BUPRENORPHINE

for Opioid Use Disorder

Module 3: Clinical Use of Buprenorphine

Patient Assessment[1-3]

Initial Assessment

- Establishment of a diagnosis of Opioid Use Disorder (OUD).
- Discussion of current opioid use.
- Evaluation of patient's readiness to participate.
- Physical exam.
- Verify no acute needs requiring hospitalization.

Subsequent Assessment

- **A comprehensive assessment can occur in a step-wise fashion over multiple visits.**
- Documentation of opioid use history, as well as other substances (including alcohol, and tobacco).
- Referral of those who need medically supervised management of alcohol, benzodiazepines and/or other substances.
- Identification and evaluation of comorbid medical and psychiatric conditions/disorders, including current medications.
- Screening for communicable diseases.
- Assessment of patient's psychosocial status: support systems (friends/family), housing, finances, legal problems, etc.

Considerations for Buprenorphine Use[1,3]

Appropriate candidates for buprenorphine treatment should at least:

- Have a diagnosis of OUD.
- Be interested in treatment.
- Be reasonably expected to adhere to the treatment.
- Have no absolute contraindication to buprenorphine (or to naloxone, if applicable).
- Understand risks/benefits.

Patients who may need additional monitoring include those who:[3]

- Also have current dependence on, or are misusing high-dose benzodiazepines or other Central Nervous System (CNS) depressants (including high amounts of alcohol).
- Have severe hepatic impairment (Child-Pugh score of 10-15). Do not use the combination product. For the monoproduct, consider starting with half the starting and titration doses of those used for patients with normal hepatic function. For patients with moderate hepatic impairment (Child-Pugh score of 7-9), combination products are not recommended; they might precipitate withdrawal. Use them cautiously for maintenance treatment in patients who have been inducted with a monoproduct. Monitor patients carefully for signs of buprenorphine toxicity due to increased buprenorphine levels.
- Be aware that The FDA issued a Drug Safety Communication in 2017 urging caution in withholding methadone or BUP from patients using benzodiazepines or alcohol, noting that the harm of not treating OUD outweighs the risk of adverse events associated with combining the medications.[5]

Buprenorphine Initiation[1-4, 9]

Goal: To find the appropriate dose of buprenorphine where withdrawal symptoms and uncontrollable cravings are eliminated, and the patient stops or significantly decreases use of other opioids.

Choice of buprenorphine agent:

- Buprenorphine/naloxone for most patients.
- Buprenorphine monotherapy in special circumstances.
- While previously it was common practice to use the monoproduct in pregnant patients, many providers now use the combination buprenorphine/naloxone product for all patients, including pregnant women.[6]

Opioid dependent patients should have mild-moderate symptoms of withdrawal prior to starting buprenorphine.

- Buprenorphine could precipitate withdrawal if given to an opioid-dependent patient experiencing opioid effects.
- Use an opioid withdrawal scale (e.g. Clinical Opiate Withdrawal Scale [COWS]) to determine if patient is experiencing mild-moderate symptoms of withdrawal to avoid risk of precipitated withdrawal.[4] Some recommend waiting until a COWS score of 6-10 or more is observed before buprenorphine is started;[5] others suggest a score of 11-12 or more.[2]
- If patient is dependent on short-acting opioids, the last dose should have been taken at least 6 to 12 hours prior.[2]
- If patient is dependent on long-acting opioids, the last dose should have been taken 24-72 hours prior.
- If a patient is on methadone, to transition to buprenorphine, gradually taper methadone to 30-40 mg (this will be done by their Opioid Treatment Provider (OTP)/methadone provider, preferably in communication with the buprenorphine provider). Continue methadone at this dose for one week (until clinically stable), and stop methadone at least 36 hours (up to 72 hours) prior to buprenorphine initiation in order for the patient to experience moderate withdrawal. Prescribers should be aware of more potential withdrawal symptoms despite precautions with switching patients from methadone to buprenorphine and provide additional support as needed.[3]
- If a patient is on naltrexone, transitioning to buprenorphine is relatively uncomplicated since there is no physical dependence seen with naltrexone; however, the initial buprenorphine dose may be lower. In this transition, buprenorphine should not be started until naltrexone has been eliminated from the patient's system: minimally 1 day for oral naltrexone or 30 days for extended-release injectable naltrexone.

Buprenorphine Initiation (continued)

Location of initiation is based on prescriber preference, patient comfort/preference, and logistics.

