Primary Care Based Treatment of Opioid Use Disorder

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July 2018 Update: Major Changes

- Updated approach to the use of naltrexone in the treatment of OUD, including a protocol (appendix I)
- New pain management recommendations for patients on buprenorphine.
- Updated Implementation Guide (link on p. 8)

June 2020 Update: Major Changes

- Recommendations updated to reflect the 2020 Update of the ASAM National Practice Guideline
- Don't delay pharmacotherapy of OUD due to lack of time to complete a full assessment.
- Elimination of the Treatment Needs Questionnaire triage tool
- Minor revisions to initiation and dosing of buprenorphine
- Availability of long acting forms of buprenorphine.
- Lack of availability of or patient's decision to decline psychosocial treatment should not preclude or delay pharmacotherapy of OUD.
- Further clarity on acute pain and perioperative management
- Resources and hyperlinks updated

EXECUTIVE SUMMARY:

Introduction

We are in the midst of an epidemic of opioid misuse and overdose deaths. Despite the extent of the problem, the majority of people with an opioid use disorder (OUD) do not receive treatment due to limited capacity, stigma, financial obstacles and other barriers.[1] With support of a multidisciplinary team, primary care clinicians can treat most patients with OUD in an integrated approach that also addresses commonly co-occurring mental and physical health issues–helping close the treatment gap. Addiction is a chronic disease of the brain, not simply a choice or personal failing, and is best treated with evidence-based treatment (medication) similar to other chronic diseases.[2] This guideline focuses on the use of buprenorphine, a partial mu opioid agonist with a long half-life that has been proven safe and effective in the treatment of OUD.[3] It should usually be used in a product including naloxone, which is poorly absorbed orally and added to deter misuse/diversion by snorting or injecting. In this guideline, "buprenorphine" refers to this combination product. Clinicians are required to obtain a waiver and DEA "X number" to prescribe buprenorphine, which requires completion of a brief training program. Naltrexone is another pharmacological treatment option, and can be prescribed without a waiver. Methadone treatment of OUD is appropriate for some patients, but can only be dispensed through a licensed treatment facility.

This document summarizes a primary care approach to treating OUD with MAT (medication for addiction treatment) and counseling. It is meant to be a brief overview, and the reader is referred to the source documents for further details. Excellent resources include the ASAM National Practice Guideline, SAMHSA MAT website, TIP 63-Medications for OUD (2020),and the Providers' Clinical Support System.

Model

Common themes of successful models of primary care based treatment of OUD include the importance of a non-physician coordinator and the use of tiered approaches.[4] D-H's SUMHI Behavioral Health Integration team endorses the Collaborative Care Model (CoCM), supplemented by the experience of other models[4] including the Vermont "hub and spoke"[5] and the "Massachusetts Nurse Care Manager Model."[6,7] It strives for a whole person-centered approach to all health issues by the primary care team, with the CoCM's care manager role (called behavioral health clinician [BHC] at D-H) extended from the traditional focus on depression and/or anxiety to also include substance use disorders. The primary care provider (PCP) shares the patient's care with the BHC, with assistance from team nurses and medical assistants. The CoCM includes a proactive, population-based approach enabled by the use of a registry, and uses outcome measurements to guide care. A consulting psychiatrist supervises the BHC, and is available to the PCP for advice and consultation. Each primary care clinic should establish a relationship with one or more nearby substance use treatment programs (e.g. opioid treatment program or intensive outpatient treatment program) to expedite referrals for patients needing a higher level of care. These relationships should be reciprocal, with stable patients being transferred from the specialty addiction treatment programs to primary care.

Clinical Approach

This approach is adopted from the American Society of Addiction Medicine National Practice Guideline,[8,9] except where otherwise referenced. Adaptations to the primary care setting, based on expert opinion, are in italics.

Assessment

The need to complete a comprehensive assessment should not delay or preclude initiating pharmacotherapy for OUD. The diagnosis of OUD should be confirmed by DSM-5 criteria (appendix A),[10] supplemented by urine drug testing. Opioid use is often co-occurring with other substance related disorders, and an inventory of past

and current substances used and past SUD treatment should be done. Psychiatric co-morbidity (especially depression, anxiety disorders, and PTSD) is common, and needs to be evaluated. An assessment of social and environmental factors should be conducted to identify facilitators and barriers to addiction treatment, and specifically to pharmacotherapy. Addiction is a multi-faceted illness, for which the use of medication(s) is but only one component of overall treatment. A physical examination should be completed, with attention to potential sequelae of substance use. The following laboratory tests may be necessary: complete blood count, liver function, hepatitis C, HIV and sexually transmitted infections, and TB. Hepatitis A and B testing and vaccination should be offered when appropriate. Women of childbearing age should be tested for pregnancy, and all women of childbearing potential and age should be queried regarding methods of contraception, given the increase in fertility that results from effective opioid use disorder treatment.

Deciding on Treatment and Setting

The choice of treatment option and setting should be a shared decision between clinician and patient, taking into account past treatment history, co-morbidity (other substance use, psychiatric, and medical), social and environmental factors, and risk of diversion. *"Decisions in Recovery" or the "Medication Options Decision Aid" in the eDH buprenorphine smartset (patient education section) can facilitate decision making around medications. Primary care based treatment is appropriate for patients who are motivated, don't have co-occurring active alcohol or sedative/hypnotic use disorder, and have stable drug-free housing. Buprenorphine is usually the best option for primary care based treatment, but naltrexone is an alternative for patients who have been opioid free for at least 7 days*. Oral naltrexone is often ineffective due to poor medication adherence, and should be reserved for highly motivated patients who are able to comply with observed dosing. Extended-release injectable naltrexone reduces, but does not eliminate, issues with medication adherence. Evidence suggests injectable naltrexone may be as effective as buprenorphine for those who can tolerate initiating the medication.[11,12] (see Appendix I for a protocol for IM naltrexone). *More structured and intensive treatment should be used for more complex patients and those not responding to primary care based treatment.* Specialty opioid treatment programs may offer daily supervised dosing of methadone and buprenorphine. Intensive Outpatient Programs offer more structure and intensive counseling for the first several weeks of treatment. Inpatient and residential treatment are reserved for the most complex patients who have not responded to less intensive options.

