UNOBSERVED "HOME" INITIATION OF BUPRENORPHINE FOR PATIENTS SNORTING OR INJECTING HEROIN/FENTANYL ANALOGS

PROVIDER PROTOCOL

Buprenorphine has a strong affinity for the mu-opioid receptor and is capable of displacing most commonly used opioids including fentanyl and heroin. Prior to starting buprenorphine, mu-opioid receptors must be unoccupied to ensure buprenorphine does not displace a full opioid agonist and trigger a "precipitated withdrawal."

A **precipitated withdrawal** occurs when a patient who is dependent on full opioid agonists (like heroin, oxycodone, methadone etc.) is given the partial opioid agonist buprenorphine. As buprenorphine's receptor affinity is higher than most full opioid agonists, it displaces the full agonist and can cause the patient to feel like they are in acute opioid withdrawal. Clinically, this means that patients must be in mild to moderate withdrawal before starting buprenorphine.

As the illicit opioid supply has shifted from heroin to contamination with fentanyl analogs, opioid withdrawal has become more unpredictable in terms of pattern, duration and timing. Due to fentanyl analog's high potency, high affinity, quick-onset and offset, long half-life and lipophilicity, patients often find themselves quickly escalating their frequency and amount of use. There is little research or formal guidance that has been published to guide clinicians treating patients using illicit fentanyl analogs. In this provider and attached patient guide, we present approaches that we have found helpful within the MOC team. Please use your clinical judgement to apply these recommendations as you see fit. We recommend you review the patient guide yourself and with your patient and make any adjustments as necessary.

If your patient is using opioid pills or methadone, please refer to our other initiation guides or call the MOC for further assistance.

Michigan Opioid Collaborative

Unobserved initiations

Unobserved initiations are a safe option for patients starting buprenorphine treatment. Multiple observational studies show similar outcomes to in-office initiation. The ASAM 2020 Opioid Use Disorder National practice guidelines state "both office-based and home-based observation is considered safe and effective."

For patients using fentanyl analogs especially, in-office initiations can be difficult because patients often struggle to time their withdrawal symptoms with their office visit.

Given the COVID-19 pandemic, it is unadvisable to have patients spend several hours in the office. Given the unique challenges of initiating a patient using fentanyl analog coupled with need for physical distancing, **we recommend considering home initiation for any willing and clinically appropriate patient.**

There are additional benefits to unobserved initiation:

- Your patient will be more comfortable
- They do not need a driver or transportation
- No need to delay initiation for scheduling
- Less burden on clinical staff time/resources
- Anonymity not compromised if in withdrawal in waiting room
- Fewer clinic visits for the patient

PATIENT SELECTION

- Does your patient feel confident they could successfully initiate at home?
- Does your patient have someone available that could assist them in dosing medication, etc.?
- Has your patient taken buprenorphine before, either prescribed or illicitly?
- Has your patient had a precipitated withdrawal before?
- Does your patient prefer an unobserved initiation?

If the answer to most questions is yes, then your patient is a great candidate for an unobserved initiation. If patient doesn't have experience with buprenorphine but feels confident they could initiate at home, consider unobserved initiation.

Patients should have an evaluation prior to initiation (but can be the same day). Labs and urine drug screens can be done same-day as initiation and are not necessary prior to planning for unsupervised initiation or prescribing medication.

NOTE - Please use your clinical judgement in proceeding with patient selection for unsupervised initiations. We do not recommend proceeding with unsupervised initiation for patients transitioning from methadone to buprenorphine. **These are complicated initiations and so we recommend you call the Michigan Opioid Collaborative for assistance.**

734-763-9500

TARGET DOSE:

First prescription

We recommend prescribing the buprenorphine-naloxone combination product unless the patient has a documented naloxone allergy, as it is a misuse deterrent formulation. However, there may be specific circumstances where you may consider the mono-product but important to consider risks (e.g. price/affordability for patient, etc).

The combination product has buprenorphine and naloxone in a 4 to 1 ratio. When the combination product is taken sublingually or buccally as directed, only the buperenorphine is active. However, if the combination product is snorted or injected, the buprenophine and naloxone are both active, and the naloxone attenuates any "rush" the patient might experience.

