring
☐ Patch
☐ Rhythm/fertility awareness methods/withdrawal
☐ None
☐ Trying to conceive
☐ Other: _____

Would you like to learn more about family planning options? ☐ 1= Yes ☐ 2 = No

Substance Use History

What substances are you currently using?
Includes quantity, most recent use, route, and frequency.
☐ 1 = Heroin
☐ 2 = Fentanyl
☐ 3 = Buprenorphine
☐ 4 = Methadone
☐ 5 = Oxycodone product
☐ 6 = Other opioid: _____
☐ 7 = Cocaine/crack cocaine
☐ 8 = Benzodiazepines
☐ 9 = Alcohol
☐ 10= Amphetamines
☐ 11= Crystal meth
☐ 12= Nicotine
☐ 13 = Cannabis
☐ 14 = Pharmaceutical (e.g., gabapentin, quetiapine, promethazine, etc.)
☐ 15 = None
☐ 16 = Other: _____

Comments:

_____

Are you seeking resources or treatment for any process addictions (examples below)?
☐ 1 = Gambling
☐ 2 = Sex
☐ 3 = Shopping
☐ 4 = Eating disorder (over-eating, bulimia, anorexia)
☐ 5 = Other: _____
☐ 6 = No

Comments: _____

Prior Substance Use Disorder Treatment History

METHADONE

Have you ever been on methadone maintenance? ☐ 1= Yes ☐ 2 = No

Where were you on methadone maintenance? _____

What was your most recent dose? _____

When was your most recent dose? _____

Why did you/are you seeking to discontinue methadone treatment?
_____

BUPRENORPHINE

Have you ever been prescribed buprenorphine before?
☐ 1= Yes ☐ 2 = No

If yes, who was prescribing your medication (prescriber and practice location)?

_____
Are you currently prescribed buprenorphine or taking it illicitly?
☐ 1= Prescribed ☐ 2 = Illicit ☐ 3 = Both

What is your daily dose of buprenorphine? _____

When was your most recent dose of buprenorphine? _____

Have you ever received an extended-release buprenorphine injection? _____

If yes, when was your most recent injection? _____

If applicable, why did you stop taking buprenorphine?

_____

NALTREXONE

Have you ever been prescribed naltrexone before?
☐ 1= Yes ☐ 2 = No

If yes, who was prescribing your medication (prescriber and practice location)?

_____

Are you currently prescribed naltrexone?
☐ 1= Yes ☐ 2 = No

If yes, are you receiving the oral or injectable formulation?
☐ 1= Oral ☐ 2 = Injectable

When was your most recent dose of naltrexone? _____

If applicable, why did you stop naltrexone treatment?

_____

Mental Health History

Have you ever been diagnosed with any of the following mental health conditions?

☐ 1 = Depression
☐ 2 = Anxiety
☐ 3 = Bipolar disorder
☐ 4 = Schizophrenia
☐ 5 = Obsessive Compulsive Disorder (OCD)
☐ 6 = Post-Traumatic Stress Disorder (PTSD)
☐ 7 = Attention Deficit Hyperactivity Disorder (ADHD)
☐ 8 = Other: _____

Are you currently taking any medication for this/these conditions(s)?
☐ 1= Yes ☐ 2 = No

If yes, what medications are you taking? _____

Who is prescribing your psychiatric medications? _____

Are you willing to sign a consent for release of information so that we can communicate with your psychiatrist, psychologist, or counselor about your treatment plan?
☐ 1=Yes ☐ 2=No

Have you ever been hospitalized for mental health issues?
☐ 1=Yes ☐ 2=No

Have you ever attempted to end your life or to hurt yourself?
☐ 1=Yes ☐ 2=No

How many times did you try to end your life or to hurt yourself? _____

***Do you currently have thoughts about hurting yourself or ending your life?**
☐ 1=Yes ☐ 2=No (If no, skip to homicide question)

If yes:
Do you currently have a plan for how you would hurt yourself or end your life?
☐ *1=Yes* ☐ *2=No*

Do you have the means to carry out your plan?
☐ *1=Yes* ☐ *2=No*

Have you ever attempted or thought about homicide (killing someone else)?
☐ *1=Yes* ☐ *2=No (If no, skip to health status)*

If yes:
Are you presently thinking about killing someone?
☐ *1=Yes* ☐ *2=No*

Do you have the means to carry this out?
☐ *1=Yes* ☐ *2=No*

****If patient screens positive to any of the above questions, the OBAT nurse must implement institutional protocols regarding acute suicidal ideation or homicidal ideation***

Health Status

Have you ever been diagnosed with any medical conditions? (Mark all that apply)
☐ 1= Head Trauma/Brain Injury (specify type): _____
☐ 2= Seizure disorder ➔ Are you on medications? ☐ 1= Yes ☐ 2 = No
☐ 3= Endocarditis
☐ 4= Skin infection
☐ 5= HIV ➔ If yes, are you currently in care? ☐ 1= Yes ☐ 2 = No
☐ 6= Hepatitis A
☐ 7= Hepatitis B ➔ If yes, have you been treated? ☐ 1= Yes ☐ 2 = No
☐ 8= Hepatitis C ➔ If yes, have you been treated? ☐ 1= Yes ☐ 2 = No
☐ 9= Tuberculosis (TB) ➔ If yes, have you been treated? ☐ 1= Yes ☐ 2 = No
☐ 10=Diabetes (specify type): _____

☐ 11=Heart disease (specify type): _____
☐ 12=Asthma (specify type): _____
☐ 13=Cancer (specify type): _____
☐ 14= Pancreatic Problems
☐ 15= Other (specify):_____
☐ 16= None

Who are your health care providers?

Are you willing to sign a consent for release of information to external health care providers listed above?
☐ 1=Yes ☐ 2=No

Past Medical History:

Current Medications:

Allergies:

Have you been tested for HIV? ☐ 1= Yes ☐ 2 = No

If yes, did you go back for the results? ☐ 1= Yes ☐ 2 = No

If yes, when was the last time you were tested? _____

Have you been tested for Hepatitis C? ☐ 1= Yes ☐ 2 = No

If yes, did you go back for the results? ☐ 1= Yes ☐ 2 = No

If yes, when was the last time you were tested? _____

Do you have any pending surgeries? ☐ 1= Yes ☐ 2 = No

Pain

Do you have chronic pain? ☐ 1=Yes ☐ 2=No

If yes, please explain:

_____

_____

If yes:
PEG Scale Assessing Pain Intensity and Interference (Pain, Enjoyment, General Activity)

0 1 2 3 4 5 6 7 8 9 10
No Pain Pain as bad as you can imagine

1) **What number best describes you pain on average in the past week? _____**

2) **What number best described how, during the past week, pain has interfered with your enjoyment of life? _____**

3) **What number best describes how, during the past week, pain has interfered with you general activity? _____**

Total PEG Score: _____

Treatment Goals

What are your goals for addiction treatment?

_____

_____

Check all appropriate boxes:

☐ OBAT program reviewed with patient including contact information, treatment goals, frequency of OBAT appointments, and indications for laboratory monitoring.

☐ OBAT treatment agreement and relevant consents reviewed with the patient. Patient voluntarily agreed to and/or signed and dated consents. A copy was given to the patient and the original was placed in the chart. Opportunity for questions provided.

☐ Provided counseling to keep medications in a safe undisclosed place, out of reach of children and visitors.

☐ Patient has been informed that buprenorphine, buprenorphine/naloxone, and naltrexone are Category C medications. Patient will inform treatment team if becomes pregnant.

☐ Labs sent (if indicated) may include complete blood count (CBC); Hepatitis A, B, and C serologies; and comprehensive metabolic panel. Standard testing is recommended to include human chorionic gonadotropin (hCG) for women of childbearing age, urine toxicology screen, and HIV testing.

☐ Overdose education provided. Patient has access to a naloxone rescue kit through their preferred pharmacy and has received instructions on how to use it.

Buprenorphine:

☐ Provided education about buprenorphine including indications; contraindications; administration; dosing; interactions; and potential side effects or adverse reactions such as: elevations in transaminases, sedation, constipation, dry mouth, and headache. Written information also provided. Patient verbalizes understanding and wishes to continue for further treatment.

☐ Contact numbers of treatment team and buprenorphine information given to patient. Patient instructed to give this information to family and friends in case patient is hospitalized.

Naltrexone:

☐ Provided education about naltrexone including indications; contraindications; administration; dosing; interactions; and potential side effects or adverse reactions such as injection site reactions, increased transaminases, depressed mood, opioid blocking effects, and decreased opioid tolerance.

☐ Provided counseling about the importance of being fully withdrawn from opioids prior to initiating naltrexone to mitigate the risk of precipitated or spontaneous withdrawal. Written info provided to patient. Patient verbalized understanding and wishes to initiate naltrexone treatment.

☐ Contact numbers of treatment team and naltrexone information given to patient. Patient instructed to give this information to family and friends in case patient is hospitalized. Patient also advised to carry on their person naltrexone medical identification such as a bracelet and/or dog tag.

Buprenorphine Initiation Note

☐ Patient presents for in-clinic initiation

Evaluated using COW scale? ☐ Yes ☐ No

Scored _____on COW Scale First Assessment

*If patient scored < 13 on COWS and/or reported illicit opioid use within 24 hours, do not proceed with in-clinic initiation and consult OBAT provider for altered treatment plan including at home initiation.

Patient self-administered _____ mg sublingually as prescribed

☐ Assessed and instructed patient in proper administration
☐ Patient observed to tolerate medication

Summary 1:
COW Scale First Assessment

Resting Pulse Rate
☐ 0 = pulse rate 80 bpm or below
☐ 1 = pulse rate 80-100 bpm
☐ 2 = pulse rate 101–120 bpm
☐ 3 = pulse rate greater than 120 bpm

Sweating
☐ 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 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 possible larger than normal for room light
☐ 2 = pupils moderately dilated
☐ 5 = pupils so dilated that only the rim of the iris is visible

Bone or Joint Aches
☐ 0 = not present
☐ 1 = mild diffuse discomfort

☐ 2 = patient reports severe diffuse aching of joints/muscle
☐ 4 = patient is rubbing joints or muscles and is unable to sit still because of discomfort

Runny Nose or Tearing
☐ 0 = not present
☐ 1 = nasal stuffiness or unusually moist eyes
☐ 2 = nose running or tearing
☐ 4 = nose constantly running or tears streaming down cheeks

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

Tremor
☐ 0 = no tremor
☐ 1 = tremor can be felt but not observed
☐ 2 = slight tremor observable
☐ 4 = gross tremor or muscle twitching

Yawning
☐ 0 = no yawning
☐ 1 = yawning once or twice during assessment
☐ 2 = yawning three or more times during assessment
☐ 4 = yawning several times per minute

Anxiety or Irritability
☐ 0 = none
☐ 1 = patient reports increasing irritability or anxiousness
☐ 2 = patient obviously irritable/anxious
☐ 4 = patient so irritable or anxious that participation in the assessment is difficult

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

Total Score _____

Score: 5 – 12 = Mild
13 – 24 = Moderate
25 – 36 = Moderately Severe
More than 36 = Severe Withdrawal

☐ **Patient presents for second initiation/re-evaluation**

Evaluated using COWS scale? ☐ Yes ☐ No

Scored _____on COWS Scale Second Assessment

Patient self-administered _____ mg sublingually as prescribed

☐ Assessed and instructed patient in proper administration
☐ Patient observed to tolerate medication

☐ **Patient presents for subsequent induction/re-evaluation**

Evaluated using COWS scale? ☐ Yes ☐ No

Scored _____on COWS Scale Second Assessment

Patient self-administered _____ mg sublingually as prescribed

☐ Assessed and instructed patient in proper administration
☐ Patient observed to tolerate medication

OBAT Nursing Follow-Up Note

Visit type:
☐ Scheduled
☐ Call back
☐ Walk-in
☐ Random call back

Reason for visit: _____

Medication for Addiction Treatment:

☐ Transmucosal buprenorphine/naloxone ☐ Transmucosal buprenorphine
☐ Injectable buprenorphine ☐ Oral naltrexone
☐ Injectable naltrexone ☐ Other: _____

Current dose of transmucosal buprenorphine product:

☐ 1 = 2 mg	☐ 4 = 8 mg	☐ 7 = 16 mg	☐ 10 = 28 mg
☐ 2 = 4 mg	☐ 5 = 10 mg	☐ 8 = 20 mg	☐ 11 = 32 mg
☐ 3 = 6 mg	☐ 6 = 12 mg	☐ 9 = 24 mg	☐ 12 = Other _____

Current dose of injectable buprenorphine:

Sublocade®:	☐ 100 mg	☐ 300 mg		
Brixadi®:	☐ 8 mg	☐ 16 mg	☐ 24 mg	☐ 32 mg
	☐ 64 mg	☐ 96 mg	☐ 128 mg	

Current dose of naltrexone:
☐ 25 mg (oral) ☐ 50 mg (oral) ☐380 mg (injectable)

Is patient taking medication for addiction treatment as directed (dose, administration, etc.)?
☐ 1 = Yes ☐ 2 = No

The patient's dose is:
☐ Stable
☐ Titrating up
☐ Tapering down

Is patient experiencing any of the following?
☐ Cravings
☐ Withdrawal symptoms
☐ Side effects
☐ Other: _____
☐ Patient denies cravings/withdrawal symptoms

Comments: _____

Has patient used any substances? (Check all that apply)
☐ Fentanyl
☐ Heroin
☐ Oxycodone
☐ Morphine
☐ Illicit buprenorphine
☐ Other opioid
☐ Cocaine
☐ Alcohol
☐ Barbiturate
☐ Benzodiazepines
☐ Amphetamines
☐ Methamphetamines
☐ Cannabinoid
☐ Nicotine/Tobacco
☐ Patient endorses no substance use
☐ Other: _____

Route of substance use:

☐ Oral
☐ Smoke/inhalation
☐ Intranasal
☐ Intrarectal
☐ Injection
☐ Other: _____

Does patient have access to nasal naloxone?
☐ 1 = Yes ☐ 2 = No

If no access to naloxone:

☐ Patient was provided with a prescription for nasal naloxone today
☐ Patient was dispensed a nasal naloxone rescue kit at time of clinic visit
☐ Patient was provided with information about how to access naloxone
☐ Patient declined naloxone at time of encounter
☐ Comment: _____

Is patient engaged in counseling or psychotherapy? ☐ 1 = Yes ☐ 2 = No

Details of psychotherapy (e.g., 1:1 counseling or group, psychiatry, name of provider, location, frequency of visits, etc.):

_____

Is there a release of information on file to collaborate? ☐ 1 = Yes ☐ 2 = No

Is patient engaged in peer support services? ☐ 1 = Yes ☐ 2 = No
Details of peer support:

_____

Is the patient currently engaged with any of the following agencies?

☐ Department of Children and Families
☐ Criminal-Legal System
☐ Vocational Training
☐ School
☐ Other/Comment: _____

Is there a release of information on file to collaborate? ☐ 1 = Yes ☐ 2 = No

Details of release of information: _____

Where is the patient currently staying?

☐ Own house or apartment
☐ House or apartment belonging to a friend or family member
☐ Residential treatment program
☐ Shelter
☐ Street
☐ Sober House
☐ Other/Comment: _____

Sexually active: ☐ 1 = Yes ☐ 2 = No

Gender identify of sexual partner(s):

☐ Man
☐ Woman
☐ Non-binary
☐ Gender nonconforming
☐ Genderfluid
☐ Intersex
☐ Other/Comment: _____

Does sexual partner identify as transgender: ☐ 1 = Yes ☐ 2 = No

Contraception? (check all that apply)
☐ Male condoms
☐ Oral contraceptives
☐ Injection (e.g., Depo-Provera)
☐ Hormonal implant
☐ Intrauterine device/contraception (IUD or IUC)

☐ Vaginal ring
☐ Patch
☐ Rhythm/fertility awareness methods/withdrawal
☐ Female barrier method (e.g., diaphragm, female condom)
☐ Permanent medical reason (e.g., menopause, bilateral tubal ligation, hysterectomy)
☐ Abstinence
☐ None
☐ Trying to conceive
☐ Other/Comment: _____

For patients with uterine reproductive capabilities: LMP: _____

If menses was more than one month ago, would you like a pregnancy test today?

☐ 1 = Yes ☐ 2 = No

If positive result:

☐ Patient desires prenatal care: offered prenatal vitamins and facilitated warm-handoff to Obstetrics and Gynecology team to begin prenatal care
☐ Patient does not wish to continue pregnancy: connected to appropriate Obstetrics and Gynecology team
☐ Patient unsure: offered prenatal vitamins and connected to appropriate Obstetrics and Gynecology team
☐ Comment: _____

Are there any medical concerns today? ☐ 1 = Yes ☐ 2 = No

If yes, details: _____

PCP Name: _____

OBAT Provider Name: _____

Was the last OBAT provider visit within 4 months? ☐ 1 = Yes ☐ 2 = No

When were the patient's last labs drawn? _____

Toxicology Screen collected? ☐ 1 = Yes ☐ 2 = No

Was recovery support and education provided today? ☐ 1 = Yes ☐ 2 = No

Was a form of injectable medication administered during the visit?

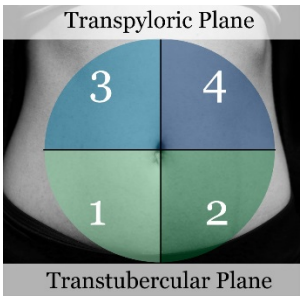
☐ No
☐ Yes: Injectable naltrexone
☐ Yes: Injectable buprenorphine

☐ Other/Comment: _____

Dose of injectable medication administered today: _____

Injection location:

☐ Right upper quadrant of gluteal muscle
☐ Left upper quadrant of gluteal muscle
☐ Transpyloric plane 1
☐ Transpyloric plane 2
☐ Transpyloric plane 3
☐ Transpyloric plane 4
☐ Other/Comment: _____



Lot: _____

Expiration: _____

Appearance of most recent injection site: _____

Prescription Drug Monitoring Program checked? ☐ 1 = Yes ☐ 2 = No

Refill sent? ☐ 1 = Yes ☐ 2 = No

Visit summary and Plan:

_____

_____

_____

Treatment Consent Forms: Transmucosal Buprenorphine Consent Form

CONSENT FOR TREATMENT WITH TRANSMUCOSAL BUPRENORPHINE

Buprenorphine is an FDA-approved medication for treatment of people with opioid use disorder. Buprenorphine is available in tablet, film, and injectable formations. The tablet and film forms of the medicine are most commonly available as a combination of two medications, buprenorphine and naloxone. The buprenorphine-mono tablet is typically reserved for pregnant women.

Buprenorphine has been shown to be a safe and effective medication for long-term treatment of opioid use disorder. However, since buprenorphine is an opioid medication, ongoing use of the medicine will result in physical dependence. Withdrawal from buprenorphine is generally less intense than withdrawal from heroin or methadone. If buprenorphine is suddenly discontinued, patients may have mild withdrawal symptoms while others may have more severe symptoms such as muscle aches, stomach cramping, or insomnia lasting several days to weeks. To minimize the possibility of opioid withdrawal, buprenorphine should be discontinued gradually and with the support of the treatment team.

Combining buprenorphine with alcohol or sedating medications, such as benzodiazepines, may be hazardous and could result in overdose or death. It is recommended to discuss all of your mediations with your health care team.

Buprenorphine tablets/films **must** be held under the tongue until the medicine completely dissolves. Buprenorphine will not be absorbed from the stomach if it is swallowed. Abstain from eating, drinking, and smoking until 15 minutes after taking the medication.

If you are dependent on opioids, like fentanyl or methadone, you should be in as much withdrawal as you can tolerate when you take your first dose of buprenorphine. Being in withdrawal ensures that the previously-used opioid will be less likely to interact with the medicine. If you are not in withdrawal, buprenorphine can quickly cause severe opioid withdrawal.

It may take several days to comfortably transition from the opioid that you had been taking to buprenorphine. After stabilizing on buprenorphine, the use of other opioids will have less of an effect. Attempts to override the buprenorphine by taking more opioids could result in an overdose.

_____

Print Name Sign Name Date

_____

Witness Date

Transmucosal Buprenorphine Consent Form, Spanish Translation

CONSENTIMIENTO PARA TRATAMIENTO CON BUPRENORFINA ADMINISTRADA POR VÍA TRANSMUCOSA

La buprenorfina es un medicamento aprobado por la Administración de Alimentos y Medicamentos (FDA, por sus siglas en inglés) para el tratamiento de personas con trastornos por consumo de opioides. La buprenorfina está disponible en forma de comprimidos, películas e inyectables. Las presentaciones de comprimidos y películas de este medicamento están disponibles más comúnmente como una combinación de dos medicamentos, buprenorfina y naloxona. El comprimido de buprenorfina sola suele reservarse para las mujeres embarazadas.

La buprenorfina ha demostrado ser un medicamento seguro y eficaz para el tratamiento a largo plazo del trastorno por consumo de opioides. Sin embargo, dado que la buprenorfina es un medicamento opioide, el uso continuado del mismo provocará dependencia física. La abstinencia de la buprenorfina suele ser menos intensa que la de la heroína o la metadona. Si la buprenorfina se interrumpe repentinamente, es posible que los pacientes experimenten síntomas de abstinencia leves, mientras que otros pueden presentar síntomas más graves, como dolores musculares, calambres estomacales o insomnio, que pueden durar desde varios días hasta semanas. Para minimizar la posibilidad de abstinencia de opioides, la buprenorfina debe suspenderse gradualmente y con el apoyo del equipo de tratamiento.

Combinar la buprenorfina con alcohol o con medicamentos sedantes como las benzodiacepinas puede ser peligroso y puede provocar una sobredosis o la muerte. Se recomienda conversar sobre todos sus medicamentos con su equipo de atención médica.

Los comprimidos/las películas de buprenorfina **deben** colocarse y mantenerse debajo de la lengua hasta que el medicamento se disuelva por completo. En caso de ser ingerida, la buprenorfina no se absorbe en el estómago. Absténgase de comer, beber y fumar por los siguientes 15 minutos después de tomar el medicamento.

Si es dependiente de los opioides, como el fentanilo o la metadona, debe encontrarse en el mayor estado de abstinencia que pueda tolerar cuando tome su primera dosis de buprenorfina. Estar en abstinencia garantiza que el opioide consumido anteriormente tendrá menos posibilidades de interactuar con el medicamento. Si no se encuentra en estado de abstinencia, la buprenorfina puede provocar rápidamente síntomas graves de abstinencia de opioides.

La transición cómoda del opioide que ha estado tomando a la buprenorfina puede tomar varios días. Después de estabilizarse con buprenorfina, el uso de otros opioides tendrá menos efecto. Los intentos de anular la buprenorfina tomando más opioides podrían dar como resultado una sobredosis.

Nombre en letra de imprenta	Firma	Fecha

Testigo	Fecha

Transmucosal Buprenorphine Consent Form, Haitian Creole Translation

KONSANTMAN POU TRETMAN AVÈK BUPRENORPHINE TRANSMIKEZ

Buprenorphine se yon medikaman ki apwouve pa FDA a pou tretman moun ki genyen twoub itilizasyon opyoyid. Buprenorphine disponib sou fòm konprime, film, ak sou fòm enjeksyon. Fòm konprime ak fòm film medikaman yo plis souvan disponib nan yon konbinezon de medikaman, buprenorphine ak naloxone. Konprime buprenorphine-mono a jeneralman rezève pou fanm ansent.

Yo te montre ke buprenorphine se yon medikaman ki san danje epi ki efikas pou tretman twoub itilizasyon opyoyid alontèm. Sepandan, lefètke buprenorphine se yon medikaman opyoyid, itilizasyon regilye medikaman an pral mennen depandans fizik. Sevraj nan buprenorphine jeneralman mwens entans pase sevraj nan ewoyin oswa methadone. Si pasyan yo kanpe buprenorphine nan toudenkou, yo kapab genyen sentòm lejè lè y ap kite l tandiske lòt moun kapab genyen plis sentòm ki grav tankou doulè nan misk, kranp nan lestomak, oswa ensomni ki dire plizyè jou jiska plizyè semèn. Pou minimize posiblite pou sevraj opyoyid la, yo dwe kanpe buprenorphine lan pwogresivman epi avèk sipò ekip tretman an.

