



**Spectrum
Health**

Primary Health

Substance Use Disorder Toolkit



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Purpose

The purpose of this clinical guideline is to provide detailed policies and protocols of the office-based addiction treatment program for the use of buprenorphine (alone and in combination with naloxone) or naltrexone (oral and extended-release injectable formulations) and acamprosate in the treatment of substance use disorders.

These policies and protocols are meant to provide best practice guidelines to clinicians utilizing buprenorphine and/or naltrexone and acamprosate for the management of opioid use disorders and alcohol use disorders in mainstream medical practices and to expand access to treatment.

Philosophy

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

Introduction

Introduction to Office Based Addiction Treatment (OBAT) Program

Federal data from the 2017 National Survey on Drug Use and Health indicates that 3.2 million people aged 12 or older in the United States (US) reported nonmedical use of prescription pain medication in the past month and 700,000 reported heroin use during the past month.¹ Largely driven by opioids, drug overdose is the leading cause of personal injury-related death in the US.² Since 1999, the rate of overdose death involving any opioid has quadrupled.³ From 2000 to 2015, more than half a million people died from drug overdoses.⁴ Additionally, in 2015, there were approximately 1.5 times more deaths in the US related to drug overdose than deaths related to motor vehicle accidents. In the same year, overdose death rates involving a synthetic opioid, such as fentanyl (not including methadone) increased by 72.2%; increased death rates attributed to synthetic opioids were seen across all demographics, regions and in numerous states.⁵ In 2016, approximately 20.1 million people in the US met criteria for a substance use disorder; however, only one in 10 of those individuals received any specialized care for their substance use disorder.¹ This treatment gap has been attributed to numerous barriers, such as lack of patient and provider knowledge of evidence-based treatments, limited treatment capacity, stigma, and financial, legislative and geographic obstacles.⁶⁻⁹

Substance use disorders are a group of chronic medical conditions defined in the *Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM-5)* of the American Psychological Association that require long-term treatment and support.¹⁰ The US Food and Drug Administration (FDA) has approved three medications for the treatment of opioid use disorder: (i) oral **methadone** (full opioid agonist); (ii) oral transmucosal, injectable, and sub-dermal implant **buprenorphine** (nonselective partial opioid agonist) and (iii) oral formulation and long-acting injectable **naltrexone** (opioid antagonist). The most effective treatment for opioid use disorder involves medication maintenance for an adequate duration of time; the effectiveness of opioid agonist maintenance for treatment of opioid use disorder has been extensively documented through randomized clinical trials, quasi-experimental designs and program evaluations.¹¹ There is evidence to support the use of injectable naltrexone for the treatment of opioid use disorder, particularly in specific populations, though, in general, treatment outcomes have been inferior to those attained with methadone and buprenorphine maintenance.¹² At sufficiently high doses, opioid agonist maintenance treatment relieves the craving for opioids.¹³ Continuous, steady-state medication maintenance treatment decreases the interaction between the opioid agonist medication (i.e., methadone or buprenorphine) and the μ -opioid receptors in the brain, blocking or attenuating the euphoric effects of illicit opioids (e.g., heroin).¹⁴

Buprenorphine/naloxone was the first medication available to treat opioid use disorder by prescription in a physician's office or clinic outside of a traditional Outpatient Treatment Program (OTP). Prior to the advent of buprenorphine/naloxone, methadone was the only medication approved by the FDA to treat opioid use disorder in the US and it can only be dispensed at licensed methadone maintenance clinics. Unlike methadone, which is a full opioid agonist, buprenorphine is a μ -opioid receptor partial agonist. Due to a slow disassociation from the opioid receptor, the withdrawal syndrome from buprenorphine is milder when compared to that resulting from full opioid agonists (i.e., methadone). Naloxone, an opioid receptor antagonist, was added to buprenorphine to deter misuse (i.e., injection) and diversion. When administered sublingually, naloxone is poorly absorbed and has little to no pharmacological effects.¹⁵ Buprenorphine without naloxone (mono tablet) is typically only prescribed to women during pregnancy and that indication has been questioned recently leading most persons prescribing during pregnancy

using buprenorphine/naloxone medications at this time. Nationally, the number of patients receiving treatment with buprenorphine/naloxone has been increasing steadily, with good treatment retention. A recent evaluation of the federal buprenorphine waiver program (DATA 2000), found that of the 433 patients on buprenorphine maintenance interviewed, at a six-month follow-up, 60% were still retained in treatment and another 15% had completed treatment.¹⁶

In 2016, over half of individuals aged 12 and older in the US reported drinking alcohol in the past 30 days; one in three reported heavy episodic alcohol use.¹ In 2016, 15.1 million people in the US had an alcohol use disorder, comprising over 75% of people in with a substance use disorder in the country. Alcohol use exists on a spectrum, beginning with abstinence and lower-risk drinking ranging all the way to severe alcohol use disorder or addiction. Typically, the severity of consequences positively correlates with consumption. Unhealthy alcohol use is associated with risk of serious chronic health conditions (e.g., liver cirrhosis) as well as risks related to acute intoxication and alcohol withdrawal, such as accidental injury and death.¹⁷ Excessive alcohol use is the fourth leading cause of preventable death in the US;¹⁸ between 2006 and 2010 there were 88,000 alcohol-related deaths in the US.¹⁹

Naltrexone is a competitive mu, kappa, and delta opioid receptor antagonist that blocks the effects of opioids by competitive binding. Naltrexone is available as an oral tablet that is taken daily, and an extended-release injectable formulation, administered intramuscularly into gluteal muscle every twenty-eight days. The FDA approved the oral formulation of naltrexone for treatment of alcohol use disorder in 2006, and the extended-release version was approved in 2010 for treatment of both alcohol use disorder and opioid use disorder following detoxification. The mechanism of action of naltrexone in alcohol use disorder is less clear, but is related to blockage of opiate receptors related to the rewarding effects of alcohol use and craving.²⁰

Acamprosate is another form of treatment for alcohol use disorder (AUD). This medication is used along with counseling and support to help people who have alcohol use disorder not drink alcohol. Acamprosate works by restoring the natural balance of chemicals in the brain (neurotransmitters).²¹

Patients with substance use disorders should be offered medication for addiction treatment and psychosocial therapies as part of a comprehensive plan to treat their disease. Like other chronic disease models, substance use disorders can be effectively managed in a primary care office or community clinic by employing models of care such as Office Based Addiction Treatment (OBAT) using a medical assistant and prescriber model. Integration of addiction treatment into office-based primary care settings is imperative to expanding access to effective addiction treatment and implementing evidence-based models of care.

Introduction to the Medical Assistant/Provider Model of OBAT

Spectrum Health's Center for Integrative Medicine (CIM) is a large office-based addiction treatment (OBAT) program. CIM OBAT Medical Assistant (MA) responsibilities encompass patient screening, rooming, referral follow up, compliance with outside counseling, education, telephone monitoring, overdose education and medication induction with supervising provider. The medical providers are responsible for on-going medical management, coordination of in office follow-up care, treatment intervention and support for patient self-management.

Primary care providers can treat this chronic illness in the same setting they treat other chronic illnesses like diabetes and hypertension. In a similar way, not all patients with hypertension need to see the cardiologist, not all patients need to see an addiction specialist. Other staff, including providers with a buprenorphine waiver, nurses, medical assistants, pharmacist, and social workers that may work within these spaces may also assist with care and care coordination.

OBAT Philosophy

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

Staffing Requirements

OBAT Clinic Provider Requirements

Buprenorphine, 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 opioid use disorder for the purpose of detoxification or maintenance treatment of patients with opioid use disorder. With DATA 2000, physicians became legally qualified to receive waiver training. In July 2016, the Comprehensive Addiction and Recovery Act was signed into law, increasing buprenorphine prescription authority to also include physician assistants and nurse practitioners. In 2018, the support act further expanded this to include all advanced practice nursing (certified nurse midwifery, certified nurse anesthetists and certified nurse specialists).

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), completion of an eight-hour approved waiver training course and one or more of the following:

- Board subspecialty certification for addiction psychiatry and addiction (*American Board of Medical Specialties*), addiction (*American Society of Addiction Medicine*), or addiction medicine (*American Osteopathic Academy of Addiction Medicine*, *American Board of Medical Specialties*, *American Board of Addiction Medicine*).
- OR-
- Participation as an investigator in one or more trials that led to the FDA approval of buprenorphine/naloxone or another schedule III-V narcotic medication used for the maintenance or detoxification treatment of opioid addiction.
- OR-
- Other training or experience deemed equivalent by either the state Medical Board or by the Secretary of Health and Human Services (HHS).

NP/PA/Nurse Midwives/CNS/CNA Waiver Eligibility: To be eligible for a waiver, these providers must complete 24 hours of approved training that covers the following topics: opioid maintenance and detoxification; clinical use of all FDA-approved drugs for medication-assisted treatment; patient assessment; treatment planning; psychosocial services; staff roles; and diversion control. These providers, who are approved to prescribe buprenorphine must be supervised by or work in collaboration with a qualifying physician if required by law in their state.

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

Patient Limits: For the first year following receipt of a waiver, providers are limited to treating 30 active patients at any given time; after the first year, they are limited to treating 100 patients at any given time (e.g., prescription written for 28 days, patient is discharged, that patient continues to count under that physician number until the end of that 28-day prescription). For a provider to become eligible to treat up to 100 patients, they need to apply to SAMHSA's Center for Substance Abuse Treatment (CSAT) at www.buprenorphine.samsha.gov for the extended waiver.

There are expanded limits to treat up to 275 patients. Eligible prescribers must complete a 'Request for Patient Increase Form' and receive approval prior to increase. To be eligible for a patient limit of 275, a provider must have a current waiver to treat up to 100 patients and must have maintained that waiver for at least one year without interruption.

Physicians wishing to increase to a patient limit of 275 must also meet one of the following requirements:

- Hold a board certification in addiction psychiatry or addiction medicine

Certifying agencies: American Board of Medical Specialties (ABMS), American Society of Addiction Medicine (ASAM), American Board of Addiction Medicine (ABAM), American Osteopathic Academy of Addiction Medicine (AOAAM).

-OR-

- Practice in a "qualified practice setting".

A "qualified practice setting" must provide professional coverage for patient emergencies during hours when the practice is closed, provide access to case management services, accept third-party payment for health service costs, utilize health information technology and be registered by their state prescription drug monitoring program where operational.

Advanced practice providers qualify for 275 patients exclusively through being in a "qualified practice setting".

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 (physician, advanced practice nurse or physician assistant) may prescribe and/or administer naltrexone. There is no limit to the number of patients that a provider could 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 patient selection and monitoring.

OBAT Medical Assistant

Qualifications: A medical assistant is a person who graduated from either an accredited medical assisting program or a medical assistant program that is housed within an accredited institution, provided that in the latter case the program includes a minimum of 720 clock-hours (or equivalent) of training, including 160 hours of clinical externship (or as required by state law). To become registered or certified one must comply with the eligibility requirements of American Medical Technologist (RMA) or American Association of Medical Assistants (CMA). Each program has an exam to become credentialed and requires an individual to get CEU's.

Responsibilities:

- Oversight of buprenorphine/naloxone and naltrexone intake data collection, stabilization, maintenance and relapse management. For medical decision making, all information gathered will be passed along to prescriber.
- Ensuring that state and federal guidelines are followed, and collaborate as needed with OBAT provider, social worker/counselors, psychiatrists, pharmacy and specialty care providers to whom the patient has been referred.
- Coordinating between OBAT provider and pharmacy: Assist with prescription processing and refills, prior authorizations, insurance issues and coordinating communication between prescribers, pharmacists and behavioral health colleagues.
- Maintain and manage accurate patient treatment lists.

Program Requirements

SAMHSA's Center for Substance Abuse Treatment (CSAT) Division of Pharmacologic Therapies

Buprenorphine Administrative Requirements:

- Certification, accreditation and waiver approval.
- Maintain accurate provider records.
- Records on dispensation of buprenorphine and buprenorphine/naloxone must be kept in accordance with DEA regulations for controlled substances as described in 21 CFR 1304.03(b).
- Records on prescription and dispensation of medications for the detoxification and maintenance treatment of opioid use disorder must be kept in accordance with DEA regulations 21 CFR 1304.03(c).
 - Maintain log to include patient identifier, name, dose, and quantity of drug prescribed/dispensed, and date.
 - Requirement may be fulfilled by keeping copies of prescriptions in the patient record. Electronic medical records where the prescription records can be accessed fulfills this requirement and there is no need to keep copies of the prescriptions in your office.

- For buprenorphine waiver compliance, the DEA only needs to review records for medications used in the treatment of opioid use disorder; therefore, an option is to keep separate records for these medications to facilitate a possible review.

Candidates for OBAT

- Patient must have a *DSM-5* diagnosis of Opioid Use Disorder (OUD) or Alcohol Use Disorder (AUD).
- Patient's goals should have the same alignment with the goals of the OBAT program.
 - Prevention/reduction of withdrawal symptoms and cravings for opioids and/or alcohol.
 - Restoration of normal physiological functions that may have been disrupted by substance use and improvement in quality of life.
- Patient can come to visits during office hours of operation.
- For patients seeking treatment: they must not have chronic pain requiring ongoing opioid management.
- Patient must be able to be treated in an office-based setting safely without harm to self or others.
- Patient should be willing to address use of other harmful and/or illicit substances. However, treatment for opioid use disorder or alcohol use disorder does not treat other forms of substance use disorder. Treatment should not be withdrawn because of ongoing use of other classes of illicit substances.
- Treatment team should carefully assess patient for appropriateness of medication treatment in an office-based setting vs. referral to a higher level of care.

Patient Initiation Roadmap

- Intake performed by OBAT provider.
- OBAT provider visit.
- Induction.
- Stabilization.
- Maintenance.

OBAT Intake

Intake Performed by Provider

See Appendix 3: Initial Patient Screening.

The OBAT 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.
 - OBAT values the uniqueness of each individual and helps each person define their own goals.
- Assessment of substance use including substance use history, current status and prior treatment.
- Review of medical, mental health and social history.

- Obtain appropriate signed consent forms to assist with collaboration of care with outside providers and supports.
- Education on medication for addiction treatment: What it is, how it works, medication administration, interactions, side-effects, potential adverse reactions, induction and maintenance processes for each of the FDA approved options.
 - The OBAT provider 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 treatment process, even in the event of a return to historical drug use. The patient's treatment plan will be augmented as necessary to assist the patient in achieving their long-term treatment goals.
- Harm reduction education: Overdose prevention education, overdose reversal with naloxone, rescue breathing, ensuring patient has access to naloxone (through community access or co-prescription).
- Mandatory screening at time of intake includes:
 - Toxicology screening and pregnancy testing.
 - HIV testing strongly recommended.
- Obtain laboratory tests as clinically needed.
 - Consider: Complete blood count, comprehensive metabolic panel, hepatic function, pregnancy test, RPR, Hepatitis A, B and C serologies.
- Review of treatment agreement and program expectations. Patient consents for treatment.
- Program expectations include:
 - Appointment frequency with OBAT provider.
 - Counseling and psychiatric assessment and follow-up if warranted.
 - Medication refills.
 - Patient-centered treatment planning and review.
 - Introduction to members of treatment team.
 - Review the medication safety brochure and discuss responsibilities for safe medication storage.
 - Review clinic hours and times available for scheduling visits, including afterhours emergency contact information.
 - If unable to meet the patient's needs, site will assist in referring the patient to another treatment setting that may be better able to meet the person's needs.

Consents

In addition to standard HIPAA laws, federal regulations mandate strict confidentiality for information about patients being treated for substance use disorders (42 CFR Part 2). Additionally, the law requires written patient consent before information about addiction treatment can be disclosed to any other source. For OBAT, this may include any communications with other providers, treatment centers, significant others or pharmacies.

Specific Actions that are Prohibited (Without Consent)

- Providing information regarding a patient's past, present, or future participation in addiction treatment.
- Disclosing or transmitting a patient's addiction-related medical records.
- Use of a letterhead that identifies the office as an addiction treatment provider.
- Providing information about those who have applied for treatment or have been interviewed, regardless of whether they actually commenced treatment.
- Providing information about deceased patients.
- Verifying information that inquirers already possess – in other words, a program can neither confirm nor deny that a patient was being treated there (SAMHSA, 1994b).
- There are some exceptions to the disclosure laws, such as in the case of medical emergencies or specific legal circumstances. Other than in the case of a medical emergency, check with your organization's legal counsel prior to making disclosures without consent.

Visit with OBAT Provider

- Provider assessment visit, with physical examination if needed and review of laboratory test results. Provider confirmation of *DSM-5* diagnosis of opioid use disorder or alcohol use disorder and assessment of appropriateness for medication treatment for addiction with either buprenorphine/naloxone or naltrexone.
- OBAT provider will manage clinical follow-ups.
- Follow-up visits with waived provider must occur at a minimum of monthly.
- Communication with OBAT provider is ongoing through EMR, phone contact by way of clinical team members and in-person communication.
- Follow-up with primary care provider as warranted based on medical needs. Often the PCP and the OBAT provider are the same and this will not apply.

Treatment Initiation, Stabilization and Maintenance

Checklist: Prior to Treatment with Buprenorphine/Naloxone

- Treatment 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 treatment.
- The patient should have counseling in place or be working towards establishing treatment with a counselor who has a working knowledge of substance use disorders. Counseling may be group-based or individual. The regulation requires the ability to refer to counseling, not the guarantee that a patient is in counseling.
- Toxicology screen completed and reviewed by OBAT provider.

- Pregnancy test for women of childbearing age.
 - If positive HCG, OBAT provider should continue treatment in collaboration with generalist OB. Where available, patient may be transferred to a specialty clinic for pregnant women with an opioid disorder. (At Spectrum Health this would be to the Maternal Fetal Medicine (MFM) office for entry into GREAT MOMs.) It is more risk to not start or stop treatment than it is to initiate or continue treatment.
- If patient presents from detoxification, OBAT provider 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 may be referred to The Center for Integrative Medicine for induction and early medication stabilization if needed. Most patients can be induced in the PCP office or at home. After early stabilization, patient will be transferred to the PCP for continued therapy.
- Patient presents to clinic for treatment.

Buprenorphine/Naloxone Induction

Prior to Induction

- Patient discontinues use of illicit opioids prior to buprenorphine/naloxone induction to avoid risk of precipitated withdrawal.
- Timeline for opioid discontinuation to be determined as part of induction treatment plan and to be based upon patient's medical status, current opioid use and disease severity.
 - Short-acting opioids: Typically discontinue 8 to 12hrs prior to scheduled induction.
 - Long-acting opioids: Typically discontinue 12 to 24hrs prior to scheduled induction.
 - Methadone: Typically discontinue 36 to 96hrs prior to scheduled induction.
- Methadone to buprenorphine transfers are especially complex due to the long half-life of methadone and unpredictable metabolic clearance. These may be best done by or in collaboration with specialty addiction services.
- Please refer to the section on methadone to buprenorphine transfers in this manual.

Day 1: Office Induction

- The patient arrives at clinic in early withdrawal, with prescription medication in hand.
- For patients who are actively using opioids other than buprenorphine, the clinical staff assesses symptoms with Clinical Opioid Withdrawal Scale (COWS), if the COWS score is >6-12, the OBAT provider instructs the patient to take the buprenorphine/naloxone as prescribed per their prescription order and per clinic protocol sublingually or in the buccal mucosa.
- For patients who are self-maintaining with buprenorphine/naloxone, assessment utilizing the COW scale may not be necessary. Use clinical judgment and refer to recent urine toxicology.

- OBAT provider supervises medication administration and educates the patient as to appropriate technique as the sublingual/buccal administration requires being kept in the mouth for a long period of time for appropriate absorption.
 - It is ok to moisten mouth prior to taking medication.
 - No eating or drinking for 15 minutes after taking medication.
 - No chewing gum or eating hard candy.
- Buprenorphine/naloxone 2/0.5mg - 4/1mg initial dose is removed by the patient from their medication bottle, taken transmucosally, observed and under instruction by the OBAT provider for proper administration.
- Reassess with COWS scale after 30 to 60 minutes and instruct patient to then take their second dose of 2 - 4mg as directed if needed, again observed and supervised by the OBAT provider for proper administration.
- Provide written instructions, establish follow-up plan.
- Dose will continue to be titrated per prescription instructions and/or until signs and symptoms of withdrawal subside. Typically, patients will titrate to 8/2mg by the end of the first day; however, this dose may be less or could be higher, and will vary according to a patient's level of physical opioid dependence at the onset of treatment and their clinical response to induction.

Day 2 though Day 7:

- The patient is instructed to take medication as prescribed. If the patient is struggling on current dose, they should call the office and a message should be sent to the provider for further instructions. If increased symptoms occur throughout the day, the patient may need to increase their dosage.
- Patient sees OBAT provider weekly for four to six weeks until stable, then every other week and progresses to monthly as clinically indicated. If a patient requires more support (i.e., comorbidity or depression) they may present in person for more frequent visits. Consideration of other supports like psychiatry or therapy should be made.

For Home Inductions: See Appendix

Buprenorphine/Naloxone Stabilization

Goal: Stabilization of dosing. Target buprenorphine/naloxone dose = 8 to 16 mg/day (in rare cases patients may need higher dose). In making this consideration a patient's physical signs and symptoms should be carefully assessed. Considerations should be made if the medication is not working because it is not the right treatment for the patient. Potentially, this individual may benefit from a different medication (i.e., naltrexone or methadone). Medication may be taken in divided doses. BID (more frequently than BID is not normally recommended).

- Narcotic blockade is typically reached at 16mg and is recommended in the early stages of treatment. (http://www.naabt.org/education/pharmacology_of_buprenorphine.cfm)
- Divided dosing is especially helpful for patients with chronic pain for dual effectiveness and avoidance of narcotic medications.

- This medication has a long half-life. Most 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 twice daily while engaged in treatment for substance use disorder or in a medical setting (e.g., hospitalization).
- Patient returns to clinic after one week for assessment, prescription renewal, urine toxicology screening, counseling, education, support and evaluation of mental health and other needs.
- No prescriptions lasting longer than one week should be given during this phase.
- Refills are permitted, but the patient must provide pharmacy information as all prescriptions are ecribed or called into the pharmacies. Patients are never given a hard copy of the prescription.
- Patient sees provider weekly for four to six weeks until stable. If toxicology screens are negative and the patient is adherent to the treatment plan, they may then progress to the maintenance phase.

Buprenorphine/Naloxone Maintenance

Once stable, clinic visits every two to four weeks, with refills that coincide with visits.

Goal: Monthly visits

- Some patients will remain on visits more frequently than monthly as patients find these visits an important part of their treatment program.
- Each decrease in visit frequency requires discussion with patient and prescriber.

Clinic Visits to Include:

- Sample collection for toxicology.
- Assessment of status: Medication dose, adherence, tolerance, side effects, cravings and withdrawal; safe storage, treatment and other substance use. Medical, social and psychiatric issues should all be addressed as indicated.
- Review of treatment plan: Visit frequency, counseling and assess need for additional support.
- OBAT provider notes should be documented in the clinical record and available to the entire clinical team.
- Lab testing: If Liver Function Tests (LFTs) were elevated, consider rechecking 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 and HIV infection.
- If there is a history of risky alcohol use, consider use of breathalyzer as appropriate and available.
- Acamprosate (Campral) and disulfiram (Antabuse) may be offered to patients with alcohol use disorder.
- Patients managed on buprenorphine/naloxone cannot be treated with any naltrexone formulation, as these medications are contraindicated.
- Waivered OBAT provider visits to occur monthly.
- Review and confirm contact information, including pharmacy of choice, at each visit.
- In addition to office visits, clinical team members can reach out to patient as needed for support.

Buprenorphine Injection Initiation: Patient Selection

Extended-release buprenorphine is the first, and currently only, once-monthly 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. It is indicated for patients that have been on a stable dose of buprenorphine treatment for a minimum of seven days. (FDA, 2017)

For the most up to date information regarding extended-release buprenorphine:

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 Extended-Release Buprenorphine:

<https://www.insupport.com/specialty-product>

Dosing

Available dosage strengths:

- 100mg/0.5ml
- 300mg/1.5ml

The recommended dose of injectable buprenorphine following induction and stabilization with transmucosal buprenorphine is 300mg monthly for the first two months, followed by a maintenance dose of 100mg monthly.