Informed Consent and Treatment Agreements[3]

Informed consent and treatment agreements can clarify expectations of both practitioner and patient and provide a structure for effective monitoring. The combined document for buprenorphine (eDH smartset, link to consent library or appendix B) or informed consent for naltrexone (consent library) should be reviewed and signed by both the practitioner and patient. Informed consent outlines the risks and benefits of the medications and other treatment options. The treatment agreement for buprenorphine includes: identifying one physician and one pharmacy to provide buprenorphine prescriptions, authorization to communicate with other named providers of care and significant others, acknowledgement that the prescription drug monitoring program (PDMP) will be used, and agreement to undergo toxicology screens and pill/film counts upon request.

Initiation and Stabilization onto Buprenorphine

Both office-based and home-based initiation of buprenorphine are considered safe and effective. An office based protocol is outlined in appendix C. Home initiation should be done with clear instructions (appendix E, available in eDH smartset) and with phone support available[13]. Opioid-dependent patients should wait until they are experiencing mild to moderate opioid withdrawal (COWS score of 8-10 [appendix D]), usually 12-16 hours after the last dose of short-acting opioid (heroin, hydrocodone, oxycodone IR), 17-24 hours after

intermediate acting opioids (Oxycontin), or 30-48 hours after methadone.[13] This should occur before taking the first dose of buprenorphine to reduce the risk of precipitated withdrawal. Initiation of buprenorphine should start with a dose of 2-4 mg. If the first dose is well tolerated, additional doses of 2-8 mg are given every 1-2 hours as needed to treat withdrawal, up to a maximum of 16 mg in the first day. The optimal maintenance dose should suppress craving and withdrawal and hold the patient in treatment. Evidence suggests that 16 mg or more may be more effective than lower doses. There is limited evidence regarding the relative efficacy of doses higher than 24mg per day, and the use of higher doses may increase the risk of diversion. Doses of greater than 16 mg/day often require insurer's prior approval. The FDA recently approved long acting forms of buprenorphine (Sublocade monthy injection, Brixandi weekly or monthly injection (not yet marketed), and Probuphine 6 month implant). Data regarding their effectiveness are limited, but they are appealing options for patients with concern for diversion or poor adherence.

Psychosocial Treatment

Patient's psychosocial needs should be assessed and patients should be offered or referred to psychosocial treatment based on their individual needs. However, a patient's decision to decline psychosocial treatment or the absence of available psychosocial treatment should not preclude or delay pharmacological treatment of OUD. *All patients should receive brief "Addiction-focused Medical Management"*[14-21] as part of their visits in primary care, which includes:

- Monitoring self-reported use, laboratory markers, and consequences
- Monitoring adherence, response to treatment, and adverse effects
- Education about OUD consequences and treatments
- Encouragement to abstain from non-prescribed opioids and other addictive substances
- Encouragement to attend community supports for recovery (e.g., mutual help groups) and to make lifestyle changes that support recovery
- Motivational Interviewing

Additional group and individual counseling, onsite or off, should be encouraged.

Monitoring of Adherence, Response to Treatment, and Diversion[3]

Effective monitoring of adherence and response to treatment can increase the likelihood of positive clinical outcomes and reduce the possibility of diversion. Monitoring should include frequent office visits (weekly in early treatment), at-visit and unannounced urine toxicology screening, pill/film counts, observed ingestion, and the use of State prescription drug monitoring programs (PDMPs). Urine toxicology should be able to detect buprenorphine in addition to drugs of concern, and be collected in a manner that ensures it is unadulterated and belongs to the patient (see protocol, appendix F). Frequency of testing should be guided by the stability of the patient. The practitioner should have the patient bring his or her medication container (or empty film wrappers) to each appointment to show that the medication is being taken as directed. Unannounced inventories can help ensure that medication is not being diverted. Observed ingestion (having the patient take the medication in front of the practitioner or a trained monitor) at the beginning of buprenorphine therapy can help the practitioner ensure that the patient takes the medication properly. Later in treatment, observing ingestion periodically can help patients adhere to therapy. PDMPs help physicians monitor whether patients are obtaining the prescribed medication, obtaining prescriptions for controlled substances from other prescribers, or refilling prescriptions early.

Responding to Patient Behaviors[3]

Practitioners should acknowledge and reinforce a patient's adherence to treatment, reduction of illicit drug use, and positive life changes. Practitioners may also respond to progress by reducing the frequency of office

visits (see "Suggested visit frequency, appendix G). Some patients will continue to illicitly use opioids and/or other substances or relapse to opioid use after a period of abstinence. Other patients may have trouble adhering to the treatment plan. Diversion or misuse of buprenorphine may also occur. Signs and behaviors suggesting risk of diversion and misuse of buprenorphine products include:

- Unsupported claims of intolerance or allergy to naloxone to obtain the mono-product, which is more subject to misuse.
- Early requests for refills for unsubstantiated reasons (e.g., prescription was "lost" or "stolen").
- Difficulty keeping appointments and/or lack of engagement in psychosocial aspects of care.
- A sudden request for a dose increase by a previously stabilized patient.
- Positive toxicology screens for illicit substance use or negative toxicology screens for buprenorphine.
- Ongoing close ties to individuals who sell opioids or have opioid use disorder but are not in treatment.

