Primary Care Based Treatment of Opioid Use Disorder

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EXECUTIVE SUMMARY:

Introduction

We are in the midst of an epidemic of opioid misuse and overdose deaths. Despite the extent of the problem, >80% 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 less complex 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 and counseling) 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 by any clinician. 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 medication assisted treatment (MAT) 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, the Vermont Buprenorphine Guideline, SAMHSA advisory, and the Providers' Clinical Support System for MAT.

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. Personnel and their roles will vary depending on local resources (e.g. sites without a BHC may use a nurse in the coordinator role). The CoCM includes a proactive, population-based approach enabled by the use of a registry, and uses outcomes 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 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. *The Treatment Needs Questionnaire (TNQ)* (appendix B) *and the "Decisions in Recovery" patient decision aid can facilitate decision making. Primary care based treatment is appropriate for less complex patients (who score <5-10 on the TNQ), usually using buprenorphine.* Oral naltrexone is another option, but is often adversely affected by poor medication adherence and should be reserved for patients who would be able to comply with observed dosing. Extended-release injectable naltrexone reduces, but does not eliminate, issues with medication adherence. *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 increasingly of 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 (appendix C) should be reviewed and signed by both the practitioner and patient. Informed consent outlines the risks and benefits of buprenorphine and other treatment options. The treatment agreement 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.

Induction and Stabilization

Induction is recommended to be observed by the clinician in their office (appendix D), but emerging evidence suggests that home induction can be considered when clear instructions are provided and phone support is available[11] (Home induction instructions-appendix F). Opioid-dependent patients should wait until they are experiencing mild to moderate opioid withdrawal (COWS score of 6-10 [appendix E]), 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.[11] This should occur before taking the first dose of buprenorphine to reduce the risk of precipitated withdrawal. Induction of buprenorphine should start with a dose of 2-4 mg. If the first dose is well tolerated, additional doses of 2-4 mg are given every 1-2 hours as needed to treat withdrawal, up to a maximum of 12 mg in the first day.[11] The optimal maintenance dose should suppress craving and withdrawal and hold the patient in treatment, usually 8-16 mg as a single daily dose. Doses above 16 mg may increase risk of diversion, and should only be used in rare instances. The FDA approves dosing up to 24 mg per day, and there is limited evidence regarding the relative efficacy of higher doses.

Psychosocial Treatment

Psychosocial treatment should be implemented in conjunction with the use of buprenorphine in the treatment of opioid use disorder. *All patients should receive primary care implemented "Addiction-focused Medical Management,"*[12-19] 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 arranged as needed and desired.

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 G). Frequency of testing should be guided by the stability of the patient. The practitioner should have the patient bring his or her medication container 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 knows how to take the medication. Later in therapy, 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 and/or increasing the patient's responsibility for his or her medication (see "Suggested visit frequency, appendix H). 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 (e.g. spouse, partner, significant others, friends) who sell opioids or have opioid use disorder but are not in treatment.

Relapse or continued substance use are not reasons for automatically 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 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 over several months) that is indefinite in duration. Continued patient visits and monitoring should be done even after buprenorphine is stopped. 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

If pharmacological treatment is considered, non-narcotic medications such as acetaminophen and NSAIDs should be tried first. Temporarily increasing buprenorphine dose and dividing the dosing may be effective for mild-moderate acute pain. Because buprenorphine binds more avidly to opioid receptors than most opioids, pain control with other mu agonists requires careful attention and titration. For severe acute pain in emergency department and inpatient settings, discontinuing buprenorphine and commencing on a high-potency opioid (such as fentanyl, which has high receptor affinity) is advisable. Patients should be monitored closely and additional interventions such as regional anesthesia should also be considered. The decision to discontinue buprenorphine before an elective surgery should be made in consultation with the attending surgeon and anesthesiologist. If it is decided that buprenorphine should be discontinued, this should occur 24-36 hours in advance of surgery (substituting 15mg BID of sustained release morphine[7]) and re-induction restarted postoperatively when the need for full opioid agonist analgesia has passed.

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 Statements

Pathways & Guidelines: 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.

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)
Decisions in Recovery: Treatment for Opioid Use Disorder Online decision aid, with link to pdf handbook
The Facts about Buprenorphine for Treatment of Opioid Addiction – hand out for patients

Resources for Family and Friends

www.shatterproof.org -a national non-profit organization dedicated to ending the devastation that addiction causes families
MAT for Opioid Addiction: Facts for Families and Friends- hand out for significant others

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 Use of Medications in the Treatment of Addiction Involving Opioid Use- full and summary versions, with associated resources
Harvard Medical School Opioid Use Disorder Education Program free online educational programs
SAMHSA TIP 40- Clinical guidelines for the use of Buprenorphine in the treatment of OUD (2004)
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

eDH Resources

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

Pertinent Links

D-H Knowledge Map Unhealthy Alcohol and Drug Use Guideline
DHMC GIM Implementation Guide

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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 Needs Questionnaire (developed for Vermont's Hub (specialty treatment center) and Spoke (primary care/outpatient) model; suggest eliminating "do you have any significant medical problems", as medical comorbidity is an argument FOR, not against, integrated primary care based treatment.)

