Fair Haven Community Health Care

Title:	Buprenorphine/Buprenorphine-Naloxone in Medication Assisted Treatment of Substance Use Disorder Protocol
Classification:	Clinical Care
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Board Approved Date:	Delegated by BOD to VP of Clinical Affairs
Monitoring Responsibility	Director of Addiction Medicine/Annually

Purpose

Buprenorphine is a schedule III controlled substance and a partial agonist at the mu opioid receptor which is FDA approved for the treatment of Opioid Use Disorder. The Drug Addiction Treatment Act of 2000 and later the Comprehensive Addiction and Recovery Act of 2016 allows qualified providers the ability to prescribe buprenorphine to treat Opioid Use Disorders in the office based setting. The below procedures will assist clinical staff in standardizing the care for patients at FHCHC who are prescribed Buprenorphine.

Protocol/Guideline

It is the practice of FHCHC that all clinical providers who have obtained a waiver from the DEA to prescribe buprenorphine for the purpose of treating patients with Opioid Use Disorders will review the below procedures which will guide the management of such patients.

Scope: all clinical providers who have obtained a waiver from the DEA to prescribe buprenorphine

Procedure:

1. At the initial visits, the clinical staff will confirm or perform the following:
    a. Medical History
    b. Addiction History including history of other use disorders
    c. Behavioral Health History
    d. Social History
    e. Medications and allergies
    f. Physical examination
    g. Labs, or review of labs, which based on individual risk factors, may include testing for HIV, Hepatitis, STDs, TB, baseline liver testing.
    h. Biological fluid which may be urine, serum or oral fluid for toxicology testing
    i. Patient education
        - Information about Buprenorphine
            - How it works
            - How it is taken
            - Common Side effects
            - Warning related to concomitant use of benzodiazepines/alcohol

- Harm reduction practices e.g. clean needle use, prevention of HIV/Hepatitis infection and transmission.
    - Role of Nasal Naloxone
    - Signing of Agreements
    - Patient expectations

2. Patients are eligible for treatment at FHCHC if they meet criteria for ASAM Level I placement, (outpatient setting). The determination of appropriateness of buprenorphine use may take multiple visits and/or 1-2 months of buprenorphine trial therapy to become clear. Motivational interviewing and moving the patient further along the stages of behavioral change should be occurring on an ongoing basis.

3. Buprenorphine Administration:
    a. **Introduction:**
    Will be done in office for patients who are new to buprenorphine but may be done at home for those who have been prescribed or used buprenorphine in the past.
        - The patient should be seen a second time within 1 – 3 days.
        - First dose can be given DOT by MD or SUPPORT STAFF; The pharmacy will deliver the first dose to the office and the SUPPORT STAFF or MD can show the patient how to take the first dose sublingually, have them wait in or near the clinic for about 1-2 hrs. to ensure tolerability and lack of adverse effects, including the possibility of precipitated withdrawal.
        - Unless opioid naïve at time of induction patients are ideally in moderate withdrawal at the time of induction and score at least a “10” on the Clinical Opiate Withdrawal Scale (COWS).
        - The first dose can be 2-4 mg. Additional doses can be given in 2-4 mg increments with time after first dose. The total daily dose on the first day cannot exceed 16 mg.
        - For patients transitioning from methadone, the dose of methadone ideally needs to be less than 30mg for past week and the patient must have remained off methadone for previous 48-72 hours.
        - Additional medications can help with withdrawal symptoms and sleep.
        - The patient is instructed to increase total dose by 4 mg a day until reaches 16 mg or until the patient feels stable.
        - When the patient is seen again, dosage level and tolerability are assessed. If the patient has symptoms and signs of withdrawal, persistent drug craving, or side effects, the dose may need to be adjusted.

    b. **Stabilization**
        - Increase the dose of buprenorphine 4 mg a day until a dose is reached that stabilizes the patient. Most will require about 16 mg a day. Some will need less while some may need as much as 24 mg/day. Does greater than 24mg/day will not be prescribed except in rare circumstances.
        - Ensure patient is taking the medication properly if not stabilizing on dose, e.g. sublingually, allowing full dissolution of tablets/films; no swallowing.
        - Once dose found that stabilizes patient’s symptoms and stops cravings, weekly visits can be implemented.