Lè yo konbine buprenorphine avèk alkòl oswa medikaman sedatif tankou benzodiazepine yo, sa kapab danjre epi kapab mennen òvèdòz oswa lanmò. Li rekòmande pou diskite sou tout medikaman ou yo avèk ekip swen sante ou an.

Konprime buprenorphine/film yo **dwe** rete anba lang lan jiskaske medikaman an fonn nèt. Buprenorphine p ap absòbe nan lestomak la si ou vale l. Evite manje, bwè, ak fimen jiska 15 minit aprè ou fin pran medikaman an.

Si ou depann de opyoyid, tankou fentanyl oswa methadone, ou dwe nan otan sevraj jan ou ka jere l lè w ap pran premye dòz Buprenorphine ou an. Lè ou nan sevraj sa vle di ke ansyen opyoyid ki te itilize a pral genyen mwens chans pou entèraji avèk medikaman an. Si ou pa nan yon sevraj, buprenorphine ka lakoz gwo sevraj opyoyid byen vit.

Li kapab pran plizyè jou pou fè tranzisyon byen alèz soti nan opyoyid w ap pran an pou ale nan buprenorphine. Aprè ou fin jwenn estabilite sou buprenorphine nan, itilizasyon lòt opyoyid la pral genyen mwens efè. Tantativ pou netralize buprenorphine nan pandan w ap pran plis opyoyid ka mennen yon òvèdòz.

Non an Lèt Detache	Siyen Non	Dat
Temwen	Dat	

Transmucosal Buprenorphine Consent Form, Portuguese Translation

CONSENTIMENTO PARA TRATAMENTO COM BUPRENORFINA TRANSMUCOSA

A buprenorfina é uma medicação aprovada pela FDA para o tratamento de pessoas com transtorno de uso opioide. Buprenorfina está disponível em formações de comprimido, filme e injetáveis. As formas de comprimidos e filmes do medicamento são mais comuns, disponíveis como uma combinação de dois medicamentos, buprenorfina e naloxona. O comprimido apenas de buprenorfina normalmente é reservado para mulheres grávidas.

A buprenorfina demonstrou ser uma medicação segura e eficaz para tratamento a longo prazo do transtorno de uso opioide. No entanto, como a buprenorfina é uma medicação opioide, o uso contínuo do medicamento resultará em dependência física. A retirada da buprenorfina é geralmente menos intensa do que a retirada da heroína ou metadona. Se a buprenorfina for descontinuada repentinamente, os pacientes podem ter sintomas leves de retirada, enquanto outros podem ter sintomas mais graves, como dores musculares, cólicas estomacais ou insônia com duração de vários dias a semanas. Para minimizar a possibilidade de retirada de opioide, a buprenorfina deve ser descontinuada gradualmente e com o apoio da equipe de tratamento.

A combinação de buprenorfina com álcool ou medicamentos sedativos, como os benzodiazepínicos, pode ser perigoso e resultar em sobredosagem ou morte. Recomenda-se discutir todas as suas mediações com sua equipe de saúde.

Comprimidos/filmes de buprenorfina **devem** ser mantidos debaixo da língua até que o medicamento se dissolva completamente. A buprenorfina não será absorvida do estômago se for ingerido. Abstenha-se de comer, beber e fumar até 15 minutos depois de tomar a medicação.

Se você for dependente de opioides, como fentanil ou metadona, deve realizar a retirada máxima possível que você consegue tolerar quando tomar sua primeira dose de buprenorfina. Estar em retirada garante que o opioide usado anteriormente seja menos provável de interagir com o medicamento. Se você não estiver em retirada, a buprenorfina pode causar rapidamente a retirada grave de opioides.

Pode levar vários dias para fazer uma transição confortável do opioide que você estava tomando para a buprenorfina. Depois de estabilizar a buprenorfina, o uso de outros opioides terá menos efeito. As tentativas de substituir a buprenorfina com mais opioides podem resultar em uma sobredosagem.

Nome legível	Assinatura	Data
Testemunha	Data	

Consent for Treatment with Injectable Buprenorphine

CONSENT FOR TREATMENT WITH INJECTABLE BUPRENORPHINE

Buprenorphine is a medicine that is used to treat opioid use disorder. Buprenorphine is an opioid which can help support recovery because it reduces craving and withdrawal symptoms, and blocks the effects of stronger and more dangerous opioids. Buprenorphine can be taken as a daily pill, or it can be taken by monthly shot. This consent form is about the monthly shot. The name of the shot is SUBLOCADE®.

Buprenorphine can be used for detoxification or maintenance therapy. Maintenance therapy can continue as long as medically necessary, it is recommended that buprenorphine treatment lasts for at least six (6) months.

SUBLOCADE® is a long-acting form of buprenorphine that is given every 28 days in the abdomen. The usual starting dose is 300 mg. Generally, after two (2) months the dose is decreased to 100 mg monthly though maintenance doses can be either 100mg or 300mg.

The patient information you need to know about SUBLOCADE® and its side effects is attached. We will review that material with you before we ask you to sign this form for treatment.

I have read this form and the patient medication form or had them read to me. I understand what they say. I was given the opportunity to ask questions. All of my questions were answered. I believe I have enough information to consent to the SUBLOCADE® shot. By signing this form I authorize my OBAT clinical team (physician, nurse practitioner, nurse), to perform subcutaneous injections of Sublocade® into my abdomen as medically appropriate.

_____ _____

Patient Name Date

_____ _____

Provider Name Date

Consent for Treatment with Injectable Buprenorphine, Spanish Translation

CONSENTIMIENTO PARA TRATAMIENTO CON BUPRENORFINA INYECTABLE

La buprenorfina es un medicamento que se usa para tratar el trastorno por consumo de opioides. La buprenorfina es un opioide que puede ayudar a apoyar la recuperación debido a que reduce los síntomas de ansiedad y abstinencia y bloquea los efectos de los opioides más fuertes y peligrosos. La buprenorfina se puede tomar como una píldora diaria, o se puede tomar mediante una inyección mensual. Este formulario de consentimiento es sobre la inyección mensual. El nombre de la inyección es SUBLOCADE®.

La buprenorfina puede usarse para la desintoxicación o la terapia de mantenimiento. La terapia de mantenimiento puede continuar tanto tiempo como sea médicamente necesario, se recomienda que el tratamiento con buprenorfina dure al menos seis (6) meses.

SUBLOCADE es una forma de buprenorfina de acción prolongada que se administra cada 28 días en el abdomen. La dosis inicial habitual es de 300 mg. Generalmente, después de dos (2) meses, la dosis se reduce a 100 mg mensuales.

Se adjunta la información del paciente que necesita saber sobre SUBLOCADE y sus efectos secundarios. Revisaremos dicho material con usted antes de pedirle que firme este formulario para el tratamiento.

He leído este formulario y el formulario de medicamento del paciente o me los han leído. Entiendo lo que dicen. Tuve la oportunidad de hacer preguntas. Todas mis preguntas fueron respondidas. Considero que tengo suficiente información para aceptar recibir la inyección de SUBLOCADE. Al firmar este formulario, autorizo a mi equipo clínico de OBAT (médico, enfermero practicante, enfermero) a administrarme inyecciones subcutáneas de Sublocade en mi abdomen según sea médicamente apropiado.

_____	_____
Nombre del paciente	Fecha
_____	_____
Nombre del proveedor	Fecha

Consent for Treatment with Injectable Buprenorphine, Haitian Creole Translation

KONSANTMAN POU TRETMAN AVÈK BUPRENORPHINE ENJEKTAB

Buprenorphine se yon medikaman ki itilize pou trete twoub itilizasyon opyoyid. Buprenorphine se yon opyoyid ki ka ede avèk retablisman akoz li redwi sentòm gwo anvi ak sentòm sevraj, epi li bloke efè opyoyid ki pi pisan ak pi danjre. Ou ka pran Buprenorphine avèk yon pilil chak jou, oswa ou ka pran l avèk yon enjeksyon chak mwa. Fòmilè konsantman sa a pale sou enjeksyon chak mwa a. Non enjeksyon an se SUBLOCADE®.

Buprenorphine ka itilize pou dezentoksikasyon oswa pou terapi antretyen. Terapi antretyen an ka kontinye toutan li medikalman nesesè, li rekòmande pou tretman buprenorphine lan dire omwen sis (6) mwa.

SUBLOCADE se yon fòm buprenorphine ki genyen yon aksyon pwolonje ke yo administre chak 28 jou nan vant. Dòz yo jeneralman kòmanse avèk li a se 300 mg. An jeneral, aprè de (2) mwa, dòz la diminye jiska 100 mg chak mwa.

Isit la w ap jwenn enfòmasyon ki fèt pou pasyan an ke ou bezwen konnen sou SUBLOCADE ak efè segondè li yo. Nou pral revize materyèl sa a avèk ou anvan nou mande w pou siyen fòmilè pou tretman sa a.

Mwen te li fòmilè sa a ak fòmilè medikaman pasyan an oswa yo te li l pou mwen. Mwen konprann sa yo di a. Yo te ban m okazyon pou poze kesyon. Yo te reponn tout kesyon mwen yo. Mwen kwè ke mwen genyen ase enfòmasyon pou bay konsantman m pou enjeksyon SUBLOCADE la. Lè mwen siyen fòmilè sa a, mwen otorize ekip klinik mwen an nan OBAT (medsen, enfimyè pratisyen, enfimyè), pou reyalize enjeksyon Sublocade anba po vant mwen jan sa apwopriye medikalman.

_____ _____

Non Pasyan an Dat

_____ _____

Non Founisè a Dat

Consent for Treatment with Injectable Buprenorphine, Portuguese Translation

CONSENTIMENTO PARA TRATAMENTO COM BUPRENORFINA INJETÁVEL

A buprenorfina é um medicamento que é usado para tratar o transtorno de uso opiáceo. A buprenorfina é um opioide que pode ajudar a apoiar a recuperação porque reduz os sintomas de desejo e retirada, e bloqueia os efeitos de opioides mais fortes e perigosos. A buprenorfina pode ser tomada como uma pílula diária, ou pode ser tomada pela injeção mensal. Esse formulário de consentimento é sobre a injeção mensal. O nome da injeção é SUBLOCADE®.

A buprenorfina pode ser usada para desintoxicação ou terapia de manutenção. A terapia de manutenção pode continuar, desde que medicamente necessário, e recomenda-se que o tratamento com buprenorfina dure pelo menos 6 (seis) meses.

SUBLOCADE é uma forma longa de atuação de buprenorfina que é aplicada a cada 28 dias no abdômen. A dose inicial de costume é de 300 mg. Geralmente, após 2 (dois) meses, a dose é diminuída para 100 mg mensais.

A informação ao paciente que você precisa saber sobre SUBLOCADE e seus efeitos colaterais estão em anexo. Vamos revisar esse material com você antes de pedirmos para você assinar este formulário para tratamento.

Eu li este formulário e o formulário de medicação do paciente, ou estes foram lidos para mim. Eu entendo o que eles dizem. Tive a oportunidade de fazer perguntas. Todas as minhas perguntas foram respondidas. Eu acredito que tenho informações suficientes para consentir com a injeção SUBLOCADE. Ao assinar este formulário, autorizo minha equipe clínica OBAT (médico, assistente de enfermagem, enfermeira) a realizar injeções subcutâneas de Sublocade no meu abdômen, conforme medicamente apropriado.

_____ _____

Nome do paciente Data

_____ _____

Nome do profissional Data

Consent for Treatment with Naltrexone

CONSENT FOR TREATMENT WITH NALTREXONE

Oral Naltrexone and Extended-Release Injectable Naltrexone

Naltrexone is an FDA-approved medication to prevent return to opioid use and treat alcohol use disorder. Maintenance therapy with naltrexone can continue as long as medically necessary, ranging from a few months to lifelong treatment.

You should not start naltrexone if you are using opioids or experiencing withdrawal from opioids. The typical recommendation is to avoid all opioids for 7-10 days before starting naltrexone treatment to avoid getting sick. Urine toxicology screens will be completed before each injection to ensure abstinence from opioids.

Since naltrexone is not an opioid, you will not have any tolerance to opioids during treatment. This means that if you were using opioids before naltrexone, you **will** be more sensitive to lower doses of opioids and at **increased risk for overdose and overdose related injury or death** should you have a resume opioid use.

It is recommended to alert your family, friends, or close contacts that you are on naltrexone and about the risk of an overdose should you return to opioid use.

To ensure that you tolerate naltrexone, patients who have never taken naltrexone should begin with a dose by mouth (tablet form). If you tolerate the tablet well, you may transition to the injectable formulation.

A reaction at the site of injection may occur. The reaction can be serious. It is important to get medical attention for reactions that get worse or that you are unsure of, including intense pain, swelling, warmth or redness, blisters, area feels hard or lump, or skin opening.

Seek emergency medical attention if you develop signs/symptoms of pneumonia including shortness of breath, wheezing, fever, and difficulty breathing. Dizziness may also occur on naltrexone treatment. Avoid driving and operating heavy or dangerous machinery until you are sure how naltrexone affects you.

Laboratory testing to monitor liver function will be completed before and during treatment, as naltrexone can affect your liver. Contact your provider immediately if you develop symptoms during treatment such as yellowing of eyes/skin, dark urine, stomach pain, loss of appetite, fatigue, and change in stool (including development of diarrhea).

You may experience depression while on naltrexone. If you develop depression, it is important to tell someone and/or alert your medical providers. If you feel like harming yourself or someone else, go to your local emergency room or call 911. You should carry alert information so others know you are on naltrexone in a medical emergency, such as a medical alert necklace, bracelet, and/or emergency card.

For patients who can become pregnant: a pregnancy test will be completed before starting naltrexone treatment. If you learn you are pregnant at any time, please alert your medical team.

If you require pain management with opioid medications in an emergency medical situation, it is important that your medical team know that you are taking naltrexone. You require medical management by providers trained in the use of anesthetic drugs and management of potential respiratory effects. Carry emergency contact information with you at all times, and have your OBAT team contacted if needed to assist in your care.

Naltrexone is only one part of your treatment. It is recommended that you seek recovery support services, along with the medical part of your treatment, to assist you in your recovery process.

_____	_____
Patient Name	Date
_____	_____
Provider Name	Date

Consent for Treatment with Naltrexone, Spanish Translation

CONSENTIMIENTO PARA TRATAMIENTO CON NALTREXONA

Naltrexona oral y naltrexona inyectable de liberación prolongada

La naltrexona es un medicamento aprobado por la Administración de Alimentos y Medicamentos (FDA, por sus siglas en inglés) para prevenir el retorno al consumo de opioides y tratar el trastorno por consumo de alcohol. El tratamiento de mantenimiento con naltrexona puede continuar mientras sea médicamente necesario, oscilando entre unos pocos meses y un tratamiento de por vida.

No debe empezar a tomar naltrexona si está consumiendo opioides o experimentando síntomas de abstinencia de los mismos. La recomendación típica es evitar todos los opioides durante 7 a 10 días antes de comenzar el tratamiento con naltrexona para evitar enfermarse. Se realizarán exámenes toxicológicos de orina antes de cada inyección para garantizar la abstinencia de opioides.

Debido a que la naltrexona no es un opioide, no tendrá ninguna tolerancia a los opioides durante el tratamiento. Esto significa que si consumía opioides antes de tomar naltrexona, **será** más sensible a las dosis más bajas de opioides y tendrá un **mayor riesgo de sobredosis y de lesiones o muerte** relacionadas con sobredosis si vuelve a consumirlos.

Se recomienda avisarles a su familia, amigos y contactos cercanos que está tomando naltrexona y sobre el riesgo de una sobredosis en caso de volver al consumo de opioides.

Debido a que la naltrexona de liberación prolongada es una inyección, esta no se puede extraer del cuerpo. Para asegurarse de que puede tolerar el medicamento, los pacientes que nunca han tomado naltrexona deben empezar con una dosis por vía oral (en forma de comprimidos). Si tolera bien el comprimido, puede pasar a la fórmula inyectable.

Es posible que se produzca una reacción en el sitio de la inyección que puede ser grave. Es importante recibir atención médica en el caso de reacciones que empeoren o de las que no esté seguro, incluyendo dolor intenso, hinchazón, calor o enrojecimiento, ampollas, sensación de endurecimiento del área o abultamiento, o grietas en la piel.

Busque atención médica de emergencia si desarrolla signos/síntomas de neumonía, incluyendo falta de aire, sibilancias, fiebre y dificultad para respirar. También pueden producirse mareos durante el tratamiento con naltrexona. Evite conducir y operar maquinaria pesada o peligrosa hasta que esté seguro de cómo le afecta la naltrexona.

Se realizarán pruebas de laboratorio para monitorear la función hepática antes y durante el tratamiento, ya que la naltrexona puede afectar su hígado. Póngase en contacto con su proveedor de inmediato si desarrolla síntomas durante el tratamiento, como coloración amarillenta de los ojos/piel, orina oscura, dolor de estómago, pérdida del apetito, fatiga y cambios en las heces (incluyendo la aparición de diarrea).

Puede experimentar depresión mientras toma naltrexona. Si desarrolla depresión, es importante informarle a alguien o alertar a sus proveedores médicos. Si siente deseos de hacerse daño a usted mismo o a otra persona, vaya a la sala de emergencias local o llame al 911. Debe llevar

consigo información de alerta para que los demás sepan que está tomando naltrexona en caso de emergencia médica, como un collar de alerta médica, una pulsera o una tarjeta de emergencia.

Para las pacientes que pueden quedar embarazadas: se les hará una prueba de embarazo antes de iniciar el tratamiento con naltrexona. Si en algún momento se entera de que está embarazada, avísele a su equipo médico.

Si necesita controlar el dolor con medicamentos opioides en caso de emergencia médica, es importante que su equipo médico sepa que usted está tomando naltrexona. Necesita tratamiento médico por parte de proveedores capacitados en el uso de medicamentos anestésicos y en el manejo de posibles efectos respiratorios. Lleve información de contacto de emergencia con usted en todo momento y haga que se comuniquen con su equipo de OBAT, en caso de ser necesario, para que brinden su ayuda en relación con su atención.

La naltrexona es sólo una parte de su tratamiento. Se recomienda que busque servicios de apoyo a la recuperación, junto con la parte médica de su tratamiento, para que le ayude en su proceso de recuperación.

_____	_____
Nombre del paciente	Fecha
_____	_____
Nombre del proveedo	Fecha

Consent for Treatment with Naltrexone, Haitian Creole Translation

KONSANTMAN POU TRETMAN AVÈK NALTREXONE

Naltrexone Oral ak Naltrexone Enjektab Ki Genyen Liberasyon Pwolonje

Naltrexone se yon medikaman ki apwouve pa FDA a pou prevni retou nan itilizasyon opyoyid ak pou trete twoub konsomasyon alkòl. Terapi antretyen avèk naltrexone ka kontinye depi li medikalman nesesè, sa ki soti nan tretman ki dire kèk mwa jiska tretman ki dire tout lavi.

Ou pa dwe kòmanse naltrexone si w ap itilize opyoyid oswa si w ap fè fas ak sevraj nan opyoyid yo. Rekòmandasyon jeneral la se pou evite tout opyoyid pandan 7-10 jou anvan ou kòmanse tretman naltrexone pou evite tonbe malad. Depistaj toksikoloji nan pipi pral fèt anvan chak enjeksyon pou asire abstinans de opyoyid yo.

Lefètke naltrexone pa yon opyoyid, ou p ap genyen okenn tolerans ak opyoyid pandan tretman an. Sa vle di ke si ou t ap itilize opyoyid anvan naltrexone, ou **pral** plis sansib ak dòz opyoyid ki pi fèb yo nan yon **risk ki ogmante pou òvèdòz ak domaj oswa lanmò ki lye ak òvèdòz** si ou ta rekòmanse yon itilizasyon opyoyid.

Li rekòmande pou alète fanmi w, zanmi w, oswa kontak pwòch ou yo ke w ap pran naltrexone epi konsènan risk yon òvèdòz si ou ta retounen nan itilizasyon opyoyid.

Akoz naltrexone ki genyen liberasyon pwolonje se yon enjeksyon, yo pa ka retire l nan kò a. Pou asire ke ou ka tolere medikaman an, pasyan ki pa te janm pran naltrexone dwe kòmanse avèk yon dòz nan bouch (fòm konprime). Si ou ka tolere konprime a byen, ou kapab chanje vin nan fòmilasyon enjektab.

Kapab genyen yon reyaksyon nan sit enjeksyon an. Reyaksyon an ka grav. Li enpòtan pou resevwa swen medikal pou reyaksyon ki agrave oswa reyaksyon ou pa sèten de yo, ki genyen ladan gwo doulè, anflamasyon, chalè oswa woujè, zanpoud, sansasyon ke zòn nan di oswa li fè boul, oswa ouvèti po.

Chèche swen medikal an ijans si ou devlope siy/sentòm nemoni ki genyen ladan souf kout, respirasyon siflan, lafyèv, ak difikilte pou respire. Kapab genyen vètij tou pandan tretman avèk naltrexone lan. Evite kondwi ak itilize machin ki lou oswa machin ki danjre jiskaske ou sèten konsènan fason naltrexone afekte w.

Tès laboratwa pou kontwole fonksyon fwa a pral fèt anvan ak pandan tretman an, paske naltrexone ka afekte fwa w. Kontakte founisè ou an touswit si ou devlope sentòm pandan tretman tankou zye/po k ap vin jòn, pipi fonse, doulè nan lestomak, pèt apeti, fatig, ak chanjman nan poupou (ki genyen ladan devlopman dyare).

Ou kapab fè fas ak depresyon pandan ou sou naltrexone. Si ou devlope depresyon, li enpòtan pou di yon moun sa epi/oswa alète founisè medikal ou yo. Si ou santi tankou ou anvi fè tèt ou mal oswa yon lòt moun mal, ale nan sal dijans lokal ou an oswa rele 911. Ou dwe pote avèk ou enfòmasyon alèt yo pou lòt moun ka konnen ou sou naltrexone nan yon ijans medikal, tankou yon kolye alèt medikal, braslè, ak/oswa kat ijans.

Pasyan ki ka vin ansent yo: yo pral fè yon tès gwosès pou yo anvan yo kòmanse tretman naltrexone nan. Si ou aprann nenpòt lè ke ou ansent, tanpri alète ekip medikal ou an.

Si ou bezwen jesyon doulè avèk medikaman opyoyid yo nan yon sitiyasyon medikal dijans, li enpòtan pou ekip medikal ou an konnen ke w ap pran naltrexone. Ou bezwen jesyon medikal nan men founisè ki fòme nan itilizasyon medikaman analjezik ak jesyon efè respiratwa potansyèl. Pote enfòmasyon kontak dijans yo avèk ou tout tan, epi fè kontakte ekip OBAT ou an si nesesè pou ede nan swen ou an.

Naltrexone se sèlman yon pati nan tretman ou an. Li rekòmande pou chèche sèvis soutyen pou retablisman, ansanm ak pati medikal nan tretman ou an, pou ede w nan pwosesis retablisman ou an.

_____ _____

Non Pasyan an Dat

_____ _____

Non Founisè a Dat

Consent for Treatment with Naltrexone, Portuguese Translation

CONSENTIMENTO PARA TRATAMENTO COM NALTREXONA

Naltrexona oral e naltrexona injetável com liberação estendida

Naltrexona é um medicamento aprovado pela FDA para evitar o retorno ao abuso de opioides e tratar distúrbios de abuso de álcool. A terapia de manutenção com naltrexona pode continuar conforme for medicamente necessário, variando de alguns meses a um tratamento para a vida inteira.

