

## Buprenorphine for the Treatment of Opioid Use Disorders

Relevant Law / Standard: DATA 2000: Title XXXV, Section 3502 of the Children's Health Act of 2000

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### **Policy and Purpose:**

This policy is intended to ensure appropriate assessment, management and monitoring of patients receiving office based treatment with buprenorphine for opioid use disorders.

### **Overview**

Buprenorphine, a partial opioid agonist, was approved by the FDA in 2002 for the treatment of opioid use disorder. Per the "Drug Addiction Treatment Act" of 2000, buprenorphine can be prescribed outside the Narcotic Treatment Program (NTP) setting by physicians who complete a federally mandated 8-hour training, and who have subsequently received a special DEA waiver to prescribe buprenorphine for opioid replacement therapy.

Buprenorphine is commonly prescribed in sublingual formulations for opioid replacement. Formulations are composed of buprenorphine alone (in generic forms and under the brand name Subutex), or buprenorphine plus the opioid antagonist naloxone (in generic form and under the brand name Suboxone). The naloxone is not absorbed sublingually and the combination formulations decrease the risk of injection/diversion. The buprenorphine/naloxone combination product is the preferred formulation at [insert]. Exceptions include the case of pregnancy or breastfeeding. Other exceptions will be addressed on a case by case basis. Since buprenorphine acts as a partial agonist as well as an antagonist at the opioid receptors, it may precipitate opioid withdrawal in the opioid dependent patient who has recently used opioid. A patient should not begin buprenorphine treatment if they have used a short-acting opioid such as heroin less than 12 hours before induction, or a long-acting opioid such as methadone less than 24 hours. Therefore, patients should only be induced on buprenorphine if they are showing objective signs of opioid withdrawal or they have been opioid-free for at least several days.

Induction can be safely done at home, as is recommended by UNM Hospitals, Project ECHO Program.

### **Patient Selection**

#### **Inclusion Criteria**

- Patient is at least 16 years old
- Patient meets DSM-5 criteria for Opioid Use Disorder

#### **Exclusion Criteria**

- Patient has serious uncontrolled/untreated psychiatric problems (suicidality, active psychosis, etc.)
- Patient has a severe alcohol use disorder
- Patient misuses benzodiazepines, sedatives or hypnotics.
- Patient has a known allergy/hypersensitivity to buprenorphine

## **Initial Assessment of Opioid Dependence and Withdrawal**

### **Patient History**

Provider should obtain medical history as below.

- Review current and past symptoms of opioid withdrawal.
- Review substance use history. Review current opioid use, i.e. type of opioid, method of administration, frequency of use, last use. Review alcohol, sedative, and other substance use/abuse. Review past opioid treatments (e.g. Methadone maintenance) including client response to treatment, and perceived effectiveness.
- Review concurrent medical/psychiatric problems, medications and labs.
- For female clients of childbearing age, address contraception.

### **Objective Data**

- Full physical exam should be done at initial assessment: Provider should include:
  - Documentation of signs and symptoms of opioid withdrawal. If present, consider assessing withdrawal severity using the Clinical Opiate Withdrawal Scale (COWS).
  - Assessment of possible needle use sequelae, including presence of track marks, abscesses, cellulitis.
  - Assessment of possible substance intoxication, including but not limited to alcohol odor, nystagmus, positive Romberg test, client disinhibition, or other altered mental status.
- Lab Results: Urine toxicology screen; pregnancy test (serum or urine HCG) for females with childbearing potential; LFTs
- Prescription monitoring program results reviewing prescriptions for opioids and benzodiazepines.

### **Patient Consent Form**

Ensure that "Buprenorphine Treatment Agreement" is reviewed and signed. (See attachment)

### **Initiating Treatment with Buprenorphine**

1. Provide "Starting Buprenorphine at Home- Home Induction Instructions"
2. Provide Patient Info Buprenorphine FAQ
3. Prescribe no more than 14 days of medication when initiating treatment
  - a. For withdrawal symptoms, give Buprenorphine 4mg SL every 6 hours as needed
  - b. Total Buprenorphine dose for 1<sup>st</sup> 24 hours typically ranges between 8-16mgs
  - c. Total Buprenorphine dose for Day 2 is typically ranges from 8-16 mgs
  - d. Total Buprenorphine dose for Day 3 is typically ranges from 12-16 mgs
  - e. Most patients experience good control of withdrawal and cravings by the end of their first 3-5 days on buprenorphine.
  - f. Target dose: The dose that results in the optimal relief of objective and subjective opioid withdrawal symptoms. This is expected to be in the range of 12 to 20mg daily, though doses from 2 to 24 mg/day may be required to suppress opioid withdrawal effects. In most cases, the maximum daily dose is 24mg.

