Caring for Patients During the COVID-19 Pandemic

ASAM COVID-19 Task Force Recommendations

A guide for addiction treatment providers and programs working to treat patients with substance use disorders safely and effectively during the COVID-19 pandemic.¹ [add legal disclaimer language]

Adjusting Medication Dosage or Formulation

Purpose of the document

The purpose of this document is to provide guidance to outpatient addiction treatment providers in selecting medications and adjusting medication dose or formulation during the COVID-19 pandemic.

Topics

1. Considerations for Opioid Use Disorder Medications
   a. Medication Selection
   b. Considerations for Formulations and Dosages of Buprenorphine
   c. Considerations for Formulations and Dosages of Naltrexone
   d. Considerations for Dosages and Take Home of Methadone
2. Considerations for Alcohol Withdrawal Management during COVID-19
3. Considerations for Nicotine Cessation Medications

Considerations for Opioid Use Disorder Medications

As always, determinations regarding selection of medications, formulations, and dosages should be made based on shared decision making with the individual patient. However, the current COVID-19 crisis has implications for the risks and benefits of different medications and formulations. This section will discuss medication selection, as well as considerations for formulations and dosages for each medication approved for the treatment of opioid use disorder.

Medication Selection

The appropriate medication should be determined based on a discussion with an individual patient about the risks and benefits of different treatment options. However, the current COVID-19 crisis may raise new concerns that may shift the risk/benefit analysis.

ASAM’s recently release focused update to the National Practice Guideline for the Treatment of Opioid Use Disorder recommends that clinicians consider the patient’s preferences, past treatment history,
current state of illness, financial abilities and insurance coverage, and treatment setting when deciding between the use of methadone, buprenorphine, and naltrexone. During the COVID-19 crisis, clinicians should also consider how the choice of medication will impact the need for in person appointments in combination with the individual’s risks associated with COVID-19.

**What are the risks associated with an in-person visit?**
- Is the patient at high risk for severe COVID-19 illness?
- Is the patient living with or caring for someone at high risk?
- Would the patient need to take mass transit or ride with another person to the visit?
- What is the patient’s level of anxiety around coming to an in person visit?
- What is the availability of appropriate personal protective equipment (PPE) for both healthcare workers in the facility and the patient?
- Is the patient experiencing any symptoms consistent with COVID or have they had any potential exposures?
- Is the patient living in a high-risk environment for COVID-19 transmission?

**What are the risks associated with not conducting an in-person visit?**
- Is the patient at high risk of adverse events related to their OUD (e.g. overdose, suicide)?
- Can the patient engage in telemedicine visits?
- Is the patient more likely to disengage from treatment?
- Can the patient appropriately and safely manage take home medications?
  - Is the patient likely to divert or misuse their medication?
- Can drug testing be safely delayed?

**When considering methadone, think about the following:**
- For new patients:
  - An in-person medical exam is required under federal regulations before initiation of methadone. (See ASAM’s Guidance for OTPs during COVID)
  - How many visits are expected during the dose titration period?
  - Can the patient engage in telemedicine visits and, if so, how safe might the patient be with take-homes during induction and stabilization?
  - Insurance coverage for the different medication options.
- For existing patients:
  - What number of take-home doses is safe for the given patient? What is their risk for adverse events with increased take-home doses?
    - It is important to consider that during this period of stress, anxiety, and social isolation even stable patients are likely to be at an elevated risk for relapse.
  - What strategies are available to minimize the risk associated with take-home doses? For example, lock boxes designed to release a single dose of methadone at a pre-set time or an increased frequency of phone or audio-visual check-ins with the patient may be helpful.
  - Is there a responsible family member or other adult who can serve as a chain-of-custody for take home doses?
  - Can the patient engage in telemedicine visits and if so, does your program have sufficient capacity to provide the needed services by telehealth to monitor patients and their response to increased take-homes?
o Is the patient a candidate for transition to buprenorphine without destabilizing their OUD?

When considering buprenorphine, think about the following:

- Federal regulations have been relaxed during this public health emergency to allow the initial medical examination for initiation of buprenorphine to occur through telehealth, including telephone only.
- Can initiation be safely accomplished through telehealth?
- Lower risk for overdose if medications are misused or if titration goes quickly
- Insurance coverage for the different medication options.
- Total cost, including mediation, may exceed OTP methadone costs if patient is self-paying.