Você não deve iniciar o uso de naltrexona se estiver usando opioides ou sofrendo retirada de opioides. A recomendação típica é evitar todos os opioides por 7-10 dias antes de começar o tratamento com naltrexona para evitar sentir-se mal. Os exames de toxicologia por urina serão realizados antes de cada injeção para garantir a abstinência de opioides.

Como naltrexona não é um opioide, você não terá nenhuma tolerância aos opioides durante o tratamento. Isso significa que, se você estiver usando opioides antes de naltrexona, você **ficará** mais sensível a doses menores de opioides e em **maior risco de sobredosagem e lesão ou morte por sobredosagem** caso volte a usar opioides.

Recomenda-se alertar a sua família, amigos ou contatos próximos que você está tomando naltrexona e sobre o risco de sobredosagem caso tenha um retorno ao uso de opioides.

Como a naltrexona liberada estendida é uma injeção, ela não pode ser retirada do corpo. Para garantir a tolerância ao medicamento, os pacientes que nunca tomaram naltrexona devem começar com uma dose oral (em forma de comprimido). Se o comprimido for bem tolerado, é possível fazer a transição para a formulação injetável.

Pode ocorrer uma reação no local da injeção. A reação pode ser grave. É importante chamar a atenção médica para reações que pioram ou que você não tem certeza, incluindo dor intensa, inchaço, calor ou vermelhidão, bolhas, área dura ou nódulo, ou abertura da pele.

Procure atendimento médico de emergência se você desenvolver sinais/sintomas de pneumonia, incluindo falta de ar, chiado, febre e dificuldade para respirar. Tonturas também podem ocorrer no tratamento com naltrexona. Evite dirigir e operar máquinas pesadas ou perigosas até ter certeza de como a naltrexona lhe afeta.

Exames de laboratório para monitorar a função hepática serão realizados antes e durante o tratamento, pois naltrexona pode afetar o seu fígado. Entre em contato imediatamente com seu médico se você desenvolver sintomas durante o tratamento, como amarelamento dos olhos/pele, urina escura, dor estomacal, pera de apetite, fadiga e mudança nas fezes (inclusive o desenvolvimento de diarreia).

Você pode sofrer depressão enquanto está tomando naltrexona. Se você desenvolver depressão, é importante dizer a alguém e/ou alertar seus médicos. Se você quiser se machucar ou outra pessoa, vá ao seu pronto-socorro local ou ligue para o 911. Você deve carregar consigo informações de alerta para que outros saibam que você está tomando neltrexona em uma emergência médica, como um colar, pulseira e/ou cartão de emergência de alerta médico.

Para pacientes que podem engravidar: um exame de gravidez será concluído antes de iniciar o tratamento com naltrexona. Se você descobrir que está grávida, alerte sua equipe médica.

Se você precisa de tratamento para dor com medicamentos opioides em uma situação médica de emergência, é importante que sua equipe médica saiba que você está tomando naltrexona. Você requer gestão médica por profissionais treinados no uso de medicamentos anestésicos e no gerenciamento de potenciais efeitos respiratórios. Carregue informações de contato de emergência consigo o tempo todo e contate a sua equipe OBAT se necessário para ajudar no seu atendimento.

Naltrexona é somente uma parte do tratamento. Recomenda-se buscar serviços de apoio à recuperação juntamente com a parte médica do seu tratamento, para ajudá-lo no processo de recuperação.

_____ _____

Nome do paciente Data

_____ _____

Nome do profissional Data

Consent for Treatment with Disulfiram

CONSENT FOR TREATMENT WITH DISULFIRAM

Disulfiram (Antabuse) is an FDA-approved medication to treat alcohol use disorder in individuals who have stopped consuming alcohol. This medication causes the body to be unable process any alcohol. When alcohol is consumed, a dose-dependent reaction occurs. Disulfiram should NOT be taken if you have consumed alcohol within the past 12 hours.

The larger the amount of the alcohol consumed, the stronger the disulfiram-alcohol reaction. The reaction can last from 30 minutes to several hours, or as long as it takes for the alcohol to be metabolized. A disulfiram-alcohol reaction may occur for up to 2 weeks after stopping medication.

A disulfiram-alcohol reaction may include trouble breathing, throbbing pain in head and neck, nausea, vomiting, sweating, thirst, palpitations, weakness, dizziness, blurred vision, and confusion. Severe reactions may involve respiratory failure, heart failure, unconsciousness, seizure, and death.

Even very small doses of alcohol can be absorbed from perfume, hand sanitizer, food items (dressings, vinegars, marinades, sauces, extracts, etc.), and alcoholic beverages, causing a disulfiram-alcohol reaction. It is important to check labels of items that will go in or on your body.

Laboratory testing to monitor liver function will be completed before and during treatment, as disulfiram can affect your liver. Contact your provider immediately if you develop symptoms such as yellowing of eyes/skin, dark urine, stomach pain, loss of appetite, fatigue, and change in stool (including the development of diarrhea).

The most common side effect of disulfiram is drowsiness, but severe adverse reactions have occurred in some individuals including liver failure, nerve irritation/neuropathy, psychosis, acne, skin rash, impotence, and inflammation of the optic nerve.

There are some medications that should not be taken with disulfiram (i.e., metronidazole, dronabinol, and certain cough medicines). It is important to let your providers know that you are prescribed disulfiram. Do not change your medications without checking with your provider.

It is not known if disulfiram is safe during pregnancy or if it can be passed into breast milk. A pregnancy test will be done before treatment begins. If you learn you are pregnant at any time please alert your medical team.

Store disulfiram at room temperature, in a light-resistant container. Keep all out of the reach of children and pets.

Alcohol use is very dangerous after starting disulfiram treatment. It is recommended to alert your family, friends and close contacts that you are on disulfiram and about the risk of a severe reaction should you have a return to use.

Disulfiram is only one part of your treatment. It is recommended that you seek recovery support services, along with the medical part of your treatment, to assist you in your recovery process.

_____	_____
Patient Name	Date
_____	_____
Provider Name	Date

Consent for Treatment with Disulfiram, Spanish Translation

CONSENTIMIENTO PARA TRATAMIENTO CON DISULFIRAM

El disulfiram (Antabuse) es un medicamento aprobado por la Administración de Alimentos y Medicamentos (FDA, por sus siglas en inglés) para tratar el trastorno por consumo de alcohol en personas que han dejado de consumirlo. Este medicamento hace que el cuerpo no sea capaz de procesar el alcohol. Cuando se consume alcohol, se produce una reacción dependiente de la dosis. El disulfiram NO debe tomarse si ha consumido alcohol en las últimas 12 horas.

Cuanto mayor sea la cantidad de alcohol consumida, más fuerte será la reacción disulfiram-alcohol. La reacción puede durar desde 30 minutos hasta varias horas, o el tiempo que tarde en metabolizarse el alcohol. Pueden producirse reacciones disulfiram-alcohol hasta 2 semanas después de suspender el medicamento.

Las reacciones disulfiram-alcohol pueden incluir problemas para respirar, dolor palpitante en la cabeza y el cuello, náuseas, vómitos, sudoración, sed, palpitaciones, debilidad, mareos, visión borrosa y confusión. Las reacciones graves pueden incluir insuficiencia respiratoria, insuficiencia cardíaca, inconsciencia, convulsiones y la muerte.

Incluso dosis muy pequeñas de alcohol pueden ser absorbidas de los perfumes, el desinfectante de manos, los alimentos (aderezos, vinagres, adobos, salsas, extractos, etc.) y las bebidas alcohólicas, provocando una reacción disulfiram-alcohol. Es importante revisar las etiquetas de los productos que vaya a consumir o a ponerse en el cuerpo.

Se realizarán pruebas de laboratorio para monitorear la función hepática antes y durante el tratamiento, ya que el disulfiram puede afectar su hígado. Póngase en contacto con su proveedor de inmediato si desarrolla síntomas como coloración amarillenta de los ojos/piel, orina oscura, dolor de estómago, pérdida del apetito, fatiga y cambios en las heces (incluyendo la aparición de diarrea).

El efecto secundario más común del disulfiram es la somnolencia, pero en algunas personas se han producido reacciones adversas graves, incluida la insuficiencia hepática, la irritación de los nervios/neuropatía, la psicosis, el acné, el sarpullido, la impotencia y la inflamación del nervio óptico.

Existen algunos medicamentos que no deben tomarse junto con el disulfiram (metronidazol, dronabinol y ciertos medicamentos para la tos). Es importante informarles a sus proveedores que le han recetado disulfiram. No haga cambios en sus medicamentos sin consultar con su proveedor.

No se sabe si el disulfiram es seguro durante el embarazo o si puede pasar a la leche materna. Se le hará una prueba de embarazo antes de iniciar el tratamiento. Si en algún momento se entera de que está embarazada, avísele a su equipo médico. No se recomienda tomar disulfiram durante la lactancia.

Conserve el disulfiram a temperatura ambiente en un recipiente resistente a la luz. Mantenga todos los medicamentos fuera del alcance de los niños y las mascotas.

El consumo de alcohol es muy peligroso después de iniciar el tratamiento con disulfiram. Se recomienda avisarles a su familia, amigos y contactos cercanos que está tomando disulfiram y sobre el riesgo de una reacción severa en caso de volver al consumo de alcohol.
El disulfiram es sólo una parte de su tratamiento. Se recomienda que busque servicios de apoyo a la recuperación, junto con la parte médica de su tratamiento, para que le ayude en su proceso de recuperación.

_____	_____
Nombre del paciente	Fecha
_____	_____
Nombre del proveedor	Fecha

Consent for Treatment with Disulfiram, Hatian Creole Translation

KONSANTMAN POU TRETMAN AVÈK DISULFIRAM

Disulfiram (Antabuse) se yon medikaman ki apwouve pa FDA a pou trete twoub konsomasyon alkòl lakay moun ki te sispann konsome alkòl. Medikaman sa a lakoz kò a pa anmezi pou trete okenn alkòl. Lè alkòl la konsome, vin genyen yon reyaksyon ki depandan de dòz la. Ou PA dwe pran Disulfiram si ou te konsome alkòl pandan 12 dènye èdtan yo.

Plis ou te konsome yon kantite alkòl ki anpil, se plis reyaksyon alkòl-disulfiram nan ap vin pi fò. Reyaksyon an ka dire soti 30 minit pou rive plizyè èdtan, oswa kantite tan ki nesesè pou alkòl la kapab metabolize. Yon reyaksyon alkòl-disulfiram kapab rive pandan jiska 2 semèn aprè ou fin kanpe medikaman an.

Yon reyaksyon alkòl-disulfiram kapab genyen ladan pwoblèm respirasyon, doulè k ap lanse nan tèt ak kou, kèplen, vomisman, transpirasyon, swaf, palpitasyon, feblès, vètij, vizyon twoub, ak konfizyon. Gwo reyaksyon kapab genyen ladan ensifizans respiratwa, ensifizans kadyak, pèt konsyans, kriz, ak lanmò.

Menm ti dòz alkòl toupiti ka absòbe nan pafen, dezenfektan pou men, atik manje yo (vinegrèt, vinèg, sòs, ekstrè, elatriye), epi bwason ki genyen alkòl, kapab lakoz yon reyaksyon alkòl-disulfiram. Li enpòtan pou verifye etikèt atik ki pral anndan kò w oswa sou kò w yo.

Tès laboratwa pou kontwole fonksyon fwa a pral fèt anvan ak pandan tretman an, paske disulfiram ka afekte fwa w. Kontakte founisè ou an touswit si ou devlope sentòm tankou zye/po k ap vin jòn, pipi fonse, doulè nan lestomak, pèt apeti, fatig, ak chanjman nan poupou (ki genyen ladan devlopman dyare).

Efè segondè ki plis komen pou disulfiram se anvi dòmi, men te genyen gwo reyaksyon negatif lakay kèk moun, sa genyen ladan ensifizans nan fwa, iritasyon nève/newopati, sikoz, akne, gratèl nan po, enpisans, ak enflamasyon nè optik la.

Genyen kèk medikaman ou pa dwe pran avèk disulfiram (metronidazole, dronabinol, ak kèk medikaman pou tous). Li enpòtan pou fè founisè ou yo konnen ke yo te preskri w disulfiram. Pa chanje medikaman ou yo san ou pa verifye sa avèk founisè ou an.

Yo pa konnen si li san danje pou yon moun pran disulfiram pandan gwosès oswa si li ka pase nan lèt tete. Yo pral fè yon tès gwosès anvan tretman an kòmanse. Si ou aprann nenpòt lè ke ou ansent tanpri alète ekip medikal ou an. Yo pa rekòmande disulfiram pandan w ap bay tete.

Konsève disulfiram nan tanperati chanm, nan yon veso ki reziste ak limyè. Konsève tout medikaman yo lwen timoun ak bèt domestik yo.

Itilizasyon alkòl trè danjre aprè yon moun fin kòmanse tretman disulfiram nan. Li rekòmande pou alète fanmi w, zanmi w ak kontak pwòch ou yo k ap pran disulfiram epi konsènan risk pou yon gwo reyaksyon si ou ta tounen konsome l.

Disulfiram se sèlman yon pati nan tretman ou an. Li rekòmande pou chèche sèvis soutyen pou retablisman, ansanm ak pati medikal nan tretman ou an, pou ede w nan pwosesis retablisman ou an.

_____ _____

Non Pasyan an Dat

_____ _____

Non Founisè a Dat

Consent for Treatment with Disulfiram, Portuguese Translation

CONSENTIMENTO PARA TRATAMENTO COM DISULFIRAM

Disulfiram (Antabuse) é um medicamento aprovado pela FDA para tratar distúrbios de consumo de álcool em indivíduos que pararam o consumo de álcool. Este medicamento faz com que o corpo não consiga processar álcool. Quando álcool é consumido, ocorre uma reação dependente da dose. Disulfiram NÃO deve ser tomado se você tiver consumido álcool nas últimas 12 horas.

Quanto maior a quantidade de álcool consumida, mais forte é a reação de disulfiram-álcool. A reação pode durar de 30 minutos a várias horas, ou o tempo que levar para que o álcool seja metabolizado. Uma reação de disulfiram-álcool pode ocorrer por até 2 semanas depois de parar com o medicamento.

Uma reação de disulfiram-álcool pode incluir dificuldades para respirar, dor na cabeça e pescoço, náusea, vômito, suor, sede, palpitações, fraqueza, tontura, visão borrada e confusão. Reações graves podem envolver paradas respiratórias, paradas cardíacas, perda de consciência, convulsão e morte.

Até mesmo pequenas doses de álcool podem ser absorvidas de perfumes, higienizadores para mãos, alimentos (molhos, vinagres, marinadas, extratos, etc.), e bebidas alcoólicas, causando uma reação de disulfiram-álcool. É importante verificar os rótulos dos itens que serão consumidos.

Exames de laboratório para monitorar a função hepática serão realizados antes e durante o tratamento, pois disulfiram pode afetar o seu fígado. Entre em contato imediatamente com seu médico se você desenvolver sintomas, como amarelamento dos olhos/pele, urina escura, dor estomacal, pera de apetite, fadiga e mudança nas fezes (inclusive o desenvolvimento de diarreia).

O efeito colateral mais comum de disulfiram é tontura, mas reações adversas graves já ocorreram em indivíduos, inclusive problemas hepáticos, irritação dos nervos/neuropatia, psicose, acne, erupções cutâneas, impotência e inflamação do nervos óptico.

Há alguns medicamentos que não devem ser tomados com disulfiram (metronidazol, dronabinol, e alguns medicamentos para tosse). É importante avisar os médicos que você está tomando disulfiram. Não mude as medicações sem consultar o seu médico.

Não se sabe se disulfiram é seguro durante a gravidez ou se pode ser passado no leite materno. Um exame de gravidez será feito antes de começar o tratamento. Se você descobrir que está grávida, alerte sua equipe médica. Disulfiram não é recomendado durante a amamentação.

Armazene o disulfiram em temperatura ambiente, em um recipiente resistente à luz. Mantenha todos os medicamentos longe do alcance de crianças e animais de estimação.

O consumo de álcool é muito perigosos depois de iniciar o tratamento com disulfiram. Recomenda-se alertar a sua família, amigos e contatos próximos que você está tomando disulfiram e sobre o risco de uma reação grave caso tenha um retorno ao uso.

Disulfiram é somente uma parte do tratamento. Recomenda-se buscar serviços de apoio à recuperação juntamente com a parte médica do seu tratamento, para ajudá-lo no processo de recuperação.

_____	_____
Nome do paciente	Data
_____	_____
Nome do profissional	Data

Consent for Release of Information

CONSENT FOR RELEASE OF INFORMATION

I, _____, BORN ON _____,
(PATIENT NAME) (PATIENT BIRTH DATE)

AUTHORIZE _____ TO
(CLINIC OR PROVIDER'S NAME)

DISCLOSE TO _____
(NAME AND LOCATION OF PERSON/ORGANIZATION TO RECEIVE INFORMATION)

THE FOLLOWING INFORMATION: _____.

THE PURPOSE OF THIS DISCLOSURE IS: _____.

THIS AUTHORIZATION EXPIRES ON: _____, OR

WHENEVER _____ IS NO LONGER PROVIDING ME WITH SERVICES.

I understand that my records are protected under the Federal regulations and cannot be disclosed without my written consent unless otherwise provided for in the regulations. I also understand that I may revoke this consent at any time except to the extent that action has been taken in reliance on it.

Signature of patient _____ Dated _____

Signature of witness _____ Dated _____

ATTENTION RECIPIENT:
Notice Prohibiting Re-disclosure

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

Consent for Release of Information, Spanish Translation
CONSENTIMIENTO PARA DIVULGACIÓN DE INFORMACIÓN

YO, _____, NACIDO EL _____,
(NOMBRE DEL PACIENTE) (FECHA DE NACIMIENTO DEL PACIENTE)

AUTORIZO A _____ A
(CLÍNICA O NOMBRE DEL PROVEEDOR)

REVELAR A _____
(NOMBRE Y UBICACIÓN DE LA PERSONA/ORGANIZACIÓN QUE RECIBIRÁ LA INFORMACIÓN)

LA SIGUIENTE INFORMACIÓN: _____.

EL PROPÓSITO DE ESTA DIVULGACIÓN ES: _____.

ESTA AUTORIZACIÓN VENCE EL: _____, O

CUANDO _____ YA NO ME PRESTE SUS SERVICIOS.

Comprendo que mis registros están protegidos por las regulaciones federales y no pueden ser divulgados sin mi consentimiento por escrito, a menos que se disponga lo contrario en dichas regulaciones. Comprendo también que puedo revocar este consentimiento en cualquier momento, salvo en la medida en que se hayan tomado acciones en función del mismo.

Firma del paciente _____ Fechado el _____

Firma del testigo _____ Fechado el _____

ATENCIÓN DESTINATARIO:
Aviso de prohibición de redivulgación

Esta información le ha sido revelada de registros protegidos por las normas federales de confidencialidad (Parte 2 del Título 42 del Código de Regulaciones Federals [C.F.R., por sus siglas en inglés]). Las normas federales le prohíben hacer cualquier otra divulgación de esta información a menos que la divulgación esté expresamente permitida por el consentimiento escrito de la persona a la que pertenece o según lo permitido por la Parte 2 del Título 42 del C.F.R. Una autorización general para la divulgación de información médica o de otro tipo NO es suficiente para este propósito. Las normas federales restringen cualquier uso de esta información para investigar o procesar criminalmente a cualquier paciente que se encuentre en tratamiento por abuso de alcohol o drogas.

Consent for Release of Information, Haitian Creole Translation
KONSANTMAN POU DIVILGASYON ENFÒMASYON

MWENMENM _____, KI TE FÈT NAN DAT _____,
(NON PASYAN AN) (DAT NESANS PASYAN AN)

OTORIZE _____ POU
(NON KLINIK OSWA NON FOUNISÈ A)

DIVILGE BAY _____
(NON AK ADRÈS MOUN NAN/ÒGANIZASYON K AP RESEVWA ENFÒMASYON YO)

ENFÒMASYON SA YO: _____.

OBJEKTIF DIVILGASYON SA A SE: _____.

OTORIZASYON SA A EKSPIRE NAN DAT: _____, OSWA

NENPÒT LÈ _____ P AP BAN M SÈVIS ANKÒ.

Mwen konprann ke dosye mwen yo pwoteje selon regleman Federal yo epi yo pa ka divilge yo san konsantman ekri m sof si sa endike yon lòt fason nan regleman yo. Epitou mwen konprann ke mwen kapab revoke konsantman sa a nenpòt lè eksepte nan mezi yo te pran yon aksyon sou baz konsantman an.

Siyati pasyan an _____ Dat _____

Siyati temwen an _____ Dat _____

POU BENEFISYÈ:
Avi ki Entèdi Re-divilgasyon

Yo te divilge enfòmasyon sa yo avèk ou apati dosye ki pwoteje pa règ konfidansyalite Federal la (42 C.F.R. Pati 2). Règ federal yo entèdi w fè nenpòt lòt divilgasyon de enfòmasyon sa yo sof si lòt divilgasyon an otorize yon fason ouvèt pa konsantman ekri moun ki posede enfòmasyon yo oswa jan li otorize yon lòt fason pa 42 C.F.R. Pati 2. Yon otorizasyon jeneral pou piblikasyon enfòmasyon medikal oswa lòt enfòmasyon PA ase pou objektif sa a. Règ federal yo mete limit sou tout itilizasyon enfòmasyon sa yo pou fè ankèt kriminèl oswa pou pouswiv tout pasyan k ap konsome alkòl oswa pasyan k ap abize dwòg.

Consent for Release of Information, Portuguese Translation
CONSENTIMENTO PARA LIBERAÇÃO DE INFORMAÇÕES

EU, _____, NASCIDO EM _____,
(NOME DO PACIENTE) (DATA DE NASCIMENTO DO PACIENTE)

AUTORIZO _____ A
(NOME DO PROFISSIONAL OU CLÍNICA)

DIVULGAR PARA _____
(NOME E LOCALIZAÇÃO DA PESSOA/ORGANIZAÇÃO A RECEBER INFORMAÇÕES)

AS SEGUINTES INFORMAÇÕES: _____.

O OBJETIVO DESTA DIVULGAÇÃO É: _____.

ESTA AUTORIZAÇÃO EXPIRA EM: _____, OU

QUANDO _____ NÃO ME PRESTAR MAIS SERVIÇOS.

Entendo que meus registros são protegidos sob os regulamentos federais e não podem ser divulgados sem o meu consentimento por escrito, salvo disposição em contrário nos regulamentos. Eu também entendo que posso revogar esse consentimento a qualquer momento, exceto na medida em que a ação tiver sido tomada em dependência dele.

Assinatura do paciente _____ Datado _____

Assinatura da testemunha _____ Datado _____

ATENÇÃO DESTINATÁRIO:
Aviso proibindo a redivulgação

Esta informação foi divulgada a você dos registros protegidos por regras federais de confidencialidade (42 C.F.R. Parte 2). As regras federais proíbem de fazer qualquer divulgação adicional dessas informações, a menos que a divulgação mais aprofundada seja expressamente permitida pelo consentimento por escrito da pessoa a quem se refere, ou conforme permitido de outra forma pela 42 C.F.R. Parte 2. Uma autorização geral para a liberação de informações médicas ou de outras informações não é suficiente para essa finalidade. As regras federais restringem qualquer uso dessas informações para investigar criminalmente ou processar qualquer paciente de abuso de álcool ou medicamentos.

OBAT Treatment Agreement and Clinic Polices

Treatment Agreement Goals:

- Engage patients in the treatment plan along with the OBAT team. Encourage patient involvement in their treatment.

- Provide reassurance about common issues, such as concerns about entering treatment (provide education around options and support), the risks of transferring care from one form of medication treatment to another, or ambivalence about such changes.

