Medications for Alcohol Use Disorder in Mental Health Settings

Brian Hurley, Keith G. Heinzerling, Catherine C. Cohen, Allison J. Ober, Katherine E. Watkins
Preface

Psychiatrists, nurse practitioners, and other prescribing clinicians who work in mental health settings are in an optimal position to treat an alcohol use disorder (AUD) that co-occurs with a primary mental health condition experienced by clients in these settings. U.S. Food and Drug Administration–approved medications for AUD are available and appropriate for use in mental health settings to enhance the effectiveness of mental health treatment. This tool provides a “how-to” guide to identifying and treating clients with a co-occurring alcohol use disorder (co-AUD) in mental health settings. It also includes a prescriber summary that defines a strategy for prescribing AUD medications in mental health settings. In Part I, we include information about identifying and diagnosing an AUD. In Part II, we review administering naltrexone long-acting injection. In Part III, we review oral medications for AUD. We devote some space to the discussion of naltrexone long-acting injection because providers might be less familiar with injectable medications and because of the difficulties using naltrexone for an AUD in the context of possible co-occurring opioid use. Audiences that will be interested in this tool include those working in mental health settings and integrated co-occurring disorder programs and any other clinicians who prescribe medications for AUD for people with mental health conditions.

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RAND Health Care Communications
1776 Main Street
P.O. Box 2138
Santa Monica, CA 90407-2138
(310) 393-0411, ext. 7775
RAND_Health-Care@rand.org
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Part I: Medications for Alcohol Use Disorder in Mental Health Settings
Using Medications for Co-AUD

Clinicians in mental health settings play an important role in identifying and treating clients who have an alcohol use disorder (AUD). Mental health clinicians who identify that a client has an AUD might offer the client treatment for the co-occurring alcohol problem in the mental health setting or refer the client to specialized drug or alcohol treatment programs or other alcohol treatment services. These services could include:

- alcohol withdrawal management programs (i.e., “detox”)
- counseling and/or medication treatment in outpatient or residential settings
- self-help groups, such as Alcoholics Anonymous
- peer services.

Epidemiologic data indicate that most clients with co-occurring disorders are far more likely to receive mental health care than substance use treatment (50 percent versus 20 percent, respectively) (Harris and Edlund, 2005). This suggests that providing treatment for an AUD in mental health settings is an important way to increase access to care. Substantial evidence documents the impact of untreated AUD on clients’ mental health, functioning, and quality of life (Center for Substance Abuse Treatment, 2009).

Clients who receive medication and clinician-delivered counseling and advice (medical-management visits) outside specialty substance use treatment can achieve similar outcomes to clients receiving specialty treatment (Anton et al., 2006).

U.S. Food and Drug Administration (FDA)–approved medications for AUD, such as oral naltrexone (ReVia®; see Part III), naltrexone long-acting injection (Vivitrol®), and oral acamprosate (Campral®; see Part III), are available for mental health clinicians to treat appropriate clients. Gabapentin and topiramate (see Part III) are off-label medications, and there is evidence supporting their efficacy in treating AUD. The addition of these medications to standard alcohol or drug use disorder counseling programs or self-help programs improves outcomes as compared with counseling or support without medication treatment (Maxwell and Shinderman, 2000).

Therefore, medications are recommended for clients with co-AUD who are receiving treatment in mental health settings (Reus et al., 2018).
This guide provides a brief overview on how to identify potential co-AUD clients and introduce them to medications for AUD, as well as an overview of the medication support process.

The medications referenced in this guide are appropriate for all mental health settings of care, including short- and long-term inpatient psychiatric hospitals, residential settings, day treatment settings, and outpatient settings. Given that clients with co-AUD are seen frequently in each of these settings, medications for AUD should be offered when a client has been identified to have a co-AUD.

**Section 1: Evaluating Clients for Co-AUD**

This section provides an overview of the steps required to evaluate a client for co-AUD in mental health settings.

We provide prompts to help identify potential co-AUD clients; *Diagnostic and Statistical Manual of Mental Disorders, 5th Edition (DSM-5)* criteria for diagnosing an AUD; and guidelines for determining whether treatment with medication is appropriate.

**Talking to Clients About Alcohol Use**

Alcohol use can cause or exacerbate insomnia and depressive, manic, anxiety, and psychotic symptoms for people with co-occurring mental health disorders. In individuals with active mental health symptoms, reducing alcohol consumption can result in improvements in wellness and quality of life (Reus et al., 2018).

Clients can become reactive when their alcohol use is discussed; clients might deny that they have a problem with alcohol or minimize the extent of their alcohol use. Even clients who are motivated to change their drinking behaviors often are ambivalent about participating in a specialized AUD psychosocial treatment because of past experiences with stigma or fear that they might fail.