Relapse or continued substance use are not reasons for discontinuing buprenorphine. Instead, this should prompt discussion with the patient and evaluation of the treatment plan. If the situation is handled well, a stronger patient–physician alliance can be formed. Changes to treatment should be made on an individual basis and could include any combination of the following: adjusting the patient's buprenorphine dosage, increasing the frequency of office visits, requiring supervised administration, intensifying counseling, or encouraging the patient to engage in more intensive peer support programs. Some patients may require more structured treatment, such as that offered in a residential program or an opioid treatment program.

Duration and Discontinuation of Buprenorphine Treatment

The optimal duration of office-based buprenorphine treatment remains unclear, and may range from a few months to a lifetime depending on the patient. A decision to discontinue buprenorphine therapy should be made based on clinical judgment and upon mutual agreement by the practitioner and patient.[3] Buprenorphine taper and discontinuation is a slow process- generally accomplished over several months. Continued patient visits and monitoring should be encouraged after buprenorphine is discontinued. Patients who discontinue buprenorphine should be made aware of the risks associated with an opioid overdose if they relapse, due to reduced tolerance.

Treating Pain while on Buprenorphine

Buprenorphine's opioid properties are often effective for pain. For acute pain and uncontrolled chronic pain, non-opioid approaches are preferred:

- Non-opioid analgesics: NSAIDs, acetaminophen, SNRIs or tricyclic anti-depressants, gabapentinoids, and topical agents.
- Physical therapy approaches: application of heat or cold, body positioning and/or positional supports; massage, pressure point or other manual therapies; stretch, movement or exercise; transcutaneous electrical or ultrasonic stimulation.
- Psycho-behavioral treatments: meditation/deep relaxation, cognitive behavioral therapy, acceptance and commitment therapy.
- Interventionalist procedures: local, regional or neuraxial anesthetics, implanted stimulators, acupuncture.

In addition to the above approaches, temporarily increasing buprenorphine dose and dividing the dosing may be effective for acute pain. For severe acute pain or planning for a procedure where need for full agonist opioids is anticipated, the approach has recently evolved. It is no longer felt that buprenorphine's partial agonist/ceiling effect interferes with the analgesic effect of other opioids (but does still blunt the euphoriant effect and respiratory depression). The traditional approach of holding buprenorphine "to allow receptors to open" (and needing to re-induce after acute pain is controlled) is associated with worsened pain control and increased risk of relapse. It is now DHMC's policy to continue buprenorphine perioperatively, and it is also

recommended to continue it for acute pain. For severe acute pain, a high-potency opioid (such as fentanyl or hydromorphone (Dilaudid), which have high receptor affinity) can be used in supervised settings, understanding that tolerance will lead to the need to use higher than usual doses. It is unclear whether full agonist adjunct treatment can be safely prescribed in the outpatient setting. BridgeToTreatment has more detail on treating acute pain. The decision to discontinue buprenorphine before an elective surgery balances concerns for severity of anticipated pain and risk of relapse, and should be made in consultation with the attending surgeon and anesthesiologist. If it is decided that buprenorphine should be discontinued, this may occur the day before or the day of surgery. Buprenorphine can be resumed when the need for full opioid analgesia has resolved. In general, the pre-surgery dose can be resumed if it was withheld for less than 2-3 days.

Naloxone

Patients who are being treated for opioid use disorder and their family members/significant others should be given prescriptions for naloxone. Patients and family members/significant others should be trained in the use of naloxone in overdose.

Qualifying Statement: Clinical Practice Guideline and pathways are designed to assist clinicians by providing a framework for the evaluation and treatment of patients. This Clinical Practice Guideline outlines the preferred approach for most patients. It is not intended to replace a clinician's judgment or to establish a protocol for all patients. It is understood that some patients will not fit the clinical condition contemplated by a guideline and that a guideline will rarely establish the only appropriate approach to a problem.

RESOURCES

Patient Resources

D-H Substance Use and Mental Health Initiative (SUMHI): Treatment and Recovery Services
D-H SUMHI: Patient Education and Support (includes mutual help groups and self-management apps, websites and books- also available in the eDH smartset under patient education)
Decisions in Recovery: Treatment for Opioid Use Disorder Online decision aid, with link to pdf handbook

Resources for Family and Friends

www.shatterproof.org -a national non-profit organization dedicated to ending the devastation that addiction causes families
opioidrecovery.org/resources - online course for patients, friends and family

Clinician Resources

PCSSMAT- Provider's Clinical Support System for MAT- comprehensive collection of resources, including a mentoring program
www.buppractice.com Training and resources
ASAM National Practice Guideline for the Treatment of Opioid Use Disorder- 2020 Update- full and summary versions, with associated resources
TIP 63-Medications for OUD – SAHMSA's comprehensive guide, updated 5/2020; part 2-addressing OUD in general medical settings
Guidance Document on Best Practices: Key components for delivering community-based MAT for OUD in NH
Brief Treatment for Substance Use Disorders: A Guide for Behavioral Health Providers: the 6 visit protocol used by LICSWs in the SUMMIT trial, which showed a Collaborative Care approach to alcohol and SUD is effective

https://www.bmcobat.org/ Boston Medical Center Office Based Addiction Treatment resources, including their clinical guideline and free CME

eDH Resources

- Treatment Agreement- available through eDH weblink to Consent Forms (primary care: buprenorphine) and in buprenorphine smartset
- Smartphrases (note templates, patient information): .BUP
    - .BUPSCREEN – triage/screening note to determine appropriateness for PC Bup
    - .BUPINTAKEBHC, .BUPINTAKERX- intake notes by BHC and prescriber
    - .BUPQUICKASSESSMENT- quick intake by prescriber (note fragment)
    - .BUPHOMEINDUCTIONPTINSTRUCTIONS – patient instructions for home induction
    - .BUPFUHISTORY, .BUPFUPLAN- note fragments to use within an existing follow-up template
    - .BUPFUNOTE- full follow-up note for prescribers
    - .BUPBHCFUNOTE- full follow-up note for BHCs
    - .BUPMA – note guiding/documenting medical assistant's pre-visit protocol
- Buprenorphine Smartset
- Buprenorphine Tab on Opioid Navigator