When considering XR-NTR, think about the following:

- Starting a patient on XR-NTX requires a period of opioid abstinence of 7-10 days. Is the patient likely to be able to sustain this at home or in an unmonitored setting? How willing is the patient to access residential treatment services as a setting to start XR-NTX? If the patient is willing to engage in residential treatment, are these services available?
- Because an injection every 3-4 weeks is required:
  - Does your facility have access to sufficient supplies of the necessary PPE for these injections? If not, is there an alternative place in the community that can provide these injections?
- What is the patient’s risk for relapse if their medication had to be delayed or discontinued?
- Insurance coverage for the different medication options.
- Oral naltrexone has not been proven to be effective for the treatment of OUD, primarily because of issues with patient adherence. This formulation is not recommended except under limited circumstances. For example, oral naltrexone can be effective in patients who are highly motivated or legally mandated to receive treatment, and/or when taking the medication is closely supervised.

Considerations for Formulations and Dosages of Buprenorphine

Buprenorphine is currently available in multiple formulations including sublingual films and tablets, a monthly extended-release injection, and a subcutaneous implant (6 months). The COVID-19 crisis may impact considerations for the formulation of buprenorphine for a given patient.

Considerations for daily formulations vs. injectable

There are several factors a clinician needs to weigh when deciding to either continue the current formulation (daily or injectable) or when considering switching between formulations with different delivery methods:

- Is the patient experiencing any symptoms consistent with COVID-19?
- Has the patient had any known exposure to an individual who has tested positive for or is suspected of having COVID?
- What is the risk to the specific patient associated with an in person visit?
  - Are they at high risk for severe COVID-19 illness?
  - Would the patient need to take mass transit to the visit?
  - What is the patient’s level of anxiety around coming to an in person visit?
• Is the patient living with or caring for someone at high risk of severe illness, such that they should not come to clinic for injection?
• Are there any anticipated risks to the patient associated with switching formulations?
  o How stable is the patient on their current medication?
  o Are they likely to be adherent with daily medication?
• How will the choice of formulation impact the anticipated frequency of in-person appointments?
  o Can the patient be safely managed through telehealth alone if taking daily buprenorphine?
  o What would be the required frequency of in-person visits for daily vs injectable formulation?
  o What would be the anticipated required frequency for drug testing, if at all during the crisis? See ASAM’s Guidance on Adjusting Drug Testing During COVID-19.
• Which formulation does the patient prefer, given the anticipated requirements for in-person appointments for each formulation?
• Does your facility have sufficient staff and PPE to accommodate in-person visits and/or provide injections?
  o Is there an alternate location where the patient can safely receive an injection?
• What is the availability of injectable buprenorphine?
  o Does the patient have insurance that will cover this formulation?
  o Does the patient have access to a site where they can receive the injection?
  o Is the treating provider able to obtain, deliver, and bill for the injections?
• Is the patient at high risk for misusing or diverting their sublingual buprenorphine?
  o Is the patient in an unstable living environment?
  o Does the patient have a history of injecting buprenorphine?
• Does the patient have the ability to engage in telehealth for ongoing visits at a less than monthly frequency?

Additional Formulation Considerations

Transitioning between formulations may require dose adjustments and titration over time. The goal is to minimize in-person encounters while safely treating the patient’s OUD (see ASAM’s Guidance on Access to Buprenorphine during COVID-19). Providers should consider the length of the prescription and availability of refills to minimize the chances that the patient will run out of medication, and minimize exposure at pharmacies.

Adjusting Buprenorphine Dosages

The stress, anxiety, and social isolation associated with the COVID-19 pandemic may exacerbate a patient’s addiction and mental health symptoms. Clinicians should check in with patients more regularly through telehealth (including telephone-based check ins) to assess the patient’s response to medication and any signs that the patient’s medication or treatment plan may need to be modified. In addition, clinicians should be alert to signs that patients may be misusing or diverting their medications, such as
patients returning early for additional medication. Programs and providers should consider how to manage these situations in the context of the COVID-19 crisis. For example,

- When to require an in-person appointment
- How to address suspected diversion (including to friends or family who lost access to their medication during this crisis)
- Moving to a shorter duration of prescriptions
- Ensuring refills have “do not fill before” dates
- Consider enhanced methods for monitoring medication adherence.

Considerations for Dosages and Take-Home Doses of Methadone
SAMHSA and the DEA have relaxed regulations on Opioid Treatment Programs (OTP’s) to enable increased telehealth and take-home doses during this public health emergency. However, providers need to weigh the risks for each individual patient associated with both OUD and COVID-19. Many aspects of this crisis may increase the risk for relapse. Patients are experiencing high levels of stress and anxiety related to the pandemic, many have or will lose their jobs, social isolation is exacerbating mental health and addiction related symptoms. These impacts have implications for the risks of increasing take-home of methadone.

Considerations for Methadone Formulation
If dispensing larger numbers of take-home doses, consider dispersible tablets instead of the liquid formulation. This formulation can be easier to secure, and safer to travel with.