As a result, it is critical that clinicians avoid saying anything that clients might perceive to be judgmental. This can include the timing and methods for conducting urine toxicology (see Part II, Section 2). It also is important for clinicians to use a motivational and nonconfrontational approach when discussing alcohol use with clients. Providers should try to build rapport with clients and use such normalizing statements as “many clients drink when they are struggling with (mental health symptoms).”
For clients who are interested in quantifying their alcohol consumption to assist in making changes in their alcohol use, clinicians can consider incorporating Drinking Tracker Cards as a component of mental health treatment (National Institutes of Health, undated).

**Identifying Clients with AUD**

The first step in determining whether a client is appropriate for treatment with medications is to assess the client for a diagnosis of an AUD.

Although clients with AUD typically drink more than the recommended healthy limits for alcohol intake, the *quantity* of alcohol consumed is not by itself sufficient for establishing a diagnosis of an AUD. In addition to quantity, the *extent* to which drinking has become compulsive, or out of the client’s control, is the critical factor to consider when assessing clients for an AUD.

A diagnosis of a current AUD is made when clients meet *two or more* of the *DSM-5* criteria for AUD in the past 12 months. See the next section, titled “*DSM-5 Criteria for Diagnosis of an AUD,*” for the complete criteria.

**To identify the presence of a current AUD, ask the client, “In the past year . . .**

- Do you feel like you need to drink more alcohol than you previously did to get the same effect?
- Do you have the ‘shakes’ when you don’t use alcohol (i.e., do you have withdrawal symptoms)?
- Do you feel like you can’t have just one drink or end up using more alcohol than you intended?
- Do you find yourself craving (having a strong desire to drink) alcohol?
- Have you been unable to stop or reduce your drinking when you have tried in the past?
- Are you spending more and more time getting alcohol, drinking alcohol, or recovering from alcohol use?
- Does your drinking get in the way of you doing other things that don’t involve alcohol, such as work or family activities?
• Do you find that you have given up doing things, such as work or family activities, because of your drinking?
• Do you find yourself continuing to drink alcohol despite problems caused or worsened by alcohol use?
• Have any bad things happened as a result of your drinking? Do you continue to drink even though it causes these bad things to happen?”

Clients with **two or more** “yes” responses in the past 12 months meet the criteria for a current AUD and might be appropriate candidates for medications for AUD, at the discretion of the treating clinician.

Clients with a past AUD and current risk of relapse also could be considered for treatment with medication.

Clients with fewer than three “yes” responses might still be appropriate for medication treatment to support their reduction of alcohol consumption at the discretion of the treating clinician and/or psychiatrist, nurse practitioner, or prescriber (Hester, 2015; Jonas et al., 2014; Palpacuer et al., 2018). For a discussion of risky drinking quantities, see *Helping Patients Who Drink Too Much: A Clinician’s Guide* (National Institute on Alcohol Abuse and Alcoholism, 2005).

When assessing the client, complete the DSM-5 AUD diagnosis worksheet (see Appendix E) and put the AUD as a secondary diagnosis on the diagnosis list. (Note: The client’s counselor or clinician might have done this step; check the diagnosis list first.)

### *DSM-5 Criteria for Diagnosis of an AUD*

**AUD Diagnostic Criteria:**

An AUD is a problematic pattern of alcohol use leading to clinically significant impairment or distress, as manifested by at least two of the following criteria, occurring within a 12-month period:

1. Alcohol often is taken in larger amounts or over a longer period than was intended.
2. There is a persistent desire or are unsuccessful efforts to cut down or control alcohol use.

- **Mild Use Disorder:** Two or Three Criteria Met
- **Moderate Use Disorder:** Four or Five Criteria Met
- **Severe Use Disorder:** Six or More Criteria Met
3. A great deal of time is spent in activities necessary to obtain alcohol, use alcohol, or recover from its effects.
4. Craving, or a strong desire or urge to use alcohol, is experienced.
5. Alcohol use is recurrent, resulting in a failure to fulfill rote obligations at work, school, or home.
6. Alcohol use is continued, despite having persistent or recurrent social or interpersonal problems caused or exacerbated by the effects of alcohol.
7. Important social, occupational, or recreational activities are given up or reduced because of alcohol use.
8. Alcohol use is recurrent in situations in which it is physically hazardous.
9. Alcohol use is continued, despite knowledge of having a persistent or recurrent physical or psychological problem that is likely to have been caused or exacerbated by alcohol.
10. Tolerance, as defined by either of the following:
   a. a need for markedly increased amounts of alcohol to achieve intoxication or desired effect
   b. a markedly diminished effect with continued use of the same amount of alcohol.
11. Withdrawal, as manifested by either of the following (see Appendix F for instructions on identification of alcohol withdrawal):
   a. the characteristic withdrawal syndrome for alcohol
   b. alcohol (or a closely related substance, such as a benzodiazepine) is taken to relieve or avoid withdrawal symptoms.