- While the majority of patients will be appropriate to receive 100mg maintenance doses, certain individuals may benefit from continued 300mg maintenance doses such as persons with 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 up to two weeks did not have clinically significant treatment outcomes.

Safety

Extended-release buprenorphine forms a solid mass upon contact with body fluids and therefore must be administered into subcutaneous tissue. Intravenous use of extended-release buprenorphine poses a significant risk including occlusion, local tissue damage, thrombotic events and death.

Extended-release buprenorphine is available only through the EXTENDED-RELEASE BUPRENORPHINE REMS Program or specialty pharmacy due to the risk of serious harm that could result from intravenous self-administration.

Notable requirements of the EXTENDED-RELEASE BUPRENORPHINE REMS Program include:

- Certified healthcare settings and pharmacies must establish processes and procedures to verify that extended-release buprenorphine 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 extended-release buprenorphine.
- Further information is available at www.sublocaderems.com or call 1.866.258.3905.

Storage and Handling

Injectable buprenorphine is a Schedule III medication. Handle with adequate security and accountability per federal and state regulations, as well as institutional protocols.

- Medication must be stored in a locked refrigerator unit.
- A logbook of injectable buprenorphine inventory and dispensing will be kept in the locked medication room.
- 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 (i.e., 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 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.

- Mark the medication each time it is removed and returned to the refrigerator.
- Discard extended-release buprenorphine if left at room temperature for longer than seven days.

Injectable Buprenorphine: Patient Selection

Candidates for Treatment with Injectable Buprenorphine Include Patients Who:

- Have begun treatment on a transmucosal formulation of buprenorphine, delivering the equivalent of 8 - 24mg of buprenorphine daily for a minimum of seven days.
 - 8mg equivalents include one 8 - 2mg SUBOXONE® (buprenorphine/naloxone) film, one 8 - 2mg sublingual buprenorphine/naloxone tablet, one 8mg Subutex® (buprenorphine) mono tablet, or one 5.7 - 1.4mg Zubsolv® (buprenorphine/naloxone) tablet.
- Patients who have a history of non-adherence to daily formulations of buprenorphine.
- Patients in sustained disease remission utilizing a transmucosal formation of buprenorphine between 8 and 24mg daily, who would like to transition to a monthly injectable medication.

Contraindications:

- 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 with chronic or acute pain that requires full-opioid analgesics.
- Patients who have been shown to be hypersensitive to buprenorphine or 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 monthly 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.
- Patients must be on an equivalent of 8 - 24mg of transmucosal buprenorphine for at least one week prior to receiving the extended-release subcutaneous injection.
 - This is to mitigate risk of precipitated withdrawal, allergic reactions, over-sedation, side effects, adverse reactions or any other intolerance of the medication.
 - Verify that patients have tolerated and are dose adjusted on transmucosal buprenorphine before administering injectable buprenorphine.
 - Toxicology screen completed and reviewed.
- Pregnancy test for women of childbearing age.
 - If positive HCG, OBAT team will assist in engaging the patient with an OB and will manage the patient in OBAT if the OB is not licensed to prescribe.
 - This medication has not been studied in pregnancy.
- Patient is approved for treatment with injectable buprenorphine by waived provider.
- Staff obtains the prescription from the waived provider and begins prior authorization process.
- Staff will coordinate the delivery of injectable buprenorphine (SUBLOCADE®). Once received staff will document according to proper procedure and lock medication in lockbox inside refrigerator.
- Staff will ensure appointment is scheduled with patient.

Once patient arrives for appointment follow extended-release buprenorphine administration standard work. (See Appendix 5)

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 resuming use.
- Have a high degree of motivation for abstinence from opioids.
- Have been successful on opioid agonists and wish to discontinue agonist therapy.
- Are not interested in agonist/partial agonist therapy to treat their opioid use disorder.
- Have not experienced successful treatment with agonist therapy.
- Have a history of alcohol use disorder.

Contraindications:

- Patients with advanced liver disease or acute hepatitis.
- Patients with moderate to severe renal impairment.
- Patients with chronic or acute pain that requires opioid analgesics.
- Patients who are unable to remain opioid free for a minimum of seven to 10 days.
- Patients with advanced psychiatric disease, active suicidal/homicidal ideation, especially if symptoms worsen during withdrawal.
- Patients who are currently physiologically opioid dependent, or taking opioids, or have an opioid positive urine screen.
- A patient who fails the naloxone/naltrexone challenge test.
- Patients who have displayed a hypersensitivity to naltrexone, PLG, carboxymethyl cellulose, or any other components of the diluent.

Special Considerations:

Pain: chronic pain must be managed with non-opioids. Acute pain requires an anesthesia consult. If a patient has a surgical procedure pending, they may want to consider delaying naltrexone treatment until after the procedure.

Cirrhosis: Naltrexone is extensively metabolized through the liver and should not be administered if AST/ALT are more than five times normal limits.

Pregnancy: 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 provider would need to evaluate the risk/benefit and appropriate consent of unknown risk should be utilized. A referral to a trained OB provider for this discussion is encouraged.

Breastfeeding: It is known that naltrexone from the oral formulation passes into breast milk. It is not known if extended-release injectable naltrexone passes into breast milk. In vivo studies indicate potential tumorigenicity. Currently, labeling from the manufacturer advises against breastfeeding while on naltrexone, both with oral and injectable formulations.

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 IM into gluteal muscle using the contents of the medication package. Alternate treatment may be considered for patients whose body habitus precludes an intramuscular gluteal injection with one of the provided needles. Consider the oral formulation.

Checklist: Prior to Naltrexone Initiation

- Treatment agreement and consents are reviewed and signed.
- Reinforce with 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 prior to initiating treatment.
- The patient should be referred to counseling. However, counseling should not be a mandatory component to treatment. Counseling may be group-based or individual.
- The patient must be cleared by psychiatry if concerning mental health history.
- Labs appropriate: HCG neg. LFTs < 5x normal.
 - If positive HCG, OBAT team will immediately assist with referral to OB.
- UTS that is negative for opioids.
 - Detoxification from opioids should be completed prior to the administration of naltrexone to prevent precipitated or spontaneous withdrawal. The patient must not be experiencing withdrawal symptoms. Patients should discontinue short-acting opioids at least three to seven days prior to starting naltrexone. If taking long-acting opioids such as methadone or buprenorphine, the patient must be off for at least seven to 10 days.
 - Detoxification from alcohol is not always necessary. However, detoxification from alcohol is recommended prior to naltrexone initiation if a patient has a history of alcohol-related seizures, delirium tremens (DTs), longstanding daily use, presence of withdrawal signs or symptoms, or as otherwise clinically indicated.
 - If patient presents from detoxification or other inpatient treatment, the OBAT provider should attempt to obtain discharge paperwork that includes medications administered (i.e., methadone or buprenorphine administered in detox will delay induction with antagonist due to risk of precipitated withdrawal). This paperwork should be reviewed by the provider.
- The provider sees patient to review medication initiation plan and prescribes medication. Oral naltrexone tablet prescription may be prescribed to pharmacy for patient to pick up. Extended-release injectable naltrexone for commercial insurance often requires insurance prior authorization this process may take several days and requires thoughtful planning. Public Medicaid covers this medication without prior authorization.
- Patient presents to clinic for induction/medication initiation.

Naltrexone Initiation

- Patients should be started on the oral form of the medication, prior to receiving the extended-release IM injection.
 - 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.
- Patient should be given an emergency card, bracelet and/or dog tag, to keep on them in case of an emergency so the emergency responders will be aware of proper care.
- The first naltrexone dose should be observed in the clinic.

Extended-Release Injectable Naltrexone Administration

- Obtain extended-release injectable naltrexone from pharmacy per written prescriber order or via “buy and bill” procedures. Standard dose is 380mg 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. This takes about 45 minutes.
 - Ensure Urine Toxicology Screen (UTS) negative for all opioids and/or negative naloxone/naltrexone challenge.
- 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 intramuscular gluteal injection every 28 days.

Special Notes:

- 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 unrefrigerated product to temperatures above 25°C (77°F). This medication should never be frozen.
 - Once at room temperature medication must be administered within seven days.
- A properly mixed suspension will be milky white, will not contain clumps and will 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.
- Administer the suspension by deep intramuscular 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.

Adverse Effects and Patient Education¹

- **Injection Site Reactions:** Medical assistants should be trained in proper techniques for IM injections to prevent problems. 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 as the result of an inadvertent subcutaneous injection.
- **Vulnerability to Opioid Overdose:** Following injection with extended-release naltrexone, a patient's opioid tolerance is reduced markedly from baseline prior to treatment. Accordingly, patients are vulnerable to potentially fatal overdose approaching the end of the dosing interval, if a dose is missed or if treatment is discontinued. Attempting to break through the opioid blockade can also result in fatal overdose. The OBAT MA should outreach to and attempt to reengage with patients who miss an injection.
- **Hepatic Injury:** There have been cases of hepatitis and clinically significant liver injury associated with extended-release injectable naltrexone. Patients should be made aware of this risk.
- **Depression and Suicide^{**}:** In pre-market clinical trials of extended-release injectable naltrexone, reports of depression were overall infrequent but more common in the group that received injectable naltrexone than the group that received the placebo. Patients should be evaluated, monitored and treated appropriately, and families and caregivers should be alerted to the need to monitor patients for depression or suicidality.

¹ Taken from: Substance Abuse and Mental Health Services Administration. Clinical Use of Extended-Release Injectable Naltrexone in the Treatment of Opioid Use Disorder: A Brief Guide. Rockville, MD: Substance Abuse and Mental Health Services Administration; 2015.

^{**}Adapted from: Alkermes. Opioid Dependence Efficacy and Safety. Vivitrol Prescribing Information. 2017. <https://www.vivitrol.com/content/pdfs/prescribing-information.pdf>

Naltrexone (Oral or Injectable) Stabilization

- Patient returns to clinic after one week for assessment, urine toxicology screening, breathalyzer, counseling, education, support, and evaluation of mental health, medical and other needs as indicated.
- If a patient misses an extended-release naltrexone injection, he/she should be instructed to receive the next injection as soon as possible. Reassess the patient status prior to administering medication. Consider naloxone/naltrexone challenge and/or UTS if opioid use is suspected or if injection has lapsed for an extended period. Augment treatment plan as needed.
- Patient sees provider every other week after first week visit for four to six weeks until stable. If the toxicology screens and breathalyzer screens are negative and the patient is adherent to the treatment plan, they may progress to the maintenance phase.

Naltrexone Maintenance

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

Clinic Visits to Include:

- Collection of samples for toxicology screening.
- Assessment of status: Any use and medical, social and psychiatric issues should be addressed as indicated.
 - For management of pain in patients who are engaged in naltrexone treatment, refer to section titled "Pain Management: Naltrexone".
- Monitor and assess for potential medication side-effects or adverse reactions: Injection site reaction, hepatic complications, gastrointestinal distress, depression, eosinophilic pneumonia, etc.
- Review of treatment plan: visit frequency, counseling, assess need for additional support.
- If there is a history of risky alcohol use, address concerns with patient, consider use of breathalyzer at each visit.
 - Acamprosate (Campral) and disulfiram (Antabuse) may also be offered to patients with problematic alcohol use at the same time as naltrexone.
- Lab testing: if liver function tests were elevated at induction, consider rechecking within one to two months or sooner depending on degree of elevation. Continue to regularly monitor LFTs thereafter.
- Review contact information, at each visit.

Acamprosate²

Acamprosate affects chemicals in the brain that may be unbalanced in a person who is addicted to alcohol. Acamprosate works by restoring this chemical balance in the brain.

- It can be used alone or in combination with either an opioid agonist or antagonist (if patient has an OUD) for alcohol use disorder as first-line therapy; there is some evidence to suggest that combination therapy may be beneficial.
- Treatment should begin as soon as identified and should be maintained if the patient continues to drink, if there is improvement in drinking amount. It should not be discontinued in the event of a return to pretreatment use.
- The approved dosing is 666mg three times a day.
- Renal function should be evaluated before initiation of the drug; if CrCl is between 30 to 50ml/min, then the medication can be renally dosed: 333mg three times a day.
- Medication should be taken with food.
- The biggest factor impacting adherence to the medication is the three times daily dosing.
- This drug should be used as part of a comprehensive psychosocial treatment program.
- Medication should not be crushed, chewed or broken as it is a delayed-release tablet.

² Multum, Cerner. "Acamprosate." Drugs.Com, www.drugs.com/mtm/acamprosate.html, 2019. Accessed 19 August 2019.

Acamprosate Side Effects

Inform patient to call office if they experience:

- Most common side effects are transient diarrhea and pruritis.
- Severe anxiety or depression; mood or behavior changes.
- Thoughts about suicide or hurting themselves.
- Swelling in their hands or feet or arrhythmias.

Ongoing Patient Management: OBAT Agreement & Clinic Policies

Treatment Plan

Goal: Engage patients in the treatment plan, along with the OBAT team. Individualize treatment to meet the needs of the patient. Encourage patient involvement in their treatment.

- Set clear expectations/guidelines.

- Explain treatment verbally and provide in written form, which patients will sign and date. This form will be kept in the patient record. Review each line and give a copy to the patient to take home for their review.
 - Encourage patients to ask questions.
 - Review this document again with the patient intermittently during treatment and as needed.
 - Provide reassurance about common issues, such as patients' concerns about entering treatment (provide education around options and support), or the risks of transferring care from one form of medication treatment to another or patients' ambivalence about such changes.
- The document 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 disease process, including in the event the patient returns to pre-treatment use patterns. The patient's treatment plan will be augmented as necessary to assist the patient in reaching identified treatment goals.
- 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 Part 42.
 - To have a means for contacting a member of the OBAT team or a colleague for emergencies at night, on weekends and when the office is closed.

Adherence to Program Policies and Treatment Protocols:

- All patients who participate in the Office Based Addiction Treatment program are required to keep all appointments with their provider. These appointments are critical to the continuation of care.
- If an appointment cannot be kept, it is the patient's responsibility to reschedule the appointment.
- Patients are expected to make an effort to arrive on time for scheduled appointments.
- Patients are required to see their OBAT provider at least once a month and more frequently if needed. If patients do not make their appointments and do not call to inform OBAT staff that they are unable to make the appointment, or arrange for rescheduling, the treatment plan may be revised to care for the patient in a medically safe manner.
 - Consider increasing visit and prescription frequency until the patient is seen by their provider. In rare cases, the treatment team may choose to do daily prescriptions until the patient is seen for an office visit by an OBAT provider.
- Patients struggling to meet program requirements may need to be referred to another program or level of care.
- Procedures for contacting the OBAT team when the office is closed:
 - All patients have access to an afterhours call center that may reach out to an afterhours prescriber, if necessary. This should be called only if the patient has a medical emergency or if they have an issue with their prescription.

Behavior Expectations

To provide an optimum treatment environment for all, patients, visitors and staff are expected to maintain appropriate behaviors in all the clinics.

Urine Toxicology Screening (UTS) Policy (See Appendix 5):

- Please see Urine Toxicology Screen (UTS) Policy and Standard work.

Tampering:

If the urine sample is questionable:

- The patient will be asked to repeat urine screen immediately; a discussion will take place to address what may be going on in an effort to assist the patient. This behavior is a concerning symptom of the patient's disease and should be treated as such. This should be considered as the patient showing that their disease is not under optimal control.
- The patient will be counseled by the OBAT provider about the importance of UTS monitoring and honesty in treatment to ensure that the team has the ability to provide appropriate treatment. Reinforce that the OBAT team is here to help if the patient is struggling.
- The patient is told that tampering may indicate the need for a referral to a higher level of care.
- When an accurate urine sample is obtained, the patient will receive their necessary medication refill or medication injection, if it can be safely administered.

Prescription Policy

Lost, Stolen or Destroyed Buprenorphine/Naloxone:

- Lost or stolen medication: Buprenorphine/naloxone prescriptions are generally not replaced; patients are informed of this at the time of intake. This notification is done both verbally as well as in writing in the OBAT plan. However, cases will be reviewed on an individual basis by the OBAT provider if requested by the patient. If a decision is made to replace the medication, it will be a one-time event and a lost/stolen prescription will not be replaced in the future should this occur. If more than a one-week supply of replacement prescription is needed, the prescription amount will go back to weekly prescriptions until it is safe for the patient to be given a larger quantity of medication.
- Destroyed/damaged: If able, the patient should be instructed to bring the medication in for the OBAT team to review. A decision will be rendered by the team on how best to proceed. If a patient reports destroyed/damaged medication, the prescription amount will go back to weekly prescriptions until the team feels it is safe for the patient to be given a larger quantity of medication.
- In all of these events: lost, stolen, destroyed, or damaged medications, prior to receiving a replacement prescription, the patient may be asked to return to the OBAT clinic for assessment and UTS. At this time, patients will receive additional education about safe handling and storage of buprenorphine/naloxone by the OBAT provider to prevent these events from reoccurring. 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 events of lost, stolen, damaged or destroyed medications, the prescriber will address this and the potential need to refer the patient to a more structured treatment setting to better safeguard their treatment and their long-term health.

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, dressers, nightstands or in any public unsecure space.
- It is easier for children to put small pieces and crumbs in their mouth.
- To prevent breakage of tablets, keep cotton or tissue in the bottle.
- Always keep in a labeled prescription bottle with child-proof cap.
- Patient's prescribed buprenorphine/naloxone 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. Carrying medication is not generally recommended.
- Avoid carrying medication in your pocket, bag, purse, or backpack.
- Avoid leaving in the bathroom, car or any public space.
- **Call 911** if an accidental exposure occurs and/or go to the nearest emergency department.
- Give all patients a copy of the safety and storage brochure and review the bullet points with them. (See Appendix 11C).
- Suggest to patients that they obtain a locked bag or a lock box to store buprenorphine/naloxone and any other controlled substances safely and out of reach. Reinforce safe storage out of common areas and away from children and others.

*Adapted from: "Protecting Others and Protecting Treatment" STATE OBOT (State Technical Assistance Treatment Expansion Office Based Opioid Treatment of Buprenorphine) and Massachusetts Department of Public Health Bureau of Substance Abuse Services (BSAS). 2016.

Addressing Patient Struggles, Relapse & Discontinuation of Treatment

- OBAT is a harm reduction model and therefore does not recommend automatic discharge for patients who struggle with substance use while engaged in medication for addiction treatment.
 - If patient use occurs, the treatment plan should first be revised to increase monitoring and supports. In case of continued use despite an intensified treatment plan, a patient may be referred to a higher level of care.
 - Clinicians should always carefully weigh the risk versus benefit of continuing treatment in an office-based setting prior to referring to another level of care. This may include the availability of other levels of care.

- Situations when the OBAT team may recommend higher levels of care:
 - Ongoing use despite adequate buprenorphine/naloxone dosing: no withdrawal symptoms and adequate blockage.
 - Opioid use during the end of an extended-release naltrexone injection dosing interval.
 - Multiple negative buprenorphine UTS results for patients taking prescription buprenorphine.
 - Ongoing use of benzodiazepines, barbiturates, cocaine/stimulants, alcohol or other central nervous system depressants (gabapentin, quetiapine, clonidine, promethazine etc.) Causing impairment, sedation, overdose, medical events and/or hazardous unsafe behaviors despite interventions by the OBAT team. **NOTE:** *Use of these substances while on medication to treat another class of substances does not constitute a reason to discontinue treatment (e.g., medications used to treat an opioid use disorder do not treat a stimulant use disorder).*
 - Presenting intoxicated (i.e., under the influence of alcohol or other substances), incidence of overdose, or hospitalization related to substance use.
 - The risk of continuing treatment outweighs the benefit.
- If the patient complies with the intensive treatment plan and has had some improvement in substance use, the team will restructure treatment as needed and continue treatment.
- Patients who are referred to a higher level of care will be reconsidered for future treatment in OBAT.

Revision of Treatment Plan

- More frequent visits.
- Shortened prescription intervals.
- Confirmation of counseling and team engagement with counselor.
- Referral to relapse prevention groups or individual therapy.
- Referral to Intensive Outpatient Program (IOP).
- Psychiatric evaluation and treatment per psychiatric assessment.
- Residential treatment.
- CPS involvement.
- Increased collaboration with community providers.
- Increased engagement with law enforcement.
- Family/support involvement.

Referral to Higher Level of Care

- Residential treatment.
- Methadone maintenance.
- Directly observed buprenorphine/naloxone daily dosing in OTP.

Buprenorphine/Naloxone:

Opioid Use and Aberrant Urine Toxicology Screen Results

- In all cases of an unexplained UTS (i.e., patient did not report substance use at visit or report inappropriate medication management at visit), the provider should discuss this result with the patient. If at the visit the patient denies the accuracy of the results, a urine confirmation test should be sent to the lab, prior to making any changes to the treatment plan.

Negative Buprenorphine

- If point of care (POC) UTS is negative and patient gives no explanation, send the urine out for a confirmatory test. The test includes checking for the presence of buprenorphine's metabolite, norbuprenorphine. If the patient provides adequate explanation regarding negative buprenorphine/naloxone to OBAT staff, the team will establish a follow-up plan for the patient to return to clinic within two weeks.
- If the patient is unable to provide an explanation regarding negative buprenorphine/naloxone, they should return to the clinic within one week of confirmatory test.
- At return visit, the negative urine confirmatory result is addressed.
 - Review medication administration and dosing schedule. Consider diversion and possible resumption of opioid use.
 - Assess and modify treatment plan as needed. If the patient is struggling, return to weekly clinic visits and prescriptions.
 - The patient's buprenorphine/naloxone dose may need to be adjusted (i.e., increased if struggling, decreased if taking less than their prescribed dose). The OBAT team will discuss plan of care prior to patient coming in for next visit, it may include adjusting a patient's medication dose.
 - If the patient denies any reason for negative buprenorphine/naloxone, and repeat is again negative, the patient may be referred to a higher level of care where additional monitoring can occur.
- Assess dose. If the dose is less than 4 - 6mg, urine may need to be sent for confirmatory testing due to the cut-off limits of the test and therefore its inability to react positive to buprenorphine despite its presence.

Positive Opioids

- Report of opioid use or positive opioid toxicology screen result is addressed by OBAT provider during visit and the treatment plan is intensified accordingly to meet the needs of the patient.
 - A report of opioid use or a positive opioid UTS may result in intensification of the treatment plan potentially including increased frequency of clinic visits, confirmed attendance, increased frequency of counseling, encouragement to attend meetings, education on substance use prevention and overdose and ensuring naloxone access through community distribution or co-prescribing. This also includes the patient returning to weekly clinic visits.
 - If the patient has three to four consecutive weeks of positive opioid urines, the patient may be assisted with a transfer to a higher level of care.
 - Again, clinicians should always carefully weigh the risk versus benefit of continuing treatment in an office-based setting prior to referring to another level of care.

Polysubstance Use

Cocaine

- Report of cocaine use or a positive cocaine UTS result is addressed by the OBAT clinical team member during the visit and the treatment plan is modified to meet the needs of the patient.
 - If the patient has a positive UTS and does not confirm using at the visit a confirmatory UTS may be ordered.
- A report of cocaine use or a positive cocaine UTS will result in intensification of the treatment plan, substance use prevention education and support. This includes the patient returning to weekly clinic visits until clinically appropriate to lengthen interval.
 - Contingency management combined with psychosocial support (CBT, counseling) has been shown to be an effective strategy for decreasing stimulant misuse and should be considered when possible.

