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ARCA Medication Guidelines and Guidelines in the Age of Fentanyl (Version 7)

The COVID-19 Pandemic has pushed us to innovate to continue serving our established patients and reach new patients in need of treatment for substance use disorders and co-occurring mental illness. ARCA has leveraged telehealth and methods of virtual care in ways unimagined prior to the pandemic. Our staff have creatively developed new processes for connecting with patients, documenting encounters, and promoting patient and community safety.

We are continuing these guidelines to standardize the medication portion of treatment. The primary audiences for these guidelines are ARCA providers and staff. However, our partnering agencies can benefit from understanding our standard ways of practice for several reasons, including patient education, development of treatment plans, coordination of services, and interagency communications. Also, partnering agencies can work with our providers to adapt aspects of each guideline—such as follow-ups, prescription fills and refills, and referrals—based on the capacity of the agency and the safety and well-being of the agency and its community.

These guidelines are just that—guidelines, not inflexible mandates on practice. We have created them by using the expertise of ARCA, national guidelines published by SAMSHA, the CDC, ASAM, and other professional and scientific organizations. More than ever, this set of guidelines is a group effort of our practice team, include our five Addiction Medicine-Board Certified Physicians. Providers may deviate from these guidelines when their clinical judgment dictates a change. In these encounters, we expect our providers to document their clinical decision-making so that patients, staff, and partnering agencies understand the process and the treatment goal.

This is a growing and changing document—much like the field of Addiction Medicine. We will continue to build guidelines as more resources, studies, and best practices become available.

Thank you for taking time to read and implement these guidelines.

Thank you,

Fred Rottnek, MD, MAHCM

Chief Medical Officer

Controlled Substances and ARCA Prescribing Patterns

Our partnering agencies have been very clear in this regard. They do not want to be perceived—rightly or wrongly—as contributing to their local overdose epidemic by providing patients, particularly those early in recovery, with 30-day supplies of controlled and/or abuseable medications. Many of our partnering agencies are being pressured by local law enforcement agencies to reduce the controlled medication burden in their communities—and we need to do our best to honor these requests.

In this spirit, we ask all prescribing providers to

- 1. Adhere to the recommended filling guidelines for buprenorphine
- 2. Apply these guidelines to other controlled substances, including benzodiazepines and amphetamines, as well as other potentially abuseable substances, such as gabapentin
- 3. Review our ARCA medication guidelines and use non-controlled/non-abuseable substances whenever possible as first line therapies.
- 4. Comfort meds should be limited to stabilization. They have fill limits on the guidelines. While these doses can be adjusted, and length of fill varied, they should have clear end dates.
- 5. Work with ARCA nursing staff to initiate 1-2 week fills of all controlled substances—again particularly during the first few months of treatment. We all recognize this is a challenging time in a patient's sobriety, and we want to minimize adverse outcomes due to supply of potentially lethal supplies of medication. ARCA nursing staff work closely with our partnering agency staff—they can provide key informative on patient progress and can recommend fill patterns.
- 6. Thirty-day supplies of controlled substances should not be considered until—at the very earliest—the 3rd month of successful treatment adherence. Again, smaller fills/partial fills can be done multiple ways—and refill authorization does not usually require a prescribing visit. Work with your nurses, your case managers, and your peer support specialist for fill recommendations.

Harm Reduction on the Continuum of Substance Use Services

ARCA provides services with a harm reduction lens.

Harm reduction is a set of practical strategies and ideas aimed at reducing negative consequences associated with drug use. It is an approach that incorporates community-driven public health strategies, including prevention, risk reduction, and health promotion, to empower people who use drugs (and their families) with the choice to live healthy, self-directed, and purpose-filled lives. Harm reduction centers the lived and living experience of people who use drugs, especially those in underserved communities.

Harm reduction incorporates a spectrum of strategies that includes safer use, managed use, abstinence, meeting people who use drugs "where they're at," and addressing conditions of use along with the use itself.⁴ Harm reduction initiatives run the gamut from medical care and disease prevention to education and linkage to addiction treatment. The defining features of harm reduction include a focus on the prevention of harm, rather than on the prevention of substance use itself.

Harm reduction is an approach that promotes health in a way that meets people where they live, accepting that not everyone is ready or capable of stopping their substance use at a given time. Instead of making judgments about where individuals living with addiction should be in regard to their health and behavior, harm reduction focuses on promoting evidence-based methods for reducing associated health risks in the current moment (e.g., preventing HIV transmission through intravenous drug use). Harm reduction emphasizes engaging directly with people who use drugs to prevent overdose and infectious disease transmission, improve physical, mental, and social wellbeing, and offer low barrier options for accessing health care services, including substance use and mental health disorder treatment.⁵

The following principles are central to harm reduction practice²:

- Accepts that licit and illicit drug use is part of our world and chooses to work to minimize its harmful effects rather than simply ignore or condemn them.
- Affirms people who use drugs themselves as the primary agents of reducing the harms of their drug use and seeks to empower individuals living with substance use disorder(s) to share information and support each other in strategies which meet their actual conditions of use.
- Recognizes that the realities of poverty, class, racism, social isolation, past trauma, sexbased discrimination, and other social inequalities affect both people's vulnerability to and capacity for effectively dealing with drug-related harm.
- Does not attempt to minimize or ignore the real and tragic harm and danger associated with licit and illicit drug use.

¹ https://harmreduction.org/about-us/principles-of-harm-reduction/

² https://www.samhsa.gov/find-help/harm-reduction

³ https://harmreduction.org/about-us/principles-of-harm-reduction/

⁴ https://harmreduction.org/about-us/principles-of-harm-reduction/

⁵ https://www.samhsa.gov/find-help/harm-reduction

Overdose Education and Naloxone Distribution

Randall Williams, MD, former Director of Missouri's Department of Health and Senior Services wrote a standing order on August 28, 2018, that allowed anyone to purchase/obtain with coverage naloxone at a Missouri pharmacy without a prescription if they align with one of the following categories. These guidelines were updated by Heidi Miller, MD on January 27, 2023.

- Persons who voluntarily request naloxone and are at risk of experiencing an opiate-related overdose, including but not limited to:
 - o Current illicit or non-medical opioid users or persons with a history of such use
 - Persons with a history of opioid intoxication or overdose and/or recipients of emergency medical care for acute opioid poisoning
 - o Persons with a high dose opioid prescription (>50 morphine mg equivalents per day)
 - o Persons with an opioid prescription and known or suspected concurrent alcohol use
 - o Persons from opioid detoxification and mandatory abstinence programs
 - o Persons entering methadone maintenance treatment programs (for addiction or pain)
 - Persons with opioid prescription and smoking/COPD or other respiratory illness or obstruction
 - o Persons with an opioid prescription who also suffer from renal dysfunction, hepatic disease, cardiac disease, HIV/AIDS
- Persons who may have difficulty accessing emergency medical services
- Persons enrolled in prescription lock-in programs
- Persons who voluntarily request naloxone and are the family member or friend of a person at risk of experiencing an opiate-related overdose
- Persons who voluntarily request naloxone and are in the position to assist a person at risk of experiencing an opiate-related overdose
- For the updated document, visit https://health.mo.gov/data/opioids/pdf/naloxone-standing-order.pdf

Coverage for nasal naloxone

- Missouri Medicaid covers nasal naloxone.
- Patients on other insurance should check with their insurance carriers for coverage. (If
 these clients are unable to afford naloxone, check with ARCA leadership for area
 resources for free naloxone).
- Please note that there is no reason for anyone in Missouri for whom naloxone is indicated not to have naloxone. It is just a matter for us to find the correct resource.

For all clients seen at ARCA who align with the above categories:

- 1. Prescribing providers prescribe one nasal naloxone (2-unit dose-pack) with two refills at the initial office visit. (See medication templates below).
- 2. All ARCA staff check with clients at each office visit if they need a refill or to check the expiration date of their current naloxone supply.
- 3. Any ARCA staff member may call in a nasal naloxone prescription for any registered client—this standing order can be called in under any prescribing provider's name or under the Medical Director's name.

- 4. Per Dr. Williams' original standing order, and continued under Dr. Miller's standing order, all clients who are prescribed naloxone must receive literacy-level appropriate education about its use. We recommend, when possible, that the client brings in someone they live with (or use with) for this education.
- 5. Use Naloxone Patient information (naloxone nasal spray)

Comfort Medications (Customize to substance(s) being addressed and payer source)

Encourage hydration prior to and curing the withdrawal process. Encourage a minimum of eight 8-oz glasses of water per day. Encourage the patient to use comfort medications. Ideally, comfort medications should start as soon as a patient begins experiencing symptoms of withdrawal.

Medications

- Trazodone 50 mg Take one tablet daily 30 mins before bedtime as needed for better sleep. #10 (no routine refill) **or** doxepin 25-50 mg #10 before bedtime as need for better sleep. Some patients may benefit from refills of sleep medications until their sleep cycles regulate. While refills may benefit in initial treatment, refills should not continue indefinitely. (Avoid anti-psychotic medications for sleep unless they are also prescribed to treat conditions with psychotic symptoms. Also avoid Z-drugs, particularly in patients being treated for SUDs).
- Compazine 10mg- Take one tablet three times daily as needed for nausea #30 (no routine refill) **or** ondansetron 4 mg tablets one tablet three times daily as needed for nausea #30 (Compazine is not on the CSTAR formulary)
- Clonidine 0.1mg- Take one tablet every 12 hours daily or every 8 hour as needed for anxiety, agitation, rapid heart rate, headache #20 Hold for BP less than 100/60 (no routine refill)
- Baclofen 10 mg orally three times daily as needed for cramping (#30) (no routine refill) **or** cyclobenzaprine 10mg- Take one tablet every 8 hours as needed for muscle cramping #30 (no routine refill) (Compazine is not on the CSTAR formulary).

Note on insomnia:

Insomnia is a common complaint among patients in treatment for a substance use disorder.^{6 7 8}. It can occur during withdrawal and persist for months or even years into recovery. However, it is important to note that benzodiazepine hypnotics are not prescribed for insomnia in patients taking opioids due to the risk of respiratory depression. The duration of insomnia in someone with opioid use disorder can vary depending on the individual and their specific circumstances.

⁶ https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6289280/

⁷ https://store.samhsa.gov/sites/default/files/d7/priv/sma14-4859.pdf

⁸ https://www.uptodate.com/contents/insomnia-in-patients-with-a-substance-use-disorder

Alcohol Withdrawal Management Triage Protocol

1. Initial RN Phone Assessment:

- Identify the patient's chief complaint and reason for seeking help.
- Obtain the patient's demographic information, including name, age, gender, and contact details.
- Assess patient's social support.
- Briefly evaluate the patient's overall pertinent medical history, including any previous instances of alcohol withdrawal, prior hospitalizations related to alcohol withdrawal, seizures, traumatic brain injury, significant comorbidities, medications, and allergies.
 - Perform the PAWSS (Prediction of Alcohol Withdrawal Severity Scale) to help guide decisions. A score above 4 puts a patient at higher risk of moderate-severe withdrawal.
- All patients with concern for alcohol withdrawal must have either a scheduled provider visit (preferably in person) or be referred to a higher level of care.
- Patients who require an in-person visit should be instructed not to drive to the visit. They will need to delegate a support person who can drive them and help with their care.
- Patients who are deemed too elevated risk for outpatient alcohol withdrawal management will be directed to either the emergency room or a facility that manages alcohol withdrawal inpatient. This includes:
 - o Patients on chronic daily **benzodiazepines**
 - o Prior history of **seizures**
 - Prior history of complicated alcohol withdrawal that included delirium tremens or other morbidity
 - o **Pregnant** patients past the first trimester
 - o Patients with no **social support**
 - o Patients with significant medical or psychiatric **comorbidities** that are not stable
- RNs are encouraged to discuss individual presenting for care with the continuity provider or Welcome Center provider to help with appropriate triage

2. Initial Clinical Evaluation for patients at the clinic:

- Assess the patient's current vital signs, including heart rate, blood pressure, respiratory rate, and temperature.
- Obtain UDS and breathalyzer
- Determine the patient's level of consciousness and any signs of confusion, hallucinations, or seizures.
- Perform the CIWA-AR (The Clinical Institute Withdrawal Assessment Alcohol Scale Revised) to objectively measure the severity of alcohol withdrawal symptoms. Moderate or above (above 8) indicates a patient may need a higher level of care. ¹⁰

⁹ https://www.mdcalc.com/calc/10102/prediction-alcohol-withdrawal-severity-scale

¹⁰ https://www.mdcalc.com/calc/1736/ciwa-ar-alcohol-withdrawal

- Assess the patient's level of tremors, agitation, diaphoresis, anxiety, and gastrointestinal symptoms (nausea, vomiting, diarrhea).
- Evaluate for signs of dehydration and electrolyte imbalances.
- RNs are encouraged to discuss individual presenting for care with the continuity provider or Welcome Center provider to help with appropriate triage

3. Risk Stratification:

- Classify the patient's alcohol withdrawal based on severity: mild, moderate, or severe.
- Identify any high-risk factors, such as a history of seizures, delirium tremens, poorly
 controlled psychiatric diagnosis, pregnancy, poor social support (no current housing or
 without a support person while going through withdrawal) or severe medical
 comorbidities.

4. Treatment Recommendations:

- Mild to Moderate Withdrawal:
- Consider outpatient management with close monitoring, education, and support.
- Support person will need education around monitoring and parameters to take patient to the ER
- Provide recommendations for hydration, nutrition, and rest.
- The provider will prescribe the patient either benzodiazepine-sparing or benzodiazepine-based protocols
- Patient will need daily RN phone visits Days 2,3 and 4 and optional provider follow-ups either via video or in person
- Severe Withdrawal:
- Recommend inpatient admission for continuous monitoring and medical intervention.
 Consult with ARCA Behavioral Health to identify resources.

5. Patient Education:

- Educate the patient and their support system about the risks of alcohol withdrawal and the importance of medical supervision.
- Discuss the potential complications of severe withdrawal, such as seizures, delirium tremens, and cardiac arrhythmias.
- Provide information on the prescribed medications, their dosages, and potential side effects
- Emphasize the importance of follow-up care and compliance with the treatment plan.

6. Follow-Up and Discharge:

- Schedule follow-up appointments with the RN and provider for ongoing assessment and adjustment of the treatment plan.
- Patient will need daily RN phone visits Days 2,3 and 4 and optional provider follow-ups either via video or in person that week
- Provide written discharge instructions outlining the treatment received, medication instructions, and signs of worsening symptoms that warrant immediate medical attention.

7. Emergency Situations:

• In case of severe symptoms (e.g., seizures, hallucinations, severe confusion), instruct the patient or their support system to seek immediate medical attention, either by calling 911 or going to the nearest emergency room.