Pertinent Links

D-H Knowledge Map Unhealthy Alcohol and Drug Use Guideline
DHMC GIM Workflows and Note Templates
Managing Challenging Situations

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APPENDICES:

Appendix A: DSM-5 Opioid Use Disorder

Diagnostic Criteria:[10]
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:

1. Opioids are often taken in larger amounts or over a longer period than was intended.
2. There is a persistent desire or unsuccessful efforts to cut down or control opioid use.
3. A great deal of time is spent in activities necessary to obtain the opioid, use the opioid, or recover from its effects.
4. Craving, or a strong desire or urge to use opioids.
5. Recurrent opioid use resulting in a failure to fulfill major role obligations at work, school, or home.
6. Continued opioid use despite having persistent or recurrent social or interpersonal problems caused or exacerbated by the effects of opioids.
7. Important social, occupational, or recreational activities are given up or reduced because of opioid use.
8. Recurrent opioid use in situations in which it is physically hazardous.
9. Continued opioid use despite knowledge of having a persistent or recurrent physical or psychological problem that is likely to have been caused or exacerbated by the substance.
10. Tolerance, as defined by either of the following:
    a. A need for markedly increased amounts of opioids to achieve intoxication or desired effect.
    b. A markedly diminished effect with continued use of the same amount of an opioid.
11. Withdrawal, as manifested by either of the following:
    a. The characteristic opioid withdrawal syndrome.
    b. Opioids (or a closely related substance) are taken to relieve or avoid withdrawal symptoms.

Note: The last 2 criteria are not considered to be met for those individuals taking opioids solely under appropriate medical supervision.

Number of criteria:	0-1	2-3	4-5	6+
Interpretation:	No SUD	Mild SUD	Moderate SUD	Severe SUD

Appendix B: Treatment Agreement (use the version on DH intranet/eDH weblink- "all location forms")

Dartmouth-Hitchcock Primary Care
BUPRENORPHINE INFORMED CONSENT AND TREATMENT AGREEMENT

Buprenorphine is an FDA approved medication for treatment of opioid use disorder (addiction) that is both a stimulator (agonist) and partial blocker of the opioid receptor. The opioid agonist effect reduces withdrawal symptoms and craving, while the blocking effect, at higher doses, prevents or lessens the effect (high) of using another opioid drug. There are other medical treatments for opiate addiction, including methadone and naltrexone. All medications should be used in together with psycho-social treatments, such as counseling, mutual help groups, and self-management apps, websites and books.

Buprenorphine can result in physical dependence similar to other opioids. Withdrawal symptoms are generally less intense than with heroin or methadone, and can be minimized by tapering gradually over several weeks to months. Buprenorphine can cause drowsiness- so you should arrange not to drive until you are accustomed to its effects. Combining buprenorphine with other substances, especially those which can cause sedation such as benzodiazepines (Valium®, Librium®, Ativan®, Xanax®, Klonopin®, etc.) or alcohol, can be dangerous. A number of deaths have been reported among persons mixing buprenorphine with sedating substances.

The partial blocking effect of buprenorphine can cause withdrawal if you take it when other opioids are still in your system. Attempts to override this blocking effect by taking more opioids could result in an opioid overdose. The form of buprenorphine that you will be taking is combined with naloxone (Narcan) to discourage snorting or injecting. Naloxone is a full opioid blocker that is not absorbed orally, but will take effect if snorted or injected – causing withdrawal.

Buprenorphine tablets/film **must** be held under the tongue until they completely dissolve. If you swallow the tablet, it will not have its full effect.

As a participant in buprenorphine treatment for opioid use disorder, I freely and voluntarily agree to accept this treatment agreement, as follows:

- I understand that medication alone is not sufficient treatment for my disease, and I agree to participate in the patient education, substance use disorder counseling and relapse prevention programs as recommended to assist me in my treatment.
- The goal of treatment is complete abstinence from all drugs of abuse. I agree to notify the clinic immediately in case of relapse, and to be open and honest about relapses during appointments. Dishonesty (positive urine test after denying use) will not be tolerated.
- I agree to keep, and be on time to, all my scheduled appointments, to not arrive at the clinic intoxicated or under the influence of drugs, and to conduct myself in a courteous manner in the clinic. It is my responsibility to call the clinic if I will be late or need to reschedule my appointment.
- I agree not to sell, share or give any of my medication to another person. I understand that such mishandling of my medication is a crime and a serious violation of this agreement.
- I agree to submit urine samples, when asked, for monitoring my use of opiates and other illicit drugs. I agree not to tamper with urine screens.
- I agree that my prescriptions can be given to me only at my regularly scheduled appointments, except for clinic scheduling issues or unusual circumstances. Missed appointments may result in my not being able to get medication until the next scheduled visit.

- I agree that the medication I receive is my responsibility and that I will keep it in a safe and secure place. Lost or stolen medication will be replaced at the discretion of my clinician. If stolen, the medication will not be replaced without a police report. My medication should never be kept in public places, and should be out of the reach of children at all times. My medication should be kept in a container that displays the prescription label.
- I agree not to obtain medications from any physicians or other sources without informing my treating team.
- I agree to take my medication as instructed. Early refills due to overuse will not be granted.
- I agree to use a single **appointed pharmacy**** to fill all my buprenorphine prescriptions, and allow my primary care team to discuss the amount and timing of medication dispensed with the pharmacy.
- I agree to random call back visits that include urine drug screens and medication counts. I understand that I need to have a working telephone contact. When called for random call backs, I need to respond within 24 hours by telephone.
- The treatment team will periodically access the State Prescription Drug Monitoring Program (PDMP) to ensure I am not receiving controlled substances from other providers.
- If I am female and of child bearing age it is strongly recommended that I utilize contraceptives while on treatment. If I become pregnant while on buprenorphine/naloxone I will alert my health provider immediately so they can assist me in the proper steps to keep me and my unborn baby safe.
- I understand that my diagnosis of opioid use disorder and treatment plan will be documented in an electronic medical record. This information will be visible to healthcare professionals involved in my care at Dartmouth-Hitchcock, but should not be visible to anyone else without my consent.
- I agree to sign a consent for release of information if needed to allow my primary care team to exchange information with my outside counselor, treatment program, probation or parole officer.