Amphetamines

- Report of illicit amphetamine use or positive amphetamine UTS result is addressed by provider during visit and the treatment plan is modified to meet the needs of the patient.
- A report of illicit amphetamine uses or a positive amphetamine UTS will result in intensification of the treatment plan, substance use prevention education and support. This includes the patient returning to weekly clinic visits until clinically appropriate to lengthen interval time.
 - If the patient reports that they are struggling with attention deficit and/or hyperactivity, offer the patient a referral to psychiatry for evaluation. Non-stimulant medication (i.e., Wellbutrin) may be tried by the OBAT prescriber.
 - If the patient reports diagnosis of ADHD and requests amphetamine medications, the patient should undergo a neuro-psych evaluation for a proper diagnosis.
 - Run prescription drug monitoring program (PDMP) to check for unreported prescribed medications.
 - Two to three UTS positive for illicit amphetamine in a row may result in further intensification of the treatment plan, such as referral to IOP and/or a substance use prevention group, increased counseling and/or increased OBAT visits.
 - Contingency management combined with psychosocial support has been shown to be an effective strategy for decreasing stimulant misuse and should be considered.

Benzodiazepines

- Report of illicit benzodiazepine use or a positive benzodiazepine UTS result is addressed by the OBAT provider during the visit and the treatment plan is intensified accordingly to meet the needs of the patient.
- If the patient has a positive UTS and does not report using at the visit, urine should be sent for confirmatory testing.

- A report of illicit benzodiazepine-use or a positive benzodiazepine UTS will result in intensification of the treatment plan, substance use prevention education and overdose prevention education. This may include the patient returning to weekly clinic visits.
 - If the patient reports they are struggling with anxiety, offer a referral to psychiatry for evaluation. Providers should make every effort to stay clear of benzodiazepines and other medications with potential for misuse. Prescribing non-controlled substances prior to referral to psychiatry may be appropriate.
- Run prescription drug monitoring program (PDMP) to check for unreported prescribed medications.
- Ongoing benzodiazepine misuse despite intensified treatment plan may result in a referral to a higher level of care.

Alcohol

- Patients with concerning alcohol use or co-morbid alcohol use disorder will be asked to submit to intermittent breathalyzer and additional clinical supports and monitoring as needed.
- Patients presenting to clinic smelling of alcohol, have a positive breathalyzer result, or report risky alcohol use may require treatment plan revision. Additionally, a safety assessment should be completed, which may include their ability to care for any accompanying children or alternate transportation home.
- Patients struggling with alcohol use and/or cravings may be offered acamprosate (Campral) or disulfiram (Antabuse). Patients managed on buprenorphine/naloxone cannot be treated with any naltrexone formulation, as these medications are contraindicated when combined together. Naltrexone may be appropriate to treat both opioid use and alcohol use disorder.
- Ongoing alcohol misuse, presenting to clinic impaired or noted ED visits or hospital events for alcohol intoxication/use may result in referral to a higher level of care.
- Clinicians should always carefully weigh the risk versus benefit of continuing treatment in an office-based setting prior to referring to another level of care.

Naltrexone Relapse and Aberrant Urine Toxicology Screen Results

- In all cases of an unexplained toxicology results (i.e., patient did not report substance use at visit), the urine should be sent for confirmatory testing.
- As with patients who are prescribed buprenorphine, clinicians should always carefully weigh the risk versus benefit of continuing treatment with naltrexone in the current treatment setting prior to referring to another level of care.

Opioids

- Report of opioid use or a positive opioid UTS result is addressed by the OBAT provider during visit and the treatment plan is intensified accordingly to meet the needs of the patient.
 - If the patient has a positive UTS and does not admit using at the visit confirmatory testing should be sent.

- Intensify OBAT plan, including increased frequency of clinic visits, confirm attendance and increase frequency of counseling, encourage meetings, provide substance use prevention education and overdose prevention education and a prescription for naloxone. This also includes the patient returning to weekly clinic visits.
- Educate the patient about the increased sensitivity to opioids and the consequential increased risk of a fatal overdose in the event of a return to pretreatment use. Reduced tolerance is especially concerning at the end of a dosing interval. However, an attempt to overcome the opioid blockade effect of extended-release injectable naltrexone is possible at any point and is extremely dangerous with the potential to cause respiratory arrest and circulatory collapse.
- If return to pretreatment use occurs towards the end of the naltrexone interval (within a week of the injection due date), restart the patient on naltrexone only after obtaining a UTS negative for opioids or a successful naloxone/naltrexone challenge has been performed. Do not administer naltrexone if opioids are in the patient's system.
- With a return to opioid use, a clinical assessment should always occur to evaluate if continuing with naltrexone treatment is in the best interest of the patient or if a different level of care should be considered.
- If the patient is unable to abstain from using opioids for a long enough period of time to safely be restarted on naltrexone, a change to buprenorphine-based treatment for referral to a higher level of care (residential addiction specialty, methadone maintenance) may occur. The patient may return to OBAT for naltrexone treatment at a later date after provider and patient meet to assess how to assist them differently in their treatment moving forward.

Alcohol

- For patients with known alcohol use disorder or concerning alcohol use, breathalyzer screening is advised as needed.
- Patients with positive alcohol screens or reporting alcohol use should receive education about the cumulative toxic liver effects of naltrexone as this medication is extensively metabolized through the hepatic system.
- Intensify OBAT plan, including increased frequency of clinic visits, urine screening and counseling. Encourage meetings and recovery supports.
- Patients struggling with alcohol use and/or cravings may be offered acamprosate (Campral) or disulfiram (Antabuse). See Appendix for Consent to Treat with Disulfiram form.
- Patients presenting to clinic appearing impaired, smelling of alcohol, having a positive breathalyzer result, providing reports of ongoing alcohol use, or noting ED admissions for alcohol use disorder will require assessment and revision of treatment plan, safety assessment and referral to higher level of care may be necessary.

Polysubstance Use

Cocaine

- Report of cocaine use or positive cocaine UTS result is addressed by OBAT provider during the visit and the treatment plan is intensified accordingly to meet the needs of the patient.
 - If the patient has a positive UTS and does not indicate they used at the visit a confirmatory test should be sent.
- A report of cocaine use or a positive cocaine UTS will result in intensification of the treatment plan, substance use prevention education and support. This includes the patient returning to weekly OBAT visits.
 - Ongoing positive urine screens for cocaine will result in further intensification of the treatment plan such as referral to IOP and/or a substance use prevention group.
 - Contingency management combined with psychosocial support has been shown to be an effective strategy for decreasing stimulant misuse and should be considered.

Amphetamines

- Report of illicit amphetamine use or positive amphetamine UTS result is addressed by the OBAT provider during the visit. The treatment plan is intensified accordingly to meet the needs of the patient.
 - If the patient has a positive UTS and does not indicate they used at the visit a confirmatory test should be sent.
- A report of illicit amphetamine-use or a positive amphetamine UTS will result in intensification of the treatment plan, substance use prevention education and support. This includes the patient returning to weekly clinic visits.
 - If the patient reports they are struggling with attention deficit and/or hyperactivity, offer the patient a referral to psychiatry for evaluation. Non-stimulant medication (i.e., Wellbutrin) may be tried by the OBAT prescriber.
 - If the patient reports a diagnosis of ADHD and is requesting amphetamine medications, the patient will be required to undergo neuro-psych evaluation for a proper diagnosis.
 - Run prescription drug monitoring program (PDMP) to check for unreported prescriptions.
 - Ongoing UTS positive for illicit amphetamine will result in further intensification of the treatment plan such as referral to IOP and/or a substance use prevention group.
 - Contingency management combined with psychosocial support has been shown to be an effective strategy for decreasing stimulant misuse and should be considered.

Benzodiazepines

- Report of illicit benzodiazepine use or positive benzodiazepine UTS result is addressed by the OBAT provider during a visit and the treatment plan is intensified accordingly to meet the needs of the patient.
 - If the patient has a positive UTS and does not report using at the visit urine should be sent for confirmatory testing.

- A positive result is addressed by the OBAT provider, substance use prevention education will be provided and the treatment plan may be intensified. A report of illicit benzodiazepine-use or a positive benzodiazepine UTS will result in intensification of the treatment plan, substance use prevention education and overdose prevention education. This includes the patient returning to weekly clinic visits.
 - If the patient reports they are struggling with anxiety, offer the patient a referral to psychiatry for evaluation. Every effort should be made to avoid medications with potential for misuse. The OBAT provider may decide to start medications prior to referral.
 - Run prescription drug monitoring program (PDMP) to check for unreported prescriptions.
 - Urine samples will be sent for confirmatory testing and identification of the benzodiazepine if positive for benzodiazepines twice in a row.
 - Two to three consecutive UTS positive for illicit benzodiazepines will result in further intensification of the treatment plan, such as referral to IOP and/or a substance use prevention group.
 - Ongoing positive illicit benzodiazepine UTS will result in referral to a higher level of care. Patient may return to OBAT for naltrexone treatment at a later date after the provider and patient meet to assess how to assist them differently in their treatment moving forward.

Presenting Impaired

Any patient who presents to the clinic intoxicated (i.e., under the influence of alcohol or any other substance) will require urgent team assessment, safety assessment and revision of their treatment plan. Additionally, if a patient who presents intoxicated is accompanied by a child or other dependent, please refer to policies regarding safety concerns and mandated reporting for your institution.

Buprenorphine/Naloxone Tapering

- A substance use disorder is a chronic and complex condition, therefore enforcing a predefined treatment duration is not recommended nor is it advised.
- Some patients may choose to taper off buprenorphine/naloxone. These patients will continue to be supported by the OBAT team and 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.
 - Buprenorphine/naloxone should be tapered over days, weeks or months, depending on patient's tolerance of symptoms.
 - A patient-centered taper is important to success.
- Upon abrupt buprenorphine discontinuation, withdrawal syndrome may occur.
 - Subjective withdrawal symptoms typically begin within the first three days.
 - Autonomic withdrawal signs (lacrimation, rhinorrhea, tremors, chills, gooseflesh).
 - General complaints include restless leg, insomnia, anxiety, abdominal distress.

- Protracted abstinence syndrome can occur and persist for months or years following discontinuation of the medication. It is important to respond to patient's protracted withdrawal symptoms to support their recovery process and avoid a return to pretreatment use.
- Tapering/transfer/discharge from program or initiation of intensive treatment plan should be considered for the following cases:
 - Negative buprenorphine screens.
 - Ongoing opioid use or use of other illicit drugs and the risk of continuing treatment outweighs the benefit.
 - Patient presents to OBAT clinic impaired, incidence of overdose, or hospitalization related to substance use and the risk of continuing treatment outweighs the benefit.
 - Multiple missed appointments or inability to contact patient.
 - Address with treatment team and document in EMR. If unable to reach patient, no further medications should be provided, in hopes this will bring the patient back in to care.
- Patients who are referred to a higher level of care or discharged, will be reconsidered for future treatment in OBAT. Patients should always be referred to alternative treatment options (i.e., methadone clinic).

Naltrexone Discontinuation

- There is no withdrawal syndrome associated with naltrexone discontinuation.
- Some patients may choose to discontinue naltrexone. These patients may continue to be supported by the OBAT provider and receive assistance in terms of monitoring and clinical management. Patients choosing to discontinue naltrexone should be encouraged to continue psychosocial therapies and mutual-help groups.
- Some patients may stop naltrexone due to side-effects or adverse reactions. In this case, alternative treatment strategies should be discussed.
- Naltrexone discontinuation should be considered for the following cases:
 - *Opioid use*: Two to three recent positive urine toxicology results for opioids and the risk of continuing treatment outweighs the benefit. Consider discontinuing naltrexone treatment sooner if opioid use is occurring towards the end of the extended-release naltrexone dosing interval as this puts the patient at increased risk for fatal overdose.
 - *Alcohol use*: Patients presenting to clinic smelling of alcohol, who have a positive breathalyzer result, provides reports of ongoing alcohol use or has noted ED admissions for alcohol use and the risk of continuing treatment outweighs the benefit.
 - Ongoing use of other illicit drugs and the risk of continuing treatment outweighs the benefit.
 - Patient presents to OBAT clinic impaired or objective reports of impairment, incidence of overdose, or hospitalization related to substance use and the risk of continuing treatment outweighs the benefit.

- Multiple missed appointments or the inability to contact patient:
 - If a patient misses an initial appointment for an extended-release naltrexone injection, he/she should be instructed to receive the next injection as soon as possible. Reassess the patient status prior to administering the medication. Perform a UTS or conduct a naloxone/naltrexone challenge if there is risk of precipitating withdrawal. Augment the treatment plan as needed.
 - Multiple missed appointments should be addressed with the patient and the treatment team. Risk may outweigh benefits of continuing naltrexone treatment; document in electronic medical record.
- Patients who are referred to a higher level of care will be reconsidered for future treatment in OBAT.

Diversion

In cases of suspected diversion (i.e., suspicious buprenorphine negative urines, requests for early refills, reports of lost/stolen/destroyed medication, requests for dose increases), the patient should be asked to come into the clinic for an assessment. This assessment should include toxicology testing. When possible, confirmatory testing (i.e., Target 32) is recommended to confirm presence of buprenorphine and its metabolite norbuprenorphine.

Any patient known to be diverting buprenorphine will be evaluated by the provider to discuss appropriate next steps and possibly transition to methadone or another level of care.

OBAT Discharge

- If a patient is discharged from OBAT, they are welcome to re-engage, except if there are administrative or safety concerns connected with the discharge.
 - Examples of administrative and safety issues: violence or criminal activity on hospital grounds, police report or other documentation of patient selling prescribed medication, inappropriate behavior in a clinic setting, and/or threatening safety of staff, providers or other patients.
 - In conditions where administrative or safety issues exist patients may be transferred to either the methadone clinic or addiction specialty care as appropriate.

Specific Populations

Methadone to Buprenorphine Transfers

Transitioning from Methadone Maintenance to Buprenorphine/Naloxone

Potential benefits of transitioning to buprenorphine/naloxone:

- Decreased risk of overdose as medication is a partial agonist.
- Integrated addiction treatment in an office-based setting with medical care and the ability to obtain FDA-approved medications for opioid use disorder at a local pharmacy.
- Work with methadone clinic staff to coordinate the methadone taper with the transition to buprenorphine/naloxone:
 - Establish with both patient and methadone clinic that, if the transition to buprenorphine/naloxone is unsuccessful (e.g., patient begins to experience withdrawal that interferes with functioning or leads to return to use or patient does not tolerate the medication), the patient may return to methadone treatment without a gap in treatment.
 - Educate patients regarding appropriate methadone dose levels for transferring to buprenorphine/naloxone. To decrease the level of physical opioid dependence and minimize the chance for precipitated withdrawal, most patients will need to have their dose tapered to 30mg before beginning buprenorphine/naloxone treatment.
- The tapering and transitioning period may include discomfort and increased risk for a return to pretreatment use. Please support patients during this process.
- Target methadone dose: 20 - 30mg daily for one to two weeks prior to transition is optimal but not always necessary.
- Alternate approach: Taper methadone dose to the point of patient discomfort; with objective withdrawal symptom documentation via Climate Opiate Withdrawal Scale (COWS), buprenorphine/naloxone can then be initiated.
- Inpatient detoxification is another option to assist a patient in the transition from methadone to buprenorphine/naloxone.
- Advise patient to arrange for time off work during the transition, family support with childcare and other responsibilities as discomfort may last between one to two weeks.
- It is not necessary to begin with buprenorphine mono-tablet (Subutex) before initiating buprenorphine/naloxone.
- Timing for last methadone dose/first buprenorphine/naloxone dose is difficult to predict.
 - Generally, at least 36 to 96 hours after the last methadone dose but utilizing clinical assessment and judgment is essential.
 - Long half-life of methadone (storage in body tissues, especially liver) causes unpredictable clearance.
 - Initiation of buprenorphine/naloxone should be guided by withdrawal symptoms objectively documented with a COWS score of 13 to 15, rather than by time since last methadone dose.

- Close monitoring and small amounts of clonidine, anxiolytics (including benzodiazepines), sedative/hypnotics, Bentyl, trazodone, and NSAIDs may be used to manage distressing withdrawal symptoms and continued during induction if prescribed by provider.
- More intensive stabilization support may be needed (e.g., telephone contact up to three times daily until maintenance dosing is attained). Frequent visits, adequate supports and supportive environment to assist in the transition.
- Providers should be experienced in induction prior to transitioning a patient from methadone maintenance to buprenorphine/naloxone.
- Where available, it is an option to transition patient to specialty addiction clinic for this transition, with the expectation that patient will return to primary care provider (PCP) after stabilization.
- Having the patient go to an inpatient detoxification to make this transition can be a safer, more effective way to get the patient from methadone maintenance to buprenorphine/naloxone.

Induction Recommendations:

- Once a COWS score of 12 to 15 is documented, start buprenorphine/naloxone at 2mg/0.5mg sublingually.
- Continue to dose patient in 2mg/0.5mg - 4mg/1mg doses every 30 to 60 minutes until physical withdrawal symptoms have been reduced to manageable levels or they are absent. Patients transitioning from methadone may require higher dosing initially and then taper down over weeks to months.
- Continue induction according to patient's prescription order, assessing symptoms of withdrawal and cravings.
- Symptom management with adjunctive medications as appropriate.
- Support and access to providers is critical in assisting patients with making this transition and not jeopardizing treatment.

Buprenorphine to Naltrexone Transfers

Transitioning from Buprenorphine/Naloxone Maintenance to Naltrexone

There have been several observational pilot studies conducted to explore the transition from buprenorphine to naltrexone. The majority were not randomized controlled trials.

- Per Mannelli et al. (2012), "Taken together, published clinical practice recommends induction to full dose naltrexone five to seven days after buprenorphine discontinuation. The studies we have reviewed here show the feasibility of transferring opioid dependent patients from buprenorphine to naltrexone in a shorter time, if an inpatient treatment option is available."²²
- A study by Kosten et al. (1993) found that administration of very low-dose oral naltrexone (1mg) did not induce significant withdrawal in buprenorphine-treated opioid dependent individuals. In participants who discontinued buprenorphine/naloxone and were given naltrexone 1mg titrated to full dose, naltrexone maintenance could be initiated in about half with only a small proportion remaining in treatment after two weeks.²³

- Sigmon et al. (2009) conducted a pilot study of 15 opioid dependent individuals enrolled to complete buprenorphine/naloxone stabilization, a two-week buprenorphine/naloxone taper and naltrexone induction once urine levels of buprenorphine/naloxone were undetectable. Overall, rates of abstinence were high during the stabilization and taper periods and decreased markedly following taper off of buprenorphine/naloxone. The authors concluded that while a two-week taper may be appropriate for a subset of individuals it is unlikely to be sufficient for the majority of individuals with opioid use disorders.²⁴
- Inpatient study by Clark et al., a small group of heroin users and buprenorphine-treated patients tapered buprenorphine in two to four days, combined with increasing doses of naltrexone. Following buprenorphine discontinuation, patients received naltrexone 50mg and were discharged. Higher withdrawal discomfort was reported in the initial two days of treatment. All patients completed the protocol. Results: 33% of patients were still taking naltrexone after four weeks, but overall opioid use was reduced by 50% or more compared with treatment admission.

Potential Benefits of Transitioning from Buprenorphine/Naloxone to Naltrexone:

- Naltrexone is a long-acting medication.
- Naltrexone tablets have a half-life of 14hrs and can/should be dosed on a once daily regimen.
- Extended-release injectable formulation is administered every 28 days. Patients receive one injection in the clinic every four weeks thus reducing the burden of daily medication dosing.
- Naltrexone indication for use includes BOTH prevention of relapse to opioids and assistance with treating alcohol use disorder.
 - Naltrexone mutes the reinforcing effects of alcohol.
- No physical opioid dependency.
 - Patients may choose to stop naltrexone treatment at any time without having to undergo opioid withdrawal.
- No psychoactive effects.
- Treatment is also provided within an established medical system with integration of addiction treatment alongside medical care with the ability to obtain FDA-approved medications for opioid use disorder and alcohol use disorder.
 - Insurance may require use of a specialty pharmacy.
- Antagonist medications such as naltrexone accelerate the opioid agonist detoxification process and are often prescribed post-detoxification to help prevent a return to pretreatment use.

Considerations:

When transitioning from buprenorphine to naltrexone, work with 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 fails (e.g., the patient begins to experience withdrawal 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 treatment.

- The long half-life of buprenorphine and slow dissociation from mu opioid receptor causes unpredictable clearance.
 - Timing for last buprenorphine dose/first naltrexone dose is difficult to predict.
 - The limited amount of available data suggests that patients may do best when tapered to 2-4mg of buprenorphine/naloxone daily for one week, waiting five to seven days between last dose of buprenorphine/naloxone and the first dose of naltrexone and then starting with low dose naltrexone by mouth.
 - Educate patients regarding appropriate buprenorphine dose levels for transferring to naltrexone. To decrease the level of physical opioid dependence and minimize the chance for severe precipitated withdrawal, most patients will need to have their dose tapered to 2mg before beginning naltrexone treatment.
 - The tapering and transitioning period will include discomfort and increased risk for return to pretreatment use. Please support patients during this process.
 - Advise patient to arrange for time off work during the transition, family support with childcare and other responsibilities as discomfort may last several days.
- Initiation of naltrexone should be guided by patient motivation, clinical judgment, UTS results that are negative for ALL opioids rather than by last 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 the patient is stable). Frequent visits, adequate supports, supportive environment to assist in the transition.
 - 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.
- Begin with naltrexone tablets for three days to one month before administering extended-release injectable naltrexone.

Suggested Buprenorphine to Naltrexone Protocol:

- Patient to reduce daily buprenorphine dose to 2mg for one week.
- Establish last dose date with patient five to seven days after final buprenorphine dose, patient to come to clinic with naltrexone tablet prescription bottle for naltrexone induction appointment with OBAT provider.
- UTS negative for all opioids.
- Negative naloxone/naltrexone challenge.
- Always initiate naltrexone treatment with oral naltrexone formulation versus extended-release injectable formulation to mitigate allergic reactions, side effects and adverse reactions. People can transition to injectable after one to two weeks of oral medication.
- Symptom management with adjunctive medications to occur as prescribed by OBAT provider.
- Support and access to providers is critical in assisting patients in making this transition and not jeopardizing their treatment.

Patients with HIV

- Naltrexone: Almost no interaction with antiretroviral medications.
- Buprenorphine/naloxone use does not interfere with clinical response to most antiretroviral medications.
- Side effects from drug interactions between HIV medications and buprenorphine/naloxone are less severe/significant than those experienced with methadone. It may be beneficial to provide some increased monitoring of both treatments.
- Reassure patients that treatment for their opioid use disorder, will not interfere with treatment for their HIV disease management, if appropriately monitored.

Considerations

- Multiple protease inhibitors may affect levels of buprenorphine and norbuprenorphine particularly ritonavir containing regimens as metabolic inhibitor.
 - Atazanavir and Darunavir have been found to cause significant increases in buprenorphine and/or norbuprenorphine levels, potentially leading to sedation and cognitive impairment.
 - Ritonavir is used as a metabolic inhibitor and can increase buprenorphine and/or norbuprenorphine levels, potentially leading to sedation and cognitive impairment.
 - Lopinavir-containing regimens may be associated with decreased norbuprenorphine levels, potentially leading to withdrawal or cravings.
 - These interactions do not contraindicate treatment but warrant close monitoring and potentially changing buprenorphine dosing.
- Some non-nucleoside reverse transcriptase inhibitors (nnrtis), particularly efavirenz, may decrease buprenorphine/naloxone levels and cause withdrawal symptoms.
 - Closer monitoring is warranted and increasing buprenorphine dosing may be indicated.
- Buprenorphine/naloxone may slightly increase protease inhibitor levels.
- Initiation of medication for opioid use disorder (MOUD) during HAART maintenance:
 - Clinical needs should determine treatment selection.
 - With opioid agonists, patients may benefit from a trial of buprenorphine/naloxone because of the more benign drug interaction profile of buprenorphine/naloxone compared with methadone.

Initiation of HAART During Buprenorphine/Naloxone Maintenance:

- Continue usual buprenorphine/naloxone dose.
- Check for medication interactions (<http://arv.ucsf.edu>).
- Monitor as appropriate.