Alcohol Detoxification Guideline (Benzodiazepine protocol)

1. Conduct and document PAWSS—see appendix. A score ≥ 4 suggests that a patient is at risk for a more complicated withdrawal process. Patients with a score ≥ 4 should be encouraged to detox in a hospital or higher acuity setting. However, not all patients are able and/or willing to do so. Document this conversation.

2. Medications

- a. Naltrexone 50mg Take 1/2 tablet the first day and then one tablet by mouth daily AFTER eating #30
- b. Librium/ Chlordiazepoxide 25mg, DO NOT drive on this medication. DO NOT drink on this medication:
 - i. Take 1 capsule every 6hrs for the first 2 days
 - ii. Take 1 capsule every 8 hours for the next 2 days
 - iii. Take 1 capsule every 12 hours for the next 2 days
 - iv. Take 1 capsule every 24 Hours for the final 2 days (no routine refill)
- c. Folic Acid (Vitamin B9) 1mg Take 1 tablet daily for 14 days (no routine refill)
- d. Thiamine (vitamin B1) 100mg Take 1 tablet daily for 14 days (no routine refill)
- e. Seizure prophylaxis: Choose one if client has had history of complicated alcohol withdrawal
 - i. Tegretol/carbamazepine 200 orally two times daily for 7 days
 - ii. Gabapentin 300 orally three times daily for 7 days

Patient instructions:

- 1. Instruct the patient to have someone at home with them for at least the first 3 days of this process. The companion can assist in medication reminders.
- 2. Instruct the patient not to take more than the prescribed medication unless authorized. If you have any questions or concerns, instruct the patient to contact ARCA Medical Staff.
- 3. Instruct the patient not to drive or operate potentially dangerous equipment while taking Librium/ Chlordiazepoxide.

Labs and Other monitoring:

- 1. Initial labs
 - a. CMP, CBC
 - b. Qualitative HCG (if female and at each visit if on medications);
 - c. UDS (and at each visit)
- 2. Follow up labs:
 - a. Routine labs and frequency if labs are within normal limits
 - i. CMP, CBC, qualitative HCG, UDS every three months if client is on naltrexone, for year 1
 - ii. CMP, CBC, qualitative HCG, UDS every six months if client is on naltrexone, for year 2 and following
 - b. Routine labs and frequency if labs are not within normal limits.
 - i. CMP and CBC every month if client is asymptomatic and until each panel is within normal limits, or
 - ii. Check with provider for frequency of labs

Alcohol Detoxification Guideline—Benzodiazepine-Sparing

1. Conduct and document PAWSS—see appendix. A score ≥ 4 suggests that a patient is at risk for a more complicated withdrawal process. Patients with a score ≥ 4 should be encouraged to detox in a hospital or higher acuity setting. However, not all patients are able and/or willing to do so. Document this conversation.

2. Medications

- a. Naltrexone 50mg Take 1/2 tablet the first day and then one tablet by mouth daily AFTER eating #30
- b. Detox and stabilization medication options include valproic acid, gabapentin, and clonidine—see Maldonado's paper above for his algorithm and addition comfort medications.
- c. Folic Acid (Vitamin B9) 1mg Take 1 tablet daily for 14 days (no routine refill)
- d. Thiamine (vitamin B1) 100mg Take 1 tablet daily for 14 days (no routine refill)

A benzodiazepine-sparing protocol for alcohol detox involves the use of non-benzodiazepine agents to manage alcohol withdrawal symptoms. This approach is aimed at reducing the risk of benzodiazepine-related adverse effects such as cognitive impairment and significant neurologic and medical side effects. [1] The following are some of the non-benzodiazepine agents that can be used in a benzodiazepine-sparing protocol for alcohol detox:

Alpha-2 agonists: These agents, such as clonidine and dexmedetomidine, can be used to manage mild to moderate alcohol withdrawal symptoms.

Example protocol #1 in which guanfacine is substituted for clonidine (in addition to comfort meds):

- Folic Acid (Vitamin B9) 1mg Take 1 tablet daily for 14 days (no routine refill)
- Thiamine (vitamin B1) 100mg Take 1 tablet daily for 14 days (no routine refill)
- Guanfacine 1mg TID for 3 days THEN
- Guanfacine 1mg BID for 2 days THEN
- Guanfacine 1mg QD for 2 days THEN STOP [2]

Anticonvulsant agents: These agents, such as carbamazepine, valproic acid, and gabapentin, can be used to manage seizures and other alcohol withdrawal symptoms.

Example protocol #2 (in addition to comfort meds, including clonidine):

- Folic Acid (Vitamin B9) 1mg Take 1 tablet daily for 14 days (no routine refill)
- Thiamine (vitamin B1) 100mg Take 1 tablet daily for 14 days (no routine refill)
- Gabapentin 1200mg loading dose once THEN
- Gabapentin 800mg TID for days 1-3 THEN
- Gabapentin 600mg TID for days 4-5 THEN
- Gabapentin 300mg TID for days 6-7 THEN STOP [2]

Example protocol #3 (in addition to comfort meds, including clonidine):

- Folic Acid (Vitamin B9) 1mg Take 1 tablet daily for 14 days (no routine refill)
- Thiamine (vitamin B1) 100mg Take 1 tablet daily for 14 days (no routine refill)
- Carbamazepine 800 mg (day 1)
- Carbamazepine 800 mg (day 2)
- Carbamazepine 600 mg (day 3)
- Carbamazepine 400 mg (day 4)
- Carbamazepine 200 mg (day 5) [3]

It's important to note that the choice of medication and dosing should be tailored to the individual patient's needs and monitored closely to ensure safety and efficacy. Additionally, a benzodiazepine-sparing protocol should be implemented in conjunction with supportive care, such as hydration and nutrition, and behavioral interventions, such as counseling and social support. ¹¹ ¹² ¹³ ¹⁴

Labs and Other monitoring;

- 1. Initial labs
 - a. CMP, CBC
 - b. Qualitative HCG (for a person with a uterus and at each visit if on medications);
 - c. UDS (and at each visit)
- 2. Follow up labs:
 - a. Routine labs and frequency if labs are within normal limits
 - i. CMP, CBC, qualitative HCG, UDS every three months if client is on naltrexone, for year 1
 - ii. CMP, CBC, qualitative HCG, UDS every six months if client is on naltrexone, for year 2 and following
 - b. Routine labs and frequency if labs are not within normal limits.
 - i. CMP and CBC every month if client is asymptomatic and until each panel is within normal limits, or
 - ii. Check with provider for frequency of labs

503% 20Benzodiazepine% 20Sparing% 20Alcohol% 20Withdrawal% 20Protocol% 20101119.pdf

¹¹ https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2789264

¹² https://sheriff.deschutes.org/SO-

¹³ https://www.aafp.org/pubs/afp/issues/2004/0315/p1443.html

¹⁴ Maldonado JR. Novel Algorithms for the Prophylaxis and Management of Alcohol Withdrawal Syndromes-Beyond Benzodiazepines. Crit Care Clin. 2017 Jul;33(3):559-599. doi: 10.1016/j.ccc.2017.03.012. PMID: 28601135

Medications for Maintenance/Chronic Care for Patients with Alcohol Use Disorder

- 1. Naltrexone
 - a. Extended-release injectable (brand name, Vivitrol)
 - b. Oral tablet
- 2. Acamprosate (brand name, Campral)
- 3. Disulfiram (brand name, Antabuse)

When comparing treatments for chronic alcohol use disorder (AUD), it's important to consider a combination of medical treatments and behavioral therapies. ¹⁵ ¹⁶ ¹⁷ Here are some key points to consider:

1. Medications

- a. Naltrexone: Reduces alcohol consumption and increases abstinence rates.
 - i. Oral naltrexone. Dose: 50-100 mg by mouth per day. Many patients have better outcomes with the 100 mg/day dose
 - ii. Extended-release naltrexone. Dose 380 mg deep IM gluteal injection every 4 weeks. Alternate buttocks for each subsequent injection. Consider also prescribing a 30-day supply of oral naltrexone for breakthrough cravings at the end of a cycle or during times of additional cravings.
- b. Acamprosate: Reduces alcohol consumption and increases abstinence rates, although the effects may be modest. This is a good alternative to naltrexone if a patient has severe liver dysfunction.
 - i. Dose: two 666 mg tablets three times a day. Encourage patient to use a pill organizer and alarms to enhance adherence.
- c. Disulfiram: Creates an unpleasant reaction when alcohol is consumed, acting as a deterrent to drinking.
 - i. Initial oral dosing 500 mg daily for two weeks
 - ii. Subsequent dosing 250 mg or 500 mg to deter patient from alcohol use

2. Behavioral Therapies:

- a. Brief Behavioral Interventions: Provide education and support to help individuals reduce their alcohol use.
- b. Support Programs: Participation in support groups such as Alcoholics Anonymous (AA) and Smart Recovery can be helpful for ongoing recovery.
- c. Individual and Group Therapy: Therapy sessions can address underlying psychological factors contributing to alcohol use and provide coping strategies.

¹⁵ SAMHSA, TIP 49: Incorporating Alcohol Pharmacotherapies Into Medical Practice, https://store.samhsa.gov/product/TIP-49-Incorporating-Alcohol-Pharmacotherapies-Medical-Practice/SMA13-4380

¹⁶ NIH, Alcohol's Effects on Health, https://www.niaaa.nih.gov/publications/brochures-and-fact-sheets/treatment-alcohol-problems-finding-and-getting-help

¹⁷ AFP, Medications for Alcohol Use Disorder, https://www.aafp.org/pubs/afp/issues/2016/0315/p457.html

- 3. Residential Treatment: In some cases, individuals with severe AUD may benefit from intensive treatment in a residential rehab center. These programs offer structured behavioral therapies and may include medical treatment for alcohol withdrawal.
- 4. Personalized Treatment: There is no one-size-fits-all solution for treating chronic alcohol use disorder. Treatment plans should be tailored to the individual's needs, preferences, and coexisting mental health conditions.

Patient Education: Alcohol Withdrawal Treatment (Providers are encouraged to modify the following text to education patients and loved ones)

Understanding Alcohol Withdrawal: Alcohol withdrawal occurs when you stop or significantly reduce your alcohol consumption after a period of heavy drinking. It can lead to a range of physical and psychological symptoms as your body adjusts to the absence of alcohol. It is important to seek medical attention to manage withdrawal safely and minimize potential risks.

Medical Supervision is Essential: Alcohol withdrawal can be unpredictable and, in some cases, dangerous. It is crucial to undergo withdrawal treatment under the guidance of a healthcare professional. This ensures your safety and helps prevent complications.

Treatment Approach:

Patient instructions:

- Instruct the patient to have someone at home with them for at least the first 3 days of this process. The companion can assist in medication reminders.
- Instruct the patient not to take more than the prescribed medication unless authorized. If you have any questions or concerns, instruct the patient to contact ARCA Medical Staff
- Instruct the patient not to drive or operate potentially dangerous equipment during the first 3 days of the protocol.
- Assessment: A healthcare provider will assess your symptoms, medical history, and overall health to determine the severity of your withdrawal. This helps tailor a suitable treatment plan.
- Medication: In some cases, medications like benzodiazepines may be prescribed to alleviate withdrawal symptoms. These medications are carefully monitored to prevent overuse or dependence.
- Hydration and Nutrition: Staying hydrated and maintaining proper nutrition is vital
 during withdrawal. Dehydration and nutrient imbalances can worsen symptoms. Aim to
 maintain urine that is pale, odorless, and plentiful. This is the best indicator of adequate
 hydration.
- Vitamin Supplementation: Thiamine (Vitamin B1) supplementation may be recommended to prevent complications from alcohol-related malnutrition.
- Monitoring: Healthcare professionals will closely monitor your symptoms, vital signs, and overall progress to adjust your treatment plan as needed. If you are going through withdrawal at home, you will need a support person to help monitor you for the first 4 days.
- Supportive Care: Emotional support is crucial during withdrawal.

 Possible Complications: Withdrawal can sometimes lead to severe symptoms like seizures, delirium tremens, or cardiac issues. Seeking medical care reduces these risks and ensures prompt intervention if complications arise.

Follow-Up Care: After completing withdrawal treatment, it's important to follow up with your healthcare provider. They will assess your progress, discuss ongoing care, and provide recommendations to maintain your sobriety.

Follow Up Appointments:

Medications Prescribed:

Seek Emergency Care for the following symptoms:

- Intense agitation, severe confusion, hallucinations (visual or auditory), or severe tremors (shakes)
- Seizures
- Delirium Tremens (DTs): Delirium tremens is a severe form of alcohol withdrawal characterized by rapid heart rate, high fever, severe confusion, agitation, and hallucinations.
- Chest Pain or Irregular Heartbeat
- Severe Vomiting or Diarrhea
- Signs of Dehydration
- Worsening Symptoms: If alcohol withdrawal symptoms are getting progressively worse rather than improving, it is a sign that medical intervention may be necessary.

Sinclair Method

The Sinclair Method is a medication-assisted, evidence-based form of treatment for alcohol use disorder (AUD) that focuses on reducing use rather than maintaining complete abstinence. ¹⁸ It was developed by Dr. John D. Sinclair and involves taking the prescription medication naltrexone one to two hours prior to drinking alcohol. Unlike traditional treatments that require complete abstinence from alcohol, the Sinclair Method allows individuals to continue drinking alcohol at the beginning of treatment. ¹⁹ The medication works by blocking the opioid receptors in the brain that are responsible for the pleasurable effects of alcohol, which can help reduce the desire to drink. Over time, consistent use of naltrexone before drinking can lead to "extinction," where an individual loses the desire to drink entirely. ²⁰

The Sinclair Method can be used to cut down risky alcohol use. It can also be used for individuals who may not want to or are not ready to cut out alcohol entirely, but they may want to drink less.

More information on implementing the Sinclair method are in the references cited in the footnotes.