Failure to comply with the above may result in intensification of monitoring and treatment or tapering of buprenorphine and discharge, depending on the severity or frequency of the issue.

****Appointed pharmacy**: _____

_____	_____	_____
Printed Name	Signature	Date
_____	_____	_____
Prescriber	Signature	Date

Appendix C: Office Induction Instructions

Most patients can be induced at home, but in-office induction may be preferable if there are concerns due to anticipation of severe withdrawal symptoms, medical comorbidities, or patient adherence.

- Patient is given a prescription for buprenorphine at the prescriber intake visit, and is instructed to fill the prescription and bring the medications to the induction appointment. The patient should abstain from opioids, with the goal of being in early withdrawal for the induction: 12-16 hours for short-acting opioid (heroin, hydrocodone, oxycodone IR), 17-24 hours for intermediate acting opioids (Oxycontin), or 30-48 hours for methadone.
- Patient arrives at clinic with buprenorphine prescription.
- Withdrawal symptoms are assessed with the Clinical Opioid Withdrawal Scale (COWS).
- If/when COWS score is ≥8, 2-4 mg of buprenorphine is administered, with education on proper technique: sublingual (or buccal for Bunavail), holding the pill or film in place without eating or drinking until it completely dissolves. If COWS score is <8, patient should be observed until withdrawal symptoms appear.
- Patient is observed for 45-60 minutes after first dose, and COWS is reassessed.
    - If patient is doing better (lower COWS, subjectively feeling better), they may be discharged and should follow the home induction directions (appendix F).
    - If patient is doing worse (increased COWS), give another dose of buprenorphine and observe another 45-60 minutes. If needed, recalcitrant withdrawal symptoms can be treated with:
        - Acetaminophen or ibuprofen for aches and pains
        - Loperamide for diarrhea and cramps
        - Diphenhydramine or trazodone for insomnia (do not prescribe benzodiazepines)
        - Clonidine 0.1 mg po q 2 hours for severe anxiety or jitters
        - Promethazine 25 mg po q 6 for nausea
    - When feeling better, patient may be discharged and should follow the home induction instructions.

Appendix D: Clinical Opiate Withdrawal Scale (COWS)[22]

For each item, circle 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 and Time ____/_____/____:_____

Reason for this assessment:_____

Resting Pulse Rate: _____beats/minute *Measured after patient is sitting or lying for one minute* 0 pulse rate 80 or below 1 pulse rate 81-100 2 pulse rate 101-120 4 pulse rate greater than 120	**GI Upset:** *over last 1/2 hour* 0 no GI symptoms 1 stomach cramps 2 nausea or loose stool 3 vomiting or diarrhea 5 multiple episodes of diarrhea or vomiting
Sweating: *over past 1/2 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	**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
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	**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
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	**Anxiety or Irritability** 0 none 1 patient reports increasing irritability or anxiousness 2 patient obviously irritable or anxious 4 patient so irritable or anxious that participation in the assessment is difficult
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	**Gooseflesh skin** 0 skin is smooth 3 piloerrection of skin can be felt or hairs standing up on arms 5 prominent piloerrection
Runny nose or tearing *Not accounted for by cold symptoms or allergies* 0 not present 1 nasal stuffiness or unusually moist eyes 2 nose running or tearing 4 nose constantly running or tears streaming down cheeks	Total Score _____ The total score is the sum of all 11 items Initials of person completing assessment: _____

Score: 5-12 = mild; 13-24 = moderate; 25-36 = moderately severe; more than 36 = severe withdrawal

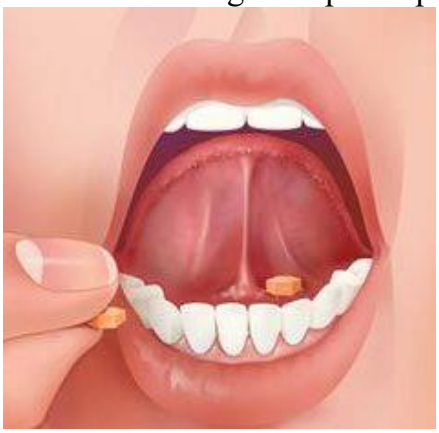
Buprenorphine: Getting Started at Home

Buprenorphine can cause withdrawal if taken while other opiates are still in your system. Therefore, the first dose should not be taken until you feel lousy from symptoms of withdrawal. It should be at least 12 hours since you used heroin or pain pills (oxycodone, Vicodin…) and 24 hours since you used methadone. The worse you feel when you begin the medication, the better it will make you feel.

You should have at least 3 of the following symptoms:

- twitching/ tremors/ shaking
- joint and bone aches
- goose pimples
- nausea or vomiting
- enlarged pupils
- bad chills or sweating
- heavy yawning
- diarrhea
- restlessness
- anxious or irritable
- stomach cramps

First Dose: 4 mg of buprenorphine- usually half of an 8mg pill or strip



- Place the pill or strip under your tongue
- Do not swallow it
- Keep it there for 15 minutes

The medicine is absorbed through the skin on the bottom of your tongue- it won't work if you swallow it. Do not eat food or drink liquids at this time.

Check in at one hour: Feel better? Good- the medication is working- don't take anymore. Still feel lousy? Don't worry, you will just need more medication. If you still have withdrawal, take another 4 mg under your tongue (the other half, if you split a pill).