Patients with Hepatitis C

Buprenorphine

- Both buprenorphine and naloxone are extensively metabolized by the liver.
- Most recent guidelines indicate that there are minimal concerns co-managing HCV and opioid use disorders utilizing buprenorphine/naloxone.²⁵
 - Current data suggests that liver injury from buprenorphine occurs rarely, however patients with hepatitis C are at higher risk of elevations in transaminases and reversible hepatic injury. Most of the evidence suggests that these elevations are related to underlying liver disease and not buprenorphine exposure. Serious hepatic injury is rare.
 - Buprenorphine maintenance may have indirect beneficial effect on liver health via reduction of illicit opioid use.
- A single-dose study of 43 patients compared buprenorphine/naloxone exposure in healthy individuals to persons with mild, moderate, or severe hepatic impairment. Study results indicate that individuals with more advanced hepatic impairment experience higher peak exposure levels of naloxone vs buprenorphine when compared to healthy subjects.¹⁵
 - Dose adjustment may be required for some patients with severe liver disease.
 - May consider mono-tablet in some cases of severe liver disease.
- There are a small number of case reports of intravenous use of buprenorphine/naloxone by patients with hepatitis C resulting in increased alanine aminotransferase levels to 30 to 50 times normal.²⁶
 - Case reports of seven patients with hepatitis C using buprenorphine/naloxone who had increased ALT 39x normal.²⁷
 - All continued buprenorphine/naloxone; 50% dose reduction in three patients.
 - All recovered without any clinical complications.
- When initiating buprenorphine/naloxone treatment it is important to do baseline hepatic testing and then retest transaminases as needed based on clinical assessment.

Naltrexone

- Naltrexone is extensively metabolized through the liver and clinical judgment should be used prior to administration in cases of advanced liver disease or acute hepatitis.
- AST and ALT should both be less than five times the upper limit of normal at treatment initiation.
- Draw follow-up AST and ALT eight to 12 weeks after initiation of naltrexone. At present there is no empirical evidence to support frequency of monitoring; clinical discretion should be used to guide frequency.²⁵
 - Cases of hepatitis and clinically significant liver dysfunction were observed in association with extended-release injectable naltrexone treatment during the clinical development program and in the post-marketing period.
 - A randomized, double-blind, placebo-controlled trial of 624 individuals with alcohol dependence (DSM-IV) and recent heavy drinking designed to assess the hepatic safety of injectable naltrexone found no difference in hepatic function at six-months between participants on injectable naltrexone at the US FDA approved dose (380mg) compared to those receiving a placebo.²⁸

- In a study of 250 participants (89% had history of HCV) at six-month follow-up, elevations in AST, ALT and GGT greater than three times the upper limit of normal were not statistically different in patients treated with injectable naltrexone compared with placebo.²⁹ The majority of participants who contributed liver enzyme level elevations greater than three times the upper limit of normal had chronic HCV infection.
- Discontinue use of extended-release injectable naltrexone in the event of symptoms or signs of acute hepatitis (e.g., abdominal pain, nausea, vomiting, fever, dark urine, clay-colored stools, jaundice, or icterus; or ALT or AST levels greater than 10x the upper limit of normal).²⁵
 - If no evidence that liver enzyme elevation is related to medication, you can restart once ALT and AST fall below 10x the upper limit of normal.
- For all patients prescribed either buprenorphine/naloxone or naltrexone, hepatic enzymes should be monitored at regular intervals throughout the course of treatment.

Patients should receive education about the signs/symptoms of liver inflammation and be advised to report these signs/symptoms to their clinical team or present to an emergency department for evaluation if present.

Pregnancy and Breastfeeding

Active Opioid Use Disorder in Pregnancy is Considered High-Risk

- First trimester: Risk for spontaneous abortion.
- Third trimester: Risk for withdrawal-induced fetal distress, premature labor and intrauterine death.
- Educate pregnant patients on the benefits of maintaining treatment during pregnancy.
 - Decreased risk for problematic opioid use and therefore reduced complications from changing doses of opioid on mother and fetus.
 - Constant levels of fetal opioid exposure result in reduced risk for adverse fetal outcomes related to multiple withdrawals.
 - Decreased rate of adverse fetal outcomes such as low birth weight.
- Incidence of neonatal abstinence syndrome is 47%.
- Both methadone and buprenorphine (both combo and mono-tablet formulations) are Category C in pregnancy.
- There is more substantial data and clinical experience utilizing methadone in pregnancy.
- In 2012, the American College of Obstetricians and Gynecologists (ACOG) concluded that there is evidence to support the use of buprenorphine as a potential first-line medication for opioid dependent women.
- A longitudinal study of 73 children evaluated at 24 months (n = 24 exposed to buprenorphine in utero, and n = 19 exposed to methadone in utero, n = 30 non-exposed controls) found no differences between groups in temperament or neurological development during the first two years of life.³⁰

- A double-blind randomized controlled trial of 175 pregnant women with opioid use disorder treated with buprenorphine or methadone maintenance compared maternal and neonatal outcomes between the two groups. A total of 131 neonates were born to mothers followed through the end of their pregnancy (58 exposed to buprenorphine and 73 exposed to methadone).³¹
 - Neonates in the buprenorphine group required significantly less morphine (mean dose, 1.1mg vs. 10.4mg) than neonates in the methadone group. They also had significantly shorter hospital stays (10.0 days vs. 17.5 days) and significantly shorter duration of treatment for neonatal abstinence syndrome (4.1 days vs. 9.9 days). The two groups did not vary with regards to maternal or neonatal adverse events.
- Additional research is still needed; a recent review comprised of preliminary findings from seven previously published studies found no evidence of adverse maternal or neonatal outcomes related to the use of buprenorphine/naloxone as compared to buprenorphine alone (mono product) or methadone.³² Currently many providers use buprenorphine/naloxone for treatment of opioid use disorder during pregnancy without complications or notable adverse events. There is no indication to switch women to buprenorphine mono product.

Buprenorphine Protocol for Pregnant Women

- Potentially provide smaller prescriptions to increase monitoring.
- Schedule more frequent follow-up visits during pregnancy.
- Refer to GREAT MOMs program if available.
- Minimal information exists on dosing changes by trimester.
- Once-daily dosing is effective in pregnancy, however many require divided dosing.
- Frequent follow up visits should include assessment, support, UTS, safety assessment, counseling, education and social determinants of health screening.
- Women should be encouraged to breastfeed provided their UTS are negative for other concerning substances and the mother is not prescribed any other medications that are contraindicated for breastfeeding.
- Breastfeeding women should be maintained on buprenorphine/naloxone.
- Buprenorphine/naloxone is passed into breast milk at 1:1 plasma: Milk ratio.
 - Because of poor oral bioavailability of buprenorphine/naloxone, the breastfeeding infant is exposed to only 1/10 of buprenorphine/naloxone ingested.
 - Breastfeeding during buprenorphine/naloxone use does not suppress neonatal abstinence syndrome. However, the close contact afforded by breastfeeding has been shown to assist with symptoms of NAS and enhances maternal-child bonding.
 - Cessation of breastfeeding is not associated with the onset of neonatal abstinence syndrome.
- Naltrexone in Pregnancy: Little research has been conducted to evaluate the safety or efficacy of naltrexone in pregnancy. Naltrexone, in both oral and injectable formulations, are considered Category C medications.

- ***Naltrexone with Breastfeeding**** It is not known if extended-release injectable naltrexone passes into breast milk. It is known that naltrexone from the oral formulation does pass into breast milk. Due to the potential tumorigenicity shown for naltrexone in animal studies, and because of the serious adverse reactions in nursing infants from injectable naltrexone, a decision should be made to either discontinue the medication or discontinue nursing. Labeling from the manufacturer advises against breastfeeding while taking naltrexone, both with oral and injectable formulations.

*Adapted from information accessed at: <https://www.vivitrol.com/important-safety-information>

For Additional Guidance Regarding the Care of Pregnant Women with Opioid Use Disorder

- Refer to the Spectrum Health Grand Rapids Encompassing Addiction Treatment with Maternal Obstetric Management (GREAT MOMs) Toolkit.

Dual Diagnosis

Buprenorphine/Naloxone

- Buprenorphine/naloxone is metabolized in the liver by the cytochrome P450 3A4 system.
- Clinical experience has not uncovered significant drug-drug interactions with buprenorphine/naloxone.
- Dosing changes are generally not necessary, as opposed to methadone dosing, which is highly influenced by concomitant medication use.
- Reassure patients with comorbid psychiatric conditions that the use of buprenorphine/naloxone is not a barrier to treatment of their psychiatric condition.

Naltrexone

- The cytochrome P450 system is not involved in naltrexone metabolism. In vitro CYP studies have demonstrated that naltrexone is not an inhibitor or inducer of major CYP enzymes.

Dual Diagnosis Treatment in OBAT

- All patients are assessed for psychiatric disorders as a component of OBAT screening procedures.
- After two to three weeks of stabilization, reassess patients for psychiatric symptomatology.
- Substance-induced psychiatric disorders generally resolve within one to two weeks of treatment initiation and cessation of substance use.
- Psychiatric symptoms that persist beyond 30 days after cessation of substance use are suggestive of an independent psychiatric condition. These patients should be offered a referral to behavioral health services for a mental health evaluation.
 - For patients engaged in psychiatry services, obtain patient signed CFR42 consent for release of information to facilitate coordination of care with mental health providers.
- **Benzodiazepines should be used cautiously with patients receiving buprenorphine/naloxone because of the potential for increased CNS depression, including sedation, respiratory depression and the potential for misuse in the patient with the disease of addiction. Patient history of benzodiazepine misuse should also be explored prior to prescribing.**

Pain Management Protocol:

Buprenorphine/Naloxone Patients Requiring Surgery

Background: These guidelines are designed for patients maintained on buprenorphine or buprenorphine/naloxone undergoing invasive procedures. There is currently a lack of evidence-based studies to direct the management of patients on buprenorphine/naloxone maintenance in the peri-procedure period. Below are guidelines using expert opinions based on pharmacological principles with the intent to avoid under-treatment of acute pain while also avoiding potential opioid withdrawal and disruption of opioid use disorder treatment. The appropriate treatment of acute pain in patients on buprenorphine/naloxone 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 may necessitate higher opioid doses at shorter dosing intervals. All patients on buprenorphine/naloxone maintenance should be co-managed with their buprenorphine/naloxone provider during the pre- and post-procedure periods.³³

Buprenorphine: Peri-Procedure Management

Recommendations:

- Daily buprenorphine/naloxone dosing remains uninterrupted. Patient takes usual buprenorphine/naloxone maintenance dose on the morning of procedure.
 - Because of its high affinity at the opioid receptor, consider fentanyl as the opioid of choice for analgesia during procedures and in the PACU for these patients.
- Continue patient's home dose of buprenorphine/naloxone post-operatively.
 - Consider splitting the patient's usual buprenorphine/naloxone dose into every eight-hour dosing (e.g., 12mg per day changed to 4mg every eight hours).
- If further pain control is needed, begin by utilizing 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 the understanding that patients with a history of OUD may require higher than usual doses due to cross tolerance and increased pain sensitivity.
- PCA's without a basal component may be considered in addition to a patient's buprenorphine if the pain is not adequately captured. If a PCA is utilized, discontinue oral PRN opioids. However, continue the patients home buprenorphine dose.
- The buprenorphine/naloxone provider should be contacted pre-and post-procedure to assist in ongoing assessment, support and pain management.
- Schedule patient to be seen by their buprenorphine/naloxone prescriber within one-week post procedure.
- Do not send patient's with more than a one-week supply of medication. Be sure this is discussed with patient's OBAT provider and that the patient is scheduled with the OBAT provider within one week of discharge for assessment.
- DO NOT DISCONTINUE THE PATIENT'S BUPRENORPHINE.

Buprenorphine: Acute and Chronic Pain Management

General principles for pain management on buprenorphine/naloxone:

- Patients physically dependent on opioids require maintenance on daily equivalence before any pain relief is achieved with opioid analgesics (the “opioid debt”).
 - Evidence-based data now supports continuing patients on their daily maintenance dose of buprenorphine/naloxone during periods of acute pain, rather than discontinuing and later restarting buprenorphine treatment. Maintaining buprenorphine/naloxone has been shown to increase pain control while allowing the patient to remain stabilized on their medication treatment for OUD.
- Reassure patient that their addiction will not be an obstacle to aggressive pain management.
- Include patient in decision-making process to alleviate anxiety.
- Establish clear goals for pain management.
- Promote pain reduction rather than elimination.
- Address associated symptoms.
- Use a multimodal approach to pain management:
 - Consider splitting the patient’s usual buprenorphine/naloxone dose into every eight-hour dosing (e.g., 12mg per day changed to 4mg every eight hours).
 - Try non-opioids and adjuvant therapies next.

Examples include acupuncture, acupressure, massage, physical therapy, hydrotherapy, mindful meditation, NSAIDs, acetaminophen, topical lidocaine, ssris, tcas, etc.
 - If patient is on less than 12mg of buprenorphine, consider a modest increase in patient’s maintenance dose.
 - Use opioid analgesics as the last option.
- If opioid analgesics are necessary for treatment of chronic pain, buprenorphine/naloxone should be discontinued and methadone maintenance initiated at a methadone treatment program.

Pain Management Protocol: Naltrexone

Background

- These guidelines are designed for patients maintained on naltrexone undergoing invasive procedures. There is currently a lack of evidence-based research to direct the management of patients prescribed naltrexone in the peri-procedure period. Below are guidelines using expert opinions based on pharmacological principles of naltrexone with the intent to avoid under-treatment of acute pain while also avoiding potential disruption of opioid use disorder and/or alcohol use disorder treatment.
- The pain-relieving effects of opioid agonists are blocked while on naltrexone. This includes pure mu agonists such as methadone or morphine derivatives, partial agonists, as well as mixed agonist/antagonists. To overcome the pharmacologic blockade of extended-release injectable naltrexone, extremely high doses of opioids are required to achieve adequate analgesia. This could lead to accidental overdose. It is therefore recommended that non-opioid analgesics be prescribed for pain management in these patients when possible. Non-steroidal anti-inflammatory agents are first line. Regional nerve blocks and dissociative analgesics such as ketamine have also been recommended. However, expert consultation by an informed experienced pain specialist should occur.³⁴
- All OBAT patients receiving naltrexone treatment should be co-managed with their OBAT provider during the pre- and post-procedure period, as well as during periods of acute and chronic pain.

OBAT Policy for Naltrexone Patients Requiring Surgery

- Patient to notify OBAT staff of expected procedure as soon as they are aware of it.
- Obtain signed consent for release of information with CFR42 for the surgical/medical team.
 - OBAT clinical team to work with surgical team to manage pre- and post-procedure pain.
- If possible, extended-release naltrexone should be discontinued four to five weeks prior to the planned surgery/procedure date.
 - May bridge patient with oral naltrexone.
 - Oral naltrexone should be discontinued 48 to 72 hours before the procedure.³⁵
- Before minor or intermediate elective surgery, the possibility of managing the pain with non-opioids needs to be balanced against the risk to the patient of exposing them to opioids.
- If a patient is to undergo major surgery where severe post-operative pain is expected, then oral naltrexone should be discontinued 72 hours beforehand. A degree of resistance to opioid analgesics should be expected, although increased sensitivity is also a possibility.
- Patients should be monitored closely with increased supports throughout the peri-procedure period.
- Schedule patient to be seen by their OBAT provider as soon as possible post-procedure to have their post-procedure pain managed and to be safely restarted on naltrexone.

Naltrexone: Chronic Pain Management

- Chronic pain requiring opioid medications is a contraindication for naltrexone.
- For patients seeking medication treatment for an opioid use disorder who also have severe chronic pain, agonist medications should be considered, including buprenorphine/naloxone or methadone maintenance therapy.
- General principles for chronic pain management for patients engaged in naltrexone treatment:
 - Include patients in decision-making process to allay anxiety.
 - Establish clear goals for pain management:
 - Pain reduction rather than elimination.
 - Improved function.
 - Addressing associated symptoms.
 - Use multimodal approach to pain management:
 - Try non-opioids initially.
 - Try adjuvant therapies next.

Naltrexone: Unanticipated Acute Pain Management

- If a patient receiving ongoing extended-release naltrexone injections experiences unanticipated severe, acute pain or requires emergent surgery, refer to “Reversal of Extended-Release Injectable Naltrexone”.
- For patients taking oral naltrexone with unanticipated acute pain:
 - Include patients in decision-making process to allay anxiety.
 - Address underlying cause of pain.
 - Establish clear goals for pain management:
 - Pain reduction rather than elimination.
 - Improved function.
 - Addressing associated symptoms.
- Use multimodal approach to pain management:
 - Try non-opioids initially.
 - Try adjuvant therapies next.
- For patients prescribed naltrexone, if opioid analgesics are absolutely necessary for treatment of unanticipated acute pain, naltrexone should be discontinued.
 - If this occurs, higher than usual doses of opioids may be attempted to overcome naltrexone’s opioid antagonist effects.
 - Prescribing opioids to a patient that has been maintained on naltrexone must be done with close observation for respiratory depression. Refer to “Reversal of Extended-Release Injectable Naltrexone.”
 - Patients should be monitored closely with increased supports throughout the acute pain period.

Reversal of Extended-Release Injectable Naltrexone¹

In an emergency in patients receiving extended-release injectable naltrexone, suggestions for pain management include regional analgesia or use of non-opioid analgesics.

- If opioid therapy is required as part of anesthesia or analgesia, patients should be continuously monitored in an anesthesia care setting by persons not involved in the conduct of the surgical or diagnostic procedure.
- The opioid therapy must be provided by individuals specifically trained in the use of anesthetic drugs and the management of the respiratory effects of potent opioids, specifically the establishment and maintenance of a patent airway and assisted ventilation.
- Regardless of the drug chosen to reverse the extended-release injectable naltrexone blockade, the patient should be monitored closely by appropriately trained personnel in a setting equipped and staffed for cardiopulmonary resuscitation.

¹ Adapted from: https://www.accessdata.fda.gov/drugsatfda_docs/label/2010/021897s015lbl.pdf

Appendix 1

DSM-5 Checklist of Diagnostic Criteria: Opioid Use Disorder

A problematic pattern of opioid use leading to clinically significant impairment or distress, as manifested by at least two of the following, occurring within a 12-month period.

Diagnostic Criterion	Meets Criterion?	Additional/ Supporting Information
Opioids are often taken in larger amounts or over a longer period than was intended.		
There is a persistent desire or unsuccessful efforts to cut down or control opioid use.		
A great deal of time is spent in activities necessary to obtain the opioid, use the opioid or recover from its effects.		
Craving, or a strong desire or urge to use opioids.		
Recurrent opioid use resulting in a failure to fulfill major role obligations at work, school or home.		
Continued opioid use despite having persistent or recurrent social or interpersonal problems caused or exacerbated by the effects of opioids.		
Important social, occupational, or recreational activities are given up or reduced because of opioid use.		
Recurrent opioid use in situations in which it is physically hazardous.		
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.		
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.		
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 three 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 two to three symptoms. Code as: F11.10 (ICD-10)
- ☐ Moderate: Presence of four to five symptoms. Code as: F11.20 (ICD-10)
- ☐ Severe: Presence of six or more symptoms. Code as: F11.20 (ICD-10)

Appendix 2

DSM-5 Checklist of Diagnostic Criteria: Alcohol Use Disorder

A problematic pattern of alcohol use leading to clinically significant impairment or distress, as manifested by at least two of the following, occurring within a 12-month period.

Diagnostic Criterion	Meets Criterion?	Additional/ Supporting Information
Alcohol is often taken in larger amounts or over a longer period than was intended.		
There is a persistent desire or unsuccessful efforts to cut down or control alcohol use.		
A great deal of time is spent in activities necessary to obtain alcohol, use alcohol or recover from its effects.		
Craving, or a strong desire or urge to use alcohol.		
Recurrent alcohol use resulting in a failure to fulfill major role obligations at work, school or home.		
Continued alcohol use despite having persistent or recurrent social or interpersonal problems caused or exacerbated by the effects of alcohol.		
Important social, occupational or recreational activities are given up or reduced because of alcohol use.		
Recurrent alcohol use in situations in which it is physically hazardous.		
Continued alcohol use despite knowledge of having a persistent or recurrent physical or psychological problem that is likely to have been caused or exacerbated by alcohol.		
Tolerance, as defined by either of the following: A. A need for markedly increased amounts of alcohol to achieve intoxication or desired effect. B. A markedly diminished effect with continued use of the same amount of alcohol.		
Withdrawal, as manifested by either of the following: A. The characteristic withdrawal syndrome for alcohol (refer to Criteria A and B of the criteria set for alcohol withdrawal, pp. 499–500). B. Alcohol (or a closely related substance, such as a benzodiazepine) is taken to relieve or avoid withdrawal symptoms.		

Specify if:

In Early Remission: After full criteria for alcohol use disorder were previously met, none of the criteria for alcohol use disorder have been met for at least three months but for less than 12 months (with the exception that Criterion 4, “Craving, or a strong desire or urge to use alcohol,” may be met).

In Sustained Remission: After full criteria for alcohol use disorder were previously met, none of the criteria for alcohol 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 alcohol,” may be met).

In a Controlled Environment: This additional specifier is used if the individual is in an environment where access to alcohol is restricted.

Current severity:

- ☐ Mild: Presence of two to three symptoms. Code as: F10.10 (ICD-10)
- ☐ Moderate: Presence of four to five symptoms. Code as: F10.20 (ICD-10)

Appendix 3

Initial Patient Screening and Intake Tool

Demographic Info

Are you pregnant at this time?

- ☐ 1 = Yes
- ☐ 2 = No
- ☐ 3 = Don't Know
- ☐ 4 = Tubal Ligation
- ☐ 5 = Menopause
- ☐ 6 = History of Hysterectomy
- ☐ 7 = Other

If no, are you on birth control? ☐ 1 = Yes ☐ 2 = No

Current Address _____

Phone _____ Is it ok to leave a message? ☐ 1 = Yes ☐ 2 = No

Phone _____

Emergency Contact _____ Phone _____

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

What substances are you currently using at this time?

Includes age of first use, date of most recent use, route, frequency and quantity.

- | | |
|---|--|
| <input type="checkbox"/> 1 = Heroin | <input type="checkbox"/> 7 = Cocaine |
| <input type="checkbox"/> 2 = Fentanyl | <input type="checkbox"/> 8 = Benzodiazepines |
| <input type="checkbox"/> 3 = Nuprenorphine/Naloxone | <input type="checkbox"/> 9 = Alcohol |
| <input type="checkbox"/> 4 = Methadone | <input type="checkbox"/> 10 = Amphetamines |
| <input type="checkbox"/> 5 = Oxycodone Product | <input type="checkbox"/> 11 = Nothing |
| <input type="checkbox"/> 6 = Other Opioids | <input type="checkbox"/> 12 = Other |

Have you ever shared needles? ☐ 1 = Yes ☐ 2 = No

Have you ever belonged to the needle exchange program? ☐ 1 = Yes ☐ 2 = No

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

Number of lifetime overdoses: _____

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

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

Recovery History

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

When was this? _____

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	_____ Driving Impaired Program
_____ Residential (Rehab or Halfway House)	_____ Methadone Maintenance
_____ Buprenorphine/Naloxone Maintenance Program	_____ Intensive Outpatient
_____ Naltrexone (Oral or Injectable)	

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

- ☐ 1 = AA
☐ 2 = NA
☐ 3 = Smart Recovery
☐ 4 = Other: _____

How many meetings do you attend each week?

- ☐ 1 = 1 to 2 per week
☐ 2 = 3 to 4 per week
☐ 3 = 5 to 6 per week
☐ 4 = Daily
☐ 5 = None
☐ 6 = Other: _____

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

Do you have any history of any other addictive behaviors such as?

- ☐ 1 = Gambling
☐ 2 = Sex
☐ 3 = Shopping
☐ 4 = Eating Disorder (Over-Eating, Bulimia, Anorexia)
☐ 5 = Other: _____
☐ 6 = None

Comments?