- Determine if in substance abuse counseling outside of FHCHC.

c. **Maintenance**
  - Weekly visits can be increased to every 2 – 4 weeks if patient is doing will and staying off heroin and other illicit drugs. Subsequently more frequent visits can be instituted if the patient begins to struggle with abstinence again.
  - Toxicology testing (observed or unobserved) should be done frequently.
  - Pill/film counts and random urine/saliva checks may be done at any time as needed.

d. **Possible Grounds for Discontinuation**
  - Missing follow up appointments acceptable reasons
  - Not attending counseling program as agreed upon in treatment plan (not showing up to counseling on-site or not bringing in proof of attendance off-site)
  - Suspected Diversion: e.g. confirmed buprenorphine-negative urine, inaccurate pill/film counts
  - Abuse, threatening behavior
  - Poor progress in ending opioid use, i.e. not off opioids within 1-3 months of starting program.
  - Benzo abuse
  - Dishonestly, i.e. falsifying urine samples

e. **Role of Support Staff**
  - Support staff can gather and provide some of the initial intake information including signing of patient agreement
  - Support staff can help with induction, including DOT and follow up.
  - Support staff can see patients during stabilization and maintenance phase of treatment as nursing visits.
  - Support staff can help with confirming patient attendance at counseling programs outside FHCHC.

f. **Substance Abuse Counseling**
  - Provider will determine if patient requires substance abuse counseling.
  - If required, patient will need to be in counseling at FHCHC or outside of FHCHC.
  - If outside of FHCHC, regular attendance at these programs should be verified.
  - Consent to communicate with the counseling program needs to be signed.
  - Patients can keep an attendance log that they bring with them to every visit. RN or MD can contact the program directly needed.
  - Counseling recommendations are based on counselor, provider and patient assessment.
  - If at any time during counseling program, the patient is struggling with abstinence, a higher level of care may be suggested.
  - Patients may be referred to inpatient programs or intensive outpatient programs (three times a week) external to FHCHC.
  - Medical provider may attend group visits periodically to discuss topics, reinforce importance of group, and to support the counselor.
  - Substance abuse treatment resources in the community should be identified—methadone clinics, addiction psychiatrists, substance abuse counselors, and substance abuse programs.
  - Multidisciplinary meetings (medical, behavioral health, care coordination) may be used to

help identify coordinate patient care and assist with team collaboration.

g. **Behavioral Health**
- Dual diagnosis of mental health and substance abuse is very common.
- Once the patient is inducted on buprenorphine and stabilized, an evaluation by psychiatry at FHCHC or external to FHCHC for diagnosis and treatment may be considered.
- Behavioral health can also be assessed by the primary care provider and the patient can be referred to psychiatry only when consultation is needed.

h. **Urine/Saliva/Serum (Toxicology Sample) Collection**
- Urine/saliva toxicology screen is collected at every visit.
- Urine/saliva toxicology screens can also be done at any time at the request of the provider.
- Urine collection may be supervised periodically if deemed necessary by the provider.

i. **Benzodiazepine/Alcohol Use**
- Patients need to be warned about the dangers of other substance misuse and abuse, which include fatalities, while taking buprenorphine.
- Prescribed stable benzodiazepine use may be approved at the discretion of the prescriber. Once stable, the prescribers will communicate about the feasibility of tapering the patient off of any benzodiazepine.

j. **Cocaine Use**
- Buprenorphine is a treatment for opioid dependency
- The goal of therapy, however, is for complete abstinence.
- Higher levels of substance abuse counseling may be needed.
- NA meetings can be emphasized.
- Behavioral health treatment and referral/engagement should be assessed or reassessed.
- Some pharmacotherapy may be tried, though no medication has yet been approved by FDA for cocaine dependency.
- The management plan and participation in buprenorphine treatment are left to the provider with input from the counselor.

k. **HIV and Hepatitis B and Infections**
- Screening for HIV and Hep B/C should be done with every patient.
- Referral to the HIV and Hep B/C services at FHCHC for patients who are found to be infected.