Later in the day: If you still have symptoms of withdrawal or the symptoms come back and it has been an hour or more after your last dose, take another 4 mg. Repeat as needed up to a maximum of 16 mg total for the day.

Day 2: Take the total number of mg used over day one in a single dose when you wake in the morning. If, after an hour or more, you feel withdrawal and your morning dose was under 16mg, take another 4mg. Maximum total daily dose is 16mg.

Day 3: Take the total number of mg used over day 2 in a single dose when you wake in the morning. If, after an hour or more, you feel withdrawal and your morning dose was under 16mg- take another 4mg. Maximum total daily dose is 16mg.

Day 4 and beyond: Take the total mg from day 3 in a single dose in the morning. This is now your daily dose. The dose can be adjusted depending on side effects (feeling tired…) or ongoing craving- you can discuss this when you follow up with your doctor.

Caution:

- **If you have bad withdrawal symptoms in spite of taking buprenorphine as directed above, contact your primary care clinic. You can take acetaminophen or ibuprofen for pain (unless told not to) and loperamide (Imodium) for diarrhea. Clonidine can be prescribed for bad anxiety or jitters.**
- **Do not take other opioids, benzodiazepines (sedating medicine) or drink alcohol while on buprenorphine.**
- **If you feel sleepy or impaired do not drive or operate a mechanical object or vehicle.**
- **Be sure to store your medication in a safe place where children and others will not have access to it.**

Appendix F: Urine Drug Testing Protocol and Medical Assistant Work Flow

Urine drug testing (UDT) is used to monitor adherence to treatment, indicated by the presence of buprenorphine and/or its metabolite norbuprenorphine, and the absence of misused drugs on testing. Specimens should be collected in a manner that protects the patient's dignity and privacy while ensuring that it is unadulterated and belongs to the patient. UDT should be done at every visit, and can be supplemented by call backs for unannounced UDT and pill counts as needed. In eDH, a "Rapid Drug Screen, Urine" (LAB4093) is ordered as a standing order, answering no to "confirmation needed". This screen tests for the presence of adulterants and of buprenorphine (but not norbupenorphine), and can be done in minutes at DH labs. Sites that aren't near labs may consider point of care testing (POC188), but it can be less accurate. "Presumptive positives" (other than buprenorphine) can be confirmed by adding on Gas Chromatography/Mass Spectroscopy (e.g. "Cocaine, Urine, Confirmation), which is sent out to Mayo and takes several days to return (these are planned to be done at DHMC starting summer 2020). The term "presumptive positive" is used in reporting rapid screen result because there are several reasons for a false positive result; GC/MS is much more accurate. Confirmation is expensive, and should only be used when necessary to verify unexpected results. If there is a concern for diversion, the presence of norbuprenorphine confirms that the patient has ingested and metabolized buprenorphine.

Medical Assistant (MA) Work Flow

- Query the PDMP and print out the results for the clinician.
- Once patient arrives, the MA brings the patient to the bathroom and asks that they leave personal belongings (purse, travel mug, etc.) in the filing cabinet and hang up their coat and other bulky clothing. The MA then instructs the patient not to flush the toilet or wash their hands until they have opened the door (no running water while the door is closed).
- The MA confirms the patient's last name and DOB, and labels a sterile specimen container (if possible, with temperature strip) ensuring that the seal on the container is unbroken.
- The MA waits outside of the restroom while the specimen is collected, listening for any signs of tampering (running water, absence of voiding sounds).
- When the patient has finished providing the specimen, the MA escorts them back to the room and completes the rooming process as usual.
- MA questions patient about the time of last use of buprenorphine and whether any illicit drugs might be expected, and documents this in the chart using the smartphrase ".BUPMA".
- MA ensures completion of the BAM questionnaire on a tablet, if not already done on myDH or on a tablet in the waiting room.
- *If POC testing*: following the rooming process, the MA performs the rapid tox screen on the urine specimen provided, records the results on a rapid tox results sheet and delivers it to the provider.
- Random observed urines can be conducted by same sex personnel in extreme situations, however this is not routine. Oral swabs (not currently available at DH) may be utilized in place of observed urines. If it becomes necessary to do observed urines the patient may be referred out to a chain of custody location for urine screening or to a higher level of care.
- A patient should not be issued a prescription for buprenorphine until a satisfactory urine is obtained.

Appendix G: Suggested Visit Frequency for Patients on Buprenorphine[23]

After induction, the patient should be seen weekly until "stable"- defined as 4 consecutive weeks of:

- No illicit substances by patient report or urine drug testing (except perhaps occasional marijuana use)
- No illicit use of sedative hypnotic drugs (e.g. benzodiazepines) or heavy alcohol
- No unexplained, unadmitted, or otherwise concerning findings on query of the Prescription Drug Monitoring Program (PDMP)
- Taking buprenorphine as directed, with no requests for early refills, lost/stolen prescriptions, etc.
- Drug craving is under reasonable control

Stable patients can transition to visits every 2-4 weeks. Patients being seen every 2-4 weeks who fail to meet the above criteria, or violate other conditions in the treatment agreement, should be seen more frequently. After at least 12 months of stability, the interval for some patients may be lengthened to every 6-12 weeks supplemented by occasional random urine testing and pill counts.

Appendix H: Dartmouth-Hitchcock IM Naltrexone (Vivitrol) Protocol for OUD

Naltrexone (usually the 28-day injection) is an alternative to opioid agonist therapy for select patients. Recent evidence suggests IM Naltrexone may be as effective as buprenorphine for those able to tolerate initiating the medication.[11,12] Patients need to be opioid free for 7-14 days prior to initiation, and will need withdrawal management (detox) if currently using. The intake process, monitoring, counseling recommendations and follow-up can be similar to those described for buprenorphine. As there is no risk of abuse or diversion, there is no need for a treatment agreement and monitoring can be less intense. Any clinician can prescribe naltrexone.