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¹⁸ https://www.sinclairmethod.org/what-is-the-sinclair-method-2/

¹⁹ https://www.verywellmind.com/the-sinclair-method-for-alcohol-addiction-recovery-7376184

²⁰ https://pubmed.ncbi.nlm.nih.gov/11386491/

Harm Reduction in Benzodiazepine Prescribing

Adapted from SAMHSA-HRSA Center for Integrated Health Solutions, Safe & Effective Use of Benzodiazepines in Clinical Practice, May 31, 2017 https://www.integration.samhsa.gov/

- 1. Generally agreed upon indications in psychiatry
 - a. Anxiety: acute and chronic (especially PD, GAD, SAD)
 - b. Acute insomnia
 - c. Acute agitation particularly in mania and psychosis
 - d. Alcohol withdrawal
 - e. Akathisia
 - f. Catatonia
 - g. Co-prescription during initiation phase of antidepressant in PD and GAD
 - h. Tremor
- 2. Disputed indications in psychiatry
 - a. Acute stress disorder
 - b. Posttraumatic stress disorder
 - c. Chronic insomnia
- 3. Relative Contraindications ²¹
 - a. Patients 65 years and older
 - b. Current substance use disorder
 - c. History of substance use disorder
 - d. Borderline Personality Disorder
 - e. Co-prescription of opiate pain medications (especially methadone and BUP/Ntx)
 - f. Clients with recent suicidal ideation and/or poor impulse control
 - g. Active use of alcohol with unreliable reports about use and increasing requests for meds, unless benzodiazepines is a component of a prescribes alcohol withdrawal guideline
- 4. Documentation standards when prescribing benzodiazepines
 - a. Documentation of a clear rational for indications, balance of indications and contraindications
 - b. Indications for *short term use* of benzodiazepines should be documented, including a timeframe for review. Follow up is necessary and includes any indications of dependence or need for a discontinuation taper.
 - c. Indications for *long term use* of benzodiazepines should be documented, including use of (or consideration of) alternative interventions. Stability of dosing should be noted along with any indications of dependence or need for a discontinuation taper.
 - d. As needed/PRN dosing should be used judiciously.
 - e. Recommendations for combined psychopharmacology treatment with psychosocial interventions to manage anxiety, distress tolerance, insomnia and drug seeking

 $^{{}^{21}\,\}underline{https://www.samhsa.gov/data/sites/default/files/DAWN-SR192-BenzoCombos-2014/DAWN-SR192-BenzoCombos-2014.pdf}$

behavior. These include Motivational Interviewing, Cognitive Behavioral Strategies and Mindfulness techniques.

5. Prescribing guidelines ²²

- a. For new patients reporting prior prescription treatment with benzodiazepines and requesting continuation
 - i. Obtain medical records from previous prescriber
 - ii. Check the PDMP's of the state in which the patient resides for flags or other concerns
 - iii. Inquire with pharmacy if they are flagged as inappropriately drug seeking
 - iv. Inquire with patient if they had been receiving benzodiazepines from more than one prescriber and/or telling him that more than one pharmacy in prior 12 months
- b. For current patient requesting new start for benzodiazepines
 - i. Inquire with patient if they had been receiving benzodiazepines from any other prescribers
 - ii. Check the PDMP's of the state in which the patient resides for flags or other concerns
- c. Safest and most effective utilization of benzodiazepines: Benzodiazepines are most effective and safe when used for limited time and or on an intermittent PRN basis. When used as a standing daily dose indefinitely they will become ineffective for a substantial portion of patients. Review of available recommendations reveals consensus expert opinion that long-term treatment with benzodiazepines should: be at the lowest effective dose possible; involve regular patient review, usually monthly; involve regular attempts to reduce or stop treatment when conditions allow; ensure adequate patient education on risks of long-term use and documentation of same; where feasible, allow for prescription by a single designated practice/GP and dispensing by a single designated pharmacy; and consider phased dispensing (for example, <1 week supply at a time). ²³ Examples of clinically appropriate uses:
 - i. Time-limited for acute situational anxiety such as death of a loved one. Instruct the patient only to use the benzodiazepine as an intermittent PRN basis and not as a standing daily dose. Instruct the patient that the medication will not be continued indefinitely and set a time in the future by which you expect the medication to be discontinued of no more than three months
 - ii. Ongoing intermittent PRN usage. Intermittent PRN usage avoids development of tolerance and reinforces self-management of anxiety and worry. It is important to instruct patients that the medication is more effective if used intermittently and tends to become ineffective if taken as an ongoing daily dose. Example of this type of prescribing is clonazepam 0.5mg, #10/month
- d. The following examples are first line treatments for anxiety. ²⁴

²² Edinoff AN, Nix CA, Hollier J, Sagrera CE, Delacroix BM, Abubakar T, Cornett EM, Kaye AM, Kaye AD. Benzodiazepines: Uses, Dangers, and Clinical Considerations. Neurol Int. 2021 Nov 10;13(4):594-607. doi: 10.3390/neurolint13040059. PMID: 34842811; PMCID: PMC8629021.

Kennedy KM, O'Riordan J. Prescribing benzodiazepines in general practice. Br J Gen Pract. 2019
 Mar;69(680):152-153. doi: 10.3399/bjgp19X701753. PMID: 30819759; PMCID: PMC6400612.
 Bandelow B, Michaelis S, Wedekind D. Treatment of anxiety disorders. Dialogues Clin Neurosci. 2017

Jun;19(2):93-107. doi: 10.31887/DCNS.2017.19.2/bbandelow. PMID: 28867934; PMCID: PMC5573566.

- i. Higher-dose SSRIs, e.g.,
 - 1. Prozac 40 to 60 mg
 - 2. Celexa 40 to 60 mg
- ii. Low dose propranolol (20-40mg twice daily) for blocking autonomic symptoms of anxiety such as sweating, palpitations, tremulous
- iii. Buspirone, with the target dose of 60 mg daily
- iv. Hydroxyzine, up to 100 mg three times daily
- v. Reduction/Elimination of caffeine
- vi. Increase of physical activity—"feeling anxious as a reminder that it's time to take a walk"

Benzodiazepine Detoxification and Treatment

Resources from the Veterans Administration, Helping Patients Taper from Benzodiazepines ²⁵

Benzodiazepine Taper Example—moderate to high dose benzodiazepine

(emphasis of *slow* taper)

Week	Clonazepam	Clonazepam	Clonidine (0.1	Gabapentin (300 mg) *
	Dose (in	Frequency*	mg dose) *	or
	mg)			Tegretol/carbamazepine
				(400 orally)
1	1	4x daily	1 2x daily	1 2x daily
2	1	4x daily	1 2x daily	1 2x daily
3	1	3x daily	1 2x daily	1 2x daily
4	1	3x daily	1 2x daily	1 2x daily
5	1	2x daily	1 2x daily	1 2x daily
6	1	2x daily	1 2x daily	1 2x daily
7	0.5	2x daily	1 2x daily	1 2x daily
8	0.5	2x daily	1 2x daily	1 2x daily
9	0.5	1 daily	1 2x daily	1 2x daily
10	0.5	1 daily as needed	1 2x daily	1 2x daily
		for anxiety	-	-
11	0	0	1 daily	1 daily
12	0	0	0	0

^{*}Scheduled

Continue Baclofen or cyclobenzaprine as needed for muscular cramping for as long as needed

 $^{{}^{25}\,\}underline{https://www.va.gov/painmanagement/docs/OSI_6_Toolkit_Taper_Benzodiazepines_Clinicians.pdf}$

Cannabis Toxicity

Signs of cannabis toxicity include: ²⁶ ²⁷

- 1. Nausea and vomiting
- 2. Anxiety and paranoia
- 3. Hallucinations
- 4. Dizziness and confusion
- 5. Increased heart rate

Other symptoms may include dry mouth, impaired perception and motor skills, red eyes, and decreased short-term memory. It is important to note that the severity and combination of these symptoms can vary from person to person and depend on factors such as the amount and strength of marijuana used.

²⁶ Turner AR, Spurling BC, Agrawal S. Marijuana Toxicity. [Updated 2023 Jul 31]. In: StatPearls [Internet]. Treasure Island (FL): StatPearls Publishing; 2023 Jan-. Available from: https://www.ncbi.nlm.nih.gov/books/NBK430823/

²⁷ Marijuana intoxication, https://www.mountsinai.org/health-library/diseases-conditions/marijuana-intoxication

Cannabis Treatment

Currently, there are no FDA-approved medications for the treatment of cannabis use disorder. ²⁸ However, some medications have shown promise in early studies or small clinical trials. These medications include:

Buspirone: This is the only medication to date that has shown efficacy for cannabis dependence in a controlled clinical trial. (Doses of up to 60 mg daily). ²⁹

Zolpidem: This sleep aid has shown promise in reducing marijuana withdrawal symptoms. (Dose of 12.5 mg) ³⁰

Bupropion: This medication has demonstrated anticraving properties for some patients. (Doses between 150 mg and 450 mg daily). ^{31 32}

Topiramate: This medication has shown preliminary efficacy in treating cannabis use disorder. (Doses titrated to 200 mg daily over four weeks then stabilized for two weeks) ³³ ³⁴

N-acetylcysteine: This medication has been used to decrease quantity and frequency of use. (Dosed at 1200 mg twice daily). ³⁵ ³⁶

²⁸ NIDA. 2021, April 13. Available Treatments for Marijuana Use Disorders. Retrieved from https://nida.nih.gov/publications/research-reports/marijuana/available-treatments-marijuana-use-disorders on 2023, September 4

²⁹ Weinstein AM, Gorelick DA. Pharmacological treatment of cannabis dependence. Curr Pharm Des. 2011;17(14):1351-8. doi: 10.2174/138161211796150846. PMID: 21524266; PMCID: PMC3171994.

³⁰ Sleep disturbance and the effects of extended-release zolpidem during cannabis withdrawal https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3119729/

³¹ Weinstein AM, Gorelick DA. Pharmacological treatment of cannabis dependence. Curr Pharm Des. 2011;17(14):1351-8. doi: 10.2174/138161211796150846. PMID: 21524266; PMCID: PMC3171994.

³² Cannabis and the Current State of Treatment for Cannabis Use Disorder https://focus.psychiatryonline.org/doi/10.1176/appi.focus.20180038

³³ Cannabis and the Current State of Treatment for Cannabis Use Disorder https://focus.psychiatryonline.org/doi/10.1176/appi.focus.20180038

³⁴ Topiramate and Motivational Enhancement Therapy for Cannabis Use among Youth: A Randomized Placebo-Controlled Pilot Study https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4940362/

³⁵ Tomko RL, Jones JL, Gilmore AK, Brady KT, Back SE, Gray KM. N-acetylcysteine: A potential treatment for substance use disorders. Curr Psychiatr. 2018 Jun;17(6):30-36, 41-42, 55. PMID: 30016376; PMCID: PMC5993450.

³⁶ https://psychnews.psychiatryonline.org/doi/full/10.1176/appi.pn.2019.6b18

Kratom:

The treatment of kratom addiction and withdrawal can vary depending on the severity of the addiction and individual needs. In general, kratom detoxification is managed similar to opioid detoxification.

- 1. Medical detox: This approach involves gradually tapering kratom from the body with FDA-approved medications. ^{37 38 39}
- 2. Medication-Assisted Treatment (MAT): MAT involves the use of FDA-approved medications, such as buprenorphine or methadone, along with counseling and behavioral therapies. While these medications are typically used for opioid addiction, they may also be considered for kratom addiction.
- 3. Supportive care: This includes providing supportive measures to manage withdrawal symptoms and addressing any physical or psychological complications that may arise during the detoxification process. Supportive care may involve the use of over-the-counter medications to manage symptoms such as diarrhea, nausea, and muscle aches.
- 4. Behavioral therapies: Counseling and behavioral therapies can be beneficial in addressing the psychological aspects of addiction and helping individuals develop coping strategies and relapse prevention skills. Cognitive-behavioral therapy (CBT) and contingency management are examples of evidence-based therapies that may be used.

³⁷ Psychiatr Clin N Am 45 (2022) 415–430 https://doi.org/10.1016/j.psc.2022.04.002 psych.theclinics.com 0193-953X/22

³⁸ Weiss, Stephanie, MD, PhD, Douglas, Heather. Treatment of Kratom Withdrawal and Dependence With Buprenorphine/Naloxone: A Case Series and Systematic Literature Review. J Addict Med. 2021;15(2):167-172. doi:10.1097/ADM.000000000000000121.

³⁹ How to Recognize and Treat Kratom Addiction, https://www.healthline.com/health/addiction/kratom-addiction

Home Induction for buprenorphine/naltrexone (BUP/NTX): Patient Instructions

1. **Buprenorphine/Naltrexone** (**BUP/Ntx**): 8mg/2mg generic tablets or films (preferred form of medication depends on formulary.

When starting medication with the standard or high dose protocol, you must wait until you are in active withdrawal. On a scale of 1-10, you want your withdrawal symptoms to be at a 7-8. You should have physical symptoms such as diarrhea, sweating, and/or shaking. This will not occur until 24 hours after the last use of opioids but often will take 72 hours or longer.

2. Induction

- a. Standard protocol Start by taking 1/4 of a film/tablet (2/0.5 mg) under your tongue. Wait 30 mins, and then take another 1/4 of a film/tablet. Continue this 4 times until you have taken a full 8/2 mg film/tablet. IF you take the first 1/4 of a film and are feeling worse, DO NOT take any more. This means you are not far enough along in your withdrawal process, and you need to go back to hydration and comfort medication to put time between your last opioid use. Once you are further along in the withdrawal process you can try to start the BUP/NTX again.
- b. High dose protocol you will start with two of the 8/2 mg films/tablets under your tongue (a total of 16/4 mg.) If you feel that your withdrawal is the same or worse after 30 minutes you may take an additional 8/2 mg film or tablet one time. If severe withdrawal symptoms persist you should call ARCA.
- c. Low dose protocol/microdosing -this will consist of a small dose of BUP/NTX that increases every day. You will continue to use your current opioid at a stable dose while the titration is being done. The opioid should remain at the usual dose you used prior to starting BUP/NTX until your BUP/NTX dose is at least 12/3 mg per day.