- Reinforce that a substance use disorder is a chronic medical condition that affects numerous aspects of a person's wellbeing. The OBAT team will support the patient throughout the recovery process, especially in the event of recurrent or ongoing use.

- Provide an opportunity for patients to ask questions and learn about available resources.

- Standardize treatment requirements across all staff members in the clinic to better assist the patient in reaching their recovery goals.

- Provide clarity and set expectations for both patients and the treatment team. For example:

    - The patient can expect:
        - To be treated with dignity and respect.
        - To be notified if the office is closed and how to seek assistance if needed.
        - That confidentiality will be maintained in compliance with CFR 42.
        - To have a means for contacting a member of the OBAT team or a colleague for emergencies at night, weekends, and when the office is closed.

    - The OBAT team can expect:
        - To be treated with dignity and respect.
        - To be notified if the patient is unable to attend an appointment.
        - To have an updated means for contacting the patient to assist with treatment needs.

Treatment Agreement Components:

The areas addressed and the level of detail in the treatment agreement should be catered to clinic needs, with the larger goal of ensuring individualized and patient-centered care. It is important that the treatment agreement reflects the practices of the clinic and is periodically reviewed to ensure that safety and harm reduction strategies are at the forefront. Depending on the setting, treatment agreements can range from two sentences long to more lengthy documents. The following information may or may not be addressed in the treatment agreement.

- *Clinical Appointments:* All patients who participate in the OBAT program must attend appointments with their OBAT providers and nurses. Appointments with the OBAT team are part of the treatment plan. It is the patient's responsibility to reschedule appointments if needed.

- *Random Call-backs*: To monitor and verify the proper use of the buprenorphine, the OBAT nurse may sporadically call the patient to come into the clinic for a random toxicology test and a medication count. The patient must return this call promptly and come to the clinic within 24 hours of the initial call with the medicine bottle and all of the remaining buprenorphine tablets or films. For this policy to function, the team must have current and accurate contact information; patients should be encouraged to keep this information up to date with staff. If the patient does not return for a random callback monitoring visit, then the OBAT team will meet and reassess the treatment plan with adjustments (e.g., shorter times between office visits, shorter prescriptions, no refills, etc.). While random callbacks may be a useful tool for assessing medication adherence, the goal is for providers and staff to cultivate a trusting relationship with patients for the disclosure of substance use or lack of medication use, for this is more beneficial for reaching overall treatment goals.

- *Counseling:* Patients are strongly encouraged to engage in counseling and/or similar intensive recovery support services; if needed, patients should receive assistance with referrals and linkages for counseling and recovery support programs from OBAT staff. Patients should not be discharged from the OBAT program if they do not comply with the counseling recommendation, as these individuals may be at increased risk for ongoing substance use and overdose. However, patients who do not engage in counseling or outside recovery support services should receive more intensive monitoring from the OBAT team.

    - Patients receiving counseling through external organizations should sign a consent to release information for OBAT staff to communicate with their therapist in order to promote recovery through coordination of care.

    - Groups, Intensive Outpatient Program (IOP), Partial Hospitalization Programs (PHP), residential programs, and halfway houses are methods of treatment that are accepted as counseling.

    - If a patient's counselor or other medical provider recommends that they seek psychiatric evaluation, then the patient is required to follow through with this and the decided-upon plan of treatment.

    - Educate patient at the onset of treatment and throughout care about the importance of adjunct counseling and recovery support and their role in recovery. Reinforce that medication alone rarely addresses all aspects of recovery, and building recovery capital will improve their chances of success.

    - Reinforce that recovery is a process that will take a lot of support, time, and commitment. Attending peer-support groups may not be the right treatment modality for the patient at the start of treatment but something that they may

choose later on. They may also decide that peer-support groups are not helpful and pursue other recovery support options. It is important that the patient is empowered and given options.

  - AA, NA, and SMART Recovery are examples of self-help treatment options.

  - For some patients, getting a sponsor or forming a healthy relationship with another person in recovery may be a goal towards which they work. Patients often report that making this connection is an important piece of their recovery process.

  - Handing out AA, NA, SMART Recovery, and other meeting books, or providing their websites to patients, is a way to assist patients by highlighting some meetings near their work or home at hours that are convenient for them.

- *Medication Refills:* Prescriptions are processed following a scheduled visit (telehealth, office, or group) or phone encounter. Patients are expected to take their medication as directed and to store it in a secure and safe location. Prescriptions should last until the next scheduled appointment. Patients must keep their scheduled appointments to obtain refills. It is encouraged that patients communicate openly with their treatment team regarding the amount of medication they are taking. Buprenorphine is a controlled substance, so patients may not be able to refill prescriptions early, including in the case of lost or stolen medication. It is ideal for patients to have an identified pharmacy whose information is kept on file to decrease the risk for pharmacy issues or red flags due to numerous pharmacies noted on the PDMP. It is strongly advised that patients do not carry buprenorphine on their person. Patients are expected to disclose to OBAT staff if they are being seen by other providers (e.g., pain management specialists, psychiatrists, counselors, physicians, etc.) and whether they have been prescribed medications by these providers.

- *Toxicology Screening:* Toxicology samples are utilized to assess treatment progress. While sample collection is a monitored process, observed sample collections are discouraged. In the event of a questionable sample, the patient will meet with the OBAT NCM to discuss any concerns. This may occur before and/or after a repeat toxicology sample is requested. At this time, it is important for the NCM to ensure that the OBAT treatment team is here to assist in the recovery process and that disclosing substance use is an important component of that process.

- *Behavior Agreement:* Patients, visitors, and staff are expected to maintain appropriate behaviors in the clinic and on the grounds of the OBAT program. As a patient in the OBAT program, the patient has made a voluntary decision to participate in this program. To provide an optimal treatment environment for all patients, they are expected to maintain appropriate behaviors including those listed below. A safe and supportive treatment environment is critical in promoting recovery; thus, behaviors that violate this policy may be grounds for discharge from the program.

- No illegal activities in the clinic environment or on hospital grounds.
- No disruptive behavior (loud or aggressive behavior, etc.) will be tolerated in the clinic.
- No verbal or physical threats towards anyone (including OBAT staff, clerical, pharmacy, other patients, etc.) will be tolerated.
- No weapons or other harmful objects are allowed on clinic property.

Sample OBAT Treatment Agreement

OBAT TREATMENT AGREEMENT

I freely and voluntarily agree to accept this treatment agreement, as follows.

I agree to do my best to keep my scheduled appointments with my provider and nurse and that it is my responsibility to call the clinic if I will be late/early or need to reschedule my appointment.

I will report any substance use and discuss high-risk behaviors with my treatment team. Being clear about these will help decrease my risk of overdose or infection and will protect my safety.

If I continue to struggle with ongoing substance use, my treatment plan may be changed, and this could require transfer to more intensive treatment.

I will attend my appointments prior to running out of prescriptions and keep my medication in a safe and secure place. I understand that my medication might not be refilled early, even if it is lost or stolen.

I will inform my provider if the medication I am receiving no longer works for me so that we can make a new treatment plan.

I agree not to sell, share, or give away any of my medication.

I will not engage in behavior that jeopardizes the safety of anyone in the clinic. Doing so may be considered reason for discharge from the program.

I will not falsify or tamper with drug tests. I understand that if I test positive for substances not prescribed to me, or if I test negative for substances that are prescribed to me, my treatment plan will be adjusted (for example, I may be asked to return to clinic more frequently).

I agree to random call-back visits that include toxicology screens and medication counts, which require me to respond within 24 hours by telephone.

I agree that if I obtain medication from any other prescribers, pharmacies, or sources that I will inform my OBAT team.

I understand that mixing buprenorphine with other substances, especially those which can cause sedation such as benzodiazepines or alcohol, can be dangerous. I understand that deaths have been reported among persons mixing buprenorphine with sedating substances.

If I am able to become pregnant and of childbearing age, I will alert my health provider if there is a chance that I am pregnant so they can assist me in the proper steps to keep me and my unborn baby safe. This does not mean I will be discharged from treatment.

If at any time I am discharged from this program I may be reconsidered at a future time.

_____	_____	_____
Printed Name	Signature	Date
_____	_____	_____
Witness Printed Name	Signature	Date

Sample OBAT Treatment Agreement, Spanish Translation

ACUERDO DE TRATAMIENTO OBAT

Acepto libre y voluntariamente este acuerdo de tratamiento, como se describe a continuación. Estoy de acuerdo en hacer todo lo posible para acudir a las citas programadas con mi proveedor y personal de enfermería y que es mi responsabilidad llamar a la clínica si voy a llegar tarde/temprano o si necesito reprogramar mi cita.

Informaré sobre cualquier consumo de sustancias y conversaré sobre los comportamientos de alto riesgo con mi equipo de tratamiento. Tener esto claro me ayudará a disminuir el riesgo de sobredosis o infección y protegerá mi seguridad.

Si continúo teniendo problemas con el consumo continuo de sustancias, es posible que se modifique mi plan de tratamiento, lo que podría requerir el traslado a un tratamiento más intensivo.

Acudiré a mis citas antes de que se me terminen las recetas y guardaré mis medicamentos en un lugar seguro y protegido. Comprendo que es posible que mi medicamento no se pueda resurtir antes de tiempo, incluso en caso de pérdida o robo.

Le informaré a mi proveedor si el medicamento que estoy tomando ya no me sirve para que podamos elaborar un nuevo plan de tratamiento.

Estoy de acuerdo en no vender, compartir o regalar ninguno de mis medicamentos.

No adoptaré comportamientos que pongan en peligro la seguridad de ninguna persona en la clínica. Hacerlo puede considerarse un motivo para ser dado de baja del programa.

No falsificaré ni manipularé las pruebas de detección de drogas. Comprendo que si doy positivo para sustancias que no me han sido recetadas, o si doy negativo para sustancias que me han sido recetadas, mi plan de tratamiento será ajustado (por ejemplo, se me puede pedir que vaya a la clínica con más frecuencia).

Estoy de acuerdo con las visitas aleatorias por llamada que incluyen exámenes toxicológicos y recuentos de medicamentos, que requieren que responda en un plazo de 24 horas por teléfono.

Estoy de acuerdo en que si obtengo medicamentos por parte de otros prescriptores, farmacias o fuentes, se lo comunicaré a mi equipo de OBAT.

Comprendo que mezclar la buprenorfina con otras sustancias, especialmente las que pueden causar sedación, como las benzodiacepinas o el alcohol, puede ser peligroso. Comprendo que se han registrado muertes entre personas que mezclan la buprenorfina con sustancias sedantes.

Si puedo quedar embarazada y estoy en edad fértil, le avisaré a mi proveedor de atención médica si existe la posibilidad de que esté embarazada para que pueda ayudarme a tomar las medidas adecuadas para mantenernos a salvo a mí y a mi bebé por nacer. Esto no significa que se me dará de baja.

Si en algún momento se me da de baja de este programa, se me podrá reconsiderar en un futuro.

_____	_____	_____
Nombre en letra de imprenta	Firma	Fecha
_____	_____	_____
Nombre del testigo en letra de imprenta	Firma	Fecha

Sample OBAT Treatment Agreement, Haitian Creole Translation

AKÒ POU TRETMAN NAN OBAT

Mwen dakò ak tout libète m epi ak tout volontè m pou aksepte akò sou tretman sa a, jan sa swiv la.

Mwen dakò pou m fè tout sa m kapab pou swiv randevou mwen genyen ki pwograme avèk founisè ak enfimyè mwen an epi se responsablite m pou rele klinik la si mwen pral anreta/si m ap vini anvan lè oswa si mwen bezwen replanifye randevou mwen an.

M ap deklare tout konsomasyon sibstans epi m ap diskite sou konpòtman wo-risk avèk ekip tretman mwen an. Lè m byen konprann sa yo, sa pral ede diminye risk pou m fè òvèdòz oswa enfeksyon epi li pral pwoteje sekirite m.

Si mwen kontinye lite avèk konsomasyon sibstans pèmanan, yo kapab chanje plan tretman mwen an, epi sa ka mande transfè nan plis tretman entansif.

Mwen prale nan randevou mwen yo anvan preskripsyon yo fini epi m ap konsève medikaman mwen yo nan yon kote ki san danje epi ki sekirize. Mwen konprann ke medikaman mwen an kapab pa renouvle bonè, menm si li pèdi oswa menm si yo vòlè l.

Mwen pral enfòme founisè mwen an si medikaman m ap resevwa a pa fonksyone pou mwen ankò pou nou ka fè yon nouvo plan tretman.

Mwen dakò pou m pa vann, pataje, oswa bay okenn nan medikaman mwen yo.

Mwen p ap angaje nan konpòtman ki mete sekirite okenn moun nan klinik la an danje. Lè mwen fè sa, sa kapab konsidere kòm rezon pou retire m nan pwogram nan.

Mwen p ap falsifye oswa trafike tès medikaman yo. Mwen konprann ke si mwen teste pozitif pou sibstans yo pa preskri m, oswa si mwen teste negatif pou sibstans yo preskri m, yo kapab ajiste plan tretman mwen an (pa egzanp, yo kapab mande m pou retounen nan klinik la pi souvan).

Mwen dakò ak vizit rapèl oaza ki genyen ladan tès toksikoloji ak kontaj medikaman, ki mande m pou reponn pa telefòn nan delè ki pa depase 24 èdtan.

Mwen dakò ke si mwen jwenn medikaman nan men nenpòt lòt preskriptè, famasi, oswa lòt sous, m ap enfòme ekip OBAT mwen an.

Mwen konprann ke lè mwen melanje buprenorphine avèk lòt sibstans, espesyalman sila yo ki ka lakoz sedasyon tankou benzodiazepine yo oswa alkòl, sa ka danjre. Mwen konprann ke yo te deklare lanmò lakay moun ki melanje buprenorphine avèk sibstans sedatif yo.

Si mwen vin tonbe ansent epi mwen nan laj pou fè timoun, mwen pral alète founisè swen sante mwen an si genyen yon chans pou m ansent pou yo ka asiste m nan etap ki apwopriye pwoteje mwenmenm avèk tibebe m lan. Sa pa vle di yo pral retire m nan tretman an.

Si nenpòt lè yo retire m nan pwogram sa a, yo kapab konsidere m yon lòt fwa alavni.

Non ak Lèt Detache	Siyati	Dat
Non Temwen ak Lèt Detache	Siyati	Dat

Sample OBAT Treatment Agreement, Portuguese Translation

CONTRATO DE TRATAMENTO OBAT

Eu concordo livre e voluntariamente em aceitar este contrato de tratamento, como segue.
Eu concordo em fazer o meu melhor para manter meus compromissos agendados com o meu profissional e enfermeiro, e que é minha responsabilidade ligar para a clínica se eu estiver atrasado/precisar ou tiver de reagendar minha consulta.

Relatarei qualquer uso de substâncias e discutirei comportamentos de alto risco com minha equipe de tratamento. Ser claro sobre isso ajudará a diminuir o risco de overdose ou infecção e proteger minha segurança.

Se eu continuar a ter dificuldades com o abuso contínuo de substâncias, meu plano de tratamento pode ser alterado, e isso poderia exigir transferência para um tratamento mais intensivo.

Comparecerei a minhas consultas antes de ficar sem prescrições, e manterei meus medicamentos em um local seguro e protegido. Entendo que meus medicamentos podem não ser recarregados antecipadamente, mesmo se perdidos ou roubados.

Informarei ao meu profissional se o medicamento tomado não mais funcionar para mim, para que possamos fazer um novo plano de tratamento.

Eu concordo em não vender, compartilhar ou dar qualquer medicamento meu.

Eu não me comportarei de forma a prejudicar a segurança de qualquer pessoa na clínica. Fazer isso pode ser considerado motivo para alta do programa.

Não falsificarei ou burlarei os exames dos medicamentos. Eu entendo que, se eu testar positivo para substâncias não prescritas para mim, ou se eu testar negativo para substâncias prescritas para mim, meu plano de tratamento será ajustado (por exemplo, posso ser solicitado a retornar para a clínica com mais frequência).

Eu concordo com visitas aleatórias que incluem exames de toxicologia e contagens de medicamentos, que exigem uma resposta dentro de 24 horas por telefone.

Eu concordo que, se eu obter medicamentos de outros médicos, farmácias ou fontes, informarei esse fato à equipe OBAT.

Eu entendo que misturar buprenorfina com outras substâncias, especialmente substâncias que podem causar sedação, como benzodiazepinas ou álcool, pode ser perigoso. Eu entendo que foram relatadas mortes entre pessoas que misturaram buprenorfina com substâncias sedativas.

Se eu tiver capacidade e a idade apropriada para engravidar, avisarei meu profissional de saúde se houver a chance de eu estar grávidas para que ele possa me ajudar a manter eu mesma e meu bebê seguros.. Isso não significa que receberei alta do tratamento.

Se eu ganhar alta deste programa em qualquer momento, poderei ser reconsiderado no futuro.

_____	_____	_____
Nome legível	Assinatura	Data
_____	_____	_____
Testemunha Nome legível	Assinatura	Data

Managing Opioid-Related Withdrawal in OBAT*

Withdrawal Symptom	Adjunctive Medication Options
Anxiety	• Hydroxyzine • Clonidine • Lofexidine
Insomnia	• Sedating antidepressant (e.g., trazodone) • Antihistamine (e.g., hydroxyzine, diphenhydramine)
Musculoskeletal Pain	• NSAIDs • Acetaminophen • Heat packs • Topical analgesics
Gastrointestinal Distress	• Antiemetic (e.g., ondansetron) • Antispasmodics (e.g., dicyclomine) • Antidiarrheal (e.g., bismuth subsalicylate) • Oral hydration
Restless legs	• Muscle relaxant (e.g., tizanidine) • Dopamine promoter (i.e., ropinirole)
Rhinorrhea	• Antihistamines (e.g., hydroxyzine, diphenhydramine)

*adapted from PCSS MAT Waiver training course

A Guide for Patients Beginning Buprenorphine Treatment

Before you begin you want to feel sick from your withdrawal symptoms

It should be at least ...

- **12 hours** since you used heroin/or pain pills
- **16 hours** since you last used fentanyl
- 48-72 hours since you used methadone
- If you used more than one drug, use the longest wait time before starting buprenorphine.

You should feel at least four of these symptoms...

- Restlessness
- Frequent yawning
- Enlarged pupils
- Runny nose/eyes
- Body aches
- Tremors/twitching
- Chills or sweating
- Anxious or irritable
- Goose bumps
- Stomach cramps, nausea, vomiting or diarrhea

Once you are ready, follow these instructions to start the medication

DAY 1:
8-24 mg of buprenorphine

Step 1.

Take the first dose

4 to 8 mg

Wait 45 minutes

- Put the tablet or strip under your tongue
- Keep it there until fully dissolved (about 15 min.)
- Do NOT eat, drink or smoke 15 min before
- Do NOT swallow the medicine

Step 2.

Still feel sick? Take next dose

4 to 8 mg

Wait 6 hours

- **You may need up to 24mg to manage withdrawal on day 1.**
- **Most will do well with 16mg**

Step 3.

Still uncomfortable? Take last dose

4 to 8 mg

Stop

- Stop after this dose
- Do not exceed 24mg on Day 1

DAY 2:
8 to 16 mg of buprenorphine

Take 8 to 16 mg dose

8 to 16 mg

- If you took 16mg or more on day 1 take a total of 16mg
- If you took less than 16mg and felt well take that dose.
- If you have questions or troubles follow up with the clinical team.

Contact the clinic or emergency number given to you if your symptoms get worse.

Boston Medical Center Office Based Addiction Treatment Training and Technical Assistance + 12/2020
Note: This is a modified version of a NIDA guidance document 2/9/2020

Guía para Pacientes que están empezando el tratamiento con Buprenorfina (Buprenorphine, en inglés) en casa

Para empezar Ud. tendría que sentirse muy enfermo con los síntomas de abstinencia

Debe haber pasado por lo menos…

- 12 horas desde que uso heroína
- 12 horas desde que aspiro pastillas para el dolor oxicodona (Oxycontin)
- 16 horas desde que uso fentanilo
- 48-72 horas desde que uso metadona (methadone)

Debiera sentir por lo menos cuatro de los siguientes síntomas:

- Intranquilidad
- Bostezo exagerado
- Pupilas dilatadas
- Moqueo nasal/ojos llorosos
- Dolor de cuerpo
- Temblores/ espasmos
- Escalofríos o sudoración
- Ansiedad o irritabilidad
- Se le pone la piel de gallina
- Cólico de estómago, náuseas, vómitos o diarrea

Una vez que está listo para empezar, siga las siguientes instrucciones para comenzar con la medicación

DÍA 1:

8-24 mg de buprenorfina (buprenorphine, en inglés)
La mayoría de las personas se sienten mejor el primer día después de tomar 8-12 mg (la dosis depende de cuando empiece).

Paso 1

Tome la primera dosis

4 a 8 mg

Espere 45 minutos

- Póngase la tableta o la tira debajo de la lengua
- Manténgala allí hasta que se disuelva completamente (más o menos 15 minutos)
- NO coma ni beba nada después de tomar la dosis.
- NO se trague la medicina

Paso 2

¿Todavía se siente enfermo? Tómese la siguiente dosis

4 a 8 mg

Espere 6 horas

La mayoría de personas se sienten mejor después de dos dosis de 8 mg.

- Puede que necesite hasta 24 mg para controlar el síndrome de abstinencia.
- La mayoria solo necesita 16 mg.

Paso 3

¿Todavía no se siente bien? Tómese la última dosis

4 a 8 mg

PARE

- Pare después de ésta dosis
- No exceda los 24 mg en el día 1

DÍA 2:

8 a mg de 16 buprenorfina (buprenorphine, en inglés)

Tome una sola dosis entre 8mg a 16 mg

La mayoría de las personas se sienten mejor con la dosis de 16 mg

8mg a 16 mg

- Si Ud. ha tomado 16 mg o más, tomése hasta 16mg.
- Si Ud. ha tomado menos de 16 mg y se encuentra bien, tomése esa dosis
- Si tiene problemas o preguntas, contacte con la clínica

Si sus síntomas se comienzan a empeorar mientras está empezando el tratamiento con buprenorfina (buprenorphine en inglés) y ésto sucede antes de su cita como paciente externo, contacte con la clínica o llame a emergencias.

Boston Medical Center Office based Addiction Treatment Training and Technical Assistance + 12/2020
Note: This is a modified version of a NIDA guidance document 2/9/2020

APPENDIX

HELPS Brain Injury Screening Tool [1]

Name: _____ **Date of Screening:** _____

Screener's Name: _____

H Have you ever Hit your Head or been Hit on the Head? ☐ Yes ☐ No

Note: Prompt client to think about all incidents that may have occurred at any age, even those that did not seem serious: vehicle accidents, falls, assault, abuse, sports, etc. Screen for domestic violence and child abuse, and also for service related injuries. A TBI can also occur from violent shaking of the head, such as being shaken as a baby or child.

E Were you ever seen in the Emergency room, hospital, or by a doctor because of an injury to your head? ☐ Yes ☐ No

Note: Many people are seen for treatment. However, there are those who cannot afford treatment, or who do not think they require medical attention.

L Did you ever Lose consciousness or experience a period of being dazed and confused because of an injury to your head? ☐ Yes ☐ No

Note: People with TBI may not lose consciousness but experience an "alteration of consciousness." This may include feeling dazed, confused, or disoriented at the time of the injury, or being unable to remember the events surrounding the injury.

P Do you experience any of these Problems in your daily life since you hit your head? ☐Yes ☐No

Note: Ask your client if s/he experiences any of the following problems, and ask when the problem presented. You are looking for a combination of two or more problems that were not present prior to the injury.