Criminal History

Have you ever been incarcerated? ☐ 1 = Yes ☐ 2 = No

What is the longest period of time you spent in jail/prison? _____

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

Are you on parole? ☐ 1 = Yes ☐ 2 = No

Are you facing any potential jail time? ☐ 1 = Yes ☐ 2 = No

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

If yes, can you tell us about them? _____

Methadone History

Have you ever engaged in a methadone maintenance program? ☐ 1 = Yes ☐ 2 = No

Are you currently on methadone maintenance? ☐ 1 = Yes ☐ 2 = No

If yes to currently on engaged in methadone treatment:

Where are you engaged in methadone maintenance? _____

What is the name of your counselor at your methadone clinic? _____

How long have you been in your current methadone maintenance program? _____

Are you receiving take-homes? ☐ 1 = Yes ☐ 2 = No

If yes, how many? _____

If not currently engaged in methadone treatment:

When were you on methadone maintenance? _____

Where were you on methadone maintenance? _____

How long were you on methadone maintenance? _____

What was your dose? _____

Why did you stop methadone treatment? _____

Buprenorphine History

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

If yes:

Where were you prescribed buprenorphine/naloxone: _____

When were you prescribed buprenorphine/naloxone? _____

What was your dose? _____

Why did you stop taking buprenorphine/naloxone? _____

Naltrexone History

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

If yes:

Where were you prescribed naltrexone: _____

When were you prescribed naltrexone? _____

What was your dose? _____

Why did you stop taking naltrexone? _____

Mental Health History

Are you currently seeing a psychiatrist, psychologist or counselor for a mental health issue?

☐ 1 = Yes ☐ 2 = No

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

What is this individual's name? _____

How often do you see them? _____

How many times have you seen this person in the last six months? _____

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

Are you willing to contract for safety, call 911 etc., per program protocol? ☐ 1 = Yes ☐ 2 = No

Health Status

Are you currently seeing a psychiatrist, psychologist or counselor for a mental health issue?

- ☐ 1 = Diabetes: *(specify type)* _____
- ☐ 2 = Heart Disease: *(specify type)* _____
- ☐ 3 = Cancer: *(specify type)* _____
- ☐ 4 = Asthma
- ☐ 5 = Tuberculosis (TB)
- ☐ 6 = Endocarditis
- ☐ 7 = Skin infection
- ☐ 8 = HIV
If yes, are you currently in care? ☐ 1 = Yes ☐ 2 = No
- ☐ 9 = Hepatitis A
- ☐ 10 = Hepatitis B
If yes, have you been treated? ☐ 1 = Yes ☐ 2 = No
- ☐ 11 = Hepatitis C
If yes, have you been treated? ☐ 1 = Yes ☐ 2 = No
- ☐ 12 = Seizure Disorder
Are you on medications? ☐ 1 = Yes ☐ 2 = No
- ☐ 13 = Head Trauma/Brain Injury
- ☐ 14 = Pancreatic Problems
- ☐ 15 = Other: *(specify type)* _____
- ☐ 16 = None

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 ever had surgery? ☐ 1 = Yes ☐ 2 = No

If yes, why did you have surgery? _____

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

If yes, please briefly explain: _____

Pain

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

Please rate your pain, on a scale from 0 to 10,
WITHOUT any pain medications prescribed or bought on the street. *(circle your answer)*

0 1 2 3 4 5 6 7 8 9 10

Please rate your pain, on a scale from 0 to 10,
WITH pain medications prescribed or bought on the street. *(circle your answer)*

0 1 2 3 4 5 6 7 8 9 10

Employment

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

If yes, what do you do for work? _____

Are you working full- or part-time? _____

What days of the week do you work, and how many hours per day do you work? _____

Social Support

What is your relationship status?

☐ 1 = Single *(skip the next question)*

☐ 2 = Married

☐ 3 = Long-Term Relationship

☐ 4 = Divorced

☐ 5 = Other: _____

Do you live with your partner/significant other? ☐ 1 = Yes ☐ 2 = No

Does your partner have a history of substance use disorder? ☐ 1 = Yes ☐ 2 = No

Is your partner/significant other currently in treatment? ☐ 1 = Yes ☐ 2 = No

How satisfied are you with the support you get from your partner/significant other?

- ☐ 1 = Very Satisfied.
- ☐ 2 = Satisfied.
- ☐ 3 = Fairly Satisfied.
- ☐ 4 = Not Satisfied.
- ☐ 5 = N/A.

Family History

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

Transportation

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

How will you get to your appointments?

- ☐ 1 = I would drive.
- ☐ 2 = I would take public transportation.
- ☐ 3 = I would walk.
- ☐ 4 = I would get a ride from a family/friend.
- ☐ 5 = Other: _____

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 you own or rent.
- ☐ 2 = In a house or apartment owned or rented by family or friends.
- ☐ 3 = Hotel.
- ☐ 4 = Alcohol or substance use treatment program.
- ☐ 5 = Shelter.
- ☐ 6 = Street or car.
- ☐ 7 = Other (specify other): _____
- ☐ 8 = Don't know.

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.
- ☐ 5 = Other: _____

Can you tell me what your goals are for treatment? _____

Appendix 4

Clinical Opiate Withdrawal Scale (COWS)

Flow-sheet for measuring symptoms over a period of time, during buprenorphine induction.

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

Patient's Name: _____ Date: _____

Buprenorphine Induction: _____

Enter scores at time zero, 30 minutes after first dose, two hours after first dose, etc.

Resting Pulse Rate: Record beats per minute. Measured after patient is sitting or lying for one minute. 0 - Pulse rate 80 or below. 1 - Pulse rate 81 to 100. 2 - Pulse rate 101 to 120. 4 - Pulse rate greater than 120.				
Sweating: Over past hour not accounted for by room temperature or patient activity. 0 - No report of chills or flushing. 1 - Subjective report of chills or flushing. 2 - Flushed or observable moistness on face. 3 - Beads of sweat on brow or face. 4 - Sweat streaming off face.				
Restlessness: Observation during assessment. 0 - Able to sit still. 1 - Reports difficulty sitting still but is able to do so. 3 - Frequent shifting or extraneous movements of legs/arms. 5 - Unable to sit still for more than a few seconds.				
Pupil Size: 0 - Pupils pinned or normal size for room light. 1 - Pupils possibly larger than normal for room light. 2 - Pupils moderately dilated. 5 - Pupils so dilated that only the rim of the iris is visible.				
Bone or Joint Aches: If patient was having pain previously, only the additional component attributed to opiates withdrawal is scored. 0 - Not present. 1 - Mild diffuse discomfort. 2 - Patient reports severe diffuse aching of joints/ muscles. 4 - Patient is rubbing joints or muscles and is unable to sit still because of discomfort.				

Runny Nose or Tearing: Not accounted for by cold symptoms or allergies. 0 - Not present. 1 - Nasal stuffiness or unusually moist eyes. 2 - Nose running or tearing. 4 - Nose constantly running or tears streaming down.				
GI Upset: Over last half hour. 0 - No GI symptoms. 1 - Stomach cramps. 2 - Nausea or loose stool. 3 - Vomiting or diarrhea.				
Tremor: Observation of outstretched hands. 0 - No tremor. 1 - Tremor can be felt, but not observed. 2 - Slight tremor observable. 4 - Gross tremor or muscle twitching.				
Yawning: Observation during assessment. 0 - No yawning. 1 - Yawning once or twice during assessment. 2 - Yawning three or more times during assessment. 4 - Yawning several times/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 - Piloerections of skin can be felt or hairs standing up on arms. 5 - Prominent piloerections.				
TOTAL SCORES with Observer's Initials				

Score:

5 to 12 = Mild; 13 to 24 = Moderate; 25 to 36 = Moderately Severe; More than 36 = Severe Withdrawal

Appendix 5

Best Practice Guidelines

Implementing Transmucosal Buprenorphine for Treatment of Opioid Use Disorder

Introduction

Improved access to pharmacotherapy is essential for combatting this epidemic as well as for improving the lives of persons struggling with addiction. Buprenorphine prescribers have an important role in bringing greater access to life-saving medication to patients and to do so in a way that promotes enduring, positive outcomes.

Buprenorphine and methadone are the first-line treatments for Opioid Use Disorder (OUD) and are associated with significant decreases in both fatal and non-fatal opioid overdoses. Long-acting naltrexone also shows some promise and may be considered as a treatment option.

Purpose

This best practice document is designed to fill information gaps and provide guidance in response to misconceptions regarding buprenorphine implementation; particularly regarding counseling, polysubstance use, assessment and diversion.

This document is focused on buprenorphine because the standards of care are evolving rapidly in response to the opioid epidemic and research defining evidence-based practices.¹

Counseling

- Federal law requires that waiver applicants attest to their capacity to refer patients for appropriate counseling and other appropriate ancillary services.² This is a relatively low-threshold requirement and does not obligate prescribers to ensure that their patients attend or participate in counseling for which referrals are made.
- Guidance from the Substance Abuse and Mental Health Services Administration (SAMHSA)³ acknowledges that there is an intrinsic psychosocial component within the medical management buprenorphine prescribers provide which benefits patients. Many patients are likely to benefit from counseling at some point in their treatment for OUD. SAMHSA's guidance regarding counseling notes that prescribers should "offer referrals for adjunctive counseling and recovery support services as needed." The guidance further states that "patients who were not interested in adjunctive addiction or mental health counseling during induction may become receptive to it when they are feeling more stable."

Polysubstance Use

- Some providers erroneously believe that prescribing buprenorphine is contrary to a standard of care when patients continue to use other opioids or other classes of drugs. Buprenorphine helps patients reduce or cease use of other opioids. Reduced opioid use is not only an acceptable outcome, it is a desirable one. There have been concerns about prescribing buprenorphine to patients who use or misuse benzodiazepines or alcohol, as the risk of adverse reactions may be higher when either of these is combined with buprenorphine. In 2017, however, the Food and Drug Administration issued a Drug Safety Communication stating that buprenorphine should not be withheld from these patients as “the harm caused by untreated opioid addiction can outweigh these risks.”⁴ Concomitant use of other opioids, cocaine, cannabis and amphetamines does not pose elevated risk in the patients taking buprenorphine and should not be a basis for terminating care.
- Maintenance with buprenorphine can reduce morbidity and mortality even when drugs other than opioids are being used and in the presence of a return to pretreatment opioid use.

Diversion of Buprenorphine

- Buprenorphine, like many medications, can be given or sold to people who are not prescribed the medicine. The literature shows that most diverted buprenorphine is used to alleviate withdrawal or maintain abstinence rather than to become intoxicated. Lack of access to prescribed buprenorphine is believed to be a prime factor in diversion of the medication.^{5,6}

Duration of Treatment

Key Point

- Treatment with buprenorphine should continue for as long as the patient is benefiting.
Risk of return to illicit opioid use is high when treatment is discontinued.

Key Resources for Implementation of Buprenorphine

- Federal Guidance:
<https://www.samhsa.gov/medication-assisted-treatment/buprenorphine-waiver-management/qualify-for-physician-waiver>
- Annals of Internal Medicine:
“The Next Stage of Buprenorphine Care for Opioid Use Disorder” by Martin et al <http://dx.doi.org/10.7326/M18-1652>
- Substance Abuse and Mental Health Services Administration Treatment Improvement Protocol (TIP) 63:
<https://store.samhsa.gov/system/files/sma18-5063fulldoc.pdf>
- U.S. Department of Health and Human Services (HHS), Office of the Surgeon General,
Facing Addiction in America: The Surgeon General’s Spotlight on Opioids. Washington, DC: HHS,
September 2018.
- Wakeman S, Barnett M.: Primary care and the opioid-overdose crisis—buprenorphine myths and realities. *N Engl J Med.* 2018;379:1–4.

References

- ¹ Martin SA, Chiodo LM, Bosse JD, Wilson A. The Next Stage of Buprenorphine Care for Opioid Use Disorder. *Ann Intern Med* ;169:628–635. Doi: 10.7326/M18-1652
- ² Drug Addiction Treatment Act of 2000 (DATA), as amended, 21 USC §823(g)(2); see also 42 CFR Part 8; Medication Assisted Treatment for Opioid Use Disorders, SAMHSA Final Rule, 81 Fed. Reg. 44712 (July 8, 2016)
- ³ Substance Abuse and Mental Health Services Administration. Medications to Treat Opioid Use Disorder. Treatment Improvement Protocol (TIP) Series 63, Full Document. HHS Publication No. (SMA) 18-5063FULLDOC. Rockville, MD: Substance Abuse and Mental Health Services Administration, 2018.
- ⁴ FDA <https://www.fda.gov/Drugs/drugsafety/ucm575307.htm>
- ⁵ Carroll JJ1, Rich JD, Green TC. The More Things Change: Buprenorphine/naloxone Diversion Continues While Treatment Remains Inaccessible. *J Addict Med*. 2018 Nov/Dec;12(6):459-465
- ⁶ Lofwall MR, Walsh SL: A review of buprenorphine diversion and misuse: the current evidence base and experiences from around the world. *J Addict Med* 8(5):315–326

Appendix 6

Treatment Program Requirements

- All patients who participate in an Office Based Addiction Treatment (OBAT) program are required to keep all appointments with their primary care providers/OBAT providers. These appointments are critical to the continuation of care.
- Refills will occur at the time of your follow up appointment with the OBAT provider.
- If an emergency or a schedule change creates a conflict with these appointments, patients need to contact the OBAT providers office as soon as possible to address the situation and reschedule the appointment.
- If an emergency arises outside of normal office hours that requires immediate attention from OBAT provider, patients should call the on-call number for the office.
- Patients are required to keep the OBAT clinic updated on all phone numbers and ways to be contacted.
- At providers discretion patient may need to come in for medication counts.
- Ongoing positive urine screens for opioids will prompt a revision of the treatment plan, and a potential referral to more structured treatment option.
- Ongoing struggles with other substances will require a restructured treatment plan potentially including referral to a higher level of care.
- It is the patient responsibility to keep the OBAT office up to date on the pharmacy of choice.
- If there are any changes in medications or medical issues including:
Surgery, medications, hospitalizations, or problems with your OBAT prescription please contact the OBAT provider office.
- Patients are expected to arrive on time for all scheduled appointments.
Appointments with providers may need to be rescheduled if patients arrive late.
- If patients do not attend for medical appointments with their OBAT provider and do not call to inform OBAT staff that they are unable to make the appointment, or arrange for rescheduling, the treatment plan will be revised as necessary.
- Buprenorphine/Naloxone: Initially prescriptions will return to weekly with weekly visits until seen by the provider. If patients continually miss OBAT prescriber appointments, then buprenorphine/naloxone prescriptions may be given as daily prescriptions (e.g., provider writes prescription for one days' supply of medication with refills) or held until the patient is seen for an office visit by an OBAT provider.

Appendix 7

Counseling

Patients in an Office Based Addiction Treatment (OBAT) program are strongly encouraged to engage in counseling and/or similar intensive recovery support through outside programs. If needed, patients should receive assistance with referrals and linkages for counseling and recovery support services. Patients are encouraged to attend a minimum of twice monthly counseling visits for the first 12 weeks of treatment. Patients should not be discharged from the OBAT Program if they do not comply with this recommendation as these individuals may be at increased risk for return to pretreatment use. However, patients who do not engage in counseling or outside support services should continue to receive more intensive monitoring.

- Patients will agree to sign consent to release information so that OBAT program staff can communicate with the patient's entire care management team, including those providing outside counseling and support.
- Patients are strongly encouraged to go to weekly or twice monthly counseling (or per the recommendations of the counselor).
- Patients will be expected to discuss their engagement in counseling and other outside services with the OBAT team.
- Groups, IOP's (Intense Outpatient Programs), residential and halfway houses are methods of treatment that are accepted as counseling.
- Role of counseling:
 - Educate patient at the onset and ongoing about the importance of adjunct counseling and recovery support and its role. Reinforce that medication alone rarely addresses all aspects of treatment and building skills will improve their chances of success.
 - Educate patients that at the start of treatment, weekly counseling, in the form of either one-on-one or in a group format, is strongly encouraged. Patients are welcome to participate in counseling specific to buprenorphine/naloxone or naltrexone, as they may find it helpful to discuss their treatment openly with others who are engaged in the same treatment.
- Role of self-help, peer-support groups:
 - Remind patients that treatment is a process that will take a lot of time and commitment. Attending peer-support groups may not be the right treatment modality for them 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 prefer other 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.
 - Encourage patients to attend meetings and to keep going, to try different meetings if one does not feel like it "fits". Encourage patients not to have high expectations, not to focus on what everyone else is or is not doing, to "take what they need and leave the rest". Remind patients that it often takes some time to build a connection and establish a sense of belonging.

- Encourage patients to join a home group, to get involved in the meetings (set up, clean up, make the coffee, etc.).
- For some patients, getting a sponsor, or forming a healthy relationship with another person who is doing well with their addiction treatment, may be a goal they work toward. Patients often report feeling that making this connection is an important piece in one's treatment.

Appendix 8

Record/Consent: RECORD OF AGREEMENT AND UNDERSTANDING OF/ CONSENT TO PARTICIPATE IN THE BUPRENORPHINE TREATMENT PROGRAM - MEDICAL GROUP

Patient Name	Date of Birth
MRN	
Physician	
FIN	

RECORD OF AGREEMENT AND UNDERSTANDING

I agree:

FOR ALL OF MY SCHEDULED APPOINTMENTS:

- To go to each appointment.
 - If I know I can not make it to the appointment, I will call the clinic at once to cancel. I will reschedule another appointment to make up for the canceled one.
 - If I have an emergency and I can't make it to the appointment, I will call the clinic to reschedule another appointment.
 - If I have a schedule change that conflicts with many of my scheduled appointments, I will call the clinic as soon as I know. The clinic will try to reschedule appointments.
 - If I have too many missed appointments, I may have to be given my medicine(s) more often. I may have to be referred to a higher level of care.
- To be early or on time to each appointment. I will call the clinic as soon as possible if I am running late.
- To be courteous while I am in the clinic. I will not act in a threatening or disruptive way.
- To not be intoxicated or under the influence of drugs when I come to the clinic. If I am, the clinic may refuse to see me, and my treatment plan will have to be changed.
- To not do any illegal activities in the clinic or on the hospital campus. If this happens, I may be immediately kicked out of the program. Refer to the policy "Dismissing a Patient from a Physician Practice" for specific information.

continued >

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I agree: (continued)

TO SAFEGUARD ALL MY MEDICINE(S). THIS MEANS I WILL:

- Take all of my medicine(s) as the prescription bottle instructs.
- Keep my medicine(s) in the bottle that has the prescription label on it.
- Be responsible and keep all of my medicine(s) in a safe and secure place.
- Not keep medicine(s) in areas where someone may be able to see/take them.
- Not keep them in shared areas in the home, at work or out in public places.
- Not keep medicine(s) where children may see or take them.
- Not sell, share or give any of my medicine(s) to another person. This is a serious violation of the agreement for treatment in this program and I may be referred to a higher level of care.

TO TELL THE CLINIC ABOUT ANY CHANGES OF INFORMATION
AS SOON AS POSSIBLE. THIS INCLUDES:

- Any phone number(s).
- All contact information (e.g., address, email, etc.).
- Any change or addition of a pharmacy. I will tell the clinic the pharmacy name, address, phone number.
- I agree to participate in all aspects of the Buprenorphine Treatment Program. Taking buprenorphine is only one part of my treatment. Education, counseling and relapse prevention programs are all available to help me in my treatment.
- To have a phone that works at all times. This is for the random check calls. The clinic must have my phone number on record.
- To tell the clinic immediately if I get additional medicine(s) from any doctors, pharmacies or other sources.
- To not tamper or alter urine screen results. If I do, I may be referred to a higher level of care.
- To not eat poppy seeds while in this treatment program. Poppy seeds may cause me to test positive for opioids.
- To be honest with my treatment team if I am struggling. The clinic is here to help me in my treatment.

I understand:

- My treatment team in the Buprenorphine Treatment Program wants to be able to help lessen your need for opioids. Buprenorphine is known as a partial opioid agonist which means it partially works like an opioid and the effect is weaker than full agonists like heroin and methadone.
- If my appointments are canceled often, I may be transferred to a more intense treatment option.
- ABOUT BUPRENORPHINE:
 - Any lost medicine(s) will not be replaced for any reason. This is a controlled substance.
 - Mixing buprenorphine with other substances can be very dangerous (especially those which can cause drowsiness such as benzodiazepines or alcohol). It can cause death.
 - If I misuse other illicit substances or medicines, my treatment team will discuss with me. My treatment plan will change in order to help me. If I continue to struggle with ongoing substance use, I may be referred to a higher level of care.

continued >

I understand: (continued)

- Spectrum Health uses the State Prescription Monitoring Program (PDMP) to review my medicine profiles. This shows if am getting controlled substances from other providers. If Spectrum Health finds I get prescriptions from other providers, they will review this information. If those medicines are found to violate this treatment agreement, the clinic will evaluate the situation and talk to me about it. I may be referred to a higher level of care.
- **ABOUT MY URINE SCREENS:**
 - The Buprenorphine Treatment Program does not have a chain-of-custody (a documented paper trail to ensure integrity of the sample) of urine toxicology screens. The purpose of my urine screens are for my treatment at Spectrum Health only. If I need to have a urine screen for legal purposes or program requirements, I must get urine screen outside of this program.
- If my urine tests positive for opioids, the clinic will evaluate the situation and talk to me about it. I may be referred to a higher level of care.
- If my urine screen tests negative for buprenorphine, the clinic will evaluate the situation and talk to me about it. I may be referred to a higher level of care.

I understand:

- If I am discharged from this program, I may be reconsidered at a future time.
- My medical information, treatment plan and record of medical care will be kept in an electronic medical record (EMR). Healthcare professionals who are involved in my care at Spectrum Health will be able to see my EMR. Spectrum Health only reviews my records as law and policy allows.

PREGNANT WOMEN

The Buprenorphine Treatment Program is designed to help me. If I become pregnant, it is important for me to also think about the health and well being of my baby. My treatment team can help both my baby and me during this time. Since buprenorphine is a partial opioid agonist, it may effect your baby. Buprenorphine is a prescribed medicine and is not an illegal substance. Taking buprenorphine while pregnant is still better than relapsing and/or using illegal substances. Here is some helpful information below.

I understand:

- My baby may be born with neonatal abstinence syndrome. This is when newborn babies experience withdrawal from opioids. If I deliver at Spectrum Health, I understand my baby will stay in the hospital for five days to be observed for signs of withdrawal (longer if the baby's treatment team decides it is necessary). This is in the best interest of my baby and myself. I will follow the expectations above when working with the providers caring for my baby in the NICU.
- Child Protective Services (CPS) role is to protect the health and safety of a child. Just because I participate in the Buprenorphine Treatment Program does not mean CPS will be involved. There are ways they may become involved:
 - If I use non-prescribed substances, I may be referred to CPS.

continued >

I understand: (continued)

- If I am using non-prescribed substances around or after 20 weeks of being pregnant, those non-prescribed substances can be detected in my baby's first poop (meconium). Meconium is the dark green substance forming the first feces of a newborn infant. This meconium can be tested after birth. If it tests positive for non-prescribed substances, it must be reported to CPS. Buprenorphine is a prescribed medicine and is not a non-prescribed substance.
- My care providers are required to report information to CPS. They are not making a personal judgment about you. They must follow the law.

CONSENT TO PARTICIPATE

I agree to participate in the Buprenorphine Treatment Program.

I have read this form or it has been explained to me. All my questions about this form have been answered.

Time _____ Date _____ Patient Signature _____

Time _____ Date _____ Witness Signature _____

If a patient is under 18 years of age or otherwise unable to consent, the following must be completed:

I, _____, hereby certify that I am the _____
of the patient; that patient is unable to consent because patient is a minor, or because:

Time _____ Date _____

Parent/Legal Guardian/Patient Advocate/Next of Kin Signature _____

Time _____ Date _____ Witness Signature _____

Interpretation Services.

I certify that I have interpreted, to the best of my ability, into and from the participant's stated primary language, _____, all oral presentations made by all of those present during the informed consent discussion.