Patient Selection: Patients should make an informed choice between opioid agonist therapy (methadone, buprenorphine) and naltrexone. Good candidates for naltrexone include patients who:

- have been opioid free for at least a week, but are at risk of relapse
- have concurrent issues with alcohol use
- are highly motivated and/or in highly supervised settings (to ensure adherence)
- are younger or have milder or briefer duration of OUD
- prefer not to use opioid agonists to treat their OUD (including occupational requirements to be opioid free, e.g. drivers, medical personnel)
- who have had success with opioid agonist therapy but would like to change to non-opioid treatment
- have not had success with opioid agonist therapy

Contraindications:

- advanced liver disease or acute hepatitis (decompensated cirrhosis, AST/ALT>5x normal)
- advanced renal disease- caution with GFR<50
- patients unable to remain opioid free for at least 7 days
- active severe depression or suicidal ideation
- pregnancy: category C with insufficient research to assess safety
- severe obesity, as injection site reactions can occur if the medication is not administered into the muscle

Before the First Injection:

- Complete a medical evaluation and discussion of treatment options as outlined in the "Assessment" and "Deciding on Treatment and Setting" sections of the guideline. This includes assessing liver and kidney function and conducting a pregnancy test and urine drug screen.
- Educate the patient about OUD and risks, benefits, and expectations of naltrexone treatment. Patients should make an informed choice to begin naltrexone and understand and sign the informed consent document (available in DH consent library).
- Establish a plan for counseling, as per "Psychosocial Treatment".
- Obtain Vivitrol- which will often involve a specialty pharmacy and completion of prior authorization forms. Many patients with private insurance are eligible for the Vivitrol Co-Pay Savings Program, which usually covers all out of pocket expenses. Vivitrol2gether Support Service can help with coverage verification, specialty pharmacy submission and co-pay assistance. The patient may call 1-800-VIVITROL, or visit https://www.vivitrol.com/opioid-dependence/support to start the process. Alternatively, the clinic can initiate by faxing ALL of the following documents to 1-877-329-8484:
    - Vivitrol2gether Support Service Enrollment Form (an editable version can be downloaded at https://www.vivitrolhcp.com/content/pdfs/vivitrol2gether-enrollment-form.pdf
    - Photocopy of the front and back of the patient's insurance card

- Prior Authorization Form (if applicable)

See https://www.vivitrolhcp.com/content/pdfs/vivitrol2gether-getting-started-brochure.pdf or the Vivitrol Ordering Job Aid in Policy Tech (19098) for further detail.

- Establish the date of last opioid use by report and confirmed by urine drug testing negative for opioids. The patient must be off short-acting opioids 5-10 days and long acting opioids for 7-14 days, balancing risk for relapse with risk for precipitated withdrawal. Assess for signs or symptoms of withdrawal (COWS can be used to quantify severity).
    - For patients who have clearly been opioid free >10-14 days and have no signs or symptoms of withdrawal, naltrexone may be initiated as soon as available. Consider starting po naltrexone (quarter tablet (12.5mg)), then the remainder of the tablet after 3 hours if tolerated) to assess patient tolerance and/or to treat the patient while awaiting procurement of IM naltrexone.
    - For patients who may have used between 5 and 14 days ago, and have no signs of symptoms of withdrawal, it is best to challenge with naloxone (0.4mg IM or 4mg intranasal) or naltrexone po (quarter tablet (12.5mg)) in a supervised setting before initiating naltrexone. Signs and symptoms of withdrawal should be assessed using the COWS at 15 and 30 minutes after naloxone and 30 and 60 minutes after naltrexone. Those without withdrawal may initiate naltrexone. If there are symptoms of withdrawal, the challenge should be repeated in 1-2 days.
    - For patients who have used opioids in the past 5-7days or are have current signs and symptoms of withdrawal, initiation of naltrexone will need to be delayed. Symptoms of withdrawal can be treated with non-opioids (clonidine, NSAIDs, loperamide…) with or without a buprenorphine taper, but it is usually best to do this in a specialty or inpatient setting.
- Give the patient (or recommend getting) an emergency card, bracelet and/or dog tag.

Nurse Injection Procedure: See Procedure 19079 in Policy Tech: "Naltrexone Injection Administration Nurse Visit- Procedure"

Follow-up

- Examine patients within a week of their first injection. If the patient's OUD is primarily managed in primary care, they should generally be seen weekly for the first month, then monthly if doing well. Content and frequency of visits should be similar to those described for patients on buprenorphine, and include an assessment of drug and alcohol use, urine drug testing, supportive counseling, and checking in on social history and involvement in mutual support and external counseling.
- Monitor and assess for potential naltrexone side effects: injection site reaction, hepatic complications, gastrointestinal symptoms, and depression. Naltrexone can rarely cause eosinophilic pneumonia.
- If liver function tests were elevated prior to treatment, they should be re-checked within 1 month of initiating naltrexone, and periodically thereafter.

Pain Management in Patients on Naltrexone

Naltrexone blocks the pain relieving effects of opioids. This effect can be overcome with extremely high doses of opioids, but this is risky and should not be done without expert consultation and intensive monitoring. Non-opioid approaches are preferred: NSAIDs are first line. In emergencies, expert consultation should be sought to consider regional nerve blocks and dissociative analgesics such as ketamine. For elective surgery where use of opioids is considered necessary, the last dose of IM naltrexone should occur 6 weeks prior to the planned date of the procedure. Consider bridging with oral naltrexone, which should be discontinued 48-72 hours before the procedure. The risk of hard to manage pain needs to be balanced against the risk of the patient relapsing.