3. Custom Dose

- a. Check with provider for schedule, rationale, and documentation needs BUP/NTX 8mg/2mg tabs/films
- b. If you have used fentanyl or other high-potency opioids, you may require a minimum maintenance dose of BUP/NTX 8/2 mg tab/film BID. TID doses are not unusual.
- c. Zubsolv Dosing
 - i. 1.4 mg buprenorphine with 0.36 mg naloxone is equivalent to 2mg BUP/Ntx (1/4 strip)
 - ii. 5.7 mg buprenorphine with 1.4 mg naloxone is equivalent to 8mg/2mg BUP/Ntx (1 strip)

4. Labs and Other monitoring;

- a. Initial labs;
 - i. CMP, CBC

- ii. Qualitative HCG (for person with a uterus and at each visit);
- iii. UDS (and at each visit)
- b. Consider a screening for HIV and hepatitis.
- c. Follow up labs:
 - i. If initial labs are within normal labs, providers do not routinely repeat labs in less than a year.
 - ii. If a patient had abnormal results found on initial labs, they should be referred to their primary care provider (PCP). If a patient does not a PCP they should be given resources to help find one

Additional Dosing Instructions: Outpatient Macrodosing 40 41

1. Initial BUP/Ntx dose on induction

- a. Dose will be tailored to the patient's clinical picture.
- b. Patients with severe OUD who are using Fentanyl may require higher doses for induction—16/4 mg 24/6 mg daily is a recommended dose.
- c. Initial and maintenance dosing depend on several client use factors
 - i. Avoid underdosing on both induction and maintenance dose. Underdosed clients are at increased risk of return to use and overdose.
 - ii. Types of opioids (e.g., prescription pills require a lower dose)
 - iii. Quantity of opioids
 - iv. Other addictive substances used routinely or episodically
 - v. Age of onset of use of addictive substances
- d. The combination product is preferred over the mono buprenorphine product; however, recent research indicates that the naloxone component in the combined product may not offer the protection previously thought.⁴²

2. Maintenance dose

- a. While it is best to maintain a client on the lowest effective dose of any therapeutic agent, be mindful, particularly in the first year of maintenance, that clients will have good days and bad days, higher craving days, and changes in their lives. This is a normal part of the recovery process.
- b. Avoid under-dosing maintenance dose.
- c. Consider some creative dosing in prescriptions, for example
 - i. Write prescriptions and instruct clients to allow for an extra 5-10 days of 4 mg BUP/Ntx
 - ii. Discuss other medications and/or non-medication tools to help on higher craving days
- d. Accountability structures
 - i. Explain at each visit that accountability structures are ways to promote client safety—they are not punishments
 - ii. UDS's and PDMP alerts are objective data that facilitate the best plan to keep the patient safe and in treatment.
 - 1. Positive UDS's and PDMP alerts should be followed by a question— What's going on?
 - iii. Using more than one illicit substance and return to use are parts of the recovery process—expect bumps along the way and work with your client to develop new/more effective coping skills
 - iv. Explore options with each community partner to promote accountabilityoriented communications. For example, staff can develop guidelines for

⁴⁰ https://www.samhsa.gov/sites/default/files/quick-start-guide.pdf

⁴¹ https://oasas.ny.gov/system/files/documents/2022/07/low-high-dose-buprenorphine-initiation.pdf

⁴² Blazes CK, Morrow JD. Reconsidering the Usefulness of Adding Naloxone to Buprenorphine. Front Psychiatry. 2020 Sep 11;11:549272. doi: 10.3389/fpsyt.2020.549272. PMID: 33061915; PMCID: PMC7517938. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7517938/

phone calls, texting, and communications with clients to promote trust and relationship building. For example,

- 1. Routine calls: "How are you doing" calls
- 2. Calls for appointment reminders

Additional Dosing Instructions: Outpatient low dose buprenorphine induction (aka, microdosing) schedule for buprenorphine-naloxone, The Bernese Method

This method has been particularly useful with patients using synthetic opioids such as fentanyl who are not able to tolerate inductions that require a period of withdrawal. This includes patients who have chronic or acute pain and patients who have had significant trauma related to precipitated withdrawal.

It is especially important that the full opioid agonist is continued until day 7 without attempting to wean. It can be stopped on the 7^{th} day without a wean.

Low Dose instructions: 43 44

- 1. Doses below use BUP/Ntx, 2 mg strips
- 2. Utilize comfort medications as listed above

Doses using BUP/Ntx, 2 mg strips

Day 1: 0.5 mg once a day

Day 2: 0.5 mg twice a day

Day 3: 1 mg twice a day

Day 4: 2 mg twice a day

Day 5: 3 mg twice a day

Day 6: 4 mg twice a day

Day 7: 12 mg (stop other opioids)

⁴³ Privia A. Randhawa BScH MPH, Rupinder Brar MD and Seonaid Nolan MD. Canadian Medical Association Journal, 2020-01-20, Volume 192, Issue 3, Pages E73-E73

⁴⁴ Hämmig R., Kemter A., Strasser J., et. al.: Use of microdoses for induction of buprenorphine treatment with overlapping full opioid agonist use: the Bernese method. Subst Abuse Rehabil 2016; 7: pp. 99-105.

Dosing Schedule (ARCA Routine BUP/Ntx Dosing Schedule)¹

(Assuming client is doing well, has no new complaints, does not need to see the provider, is taking BUP/Ntx, and has negative UDS).

Based on positive drug screens for controlled substances, the client may be taken back to any previous month in the guideline, or the client may be restarted at Week #1

Month	Week	Visit	Prescription	Refill?
1	1	Prescribing Provider	8 days	Three refills available, but must be authorized by RN or trained staff ²
	2	RN or trained staff	RN or trained staff authorizes refill ³	
	3	RN or trained staff	RN or trained staff authorizes refill	
	4	RN or trained staff	RN or trained staff authorizes refill	
2	1	Prescribing Provider	15 days ⁴	One refill available, but must be authorized by RN or trained staff
	3	RN or trained staff	RN or trained staff authorizes refill	No
3	1	Prescribing Provider	30 days (if 16 mg or less) ⁵	No

^{*}Defined here as a 4-week block

Notes:

- 1. If a prescribing provider deviates from this process, he/she must document medical decision-making in the encounter.
- 2. The prescribing provider indicates if follow-up checks and prescription authorization visits are in-person or via telephone.
- 3. RN or trained staff completes Staff Check-in Sheet for Patients on BUP/Ntx form (TBD)
- 4. If a client is on more than 16 mg of BUP/Ntx, refills can only be called in for 2 weeks supply. Scripts may be written for a 2-week supply with one refill, but the nurse must call the pharmacy to authorize the refill.
- 5. Provider decides with RN or trained staff at agency site if the client has demonstrated behaviors and treatment adherence that allow a complete 30-day prescription fill.

Additional Dosing Instructions

- 1. Initial BUP/Ntx dose on induction
 - a. Many of our client do well starting on 4-8 mg, most do well at 8mg
 - b. However, many of our clients need higher doses for induction—sometimes up 16 mg, rarely up to 24 mgs.
 - c. Initial and maintenance dosing depend on several client use factors. Avoid underdosing on both induction and maintenance dose. Under-dosed clients are at increased risk of overdose. (Severity of factors below suggest higher induction dose and maintenance dose)
 - i. Types of opioids
 - ii. Quantity of opioids
 - iii. Other addictive substances used routinely or episodically
 - iv. Age of onset of use of addictive substances

2. Maintenance dose

- a. While it is best to maintain a client on the lowest effective dose of any therapeutic agent, be mindful, particularly in the first year of maintenance, that clients will have good days and bad days, higher craving days, and changes in their lives. This is a normal part of the recovery process
 - i. Avoid under-dosing maintenance dose.
 - ii. Consider some creative dosing in prescriptions, for example
 - 1. Write prescriptions and instruct clients to allow for an extra 5-10 days of 4 mg BUP/Ntx
 - 2. Discuss other medications and/or non-medication tools to help on higher craving days

3. Accountability structures

- a. Explain initially, and frequently, that accountability structures are ways to promote client safety—they are not punishments
- b. UDS's and PDMP alerts are conversation starters, not sledgehammers.
 - i. Positive UDS's and PDMP alerts should be followed by a question—*What's going on?*
 - ii. Polysubstance use and relapse are parts of the recovery process—expect bumps along the way and work with your client to develop new/more effective coping skills
- c. Explore options with each community partner to promote accountability-oriented communications. These include
 - i. Staff can count BUP/Ntx wrappers since last visit
 - ii. Staff can develop guidelines for phone calls, texting, and communications with clients to promote trust and relationship building. For example,
 - 1. Routine calls: "How are you doing" calls
 - 2. Calls for appointment reminders

4. BUP/Ntx tapering

- a. Tapering and discontinuing BUP/Ntx for a client who wants BUP/Ntx maintenance and is responding well to BUP/Ntx therapy is not a recommended treatment priority.
- b. When a client responds well to a therapeutic dose of BUP/Ntx, the therapeutic goal is

- i. Patient's ongoing engagement in treatment
- ii. Patient utilization of resources to stabilize his/her life—including appropriate therapy, utilizing of agency and partner resources
- iii. Time on BUP/Ntx therapy to allow the client's neurological system to heal/repair
- c. If anyone on the treatment team becomes aware that a client wants to discontinue BUP/Ntx, inform the prescribing provider and the RN or staff member coordinating the client's care.
 - Explicitly share risks associated with BUP/Ntx discontinuation, including 50-90% relapse,
 - https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4382404/
 - ii. Ask the client for reasons why the client wants to discontinue treatment
 - 1. Is it the client's choice, or is the client receiving pressure from an external source, e.g., family member, loved one, criminal justice system?
 - 2. What isn't working with the current treatment plan?
 - 3. Assess for under-dosing
- d. If the client still wants to discontinue BUP/Ntx,
 - i. Encourage a slow taper and use of Vivitrol or another agent
 - ii. Encourage continued participation in other elements of the treatment plan and other agency programs

Sublocade (buprenorphine extended release) 45

- 1. Indications and patient selection
 - a. SUBLOCADE is indicated for the treatment of moderate to severe OUD in patients who have initiated treatment with a transmucosal buprenorphine-containing product, followed by dose adjustment for a minimum of 7 days
 - b. Patients appropriate for SUBLOCADE are adults who have initiated treatment on a tr ansmucosal buprenorphine containing product delivering the equivalent of 8 to 24 mg of BUP daily
- 2. Recommended dosing
 - a. The recommended dose of SUBLOCADE following induction and dose adjustment with transmucosal buprenorphine is 300 mg monthly for the first two mon ths followed by a maintenance dose of 100 mg monthly. A follow-up dose of 300 mg/month is also acceptable, particularly for patients on very high opioid doses prior to BUP and Sublocade induction.
 - b. A patient who misses a dose should receive the next dose as soon as possible, with the following dose given no less than 26 days later.
 Occasional delays in dosing up to 2 weeks are not expected to have a clinically significant impact on treatment effect.
- 3. Clinically significant drug interactions
 - a. Benzodiazepines and other CNS depressants
 - b. Serotonergic drugs
 - c. Inhibitors of CYP3A4, e.g., macrolide antibiotics, azole-antifungals, and protease inhibitors
 - d. CYP3A4 inducers, e.g., rifampin, carbamazepine, phenytoin, phenobarbital
 - e. Antiretrovirals
 - i. NNRTI's
 - ii. Protease inhibitors
 - iii. NRTI's
 - iv. MAOI's
 - f. Muscle relaxants
 - g. Diuretics
 - h. Anticholinergics

⁴⁵ https://www.sublocade.com/

Policy for Administration of Sublocade at ARCA (1430 Olive location):

- 1. Purpose: This policy provides intermediate guidelines for the safe and effective administration of Sublocade, a medication used for the treatment of opioid use disorder.
- 2. **Scope:** This policy applies to all healthcare professionals involved in the administration of Sublocade, including physicians, advanced practice nurses, nurses, and pharmacists.
- 3. **Medication Administration**: Sublocade should only be administered by a healthcare professional who has been trained in the proper administration of the medication.
- 4. **Patient Selection**: Sublocade is indicated for the treatment of opioid use disorder in adult patients who have initiated treatment with a transmucosal buprenorphine-containing product and who have demonstrated treatment stability. Patients should be assessed for their suitability for treatment with Sublocade before therapy starts.
- 5. **Dosage and Administration**: Sublocade should be administered once every 4 weeks as a subcutaneous injection in the abdominal area. The dose of Sublocade should be individualized based on the patient's opioid use disorder history and current treatment status
- 6. **Monitoring:** Patients receiving Sublocade should be monitored for potential adverse reactions, including injection site reactions and opioid withdrawal symptoms. Patients should also be monitored for the potential for opioid overdose and for signs of medication diversion or abuse.
- 7. **Documentation**: All administration of Sublocade should be documented in the patient's medical record, including the date and time of administration, the dose, the site of injection, and any adverse reactions or other observations.

Procedure for Administration of Sublocade:

- 8. All SORDA, CSTAR-DA or MAT-PDOA clients are eligible to receive Sublocade. Order medication as typical with any other medication. (Sublocade order must be sent to Genoa pharmacy.)
- 9. **Missouri Medicaid** covers Sublocade. **Private insurance** patients will be case-by-case, and coverage must be ascertained before receiving the medicine.

10. Order the Medication from Genoa Pharmacy:

- a. Contact the pharmacy to place an order: Providers should e-prescribe the preferred Sublocade dose at least one week ahead of the administration visit so Genoa can be assured it will be in stock. Genoa will try to keep two injections at each strength (300 mg/1.5 ml and 100 mg) in stock on reserve, but this is not guaranteed. The provider can then schedule an RN visit or f/u provider visit for the day the patient is to receive the Sublocade.
- b. Prescribing provider MUST have an active DEA license registered at ARCA Olive for the medication to be dispensed from Genoa and given at ARCA/Olive. Sublocade may not be administered at other sites (including ARCA/West County and partner agencies.)
- c. **Schedule a pickup:** The nurse schedules a pickup time with the pharmacy.

- 11. **Prepare the Medication**: Prior to administration, the healthcare professional should verify the medication, the dose, and the expiration date. The Sublocade should be stored in a refrigerator at Genoa and administered at room temperature. Do not open the product package until the patient is in person and prepared to receive the injection.
- 12. **Obtain or Confirm Consent**: The healthcare professional should obtain informed consent from the patient prior to administering the medication. The patient should be informed of the potential benefits and risks associated with Sublocade treatment.
- 13. Labs obtained prior to Administration: Point of Care UDS and urine pregnancy
- 14. **Administer the Medication**: The healthcare professional should administer the Sublocade as a subcutaneous injection in the abdominal area as discussed in training and as illustrated in the product insert, avoiding areas near major nerves or blood vessels.
- 15. **Monitor the Patient**: Following administration, the healthcare professional should monitor the patient for 15 minutes for potential adverse reactions, including injection site reactions and opioid withdrawal symptoms. The patient should be advised to report any symptoms or concerns to the healthcare professional.
- 16. **Document the Administration**: The healthcare professional should document the administration of Sublocade in the patient's medical record, including the date and time of administration, the dose, the site of injection, and any adverse reactions or other observations.
 - a. **RN Document** The Sublocade log is accessible through RN Document menu, then by selecting the Sublocade Log.
- 17. **Schedule the Next Injection Appointment with the Patient**: Document this appointment per routine. If the next injection will be an RN visit only, the RN should notify the provider so they can put in the order for Sublocade at that time.

Provider Protocol for Sublocade

- 1. **Stabilization:** Candidates for Sublocade should be stabilized on sublingual Buprenorphine at a minimal daily dose of 8 mg for at least 7 days total before beginning Sublocade.
- 2. **Initial Dose:** The initial Sublocade injection will be 300 mg/1.5 ml SQ.
- 3. **Second Dose:** The second Sublocade injection will usually be 300 mg/1.5 ml SQ.
- 4. **Maintenance Dose**: Third dose or thereafter will be 100 mg/0.5 ml SQ monthly.
- 5. **Persistent Opioid Cravings:** There will be some variability in sustained serum levels of Buprenorphine amongst patients who receive Sublocade. Due to this variability, there will be a subset of patients with significant cravings while on Sublocade. To prevent discontinuation of Sublocade and return to use the following strategies can be utilized:
 - a. Providers may prescribe a low dose of additional Buprenorphine (i.e., Suboxone 4/1 mg or 2/0.5 mg) that the patient may take in a PRN or scheduled fashion.
 - b. Patients with persistent significant cravings may be maintained on the higher dose injection (300 mg/1.5 ml SQ monthly.)
 - c. Providers should provide appropriate documentation and have shared decision making with the patient around these off-label options.