Mark all that apply:

☐ Headaches ☐Dizziness ☐ Anxiety
☐Depression ☐Difficulty concentrating ☐Difficulty remembering
☐Poor problem solving ☐Change in relationships with others
☐Difficulty performing your job/school work/daily tasks
☐Poor judgment (fired from job, suspended/expelled from school or day program, arrests, fights)

S Any significant Sicknesses? ☐ Yes ☐ No

Note: Traumatic brain injury implies a physical blow to the head, but acquired brain injury may also be caused by medical conditions, such as: brain tumor, meningitis, West Nile virus, stroke, seizures. Also screen for instances of oxygen deprivation such as following a heart attack, carbon monoxide poisoning, near drowning, near suffocation, failed suicide attempts, substance abuse and overdose history.

For Score Go to Next page

HELPS Brain Injury Screening Tool [1]

MASSACHUSETTS

Traumatic Brain Injury (TBI), an alteration in brain function or other evidence of brain pathology, caused by an external force, is a common problem. Often traumatic brain injuries are undiagnosed or misdiagnosed. Not everyone who experiences a TBI will have long term impairments or problems. Alternatively, some people who do suffer from a TBI will not realize that subsequent problems are due to the earlier injury. Even a minor injury can result in lasting problems. **To guide you through the screening process each letter in the HELPS acronym stands for a question to ask the consumer.**

The screening tool is recommended to be administered and used as needed in the following situations:

- Routinely completed at Intake, Reassessment AND/OR Redetermination of services.
- When there is any suspected trauma that could have caused a brain injury.
- When a consumer is having difficulty functioning or is exhibiting unexplained behaviors.
- When you suspect the possibility of a dual diagnosis, such as substance abuse, depression, etc., and TBI.

SCORING THE HELPS SCREENING TOOL

A HELPS screening is considered positive for a possible TBI when the following 3 items are identified:

1. An event that could have caused a brain injury (yes to H, E **or** S), **AND**
2. A period of loss of consciousness or altered consciousness after the injury or another indication that the injury was severe (yes to L or E), **AND**
3. The presence of two or more chronic problems listed under P that were not present before the injury.

THINGS TO CONSIDER

- A positive screening is **not sufficient to diagnose TBI** as the reason for current symptoms and difficulties - other possible causes may need to be ruled out.
- **Some individuals could present exceptions** to the screening results, such as people who do have TBI-related problems but answered “no” to some questions.
- Consider positive responses within the context of the person’s self-report and documentation of altered behavioral and/or cognitive functioning

RECOMMEND NEXT STEPS

- Confer with the consumer about your findings.
- Advise the consumer to seek further medical evaluation with his/her Primary Care Physician
- Report positive TBI screening tool score result to Team supervisor or RN.
- Document reasons for suspecting a TBI and HELP tool score in the consumer file.
- Adjust service plan/goals when appropriate.
- Refer consumer for other resources or services for which he/she may be eligible for.
- Support him/her with follow through -if needed for specialty referrals and or medical treatment of TBI.
- **Make accommodations for symptoms of TBI** (e.g. cuing for problems with memory or initiation).

Accommodations and Compensatory Strategies For Cognitive Deficits Resulting from a Brain Injury

This handout is organized by cognitive deficit, followed by how the deficit may appear when interacting with an individual, and compensatory strategies/accommodations that may be helpful while working together. An individual may have one or more of these impairments.

Note that some symptoms of brain injury can be masked by other medical conditions or exacerbated by co-morbidities such as age, poor health, substance use, and mental illnesses. Customize your approach in partnership with the individual. Pick strategies that are achievable for the individual. Build in support for follow through of selected strategies outside your time together. Identify people or means to reinforce compensatory strategies. Make sure to check in with the individual and assess if strategies are working, otherwise readjust.

For those with cognitive deficits:

- Find out whether the individual is able to comprehend both written and spoken language (if someone is not able to speak (or speak easily), inquire as to alternative methods of expression (e.g., writing or gestures)**
- Ask how well, or if the person is able to read and write
- Ask the individual "what helps you with _____?" (i.e., cognitive deficit or ADL)
- Apply contextual understanding of the person by asking (e.g. understand what has and hasn't worked in the past, and how can you help)

Type of Deficit	Appearance (What it may look like)	Accommodations and Compensatory Strategies
Attention and Concentration	• Fidgeting, squirming in seat • Unable to sit still • Low frustration tolerance • Talks excessively • Unable to stay on topic • Impulsivity (disinhibition)	• Grab the individuals' attention prior to beginning a task ○ Check to make sure there is good eye contact ○ Don't give instruction while individual is busy or preoccupied with another task or activity; stop the individual from what he or she is doing to make sure you have their attention ○ Begin an activity with something engaging and/or involves participation ○ Focus on one task at a time • During tasks, reduce distractions ○ Have individual work in environment that is quiet and that has few interruptions (such as persons walking through work area, etc.) • Keep instructions brief, simple, and to the point ○ Shorten tasks and sentences ○ Use cue words to alert the individual to pay attention (e.g., "look", "listen") • Establish non-verbal cueing system (eye contact, touch) Additional Considerations:

		○ Have client participate in discussion and development of plan ○ Use frequent short breaks or rest periods ○ Ask individual to repeat or summarize information back in own words to insure comprehension ○ Remind the individual to focus, and learn to monitor focus ○ Ear plugs and sunglasses are helpful for some individuals to reduce excess sensory stimuli ○ Develop routines and stick with them ○ Watch for signs of fatigue or overload ○ Keep regular sleep schedule ○ Avoid alcohol and other drugs
Slow Processing	• Slow to respond • Appears to not be paying attention • Appears confused • Does not follow instructions	• Simplify information ○ You may choose to say one piece of information at a time • Speak slowly ○ To ensure comprehension, ask the individual to summarize and rephrase back to you what they heard • Provide additional time for individual to review information ○ Include additional time as needed for the person to process and respond ○ Count silently to yourself after asking a question to allow for extra time • Utilize checklists and a written schedule of routines • Provide cues for organizing (“first do this, then do this”) • Offer assistance with completing forms • Additional considerations: ○ Slower cognitive processes can be accompanied by slower physical or motoric activity; the individual may need a longer period of time to complete tasks. ○ Watch for individual being overwhelmed by the information being shared ○ Be patient.
Memory		• Repeat information and summarize • Keep information tangible and relevant • Provide a written summary, cue them to record important information (e.g., dates and action items)

Memory	• Unable to remember more than one thing at a time
	• Unable to remember details
	• Appears disorganized
	• Appears to have an "attitude problem"
	• Appears manipulative
		• Considering writing down step-by-step directions (including a written schedule of a daily routine)
		• Teach individual to use a remind system (e.g., a planner) and review new information frequently
		  ○ Use an **information logbook** (for communication of persons working different schedules)
		  ○ Encourage individual to use self-reminders, such as post-it notes or notebooks
		• Stick to routine as much as possible
		• Practice and reinforce strategies until they become automatic
		• Teach **"chunking"** as a way to aid in retention (individual pieces of information are broken down and then meaningfully grouped together)
		• If reading/writing is difficult:
		  ○ Use an audio recorder
		• Additional Considerations:
		  ○ utilizing smart phone features such as calendar, alarms, notes
		  ○ Label cabinets, drawers, and closets (using words or pictures)
		  ○ Break tasks into smaller pieces, add additional steps after the initial tasks have been mastered, and link new learning to previous knowledge
		  ○ Shorter, more frequent work shifts are preferable to longer, less frequent shifts
		  ○ Keep regular sleep schedule
		  ○ Avoid alcohol and other drugs
		
		Things to do at home:
		• Use "word association" - Names, faces, grocery list
		• Repeat things out loud - Say it multiple times
		• Agree on the same place for regularly used items (keys, calculator, etc.) - Ask everyone in home to return things to the chosen spot.
		• Use sound or sight cues - Wristwatch alarms, egg/stove timers, post-it notes, bulletin boards or stickers
		• Set up: 1) filing and bill payment systems, 2) a message center, 3) organize and label cupboard, 4) use storage containers/boxes
		• Make a meal plan with favorite dishes and the groceries needed, make a monthly schedule of meals,

Memory		grocery shop using a check list • Practice **safe** habits: 1) use appliances with automatic shut-off, 2) stay in the kitchen when cooking, 3) use a timer or set and alarm when cooking, 4) avoid cooking when extremely tired or distracted • Focus on diet (promote intake of anti-inflammatory / antioxidant foods)
Executive Function	**Impaired Sensory Motor Skills:** • Appear overwhelmed • Emotional melt down • Irritable, short fused • May appear oppositional • Shuts down **Reasoning:** • Concrete thinkers • Cannot think of alternative solutions • Difficulties answering open-ended questions • Difficulties learning from experience, cause and effect **Difficulty with initiating action and/or following through with tasks**: • Appears lazy or spacey	**Impaired Sensory Motor Skills:** • Keep environment quiet ○ Keep noise and lights to a minimum • Keep sessions short to minimize onset of headaches and fatigue • Schedule rest periods and breaks from planned activities **Reasoning:** • Point out possible consequences of decisions, short and long-term • Ask, "Is this a good idea? What might happen? Is this consistent with your goals?" • Teach step by step approach to problem solving using reasoning • Use graphic organizers or flow charts to help with decision-making • Avoid open-ended questions • Offer two options instead • Speak concretely • Be clear on expectations and consequences of risk-taking behaviors • Be supportive and continually identify strengths **Difficulty with initiating action and/or following through with tasks**: • Encourage the client to focus on one step at a time • Ask client to repeat instructions to ensure comprehension • Use underlining and highlighting for significant parts

Executive Function	• Appears unmotivated • Follower • Needs constant cuing • Lags in independent living	of directions. Checklists and calendars (as previously mentioned) can help organize • Use color-coding • Break complex directions into small steps and assign action items • Help the person get started • Repeat instructions or intervention multiple times in different ways • Help the person learn to refer to checklists when "stuck" in order to move onto the next step. Overtime this may become familiar routine • Timers or alarms can be used to alert a person to begin a task, as well as set time limits (kitchen or stove timers and smart phone) • Additional considerations: o Offer rewards. o Write down expectations. o Check in with individual to problem solve any issues that may arise in course of task completion. o Allow individual to work in established routine, disruptions to routine can lead to confusion. o Developing a cueing system that may involve family and friends. o A lack of initiation is not equal to a lack of motivation. o Keep regular sleep schedule. o Avoid alcohol and other drugs. o Ask about mood and clarify poor initiation versus depression
Executive Function	**Difficulty with mental flexibility (including abstract thought, generalizing, considering others' perspectives)**: • Difficulties taking feedback • Perseverate • Resistant • Can appear	**Difficulty with mental flexibility (including abstract thought, generalizing, considering others' perspectives)**: • Develop and practice routines, and plan ahead for changes in routines • Prepare for transitions • Help develop alternative plans • Assist in prioritizing goals, breaking them down into small tangible tasks • Provide respectful feedback to obvious problem areas

Executive Function	stubborn or argumentative
	• May appear to lack empathy
		• Practice strategies in multiple environments with different staff/support persons
		• Try to plan for obstacles by creating a back-up plan
		• Provide direction in clear, direct and concise manner
		• Verbalize impact of actions on others
		
		Planning and Organization:
		• Encourage the person to develop and maintain day-to-day routines
		• Identify a physical space to keep important items such as keys, glasses, etc.
		• Encourage the use of an organizing system such as "to do" lists, planners/calendars, smart phone apps (e.g. those developed to meet the needs of those with cognitive deficits)*
		• Prompt the person to write down key information
		• Teach: "Think, Plan, Do!"
		• Remind individual of activity:
		  ○ Purpose
		  ○ Expectations along the way
		  ○ Final outcome
		  ○ Goal*
		• Provide directions and/or instructions several times, and ask the person to repeat the information back to you
		
		Self-awareness and insight:
		• **Plan. Practice. Promote.**
		• Plan ahead for situations that may bring about poor judgement and talk about potential obstacles
		• Practice positive interactions ahead of time
		• Cue for compensatory strategies
		• Promote positive behavior with encouragement/praise/reward
		• Stop and address undesirable behaviors immediately
		• Provide alternative comments or choices that could have been made
		• Be patient, know this is not happening on purpose.
		• Gradually expose the person to reality testing situations
		• Point out possible negative consequences of a

Executive Function		person's unrealistic plan • Place external limitations when necessary (e.g. remove the car) **Problem solving and judgement:** • Simple, straightforward, concrete tasks are best. • Be patient. Point out issues in a kind, easy manner • Try to plan for problems that are sure to arise; write a simple sheet of everyday problem occurrences and their solutions down for the individual. Cue the individual to write information down. • Promote positive behavior • Stop and address undesired behavior immediately. • Always make sure individual has an identified, clear chain of command. The individual should always be aware of his or her supervisor, particularly when multiple supervisors oversee a particular group **Difficulty recognizing own limitations:** • Give honest, non-confrontational feedback about performance, with suggestions on how to remedy problem • Videotaping is sometimes helpful. • Be sure to recognize the positive. **Spatial disorientation:** • Signs or Directions in Hallways • Travel Training
Emotional and Behavioral	• Over/under reaction • Difficulties with anger management • Melt down • Can appear emotionally "flat" • Difficulties making friends • Can appear argumentative	• Avoid focusing only on individuals' deficits • Promote self-awareness by stopping and addressing undesired behavior immediately • Don't interpret lack of emotion as a sign of lack of interest • Practices positive social interactions. Provide alternative comments or choices that could have been made • Suggest breaks if the individual becomes irritable or agitated • Speak in a quiet calm manner if individual is irritable or agitated and try to avoid escalating

Emotional and Behavioral **Emotional and Behavioral**		**Depression:** • Positive response with therapy, medications, and exercise • Clarify mood issues (sadness) versus poor initiation and/or "flat affect" which may be the result of brain injury **Anxiety:** • Start meeting with a review of the last, starting with the positives • Minimize anxiety with reassurance, education, and structure • Take breaks • Simplify Tasks **Emotional Lability:** • Utilize stress management and relaxation techniques • Incorporate mindfulness exercises to aid clients in accurately identified internal emotional states: progressive relaxation, body scans, deep breathing exercises **Anger:** • Recognize that outbursts are common and help others not to take it personally • Learn to detect early warning signals: • Physical: muscle tension, sweating • Emotional: irritated, frustrated • Cognitive: racing thoughts, jumbled thoughts • Have a signal and the individual should learn to take a "time out" or a "break" **Psychosis**: • Be clear with what you are working on together • Stress that everyone has structures and rules to follow • Always set the stage, maybe take a few deep breathes **Inappropriate Behavior, Impulsivity, Disinhibition, Lack of Social Judgment:** • Teach "stop, think, act", encourage a person to slow down and think about the consequences of a

Emotional and Behavioral		behavior/activity before deciding to act
		• Respond to the inappropriate behavior with feedback
		  ○ Be clear when articulating expectations, limits and behavior consequences
		  ○ Give honest, non-confrontational feedback about performance, with suggestions on how to remedy problem.
		  ○ Verbalize the impact of actions on others.
		  ○ Be sure to recognize the positive.
		  ○ Hold individuals accountable for their own actions, natural consequences are a valuable teaching tool.
		  ○ Withholding feedback helps no one. Constructive feedback raises awareness.
		
		• Additional considerations:
		  ○ Use Arm's Length Rule.
		  ○ Remove objects from environment that may be harmful

Communication		**Communication (Interpersonal):** • Determine if written word improves communication • Pragmatics: are the problems communicating related to initiation, turn taking, making a point, trouble keeping up with the conversation, trouble sticking to the topic – set topic boundaries **Communication Ideas**: • Ask people to get your attention before starting to talk to you • You need time to shift your attention and focus on them • Ask people to be brief, simple and to the point • Encourage people to take notice of the speed they talk and how much they say • Repeat back information to make sure you understood it • Keep background noise as low as possible - Turn off music/TV • Avoid large groups of people with a lot of talking - Stand or sit in a corner so that noise is not all around you • Reading a letter or note gives you more time to think

		about it - Ask Family and friends to write things down • Decide on what you have to remember and focus only on that - Do not try to remember **everything**
Mental Fatigue		**Mental Fatigue:** • Frequent short breaks or rest periods. • Help individual determine best time of day for work, some individuals tire in early afternoon, others have more difficulties in the morning. • Present information in small segments, watch for signs of overload. • Start with shorter shifts, endurance often builds in time.
Language	**Social Pragmatics:** • Do not interpret body language • Inappropriate eye contact • Personal Bubble • Say too little or too much • Little awareness of inappropriate behavior **Receptive:** • Say "huh" frequently • Confused • Struggle with abstract language/ sarcasm • May withdraw	**Social Pragmatics:** • Provide direct, structured and concrete feedback • Do not rely on body language to convey a message • Role play • Videotape interactions **Receptive:** • Be direct • Avoid abstract humor, sarcasm, metaphors, colloquialisms, etc. • Allow wait time for person to process what has been said • Provide instructions/directions slowly and one at a time • Ask if it would be helpful to repeat or rephrase your message • Let the individual know that you value their input, thoughts, and feelings • Consider written instructions if reading is easier for individual

	Expressive: • Poor grammar or immature speech • Difficult to follow in conversation • Difficulty staying on topic • Difficulties navigating social rules • May withdraw	**Expressive:** • Redirect if the individual is off topic • Provide opportunities to practice expression • Role play common real-life conversations • Teach individual to rehearse silently before replying • Be patient and allow person time to respond • Generate written scripts for simple interactions in advance
Accessibility		**Accessibility**: • Take into account the needs of individuals with developmental (e.g. intellectual) disabilities who may have deficits in allover mental capacities. • Ensure appropriate materials for those who are blind or visually impaired (e.g. braille or other alternative formats such as large print or electronic font). • Ensure appropriate materials for those who are deaf or hard of hearing
Other Considerations		**General Principles** • Individualized planning and care • Trauma-informed care – many individuals with disabilities have experienced physical, or sexual abuse, or other trauma • Consider vulnerable populations such as people of color, LGBTQ+, and potentially additional & intersecting sources of stress • Integrated and specialized services • Consider providing pain-coping strategies - many adults with disabilities experience persistent pain

TBI SPP Traumatic Brain Injury State Partnership Program

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PEG Scale Assessing Pain Intensity and Interference (Pain, Enjoyment, General Activity)

1. What number best describes your pain on average in the past week?

0	1	2	3	4	5	6	7	8	9	10
No Pain										Pain as bad as you can imagine

2. What number best describes how, during the past week, pain has interfered with your enjoyment of life?

0	1	2	3	4	5	6	7	8	9	10
	Does not interfere									Completely interferes

3. What number best describes how, during the past week, pain has interfered with your general activity?

0	1	2	3	4	5	6	7	8	9	10
	Does not interfere									Completely interferes

Computing the PEG Score.

Add the responses to the three questions, then divide by three to get a mean score (out of 10) on overall impact of points.

Using the PEG Score.

The score is best used to track an individual's changes over time. The initiation of therapy should result in the individual's score decreasing over time.

Source.

Krebs, E. E., Lorenz, K. A., Bair, M. J., Damush, T. M., Wu, J., Sutherland, J. M., Asch S, Kroenke, K. (2009). Development and Initial Validation of the PEG, a Three-item Scale Assessing Pain Intensity and Interference. Journal of General Internal Medicine, 24(6), 733–738. http://doi.org/10.1007/s11606-009-0981-1

Perioperative Management of Non-Pregnant Patients on Maintenance Therapy for Opioid Dependence

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Section:	Pharmacy

Perioperative Management of Non-Pregnant Patients on Maintenance Therapy for Opioid Dependence

Buprenorphine, methadone, and naltrexone are pharmacologic therapies indicated for maintenance treatment of opioid use disorder. The appropriate treatment of acute pain in patients on buprenorphine and methadone maintenance includes continuing the patient's baseline opioid requirements to avoid increased pain sensitivity associated with opioid withdrawal. Thus, daily opioid maintenance treatment requirements must be met before attempting to achieve analgesia. These patients have also been shown to have increased pain sensitivity and cross-tolerance to opioid analgesics, therefore adequate pain control will often necessitate higher opioid doses at shorter dosing intervals. All patients on buprenorphine and methadone maintenance should be co-managed with their buprenorphine or methadone provider during the pre- and post-procedure period. Addiction medicine is available for consultation to assist with recommendations for opioid use disorder management in the postoperative period.

These guidelines are designed for patients maintained on chronic opioids, buprenorphine, methadone or naltrexone therapy undergoing invasive procedures. There is currently a lack of evidence-based studies to direct the management of patients on buprenorphine, methadone, or naltrexone maintenance in the peri-procedural period. Below are guidelines using expert opinion based on pharmacological principles with the intent to avoid subtherapeutic acute pain management while also preventing opioid withdrawal and disruption of opioid use disorder management.

See Table 1 for recommendations for perioperative management.

For additional information or clinical questions contact the Addiction Medicine consult service at pager 6226 (NCAN).

References:

Reginald LD et al. Overriding the blockade of antinociceptive actions of opioids in rats treated with extended-release naltrexone. Pharmacology, Biochemistry and Behavior 2008;89:515-522.
Roberts DM, Meyer-Witting M. High-dose buprenorphine: perioperative precautions and management strategies. Anaesth Intensive Care 2005;33:17-25.
Alford DP, et al. Acute Pain Management for Patients Receiving Maintenance Methadone or Buprenorphine Therapy. Ann Intern Med 2006:144(2): 127-134.

Responsibility: Nurses, physicians, pharmacists

Other Related Guidelines or Policies: Methadone and Buprenorphine during Pregnancy, Epidural and Intrathecal Analgesia, Sedation and Pain Control – ICU, Pain Management (Adult), Patient-Controlled Analgesia (PCA) - Adult
Section: Pharmacy
Originated from: Daniel Alford, MD, Colleen LaBelle, RN, Mauricio Gonzalez, MD, Samantha Bastow, PharmD, Peter Golenia, PharmD, BCPS
Reviewed by: William Vincent, PharmD (9/14), Kevin Yeh, PharmD & William Vincent, PharmD (2/16)
Approved by: Formulary Management Committee (4/12)

Perioperative Management of Non-Pregnant Patients on Maintenance Therapy for Opioid Dependence

Table 1

Opioid Dependence Patient Category	Pre-operative Pain Recommendations	Post-operative Pain Recommendations
Chronic Pain on Chronic Opioid Therapy **Inclusion:** Patient on chronic opioids > 2 weeks or with other signs of physical dependence. Does not include patients taking occasional or prn opioids for breakthrough pain.	Continue standing opioid dose the day of surgery. Hold any usual PRN breakthrough opioid doses the day of surgery.	Continue equivalent chronic opioid dose (IV if patient strict NPO) with hold parameters for sedation. For acute postoperative pain, utilize multimodal pain management with non-opioid medications (NSAID, acetaminophen, epidural/spinal analgesia, nerve blocks) as indicated. If opioids are required for breakthrough pain, patients with history of chronic opioid use may require higher than usual doses due to cross tolerance. PCA's may be considered if pain is not adequately captured. This may be utilized with or without a basal component.
Methadone Maintenance Therapy	Confirm methadone dose with patient's methadone maintenance treatment program (MMTP). Continue usual dose of methadone the day of surgery. The patient may need to arrange home doses of methadone ("medical take home doses") with his or her MMTP if they are unable to go to the MMTP on the day of surgery. If this is not possible, the patient should receive his or her usual confirmed methadone dose in the pre-operative area.	Continue usual daily methadone dose. If the patient is strict NPO, they should receive 50%-75% of their usual methadone dose given IV, divided into 2-4 doses/day (e.g. if usual dose is 60 mg PO daily, appropriate IV doses would be approximately 15 mg IV BID or 10 mg IV TID). For acute postoperative pain, utilize multimodal pain management with non-opioid medications (NSAID, acetaminophen, epidural/spinal analgesia, nerve blocks) as indicated. If opioids are required for breakthrough pain, patients with history of opioid use disorder may require higher than usual doses due to cross tolerance and increased pain sensitivity. PCA's without basal component may be considered in addition to patient's methadone if pain is not adequately captured. Remember to discontinue other oral PRN opioids.