Resources:
Naltrexone Essentials DH Intranet Page
Step by Step Guide for Clinicians
Preparation and Injection of Vivitrol Video
Podcast: Naltrexone as Treatment for OUD (40 minutes)
SAMHSA TIP 63: Medications for OUD (Chapter 3C)

Referral Guidance for Buprenorphine Treatment at GIM Lebanon

MAT (medicines for addiction treatment, formerly medication-assisted treatment), which combines pharmacotherapy with counseling and other behavioral therapies, is the most effective therapy for Opioid Use Disorder. MAT options include methadone clinics, buprenorphine through drug treatment programs, and buprenorphine of naltrexone through primary care. The choice of treatment option and setting should be a shared decision between clinician and patient, taking into account past treatment history, co-morbidity (other substance use, psychiatric, and medical), social and environmental factors, and risk of diversion. Primary care based treatment is appropriate for less complex patients, and follows the Collaborative Care Model: the primary care provider (PCP) shares the patient's care with the Behavioral Health Clinician (BHC). To best integrate care, the buprenorphine prescriber would be the PCP. PCPs can get a waiver to prescribe after completing a brief training program.

Patients appropriate for primary care based buprenorphine need to meet the following criteria:

- Diagnosis of moderate to severe opioid use disorder (see below- patients experimenting with illicit opioids or on opioids for chronic pain with clinician concerns may not have OUD).
- Patient acknowledges that they have a substance use disorder, and is motivated to change.
- No illicit use of benzodiazepines, barbiturates, or heavy alcohol (stable low-moderate doses of prescription benzodiazepines are allowed, but discouraged).
- No significant, uncontrolled psychiatric problems
- Relatively good psycho-social situation: stable drug free housing, employment or school, some supportive and drug free relationships
- Live within 50 mile driving distance
- Willingness to: undergo an intake visit and at least weekly follow-up visits initially, and submit to urine drug tests and pill counts.

For good candidates, involve the BHC in person or by sending an eDH message. More complex patients should be referred to the DHMC Addition Treatment Program (ATP) at 653-1860 or the local Doorway (211). DHMC Crisis and Consultation Services: 1-800-556-6249.

Diagnosis of Substance Use Disorder (DSM-5)

- ☐ Taking substance more or longer than intended
- ☐ Inability to cut down or stop
- ☐ Spending a lot of time getting/using/recovering
- ☐ Cravings and urges
- ☐ Not meeting responsibilities at home, work, school
- ☐ Continued use despite causing problems in relationships
- ☐ Giving up important social, occupational, recreational activities
- ☐ Recurrent use leading to danger
- ☐ Continued use when causing or worsening a physical or psychological problem
- ☐ Tolerance (needing more to get same effect)
- ☐ Withdrawal symptoms relieved by taking more

Number of criteria:	0-1	2-3	4-5	6+
Interpretation:	No SUD	Mild SUD	Moderate SUD	Severe SUD

Buprenorphine: Summary and Advice for Covering Nurses and Clinicians

Buprenorphine is a partial agonist with high affinity for the mu opioid receptor and a long half-life. These pharmacologic properties reduce its euphoriant properties ("high") and make it effective in the treatment of opioid use disorder. The agonist effects, prevalent at lower doses, help manage craving and withdrawal. At higher doses (12-16 mg), the antagonist effect predominates and blocks the effect of other opioids. This also creates a "ceiling effect", making overdose less likely. Buprenorphine is a class 3 controlled substance and a waiver is required in order to prescribe it. Clinicians can learn about getting a waiver here. It is usually used in a tablet or film combined with naloxone, which is minimally absorbed orally and added to deter misuse/diversion by snorting or injecting.

Patients receiving buprenorphine in GIM are co-managed by a prescribing clinician and a behavioral health clinician (LICSW). Patients are required to sign a treatment agreement, and should only be receiving prescriptions for buprenorphine at in-person visits. Patients should not call off-hours for refills, and covering clinicians cannot prescribe without a waiver. For more information, see KM Primary Care Based Treatment for Opioid Use Disorder guideline.

Withdrawal symptoms during induction: Because of the mixed agonist/antagonist effect, buprenorphine can precipitate withdrawal when being initiated in patients on high doses of opioids- especially longer acting agents. Patients doing a home induction should have received instructions (see guideline) - and should try repeating the starting dose of buprenorphine hourly as instructed. If significant symptoms persist, they can be treated with the following OTC and prescription medications:

- Acetaminophen or ibuprofen for aches and pains
- Loperamide for diarrhea and cramps
- Diphenhydramine or trazodone for insomnia (do not prescribe benzodiazepines)
- Clonidine 0.1 mg po q 2 hours for severe anxiety or jitters
- Promethazine 25 mg po q 6 for nausea

Treating Pain in Patients on Buprenorphine:

Buprenorphine's opioid properties are often effective for pain. For acute pain and uncontrolled chronic pain, non-opioid approaches are preferred:

- Non-opioid analgesics: NSAIDs, acetaminophen, SNRIs or tricyclic anti-depressants, gabapentinoids, and topical agents.
- Non-drug approaches: physical therapy, psycho-behavioral treatments, interventionalist procedures

In addition to the above approaches, temporarily increasing buprenorphine dose and dividing the dosing may be effective for acute pain. For severe acute pain or planning for a procedure where need for full agonist opioids is anticipated, the approach has recently evolved. It is no longer felt that buprenorphine's partial agonist/ceiling effect interferes with the analgesic effect of other opioids (but does still blunt the euphoriant effect and respiratory depression). The traditional approach of holding buprenorphine "to allow receptors to open" (and needing to re-induce after acute pain is controlled) is associated with worsened pain control and increased risk of relapse. It is now DHMC's policy to continue buprenorphine perioperatively, and it is also recommended to continue it for acute pain. For severe acute pain, a high-potency opioid (such as fentanyl or hydromorphone (Dilaudid), which have high receptor affinity) can be used in supervised settings, understanding that tolerance will lead to the need to use higher than usual doses. It is unclear whether full agonist adjunct treatment can be safely prescribed in the outpatient setting. BridgeToTreatment has more detail on treating acute pain.