Time _____ Date _____ Interpreter Signature _____

Interpreter Name (print) _____

Appendix 9

Record: ACKNOWLEDGMENT OF OPIOID START TALKING

(MUST BE INCLUDED IN THE PATIENT'S MEDICAL RECORD)

Michigan Department of Health and Human Services

Patient Name		Date of Birth
Name of Controlled Substance Containing An Opioid		
Dosage	Quantity Prescribed (for a minor, if signature is not the parent or guardian, the prescriber must limit the opioid to a single, 72 hour supply).	
Number of Refills		
<p>A controlled substance is a drug or other substance that the United States Drug Enforcement Administration has identified as having a potential for abuse. My provider shared the following:</p> <ul style="list-style-type: none"> a. The risks of substance use disorder and overdose associated with the controlled substance containing an opioid. b. Individuals with mental illness and substance use disorders may have an increased risk of addiction to a controlled substance. (Required only for minors.) c. Mixing opioids with benzodiazepines, alcohol, muscle relaxers, or any other drug that may depress the central nervous system can cause serious health risks, including death or disability. (Required only for minors.) d. For a female who is pregnant or is of reproductive age, the heightened risk of short and long-term effects of opioids, including but not limited to neonatal abstinence syndrome. e. Any other information necessary for patients to use the drug safely and effectively as found in the patient counseling information section of the labeling for the controlled substance. f. Safe disposal of opioids has shown to reduce injury and death in family members. Proper disposal of expired, unused or unwanted controlled substances may be done through community take-back programs, local pharmacies, or local law enforcement agencies. Information on where to return your prescription drugs can be found at http://www.michigan.gov/deqdrugdisposal. g. It is a felony to illegally deliver, distribute or share a controlled substance without a prescription properly issued by a licensed health care prescriber. 		

continued >

MDHHS-5730 (4-18a)

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I acknowledge the potential benefits and risks of an opioid medication as described by my provider along with the responsibility of properly managing my medication as stated above.	
Signature of Prescriber (when prescribing to a minor).	Date
Signature of Patient (if a minor, patient's parent/guardian).	Date
Signature of Patient's Representative or Other Authorized Adult.	Date
Printed Name of Parent/Guardian; Patient's Representative or Other Authorized Adult.	
<p>The Michigan Department of Health and Human Services (MDHHS) does not discriminate against any individual or group because of race, religion, age, national origin, color, height, weight, marital status, genetic information, sex, sexual orientation, gender identity or expression, political beliefs or disability.</p>	<p>AUTHORITY: PCA 246 of 2017, MCL 333.7303b and MCL 333.7303c</p> <p>COMPLETION: Required.</p> <p>PENALTY: Probation, limitation, denial, fine, suspension, revocation or permanent revocation.</p>

Consent: CONTROLLED SUBSTANCE THERAPY

Patient Name	Date of Birth
MRN	
Physician	
FIN	

My primary provider (physician/clinic) for controlled substances is: _____


What is this agreement about?

- Information about controlled substance medicine.
- Following a safe treatment plan.
- Making sure state and federal laws are followed regarding controlled substances.
- Rules to follow when receiving controlled substances.

What do I need to know when I take controlled substance medication for a long time?

- I could become dependent on the medication. If I stop the medicine suddenly, I could have uncomfortable or dangerous withdrawal symptoms.
- I may develop serious constipation. I could have trouble urinating.
- I may have drowsiness, nausea, itching and trouble sleeping – not enough or too much.
- It could affect my sexual function.
- It can slow my breathing.
- It may be dangerous if I take more medicine than my primary provider ordered or if mixed with alcohol. This could result in damage to my organs or even death.
- If I become pregnant, it can cause serious risks to my unborn baby.

continued >

White - Chart		Yellow - Patient	
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RULES FOR CONTROLLED SUBSTANCE THERAPY

1. I can get refills for my controlled substance medicine only from my primary provider.
2. I will not be able to get a refill or prescription for controlled substance medication from any other provider, urgent care, or emergency room
3. I will request a refill prescription for my controlled substance medicine during business hours Monday through Friday. I will NOT be able to get a refill on the weekends and after hours.
4. My primary provider may get information about me from any pharmacist or my referring doctor about my use of medicines. I will tell my primary provider about any other medicines or substances I am taking. I will not take any prescription medicines that are not prescribed for me.
5. I will tell my primary provider (or another one who has been assigned) about any side effects with controlled substance and pain-related medicines. If I have a serious side effect after hours or on the weekend, I may contact my primary provider's office on-call answering service. I may also seek treatment at an urgent care center or the emergency room.
6. I will take my controlled substance medication exactly as ordered by my primary provider. I will not change the dose or time schedule unless my primary provider says to do so.
7. I will not use any illegal controlled substance.
8. I will tell my primary provider if I choose to participate in the Michigan Medical Marijuana Program. I understand my primary provider may choose to no longer prescribe controlled substances for me. My primary provider may need to safely wean me from the controlled substance.
9. I will be responsible for my medicine. I will not sell, trade, or share any controlled substance medicine. I understand my primary provider will not replace any lost, forgotten or stolen medication.
10. I will keep my follow-up appointments. If I do not, I understand my primary provider may not provide any more prescriptions for controlled substances and may also discharge me from the practice.
11. My primary provider will evaluate me on a regular basis to see if this treatment benefits me.
12. My primary provider may request a drug screen to check for other medicines and substances. I agree to a pill count if I am asked.
13. If female: I must not currently be pregnant. I must agree to inform my primary provider if I become pregnant, if I am attempting to become pregnant or if I am engaging in unprotected sex (and am of child-bearing age).

AGREEMENT

- I have read this form or had it read to me in words I can understand.
- I understand and agree to the rules described above.
- If I do not follow the rules I know I may not receive any more prescriptions for controlled substances. I may also be dismissed from the practice.
- I also understand the side effects of controlled substances. If I still have questions, I will ask my primary provider for written information on the side effects of the controlled substances that the provider is prescribing for me.

continued >

Below are signatures for patient or parent/guardian (if patient is under 18 years of age) and witness.

Time _____ Date _____ Patient Signature _____

Time _____ Date _____ Parent/Guardian Signature _____

Time _____ Date _____ Witness Signature _____

I certify that I have interpreted, to the best of my ability, into and from the participant's stated primary language,
_____, all oral presentations made by all of those present
during the informed consent discussion.

Time _____ Date _____ Interpreter Signature _____

Interpreter Name (print) _____

Consent: GENERAL, TREATMENT AND RELEASE OF INFORMATION

Patient Name (printed)	Medical Record Number
Account Number	Date

NOTICE OF NONDISCRIMINATION

Spectrum Health complies with applicable Federal civil rights laws and does not discriminate on the basis of race, color, national origin, age, disability or sex. Spectrum Health does not exclude people or treat them differently because of race, color, national origin, age, disability or sex. See pages 3 and 4 for the complete notice of nondiscrimination as well as availability of language assistance.

I agree:

- To examination and treatment by doctors and other healthcare professionals at Spectrum Health including Telemedicine.
- That the doctor may change my care to benefit my life or health.
- If I am here to give birth, the doctor and other healthcare professionals may give care to my baby.

I understand that:

- I will ask questions.
- No one has made promises about the results of my treatment or care.
- Students and staff may see me and look at my medical record for teaching or research purposes.
- The staff will double-check who I am. They will ask what I am having done. This is to protect me.
- Some doctors and staff are not employees of Spectrum Health. I know that Spectrum Health is not responsible for their care or other actions. I also know I will receive separate bills from them even though they provide services to me at a Spectrum Health location. I will work with their offices to answer questions about my insurance.
- Michigan law allows healthcare providers to test my blood for HIV (AIDS virus) or Hepatitis without my consent if someone who has helped in my care is exposed to my blood or body fluids.
- A copy of the Spectrum Health Financial Assistance Eligibility Policy is available upon request at all registration areas and on our website at www.spectrumhealth.org.
- Spectrum Health will not tolerate discrimination against my doctor, other healthcare professionals or staff because of race, color, gender, national origin, age, disability, sex or any other basis prohibited by federal, state or local law.

continued >

DO NOT MARK BELOW THIS LINE BARCODE ZONE DO NOT MARK BELOW THIS LINE



My Medical Information.

- SPECTRUM HEALTH MAY RELEASE MY MEDICAL INFORMATION TO:
 - Insurance companies, health plans and administrators for payment of services I receive.
 - Government agencies like Medicare and Medicaid or as required by law.
 - My doctors and others involved in my care now or in the future.
 - My employer, if the records are related to care or services paid for by my employer, or for other purposes that are allowed under law.
 - Any person or entity responsible to pay all or part of my bill.
- I agree that Spectrum Health can take my picture and save it to my electronic medical record. I understand that Spectrum Health will use this picture for identification purposes with the goal of improving my patient experience as I move throughout the Spectrum Health system.
- I understand Spectrum Health will keep my medical information according to State law, Federal law and policy. I also understand that my medical information may be stored electronically and may be sent to or received from other healthcare providers and/or payers electronically. This includes my diagnosis (what is wrong with me), treatments (what we are doing to make me better), and medicine or prescription information about my mental health, infectious diseases like HIV, and other problems like drug or alcohol use may be included.
- In some cases, Spectrum Health is required by law to report medical information to an agency like the health department. This may include information about HIV, TB and other diseases.

Privacy Notice.

- I have rights and responsibilities when I receive services. Spectrum Health has given me its Notice of Privacy Practices, and I have had an opportunity to ask questions about the information in the Notice.

Valuables.

- Spectrum Health would like its patients to leave valuables at home or with family members. I agree Spectrum Health is not responsible for safeguarding my property.

Consent to Call.

- I have provided residential and/or cellular telephone numbers and an email address to Spectrum Health. I consent to receive auto-dialed and/or pre-recorded telephone calls, text messages and/or emails from Spectrum Health and/or its agents/third parties at any of these phone numbers for communication including billing purposes. I understand that my consent to call is not a condition of my treatment.

Authorization to Receive Payment.

- Spectrum Health is authorized to act on my behalf in the collection of benefits from any third party and in the endorsement of checks payable to me and/or Spectrum Health. I understand that Spectrum Health is authorized to seek payment from any third party and from me.

continued >

Assignment.

- I assign Spectrum Health:
 - All benefits, claims, and any and all other rights, including the right to bill and talk to any third party for the purpose of seeking payment.
 - The right to file suit or intervene in any lawsuit or proceeding which involves my charges at Spectrum Health.
 - The right to take any other action seeking payment of my Spectrum Health charges.
- This assignment includes, but is not limited to, the right to appeal the denial of payment of my Spectrum Health charges from any payer, including any employer-sponsored benefit plan, insurance policy or insurance coverage provided by law or contract. I authorize Spectrum Health to act on my behalf to pursue an ERISA benefit claim or to appeal an adverse benefit determination. I agree to assist Spectrum Health in the pursuit of all insurance benefits and agree to pay all co-insurance, co-payments and deductibles required by any insurance plan.
- I also assign to Spectrum Health, and agree that I waive, any and all rights to settle, release or retain payment of my Spectrum Health charges, or take any other action which would in any way compromise payment or reimbursement of my Spectrum Health charges.

Billing.

- I authorize any insurance company, responsible for payment of my medical care and treatment, to pay Spectrum Health for the services given. I understand that I am responsible for any charges not covered by insurance.
- I agree that if my account is not paid when due, and the hospital should retain a lawyer and/or collection agency for collection, I will be responsible to reimburse the hospital for all costs, charges and fees associated with the collection of the amount due including, but not limited to, reasonable interest, legal costs in the event suit is filed and reasonable lawyer fees and/or reasonable collection agency fees including those based on a percentage of the debt.

Patient Signatures.

I have read this form and I understand it. All my questions have been answered.

Time _____ Date _____ Patient Signature _____

Patient is under 18 years of age or otherwise unable to consent because _____

Time _____ Date _____

Parent/Legal Guardian/Patient Advocate/Next of Kin Signature _____

Printed Name _____

continued >

Staff Signatures.

Time _____ Date _____ Witness _____

Second witness needed for verbal consent.

Time _____ Date _____ Witness _____

Interpretation Services.

I certify that I have interpreted, to the best of my ability, into and from the participant's stated primary language, _____, all oral presentations made by all of those present during the informed consent discussion.

Time _____ Date _____ Interpreter Signature _____

Interpreter Name (print) _____

continued >

Consent: GENERAL, TREATMENT AND RELEASE OF INFORMATION

Patient Name (printed)	Medical Record Number
Account Number	Date

Notice of Nondiscrimination:

Spectrum Health complies with applicable Federal civil rights laws and does not discriminate on the basis of race, color, national origin, age, disability or sex. Spectrum Health does not exclude people or treat them differently because of race, color, national origin, age, disability or sex.

SPECTRUM HEALTH:

- Provides free aids and services to people with disabilities to communicate effectively with us, such as:
 - Qualified sign language interpreters.
 - Written information in other formats (large print, audio, accessible electronic formats, other formats).
- Provides free language services to people whose primary language is not English, such as:
 - Qualified interpreters.
 - Information written in other languages.

If you need these services, contact Spectrum Health Language Services at 616.267.9701, 1.844.359.1607 (TTY:711).

If you believe that Spectrum Health has failed to provide these services or discriminated in another way on the basis of race, color, national origin, age, disability, or sex:

- You can file a grievance with:

Director, Patient Experience

100 Michigan Street NE, MC 006

Grand Rapids, MI 49503

616.391.2624 or toll free: 1.855.613.2262

patient.relations@spectrumhealth.org

You can file a grievance in person, by mail or by email. If you need help filing a grievance, the Director of Patient Experience is available to help you.

- You can also file a civil rights complaint with the U.S. Department of Health and Human Services, Office for Civil Rights electronically through the Office for Civil Rights Complaint Portal, available at <https://ocrportal.hhs.gov/ocr/portal/lobby.jsf>, or by mail or phone at:

U.S. Department of Health and Human Services

200 Independence Avenue SW, Room 509F, HHH Building

Washington, DC 20201

1.800.368.1019 or 1.800.537.7697 (TDD)

Complaint forms are available at <http://www.hhs.gov/ocr/office/file/index.html>.

continued >

Contact Us.

Español (*Spanish*)

ATENCIÓN: Si usted habla español, tiene a su disposición servicios gratuitos de asistencia lingüística. Llame al 1-844-359-1607 (TTY: 711).

العربية (*Arabic*)

ملحوظة: إذا كنت تتحدث أذكر اللغة، فإن خدمات المساعدة اللغوية تتوافر لك بالمجان. اتصل برقم 1-844-359-1607 (رقم هاتف الصم والبكم: 711).

中文 (*Chinese*): 國語/普通話 (*Mandarin*), 粵語 (*Cantonese*)

請注意：如果您講中文，你可以獲得免費的語言輔助服務。請撥打1-844-359-1607（TTY 手語翻譯：711）。

Tiếng Việt (*Vietnamese*)

CHÚ Ý: Nếu bạn nói Tiếng Việt, có các dịch vụ hỗ trợ ngôn ngữ miễn phí dành cho bạn. Gọi số 1-844-359-1607 (TTY: 711).

Ako govorite srpsko (*Serbian, Croatian or Bosnian*)

OBAVJEŠTENJE: Ako govorite srpsko-hrvatski, usluge jezičke pomoći dostupne su vam besplatno. Nazovite 1-844-359-1607 (TTY: 711). (TTY-Telefon za osobe sa oštećenim govorom ili sluhom: 711).

አማርኛ (*Amharic*)

ማስታወሻ: የሚናገሩት ቋንቋ አማርኛ ከሆነ የትርጉም እርዳታ ድርጅቶች፣ በነጻ ሊያገኙበት ተዘጋጅተዋል፡ ወደ ሚከተለው ቁጥር ይደውሉ፡ 1-844-359-1607. (መስማት ለተሳናቸው፡ (TTY: 711).

नेपाली (*Nepali*)

ध्यान दिनुहोस्: तपाईंले नेपाली बोल्नुहुन्छ भने तपाईंको निम्ति भाषा सहायता सेवाहरू निःशुल्क रूपमा उपलब्ध छ । फोन गर्नुहोस् 1-844-359-1607 (टिडिवाइ: (TTY: 711).

Thuɔŋjan (*Nilotic – Dinka*)

PIN KENE: Na ye jam në Thuɔŋjan, ke kuony yenë koc waar thook atö kuka lëu yök abac ke cín wënh cuatë piny. Yuopë 1-844-359-1607 (TTY: 711).

Kiswahili (*Swahili*)

KUMBUKA: Ikiwa unazungumza Kiswahili, unaweza kupata, huduma za lugha, bila malipo. Piga simu 1-844-359-1607 (TTY: 711).

فارسی (*Farsi*)

توجه: اگر به زبان فارسی گفتگو می کنید، تسهیلات زبانی بصورت رایگان برای شما فراهم می باشد. با 1.844-359-1607 (TTY: 711) تماس بگیرید.

Français (*French*)

ATTENTION: Si vous parlez français, des services d'aide linguistique-vous sont proposés gratuitement. Appelez le 1.844-359-1607 (TTY: 711).

(*Burmese*)

အသိပေးခြင်း

သင်ပြောသော ဘာသာစကားကို အခမဲ့ ဘာသာပြန်
ရှိပါသည်။ ဖုန်းခေါ်ရန်

فارسی دری (*Dari*)

توجه اگر به زبان دری صحبت می کنید، خدمات کمک زبانی بصورت رایگان برای شما در دسترس است. تماس ب 1-844-359-1607 (TTY: 711).

Kreyòl Ayisyen (*Haitian Creole*)

ATANSYON: Si ou pale Kreyòl Ayisyen, gen èd nan lang ki disponib gratis pou ou. Rele nimewo 1-844-359-1607 (TTY: 711).

continued >

Contact Us.

Ikinyarwanda (*Kinyarwanda*)

ICYITONDERWA: Niba uvuga ikinyarwanda, serivisi z'ubufasha ku byerekeye ururimi, urazihabwa, ku buntu.

Hamagara 1-844-359-1607 (ABAFITE UBUMUGA BW'AMATWI BIFASHISHA ICYUMA CYANDIKA -TTY: 711).

Soomaali (*Somali*)

DIGTOONI: Haddii aad hadasho Soomaali, adeegyada caawimada luqadda, oo bilaasha, ayaad heli kartaa. Wac 1.844-359-1607 (TTY: 711).

اللغة السودانية (*Sudanese*)

انتباه: إذا كنت تتحدث اللغة السودانية، خدمات المساعدة بلغتك متاحة مجاناً. اتصل على الأرقام 1-844-359-1607 (رقم الصم والبكم: 711).

தமிழ் (*Tamil*)

கவனம்: நீங்கள் தமிழ் பேசினால், உங்களுக்கு இலவசமான மொழி உதவிச் சேவைகள்

கிடைக்கின்றன. இந்த எண்ணை அழைக்கவும்: 1-844-359-1607 (TTY: 711).

ትግርኛ (*Tigrinya*)

ትኩል: ትግርኛ ኢንጅር ትላረብኩኑ፡ ናይታዕታይ ደገፍ ኣልግሎታት፡ ብፍጹም ክረክብኩኑ ኣየገብርኩም፡ ደሙ 1.844-359-1607 (TTY: 711)።

Consent/Record/Authorization: VIVITROL INJECTION - MEDICAL GROUP

Patient Name	Date of Birth
MRN	
Physician	
FIN	

CONSENT

Vivitrol is a medicine used to treat opioid and alcohol use disorder. It does this by binding and blocking opioid receptors to help lessen opioid and alcohol cravings. It is an extended-release version of naltrexone. This means that medicine is delivered continuously to your body over a one month period.

- It is injected by a healthcare professional into the muscle.
- It should be used along side other recovery activities like therapy/counseling.

CONSENT

- It may lessen my opioid and alcohol use.
- It may lessen my risk of overdose.
- I do not have to take something daily. This may make it easier to follow my treatment plan.

continued >

DO NOT MARK BELOW THIS LINE BARCODE ZONE DO NOT MARK BELOW THIS LINE



RISKS

If I use opioids while being given Vivitrol, the risks are:

- Very difficult opioid withdrawal symptoms:
 - Runny nose, anxiety, nausea, vomiting, belly pain, diarrhea and/or muscle aches/pains.
 - Difficulty treating my pain if I am physically injured.
 - Accidental overdose and/or death, because Vivitrol creates an increased sensitivity to opioids.
- It may be easier to overdose if I stop taking Vivitrol then restart it again.

Vivitrol possible side effects:

- Injury to my liver
- Lung infection (pneumonia)
- Severe allergic reaction(s) including difficulty breathing and drop of blood pressure.
- Nausea
- Vomiting
- Headache
- Dizziness
- Tiredness
- Depression and/or thoughts of suicide

ALTERNATIVES

- There are other treatment choices for my opioid and/or alcohol use disorder.
- I have the choice to have no treatment at all.

RECORD OF AGREEMENT

- I have not used opiates within the past seven to 10 days before my first injection.
- Before each injection, I will receive a urine test to check for opioids in my body. This is to keep me safe from a possible withdrawal.
- FOR FEMALES: If I am, may be or become pregnant, I will tell my healthcare provider because Vivitrol may not be the best treatment choice.
- I may see another healthcare provider for my opiate and/or alcohol addiction.
- I may refuse to be given Vivitrol.
- I have not been given any promises (guarantees) about Vivitrol therapy.
- I understand Vivitrol by itself may not fully treat my opiate and/or alcohol disease. It should be combined with other forms of treatment to get the best care for me and my disease.

continued >

AUTHORIZATION

I authorize my doctor/designated healthcare provider to give me Vivitrol.

I have read this form or it has been explained to me. All my questions about this form have been answered.

Time _____ Date _____ Patient Signature _____

Time _____ Date _____ Witness Signature _____

If a patient is under 18 years of age or otherwise unable to consent, the following must be completed:

I, _____, hereby certify that I am the _____
of the patient; that patient is unable to consent because patient is a minor, or because:

Time _____ Date _____

Parent/Legal Guardian/Patient Advocate/Next of Kin Signature _____

Time _____ Date _____ Witness Signature _____

Interpretation Services.

I certify that I have interpreted, to the best of my ability, into and from the participant's stated primary language, _____, all oral presentations made by all of those present during the informed consent discussion.

Time _____ Date _____ Interpreter Signature _____

Interpreter Name (print) _____

Job Breakdown: AMBULATORY STANDARD WORK

Essential Steps (check all that apply):		SWEAT Document Number: 10053 v2	Revision Date: (Owner Use Only) 03.04.2019
	Delivery System		
x	Service Line(s), list: Primary Health		
	Department(s), list:		
Customization Applicable to Site:		Site Number:	Implementation Date:
Workflow Title: Ordering Sublocade® (buprenorphine naloxone) and logging it from the pharmacy.		Why is this Standard Work Important? To ensure understanding of ordering process for Sublocade.	

STEP	WHO Scope of Practice	WHAT Major Steps	HOW Key Points	WHY System & Regulatory Requirements					LINKS
				Patient Experience	Quality	Patient Privacy	Patient Safety	Policy	
1	Waivered Provider	Review Sublocade® reference documents.	<ul style="list-style-type: none"> REMS policy #22904. Buprenorphine extended-release injection REMS Reference Document. 	x	x		x	x	REMS Policy REMS Medication Reference Document Buprenorphine Extended-Release (Sublocade)
2	Waivered Provider	Prescribe Sublocade® by placing an order in EPIC.	<ul style="list-style-type: none"> Provider to communicate to clinical staff that medication has been ordered. Patient must be on oral buprenorphine for seven days prior to first injection. Medication has to be ordered through a specialty pharmacy as a patient-specific prescription. Order must be placed at least two weeks prior to first injection. Record Sublocade® on patient's current medication list as a historical medication. 	x	x	x	x		
3	Clinical Team Member	Begin Prior Authorization (PA) process with patient's insurance company.	<ul style="list-style-type: none"> PA process begins when order is placed with the specialty pharmacy. Sublocade® is considered a pharmacy benefit. Fill out PA form and submit with urine toxicology marking form as urgent. 	x	x	x	x		

4	Clinical Team Member	Once PA approved, notify specialty pharmacy to begin processing order.	<ul style="list-style-type: none"> Specialty pharmacy will overnight the medication to the office of the prescriber. inSupport Resources and Tools - Specialty Pharmacy List. Notify pharmacy of patient's appointment date and time. 	x	x	x	x		inSupport Resources and Tools
5	Provider/ Clinical Team Member	Receive Sublocade® from Specialty Pharmacy and document.	<ul style="list-style-type: none"> Management of Controlled Substances Policy #7765. Sublocade® is a CIII controlled substance it should be handled, managed, and stored per policy. Handle, manage, store patient-specific/ patient-supplied medication according to policy (forthcoming). Once logged, the medication must be secured (locked in the lock box) in the refrigerator – and the refrigerator must be locked. Medication must be stored refrigerated at 36 – 46 degrees Fahrenheit (2 to 8 degrees Celsius). Temperature Controlled Storage Policy #3072 	x	x	x	x		Management of Controlled Substances Policy Temperature Controlled Storage Policy

Document Owner/Authors/SWEAT Approval (office use only)

Document Owner:	Kristi Smith, Admin Support Coordinator	SWEAT Approval Dates:
Contributors:	Jodi Swain, Clinical Ops Specialist Lisa Baar, Clinical Ops Specialist Kelli Santangelo, Pharmacy Buyer Chris Kowalski, Clinical Pharmacy Specialist	02.21.2019

Site Customization Owners:	
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Job Breakdown: AMBULATORY STANDARD WORK

Essential Steps (check all that apply):		SWEAT Document Number: 10056 v3	Revision Date: (Owner Use Only) 07.30.2019
	Delivery System		
x	Service Line(s), list: All Ambulatory/HOD		
	Department(s), list:		
Customization Applicable to Site:		Site Number:	Implementation Date:
Workflow Title: Urine Drug Screen (UDS) Point of Care Testing.		Why is this Standard Work Important? To ensure that urine drug screens are processed correctly.	