- 6. **Dosing Frequency:** Sublocade should be dosed once a month with at least 26 days between doses.
- 7. **Missed Dose:** If a dose is missed, the patient should receive the next dose at the strength of the missed dose as soon as possible. The follow up shot should be scheduled at least 26 days after.
- 8. **Chronic Liver Disease:** Sublocade should be avoided in patients with moderate or severe liver disease (Child-Pugh Class B or C.) Initial labs including CMP, Hepatitis panel and HIV should be obtained at the initial visit for treatment with Sublocade.
- 9. **Pregnancy:** Sublocade is not approved for use during pregnancy, but a prescriber may consider it in very high-risk situations.

Naltrexone Extended Release (Vivitrol) Induction Guideline

Naltrexone safety: Naltrexone and Vivitrol are safe in most patients who have chronic liver disease. The exception is severe liver disease Child Pugh Class C or patients with uncompensated cirrhosis. Patients who have signs and symptoms of acute hepatitis (jaundice, new onset ascites or encephalopathy) should have labs checked prior to starting treatment with Vivitrol but otherwise the shot can be given on the initial visit. ⁴⁶

- 1. On the initial visit, client can be started on oral naltrexone 50mg #30 if there is a question of significant liver disease.
 - a. 1/2tab with food if UDS negative for opiates, BUP/Ntx, and methadone, and the urine qualitative HCG is negative.
 - b. If tolerated take other 1/2 tab in 30 mins, then take 1 tab daily with food.
 - c. CBC, CMP and qualitative HCG (if female) is drawn
- 2. If client's labs are WNL and qualitative HCG is negative, client may receive a Vivitrol injection. (If client's labs are not WNL/negative, check with the medical provider or medical director for additional orders). ⁴⁷
- 3. Patients without a history of severe liver disease and without signs and symptoms of liver disease can begin Vivitrol on the initial visit.
- 4. Initial Vivitrol injection
 - a. All clients receiving Vivitrol must sign a consent with two contacts. The first could be a family member and the second an emergency contact.
 - b. Once this is completed, the client may receive an injection. Vivitrol 380mg #1 Administer deep IM every 4 Weeks. Start if Labs are within normal limits.
 - c. Once Vivitrol is started, client may take Naltrexone 50mg daily as needed for cravings.
 - d. Schedule a return visit for 24-28 days. Schedule this as a provider visit or nurse visit, based on the provider's orders.
- 5. Delayed or missed visits
 - a. If the client does not show up the scheduled day, call the client and remind him/her of the appointment. If you cannot contact the client, and the client has not shown up within a 32-day window, call the family member and if no response within 24 hours, call the emergency contact.
 - b. Window for Vivitrol injections: Vivitrol can be safely administered up to 33 days past the last shot.
 - c. Although the product information states the therapeutic effects last 28 days, the medication lasts longer, especially after the second injection. If there is any concern on the part of the client or clinical staff, a naltrexone tablet can be administered. Give half tablet (25 mg), wait 15 minutes and if the client shows no signs of withdrawal, administer the injection. This procedure can often be utilized up to 35 days even in cases of the client testing positive for opioids.

⁴⁶ Naltrexone for alcohol use disorder: Hepatic safety in patients with and without liver disease, https://aasldpubs.onlinelibrary.wiley.com/doi/epdf/10.1002/hep4.2080

⁴⁷ Monitoring of Liver Function Tests in Patients Receiving Naltrexone or Extended-Release Naltrexone, https://pcssnow.org/wp-content/uploads/2014/10/PCSS-MAT-NTX-Liver-Safety-Guideline1.pdf

- d. If the client comes to the clinics after 35 days or longer, assume the client has relapsed and needs detox. Contact the client's provider or the medical director for orders. The best approach is a short detox using buprenorphine. If the client does not want buprenorphine, other detox guidelines can be utilized.
- e. Under no circumstances should a client on Vivitrol for OUD be sent away without the Vivitrol, direct observed ingestion of oral naltrexone, or opioid detox medswith or without buprenorphine. Contact the client's provider or medical director for orders.
- 6. Labs and Other monitoring;
 - a. Initial labs;
 - i. CMP, CBC
 - ii. Qualitative HCG (for a person with a uterus and at each visit);
 - iii. UDS (and at each visit)
 - b. Consider a screening for HIV and hepatitis.
 - c. Follow up labs:
 - i. If initial labs are within normal labs, providers do not routinely repeat labs in less than a year. Repeat labs every 3-6 months if there is co-occurring liver conditions (e.g., HCV) or a new hepatic-related diagnosis.
 - ii. If a patient had abnormal results found on initial labs, they should be referred to their primary care provider (PCP). If a patient does not a PCP they should be given resources to help find one
- 7. Additional resources on Vivitrol can be found on Alkermes' website 48

⁴⁸ https://www.vivitrolhcp.com/

Processes For Patients on Methadone Therapy at ARCA

When evaluating patients who are on methadone maintenance for OUD, it is important to ensure their safety, continuity of care, and appropriate management of their methadone treatment. Below is a general protocol to consider for patients on methadone maintenance who are seeking care at ARCA:

- 1. Ensure clear communication between the patient's OTP/provider and the ARCA team prior to the patient being enrolled in the Welcome Center. The patient will need to sign an ROI to allow ARCA clinicians to talk to the Opioid Treatment Program (OTP)/OTP. The initial RN should contact the OTP and speak to the head RN to determine if they know the patient is seeking care at ARCA and why.
 - a. West End Clinic 314-381-0560
 - b. Center For Life Solutions 314-731-0100 mainline; Director Zhanna Keeton 314-283-7311
- 2. Patients can be seen at ARCA for mental health care while they are enrolled in the OTP. The OTP needs to be aware that the patient is seen at ARCA. Clinical communication should be provided by the provider after each appointment, and this will need to be faxed to the OTP.
- 3. Patients can NOT receive substance use medication treatment at both the OTP and ARCA. This includes treatment for alcohol use disorder, sedative use disorder and stimulant use disorder.
- 4. Patients who are leaving the OTP and changing to ARCA can get substance use treatment from ARCA. This will be contingent on allowing the ARCA team to contact the OTP prior to the initial appointment.
- 5. Document the patient's methadone dosage, last administration time, and any relevant medical history. This will need to be updated at each ARCA visit.
- 6. Avoid Drug Interactions: Be cautious of potential drug interactions that can affect the metabolism or effectiveness of methadone. Be aware of medications that cause QT prolongation and the risk of additive risk with Methadone. Consult a pharmacist or the methadone provider to assess any potential interactions with other medications being administered.

Guideline for Tapering Buprenorphine

BUP tapering and discontinuation is only done at the client's request. No staff member or contracted provider should coerce or otherwise force a client to taper off BUP for any reason. If a prescribing provider thinks it may be in the client's interest to discontinue BUP, he or she should contact the ARCA Medical Director prior to any change in treatment plan so that options can be reviewed and discussed.

Tapering

If, after weighing the risks of relapse a client chooses to discontinue buprenorphine, the client should do so through a safe, structured guideline. The client should consult with the treatment team to agree upon a longer or a shorter taper based on the client's history and resources. Special planning must be focused on the 5-7 day "BUP/Ntx wash-out period" between the last BUP/Ntx dose and the first Vivitrol injection. The client and the treatment must successfully develop a support and resource plan to mitigate risk of relapse during this period.

Note that the rate of taper has more to do with percent decrease than absolute dose decrease. In other words, it is often easier for clients to go from 14 mg to 12 mg than 6 mg to 4 mg.*

*Doses described on this page were established with the original BUP/Ntx® sublingual tablets and should be adjusted for the formulation you are using.

Guidelines Recommend Longer Tapering

Guidelines on medication-assisted treatment produced by ASAM recommend that tapering and stopping buprenorphine should be achieved slowly, usually over several months, with close monitoring (ASAM, 2015). Furthermore, they recommend that clients remain in treatment for ongoing monitoring, even after buprenorphine is completely discontinued. A long period may be more favorable for clients who would be less willing or able to seek outside support during treatment. Additionally, a lengthier process may help decrease the severity and occurrence of withdrawal symptoms as the client's dose is tapered. Slower tapers typically are conducted at the rate of 2 mg decrease of BUP/Ntx every 7-10 days.

Tapering Off Buprenorphine Protocol

Tapering off buprenorphine should be done under the guidance of a healthcare professional, as individual needs and responses to the tapering process can vary.

- 1. Assess readiness: Ensure that the patient has been stable on buprenorphine for an extended period (preferably more than one year) and has demonstrated consistent abstinence from illicit opioids. The patient should also have new behavioral techniques to manage cravings and other challenges that come with lowering agonist therapies.
- 2. Develop a tapering plan: Work with the patient and healthcare provider to create a personalized tapering schedule. A common approach is to reduce the buprenorphine dose by 25% every 10 days. The pace of the taper may need to be adjusted based on the patient's response and comfort level.

- 3. Monitor withdrawal symptoms: Keep track of any withdrawal symptoms experienced during the tapering process. If a dose decrease causes significant discomfort, pause the taper and consult with the healthcare provider.
- 4. Provide support: Increase emotional and practical support during the tapering process. Encourage the patient to engage in healthy coping strategies, such as exercise, counseling, or support groups.
- 5. Use adjuvant medications: If necessary, consider using additional medications, including routine comfort medications, to help manage withdrawal symptoms during the tapering process.
- 6. Adjust the tapering schedule: Be prepared to adjust the tapering schedule based on the patient's response. The hardest part of the taper may be reducing the dose from 2mg to 0mg[10]. If needed, slow down the tapering process during this stage to ensure patient comfort.
- 7. Maintain communication: Keep open lines of communication between the patient and healthcare provider throughout the tapering process. This will allow for any necessary adjustments to the tapering plan and provide support for the patient.

Remember that tapering off buprenorphine should be a collaborative process between the patient and healthcare provider, and the protocol should be tailored to the individual's needs and circumstances.

Transitioning from BUP/Ntx to Naltrexone Extended Release (Vivitrol) Guideline

- 1. At the initial visit, the provider will order lab tests (CMP, CBC with Diff, and qualitative HCG Qualitative, if applicable).
- 2. Follow the BUP/Ntx taper guideline above.
- 3. Comfort medications:
 - a. Trazodone 100mg Take one tablet daily 30 mins before bedtime AS NEEDED for sleep. Allow 7-8hours of sleep #14 (no routine refill)
 - b. Compazine 10mg- Take one tablet three times daily AS NEEDED for Nausea #30 (no routine refill)
 - c. Clonidine 0.1mg- Take one tablet EVERY 12 hours daily AS NEEDED for anxiety, agitation, rapid heart rate, headache #20 Hold for BP less than 100/60 (no routine refill)
 - d. Baclofen 10 mg orally three times daily as needed for cramping (#30) (no routine refill) or Flexeril 10mg- Take one tablet every 8 hours daily as needed for muscle cramping #30 (no routine refill)
- 4. While on a slow BUP/Ntx taper, the client must see the provider every month.
- 5. If the client tests positive for opiates 2 consecutive times after the initial appointment with the provider, the client will be scheduled with the provider the following week. The provider will determine whether BUP/Ntx will be continued until seeing provider.
- 6. For the client to receive naltrexone, their system needs to be free of BUP/Ntx and opiates, preferably for 3-8 days.
 - a. If client returns to start naltrexone/Vivitrol but is positive for BUP/Ntx, schedule an RN appointment for approximately 3 days later, and continue to do this until negative for BUP/Ntx (and opiates).
 - b. If client returns to start naltrexone/Vivitrol, but is positive for opiates, reschedule with the provider for their next available appointment time.
- 7. When the client returns after their "BUP/Ntx wash-out period" for their transition to naltrexone/Vivitrol, and the client is negative from BUP/Ntx and opiates, RN will administer naltrexone 25 mg po with food. After receiving dose, client will be observed for 30 minutes. If no negative reaction is noted or reported, dose will be repeated, and client will be observed for an additional 30 minutes, unless otherwise indicated.
- 8. If there is no negative reaction, the client will receive either a 1-month prescription for naltrexone or the Vivitrol injection.
- 9. Patient will return approximately every 28 days for an additional prescription or injection.
- 10. During this time, the client will be seen by the provider every 3 months, unless otherwise indicated.
- 11. Follow up labs:
 - a. Routine labs and frequency if labs are within normal limits
 - i. CMP, qualitative HCG, UDS every three months if client is on Vivitrol
 - b. Routine labs and frequency if labs are not within normal limits.
 - i. CMP and CBC every month if client is asymptomatic and until each panel is within normal limits, or
 - ii. Check with provider for frequency of labs

The Shane Parish/Salvation Army BUP/Ntx taper towards Naltrexone Extended Release (Vivitrol) Induction

Day	Tablet dose	# of tablets	# tablets to dispense
1 & 2	2 mg/ 0.5 mg	4	8
3 & 4	2 mg/ 0.5 mg	3	6
5 & 6	2 mg/ 0.5 mg	2	4
7 & 8	2 mg/ 0.5 mg	1	2
Total			20

- 1. Encourage regular hydration throughout process.
- 2. Provide comfort medications, see above, throughout process
- 3. Then, after 8 days administer Vivitrol.

Methadone to BUP/Ntx Guideline

Methadone tapering and discontinuation and initiation onto BUP is only done at the client's request. No staff member or contracted provider should coerce or otherwise force a client to taper off methadone for any reason.

Methadone has a long record of accomplishment as an effective medication for OUD; however, the barriers for treatment access and maintenance are significant and methadone has a high overdose potential—particularly when someone uses it in combination with other substances. The increased utilization of BUP and the greater acceptance of client services for OUD (other than OTP's) has resulted in increased number of clients choosing to transfer from methadone to BUP treatment for their OUD.

ARCA has a successful record of accomplishment in providing these services. However, this transfer of services can be challenging and requires

- 1. Clear and encouraging client education about the process. Including the acknowledgement that the client will likely be uncomfortable for a few hours during the transfer—despite our best efforts at providing comfort medications.
- 2. Clear communication among ARCA team member for a clear treatment plan and shared language around process and expectation
- 3. Customization of the process for each client, including
 - a. Office detox/transfer vs. home detox/transfer
 - b. Frequency of initial visits with providers and/or staff during the medication transfer
 - c. Frequency of phone checks with the client during the transfer process

Methadone-BUP Process

- 1. In the initial assessment, include the following information:
 - a. How much methadone is the client usually taking daily?
 - b. How long has the client used methadone?
 - c. How consistently has the client use methadone? Has the client missed doses sporadically? Routinely?
- 2. Amount of daily dose of methadone at time of transfer to BUP
 - a. Most resources recommend that a client should be on 30 mg or less at time of transfer; however, there is not much research to support this number. Ideally, we would like a client to be at 30 mg or less for transfer to BUP. If a potential client goes to an OTP for services and want to transfer to BUP under our care, recommend that they taper down to 30 mg.
 - b. Many people, however, cannot taper down to 30 mg prior to transfer to BUP. The following guideline has been developed for people on a daily dose of methadone at 50 mg or less. Providers should contact ARCA leadership if clients have a higher daily dose than 50 mg—with the client's full assessment--so that treatment plans can be previewed for best client outcomes.