Perioperative Management of Non-Pregnant Patients on Maintenance Therapy for Opioid Dependence

		On discharge, the patient should be given a "last dose letter" addressed to the MMTP and whether any modifications have been made. The discharge case manager and patient may need to arrange for home doses of methadone ("medical take home doses") with his or her MMTP if he or she is unable to go to the MMTP on the days of after discharge.
Buprenorphine Maintenance Therapy	Take AM dose of buprenorphine on the day of the procedure.	Continue patient's home dose of buprenorphine post-operatively. Consider splitting patient's totally daily buprenorphine dose into q8h schedule for better pain coverage. For acute postoperative pain, utilize multimodal pain management with non-opioid medications (NSAID, acetaminophen, epidural/spinal analgesia, nerve blocks) as indicated. If opioids are required for breakthrough pain, patients with history of opioid use disorder may require higher than usual doses due to cross tolerance and increased pain sensitivity. PCA's without basal component may be considered in addition to patient's buprenorphine if pain is not adequately captured. Remember to discontinue other oral PRN opioids.
Naltrexone (oral or depot) Maintenance Therapy	Discontinue oral naltrexone 72 hours before surgery. Discontinue depot naltrexone 1 month prior to elective surgery, if possible.	Utilize multimodal pain management with non-opioid medications (NSAIDs, acetaminophen, epidural/spinal analgesia, nerve blocks) as indicated. If surgery performed emergently or naltrexone was not discontinued prior to surgery, naltrexone should be discontinued postoperatively. If this occurs, higher than usual doses of opioids may be attempted to overcome naltrexone's opioid antagonist effects. This must be done with close observation for respiratory depression.

DSM-5 CHECKLIST OF DIAGNOSTIC CRITERIA: OPIOID USE DISORDER

Patient Name: _____ **Provider Name:** _____

Date: _____ **Provider Signature:** _____

Opioid Use Disorder is defined as a problematic pattern of opioid use leading to clinically significant impairment or distress, as manifested by at least 2 of the following, occurring within a 12-month period:

Diagnostic Criteria	Meets Criterion?	Additional/Supporting Information
1. Opioids are often taken in larger amounts or over a longer period than was intended.		
2. There is a persistent desire or unsuccessful efforts to cut down or control opioid use.		
3. A great deal of time is spent in activities necessary to obtain the opioid, use the opioid, or recover from its effects.		
4. Craving, or a strong desire or urge to use opioids.		
5. Recurrent opioid use resulting in a failure to fulfill major role obligations at work, school, or home.		
6. Continued opioid use, despite having persistent or recurrent social or interpersonal problems caused or exacerbated by the effects of opioids.		
7. Important social, occupational, or recreational activities are given up or reduced because of opioid use.		
8. Recurrent opioid use in situations in which it is physically hazardous.		
9. Continued opioid use, despite knowledge of having a persistent or recurrent physical or psychological problem that is likely to have been caused or exacerbated by the substance.		
10. Tolerance,* as defined by *either* of the following:		
A. A need for markedly increased amounts of opioids to achieve intoxication or desired effect.		
B. A markedly diminished effect with continued use of the same amount of an opioid.		

Diagnostic Criteria	Meets Criterion?	Additional/Supporting Information
11. Withdrawal,* as manifested by *either* of the following:		
A. The characteristic opioid withdrawal syndrome.		
B. Opioids (or a closely related substance) are taken to relieve or avoid withdrawal symptoms.		

***Note:** This criterion is not considered to be met for those individuals taking opioids solely under appropriate medical supervision.

Specify if:

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 that Criterion 4, "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 that Criterion 4, "Craving, or a strong desire or urge to use opioids," may be met).

On maintenance therapy: This additional specifier is used if the individual is taking a prescribed agonist medication, such as methadone or buprenorphine, and none of the criteria for opioid use disorder have been met for that class of medication (except tolerance to, or withdrawal from, the agonist). This category also applies to those individuals being maintained on a partial agonist, an agonist/antagonist, or a full antagonist such as oral naltrexone or depot naltrexone. In a controlled environment: This additional specifier is used if the individual is in an environment where access to opioids is restricted.

Current severity:

☐ *Mild:* Presence of 2–3 symptoms. **Code as: F11.10 (ICD-10)**

☐ *Moderate:* Presence of 4–5 symptoms. **Code as: F11.20 (ICD-10)**

☐ *Severe:* Presence of 6 or more symptoms. **Code as: F11.20 (ICD-10)**

After completion, scan this form into the patient's record. Make a copy for the patient.

American Psychiatric Association. (2013). Diagnostic and statistical manual of mental disorders (5th ed.). Arlington, VA: American Psychiatric Publishing.

CLINICAL TOOLS: COWS SCALE

OPIOID WITHDRAWAL RECORD (INDUCTION FORM)

(Adapted from Clinical Opioid Withdrawal Scale)

Patient Name: _____ **Treatment Start Date:** _____

Provider Name: _____ **Date:** _____

Select the number/description that best corresponds to your patient's present symptoms.

Parameter	**Baseline Observation Administer** 1st Dose _____ mg Time given _____	**1st Dose Observation** _____ min. After 1st dose	**1st Dose, 2nd Observation** (if needed) _____ min. After 1st dose	**2nd dose** (if needed) _____ mg Time given _____	**2nd Dose Observation** _____min. After 2nd dose
Resting pulse rate _____beats/min *Measure after patient is sitting/lying for 1 minute* 0 pulse rate 80 or below 1 pulse rate 81–100 2 pulse rate 101–120 4 pulse rate greater than 120	☐ 0 ☐ 1 ☐ 2 ☐ 4	☐ 0 ☐ 1 ☐ 2 ☐ 4	☐ 0 ☐ 1 ☐ 2 ☐ 4	☐ 0 ☐ 1 ☐ 2 ☐ 4	☐ 0 ☐ 1 ☐ 2 ☐ 4
Sweating *Over past 30 minutes; 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	☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4	☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4	☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4	☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4	☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4
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	☐ 0 ☐ 1 ☐ 3 ☐ 5	☐ 0 ☐ 1 ☐ 3 ☐ 5	☐ 0 ☐ 1 ☐ 3 ☐ 5	☐ 0 ☐ 1 ☐ 3 ☐ 5	☐ 0 ☐ 1 ☐ 3 ☐ 5
Tremors *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	☐ 0 ☐ 1 ☐ 2 ☐ 4	☐ 0 ☐ 1 ☐ 2 ☐ 4	☐ 0 ☐ 1 ☐ 2 ☐ 4	☐ 0 ☐ 1 ☐ 2 ☐ 4	☐ 0 ☐ 1 ☐ 2 ☐ 4
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	☐ 0 ☐ 1 ☐ 2 ☐ 5	☐ 0 ☐ 1 ☐ 2 ☐ 5	☐ 0 ☐ 1 ☐ 2 ☐ 5	☐ 0 ☐ 1 ☐ 2 ☐ 5	☐ 0 ☐ 1 ☐ 2 ☐ 5
GI upset *Over past 30 minutes* 0 no GI symptoms 1 stomach cramps 2 nausea or loose stool 3 vomiting or diarrhea 5 multiple episodes of diarrhea or vomiting	☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 5	☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 5	☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 5	☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 5	☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 5
Anxiety or irritability 0 none 1 patient reports increasing irritability or anxiousness 2 patient obviously irritable/anxious 4 patient so irritable/anxious that participation in assessment is difficult	☐ 0 ☐ 1 ☐ 2 ☐ 4	☐ 0 ☐ 1 ☐ 2 ☐ 4	☐ 0 ☐ 1 ☐ 2 ☐ 4	☐ 0 ☐ 1 ☐ 2 ☐ 4	☐ 0 ☐ 1 ☐ 2 ☐ 4

Parameter	**Baseline Observation Administer** 1st Dose _____ mg Time given _____	**1st Dose Observation** _____ min. After 1st dose	**1st Dose, 2nd Observation** (if needed) _____ min. After 1st dose	**2nd dose** (if needed) _____ mg Time given _____	**2nd Dose Observation** _____min. After 2nd dose
Bone or joint aches *If patient was having pain previously, gauge the additional component attributed to opioid withdrawal only* 0 not present 1 mild diffuse discomfort 2 patient reports severe diffuse aching of joints/muscles 4 patient is rubbing joints or muscles and is unable to sit still because of discomfort	☐ 0 ☐ 1 ☐ 2 ☐ 4	☐ 0 ☐ 1 ☐ 2 ☐ 4	☐ 0 ☐ 1 ☐ 2 ☐ 4	☐ 0 ☐ 1 ☐ 2 ☐ 4	☐ 0 ☐ 1 ☐ 2 ☐ 4
Yawning *Observation during assessment* 0 no yawning 1 yawning once or twice during assessment 2 yawning three or more times during assessment 4 yawning several times/minute	☐ 0 ☐ 1 ☐ 2 ☐ 4	☐ 0 ☐ 1 ☐ 2 ☐ 4	☐ 0 ☐ 1 ☐ 2 ☐ 4	☐ 0 ☐ 1 ☐ 2 ☐ 4	☐ 0 ☐ 1 ☐ 2 ☐ 4
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	☐ 0 ☐ 1 ☐ 2 ☐ 4	☐ 0 ☐ 1 ☐ 2 ☐ 4	☐ 0 ☐ 1 ☐ 2 ☐ 4	☐ 0 ☐ 1 ☐ 2 ☐ 4	☐ 0 ☐ 1 ☐ 2 ☐ 4
Gooseflesh skin 0 skin is smooth 3 skin piloerection can be felt or hairs standing up on arms 5 prominent piloerection	☐ 0 ☐ 3 ☐ 5	☐ 0 ☐ 3 ☐ 5	☐ 0 ☐ 3 ☐ 5	☐ 0 ☐ 3 ☐ 5	☐ 0 ☐ 3 ☐ 5
Total Score _____ Total score is the sum of all 11 items • 5–12 = mild • 13–24 = moderate • 25–35 = moderately severe • >36 = severe withdrawal					

Wesson, D. R., & Ling, W. (2003). The Clinical Opiate Withdrawal Scale (COWS). *Journal of Psychoactive Drugs*, 32(2), 253–259.

After completion, scan form into patient record and provide a copy to the patient.

Pharmacotherapy for Alcohol Use Disorder

	Naltrexone Oral	Naltrexone Injectable	Acamprosate	Disulfiram	Topiramate[1]	Gabapentin[1]
Indications	**AUD (DSM diagnosis) with:** – Pretreatment abstinence not required but may improve response – Initial engagement in addiction-focused medical management and/or other recommended psychosocial intervention	**AUD (DSM diagnosis) with:** – Pretreatment abstinence not required but may improve response – Willingness to receive monthly injections – Difficulty adhering to an oral regimen – Initial engagement in addiction-focused medical management and/or other recommended psychosocial intervention	**AUD (DSM diagnosis) with:** – Abstinence at treatment initiation – Initial engagement in addiction-focused medical management and/or other recommended psychosocial intervention	**AUD (DSM diagnosis) with:** – Abstinence > 12 hours and BAL = 0 – Combined cocaine dependence – Previous response to disulfiram – Capacity to appreciate risks and benefits and to consent to treatment – Initial engagement in addiction-focused medical management and/or other recommended psychosocial intervention – **Note:** more effective with monitored administration (i.e. in clinic, with spouse, with probation officer)	**AUD (DSM diagnosis) [off label] with:** – Pretreatment abstinence not required but may improve response – Initial engagement in addiction-focused medical management and/or other recommended psychosocial intervention	**AUD (DSM diagnosis) [off label] with:** – Pretreatment abstinence not required but may improve response – Initial engagement in addiction-focused medical management and/or other recommended psychosocial intervention
Contraindications	– Receiving opioid agonists – Physiologic opioid dependence with use within past 7 days – Acute opioid withdrawal – Failed naloxone/ naltrexone challenge test – Positive urine opioid screen – Acute hepatitis or liver failure – Hypersensitivity	– Receiving opioid agonists – Physiologic opioid dependence with use within past 7 days – Acute opioid withdrawal – Failed naloxone/ naltrexone challenge test – Positive urine opioid screen – Acute hepatitis or liver failure – Hypersensitivity – Inadequate muscle or body habitus too large for supplied injection needle	– Hypersensitivity – Severe renal insufficiency (CrCl ≤ 30 mL/min)	– Severe cardiovascular, respiratory, or renal disease – Severe hepatic dysfunction (i.e. transaminase level > 3 times upper limit of normal or abnormal bilirubin) – Severe psychiatric disorders, especially psychotic and cognitive disorders and suicidal ideation – Poor impulse control – Metronidazole or ketoconazole therapy, which already induce a similar reaction to alcohol – Hypersensitivity	– No contraindications in manufacturer's labeling	– Hypersensitivity – History of misuse

Pharmacotherapy for Alcohol Use Disorder *(continued)*

	Naltrexone Oral	Naltrexone Injectable	Acamprosate	Disulfiram	Topiramate[1]	Gabapentin[1]
Warnings/ Precautions	– Active liver disease – Severe renal failure – Breastfeeding—not advised, proven teratogenicity in animal studies – Acute/chronic pain – History of severe depression, acute psychiatric illness – Pregnancy category C	– Active liver disease – Uncertain effects (no data) in moderate to severe renal insufficiency – Injection site reactions – Use intramuscular injections with caution in patients with thrombocytopenia or coagulation disorders – Breastfeeding—not advised, proven teratogenicity in animal studies – Acute/chronic pain – History of severe depression, acute psychiatric illness – Pregnancy category C	– Monitor for emergence of depression or suicidality – Reduce dose in patients with renal insufficiency, including the elderly – Pregnancy category C	– Alcohol-disulfiram reaction; patients must be vigilant to avoid alcohol in all forms, including mouthwash, over-the-counter medications, etc. – Pregnancy category C	– Do not abruptly discontinue therapy; taper dosage gradually – Cognitive dysfunction, psychiatric disturbances, and sedation may occur with use – Increased risk of suicidal ideation with antiepileptic agents, including topiramate – Pregnancy category C	– Do not abruptly discontinue therapy; taper dosage gradually – May cause CNS depression, including somnolence/dizziness – Increased risk of suicidal ideation with antiepileptic agents, including topiramate – Pregnancy category C
Baseline Evaluation	– Liver transaminase levels – Bilirubin within normal limits – Urine beta-HCG for females – Toxicology screen	– Liver transaminase levels – Bilirubin within normal limits – CrCl (estimated or measured) ≥ 50 mL/min – Ensure patient has adequate muscle for injection – Urine beta-HCG for females – Toxicology screen	– CrCl (estimated or measured) – Urine beta-HCG for females	– Liver transaminase levels – Physical assessment – Psychiatric assessment – Electrocardiogram if indicated by history of cardiac disease – Verify abstinence with breath or BAL – Urine beta-HCG for females	– Assess renal function – Urine beta-HCG for females	– Assess renal function – Urine beta-HCG for females
Dosage and Administration	– 50-100 mg orally 1 time daily	– 380 mg 1 time monthly by deep intramuscular injection	– 666 mg orally 3 times daily, preferably with meals	– 250 mg orally 1 time daily (range, 125-500 mg daily)	– Titrate up gradually over several weeks to minimize side effects – Initiate at 50 mg/day; increase to a maximum dose of 100 mg 2 times daily	– Titrate up gradually over several weeks to minimize side effects – Initiate at 300 mg on day 1 and increase by 300 mg daily as tolerated to target of 1800 mg daily, administered in 3 divided doses
Alternative Dosing Schedules	– 25 mg 1 or 2 time(s) daily with meals to reduce nausea, especially during the first week – 100 mg on Monday and Wednesday and 150 mg on Friday	– Geriatric patients with CrCl < 70 mL/min/1.73m^2: give initial dose of 25 mg/day followed by incremental increases of 25 mg at weekly intervals until an effective dose is reached	– NA	– Reduce dose to 125 mg to reduce side effects – For monitored administration, consider giving 500 mg on Monday, Wednesday, and Friday		– NA

Pharmacotherapy for Alcohol Use Disorder *(continued)*

	Naltrexone Oral	Naltrexone Injectable	Acamprosate	Disulfiram	Topiramate[1]	Gabapentin[1]
Dosing in Special Populations	– **Hepatic or renal insufficiency:** use caution	– **Mild renal insufficiency (CrCl 50-80 mL/min):** no dosage adjustment necessary – Uncertain effects (no data) in moderate to severe renal insufficiency	– **Moderate renal insufficiency (CrCl 30-50 mL/min):** 333 mg 3 times daily – Do not administer to patients with severe renal insufficiency (CrCl ≤ 30 mL/min)	– NA	– **CrCl < 70 mL/min/1.73m^2:** administer 50% dose and titrate more slowly – **CrCl < 70 mL/min/1.73m^2:** administer 50% dose and titrate more slowly	– Dosage must be adjusted for renal function, consider target dose < 1800 mg daily when CrCl < 60 mL/min
Adverse Effects	– **Common:** Nausea – **Other:** Headache, dizziness, nervousness, fatigue, insomnia, vomiting, anxiety, somnolence	– **Major:** Eosinophilic pneumonia, depression, suicidality – **Common:** Injection-site reactions, injection-site tenderness, injection-site induration, nausea, headache, asthenia	– **Major:** Suicidality 2.4% (vs. 0.8% on placebo during first year in clinical trials) – **Common:** Diarrhea (16%) – **Other:** Anxiety, asthenia, depression, insomnia	– **Major:** Hepatoxicity, peripheral neuropathy, psychosis, delirium, severe disulfiram-ethanol reaction – **Common:** Somnolence, metallic taste, headache	– **CNS:** Paresthesia, nervousness, fatigue, ataxia, drowsiness, lack of concentration, memory impairment, confusion – **Gastrointestinal:** Abdominal pain, anorexia	– **CNS:** Dizziness, drowsiness, ataxia, fatigue – **Gastrointestinal:** diarrhea, nausea/vomiting, abdominal pain
Drug Interactions	– Opioid-containing medication, including over-the-counter preparations – Thioridazine (increased lethargy and somnolence)	– Opioid-containing medication, including over-the-counter preparations – Thioridazine (increased lethargy and somnolence)	– **Naltrexone:** 33% increase in Cmax of acamprosate (no dosage adjustment is recommended) – **Antidepressants:** Weight gain and weight loss more common than with either medication alone	– Alcohol-containing medication, including over-the-counter preparations – Drug-drug interactions may occur with phenytoin, warfarin, isoniazid, rifampin, diazepam, chlordiazepoxide, imipramine, desipramine, and oral hypoglycemic agents	– Use extreme caution if used concurrently with alcohol or other CNS depressants – Topiramate may decrease the serum concentrations of contraceptives and decrease their effectiveness	– Use extreme caution if used concurrently with alcohol or other CNS depressants – Antacids may decrease levels of gabapentin
Monitoring	– Repeat liver transaminase levels at 6 and 12 months and then every 12 months thereafter – Discontinue medication and consider alternatives if no detectable benefit after an adequate trial (50 mg daily for 3 months)	– Repeat liver transaminase levels at 6 and 12 months and then every 12 months thereafter – Discontinue medication and consider alternatives if no detectable benefit after an adequate trial	– Monitor serum creatinine/ CrCl, particularly in the elderly and in patients with renal insufficiency – Maintain therapy if relapse occurs	– Repeat liver transaminase levels within the first month, then monthly for first 3 months and periodically thereafter as indicated – Consider discontinuation in event of relapse or when patient is not available to be supervised or counseled	– Monitor serum creatinine/ CrCl periodically, particularly in patients with renal insufficiency and in geriatric patients – Monitor for change in behavior that might indicate suicidal thoughts or depression – Discontinue medication and consider alternatives if no detectable benefit after an adequate trial (300 mg daily for 3 months)	– Monitor serum creatinine/ CrCl periodically, particularly in patients with renal insufficiency and in geriatric patients – Monitor for change in behavior that might indicate suicidal thoughts or depression – Gabapentin has the potential for misuse when taken in supratherapeutic doses; monitor quantities prescribed and usage patterns – Discontinue medication and consider alternatives if no detectable benefit from at least 900 mg daily for 2-3 months

Pharmacotherapy for Alcohol Use Disorder *(continued)*

	Naltrexone Oral	Naltrexone Injectable	Acamprosate	Disulfiram	Topiramate[1]	Gabapentin[1]
Patient Education	– Discuss compliance-enhancing methods – Negotiate commitment from patient regarding monitored ingestion – Side effects, if any, tend to occur early in treatment and can typically resolve within 1-2 weeks after dose adjustment – If signs and symptoms of acute hepatitis occur, discontinue naltrexone and contact provider immediately – Very large doses of opioids may overcome the effects of naltrexone and lead to serious injury, coma, or death – Small doses of opioids, such as in analgesic, antidiarrheal, or antitussive drugs may be blocked by naltrexone and fail to produce a therapeutic effect – Patients who have previously used opioids may be more sensitive to toxic effects of opioids after discontinuing naltrexone	– Report any concerning injection site reactions – Report any new or worsening depression or suicidal thoughts – May cause allergic pneumonia; contact provider if patient develops signs and symptoms of pneumonia	– Report any new or worsening depression or suicidal thoughts	– Avoid alcohol in food and beverages, including medications – Avoid disulfiram if alcohol intoxication is present – May cause sedation; use caution operating vehicles and hazardous machinery – Discuss compliance-enhancing methods – Family members should not administer disulfiram without informing patient – Provide patients with wallet cards that indicate the use of disulfiram	– Administer without regard to meals – It is not recommended to crush, break, or chew immediate-release tablets due to bitter taste – Caution patients about performing tasks requiring mental alertness	– Take first dose on first day at bedtime to minimize somnolence and dizziness – Caution patients about performing tasks requiring mental alertness

[1] Not FDA-labeled for treatment of AUD

Abbreviations: AUD: alcohol use disorder; BAL: blood alcohol level; Cmax: maximum concentration; CNS: central nervous system; CrCl: creatinine clearance; DSM: Diagnostic and Statistical Manual of Mental Disorders; HCG: human chorionic gonadotropin; m: meter(s); mg: milligram(s); min: minute(s); mL: milliliter(s)

Adapted from Department of Veteran Affairs. The Management of Substance Use Disorders Work Group. (December 2015). *VA/DoD Clinical Practice Guideline for the Management of Substance Use Disorders*. Version 3.0-2015.