STEP	WHO Scope of Practice	WHAT Major Steps	HOW Key Points	WHY System & Regulatory Requirements				LINKS
				Patient Experience	Safety	Quality	Policy	
1	Clinical Team Member	During chart prep, MA will pend POCT DRUG SCREEN (Alere DX 14 ICUP) {POC 525} standing order.	<ul style="list-style-type: none"> Once patient is checked in, release UDS order. 	x	x	x		
2	Clinical Team Member	Place bluing tablet in the toilet in and tank. Then obtain Alere iCup and testing lid.	<ul style="list-style-type: none"> Bluing Tablet Lawson #83577. Alere iCUP Lawson #17992. If toilet is an automatic flush find out from facilities, if they can turn off the auto flush to make it a manual flush. Call has to be placed to facilities (ICCB puts tape over sensor). 	x	x			
3	Clinical Team Member	Instruct patient to wash their hands.	<ul style="list-style-type: none"> Have patient wash their hands prior to collecting specimen. This step must be observed by the Clinical team member. 	x	x	x		
4	Clinical Team Member	Give patient the Alere iCup.	<ul style="list-style-type: none"> Label the specimen according to the link. Instruct the patient to hand the specimen directly to clinical team member after they urinate into the specimen cup. Instruct patient that after specimen is received, to flush the toilet and wash their hands. Do not use restroom pass through. This ensures an accurate temperature. 	x	x	x	x	Labeling Policy #9955

5	Clinical Team Member	Begin processing specimen.	Complete the following in front of the patient: <ul style="list-style-type: none"> • Take the urine directly from the patient. • Verify the temperature, by looking at the dual temperature strip label on the iCUP. • Secure the test device cap on the Alere iCUP. 	x	x	x		
6	Clinical Team Member	Turn the cup on its side to activate testing.	<ul style="list-style-type: none"> • Note: A minimum of 30ml's are required for the test. • Refer to link. 	x	x	x	x	Urine Drug Screen iCUP Policy
7	Clinical Team Member	Set the timer for five minutes. Then either place or clip the timer to pocket.	<ul style="list-style-type: none"> • DO NOT interpret UDS results after eight minutes, as any results after eight minutes is invalid. • NO EXCEPTIONS! • Refer to link. 	x	x	x	x	Urine Drug Screen iCUP Policy
8	Clinical Team Member	Escort patient.	<ul style="list-style-type: none"> • Escort patient to exam room and finish rooming process following the standard workflow OR exit door if visit is complete. 	x	x	x		
9	Clinical Team Member	When timer alarms, return to specimen to complete interpretation.	Interpretation: <ul style="list-style-type: none"> • Negative = Colored lines appear in both the control and test region. • Positive = Colored lines appear in the control region and NO lines appear at a specific drug test region. • Invalid = NO lines appear in the control region. • Review Image in link. 	x	x	x	x	Urine Drug Screen iCUP Policy
10	Provider/ Clinical Team Member	Document results in patient's chart.	<ul style="list-style-type: none"> • Open patient's chart and document the test results in EPIC. • Document Temperature in comments section. • VERBALLY notify provider of any unexpected results.* • Notify Provider of UDS results, only after results have been entered into the patient's chart. NO EXCEPTIONS. 	x	x	x		
11	Provider/ Clinical Team Member	Send urine specimen to lab for confirmation if provider orders a test.	<ul style="list-style-type: none"> • Order Confirmation test (TARGET 32), clinical team member will process specimen and send to the lab. 	x	x	x		


Document Owner/Authors/SWEAT Approval (office use only)

Document Owner:	Kristi Smith, Admin Support Coordinator	SWEAT Approval Dates:
Contributors:	Jodi Swain, Clinical Ops Specialist Lisa Baar, Clinical Ops Specialist	02.21.2019

Site Customization Owners:	
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Job Breakdown: AMBULATORY STANDARD WORK

Essential Steps (check all that apply):		SWEAT Document Number: 10052 v3	Revision Date: (Owner Use Only) 05.28.2020
	Delivery System		
x	Service Line(s), list: Primary Health		
	Department(s), list:		
Customization Applicable to Site:		Site Number:	Implementation Date:
Workflow Title: Naltrexone (Vivitrol®) Administration.		Why is this Standard Work Important? To ensure safe and effective use of Vivitrol® in accordance with REMS Program.	

STEP	WHO Scope of Practice	WHAT Major Steps	HOW Key Points	WHY System & Regulatory Requirements					LINKS
				Patient Experience	Medication Safety	Patient Safety	Infection Control	Policy	
1	Clinical Team Member	Validate & verify Vivitrol® order availability.	One hour before scheduled visit: <ul style="list-style-type: none"> • Ensure Vivitrol® is on the patient's medication list-list as a historical medication. • Check when patient received last Vivitrol injection. • If they are due for a dose, order and pend. • Injections can be given every four weeks (28 days) after previous dose given. • Must be opioid free for seven to 10 days, prior to dose. 	x	x				
2	Clinical Team Member	Begin medication warming process one hour before scheduled visit.	<ul style="list-style-type: none"> • Once order is signed by the provider, staff may remove medication from the refrigerator to begin the warming process. • Place label on medication box. Be sure to complete date out and time out on label.  <ul style="list-style-type: none"> • Staff to set timer for 45 minutes and keep timer with them. • Site may customize where the medication is held/kept during warming process. • If patient "no shows", complete time back in refrigerator and place medication back in the refrigerator. (The medication can go in and out of the refrigerator two times. On the third time out of the refrigerator the medication must be administered or discarded.) 	x		x			

3	Clinical Team Member	Room patient upon arrival.	<ul style="list-style-type: none"> Room patient using the approved customized sites standard workflow. 	x	x	x	x	x	
4	Clinical Team Member	Verify/Complete POC Testing.	<ul style="list-style-type: none"> Reference Urine Drug Screen SW. Urine pregnancy test (POC #7). 	x	x	x	x	x	Urine Drug Screen SW
5	Provider/ Clinical Team	Review REMS reference documents.	<ul style="list-style-type: none"> REMS policy #22904. REMS Medication Reference Document: Naltrexone (Vivitrol®). 	x	x	x	x	x	REMS Policy REMS Medication Reference Document Naltrexone (Vivitrol)
6	Provider	Counseling Patient.	<ul style="list-style-type: none"> Counsel the patient on the risks associated with Vivitrol® use and document accordingly. 	x	x	x	x	x	
7	Clinical Team Member	Provide patient with Medication Guide with every Vivitrol® injection administration.	<ul style="list-style-type: none"> REMS policy #22904. Provide patient with Medication Guide. REMS Medication Reference Document: Naltrexone (Vivitrol®) 	x	x	x	x	x	REMS Policy Vivitrol Medication Guide REMS Medication Reference Document Naltrexone (Vivitrol)
8	Provider	Obtain informed consent and review therapy agreement, with each Vivitrol® injection.	<ul style="list-style-type: none"> Reference Informed Consent Policy #817. Review and sign Vivitrol® therapy agreement. Document number X-22923. 	x	x	x	x	x	Informed Consent Policy Vivitrol Sheet
9	Clinical Team Member	Upload Documents.	<ul style="list-style-type: none"> Upload signed documents into patient's chart. Attach form to the medication order. 	x	x	x	x	x	
10	Clinical Team Member	Prepare medication for administration.	<ul style="list-style-type: none"> Injectable Medications Policy 22071. Medication Administration Policy 11461. Firmly tap the VIVITROL® microspheres vial on a hard surface, ensuring the powder moves freely. Remove flip-off caps from vials. Place the one inch preparation needle on the syringe and withdraw 3.4 mL of the diluent from the diluent vial. Some diluent will remain in the diluent vial. Inject the 3.4 mL of diluent into VIVITROL® microsphere vial. Mix the powder and diluent by vigorously shaking the vial for approximately one minute. Ensure that the dose is thoroughly suspended prior to proceeding to next step. A PROPERLY MIXED SUSPENSION WILL BE MILKY WHITE, WILL NOT CONTAIN CLUMPS, AND WILL MOVE FREELY DOWN THE WALLS OF THE VIAL. Immediately after suspension, withdraw 4.2 mL into the syringe using the same preparation needle. Remove the preparation needle and replace with appropriately selected administration needle for immediate use. Key techniques to avoid injection site reactions. Pull the sheath away from the needle – do not twist the sheath because it could result in loosening the needle. Prior to injecting, tap the syringe to release any air bubbles, then push gently on the plunger until just 4 mL of the suspension remains in the syringe. 	x	x	x	x	x	Injectable Medications Policy Medication Administration Policy Injection Safety Information Key Techniques to Avoid Injection Site Reactions

11	Clinical Team Member	Administer Vivitrol® injection.	<ul style="list-style-type: none"> • VIVITROL® must NOT be given intravenously, subcutaneously or in adipose tissue. • Key techniques to avoid injection site reactions. • Select the appropriate needle for an intramuscular injection based on patient body habitus: <ol style="list-style-type: none"> a. 1 1/2-inch TERUMOR Needle. b. 2-inch TERUMOR Needle. • Injectable Medications Policy #22071. • Medication Administration Policy #11461. • Administer the suspension by deep intramuscular (IM) injection into a gluteal muscle, alternating ventrogluteal every month. • Remember to aspirate for blood before injection. • If blood aspirates or the needle clogs, do not inject. • Change to the spare needle provided in the carton and administer into an adjacent site in the same gluteal region, again aspirating for blood before injection. • Inject the suspension in a smooth and continuous motion. 	x	x	x	x	x	Key Techniques to Avoid Injection Site Reactions Injectable Medications Policy Medication Administration Policy
12	Clinical Team Member	Monitor Patient.	<ul style="list-style-type: none"> • Patient's first injection requires 20 minutes for observation to ensure no adverse reactions occur. • For follow up injections patients should wait 10 minutes for observation so no adverse reactions occur. • Vivitrol® injections may be followed by pain, tenderness, induration, swelling, erythema, bruising, or pruritus; however in some cases injection site reactions may be very severe. 	x	x	x	x	x	
13	Clinical Team Member	Recheck Site.	<ul style="list-style-type: none"> • After 20 minutes of initial injection or 10 minutes after completing a follow-up recheck on the site of injection to ensure no adverse reactions are occurring and document in a note in the patient record. 	x	x	x	x	x	
14	Clinical Team Member	Document Medication.	<ul style="list-style-type: none"> • Document medication administration in medical record. • Document that Medication Guide was given to patient. 	x	x	x	x	x	

Document Owner/Authors/SWEAT Approval (office use only)		
Document Owner:	Kristi Smith, Admin Support Coordinator	SWEAT Approval Dates:
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Site Customization Owners:		

Job Breakdown: AMBULATORY STANDARD WORK

Essential Steps (check all that apply):		SWEAT Document Number: 10051 v2	Revision Date: (Owner Use Only) 03.04.2019
	Delivery System		
x	Service Line(s), list: Primary Health		
	Department(s), list:		
Customization Applicable to Site:		Site Number:	Implementation Date:
Workflow Title: In-Office Administration of Sublocade® (buprenorphine extended-release injection).		Why is this Standard Work Important? To ensure safe and effective use of Sublocade in accordance with REMS Program.	

STEP	WHO Scope of Practice	WHAT Major Steps	HOW Key Points	WHY System & Regulatory Requirements				LINKS
				Patient Experience	Quality	Patient Safety	Policy	
Serious HARM or DEATH could result if administered intravenously. REMS Policy.								
1	Provider/ Clinical Team Member	Review Sublocade® reference documents.	<ul style="list-style-type: none">REMS policy #22904.Buprenorphine extended-release injection REMS Reference Document.	x	x	x		REMS Policy REMS Reference Document
2	Provider	Place order for clinic administered medication (Sublocade®) in EHR.	<ul style="list-style-type: none">In add orders, in Epic provider enters medication name and dosage amount.Provider then signs order.	x	x	x		Medication Orders Policy
3	Clinical Team Member	Remove medication from the refrigerator and inventory/document according to policy.	<ul style="list-style-type: none">Management of Controlled Substances Policy #7765.Sublocade® is a CIII controlled substance and should be handled, managed, stored and inventoried according to policy.	x	x	x	x	Management of Controlled Substances Policy
4	Clinical Team Member	Transfer medication to secured, room temperature, non-patient location.	<ul style="list-style-type: none">Lock medication in cabinet.Allow medication to reach room temperature.Set a timer for 15 minutes.	x	x	x		
5	Provider	Informed consent.	<ul style="list-style-type: none">Review and have patient sign.Informed Consent Policy #817.Answer any questions patient may have.	x	x	x	x	Informed Consent Policy
6	Clinical Team Member	Prepare medication for administration.	<ul style="list-style-type: none">Follow manufacturer's instructions per package insert.Injectable Medications Policy #22071.Label medication per Labeling of Medication Policy #7770.	x	x	x	x	Injectable Medications Policy Labeling of Medication Policy

7	Provider/ Clinical Team Member	Enter patient room together to administer Sublocade® injection.	Serious HARM or DEATH could result if administered intravenously. <ul style="list-style-type: none"> Medication Administration Policy #11461. Administer medication subcutaneously under direct supervision of provider. Medication must be given in subcutaneous tissue of abdomen. Rotate injection site. 	x	x	x	x	Medication Administration Policy
8	Clinical Team Member	Document medication administration in patient's chart.	<ul style="list-style-type: none"> Follow Epic process for medication administration and documentation (completing required fields). Enter route, injection site where administered, administration date and time, NDC number, lot number, and expiration date. .mardetails .marsummary 	x	x	x		
9	Provider	Document in the patient's Encounter Note the current injection site and date of next injection.	<ul style="list-style-type: none"> Provider to document where current injection was administered. Site location should be documented as RUQ, LUQ, RLQ, or LLQ. Provider to document planned date of next injection. Patient may return in 26-42 days for next injection. Medication is typically administered monthly. Copy and paste this information into patient instructions. 	x	x	x		
10	Provider/ Clinical Team Member	Monitor patient.	<ul style="list-style-type: none"> Following injection, patient shall wait in patient room for 20 minutes for observation. After 20 minutes, observe patient's injection site for redness or swelling and seek feedback from patient on pain at injection site (if significant findings, notify provider). If patient is not having any symptoms or reactions, patient is free to check out. 	x	x	x		
11	Clinical Team Member	Wasting medication when indicated.	<ul style="list-style-type: none"> Management of controlled substances. 	x	x	x	x	Management of Controlled Substances Policy

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Job Breakdown: AMBULATORY STANDARD WORK

Essential Steps (check all that apply):		SWEAT Document Number: 10054 v2	Revision Date: (Owner Use Only) 06.23.2020
	Delivery System		
	Service Line(s), list:		
x	Department(s), list: Center for Integrated Medicine ONLY		
Customization Applicable to Site:		Site Number:	Implementation Date:
Workflow Title: Suboxone® (buprenorphine and naloxone) In-Office Administration		Why is this Standard Work Important? To ensure safe and effective use of Suboxone in accordance with REMS Program.	

STEP	WHO Scope of Practice	WHAT Major Steps	HOW Key Points	WHY System & Regulatory Requirements				LINKS
				Patient Experience	Patient Safety	Quality	Policy	
Serious HARM or DEATH could result if administered intravenously. REMS Policy.								
1	Provider/ Clinical Team Member	Review Sublocade® reference documents.	<ul style="list-style-type: none">REMS policy #22904.Buprenorphine-Containing Products REMS Reference Document.Buprenorphine Treatments/Program Requirement Agreement.	x	x	x	x	REMS Policy REMS Medication Reference Document: Buprenorphine-Containing Transmucosal Products and Buprenorphine/Naloxone (Suboxone and Subutex)
2	Clinical Team Member	Run pre-treatment screening test.	<ul style="list-style-type: none">If the patient is a female: A POC Pregnancy test (POC #7) must be run prior to starting patient on buprenorphine treatment to ensure this is the best treatment for the patient.If positive, provider to counsel patient.	x	x	x		
3	Provider	Order Suboxone® in EPIC for patient in-office administration.	<ul style="list-style-type: none">Enter order for Suboxone as a clinically administered medication.Be sure that “during visit” is checked.After order is selected, complete fields, be sure that class is “administered in office”, and sign the order.	x	x	x		
4	Provider	Obtain patient signature on forms.	<ul style="list-style-type: none">Consent form.Must be completed before in-office administration and before a prescription is sent to the pharmacy.	x	x	x		Buprenorphine Treatment Consent

5	Provider/ Supervisor/ Manager/ Trained Clinical Team Member	Retrieve Suboxone from CMC lab area and transport through secured hallway.	<ul style="list-style-type: none"> • Must comply with Management of Controlled Substances Policy #7765. • Two authorized staff members must be present. • Selected, trained, departmental, clinical staff are determined by clinic leadership. • Controlled Substance Storage and Handling Standard Work. • Do not go through the front of either clinic with Suboxone. • **Ordering provider is to accompany the clinical team member to the patient's exam room. 	x	x	x	x	Management of Controlled Substances Policy Controlled Substance Storage and Handling Standard Work 10036
6	Provider/ Clinical Team Member	Administer medication (in-office).	<ul style="list-style-type: none"> • Medication Administration Policy #11461. • Cut the Suboxone® strip, if necessary, to provide correct dose. • Place strip directly into the patient's hand. • Instruct patient on how to appropriately take the med. • If dose ordered, does not require administration of the full film (i.e. partial dose), the MA will write two-patient identifiers on the Dixie cup and place in the locked drawer in the patient's exam room. • Provider to evaluate patient and repeat Step 3 as indicated. • Collaborate with provider for reevaluation time period and set reminder-timer accordingly to indicate when to administer the next dose. • Repeat as directed by provider. • Clinical staff can leave the room once dose is administered to the patient, any remaining dose is secured and each dose documentation is complete in the patient's MAR. 	x	x	x	x	Medication Administration Policy
7	Provider/ Clinical Team Member	Medication waste if indicated.	<ul style="list-style-type: none"> • If the final dosage does not equal a full strip during office administration refer to policy #7765. • Management of Controlled Substances. 	x	x	x	x	Management of Controlled Substances Policy

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Site Customization Owners:		

Appendix 10

Local Resources (Kent County)

Network 180

616.336.3909

Crisis services, psychiatric services, recovery management, target case management.

Mel Trotter Ministries

616.454.8249

Helps with housing needs.

Degage Ministries

616.454.1661

Emergency housing for women.

Dwelling Place

616.454.0928

Low income housing resources.

United Way 211 Program

211

Basic needs including food, shelter and clothing.

Salvation Army

616.454.1459

Detox Treatment for substance use disorder, emergency housing, short-term residential stabilization for SUD, long-term residential treatment for SUD.

Our Hope Association

616.451.2019

Residential substance use services for women.

Family Outreach Center

616.247.3815

Outpatient mental health, SUD and co-occurring disorder.

Family engagement program, recovery management.

Interact

616.259.7900

Assertive community treatment.

Hope Network

616.454.4777

Targeted case management and recovery.

Arbor Circle

616.459.7215

Outpatient mental health, SUD and co-occurring. Family engagement, recovery management, women's case management, specialty pregnancy assistance and SUD at Kent County Jail.

Cherry Health

616.965.8200

Outpatient mental health, MOUD, methadone, target case management, primary medical care, vision and dental care.

Pine Rest

616.455.5000

Inpatient psychiatric, hospitalization, partial psych hospitalization, short-term co-occurring hospitalization, residential SUD treatment, targeted case management, outpatient mental health, SUD and co-occurring, street reach program.

Forest View Psychiatric Hospital

616.942.9610

Inpatient psychiatric hospitalization and partial hospitalization.

Spectrum Health Center for Integrative Medicine:

616.391.6120

SUD specialty treatment, on-site therapy, co-occurring and infectious disease.

Recovery Allies of West Michigan

616.734.3173

SUD recovery, advocates, trainings.

Appendix 11

Clinical Tool: Pharmacotherapy for Opioid Use

Methadone	Buprenorphine/ Naloxone	Naltrexone
Indications		
<ul style="list-style-type: none"> • OUD (DSM diagnosis) and patient meets Federal OTP Standards (42 C.F.R. §8.12). 	<ul style="list-style-type: none"> • OUD (DSM diagnosis). • Willingness and stability to receive, store and administer weekly supply of buprenorphine/naloxone. 	<p>OUD (DSM diagnosis) with:</p> <ul style="list-style-type: none"> • Prevention of return to pretreatment use following opioid detoxification. • Treatment for alcohol use disorders. • Willingness and stability to receive monthly injections.
Contraindications		
<ul style="list-style-type: none"> • Hypersensitivity. 	<ul style="list-style-type: none"> • Hypersensitivity. • Chronic pain requiring opioid management beyond buprenorphine. 	<ul style="list-style-type: none"> • Receiving opioid agonists. • Physiologic opioid dependence. • Failed naloxone challenge or naltrexone challenge test. • Positive urine opioid screen. • Acute hepatitis or liver failure. • Hypersensitivity. • Advanced psychiatric disease, active suicide ideation. • Breastfeeding – oral naltrexone has shown tumorigenicity in animal studies.
Warnings/Precautions		
<ul style="list-style-type: none"> • 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, overdose). • Use of opioid antagonists. • Pregnancy. 	<ul style="list-style-type: none"> • Buprenorphine/naloxone may precipitate withdrawal in patients on full agonist opioids. • Use caution in patients with respiratory, liver or renal insufficiency. • Concurrent benzodiazepines or other CNS depressants, including opioids and active AUD (potential respiratory depression, overdose). • Use of opioid antagonists (e.g., parenteral naloxone, oral or parenteral nalmeferene, naltrexone). • Pregnancy Category C. 	<ul style="list-style-type: none"> • 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 a return to pretreatment opioid use. • Pregnancy Category C.