- 3. Educate the client on the treatment plan
 - a. The transfer works best when the client blood level of methadone is in the 30-50 mg dose. The half-life of methadone is 55 hours. For example
 - If someone takes 60 mg and she stops methadone on Day 1, she will typically have a blood level around 30 mg on Day 3, and around 15 mg on Day 4
 - ii. If some takes 100 mg daily and he stops methadone on Day 1, he will typically have a blood level around 50 mg on Day 3, 25 mg on Day 4, and 13 mg on Day 5.
 - iii. Ideally, we would like a client to be at as low a dose of methadone as possible prior to transfer. This is because BUP has a ceiling opioid effect, and methadone does not. Since a patient is usually very uncomfortable coming off the methadone, we can initiate the BUP on the day that corresponds to the 30-50mg level.
 - b. Prescribe the following medications for transfer to BUP
 - i. Standard ARCA opioid comfort meds. The client should start these on the first day methadone is discontinued
 - c. On the day Subutex is initiated
 - i. Office inductions should be encouraged for all patients, but it should be strongly encouraged for all patient who were on 30 mg of methadone or more per day.
 - ii. When starting medication, the client must be in active withdrawal. On a scale of 1-10 (10 most severe), the client's withdrawal symptoms should be at a 7-8. The patient should be on scheduled doses of comfort medications.
 - iii. The patient starts by taking 1/4 of a film under the tongue. The client waits 15mins, and then takes another 1/4 of a film. The patient should add 2 mg of Subutex every 15 minutes until cravings are controlled and withdrawal symptoms subside.
 - iv. Maximum dose of Subutex at Day #1: 16 mg
 - d. For the next two days
 - i. Provider or delegate should assess client for adequacy of dosing using a SOWS assessment.
 - ii. Continue or increase this cumulative dose, up to 24 mg, once daily
 - iii. Continue comfort meds as prescribed
 - iv. Have patient follow up with ARCA prescribing provider and/or staff as indicated. Intensify monitoring for patients who had higher methadone doses, co-occurring disorders, fewer personal and social resources, and previous unsuccessful transfers.
 - e. On Day #4, the client switches over to BUP/Ntx after an assessment.
 - i. Discuss with the patient the level of BUP dosing—is it controlling cravings? Is it causing side effects, and requiring a reduction in dose?
 - f. Day #5 and beyond, the client's care follows the ARCA BUP/Ntx guideline.

Key Points of Patient Education for Buprenorphine

Before starting OUD treatment with buprenorphine, clients should:

- Tell providers the prescribed and over-the-counter medications they take, to allow drug interaction assessment.
- Understand the goal of the first week of treatment: To improve withdrawal symptoms without over-sedation.
- Tell providers if they feel sedated or euphoric within 1 to 4 hours after their dose.
- Be given the appropriate buprenorphine medication guide.
- Know possible side effects, including:
- Headache.
- Dizziness.
- Nausea.
- Vomiting.
- Sweating.
- Constipation.
- Sexual dysfunction.
- Agree to store medication securely and out of the reach of others.
- Alert providers if they discontinue medications, start new ones, or change their medication dose.
- Understand that discontinuing buprenorphine increases risk of overdose death upon return to illicit opioid use.
- Know that use of alcohol or benzodiazepines with buprenorphine increases the risk of overdose and death.
- Understand the importance of informing providers if they become pregnant.
- Tell providers if they are having a procedure that may require pain medication.
- Be aware of resources through which to obtain further education for:
 - Themselves (https://store.samhsa.gov/product/SMA16-4993).
 - Their families and friends (http://www.ct.gov/dmhas/lib/dmhas/publications/MAT-InfofamilyFriends.pdf).

Key Points of Patient Education for Naltrexone

- Do not use any opioids in the 7 to 10 days (for short acting) or 10 to 14 days (for long acting) before starting XR-NTX, to avoid potentially serious opioid withdrawal symptoms. Opioids include:
- Heroin, fentanyl, carfentanil
- Prescription opioid analgesics, such as oxycodone, oxycontin, hydrocodone (including tramadol)
- Cough, diarrhea, or other medications that contain codeine or other opioids
- Methadone
- Buprenorphine
- Seek immediate medical help if symptoms of allergic reaction or anaphylaxis occur, such as:
- Itching
- Swelling
- Hives
- Shortness of breath
- Throat tightness
- Do not try to override the opioid blockade with large amounts of opioids
- Understand the risk of overdose from using opioids near the time of the next injection, after missing a dose, or after stopping medications.
- Report rare injection site reactions including:
- Pain
- Skin hardening
- Lumps
- Blisters
- Blackening and/or bruising
- Scabs
- An open wound

Some of these reactions could require surgery to repair (rarely).

- Report signs and symptoms of hepatitis
- Report depression or suicidal thoughts. Seek immediate medical attention if these symptoms develop
- Seek medical help if symptoms of pneumonia appear (e.g., shortness of breath, fever).
- Tell providers of naltrexone treatment, as treatment differs for various types of pneumonia.
- Inform all healthcare professionals of XR-NTX treatment.
- Report pregnancy.
- Inform providers of any upcoming medical procedures that may require pain medication.
- Understand that taking naltrexone may result in difficulty achieving adequate pain control if acute medical illness or trauma causes severe acute pain.
- Wear medical alert jewelry and carry a medical alert card indicating you are taking XR-NTX. A client wallet card or medical alert bracelet can be ordered at 1-800-848-4876.

ARCA Clients Presenting with Reports of ADD/ADHD

A common presentation at ARCA is Adult ADD/ADHD. And this presentation often co-occurs with other behavior health issues and/or addictions. Many people with ADD/ADHD require medications for treatment. And, since many of the medications for ADD/ADHD are controlled and addictive, sustained use of these medications can be problematic for clients, families, and communities.

ARCA has a structured approach to diagnosing and treating ADD/ADHD ^{49 50 51 52}

- 1. For an accurate diagnosis of ADD and ADHD in an adult, ARCA recommends the following:
 - a. A history of the adult's behavior as a child
 - b. An interview with the adult's life partner, parent, close friend, or other close associate
 - c. A thorough physical exam that may include neurological testing
 - d. Psychological testing
- 2. Other useful resources that the ARCA treatment team uses for confirming Adult ADHD include
 - a. Medical records that report diagnosis and treatment
 - b. Pharmacy records that indicate medication treatment
- 3. ARCA uses a validated screening test for ADD/ADHD, ARCA uses the ASRS. See Resource #1 below.
 - a. At the initial visit
 - b. To gauge treatment progress
 - c. At least annually if treatment is chronic
- 4. Unless there are significant barriers due to patient finances, ARCA clients receive a trial with a non-stimulant/non-controlled medications. Examples include
 - a. Atomoxetine (Strattera)
 - b. Guanfacine (Intuniv)
 - c. Clonidine (Kapvay)
 - d. Wellbutrin (Bupropion)
- 5. If the patient's symptoms are not controlled, ARCA providers will consider prescribing stimulants—as monotherapy or combined with the medications above. Stimulants include
 - a. Dexmethylphenidate (Focalin)
 - b. Dextroamphetamine(Dexedrine)

⁴⁹ Adult ADHD Self-Report Scale (ASRS-v1.1) Symptom Checklist, https://add.org/wp-content/uploads/2015/03/adhd-questionnaire-ASRS111.pdf

⁵⁰ SAMHSA ADD/ADHD, https://www.samhsa.gov/treatment/mental-disorders/adhd

⁵¹ ADHD Justice Support Center, http://adhdjustice.add.org/

⁵² ADHD in Adults, https://www.webmd./add-adhd/guide/adhd-adults#3

- c. Amphetamine/Dextroamphetamine (Adderall, Adderall XR)
- d. Lisdexamfetamine (Vyvanse)
- e. Methylphenidate (Concerta, Daytrana, Metadate, Methylin, Ritalin, Quillivant XR)

Medications to Consider for Cocaine Use Disorder

Since there are no FDA-approved medications for treatment of cocaine use disorder, we have limited options for treatment. And much of the buzz on the street is simply that buzz and anecdotes.

Researchers have investigated pharmacologic treatments for cocaine addiction, and some medications have shown promising results. Here are some of the medications that have been studied:

- Disulfiram: This medication is used to treat alcoholism, but it has also shown efficacy for cocaine relapse prevention. Scientists do not yet know exactly how disulfiram reduces cocaine use, though its effects may be related to its ability to inhibit an enzyme that converts dopamine to norepinephrine. ⁵³
- Topiramate: This anticonvulsant medication is often used to treat epilepsy and has been shown to help reduce cocaine use in people with cocaine use disorder. It may also be helpful for people with co-occurring cocaine use disorder to potentially reduce alcohol use. 54
- Methylphenidate and amphetamine products: Evidence supports the use of methylphenidate, another ADHD medication, or amphetamine products for cocaine use disorder, with the strongest evidence for extended-release formulations of these medications. ⁵⁵

So, what can you do as a provider?

- 1. Considering screening anyone with this history with the Adult ADHD screen. ⁵⁶ Treat results as appropriate.
- 2. Check with the patient to see if he/she is interested in CBT. Direct admit SOR patients have access to ARCA therapists.
- 3. Consider treatment with non-FDA approved medications, after consideration of cooccurring conditions and drug-drug interactions—as usual. If you decide to prescribe,
 make sure the patient understands risks/benefits of taking a medication that is not
 approved by the FDA. Be sure to document this in the note. I'd recommend starting with
 a naltrexone and bupropion combination unless there are any contraindications.
- 4. Utilize peers for telephone follow-up and documentation of outcomes—in addition to typical follow-ups. We need to track what works for our patient population.

⁵³ New Medications for the Treatment of Cocaine Dependence https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2994240/

⁵⁴ The treatment of cocaine use disorder https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6795516/

⁵⁵ The ASAM/AAAP Clinical Practice Guideline on the Management of Stimulant Use Disorder https://downloads.asam.org/sitefinity-production-blobs/docs/default-source/guidelines/stimulant-gudie/stud-etd-tables-pc-may-2023.pdf?sfvrsn=c23de635_3

⁵⁶Adult ADHD Self-Report Scale (ASRS-v1.1) Symptom Checklist Instructions https://add.org/wp-content/uploads/2015/03/adhd-questionnaire-ASRS111.pdf

Medications to Consider for Methamphetamine Use Disorder

Since there are no FDA-approved medications for treatment of amphetamine use disorder, we have limited options for treatment. And much of the buzz on the street is simply that buzz and anecdotes.

Two therapies that show promise in short term are cognitive behavioral therapy (CBT) and contingency management (CM). ⁵⁷

No medications have had terrific results when prescribed off label.

But the most promising approach from the article above have included naltrexone, bupropion, topiramate, and stimulants.

- Anecdotal approaches usually emphasize dual therapy—usually oral naltrexone and bupropion, at typical doses
- Topiramate is not on the DMH formulary, but it is on other formularies.
- And, of course, prescribing stimulants to treat AMP use disorder can be problematic.

So, what can you do as a provider?

- 1. Considering screening anyone with this history with the Adult ADHD screen. ⁵⁸ Treat results as appropriate.
- 2. Check with the patient to see if he/she is interested in CBT. Direct admit SOR patients have access to ARCA therapists.
- 3. Consider treatment with non-FDA approved medications, after consideration of cooccurring conditions and drug-drug interactions—as usual. If you decide to prescribe,
 make sure the patient understands risks/benefits of taking a medication that is not
 approved by the FDA. Be sure to document this in the note. I'd recommend starting with
 a naltrexone and bupropion combination unless there are any contraindications.
- 4. Utilize peers for telephone follow-up and documentation of outcomes—in addition to typical follow-ups. We need to track what works for our patient population.

⁵⁷ Pharmacotherapy for methamphetamine/amphetamine use disorder-a systematic review and meta-analysis https://www.ncbi.nlm.nih.gov/pubmed/31328345

⁵⁸ Adult ADHD Self-Report Scale (ASRS-v1.1) Symptom Checklist Instructions https://add.org/wp-content/uploads/2015/03/adhd-questionnaire-ASRS111.pdf

Guidelines for Treatment of Nicotine Use Disorder

Use the tools in the appendix to assess patient's readiness to change regarding alcohol use. These tools also include motivational language to help the patient move forward in behavioral change. They also include instructions to help patient prepare for quit date and engage in positive change.

1. Bupropion (Zyban®, Wellbutrin®)

<u>Dose</u>: 150 mg QD x 3 days, then BID for 2-3 months. Some patients may require longer maintenance therapy for up to 6 months. Quit date is set for within the first 1-2 weeks of therapy.

*Dose should not exceed 300 mg QD due to a dose-dependent increased risk of seizure *Dosing frequency must be reduced in hepatic impairment and renal impairment. There are no exact recommendations for this dosing reduction; clinical judgment will be used. In severe hepatic cirrhosis, the dose should be 150 mg QOD.

<u>Administration</u>: Twice daily dosing should be taken 12 hours apart, but if insomnia occurs, the doses may be taken 8 hours apart. Dose may be decreased to 150 mg QD if side effects occur. If patient has made no progress after 7 weeks, may consider discontinuing therapy.

<u>Contraindications</u>: Bupropion will not be used in patients with seizure disorders, a history of or a current diagnosis of anorexia or bulimia, or with concomitant MAOIs.

Other concerns: If patient is currently pregnant, treatment will be discussed with the referring physician before beginning therapy. Check for drug interactions

2. Varenicline (Chantix)

<u>Dose:</u> 0.5mg PO once daily for three days, then 0.5mg PO BID for four days, then increase to 1mg PO BID

<u>Administration:</u> Take by mouth with water. Begin one week before quit date. Continue for 12 to 24 weeks.

Contraindications: None known

Other Concerns: Pregnancy Category C. Potential for serious neuropsychiatric symptoms, observe for changes in behavior and/or suicidal ideation.

Side effects: Nausea, sleep disturbance, constipation, vomiting.

Guidelines for Treatment of Nicotine Use Disorder (Nicotine substitution therapy)

1. Nicotine Patch

Doses:

NicoDerm CQ (24 hours) OTC 21 mg (4 wk.), 14 mg (2 wk.), 7 mg (2 wk.)

Nicotrol (16 hr.) OTC 15 mg (8 wk.)

Habitrol (24 hr.) Rx: 21 (4 wk.), 14 mg (2 wk.), 7 mg (2 wk.)

ProStep (24 hr.) OTC 22 mg (4 wk.), 11 mg (4 wk.)

**Different or longer regimens may be used, depending on patient specific issues and based on clinical judgment

**Patient's starting patch dose will be correlated as best as possible to their current cigarette intake; one cigarette = 1mg nicotine. The max dose of patches proven to be safe and effective is 44 mg.