4. Consider adjunctive medications
  - a. Additional medications can be prescribed/provided for symptom management. An EHR template is in place to assist with ordering these medications. These may include the following:
    - i. Clonidine 0.1 to 0.3mg PO q4 to 6 hours PRN lacrimation, diaphoresis, rhinorrhea, piloerection
    - ii. Promethazine 25mg PO q4 to 6 hours PRN nausea/vomiting
    - iii. Ondansetron 4-8mg PO q4 to 6 hours PRN nausea, agitation
    - iv. Loperamide 4mg PO x 1 PRN diarrhea, then 2mg PO PRN each loose stool or diarrhea thereafter, NTE 16mg/24h;
    - v. Ibuprofen 400 to 800 mg PO 4 to 6 hours with food prn myalgias/arthralgias, NTE 2400mg/24hours.
    - vi. Trazodone 50mg PO at bedtime prn insomnia

### **Buprenorphine Maintenance Therapy**

- **MD Visit Frequency:** It is recommended that following initiation of buprenorphine, the frequency of MD visits be at least monthly for the first 3 months. Pending stability and adherence, MD visit frequency may increase or decrease.
- **Counseling:** It is recommended that patients on buprenorphine see a counselor with experience in treatment of opioid use disorder regularly to support the treatment plan. After the patient has stabilized, counseling sessions may decrease based on patient needs and provider plan. Providers may choose to require patients to attend groups or individual counseling as part of the treatment plan.
- **Prescription Drug Monitoring Program:** Physicians (or their surrogates) will check PMPs prior to each prescription of buprenorphine to ensure no additional opioid, benzodiazepine or other prescriptions were obtained from other sources.
- **Urine Toxicology:** Though there are no Federal or State regulations requiring toxicology screens for patients receiving buprenorphine, the provider might find it helpful to order toxicology screens weekly during the initiation period and then every 4-8 weeks to assess patient stability. If the provider has concerns about the patient, more frequent urine screens are encouraged. Tests for other alcohol screening can be added to the standard screen on a case-by-case basis. Assaying for buprenorphine is available and should be considered any time there is any suspicion of diversion, as this can confirm the patient's use of the medication by identifying metabolites in the urine.
- **Cross coverage:** Other providers with DATA 2000 waivers can be available to provide care if the treating provider is not available. This may or may not include prescribing of buprenorphine.
- **Patients transferring care:** Every effort will be made to avoid precipitated opioid withdrawal during transfer of care. New patients presenting to the practice requesting continuation of maintenance buprenorphine will follow the guidelines for a signed contract, review of outside records, PMP report, and urine toxicology screening.

## Documentation and Compliance

- Medical Staff Office and Pharmacy will keep on file a copy of the DEA DATA 2000 waiver for each [INSERT] physician prescribing buprenorphine.
- Each provider will maintain a paper or electronic log of all patients they are treating who are receiving buprenorphine for opioid dependence, with close attention to the patient limits for each prescribing provider.
- A paper copy of each buprenorphine prescription written will be filed in the patient's paper chart.
- All buprenorphine prescriptions should include both the physician's DEA number and the "X" DEA number which denotes buprenorphine provider status.
- If a DEA audit occurs, the audited physician should be prepared to present documentation of their waiver to prescribe buprenorphine, paper or electronic treatment log, and paper or electronic documentation of prescriptions they have written.
- In addition to standard HIPAA laws, federal regulations mandate strict confidentiality for information about patients being treated for substance use disorders (42 CFR Part 2). Additionally, the law requires written patient consent before information about substance abuse treatment can be disclosed to any other source.

## Attachments

1. Buprenorphine Treatment Agreement
2. Clinical Opiate Withdrawal Scale (COWS)
3. Starting buprenorphine at home- home induction instruction
4. Buprenorphine patient info FAQ

## References

1. [Clinical Guidelines for the Use of Buprenorphine in the Treatment of Opioid Addiction](#). SAMHSA, 2004.
2. Guidelines for Prescribing Buprenorphine as Opiate Replacement Therapy for Opiate Dependence in the CHN. OBIC, 2013
3. [How-to Guide](#). BupPractice.com
4. New Mexico Guidelines for Medical Providers who Treat Opioid Addiction Using Buprenorphine. New Mexico Behavioral Health Collaborative, 2012.