Office Initiation

- Providers may do a few office initiations for provider and staff to see how initiations work, to allow for patients' comfort during the initiation.
- Recommended for patients who have experienced precipitated withdrawals previously (such as when using street-purchased buprenorphine), have never used buprenorphine, or who request an office initiation.
- Recommended for patients who are switching from methadone to buprenorphine.[7]

Unobserved or "Home" initiation[8,9]

- Is commonly used in many settings and practices.
- Studies suggest this is feasible and safe.
- Many patients have already been exposed to buprenorphine, either illicitly or in previous treatment episodes, and therefore are familiar with the need to be in mild-moderate withdrawal before starting initiation.
- Review with patients that they must be in mild-moderate withdrawal before taking the first dose. Review the COWS scale.
- Provide a written handout with information on how to do a home initiation.
- Provide a phone number to call if there is a problem with the initiation.
- Have someone call the patient on the day of their home initiation to check on how they are doing.
- Arrange a follow-up appointment in one week (some practices may prefer to see the patient back in one to three days). Visits can be done in-person or by telehealth.

Initiation Dose

- **Initial dose: 2-4 mg sublingual (SL) buprenorphine; may be repeated after 30-60 minutes if no symptoms of precipitated withdrawal occur.[2]**
- **If precipitated withdrawal occurs, reduce the repeat dose to 2 mg buprenorphine every 1-2 hours.**
- **Maximum dose on the first day is generally 16 mg.[3]**

Buprenorphine Stabilization Phase[1-3]

Goal: To decrease cravings and use of illicit opioids and to provide a "blocking dose" to prevent use of illicit opioids.

Initiation

- Initial dose should be 2/0.5-4/1mg and titrated up every 30-60 minutes in 2/0.5-4/1mg increments according to the patient's symptoms up to 16mg on day one. Then may adjust in 4/1mg increments over the course of a few days up to 24/2mg if required.
- **Most patients need 12 to 24 mg buprenorphine daily.**
- Insurance programs may require prior authorization for doses greater than 24 mg.[10]
- FDA approved doses: maximum of 24 mg/day.[11]

Buprenorphine Maintenance Phase[2,3]

- Duration: As with any chronic condition, the patient may need to remain on treatment indefinitely. Anecdotally, many providers start by recommending a year to the patient.
- Continue consideration of psychosocial needs of patient, and refer appropriately as required.

Treatment Monitoring[1]

Frequency of visits:

- Stabilization phase: at least weekly
- Once stable, may increase time between visits, up to every 30 days

Complex patients:

- Consider specialist consult with experienced provider or addictions specialist. Refer patient to appropriate service that meets the needs and goals of the patient. Refer as needed.
- Some patients may better meet their goals in a more structured and supervised environment.

Toxicology testing:[3]

- Urine (most frequently used test).
- Methadone and heroin metabolites are detected in routine screens.
- Important to test periodically for buprenorphine metabolites to evaluate adherence.
- Do not need to observe urine specimens unless there are concerns about tampering.
- Clinicians should determine what substances they wish to evaluate to determine which screening tool should be used.

Discontinuation of Buprenorphine[1]

- Most patients will require long-term treatment; duration of treatment may be indefinite.
- When discontinuing, taper slowly; continue psychosocial services.
- Tapering can always be stopped and dose increased again if patient requests or if the taper was not tolerated.
- Continue to assess opioid and other drug-use status throughout the taper and after.
- Before tapering from buprenorphine, establish a plan for follow-up visits and a specific plan to immediately resume treatment if patient experiences cravings or relapses. These are not patients who should be on a wait list.
- **Use of multiple drugs is common among patients presenting for buprenorphine treatment. There is no medical rationale for discontinuing buprenorphine in most patients who are engaged in and receiving benefits from treatment despite continued use of other drugs.**

Medically Supervised Withdrawal with Buprenorphine[1]

For medically supervised withdrawal (often referred to as detoxification) of short-acting opioids or from Opioid Agonist Treatment (OAT) with methadone.

Goal: To transition from physical dependence on opioids

Medically supervised withdrawal without OAT is not adequate treatment for OUD. Patients and families need to appreciate this, along with the risks of overdose after discontinuation of opioids.

- Initial dose: 2-4 mg SL buprenorphine; may be repeated after 30-60 minutes if no symptoms of precipitated withdrawal occur.
- If precipitated withdrawal occurs, reduce the repeat dose to 2 mg buprenorphine every 1-2 hours.
- Maximum dose on the first day is generally 16 mg and/or provision of naloxone.
- Naloxone training and prescription and/or naloxone kits should be provided in these situations.
- Encouragement to begin OAT should be provided if cravings or relapse occur.
- Outcomes are better if patients continue with OAT.

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