If current smoking is <15 CPD, may consider starting with 14 mg patches If current smoking is >30 CPD, may consider starting with a higher dose of nicotine patches.^{2, 3}

<u>Administration</u>: Apply patch to hairless area between neck and waist, rotating sites. If vivid dreams occur with the 24-hour patch, this effect may be less with the 16-hour patch.

<u>Contraindications</u>: Smoking while on the patch; immediately post-MI (within 2 weeks), serious arrhythmias, or serious or worsening angina

Other concerns: If patient is currently pregnant or has severe vascular disease, treatment will be discussed with the referring physician before beginning therapy.

Side Effects: skin irritation, vivid dreams, insomnia, GI complaints¹

2. Nicotine gum (Nicorette – OTC)

<u>Dose</u>: 30 2 mg pieces/day (max) or 20 4 mg pieces/day (max). Patients with high nicotine dependence (previous severe withdrawal symptoms, smoking >1 PPD, or smoking first cigarette within 30 minutes of waking) or those smoking >25 CPD should be advised to use 4 mg gum.

Administration: Chew until peppery taste or "tingling" is felt, then "park" the gum between gum and cheek until sensation is gone (usually 1-3 minutes). Rechew every few minutes and "park" again. Chew each piece for 30 minutes, with 1 piece every 1-2 hours. Do not eat or drink anything except water 15 minutes before or during chewing. Taper dose slowly. Not to be used for more than 6 months. Also, may be useful for prn use only, especially in combination with other agents.

<u>Contraindications</u>: immediately post-MI (within 2 weeks), serious arrhythmias, or serious or worsening angina

Xylazine Toxicity and/or Overdose:

In the event of a suspected xylazine overdose, call 911 and provide immediate medical assistance. Xylazine is a non-opioid veterinary tranquilizer that has been increasingly found in illicit drugs, particularly when combined with opioids like fentanyl. ⁵⁹ 60 61 Naloxone, an opioid overdose reversal medication, should still be administered in cases of suspected xylazine overdose due to the frequent use of xylazine with opioids. However, naloxone is effective in reversing the effects of xylazine itself.

Signs and symptoms of xylazine-involved overdose include drowsiness, slowed breathing, lethargy, apnea, dry mouth, hypertension, tachycardia followed by hypotension and bradycardia, hyperglycemia, hypothermia, coma, dysrhythmia, and death. Since xylazine is a sedative, rescue breathing is an effective overdose response strategy and should be performed until Emergency Medical Services (EMS) arrive.

There is no FDA-approved antidote for xylazine overdose in humans, and the mainstay of treatment remains supportive care. Health care professionals should continue to administer naloxone for opioid overdoses and consider xylazine exposure if patients are not responding to naloxone or when there are signs or symptoms of xylazine exposure.

⁵⁹ What You Should Know About Xylazine, https://www.cdc.gov/drugoverdose/deaths/other-drugs/xylazine/faq.html

⁶⁰ FDA alerts health care professionals of risks to patients exposed to xylazine in illicit drugs, https://www.fda.gov/drugs/drug-safety-and-availability/fda-alerts-health-care-professionals-risks-patients-exposed-xylazine-illicit-drugs

⁶¹ Malayala SV, Papudesi BN, Bobb R, Wimbush A. Xylazine-Induced Skin Ulcers in a Person Who Injects Drugs in Philadelphia, Pennsylvania, USA. Cureus. 2022 Aug 19;14(8):e28160. doi: 10.7759/cureus.28160. PMID: 36148197; PMCID: PMC9482722.

Xylazine Wound Care

Wound care for xylazine-induced wounds is essential to prevent serious infections and complications. ⁶² Some wounds are a result of infection; others can result from impaired circulation. So not all wounds require antibiotics. Although there is no specific classification system or guidelines for managing xylazine-related wounds, some general recommendations can be followed:

- 1. Avoid using rubbing alcohol and hydrogen peroxide for wound treatment.
- 2. Cleanse wounds regularly with soap and water.
- 3. Cover wounds with nonadherent dressings, changing them daily if possible.
- 4. Refer patients to a primary care provider, FQHC, and/or wound care specialist for debridement and pain management.
- 5. Focus on moist wound management principles, promoting debridement of non-viable tissue and biofilm, and using antimicrobial dressings to reduce the risk of infection.
- 6. Surgical treatment, such as serial debridement to remove eschar and necrotic tissue, may be necessary depending on the severity and extent of structural involvement.

It is important to note that there is a lack of research and consensus on the best practices for treating xylazine-specific wounds. The recommendations provided here are based on general wound care principles and the experiences of healthcare providers who have treated patients with xylazine-induced wounds.

⁶² Managing Patients Taking Xylazine-Adulterated Opioids in Emergency, Hospital, and Addiction Care Settings, https://nida.nih.gov/news-events/meetings-events/2023/06/managing-patients-taking-xylazine-adulterated-opioids-emergency-hospital-addiction-care-settings

ARCA Patient-Practice Medication Agreement

I agree to accept the following treatment agreement for medications prescribed to me by an ARCA provider:

- 1. I understand that I will ask my healthcare provider or an ARCA nurse if I have medication questions or concerns.
- 2. I understand that I will ask my healthcare provider or an ARCA nurse if I have medication questions or concerned about the risks and benefits of other treatment for opioid use disorder (including methadone, naltrexone, and nonmedication treatments).
- 3. I will keep my medication in a safe, secure place away from children (for example, in a lockbox). My plan is to store it [describe where and how] _______
- 4. I will take the medication exactly as my healthcare provider prescribes. If I want to change my medication dose, I will speak with my healthcare provider first. Taking more medication than my healthcare provider prescribes or taking it more than once daily as my healthcare provider prescribes is medication misuse and may result in supervised dosing at the clinic. Taking the medication by snorting or by injection is also medication misuse and may result in supervised dosing at the clinic, referral to a higher level of care, or change in medication based on my healthcare provider's evaluation.
- 5. I will be on time to my appointments and respectful to the office staff and other clients.
- 6. I will keep my healthcare provider informed of all my medications (including over-the-counter medications, herbs, and vitamins) and medical problems.
- 7. If I am taking buprenorphine, I agree not to obtain or take prescription opioid medications prescribed by any other healthcare provider without consulting my buprenorphine prescriber.
- 8. If I am going to have a medical procedure that will cause pain, I will let my healthcare provider know in advance so that my pain will be adequately treated.
- 9. If I miss an appointment or lose my medication, I understand that I may not get more medication until my next office visit. I may also have to start having supervised buprenorphine dosing.
- 10. If I come to the office intoxicated, I understand that my healthcare provider may not see me, and I may not receive more medication until the next office visit.
- 11. I understand that it's illegal to give away or sell my medication; this is diversion. If I do this, my treatment may require referral to a higher level of care, supervised dosing at the clinic, and/or a change in medication based on my healthcare provider's evaluation.
- 12. Violence, threatening language or behavior, or participation in any illegal activity at the office will result in treatment termination from the clinic.
- 13. I understand that random urine drug testing is a treatment requirement. If I do not provide a urine sample, it will count as a positive drug test.

14. I understand that I will be called at random times to bring my medication container into the office for a pill or film count. Missing medication doses could result in supervised dosing or referral to a higher level of care at this clinic and/or potentially at another treatment provider based on my individual needs.

15. If I am receiving **buprenorphine** as treatment,

- a. I understand that I will ask my healthcare provider or an ARCA nurse if I have questions or concerned about buprenorphine and other medications.
- b. I understand that initially I will have weekly office visits until I am stable. I will get a prescription for 7 days of medication at each visit.
- c. I can be seen every 2 weeks in the office starting the second month of treatment if I have negative urine drug tests. I will then get a prescription for 14 days of medication at each visit.
- d. I will go back to weekly visits if I have a positive drug test. I can go back to visits every 2 weeks when I have two negative drug tests in a row again.
- e. I may be seen less than every 2 weeks based on goals made by my healthcare provider and me.
- f. I understand that people have died by mixing buprenorphine with alcohol and other drugs like benzodiazepines (drugs like Valium, Klonopin, and Xanax).
- g. I understand that treatment of opioid use disorder involves more than just taking medication. I agree to comply with my healthcare provider's recommendations for additional counseling and/or for help with other problems.
- h. I understand that there is no fixed time for being on buprenorphine and that the goal of treatment is for me to stop using all illicit drugs and become successful in all aspects of my life.
- i. I understand that I may experience opioid withdrawal symptoms when I stop taking buprenorphine.
- j. I have been educated about the increased chance of pregnancy when stopping illicit opioid use and starting buprenorphine treatment and been informed about methods for preventing pregnancy.
- k. I understand that my medication must be protected from theft or unauthorized use. I understand that BUP/Ntx must be stored safely, and securely where it cannot be taken accidentally by children, pets, or be stolen. If my medications are stolen, I will file a report with the police and bring a copy to my next visit. If another person ingests my BUP/Ntx, I will immediately call 911 or Poison Control at 1-800-222-1222. I agree to take full responsibility for the safekeeping of my buprenorphine. Lost or stolen buprenorphine will not be refilled before the date it was due to be renewed unless I can give the clinic a copy of the police report of the loss. I understand my provider reserves the right to refuse refills. I also understand that if more that if my medications are reported lost or stolen more than twice, I may be dismissed from the buprenorphine maintenance clinic and I may not be given any refills for my medication.

- 16. If I am receiving Vivitrol, Sublocade, or other long-acting injectable as treatment,
 - a. I understand that I will ask my healthcare provider or an ARCA nurse if I have questions or concerned about buprenorphine and other medications.
 - b. I understand that there is no fixed time for being on the medication and that the goal of treatment is for me to stop using all illicit drugs and become successful in all aspects of my life.
 - c. I understand that my risk of overdose increases if I go back to using opioids after stopping the medication.
 - d. I have been educated about the increased chance of pregnancy when stopping illicit opioid use and starting naltrexone treatment and have been informed about methods for preventing pregnancy.
 - e. I have been informed that if I become pregnant during naltrexone treatment, I should inform my provider and discuss the risks and benefits of continuing to take naltrexone.
 - f. I am aware of the following guideline if I am do not show up for a schedule appointment for an injection, ARCA staff will call me and remind me of the appointment. If I cannot be contacted and I do not show up at ARCA within 32 days following my last injection, ARCA staff will my first contact (family member or friend). If I do not respond to ARCA with 24 hours of that call, ARCA will call my emergency contact.
- 17. I agree that a network of support is an important part of my recovery, and honest communication among people within the network is important for my treatment. I will provide authorization to allow telephone, email, or face-to-face contact, between the clinic staff and providers, therapists, peer specialists, probation or parole officers, the Department of Social Services, and parents to discuss my treatment and progress. I consent to allow the staff of the MAT clinic to provide others with information regarding my medication usage as needed for my treatment or as otherwise permitted or required by law.
- 18. If I miss an appointment or if I need to reschedule an appointment for a later date, I understand that my medications may not be refilled until the time of my next scheduled appointment with a buprenorphine provider. I understand that if I miss, or am late to, three appointments and did not call the clinic in advance, and provide at least 24hr notice, I may be dismissed from the buprenorphine maintenance clinic and I may not be given any refills for my medication. I may also be given a lower dose, enough to sustain and avoid withdrawal.
- 19. Other specific items unique to my treatment include:

Patient's Name (print) and cell #:	
Patient's Signature:	Date:
My first contact (family member or friend) and cell #:	
My second (emergency) contact (if on Vivitrol) and cell #:	
Witness:	
This form is adapted from the American Society of Addiction Med	dicine's Sample Treatment Agreement

Client-Provider Continuity at ARCA

Client continuity with a treatment team is a necessary component of safe, effective care. However, prescribing provider continuity is not always possible with ARCA providers due to

- ARCA's provision of same day/next day services to new clients
- ARCA's commitment to flexibility in provision of urgent telehealth services to partnering agencies

In order to promote continuity in client services, ARCA is developing policies and procedures for the following situations:

- 1. **Missed appointments:** If a patient misses an appointment and is at risk of running out of medications—but is otherwise stable, contact your ARCA RN so that the RN can request an adequate refill until the client can be scheduled with his/her continuity provider. If the provider is not readily available, the RN can contact the ARCA Medical Director. If the missed appointments become habitual, contact your ARCA supervisor for discussion.
- 2. **Managing client requests to change prescribing providers**: Occasionally a client may request to change prescribing providers. When a client makes this request,
 - a. Inquire and document the reason in the medical record
 - b. Inform the client that due to safety, efficacy, and continuity concerns, a client can change an ARCA continuity provider only after six months after initiation of treatment—unless the change is approved by ARCA's Medical Director.
 - c. Share the request verbally with your ARCA RN, so that the RN can evaluate the request, and, if necessary, discuss with the ARCA Medical Director.

ARCA Clients Participating in Treatment Courts

Treatment courts (aka, Drug Courts and/or Mental Health Courts) have grown in popularity in recent decades and have generally shown positive results for client involved. ⁶³ ⁶⁴ ⁶⁵

Treatment courts, however, have been somewhat uneven in their acceptance of medication use among their clients. Some still do not accept any medications, while other judges support use of all evidence-based treatments. While ARCA advocates for all evidence-based treatments, ARCA also realizes that our community partners must work with treatment courts in ways that are realistic and beneficial for all stakeholders. In this spirit, ARCA promotes the following practices and behaviors:

- 1. Know the collaborating agency's treatment court contact
 - a. Is the agency the treating agency for clients in the drug-related court, the mental health-related court, or both?
 - b. What is the history and the culture of the treatment court?
 - c. How are prescription medications viewed? Opioid agonists? Opioid antagonists? Other controlled substances? Other medications?
 - d. What are typical practices on duration of treatment/program? Duration of medication coverage?
 - e. How is psychotherapy integrated? Individual therapy? Group therapy? Family therapy?
 - f. What happens when a client "graduates" from the treatment court?
 - g. What is the best way to communicate? Routinely? Urgently?
- 2. Minimize prescription of controlled medications.
 - a. Trial use of non-controlled medications before utilization of controlled medications. (See ARCA medication guidelines for treatment of anxiety disorders and responsible benzodiazepine prescribing).
 - b. When buprenorphine (BUP)—and other controlled substances--are prescribed, prescribing providers and RN's collaborate with agency treatment court contacts on defining best fill and refill practices for their program.