TREATMENT NEEDS QUESTIONNAIRE

Patient Name/ID: _____ Date: Staff Name/ID: ____

Ask patient each question, circle answer for each	Yes	No
Have you ever used a drug intravenously?	2	0
If you have ever been on medication-assisted treatment (e.g. methadone, buprenorphine) before, were you successful? (If never in treatment before, leave answer blank)	0	2
Do you have a chronic pain issue that needs treatment?	2	0
Do you have any significant medical problems (e.g. hepatitis, HIV, diabetes)?	1	0
Do you ever use cocaine, even occasionally?	2	0
Do you ever use benzodiazepines, even occasionally?	2	0
Do you have a problem with alcohol, have you ever been told that you have a problem with alcohol or have you ever gotten a DWI/DUI?	2	0
Do you have any psychiatric problems (e.g. major depression, bipolar, severe anxiety, PTSD, schizophrenia, personality subtype of antisocial, borderline, or sociopathy)?	1	0
Are you currently going to any counseling, AA or NA?	0	1
Are you motivated for treatment?	0	1
Do you have a partner that uses drugs or alcohol?	1	0
Do you have 2 or more close friends or family members who do not use alcohol or drugs?	0	1
Is your housing stable?	0	1
Do you have access to reliable transportation?	0	1
Do you have a reliable phone number?	0	1
Did you receive a high school diploma or equivalent (e.g. did you complete > 12 years of education)?	0	1
Are you employed?	0	1
Do you have any legal issues (e.g. charges pending, probation/parole, etc)?	1	0
Are you currently on probation?	1	0
Have you ever been charged (not necessarily convicted) with drug dealing?	1	0

Totals _____ + _____

Total possible points is 26
Scores 0-5 excellent candidate for office based treatment
Scores 6-10 good candidate for office based treatment with tightly structured program and on site counseling
Scores 11-15 candidate for office based treatment by board certified addiction physician in a tightly structured program or HUB induction with follow up by office based provider or continued HUB status
Scores above 16 candidate for HUB (Opioid Treatment Program-OTP) only

Appendix C: Treatment Agreement

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 D: 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 >6, 2-4 mg of buprenorphine is administered, with education on proper technique: sublingual (or buccal for Bunavail or Belbuca), holding the pill or film in place without eating or drinking until it completely dissolves. If COWS score is <6, 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 E: Clinical Opiate Withdrawal Scale (COWS)[20]

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

Appendix F: Home Induction Instructions

Buprenorphine: Getting Started at Home

Buprenorphine is both a blocker and stimulator (agonist) of the opiate 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. This partial opioid blocking effect also means that 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 significant symptoms of withdrawal: anxiety, restlessness, cramps, nausea, diarrhea, shakes, goosebumps, yawning, sweating, and fast heartbeat. This usually occurs 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. The worse you feel when you begin the medication, the better it will make you feel. Buprenorphine is not absorbed well if swallowed, so it is taken sublingually (allowed to dissolve under the tongue).

Dosing Instructions:
Day 1: Take 2-4mg of buprenorphine under the tongue when you feel significant withdrawal. Be sure to let this dissolve completely under your tongue and DO NOT eat or drink anything while it is dissolving. Wait at least 1 hour. If you still have symptoms of withdrawal you can repeat this dose, but don't take more if you're feeling ok. If withdrawal symptoms are still present after waiting another hour, or if symptoms return later- take another dose. Repeat as needed up to a maximum of 12 mg on day 1.

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- take another initial dose (2-4mg). Maximum total dose for day 2 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 initial dose (2-4mg). Maximum total dose for day 3 is 16mg.

Day 4 and beyond: Take the total mg from day 3 in a single dose in the morning.

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 G: 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 "DAU Request" (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 (eg "Cocaine, Urine, Confirmation), which is sent out to Mayo and takes several days to return. 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 the patient is arrived, the MA brings the patient to an exam room and asks that they leave personal belongings (purse, travel mug, etc.) and bulky clothing in the room. The MA then escorts the patient to the restroom, 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".
- *For the Lebanon GIM pilot*: 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 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 H: Suggested Visit Frequency[21]

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 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 4 weeks. Patients being seen every 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 6 months of stability, the interval can be lengthened to every 12 weeks supplemented by occasional random urine testing and pill counts.

Referral Guidance for Buprenorphine Treatment at GIM Lebanon

Medication-assisted treatment (MAT), which combines opioid agonist therapy 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 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 use of benzodiazepines, barbiturates, or heavy alcohol.
- No significant, uncontrolled psychiatric problems
- Relatively good psycho-social situation: stable drug free housing, employment or school, some supportive and drug free relationships
- Willingness to: undergo an intake visit and at least weekly follow-up visits initially, get involved with counseling, 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. 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: Non-narcotic medications such as acetaminophen and NSAIDs should be tried first. Temporarily increasing buprenorphine dose and dividing the dosing may be effective for mild-moderate acute pain. Because buprenorphine binds more avidly to opioid receptors than most opioids, pain control with other mu agonists requires careful attention and titration. For severe acute pain in emergency department and inpatient settings, discontinuing buprenorphine and commencing on a high-potency opioid (such as fentanyl, which has high receptor affinity) is advisable. Patients should be monitored closely and additional interventions such as regional anesthesia should also be considered. The decision to discontinue buprenorphine before an elective surgery should be made in consultation with the attending surgeon and anesthesiologist. If it is decided that buprenorphine should be discontinued, this should occur 24 – 36 hours in advance of surgery (substituting 15mg BID of sustained release morphine) and re-induction restarted postoperatively when the need for full opioid agonist analgesia has passed.