Pharmacotherapy for Opioid Use Disorder

	Methadone	Buprenorphine/Naloxone or Buprenorphine	Naltrexone
Indications	– DSM diagnosis of OUD and patient meets Federal OTP Standards (42 CFR 8.12(e)). More information at http://store.samhsa.gov/shin/content/PEP15-FEDGUIDEOTP/PEP15-FEDGUIDEOTP.pdf	– DSM diagnosis of OUD – Willingness and stability to receive, store, and administer weekly medication	**DSM diagnosis of OUD with:** – Prevention of relapse to opioid dependence/use following detoxification – Treatment for alcohol use disorder – Willingness and stability to receive monthly injections
Contraindications	– Hypersensitivity	– Hypersensitivity – Chronic pain that requires opioid treatment beyond buprenorphine	– Hypersensitivity – Receiving opioid agonists – Physiologic opioid dependence – Failed naloxone challenge or naltrexone challenge test – Positive urine opioid screen – Acute hepatitis or liver failure – Advanced psychiatric disease, active suicidal ideation – Breastfeeding
Warnings/ Precautions	– Concurrent enrollment in another OTP – Prolonged QTc interval – Use caution in patients with respiratory, liver, or renal insufficiency – Concurrent benzodiazepines or other CNS depressants including opioids and active AUD (potential respiratory depression) – Use of opioid antagonists (including parenteral naloxone, oral or parenteral nalmefene, naltrexone) – Pregnancy category C	– Buprenorphine/naloxone may precipitate withdrawal in patients on full agonist opioids – Use caution in patients with respiratory, liver, or renal insufficiency – Current benzodiazepines or other CNS depressants, including opioids and active AUD (potential respiratory depression, overdose) – Use of opioid antagonists (eg, parenteral naloxone, oral or parenteral nalmefene, naltrexone) – Pregnancy category C	– Active liver disease, cirrhosis – Moderate to severe renal insufficiency; unknown effects – Thrombocytopenia or coagulation disorders – Chronic and/or acute pain must be managed with non-opioids – Large body habitus – Vulnerability for fatal opioid overdose in case of relapse to opioids – Pregnancy category C
Baseline Evaluation	– Consider electrocardiogram and physical examination for patients at risk of QT prolongation or arrhythmias – Toxicology screen	– Liver transaminases – Urine beta-HCG for females – Toxicology screen	– Liver transaminase levels < 5x upper limit of normal – CrCl (estimated or measured) 50 mL/min or greater – Ensure patient has adequate muscle mass for injection – Urine beta-HCG for women – Toxicology screen

Pharmacotherapy for Opioid Use Disorder *(continued)*

	Methadone	Buprenorphine/Naloxone or Buprenorphine	Naltrexone
Dosage and Administration	– **Initial dose:** 15-20 mg single dose, maximum 30 mg – **Daily dose:** Maximum 40 mg/day on first day – **Usual dosage range for optimal effects:** 60-120 mg/day – Titrate carefully, consider methadone's delayed cumulative effects – Administer orally in single dose – Individualize dosing regimens – Daily visits at MAT clinic, may receive take-home doses per clinic protocol	**Sublingual dosing:** – **Induction:** Patient presents in mild-moderate withdrawal – **Induction dose:** 2-4 mg initial dose, titrate per prescription instructions and/or until withdrawal symptoms subside – Typical Day 1 dose = 8 mg – **Days 2-7:** Patient takes total dose equivalent from Day 1 upon awakening. Check in with clinical team. May titrate up to 16 mg. – **Stabilization/maintenance:** Target dose = 8-16 mg (max 24 mg daily) may be taken in QD or BID dosing regimen – Weekly visits/prescriptions until stable, then biweekly and eventually monthly or random call-back basis	– To be administered after negative urine toxicology screen and/or successful naltrexone/naloxone challenge – **Oral:** 25-50 mg by mouth daily – **ER injectable:** 380 mg every 28 days by deep intramuscular gluteal injection – Alternate injection sites – Weekly visits until stable, then biweekly, may progress to clinic visits every 28 days occurring on the date of patient's extended-release naltrexone injection
Alternative Dosing Schedules	– Give in divided doses based on peak and trough levels that document rapid metabolism that justifies divided doses	– Divided dosing helpful for patients with chronic pain for dual effectiveness and avoidance of narcotic medications – Residential programs may require specific Sig	– For patients with coagulation disorders, thrombocytopenia, or large body habitus, consider remaining on oral formulation
Adverse Effects	– **Major:** Respiratory depression, shock, cardiac arrest, prolongation of QTc interval on electrocardiogram and torsades de pointes ventricular tachycardia – **Common:** Lightheadedness, dizziness, sedation, nausea, vomiting, sweating, constipation, edema – **Less common:** Sexual dysfunction	– **Major:** Hepatitis, hepatic failure, respiratory depression (usually when misused intravenously or if combined with other CNS depressants) – **Common:** Headache, pain, abdominal pain, insomnia, nausea, vomiting, sweating, constipation – **Sublingual buprenorphine/naloxone film:** Oral hypoesthesia, glossodynia, oral mucosal erythema	– **Major:** Eosinophilic pneumonia, depression, suicidality – **Common:** Injection-site reaction, tenderness, induration, nausea, abdominal pain, anorexia, headache, asthenia

Pharmacotherapy for Opioid Use Disorder *(continued)*

	Methadone	Buprenorphine/Naloxone or Buprenorphine	Naltrexone
Drug Interactions	– **Drugs that reduce serum methadone levels:** Ascorbic acid, barbiturates, carbamazepine, ethanol (chronic use), interferon, phenytoin, rifampin, efavirenz, nevirapine, other antiretrovirals with CYP3A4 activity – **Drugs that increase serum methadone level:** Amitriptyline, atazanavir, atazanavir/ritonavir, cimetidine, delavirdine, diazepam, fluconazole, fluvoxamine, ketoconazole, voriconazole – Opioid antagonists may precipitate withdrawal	– Metabolized in the liver by cytochrome P450 3A4 system – **Drugs that reduce serum buprenorphine level:** Ascorbic acid, barbiturates, interferon, carbamazepine, ethanol (chronic use), phenytoin, rifampin, efavirenz, nevirapine, other antiretrovirals with CYP3A4 activity – **Drugs that increase serum buprenorphine level:** Amitriptyline, atazanavir, atazanavir/ritonavir, cimetidine, delavirdine, diazepam, fluconazole, fluvoxamine, ketoconazole, voriconazole – **Opioid partial agonist:** Buprenorphine/naloxone or buprenorphine may precipitate opioid withdrawal – Opioid antagonists may precipitate withdrawal	– Opioid-containing medications, including over the counter preparations – Thioridazine (increased lethargy and somnolence)
Monitoring	– Signs of respiratory and CNS depression – Frequent toxicology screening	– Liver function tests prior to initiation and during therapy as needed – Frequent toxicology screening	– Repeat liver transaminase levels at 6 and 12 months and then every 12 months thereafter – Increase hepatic monitoring in cases of mild to moderate elevation (1-5x upper limit of normal – Frequent toxicology screening

Abbreviations: OUD: opioid use disorder; UTS: urine toxicology screening; Cmax: maximum concentration; CNS: central nervous system; CrCl: creatinine clearance; DSM: Diagnostic and Statistical Manual of Mental Disorders; HCG: human chorionic gonadotropin; m: meter(s); mg: milligram(s); min: minute(s); mL: milliliter(s)

Adapted from Department of Veteran Affairs. The Management of Substance Use Disorders Work Group. (December 2015). *VA/DoD Clinical Practice Guideline for the Management of Substance Use Disorders.* Version 3.0-2015.

MEDICATION GUIDE

SUBLOCADE (SUB-lo-kade) (buprenorphine extended-release) injection, for subcutaneous use, (CIII)

What is the most important information I should know about SUBLOCADE?

- Because of the serious risk of potential harm or death from self-injecting SUBLOCADE into a vein (intravenously), it is only available through a restricted program called the SUBLOCADE REMS Program.
  - SUBLOCADE is not available in retail pharmacies.
  - Your SUBLOCADE injection will only be given to you by a certified healthcare provider.
- SUBLOCADE contains a medicine called buprenorphine. Buprenorphine is an opioid that can cause serious and life-threatening breathing problems, especially if you take or use certain other medicines or drugs.
- Talk to your healthcare provider about naloxone. Naloxone is a medicine that is available to patients for the emergency treatment of an opioid overdose. If naloxone is given, you must call 911 or get emergency medical help right away to treat overdose or accidental use of an opioid.
- SUBLOCADE may cause serious and life-threatening breathing problems. Get emergency help right away if you:
  - feel faint
  - feel dizzy
  - are confused
  - Feel sleepy or uncoordinated
  - have blurred vision
  - have slurred speech
  - are breathing slower than normal
  - cannot think well or clearly

Do not take certain medicines during treatment with SUBLOCADE. Taking other opioid medicines, benzodiazepines, alcohol, or other central nervous system depressants (including street drugs) while on SUBLOCADE can cause severe drowsiness, decreased awareness, breathing problems, coma, and death.

- In an emergency, have family members tell emergency department staff that you are physically dependent on an opioid and are being treated with SUBLOCADE.
- You may have detectable levels of SUBLOCADE in your body for a long period after stopping treatment with SUBLOCADE.

What is SUBLOCADE?

SUBLOCADE is a prescription medicine used to treat adults with moderate to severe addiction (dependence) to opioid drugs (prescription or illegal) who:

- have received treatment with an oral transmucosal (used under the tongue or inside the cheek) buprenorphine-containing medicine for 7 days **and**
- are taking a dose that controls withdrawal symptoms for at least seven days.
- SUBLOCADE is part of a complete treatment plan that should include counseling.

Who should not take SUBLOCADE?

Do not use SUBLOCADE if you are allergic to buprenorphine or any ingredient in the prefilled syringe (ATRIGEL® delivery system). See the end of this Medication Guide for a list of ingredients in SUBLOCADE.

Before starting SUBLOCADE, tell your healthcare provider about all your medical conditions, including if you have:

- trouble breathing or lung problems
- a curve in your spine that affects your breathing
- Addison's disease
- an enlarged prostate (men)
- problems urinating
- liver, kidney, or gallbladder problems
- alcoholism
- a head injury or brain problem
- mental health problems
- adrenal gland or thyroid gland problems

Tell your healthcare provider if you are:

- **pregnant or plan to become pregnant.** If you receive SUBLOCADE while pregnant, your baby may have symptoms of opioid withdrawal at birth that could be life-threatening if not recognized and treated. Talk to your healthcare provider if you are pregnant or plan to become pregnant.
- **breastfeeding or plan to breastfeed.** SUBLOCADE can pass into your breast milk and harm your baby. Talk to your

healthcare provider about the best way to feed your baby during treatment with SUBLOCADE. Monitor your baby for increased drowsiness and breathing problems if you breastfeed during treatment with SUBLOCADE.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins and herbal supplements.

How will I receive SUBLOCADE?

- You will receive SUBLOCADE by your healthcare provider as an injection just under the skin (subcutaneous) of your stomach (abdomen). You will receive SUBLOCADE monthly (with at least 26 days between doses).
- SUBLOCADE is injected as a liquid. After the injection, SUBLOCADE changes to a solid form called a depot. The depot may be seen or felt as a small bump under your skin at the injection site on your abdomen for several weeks. The depot will get smaller over time.
- Do not try to remove the depot.
- Do not rub or massage the injection site.
- Try not to let belts or clothing waistbands rub against the injection site.
- If you miss a dose of SUBLOCADE, see your healthcare provider to get your SUBLOCADE injection as soon as possible.

What should I avoid while being treated with SUBLOCADE?

- **Do not drive, operate heavy machinery, or perform any other dangerous activities until you know how SUBLOCADE affects you.** Buprenorphine can cause drowsiness and slow reaction times. SUBLOCADE can make you sleepy, dizzy, or lightheaded. This may happen more often in the first few days after your injection and when your dose is changed.
- **You should not drink alcohol** or take prescription or over-the-counter medicines that contain alcohol during treatment with SUBLOCADE, because this can lead to loss of consciousness or even death.

What are the possible side effects of SUBLOCADE?

SUBLOCADE can cause serious side effects, including:

- **Trouble breathing.** Taking other opioid medicines, benzodiazepines, alcohol, or other central nervous system depressants during treatment with SUBLOCADE can cause breathing problems that can lead to coma and death.
- **Sleepiness, dizziness, and problems with coordination.**
- **Physical dependence.**
- **Liver problems**. Call your healthcare provider right away if you notice any of these symptoms:
  - your skin or the white part of your eyes turns yellow (jaundice)
  - dark or “tea-colored” urine
  - light colored stools (bowel movements)
  - loss of appetite
  - pain, aching, or tenderness on the right side of your stomach area
  - nausea
- Your healthcare provider should do blood tests to check your liver before you start and during treatment with SUBLOCADE.
- **Allergic reaction.** You may have a rash, hives, swelling of your face, wheezing, low blood pressure, or loss of consciousness. Call your healthcare provider or get emergency help right away.
- **Opioid withdrawal.** Call your healthcare provider right away if you get any of these symptoms:
  - shaking
  - sweating more than normal
  - feeling hot or cold more than normal
  - runny nose
  - watery eyes
  - goose bumps
  - diarrhea
  - vomiting
  - muscle aches
- **Decrease in blood pressure.** You may feel dizzy when you get up from sitting or lying down.
- **The most common side effects of SUBLOCADE include:**

- constipation
- headache
- nausea
- injection site itching
- vomiting
- increase in liver enzymes
- tiredness
- injection site pain
- SUBLOCADE may affect fertility in males and females. Talk to your healthcare provider if this is a concern for you.

These are not all the possible side effects of SUBLOCADE.

Call your doctor for medical advice about side effects. You may report side effects to the FDA at 1-800-FDA-1088.

General information about SUBLOCADE

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. You can ask your doctor or pharmacist for information that is written for healthcare professionals.

What are the ingredients in SUBLOCADE?

Active ingredient: buprenorphine

ATRIGEL® delivery system: biodegradable 50:50 poly(DL-lactide-co-glycolide) polymer and a biocompatible solvent, *N*-methyl-2-pyrrolidone (NMP).

Manufactured for Indivior Inc., North Chesterfield, VA 23235 by AMRI, Burlington, MA 01803

SUBLOCADE® is a registered trademark of Indivior UK Limited.

For more information, go to www.SUBLOCADE.com or call 1-877-782-6966.

This Medication Guide has been approved by the U.S. Food and Drug Administration. Issued: 03/2021

MEDICATION GUIDE

VIVITROL® (viv-i-trol)
(naltrexone for extended-release injectable suspension)

Read this Medication Guide before you start receiving VIVITROL injections and each time you receive an injection. There may be new information. This information does not take the place of talking to your healthcare provider about your medical condition or your treatment.

What is the most important information I should know about VIVITROL?

VIVITROL can cause serious side effects, including:

1. **Risk of opioid overdose.**

   You can accidentally overdose in two ways.

- VIVITROL blocks the effects of opioids, such as heroin or opioid pain medicines. **Do not** take large amounts of opioids, including opioid-containing medicines, such as heroin or prescription pain pills, to try to overcome the opioid-blocking effects of VIVITROL. This can lead to serious injury, coma, or death.
- After you receive a dose of VIVITROL, its blocking effect slowly decreases and completely goes away over time. If you have used opioid street drugs or opioid-containing medicines in the past, using opioids in amounts that you used before treatment with VIVITROL can lead to overdose and death. You may also be more sensitive to the effects of **lower** amounts of opioids:
  - o after you have gone through detoxification
  - o when your next VIVITROL dose is due
  - o if you miss a dose of VIVITROL
  - o after you stop VIVITROL treatment

  It is important that you tell your family and the people closest to you of this increased sensitivity to opioids and the risk of overdose.

You or someone close to you should call 911 or get emergency medical help right away if you:

- have trouble breathing
- become very drowsy with slowed breathing
- have slow, shallow breathing (little chest movement with breathing)
- feel faint, very dizzy, confused, or have unusual symptoms

Talk to your healthcare provider about naloxone, a medicine that is available to patients for the emergency treatment of an opioid overdose.

Call 911 or get emergency medical help right away in all cases of known or suspected opioid overdose, even if naloxone is administered.

2. **Severe reactions at the site of the injection (injection site reactions).** Some people on VIVITROL have had severe injection site reactions, including tissue death (necrosis). Some of these injection site reactions have required surgery. VIVITROL must be injected by a healthcare provider. Call your healthcare provider right away if you notice any of the following at any of your injection sites:
   - intense pain
   - the area feels hard
   - large area of swelling
   - lumps
   - blisters
   - an open wound

- a dark scab

Tell your healthcare provider about any reaction at an injection site that concerns you, gets worse over time, or does not get better by two weeks after the injection.

3. **Sudden opioid withdrawal.**

Anyone who receives a VIVITROL injection must not use any type of opioid (must be opioid-free) including street drugs, prescription pain medicines, cough, cold, or diarrhea medicines that contain opioids, or opioid dependence treatments, buprenorphine or methadone, **for at least 7 to 14 days** before starting VIVITROL. Using opioids in the 7 to 14 days before you start receiving VIVITROL may cause you to suddenly have symptoms of opioid withdrawal when you get the VIVITROL injection. **Sudden opioid withdrawal can be severe, and you may need to go to the hospital**.

You must be opioid-free before receiving VIVITROL unless your healthcare provider decides that you don't need to go through detox first. Instead, your doctor may decide to give your VIVITROL injection in a medical facility that can treat you for sudden opioid withdrawal.

4. **Liver damage or hepatitis.** Naltrexone, the active ingredient in VIVITROL, can cause liver damage or hepatitis.

Tell your healthcare provider if you have any of the following symptoms of liver problems during treatment with VIVITROL:

- stomach area pain lasting more than a few days
- dark urine
- yellowing of the whites of your eyes
- tiredness

Your healthcare provider may need to stop treating you with VIVITROL if you get signs or symptoms of a serious liver problem.

What is VIVITROL?

VIVITROL is a prescription injectable medicine used to:

- treat alcohol dependence. You should stop drinking before starting VIVITROL.
- prevent relapse to opioid dependence, **after** opioid detoxification.

  This means that if you take opioids or opioid-containing medicines, you must stop taking them before you start receiving VIVITROL. **See "What is the most important information I should know about VIVITROL?"**

To be effective, treatment with VIVITROL must be used with other alcohol or drug recovery programs such as counseling. VIVITROL may not work for everyone.

It is not known if VIVITROL is safe and effective in children.

Who should not receive VIVITROL?

Do not receive VIVITROL if you:

- are using or have a physical dependence on opioid-containing medicines or opioid street drugs. **See "What is the most important information I should know about VIVITROL?"**

  To see whether you have a physical dependence on opioid-containing medicines or opioid street drugs, your healthcare provider may give you a small injection of a medicine called naloxone. This is called a naloxone challenge test. **If you get symptoms of opioid withdrawal after the naloxone challenge test, do not start treatment with VIVITROL at that time.** Your healthcare provider may repeat the test after you have stopped using opioids to see whether it is safe to start VIVITROL.

- are having opioid withdrawal symptoms. Opioid withdrawal symptoms may happen when you have been taking opioid-containing medicines or opioid street drugs regularly and then stop.

  Symptoms of opioid withdrawal may include: anxiety, sleeplessness, yawning, fever, sweating, teary eyes, runny nose, goose bumps, shakiness, hot or cold flushes, muscle aches, muscle twitches, restlessness, nausea and vomiting, diarrhea, or stomach cramps. **See "What is the most important information I should know about VIVITROL?"** Tell your healthcare provider if you have any of these symptoms before taking VIVITROL.

- are allergic to naltrexone or any of the ingredients in VIVITROL or the liquid used to mix VIVITROL (diluent). See the end of this Medication Guide for a complete list of ingredients in VIVITROL and the diluent.

What should I tell my healthcare provider before receiving VIVITROL?

Before you receive VIVITROL, tell your healthcare provider if you:

- have liver problems
- use or abuse street (illegal) drugs
- have hemophilia or other bleeding problems
- have kidney problems
- have any other medical conditions
- are pregnant or plan to become pregnant. It is not known if VIVITROL will harm your unborn baby.
- are breastfeeding. It is not known if VIVITROL passes into your milk, and if it can harm your baby. Naltrexone, the active ingredient in VIVITROL, is the same active ingredient in tablets taken by mouth that contain naltrexone. Naltrexone from tablets passes into breast milk. Talk to your healthcare provider about whether you will breastfeed or take VIVITROL. You should not do both.

Tell your healthcare provider about all the medicines you take, including prescription and non-prescription medicines, vitamins, and herbal supplements.

Especially tell your healthcare provider if you take any opioid-containing medicines for pain, cough or colds, or diarrhea. **See "What is the most important information I should know about VIVITROL?"**

If you are being treated for alcohol dependence but also use or are addicted to opioid-containing medicines or opioid street drugs, it is important that you tell your healthcare provider before starting VIVITROL to avoid having sudden opioid withdrawal symptoms when you start VIVITROL treatment.

Know the medicines you take. Keep a list of them to show your healthcare provider and pharmacist when you get a new medicine.

How will I receive VIVITROL?

- VIVITROL is injected by a healthcare provider, about 1 time each month.
- VIVITROL must be injected by a healthcare provider. Do not attempt to inject yourself with VIVITROL. Serious reactions, some that may require hospitalization, might happen.
- VIVITROL is given as an injection into a muscle in your buttocks using a special needle that comes with VIVITROL.
- After VIVITROL is injected, it lasts for a month and it cannot be removed from the body.
- If you miss your appointment for your VIVITROL injection, schedule another appointment as soon as possible. **See "What is the most important information I should know about VIVITROL?"**
- Whenever you need medical treatment, be sure to tell the treating healthcare provider that you are receiving VIVITROL injections and mention when you got your last dose. This is important because

VIVITROL can also block the effects of opioid-containing medicines that might be prescribed for you for pain, cough or colds, or diarrhea.

- Carry written information with you at all times to alert healthcare providers that you are taking VIVITROL, so that they can treat you properly in an emergency. Ask your healthcare provider how you can get a wallet card to carry with you.

What should I avoid while receiving VIVITROL?

Do not drive a car, operate machinery, or do other dangerous activities until you know how VIVITROL affects you. VIVITROL may make you feel dizzy and sleepy. **See "What are the possible side effects of VIVITROL?"**

What are the possible side effects of VIVITROL?

VIVITROL can cause serious side effects, including:

- **See "What is the most important information I should know about VIVITROL?"**
- **Depressed mood.** Sometimes this leads to suicide, or suicidal thoughts, and suicidal behavior. Tell your family members and people closest to you that you are taking VIVITROL.

  You, a family member, or the people closest to you should call your healthcare provider right away if you become depressed or have any of the following symptoms of depression, especially if they are new, worse, or worry you:

  - You feel sad or have crying spells.
  - You are no longer interested in seeing your friends or doing things you used to enjoy.
  - You are sleeping a lot more **or** a lot less than usual.
  - You feel hopeless or helpless.
  - You are more irritable, angry, or aggressive than usual.
  - You are more or less hungry than usual or notice a big change in your body weight.
  - You have trouble paying attention.
  - You feel tired or sleepy all the time.
  - You have thoughts about hurting yourself or ending your life.
- **Pneumonia.** Some people receiving VIVITROL treatment have had a certain type of pneumonia that is caused by an allergic reaction. If this happens to you, you may need to be treated in the hospital. Tell your healthcare provider right away if you have any of these symptoms during treatment with VIVITROL:
  - shortness of breath or wheezing
  - coughing that does not go away
- **Serious allergic reactions**. Serious allergic reactions can happen during or soon after an injection of VIVITROL. Tell your healthcare provider or get medical help right away if you have any of these symptoms of a serious allergic reaction.
  - skin rash
  - swelling of your face, eyes, mouth, or tongue
  - trouble breathing or wheezing
  - chest pain
  - feeling dizzy or faint

Common side effects of VIVITROL may include:

- nausea. Nausea may happen after your first VIVITROL injection and usually improves within a few days. Nausea is less likely with future injections of VIVITROL.
- sleepiness
- headache
- dizziness
- vomiting
- decreased appetite
- painful joints
- muscle cramps
- cold symptoms
- trouble sleeping
- toothache

Tell your healthcare provider if you have any side effect that bothers you or that does not go away.

These are not all the side effects of VIVITROL. For more information, ask your healthcare provider or pharmacist.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

General information about VIVITROL

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. This Medication Guide summarizes the most important information about VIVITROL. If you would like more information, talk with your healthcare provider. You can ask your healthcare provider or pharmacist for information about VIVITROL that is written for health professionals.

For more information about VIVITROL call 1-800-848-4876, Option #1 or go to www.vivitrol.com.

What are the ingredients in VIVITROL?

Active ingredient: naltrexone

Inactive ingredients: polylactide-co-glycolide (PLG)

Diluent ingredients: carboxymethylcellulose sodium, polysorbate 20, sodium chloride, sodium hydroxide and hydrochloric acid as pH adjusters, in water for injection.

This Medication Guide has been approved by the U.S. Food and Drug Administration.

Manufactured and marketed by:

Alkermes, Inc.
852 Winter Street
Waltham, MA 02451-1420

Revised: March 2021

WORDS MATTER:

What we say and how we say it makes a difference to our patients with substance use disorder.