⁶³ https://bjatta.bja.ojp.gov/ocp/national-association-drug-court-professionals

⁶⁴ https://ndcrc.org/

⁶⁵ https://www.motreatmentcourts.org/

ARCA Policy on Lost and Reported Stolen Medications

The following policy is part of the Buprenorphine Treatment Agreement; however, it applies to all controlled substances:

I understand that my medication must be protected from theft or unauthorized use. I understand that BUP/Ntx must be stored safely, and securely where it cannot be taken accidentally by children, pets, or be stolen. If my medications are stolen, I will file a report with the police and bring a copy to my next visit. If another person ingests my BUP/Ntx, I will immediately call 911 or Poison Control at 1-800-222-1222. I agree to take full responsibility for the safekeeping of my buprenorphine. Lost or stolen buprenorphine will not be refilled before the date it was due to be renewed unless I can give the clinic a copy of the police report of the loss. I understand my provider reserves the right to refuse refills. I also understand that if more that if my medications are reported lost or stolen more than twice, I may be dismissed from the buprenorphine maintenance clinic and I may not be given any refills for my medication.

If a patient reports a second prescription lost or stolen, more than twice, the ARCA RN engaged in the patient's care calls the Medical Director (or his/her designate) to report the event using the SBAR technique:

- **Situation** (Why are you calling?) **Background** (What are the facts around the patient situation?)
- **Assessment** (What do you think is going on with the patient that has created this event?)
- **Recommendation** (What do you think we should do in this situation? This serves as the start of the conversation).

ARCA Policy on Missed Appointments

The following policy is part of the Buprenorphine Treatment Agreement; however, it applies to all patient appointments:

If I miss an appointment or if I need to reschedule an appointment for a later date, I understand that my medications may not be refilled until the time of my next scheduled appointment with a buprenorphine provider. I understand that if I miss, or am late to, three appointments and did not call the clinic in advance, and provide at least 24hr notice, I may be dismissed from the buprenorphine maintenance clinic and I may not be given any refills for my medication. I may also be given a lower dose, enough to sustain and avoid withdrawal.

If a patient misses a third consecutive appointment, the ARCA RN engaged in the patient's care calls the Medical Director (or his/her designate) to report the event using the SBAR technique:

- **Situation** (Why are you calling?) **Background** (What are the facts around the patient situation?)
- **Assessment** (What do you think is going on with the patient that has created this event?)
- **Recommendation** (What do you think we should do in this situation? This serves as the start of the conversation)



Leaders in Addiction Medicine

October 28, 2023

ARCA Patient,

ARCA is committed to supporting you as you work towards your recovery. We are honored that you have chosen us as your medical provider.

Part of our responsibility as a medical practice is to provide both effective and frugal medicine. Frugal medicine means that we do not waste money or resources in our practice, this is especially important when we prescribe medications.

We routinely try to prescribe generic medications to make sure we are practicing frugally. Generic medications have the same active ingredients but once a generic form of a medication is available, it is available at a lower cost.

One example of a medication being offered in a generic alternative is buprenorphine/naloxone. Brands of this medication include Suboxone and Zubsolv. Depending on the funding source that reimburses ARCA for your care, the tablet is less expensive. Sometimes the film is less expensive. We will always prescribe the less expensive form. And this form will change depending on the changes in the pharmaceutical market.

Practicing frugally allows us to stretch the funding we receive from state and federal programs to serve more people.

While we understand that some patients prefer the film over the tablet, we ask you to work with us by using the tablet. Help us stretch our budgets so we can help more people in their recovery.

And, as always, please let us know what questions you have.

Thank you,

Fred Rottnek, MD

Medical Director

Prediction of Alcohol Withdrawal Severity Scale (PAWSS)

Maldonado et al, 2015

Part A: Threshold Criteria: Have you consumed any amount of alcohol (i.e., been drinking) within the last 30 days? OR did the patient have a	("Y" or "N", no point)
"+" BAL on admission? IF the answer to either is YES, proceed with test:	
Part B: Based on patient interview:	(1 point each)
1. Have you been recently <u>intoxicated/drunk</u> , within the last 30 days?	
 Have you <u>ever</u> undergone alcohol use disorder rehabilitation treatment or treatment for alcoholism? (i.e., in-patient or out-patient treatment programs or AA attendance 	
3. Have you <u>ever</u> experienced any previous episodes of alcohol withdrawal, regardless of severity?	
4. Have you <u>ever</u> experienced blackouts?	
5. Have you ever experienced alcohol withdrawal seizures?	
6. Have you ever experienced delirium tremens or DT's?	s
7. Have you combined alcohol with other "downers" like benzodiazepines or barbiturates, during the last 90 days?	
8. Have you combined alcohol with any other substance of abuse, <u>during the last 90 days</u> ?	
Part C: Based on clinical evidence:	(1 point each)
9. Was the patient's blood alcohol level (BAL) on presentation ≥ 20	00?
 Is there evidence of increased autonomic activity? (e.g., HR > 120 bpm, tremor, sweating, agitation, nausea) 	
Tota	l Score:

Notes: Maximum score = 10. This instrument is intended as a SCREENING TOOL. The greater the number of positive findings, the higher the risk for the development of AWS.

Laboratory Testing for Commonly Prescribed Medications

Medication	Baseline	Follow-up	Therapeutic Drug Monitoring
Antidepressants			
All	TSH	As clinically indicated	N/A
Mood stabilizers			
Lithium	CBC, BMP, TSH, U- HCG ⁶⁶	CBC, BMP every 6 months; TSH every 12 months	Level 1 month after every increase; with stable dose, q3 x 2; then every 6-12 months
Divalproex	CBC, LMT, TSH, U- HCG ⁶⁷	CBC, LFT q3 months x 3, then every 12 months; TSH every 12 months	Level 1 month after every increase; with stable dose, every 12 months
Carbamazepine	CBC, CMP, TSH, U- HCG ⁶⁸	CBC, CMP q3 months x 3, then every 12 months; TSH every 12 months	Level 1 month after every increase; with stable dose, q3 x 2; then every 6-12 months
Lamotrigine	TSH	N/A	N/A
Atypical antipsychotics			
All, including clozapine	Glucose or HgA1c, Lipid panel	Glucose or HgA1c, Lipid panel at 3 months, then every 12 months	N/A
Clazapine	CBC (per REMS protocol) ⁶⁹	Per REMS protocol	N/A

 $^{^{66}}$ Sexually active females should use at least one form of contraception while on this medication 67 Sexually active females should use at least one form of contraception while on this medication

⁶⁸ Sexually active females should use at least one form of contraception while on this medication ⁶⁹ <u>https://www.newclozapinerems.com/home#</u>

Common cross-reactivity and adverse reactions from ADM medications

Drug Interactions Between Methadone or Buprenorphine and other Medications 70

Medications	Methadone	Buprenorphine
HIV Medications		
AZT	Increase in AZT concentrations; possible AZT toxicity	No clinically significant interaction
Didanosine (in tablet form)	Significant decrease in didanosine concentrations.	
Stavudine	Significant decrease in stavudine concentrations.	
Delavirdine	Increased methadone (and LAAM) concentrations; no cognitive impairment	Increased buprenorphine concentrations; no cognitive impairment
Atazanavir	Not associated with increased levels of methadone	Significant increases in buprenorphine and report of cognitive dysfunction
Darunavir	Opiate withdrawal may occur	
Efavirenz	Opiate withdrawal may occur	No clinically significant interactio
Fosamprenavir	Data suggest that the PK interaction is not clinically relevant; however, patients should be monitored for opiate withdrawal symptoms	
Nelfinavir	Methadone levels are decreased. Opiate withdrawal may occur	
Nevirapine	Opiate withdrawal may occur	No clinically significant interaction

⁷⁰ Adapted from McCance-Katz EF, Sullivan LE, Nallani S. Drug interactions of clinical importance among the opioids, methadone and buprenorphine, and other frequently prescribed medications: a review. Am J Addict. 2010 Jan-Feb;19(1):4-16. doi: 10.1111/j.1521-0391.2009.00005.x. PMID: 20132117; PMCID: PMC3334287.

Medications	Methadone	Buprenorphine
HIV Medications		
Lopinavir/ritonavir	Opiate withdrawal may occur	No clinically significant interaction

Tuberculosis Medications	Methadone	Buprenorphine
Rifampin	Opiate withdrawal may occur	Opiate withdrawal may occur
Rifabutin	No clinically significant interaction	Not studied
Hepatitis C		
Interferon	No clinically significant interaction	
Ribavirin	Not studied	
Other Infections		
Fluconazole	Increased methadone plasma concentrations	
Voriconizole	Increased methadone plasma concentrations	
Ciprofloxacin	Increased methadone plasma concentrations	
Biaxin	Increased methadone plasma concentrations	

Antidepressants		
Fluoxetine	Not associated with increased levels of methadone	
Fluvoxamine	May cause increased methadone plasma levels and discontinuation has been associated with onset of opioid withdrawal	
Sertraline	No associated adverse drug interaction	No clinically significant interaction
Citalopram	No clinically significant interaction	No clinically significant interaction
Mirtazepine	No clinically significant interaction	
Duloxetine	Potentially lead to increased duloxetine exposure	
Amitriptylene	Could be associated with increases in plasma methadone concentrations	
St. John's Wort	Increased metabolism and elimination of methadone	Increased metabolism and elimination of buprenorphine
Desipramine	Associated with increased desipramine levels	
Dextromethorphan	Associated with delirium	

Antipsychotics	Methadone	Buprenorphine
Quetiapine	Increased plasma methadone concentrations	
Risperidone	No clinically significant interaction	No clinically significant interaction
Clozapine	No clinically significant interaction	No clinically significant interaction
Aripiprazole	No clinically significant interaction	No clinically significant interaction
Olanzepine	No clinically significant interaction	No clinically significant interaction
Ziprasodone	No clinically significant interaction	No clinically significant interaction
Anxiolytics	Methadone	Buprenorphine
Diazepam	Associated with increased sedation and impaired performance on psychological tests	
Alprazolam	Fatalities have been associated	

Anticonvulsants	Methadone	Buprenorphine
Carbamazepine	Associated with opiate withdrawal	Not studied
Phenytoin	Associated with opiate withdrawa	Not studied
Phenobarbital	Associated with opiate withdrawal	Not studied
Oxcarbazepine	No clinically significant interaction	No clinically significant interaction
Lamotrigene	No clinically significant interaction	No clinically significant interaction
Topiramate	No clinically significant interaction	No clinically significant interaction
Psychostimulant Medications	Methadone	Buprenorphine
Methylphenidate	No clinically significant interaction	No clinically significant interaction
Pemoline	No clinically significant interaction	No clinically significant interaction
Modafinil	No clinically significant interaction	No clinically significant interaction
Antihistamines		
Promethazine	May have synergistic depressant effect	
Diphenhydramine	May have synergistic depressant effect	

Cardiac and Pulmonary Disease Medications	Methadone	Buprenorphine
Digoxin	Not studied	Not studied
Quinidine	Not studied	Not studied
Verapamil	Not studied	Not studied
Heparin	Not studied	Not studied
Theophylline	Not studied	Not studied
Aspirin	No clinically significant interaction	
Psychostimulants	Methadone	Buprenorphine
Cocaine	Decrease in trough methadone concentrations	Increased metabolism and diminished plasma concentrations
Methamphetamine	No clinically significant interaction	
Alcohol	Severe adverse events including death (84), Alcohol appears to be eliminated more frequently	Not studied

APPROVED MEDICATIONS LIST: (PROCEDURE CODE 99199)

All CSTAR, Primary Recovery Plus (PR+), DOC and SROP Programs

SUBSTANCE USE DEPENDENCE MEDICATIONS:

acamprosate (Campral)

buprenorphine/naloxone products

(Suboxone; Bunavail)

buprenorphine products (without naloxone:

Subutex)

disulfiram (Antabuse)

naltrexone (oral)

Naloxone nasal/IM (Narcan)

Vivitrol (bill as 99199 with modifier HK)

Sublocade

ANTIDEPRESSANTS:

amitriptyline (Elavil)

bupropion (Wellbutrin, Zyban)

citalopram (Celexa)

doxepin (Sinequan)

duloxetine (Cymbalta)

escitalopram oxalate (Lexapro)

fluoxetine (Prozac)

fluvoxamine maleate (Luvox)

imipramine (Tofranil)

mirtazapine (Remeron)

nortriptyline (Pamelor)

paroxetine (Paxil)

sertraline (Zoloft)

trazodone (Desyrel)

venlafaxine (Effexor)

ANTI-PSYCHOTICS:

haloperidol (Haldol)

olanzapine (Zyprexa)

risperidone (Risperdal)

quetiapine (Seroquel)

chlorpromazine (Thorazine)

loxapine (Loxitane)

ANTI-EMETIC:

ondansetron (Zofran)

metoclopramide (Reglan)

promethazine (Phenergan)

MOOD STABILIZERS:

Divalproex (Depakote)

lithium (Eskalith, Lithobid)

TOBACCO DEPENDENCE:

bupropion SR (Wellbutrin SR)

Nicotine gum

Nicotine inhaler

Nicotine lozenge

Nicotine nasal spray

Nicotine patch

varenicline (Chantix)

OTHER Classifications:

atomoxetine hydrochloride (Strattera)

amantadine (Symmetrel)

baclofen (Lioresal)

benztropine (Cogentin)

buspirone (Buspar)

carbamazepine (Tegretol)

clonidine (Catapres)

gabapentin (Neurontin)

hydroxyzine pamoate (Vistaril)

hydroxyzine hydrochloride (Atarax)

methylphenidate (Ritalin)

mixed salts amphetamine (Adderell)

prazosin (Minipress)

topiramate (Topamax)

divalproex sodium (Depakote)

Folic Acid

propranolol (Inderal)

Thiamine

trimethobenzamide (Tigan)

Prochlorperazine suppositories (Compazine)

Updated 07/06/2022

Other: (Only available if the drug override box is checked on the Admissions page in CIMOR; requires authorization from DBH)

MODIFIED MEDICAL INPATIENT DETOX MEDICATION LIST (in addition to medications listed above):

(BILLED AS PROCEDURE CODE 99199 SC)

chlordiazepoxide (Librium)* clonazepam (Klonopin) lorazepam (Ativan) *

Other: (Only available if the drug override box is checked on the Admissions page in CIMOR; requires authorization from DBH)

*Note:

- Five medications were removed from the above list (effective 12/1/18): diazepam (Valium); dicyclomine (Bentyl); lithium; methocarbamol (Robaxin); phenobarbital (Solfoton).
- Zubsolv was removed from the above list effective 08/27/19.
- Prochlorperazine (Compazine) removed from the above list effective 12/22/2020.
- Prochlorperazine suppositories and Naloxone (nasal/IM) added effective 12/21/21.
- Sublocade was added effective 07/06/2022.

Links to Missouri Medicaid, MoHealthNet Formularies and Resources

- 1. Pharmacy Clinical Edits and Preferred Drug Lists, https://dss.mo.gov/mhd/cs/pharmacy/pages/clinedit.htm
- 2. Opioid Policy Update, https://dss.mo.gov/mhd/cs/pharmacy/pdf/mhd-opioid-policy-update.pdf
- 3. MoHealthNet Drug Prior Authorization, https://dss.mo.gov/mhd/cs/pharmacy/pdf/dpa-fillable.pdf