Baseline Evaluation CXC		
<ul style="list-style-type: none"> Consider baseline electrocardiogram and physical examination for patients at risk for QT prolongation or arrhythmias. Toxicology screen. 	<ul style="list-style-type: none"> Liver transaminases. Urine beta-HCG for females. Toxicology screen. 	<ul style="list-style-type: none"> Liver transaminase levels >5x upper normal limits. CrCl (estimated or measured) 50ml/min or greater. Ensure patient has adequate muscle mass for injection. Urine beta-HCG for females. Toxicology screen.
Dosage and Administration		
<ul style="list-style-type: none"> Initial Dose: 15 - 20mg single dose, maximum 30mg. Daily Dose: Maximum 40mg/day on first day. Usual Dosage Range for Optimal Effects: 60 - 120mg/day. Titrate carefully, consider methadone's delayed cumulative effects. Administer orally in single dose. Individualize dosing regimens. Daily visits at OTP clinic, may receive take-home doses per clinic protocol and federal regulations. 	<p>Sublingual Dosing:</p> <ul style="list-style-type: none"> Induction: Patient to present in mild-moderate withdrawal. Induction Dose: 2 - 4mg initial dose, titrate per prescription instructions and/or until withdrawal symptoms subside. Typical Day 1 Dose = 8mg. Day 2 to 7: Take total dose equivalent from day one upon awakening. Check in with clinical team. May titrate up to 16mg. Stabilization/Maintenance: Target dose = 8 - 16mg (max 24mg daily) may be taken in single or bid dosing regimen. Weekly visits/prescriptions until stable, then biweekly, and eventually monthly. 	<ul style="list-style-type: none"> To be administered after negative UTS and/or successful naltrexone/naloxone challenge. Oral: 25 - 50mg by mouth daily ER Injectable: 380mg 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		
<ul style="list-style-type: none"> Give in divided daily doses based on peak and trough levels that document rapid metabolism that justifies divided doses. 	<ul style="list-style-type: none"> Divided dosing helpful for patients with chronic pain for dual effectiveness and avoidance of narcotic medications. Residential programs may require specific Sig. 	<ul style="list-style-type: none"> Consider remaining on oral formulation for patients with coagulation disorders, thrombocytopenia or large body habitus.
Dosing in Special Populations		
<ul style="list-style-type: none"> Renal or Hepatic Impairment: Reduce dose. Elderly or Debilitated: Reduce dose. 	<ul style="list-style-type: none"> Hepatic Impairment: Reduce dose. For concurrent chronic pain, consider dividing total daily dose into bid, tid or qid daily administration. 	<ul style="list-style-type: none"> Mild Renal Insufficiency (CrCl 50 - 80ml/min): No dosage adjustment necessary. Uncertain effects (no data) in moderate to severe renal insufficiency.

Adverse Effects		
<ul style="list-style-type: none"> • 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. 	<ul style="list-style-type: none"> • 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. 	<ul style="list-style-type: none"> • Major: Eosinophilic pneumonia, depression, suicidality. • Common: Injection-site reaction, injection site tenderness, injection site induration, nausea, abdominal pain, anorexia, headache, asthenia.
Drug Interactions		
<ul style="list-style-type: none"> • 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. 	<ul style="list-style-type: none"> • 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. 	<ul style="list-style-type: none"> • Opioid-containing medications, including over the counter preparations. • Thioridazine (increased lethargy and somnolence).
Monitoring		
<ul style="list-style-type: none"> • Signs of respiratory and CNS depression. • Frequent toxicology screening. 	<ul style="list-style-type: none"> • Liver function tests prior to initiation and during therapy as needed. • Frequent toxicology screening. 	<ul style="list-style-type: none"> • Repeat liver transaminase levels at six and 12 months and then every 12 months thereafter. • Increase hepatic monitoring in cases of mild to moderate elevation (1 to 5x normal limits). • Frequent toxicology screening.

Source: This chart was 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.

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).

Appendix 12

Vivrol® Tip Sheet (Injectable Naltrexone)

Prior to Injection

- Obtain poc UTS (must be negative for all opioids) at every visit.
If female, patients must also have poc HCG done.
- Treatment agreement and consents are reviewed and signed with patient.
- Patient should be started on oral naltrexone a minimum of seven days prior to starting injectable naltrexone.
- Patient must also be off all opioids seven to 10 days prior to injection.
- Obtain COWS.
- DO NOT perform naltrexone challenge if patient is showing signs of withdrawal.
DO NOT start patient on naltrexone.
- Ensure order is placed and signed in chart by provider.
- Must warm medication for 45 minutes prior to injection.
- Reconstitute medication following medication packet insert and use ONLY needles supplied by manufacturer.
- Select proper sized needle based on patient body habitus.
 - Two different size needles provided by manufacturer.
- Properly mixed suspension will be milky white with NO clumps.

Injection

- Inject 380mg IM gluteal every 28 days alternating site sides.
 - MUST NOT be given subcutaneously or intravenously.
 - Aspirate for blood prior to injecting.
- If needle clogs while injecting must replace needle with manufacturer provided replacement.

Post Injection

- Document medication administration in patient's chart.
- Advise patient to contact clinic or emergency department in the event of suspected injection site reaction or other adverse reaction.
- Patient should have counseling in place or be referred to counseling. Counseling should not be mandatory.
- Important to monitor Liver Function Test.
 - LFTs should be drawn every three months.

Adverse Effects and Patient Education

- Injection site reaction.
- Vulnerability to opioid overdose.
- Hepatic injury.
- Depression and suicide.

Appendix 13

Extended-Release Injectable Buprenorphine Tip Sheet

SUBLOCADE® (Injectable Buprenorphine) Tip Sheet Schedule III Medication

Dosing

- 100mg/0.5ml.
- 300mg/1.5ml.
- Typical dosing is 300mg the first two months followed by a maintenance dose of 100mg monthly.
- Should be given no less than 26 days apart.
- If a dose of injectable buprenorphine is missed the patient should receive the next dose as soon as possible.

Safety

- Medication forms a solid mass upon contact with body fluid, therefore must be administered into subcutaneous tissue.
- Intravenous use of injectable buprenorphine poses a significant risk of potential occlusion, local tissue damage, thrombotic events and death.
- Injectable buprenorphine is available only through the SUBLOCADE REMS program or specialty pharmacy due to the risk of serious harm that could result from intravenous self-administration

Schedule III medication should follow storage and handling policy compliant with DEA regulations.

Patient Selection

- Patients who have a history of nonadherence to daily formulations and patients in sustained treatment who would like to transition to a monthly injectable.

Contraindications

- Patients who are opioid naïve.
- Patients with advanced liver disease or acute hepatitis.
- Patients with moderate to severe renal impairment.
- Patient with chronic or acute pain that requires full opioid analgesics.

Prior to Injection

- Obtain a poc UTS (must be negative for all opioids).
- Female patients must also have a poc HCG done.
 - If positive HCG, OBAT team will assist patient engagement with GREAT MOMs team and will manage the patient in OBAT until first appointment occurs or will continue treatment in collaboration with generalist OB.
- Treatment plan and consents are reviewed and signed with patient.
- Patients must be on an equivalent of 8 - 24mg of transmucosal buprenorphine for at least one week prior to receiving the extended-release subcutaneous injection.
 - This is to mitigate risk of precipitated withdrawal, allergic reactions, over-sedation, side effects, adverse reactions or any other intolerance to the medication.
- Patient is approved for treatment with injectable buprenorphine by OBOT provider.
- Staff will coordinate the delivery of injectable buprenorphine. Once received staff will document according to proper procedure and lock medication in lockbox inside refrigerator.
- Staff will ensure appointment is scheduled with patient.

Once patient arrives for appointment follow SUBLOCADE administration standard work.

Appendix 14

Buprenorphine/Naloxone Tip Sheet

Common Brands	Equivalent Dosing					
Suboxone®		2 - 0.5mg	4 - 1mg	8 - 2mg	12 - 3mg	
Zubsolv®	0.7 - 0.18mg	1.4 - 0.36mg	2.9 - 0.71mg	5.7 - 1.4mg	8.6 - 2.1mg	11.4 - 2.9mg
Bunavail®			2.1 - 0.3mg	4.2 - 0.7mg	6.3 - 1.0mg	

Opioid Discontinuation

- Timeline for opioid discontinuation to be determined as part of induction treatment plan and to be based upon patient's medical status, current opioid use and physiologic opioid dependence.
 - Short-acting opioids: Typically discontinue eight to 12 hours prior to scheduled induction.
 - Long-acting opioids: Typically discontinue 12 to 24 hours prior to scheduled induction.
 - Methadone: Typically discontinue 36 to 96 hours prior to scheduled induction.
- Methadone to buprenorphine transfers are especially complex due to the long half-life of methadone and unpredictable metabolic clearance.

Prior to Treatment

- Obtain poc UTS (must be negative for all opioids). If female, patient must also have poc HCG done.
- Treatment agreement and consents are reviewed and signed with patient.
 - Notify patient for the first four to six weeks, weekly visits are required. Once clinically appropriate, visits will transition to every other week progressing to monthly visits.
- Verify patients previous use of buprenorphine/naloxone.
 - If patient has used medication before home induction is possible.
 - If patient has NOT used medication before in office induction is recommended.
- Patient should have counseling in place or be referred to counseling. Counseling should not be mandatory.
- Patient discontinues use of illicit opioids prior to buprenorphine/naloxone induction to avoid risk of precipitated withdrawal.
- Patient is responsible for proper medication storage.
 - Lock box (safe location).
 - Medication should not be kept by the sink, on your person or in your purse.
- Important to monitor liver enzymes.
 - LFTs should be drawn every three months.

Induction

- Perform COWS
 - Patient needs to be in early withdrawal.
 - If patient scores a six to 12, medication can be started in the office.
- Initial dose of 2 - 4mg
 - Re-access patient after 30 to 60 minutes.
 - If appropriate have patient take second dose of 2 - 4mg.
 - Maximum 1st day dose is usually 8mg of buprenorphine, but may be more as clinically indicated.

FAQs

- Narcotic blockade is usually reached at 8 - 16mg.
- Divided dosing is helpful for patients with chronic pain for dual effectiveness and avoidance of narcotic medications. Majority of patients take this medication twice daily.
- Medication has a long half-life.
- Once stable, a patient should be seen monthly.
- Prescriptions should be written for no more than 28 days at a time.

Appendix 15

Home Induction Patient Instructional Sheet

These instructions will help guide you through the process of starting on a buprenorphine product at home. (Suboxone®, Zubsolv®, Subutex®, Bunavail® or buprenorphine-naloxone.)

Stop the use of illicit opioids and pain pills (heroin, hydrocodone, etc.) prior to starting buprenorphine/naloxone induction to avoid risk of precipitated withdrawal.

- You should stop using typically 12 to 24 hours prior to starting medication.
- Methadone: Should be a minimum of 24 hours prior to beginning buprenorphine containing products, depending on dose of methadone being taken.

Before starting medication, ensure you have five of the following withdrawal symptoms:

- | | | |
|----------------|--------------------------|--------------------------|
| • Yawning | • Hot Flashes | • Muscles Twitch |
| • Sweating | • Bones and Muscles Ache | • Cramps in Your Stomach |
| • Running Nose | • Unable to Sit Still | • Feel Like Using |
| • Goose Bumps | • Nauseous | • Enlarged Pupils |
| • Shakes | • Feel Like Vomiting | |

THINGS NOT TO DO WITH BUPRENORPHINE:

- DON'T use Buprenorphine when you are high – it will make you dope sick!
- DON'T use Buprenorphine with alcohol – this combination is *not safe*.
- DON'T use Buprenorphine with benzos (like Xanax (“sticks”), Klonopin, Valium, Ativan) unless you have discussed it with your Buprenorphine provider.
- DON'T use Buprenorphine if you are taking pain killers until you talk to your doctor.
- DON'T use Buprenorphine if you are taking more than 60 mg of methadone.
- DON'T swallow Buprenorphine – it gets into your body by melting under your tongue.
- DON'T lose your Buprenorphine – it can't be refilled early.

Before taking first dose of buprenorphine, take a drink of water.

You will only want to start with 4mg of buprenorphine.

This is one half of an 8mg sublingual film strip.

1. Start with full film.



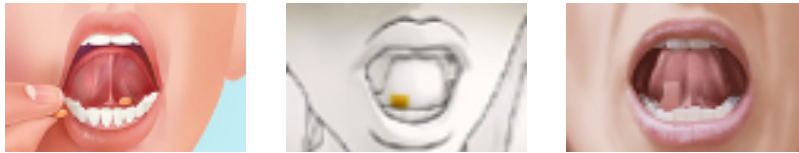
2. Cut film in half.



3. This is your first dose.



Place 4mg of buprenorphine under your tongue.



Then let the medication dissolve. The medication is orange flavored and has a bitter aftertaste.

- Do not eat or drink (this includes gum) for 15 minutes after taking the medication
- No acidic drinks (examples: coffee, soda pop, grapefruit juice or orange juice) before or after taking the medication
- It is okay to rub a small, strong mint (example: the small Altoids) on your tongue to help with the flavor before putting the Buprenorphine in your mouth. Be sure it is a small mint that does not make you produce a lot of saliva.

After one hour, how are you feeling?

- Feel better? Good, the medicine is working. Don't take anymore until six to 12 hours later.
- How are you feeling? If you begin having withdrawal symptoms later in the day take the other half of the strip 4mg. If you don't have withdrawal symptoms don't take more until the next day.

Still feel withdraw symptoms after one hour?

- If you still have feelings of withdrawal symptoms, put the remaining 4mg strip under your tongue.
- Then wait six to 12 hours if you still feel withdrawal symptoms take another 4mg. If you feel better don't take any more until the next day.
- *Don't take more than 16mg in 24 hours. Unless the prescriber authorizes it.*

How much was taken?

	Time	Dose
Day 1	_____ am/pm	_____ mg
	_____ am/pm	_____ mg
	_____ am/pm	_____ mg
Day 2	_____ am/pm	_____ mg
	_____ am/pm	_____ mg
	_____ am/pm	_____ mg

My Next Appointment Date _____ **Time** _____

Office Number: _____

- Imodium (loperamide) – for diarrhea.
- Bentyl (dicyclomine) – for stomach cramping.
- Zofran (ondansetron) – for nausea.
- Clonidine for general withdrawal symptoms including sweats and anxiety.

Instructions for how to take these medications will be on the prescription bottle. As always, please call the office with any questions or concerns with this process. If you have trouble paying for the medication, please contact the office about insurance and payment assistance options.

Appendix 16

Overdose Handout for Patients

1

**KNOW THE SIGNS
OF OVERDOSE.
SAVE A LIFE.**

**Signs of opioid overdose
may include:**

- Breathing that is slow or shallow – or not breathing at all.
- Very sleepy and not responding to your voice or touch.
- Blue or grayish shin color, with dark lips and fingernails.
- Snoring or gurgling sounds.

**If there are symptoms
of an overdose:**

- Tap, shake and shout at the person to get a response.
- If there is still no response, rub knuckles on the breast bone.
- If not or little response, call 911.

Opioids include: Heroin, codeine, fentanyl, hydrocodone (i.e. Vicodin), hydromorphone, morphine, oxycodone (i.e. Oxycontin, Percocet), etc.

2

**CALL 9-1-1.
AN OVERDOSE IS A
MEDICAL EMERGENCY.**

An opioid overdose can cause a coma or death within minutes. A medication called naloxone (Narcan) can reverse an overdose and save a life.

When you call 9-1-1.

- Give the address.
- Tell them it is an overdose so they can bring naloxone (Narcan). Or say, "My friend is not breathing."
- Stay with the person. The 9-1-1 Good Samaritan law provides protection from arrest and prosecution for drug possession.

**While you wait for
the ambulance:**

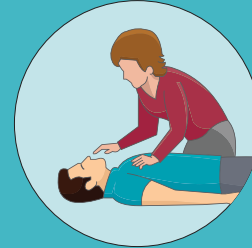
- Do rescue breathing.
- Give naloxone (Narcan) if you have it.
- If you have to leave the person for any amount of time, place the person on their side.

Tell the ambulance staff anything you can about any alcohol or drugs the person has taken. If you cannot stay, leave a note with the information.

3

**DO RESCUE BREATHING
IF BREATHING IS SLOWED
OR STOPPED.**

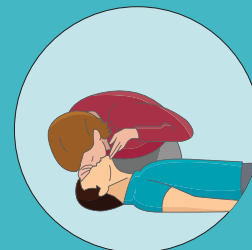
1. Make sure nothing is in the mouth.



2. Tilt head back, lift chin, pinch nose.



3. Breathe in mouth once every five seconds.



Appendix 17

Clinical Tool: Pharmacotherapy for Alcohol Use

Naltrexone Oral	Naltrexone Injectable	Acamprosate	Disulfiram
Indications			
<p>AUD (DSM Diagnosis) with:</p> <ul style="list-style-type: none"> • Pretreatment abstinence not required but may improve response. • Initial engagement in addiction-focused Medial Management and/or other recommended psychosocial intervention. 	<p>AUD (DSM Diagnosis) with:</p> <ul style="list-style-type: none"> • Pretreatment abstinence not required but may improve response. • Willingness to receive monthly injections. • Difficulty adhering to an oral regimen. • Initial engagement in addiction-focused Medial Management and/or other recommended psychosocial intervention. 	<p>AUD (DSM Diagnosis) with:</p> <ul style="list-style-type: none"> • Abstinence at treatment initiation. • Initial engagement in addiction-focused Medial Management and/or other recommended psychosocial intervention. 	<p>AUD (DSM Diagnosis) with:</p> <ul style="list-style-type: none"> • Abstinence >12 hours and BAL=0. • Combined cocaine use. • Previous response to disulfiram. • Capacity to appreciate risks and benefits and to consent to treatment. • Initial engagement in addiction-focused Medial Management. and/or other recommended psychosocial intervention. • Note: More effective with monitored administration (e.g., in clinic, with spouse, with probation officer).
Contraindications			
<ul style="list-style-type: none"> • Receiving opioid agonists. • Physiologic opioid dependence with use within past seven days. • Acute opioid withdrawal. • Failed naloxone/naltrexone challenge test. • Positive urine opioid screen. • Acute hepatitis or liver failure. • Hypersensitivity. 	<ul style="list-style-type: none"> • Receiving opioid agonists. • Physiologic opioid dependence with use within past seven days. • Acute opioid withdrawal. • Failed naloxone/naltrexone challenge test. • Positive urine opioid screen. • Acute hepatitis or liver failure. • Hypersensitivity. • Inadequate muscle mass or body habitus too large for supplied injection needles. 	<ul style="list-style-type: none"> • Hypersensitivity. • Severe renal insufficiency (CrCl ≤30ml/min). 	<ul style="list-style-type: none"> • Severe cardiovascular, respiratory or renal disease. • Severe hepatic dysfunction (i.e., transaminase levels >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.

Warnings/Precautions			
<ul style="list-style-type: none"> • Active liver disease. • Severe renal failure. • Breastfeeding – not advised, proven teratogenicity in animal studies. • Acute/chronic pain. • Hx severe depression, acute psychiatric illness. • Pregnancy Category C. 	<ul style="list-style-type: none"> • 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. • Acute/chronic pain. • Breastfeeding – not advised. • Hx severe depression, acute psychiatric illness. • Pregnancy Category C. 	<ul style="list-style-type: none"> • Monitor for emergence of depression or suicidality. • Reduce dose in patients with renal insufficiency, including elderly. • Pregnancy Category C. 	<ul style="list-style-type: none"> • Alcohol-disulfiram reaction; patients must be vigilant to avoid alcohol in all forms including mouth-wash, over the counter medications, etc. • Pregnancy Category C.
<ul style="list-style-type: none"> • Liver transaminase levels. • Bilirubin within normal limits. • Urine beta-HCG for females. • Toxicology screen. 	<ul style="list-style-type: none"> • Liver transaminase levels. • Bilirubin within normal limits. • CrCl (estimated or measured) 50ml/min or greater. • Ensure patient has adequate muscle mass for injection. • Urine beta-HCG for females. • Toxicology screen. 	<ul style="list-style-type: none"> • CrCl (estimated or measured). • Urine beta-HCG for females. 	<ul style="list-style-type: none"> • 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.
Dosage and Administration			
<ul style="list-style-type: none"> • 50 - 100mg orally one time daily. 	<ul style="list-style-type: none"> • 380mg one time monthly by deep intramuscular injection. 	<ul style="list-style-type: none"> • 666mg orally three times daily, preferably with meals. 	<ul style="list-style-type: none"> • 250mg orally one time daily (range, 125 - 500mg daily).
<ul style="list-style-type: none"> • 25mg one or two time(s) daily with meals to reduce nausea, especially during the first week. • 100mg on Monday and Wednesday and 150mg on Friday. 			<ul style="list-style-type: none"> • Reduce dose to 125mg to reduce side effects. • For monitored administration, consider giving 500mg on Monday, Wednesday and Friday.
<ul style="list-style-type: none"> • Hepatic or renal insufficiency: Use caution. 	<ul style="list-style-type: none"> • Mild renal insufficiency (CrCl 50 - 80ml/min): No dosage adjustment necessary. • Uncertain effects (no data) in moderate to severe renal insufficiency. 	<ul style="list-style-type: none"> • Moderate renal insufficiency (CrCl 30 - 50ml/min): 333mg three times daily. • Do not administer to patients with severe renal insufficiency (crcl \leq 30ml/min). 	

Adverse Effects			
<ul style="list-style-type: none"> • Common: Nausea. • Other: Headache, dizziness, nervousness, fatigue, insomnia, vomiting, anxiety, somnolence. 	<ul style="list-style-type: none"> • Major: Eosinophilic pneumonia, depression, suicidality. • Common: Injection site reactions, injection site tenderness, injection site induration, nausea, headache, asthenia. 	<ul style="list-style-type: none"> • Major: Suicidality 2.4% (vs. 0.8% on placebo during the first year in clinical trials). • Common: Diarrhea (16%). • Other: Anxiety, asthenia, depression, insomnia. 	<ul style="list-style-type: none"> • Major: Hepatotoxicity, peripheral neuropathy, psychosis, delirium, severe disulfiramethanol reaction. • Common: Somnolence, metallic taste, headache.
<ul style="list-style-type: none"> • Opioid-containing medications, including over the counter preparations. • Thioridazine (increased lethargy and somnolence). 	<ul style="list-style-type: none"> • Opioid-containing medications, including over the counter preparations. • Thioridazine (increased lethargy and somnolence). 	<ul style="list-style-type: none"> • 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. 	<ul style="list-style-type: none"> • Alcohol containing medications, including over the counter preparations. • Drug-drug interactions may occur with phenytoin, warfarin, isoniazid, rifampin, diazepam, chlordiazepoxide, imipramine, desipramine and oral hypoglycemic agents.
Monitoring			
<ul style="list-style-type: none"> • Repeat liver transaminase levels at six and 12 months and then every 12 months thereafter. • Discontinue medication and consider alternatives if no detectable benefit after an adequate trial (50mg daily for three months). 	<ul style="list-style-type: none"> • Repeat liver transaminase levels at six and 12 months and then every 12 months thereafter. • Discontinue if there is no detectable benefit within three months. 	<ul style="list-style-type: none"> • Monitor serum creatinine/ CrCl, particularly in the elderly and in patients with renal insufficiency. • Maintain therapy if return to pretreatment use occurs. 	<ul style="list-style-type: none"> • Repeat liver transaminase levels within the first month, then monthly for first three months, and periodically thereafter as indicated. • Consider discontinuation in event of return to pretreatment use or when patient is not available for supervision.

Adverse Effects			
<ul style="list-style-type: none"> • Discuss compliance enhancing methods. • Negotiate commitment from the patient regarding monitored ingestion. • Side effects, if any, tend to occur early in treatment and can typically resolve within one to two weeks after dosage adjustment. 	<ul style="list-style-type: none"> • Report any concerning injection site reactions. • Report any new or worsening depression or suicidal thinking. • May cause allergic pneumonia; contact provider if patient develops signs and symptoms of pneumonia. 	<ul style="list-style-type: none"> • Report any new or worsening depression or suicidal thinking. 	<ul style="list-style-type: none"> • Avoid alcohol in food and beverages, including medications. • Avoid disulfiram if alcohol intoxicated. • May cause sedation; 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.
<ul style="list-style-type: none"> • 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 discontinuation of naltrexone. 			

Source: 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

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).

Appendix 18

Acronyms

BSAS: Bureau of Substance Abuse Services
CIM: Center for Integrative Medicine
CFR-42: Code of Federal Regulations, Title 42
CNS: Central Nervous System
COWS: Clinical Opioid Withdrawal Scale
CPS: Child Protective Services
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
DSM: Diagnostic and Statistical Manual of Mental Disorders
EtOH: Alcohol
FDA: Food and Drug Administration
HCG: Human Chorionic Gonadotropin
HIPAA: Health Insurance Portability and Accountability Act
IOP: Intensive Outpatient Program (Counseling)
LFT: Liver Function Test
MOUD: Medication for Opioid Use Disorder
NAS: Neonatal Abstinence Syndrome
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
UTS: Urine Toxicology Screening

Appendix 19

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