Considerations for Methadone Dosing
Opioid Treatment Program (OTPs) should consider promoting physical distancing through the use of telehealth and increased take home doses, when safe and appropriate (See ASAM’s COVID Guidance for OTPs). Programs should also make changes to how patients flow through their facility to ensure patients and staff can maintain 6+ feet of distance.

The stress, anxiety, and social isolation associated with the COVID-19 pandemic may exacerbate a patient’s addiction and mental health symptoms. Clinicians should check in with patients more regularly through telehealth (including telephone-based check ins) to assess the patient’s response to medication and any signs that the patient’s medication or treatment plan may need to be modified.

In addition, OTPs should be aware of the safety risks associated with increased take home doses of methadone, and the need for increased patient monitoring. Clinicians should be alert to signs that patients may be misusing or diverting their medications, such as patients returning early for additional medication. Programs and providers should consider how to manage these situations in the context of the COVID-19 crisis. For example,

- When to require an in-person appointment
- How to address suspected diversion (including to friends or family who lost access to their medication during this crisis)
- Moving to smaller number of take-home doses.
Programs should also explore methods for minimizing patient risks related to take-home methadone. For example:

- Consider enhanced methods for monitoring medication adherence
  - Specially designed lock boxes with controlled release, enabling one dose to be released once per day at a specific time.
  - If these tools are too expensive for the program to cover, the program could consider exploring funding options with the State Opioid Treatment Authority as there may be opportunities for using SOR or CARES funding for this purpose.
- Using telehealth to monitor the patients daily dosing, including ensuring that remaining doses are all accounted for
- Engaging the patient’s family or support system to manage and monitor dosing, if the patient has a reliable support system that could play this role
- Increased telephonic check-ins.

The COVID-19 crisis will force clinicians to make some very challenging clinical decisions as they try to balance the risks associated with OUD versus those associated with the coronavirus, for individual patients, staff, and public health. Programs and providers should also consider what data you have access to that can help you assess the impact of the changes you or your program is implementing. While you may have limited access to local and state level data during the crisis, consider what data you can collect in your own practice or program. For example:

- Early returns/early refills
- Suspected misuse or diversion (among patients considered to be stable vs. less stable)
- Patient hospitalizations
- Unexpected drug screen results (if you are continuing to conduct drug screens).
Considerations for Formulations and Dosages of Naltrexone

Naltrexone is available in an extended release injectable formulation (XR-NTR) and as an oral tablet. However, only the extended release formulation has been proved effective for the prevention of relapse to OUD. XR-NTR requires in-person visits for an injection every 3-4 weeks (the standard dosing is every 4 weeks but some patients who metabolize naltrexone more rapidly benefit from dosing every 3 weeks. See ASAM’s National Practice Guideline for the Treatment of OUD. In determining whether XR-NTR is the right medication for a given patient during the COVID-19 crisis. There are several factors a clinician needs to weigh:

• Is the patient experiencing any symptoms consistent with COVID-19 or have they had any potential exposures?
• Starting a patient on XR-NTX requires a period of opioid abstinence of 7-10 days. Is the patient likely to be able to sustain this at home or in an unmonitored setting? How willing is the patient to access residential treatment services as a setting to start XR-NTX? If the patient is willing to engage in residential treatment, are these services available?
• Is the patient a candidate for oral naltrexone?
  o Oral naltrexone has not been proven to be effective for the treatment of OUD, primarily because of issues with patient adherence. This formulation is not recommended except under limited circumstances. For example, for highly motivated patients who can be closely supervised in taking the medication.
  o Is the patient likely to be adherent with the oral medication?
• Is the patient a candidate for buprenorphine?
  o What is the patient’s risk for relapse if XR-NTR is discontinued?
  o Is the patient likely to be adherent with daily buprenorphine?
  o Does the patient have any contraindications to buprenorphine?
• What is the risk to the specific patient associated with an in person visit?
  o Are they at high risk for severe COVID-19 illness?
  o Are they living with or caring for someone at high risk of severe illness?
  o Would the patient need to take mass transit to the visit?
  o What is the patient’s level of anxiety around coming to an in person visit?
• Does your facility have sufficient staff and PPE to provide injections?
  o Is there an alternate location where the patient can safely receive an injection?
• Which formulation and medication does the patient prefer, given the need for monthly in-person appointments for injections for XR-NTR?

Resources:


• Guidance for Buprenorphine Treatment Providers: https://www.asam.org/Quality-Science/covid-19-coronavirus/access-to-buprenorphine

SAMHSA’s COVID-19 Resources: https://www.samhsa.gov/coronavirus

Considerations for Alcohol Withdrawal Management

During the COVID-19 pandemic access to alcohol may be reduced in some areas, which may increase the risk for alcohol withdrawal. At its most severe alcohol withdrawal can cause seizures, delirium, and even death. ASAM recently released Clinical Practice Guidelines for Alcohol Withdrawal Management. These guidelines provide recommendations for determining the appropriate level of care for a given patient. However, the risks associated with COVID-19 may influence this determination.