We find that an initial target dose of **16-4 mg** for any patient using heroin/fentanyl analog. An initial target dose of buprenorphine-naloxone 16-4 mg has been associated with **decreased relapse** and decreased **loss to follow-up**. Patients using fentanyl analogs may need higher doses of buprenorphine, so your patient may continue to feel withdrawal symptoms at a dose of 16-4 mg and need doses as high as 24-6 mg qd. (Many insurances do not cover doses higher than 24 mg of buprenorphine qd.)

Films are preferred for initiation because they can be split into multiple pieces. However, your patient may only be able to obtain tablets. These can be split in half, but it is difficult to split them further. If using tablets, we recommend adjusting the protocol based on the strength of the tablets your patient can obtain (e.g. 2mg, 4mg or 8mg).

The patient materials assume a prescription for 8-2 mg buprenorphine/naloxone films. However, if your patient is only able to obtain tablets, you can ask the patient to split them as best they can.

Buprenorphine is FDA-approved for once daily dosing for opioid use disorder. However, anecdotally most patients prefer split dosing (BID). Consider TID/QID dosing if also treating pain, as the analgesic effect of buprenorphine is 6-8 hours.

Do not send more than 7 days of medication for first prescription and please consider co-prescribing naloxone. Make sure to include your DEA X-license number and note "dispense as directed by MD" in note to pharmacy.

FOLLOW-UP VISIT ON DAY 3-7

Evaluate patient response to buprenorphine. Ask about withdrawal symptoms, cravings, adverse effects, and continued drug use.

If patient reports withdrawal symptoms, significant cravings, or has continued opioid use, increase their dose to 20-5 mg buprenorphine/naloxone and follow-up with the patient in one week to reassess response.

Stress importance of taking medication on schedule. Do not use PRN for withdrawal symptoms after initiation is complete.

Consider telehealth for follow-up and new patient visits. During the COVID pandemic, DEA regulations allow provider to initiate buprenorphine via telehealth.

If you have other support staff like RN or MSW, consider scheduling patient for follow-up with them as well.

Please review patient guide for additional instructions.

Please note that SAMHSA's Guide Tip 63 states:

Always individualize dosing. The FDA label recommends a maximum buprenorphine/naloxone dose of 8 mg on Day 1 and 16 mg on Day 2. When dosing outside of FDA recommendations, document the clinical rationale, including risks and benefits. Remember that some patients stabilize on lower doses.

References

- American Society of Addiction Medicine. (2020) ASAM National Practice Guideline for the treatment of opioid use disorder: 2020 Focused update. https://www.asam.org/docs/default-source/quality-science/npg-jam-supplement.pdf?sfvrsn=a00a52c2_2
- Cunningham CO, et al. A comparison of buprenorphine initiation strategies: patient-centered home-based initiations versus standard-of-care office-based initiations. J Subst Abuse Treat. 2011;40:349-56.
- Fareed A, et al. Effect of buprenorphine dose on treatment outcome. J Addict Dis. 2012;31:8-18.
- Gunderson EW, Wang XQ, Fiellin DA, Bryan B, Levin FR. Unobserved versus observed office buprenorphine/naloxone initiation: a pilot randomized clinical trial. Addict Behav. 2010;35:537-40.
- Hser Y, et al. Treatment retention among patients randomized to buprenorphine/naloxone compared to methadone in a multi-site trial. Addiction. 2014;109:79-87.
- Lee JD, et al. Home buprenorphine/naloxone initiation in primary care. J Gen Intern Med. 2009;24:226-32.
- Leonardi C, et al. Multi-centre observational study of buprenorphine use in 32 Italian drug addiction centres. Drug Alcohol Depend. 2008;94:125–132.
- Substance Abuse and Mental Health Services Administration. (2020) Medications for Opioid Use Disorder. Treatment Improvement Protocol Tip 63. (Publication number PEP20-02-01-006). U.S. Department of Health and Human Services. https://store.samhsa.gov/product/TIP-63-Medications-for-Opioid-Use-Disorder-Full-Document/PEP20-02-01-006