NON-STIGMATIZING LANGUAGE	STIGMATIZING LANGUAGE
• Person with a substance use disorder	• Substance abuser or drug abuser • Alcoholic • Addict • User • Abuser • Drunk • Junkie
• Substance use disorder or addiction • Use, misuse • Risky, unhealthy, or heavy use	• Drug habit • Abuse • Problem
• Person in recovery • Abstinent • Not drinking or taking drugs	• Clean
• Treatment or medication for addiction • Medication for Addiction Treatment • Positive, negative (toxicology screen results)	• Substitution or replacement therapy • Medication-Assisted Treatment • Clean, dirty

BOSTON MEDICAL CENTER
Grayken Center for Addiction Medicine

Annual questionnaire

Once a year, all our patients are asked to complete this form because drug and alcohol use can affect your health as well as medications you may take.
Please help us provide you with the best medical care by answering the questions below.

Patient name: _____

Date of birth: _____

Are you currently in recovery for alcohol or substance use? ☐ Yes ☐ No

Alcohol: One drink =

12 oz. beer

5 oz. wine

1.5 oz. liquor (one shot)

	None	1 or more
MEN: How many times in the past year have you had 5 or more drinks in a day?	○	○
WOMEN: How many times in the past year have you had 4 or more drinks in a day?	○	○

Drugs: Recreational drugs include methamphetamines (speed, crystal), cannabis (marijuana, pot), inhalants (paint thinner, aerosol, glue), tranquilizers (Valium), barbiturates, cocaine, ecstasy, hallucinogens (LSD, mushrooms), or narcotics (heroin).

	None	1 or more
How many times in the past year have you used a recreational drug or used a prescription medication for nonmedical reasons?	○	○

Step-by-Step Clinical Discussion Tool

Patient presents with the following symptoms: Pain in the muscles, diarrhea, vomiting, or nausea, restlessness or sweating, anxiety, dilated pupil or watery eyes Also common: cramping abdominal pain, fast heart rate, excessive yawning, goose bumps, insomnia, or tremor

1

Screen patient for substance use disorders and co-occurring mental and medical disorders

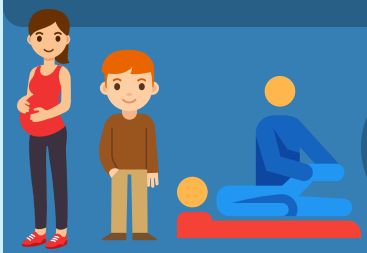
OUD: The Tobacco, Alcohol, Prescription medications, and other Substance (TAPS) Tool
Tobacco use | Assess IV drug use | Drug treatment history | Depression PHQ-2 | Chronic pain
Women pregnant, use of contraception | Overdose education and naloxone prescription
HIV viral hepatitis

2

Positive Screen

Brief Motivational Interview

1. Provide feedback and review screening results. Express concern for health.
2. Recommend cessation/reduction
3. Urge patient to consider treatment.



3

Consider Treatment Options

Special considerations:

- Under 18 years of age
- Pregnant
- Chronic pain. Some patients benefit from moderate analgesic benefits of buprenorphine. Mild or moderate pain attempt 2-4 weeks of low doses of buprenorphine. If patient declines treatment, refer to opioid treatment program. Methadone provides more analgesic if full opioid agonist for pain is needed.

4

Shared Decision-Making

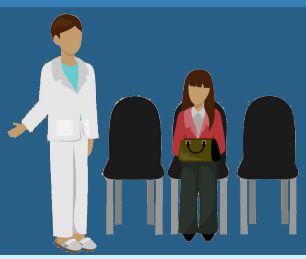
- DOD VA Practice Guidelines
- Click chart page 7 from workgroup
- 42 CFR-part 2

5

Initiating Treatment

Which medication is best suited for the patient's needs

- Buprenorphine?
- Methadone?
- Naltrexone?



6

Continuum of Care

- Stabilize patient and plan to see them weekly in the early stages to determine clinical needs and dose adjustments. *Note: It is not uncommon for patients to need increased dosage to address craving and other needs. Importance of drug screens to help determine if adjustments in dosage are needed.*
- Discuss support groups

Resources and Lessons Learned for Correctional and Detention Facilities Preparing for the Release of Persons with Substance Use Disorder during COVID-19

Linking people with substance use disorder (SUD) to care and treatment as they return to their communities is an important consideration for correctional and detention facilities anticipating scheduled releases or seeking to reduce incarcerated populations in response to the COVID-19 pandemic.

Numerous studies demonstrate that the post-release period is an especially common time for fatal drug overdoses, particularly opioid overdoses.[i, ii, iii] Linkage to care and treatment, including access to medications for opioid use disorder **(MOUD)** and provision of naloxone, an opioid overdose reversal drug, can help ensure the safety of those released. Research shows that providing incarcerated people buprenorphine or methadone, two of three medications used to treat opioid use disorder, while persons are in custody or for at least 4 weeks in the community after release, is associated with significant reductions in overdose deaths in the immediate post-release period.[iv, v]

These critically important linkages to care can be logistically complex during the COVID-19 pandemic, especially in the case of unscheduled or early release. This resource highlights strategies and lessons learned based on conversations with several criminal justice professionals who have linked people granted early release to care and treatment for SUD during the COVID-19 pandemic. Many of these considerations apply to early and scheduled releases and constitute best practices even in the absence of COVID-19. Their application ultimately will depend on locally available programs and resources.

BEFORE RELEASE

Begin coordinating post-release care early

- Consider screening all incarcerated individuals for SUD with an evidence-based screening tool at the earliest possible opportunity, ideally during intake or booking, and start persons with SUD on treatment upon incarceration.
- Review early release criteria for your community, if applicable, and identify people with SUD who may be eligible for early release due to COVID-19.
- Even if early release is not indicated, use screening results to start planning post-release care and treatment. Ideally,
  - » start planning immediately, given that some people have shorter stays.
  - » work with incarcerated people to identify appropriate community-based treatment providers, including those providing MOUD, in addition to other needed services and support.
  - » assist with making initial appointments with community providers in advance, if possible.
  - » delegate planning to reentry coordinators, case managers, or other transitional support staff, if available.

- In case pre-release planning is not always possible, identify SUD treatment and other service providers in the community (including syringe service, housing, primary care, and nutritional support programs) who are able to accept recently released people. Share their contact information when the person is released. Building partnerships with treatment and service providers in advance is important for success.
- As mentioned, provide contact information to people being released and assist with making appointments if possible. If persons with SUD do not have insurance, ensure that all eligible people are enrolled or reenrolled in Medicare and/or Medicaid before release to facilitate connections to community providers.
- For persons being transferred to another facility, provide temperature and symptom checks before transfer.

Follow CDC guidelines for screening people for COVID-19 prior to release. This is critical to reduce community transmission and ensure linkage, as some community-based providers may require a negative COVID-19 test result to receive SUD care.

Assist in ensuring that medications for opioid use disorder are provided continuously at the correctional facility

- Some strategies that jails and prisons can follow to support provision of MOUD to people who need it include:
  - » using telehealth to initiate or continue patients on medication without an in-person visit, in accordance with SAMHSA regulations during the national emergency declared in response to the COVID-19 pandemic.
  - » shifting to cell-side dosing, where medications are administrated to individuals in their cells as opposed to a shared dosing room.
  - » planning for staffing shortages that could affect service delivery.
  - » reserving the clinical space required for initiating MOUD.
- Sustaining access to MOUD for incarcerated populations both on-site and after release is critical for reducing their chances of nonfatal or fatal overdose upon release and increasing likelihood of getting treatment in the community.

Prepare for immediate medication-related treatment needs in the post-release period

For Persons Receiving MOUD During Incarceration:

- In alignment with other COVID-19 guidance for prescribing and dispensing medication, consider steps to ensure that anyone taking MOUD is provided enough medication or a bridge prescription to last until their first appointment with a community-based provider post-release. If their appointment date is unknown, consider providing a 14–28 day supply of medication.
  - » For buprenorphine: To begin treatment for opioid use disorder the patient must abstain from using opioids for at least 12 to 24 hours and be in the early stages of opioid withdrawal.
  - » For naltrexone: To reduce the risk of withdrawal symptoms, patients should wait at least 7 days after their last use of short-acting opioids and 10 to 14 days for long-acting opioids, before starting naltrexone.

For Persons NOT Receiving MOUD During Incarceration:

- If MOUD is not available to individuals who need it during incarceration, consider offering extended-release buprenorphine or naltrexone injections at the time of release, if medically appropriate, along with linkage to continued medication treatment with a community-based provider. Ensure that people being released are also aware that, during the pandemic, SAMHSA allows buprenorphine to be prescribed via telehealth without an in-person examination.

Use educational and training videos

- Facilities can show educational videos on relevant topics, such as MOUD, recovery, harm reduction, and overdose prevention and response, to supplement information typically provided by staff.

For additional linkage to care resources, please see Public Safety-led Linkage to Care Programs in 23 States.

POST RELEASE

Provide additional harm reduction and recovery resources at release

- Consider arranging for peer recovery specialists or other transitional support staff to meet people at discharge with vehicles that allow for social distancing to protect yourself when using transportation.
- Provide other critical resources, such as naloxone kits and information on how to join an online recovery support group, develop an overdose prevention plan, and enroll in a local syringe services program.

Follow up with recently released persons

- If staffing and resources permit, have transitional support staff follow up with recently released individuals in the community to ensure linkage to and retention in care and treatment.
    - » Use information from follow-up with recently released people to inform updates to release processes.

Strive for warm handoffs to community-based providers

- In contrast to cold handoffs, which involve the provision of information or referrals that put the burden of follow-up on the recently released person, warm handoffs link people directly to treatment and other support services, such as housing, employment, and vocational training. Warm handoffs to community-based providers can lead people to engage more with services after their release.
- Strategies may include connecting people with post-release providers before release, facilitating transportation to services upon discharge and in the weeks and months that follow, and pairing individuals with peers for ongoing assistance with navigating systems of treatment and care.

SPOTLIGHT

In response to COVID-19, one county jail in the Midwest reduced its jail population by half within 1 week, resulting in the early release of approximately 600 people. During this period, all behavioral staff transitioned to providing services via telehealth, with the exception of two mental health workers who continued working onsite with personal protective equipment (PPE). Reentry case managers and peer recovery coaches continued in-person meetings with people outside the facility at the time of their release (with appropriate PPE). Behavioral health staff also adjusted their schedules to include night and weekend hours to be able to screen as many people as possible for substance use disorder (SUD) before release. Staff followed up with 100% of people released to offer linkage to care and treatment in the community, whether or not they had a case manager visit before release.

ADDITIONAL RESOURCES

CDC Interim Guidance on Management of Coronavirus Disease 2019 (COVID-19) in Correctional and Detention Facilities

Toolkit page COVID-19 toolkit for correctional facilities

SAMHSA DEA/SAMHSA Guidance Buprenorphine Telemedicine

SAMHSA SAMHSA FAQs for the provision of methadone and buprenorphine for the treatment of Opioid Use Disorder in the COVID-19 emergency

SAMHSA SAMHSA Medication assisted treatment

SAMHSA Buprenorphine Practitioner Locator

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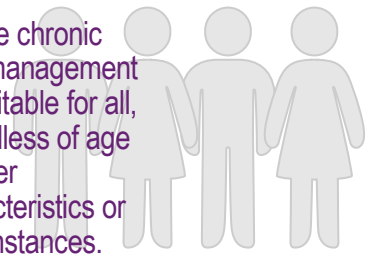
Management of Opioid Use and Misuse in Older Adults: High-Leverage Changes for Improvement

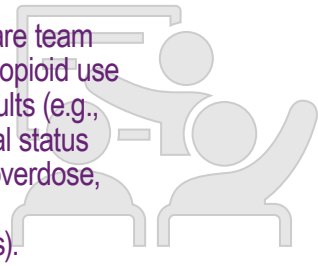
EQUITY

Ensure chronic pain management is equitable for all, regardless of age or other characteristics or circumstances.



EDUCATION

Educate care team on risks of opioid use in older adults (e.g., falls, mental status changes, overdose, medication interactions).



RISK ASSESSMENT

Develop workflows to assess/screen for opioid-related risks (e.g., misuse, opioid use disorder (OUD), delirium, falls).

OUD ASSESSMENT AND TREATMENT

Assess for OUD in older adults and provide treatment for those who meet criteria.

PROCESS AND WORKFLOWS

Develop workflows that define roles and promote coordinated team-based care for older adults on opioids.

SHARED DECISION-MAKING AND PATIENT ACTIVATION

Engage in shared decision-making and patient-centered goal setting when developing care plans.

NON-PHARMACOLOGIC PAIN MANAGEMENT

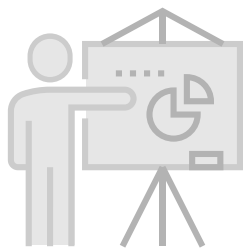
Increase access to non-pharmacologic approaches to chronic pain management including self-management support and linkages to community resources.

MEDICATION MANAGEMENT

Integrate medication management protocols for older adults on opioids (e.g., medication reconciliation, tapering protocols, treatment agreements).

OPIOID DATA

Identify, track, monitor, and pro-actively follow-up with older adults on opioids.



Agency for Healthcare Research and Quality

Please direct questions to:
Opioids_OlderAdults@abtassoc.com

SAMHSA
Opioid Overdose Prevention TOOLKIT

Five Essential Steps for First Responders

SAMHSA
Substance Abuse and Mental Health Services Administration

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SAMHSA Opioid Overdose Prevention Toolkit

FIVE ESSENTIAL STEPS FOR FIRST RESPONDERS

Overdose is common among persons who use illicit opioids such as heroin and among those who misuse medications prescribed for pain such as oxycodone, hydrocodone, methadone, buprenorphine, and morphine. The incidence of opioid overdose is rising nationwide. In 2016, more than 42,000 of the drug overdose deaths in the United States involved some type of opioid, including heroin.[1]

To address the problem, emergency medical personnel, health care professionals, people who use drugs, and other community members who may witness and respond to an overdose are being trained in the use of the opioid antagonist medication naloxone, which can reverse the potentially fatal respiratory depression caused by opioid overdose. (Note that naloxone has no effect on non-opioid overdoses, such as those involving cocaine, benzodiazepines, or alcohol.[2])

The steps outlined in this section are recommended to reduce the number of deaths resulting from opioid overdoses.

STEP 1: EVALUATE FOR SIGNS OF OPIOID OVERDOSE

Signs of **OVERDOSE**, which often results in death if not treated, include:[2]

- Unconsciousness or inability to awaken.
- Slow or shallow breathing or breathing difficulty such as choking sounds or a gurgling/snoring noise from a person who cannot be awakened.
- Fingernails or lips turning blue/purple.

If an opioid overdose is suspected, stimulate the person:

- Call the person's name.
- If this doesn't work, vigorously grind knuckles into the sternum (the breastbone in middle of chest) or rub knuckles on the person's upper lip.
- If the person responds, assess whether he or she can maintain responsiveness and breathing.
- Continue to monitor the person, including breathing and alertness, and try to keep the person awake and alert.

If the person does not respond, call 911, provide rescue breathing if the person is not breathing on their own, and administer one dose of naloxone.

STEP 2: CALL 911 FOR HELP

AN OPIOID OVERDOSE NEEDS IMMEDIATE MEDICAL ATTENTION. An essential step is to get someone with medical expertise to see the person as soon as possible. If no emergency medical services (EMS) or other trained personnel is on the scene, activate the 911 emergency system immediately. All you have to say is "Someone is unresponsive and not breathing." Be sure to give a specific address and/or description of your location. After calling 911, follow the dispatcher's instructions. If appropriate, the 911 operator will instruct you to begin CPR (technique based on rescuer's level of training).

STEP 3: ADMINISTER NALOXONE

If the person overdosing does not respond within 2 to 3 minutes after administering a dose of naloxone, administer a second dose of naloxone.

Naloxone should be administered to anyone who presents with signs of opioid overdose or when opioid overdose is suspected. Naloxone is approved by the Food and Drug Administration (FDA) and has been used for decades by EMS personnel to reverse opioid overdose and resuscitate individuals who have overdosed on opioids. Research has shown that women, older people, and those without obvious signs of opioid use disorder are undertreated with naloxone and, as a result, have a higher death rate.[3] Therefore, it is also important to consider naloxone administration in women and the elderly found unresponsive with opioid overdose.

Naloxone can be given by intranasal spray and by intramuscular (into the muscle), subcutaneous (under the skin), or intravenous injection.[4]

All naloxone products are effective in reversing opioid overdose, including fentanyl-involved opioid overdoses, although overdoses involving potent (e.g., fentanyl) or large quantities of opioids may require more doses of naloxone.

DURATION OF EFFECT. The duration of effect of naloxone depends on dose, route of administration, and overdose symptoms[5] and is shorter than the effects of some opioids. The goal of naloxone therapy should be to restore adequate spontaneous breathing, but not necessarily complete arousal.[5]

More than one dose of naloxone may be needed to revive someone who is overdosing. People who have taken longer acting or more potent opioids may require additional intravenous bolus doses or an infusion of naloxone.[6]

Comfort the person being treated, as withdrawal triggered by naloxone can feel unpleasant. Some people may become agitated or confused, which may improve by providing reassurance and explaining what is happening.

SAFETY OF NALOXONE. The safety profile of naloxone is remarkably high, especially when used in low doses and titrated to effect.[2] When given to individuals who are not opioid intoxicated or opioid dependent, naloxone produces no clinical effects, even at high doses. Moreover, although rapid opioid withdrawal in opioid-tolerant individuals may be unpleasant, it is not life threatening.

Naloxone can be used in life-threatening opioid overdose circumstances in pregnant women.[7]

The FDA has approved an injectable naloxone, an intranasal naloxone, and a naloxone auto-injector as emergency treatments for opioid overdose. People receiving naloxone kits that include a syringe and naloxone ampules or vials should receive brief training on how to assemble and administer the naloxone to the victim. The nasal spray is a prefilled, needle-free device that requires no assembly and that can deliver a single dose into one nostril. The auto-injector is injected into the outer thigh to deliver naloxone to the muscle (intramuscular) or under the skin (subcutaneous). Once turned on, the currently available device provides verbal instruction to the user describing how to deliver the medication, similar to automated defibrillators. Both the nasal spray and naloxone auto-injector are packaged in a carton containing two doses to allow for repeat dosing if needed.

FENTANYL-INVOLVED OVERDOSES. Suspected opioid overdoses, including suspected fentanyl-involved overdoses, should be treated according to standard protocols.[8] However, because of the higher potency of fentanyl and fentanyl analogs compared to that of heroin, multiple doses of naloxone may be required to reverse the opioid-induced respiratory depression from a fentanyl-involved overdose.[8,9,10]

Many anecdotes report more rapid respiratory depression with fentanyl than with heroin, although other reports do not reflect such rapid depression.[11]

Because of these effects, quicker oxygenation efforts and naloxone delivery may be warranted with fentanyl-involved overdoses compared with heroin-only overdoses. However, naloxone is an appropriate response for all opioid overdoses, including fentanyl-involved overdoses.

STEP 4: SUPPORT THE PERSON'S BREATHING

Ventilatory support is an important intervention and may be lifesaving on its own. Rescue breathing can be very effective in supporting respiration, and chest compressions can provide ventilatory support.[12,13] Rescue breathing for adults involves the following steps:

- Be sure the person's airway is clear (check that nothing inside the person's mouth or throat is blocking the airway).
- Place one hand on the person's chin, tilt the head back, and pinch the nose closed.
- Place your mouth over the person's mouth to make a seal and give two slow breaths.
- Watch for the person's chest (but not the stomach) to rise.
- Follow up with one breath every 5 seconds.

Chest compressions for adults involve the following steps:

- Place the person on his or her back.
- Press hard and fast on the center of the chest.
- Keep your arms extended.

STEP 5: MONITOR THE PERSON'S RESPONSE

All people should be monitored for recurrence of signs and symptoms of opioid toxicity for at least 4 hours from the last dose of naloxone or discontinuation of the naloxone infusion. People who have overdosed on long-acting opioids should have more prolonged monitoring.[2,5,6]

Most people respond by returning to spontaneous breathing. The response generally occurs within 2 to 3 minutes of naloxone administration. (Continue resuscitation while waiting for the naloxone to take effect.)[2,5]

Because naloxone has a relatively short duration of effect, overdose symptoms may return.[2,5,6] Therefore, it is essential to get the person to an emergency department or other source of medical care as quickly as possible, even if the person revives after the initial dose of naloxone and seems to feel better.

SIGNS OF OPIOID WITHDRAWAL. The signs and symptoms of opioid withdrawal in an individual who is physically dependent on opioids may include body aches, diarrhea, tachycardia, fever, runny nose, sneezing, piloerection (gooseflesh), sweating, yawning, nausea or vomiting, nervousness, restlessness or irritability, shivering or trembling, abdominal cramps, weakness, tearing, insomnia, opioid craving, dilated

pupils, and increased blood pressure. These symptoms are uncomfortable, but not life threatening. After an overdose, a person dependent on opioids should be medically monitored for safety and offered assistance to get into treatment for opioid use disorder.

If a person does not respond to naloxone, an alternative explanation for the clinical symptoms should be considered. The most likely explanation is that the person is not overdosing on an opioid but rather some other substance or may be experiencing a non-overdose medical emergency.

In all cases, support of ventilation, oxygenation, and blood pressure should be sufficient to prevent the complications of opioid overdose and should be given priority if the response to naloxone is not prompt.

DO'S AND DON'TS WHEN RESPONDING TO OPIOID OVERDOSE

- DO attend to the person's breathing and cardiovascular support needs by administering oxygen or performing rescue breathing and/or chest compressions.
- DO administer naloxone and utilize a second dose, if no response to the first dose.
- DO put the person in the "recovery position" on the side, if you must leave the person unattended for any reason.
- DO stay with the person and keep the person warm.
- DON'T slap or forcefully try to stimulate the person; it will only cause further injury. If you cannot wake the person by shouting, rubbing your knuckles on the sternum (center of the chest or rib cage), or light pinching, the person may be unconscious.
- DON'T put the person into a cold bath or shower. This increases the risk of falling, drowning, or going into shock.
- DON'T inject the person with any substance (e.g., saltwater, milk, stimulants). The only safe and appropriate treatment is naloxone.
- DON'T try to make the person vomit drugs that may have been swallowed. Choking or inhaling vomit into the lungs can cause a fatal injury.

NOTE: All naloxone products have an expiration date, so it is important to check the expiration date and obtain replacement naloxone as needed.

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APPENDIX 16: LIST OF ACRONYMS

BMC: Boston Medical Center

BSAS: Bureau of Substance Abuse Services

CFR-42: Code of Federal Regulations, Title 42

CNS: Central Nervous System

COWS: Clinical Opioid Withdrawal Scale

CSAT: SAMHSA's Center for Substance Abuse Treatment

CSS: Clinical Stabilization Services (short-term inpatient stabilization)

DATA 2000: Drug Addiction Treatment Act of 2000

DEA: US Drug Enforcement Agency

DCF: Department of Children and Families

DSM: Diagnostic and Statistical Manual of Mental Disorders

ETOH: Alcohol

FDA: Food and Drug Administration

GC/MS: Gas Chromatography/Mass Spectrometry

HCG: Human Chorionic Gonadotropin

HIPAA: Health Insurance Portability and Accountability Act

IOP: Intensive Outpatient Program (counseling)

LFT: Liver Function Test

NAS: Neonatal Abstinence Syndrome

NCM: Nurse Care Manager

NSAID: Non-steroidal Anti-inflammatory Drug

NSDUH: National Survey on Drug Use and Health

OBAT: Office Based Addiction Treatment

OUD: Opioid Use Disorder

OTP: Outpatient Treatment Program (daily medication administration treatment)

PCA: Patient Controlled Analgesia

PDMP: Prescription Drug Monitoring Program

STATE-OBAT: State Technical Assistance and Treatment Expansion of Office Based Addiction Treatment with buprenorphine and naltrexone formulation

TSS: Transitional Stabilization Services (inpatient "holding" facility)

UTS: Urine Toxicology Screening

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