Providers should consider:

- Can the patient be safely monitored in an ambulatory care setting, or at home?
  - Does the patient have safe housing?
  - Does the patient have support at home?
  - Can the patient maintain the necessary telephone-based contact?
  - Can the patient follow the necessary medication instructions?
- Does the patient need inpatient care?
  - Are they at risk of severe or complicated withdrawal?
  - Does the patient have a history of seizures or delirium tremens?
  - Does the patient have medical comorbidities likely to complicate their withdrawal treatment?
- Is the patient experiencing any symptoms consistent with COVID-19 or have they had any potential exposures?
  - How severe are their symptoms? How is this likely to impact their alcohol withdrawal symptoms?
  - Does your facility have the capacity to provide remote monitoring and services for patients with alcohol withdrawal syndrome?
  - If providing residential or inpatient services, does your facility have the capacity to manage patients with, or suspected of having, COVID-19?
- What is the risk to the specific patient associated with inpatient care?
  - Are they at high risk for severe COVID-19 illness?
  - Are they living with or caring for someone at high risk of severe illness?
  - What is the patient’s level of anxiety around inpatient care?

When treating in an outpatient setting with home monitoring, consider a higher dosing protocol. In the context of COVID-19, the community has diminished access to monitored environments where clinician-administered assessments of withdrawal are feasible. While there is an elevated risk of adverse effects (typically sedation) from withdrawal medications, these are outweighed by the risk of under-treated alcohol withdrawal syndrome.

- Consider using the short alcohol withdrawal scale (SAWS) which can be self-administered.
- Communities should consider launching an “on-call” line for urgent SUD and withdrawal management services where patients can be triaged to determine if they need inpatient care.
- Consider developing standard protocols for specific settings where alcohol withdrawal management may be needed. For example:
  - Protocols for management of low acuity alcohol withdrawal in emergency shelters for people experiencing homelessness
Protocols for COVID-19 quarantine sites staffed by nurses which may be able to handle more moderate acuity patients.

See sample protocols, courtesy of Dr. Brian Hurley MD, MBA, DFASAM (see the content disclaimer):

- Management of OUD, AUD, and withdrawal in Low Acuity Settings
- Management of OUD, AUD, and withdrawal in quarantine sites

When patients are treated for alcohol withdrawal the provider should work to engage the patient in treatment for alcohol use disorder.

FDA-approved Medications for Alcohol Use Disorder (MAUD)

- Naltrexone 25-50mg oral once daily (must ensure opioid abstinence for at least 7 to 10 days)
- Naltrexone ER 380mg IM once every 28 days intramuscular (gluteal) injection (must ensure opioid abstinence for at least 7 to 10 days)
- Acamprosate 333-666mg oral TID
- Disulfiram 250-500mg oral once daily.

See APA’s Practice Guideline for the Pharmacological treatment of Patients with Alcohol Use Disorder.

Resources:

ASAM’s Clinical Practice Guideline for Alcohol Withdrawal Management: https://www.asam.org/Quality-Science/quality/guideline-on-alcohol-withdrawal-management

Considerations for Dosages and Formulations of Nicotine Cessation Medications

Early research suggests that smoking is associated with increased risk for severe COVID-19 illness. In addition, the COVID-19 response, including quarantine and physical distancing measures can limit access to nicotine-containing products (cigarettes, chew, tobacco, vape) and/or limit opportunities to smoke. Finally, this period of stress, anxiety, isolation, can lead to relapse among former smokers.

Clinicians should continue to screen patients for nicotine use and support individuals interested in nicotine cessation. It is important for patients to continue to have access to nicotine replacement therapy (NRT) and other medications and support services. Providers should continue to recommend online and telephone-based support for nicotine cessation including quit lines and apps. Smokefree.gov provides helpful resources for patients. Providers should continue to offer medications to support nicotine cessation. FDA-approved medications include:

- Varenicline 0.5mg PO daily x 3 days, then 0.5mg PO BID x 4 days, then 1mg PO BID
- Bupropion 150mg PO daily x 3 days, then 150mg PO BID
- Nicotine replacement therapies including patches, gum, lozenges, nasal spray and inhalers
  - 21mg patch for >10 cigarettes/day
  - 14mg patch for <10 cigarettes/day
  - 7mg patch use for tapering

Resources:

2018 ACC Expert Consensus Decision Pathway on Tobacco Cessation Treatment: http://www.onlinejacc.org/content/72/25/3332