Specify whether the client is
in early remission: After full criteria for an AUD were met, none of the criteria for an AUD have been met for at least three months but for less than 12 months (with the exception that criterion 4, craving, may be met).

in sustained remission: After full criteria for an AUD were met, none of the criteria for an AUD have been met at any time during a period of 12 months or longer (with the exception that criterion 4, craving, may be met).

Specify whether the client is in a controlled environment: This additional specifier is used if the individual is in an environment where access to alcohol is restricted.

Code based on current severity. (Note for International Classification of Diseases, 10th Revision, Clinical Modification [ICD-10-CM] codes: If an alcohol intoxication, alcohol withdrawal, or another alcohol-induced mental disorder also is present, do not use the codes below for an AUD. Instead, the co-morbid AUD is indicated in the fourth character of the alcohol-induced disorder code.)
For example, if there is co-morbid alcohol intoxication and an AUD, only the alcohol intoxication code is given, with the fourth character indicating whether the co-morbid AUD is mild, moderate, or severe: F10.129 for a mild AUD with alcohol intoxication or F10.229 for a moderate or severe AUD with alcohol intoxication.

**Specify current severity using the following codes:**
305.00 (F10.10) Mild: presence of two or three symptoms
303.90 (F10.20) Moderate: presence of four or five symptoms
303.90 (F10.20) Severe: presence of six or more symptoms.

**For clients with problematic alcohol use who do not meet the DSM-5 criteria for an AUD,** the clinician should advise them to cut down on their drinking, explain how their alcohol consumption could be affecting their health, and schedule a follow-up visit to ensure that they have reduced their alcohol intake. Medications for AUD can be prescribed to clients with risky drinking without a confirmed AUD if the clients are interested in medications to support reducing their alcohol consumption (Hester, 2015; Jonas et al., 2014; Palpacuer et al., 2018).

**Possible prompts (using a motivational interviewing style) include the following:**
- Based on the information you provided, your drinking is higher than the recommended limits for a healthy adult.
- I am concerned about your drinking and wondered if you would be open to exploring some ways to cut down.
- If you wanted to cut down to less harmful amounts, such as fewer than (women: one drink per day on average; men: two drinks per day on average or fewer, depending on condition), how might you do it? What have you tried in the past?
- I know you can do this, and I am happy to help.
- You are the only one who can change your behavior.

During a follow-up assessment or during visits with a mental health clinician, counselor, peer, and/or community worker, if clients are identified as having an AUD, they might be appropriate for treatment with medication at that time.
Assess Client Appropriateness for Treatment with Medication

The next step is to perform a history and mental status exam to determine whether the client is appropriate for treatment with medication. In general, clients with an AUD are appropriate for medication treatment when they accept medications that support changing their alcohol consumption and when they do not have a medical contraindication to the medication(s) that they find acceptable.

Assess and Address the Need for Alcohol Withdrawal Management

Clients who are in alcohol withdrawal or who have a history of hospitalization for severe alcohol withdrawal, seizures, or delirium tremens should be treated in a facility that manages alcohol withdrawal and might receive therapy with medications for AUD concurrent with alcohol withdrawal management.

1. Ask the client about his or her history with alcohol withdrawal.
2. Assess the level of alcohol withdrawal. If you are in doubt about alcohol withdrawal, use the Clinical Institute Withdrawal Assessment for Alcohol Scale, Revised (CIWA-Ar) (Appendix F) to determine the level of withdrawal.
3. Clients who are medically unstable or have severe alcohol withdrawal symptoms should be referred to the nearest emergency department or available withdrawal management facility.

Alcohol Withdrawal

Alcohol withdrawal can range in severity from mild symptoms that require little medical treatment to severe and life-threatening conditions, such as delirium tremens, that require aggressive treatment in an intensive care unit. Symptoms of alcohol withdrawal might occur within six to 12 hours after the client’s last drink but might not peak until three to five days of alcohol abstinence. Prior to recommending that a client with AUD stop or reduce their alcohol consumption, any clinician can assess the client for current alcohol withdrawal symptoms and the risk of developing severe alcohol withdrawal symptoms in the future.
Assessing Alcohol Withdrawal with the CIWA-Ar

1. Complete the CIWA-Ar worksheet (see Appendix F). At the top of the worksheet, record the date and time of the client's last drink. Note: Clients with recent alcohol intake might have minimal withdrawal symptoms but can develop symptoms later in the course of alcohol abstinence.

2. Add the scores for each question to obtain the total CIWA-Ar score for the client and use it to assess the severity of current alcohol withdrawal symptoms according to the table.

<table>
<thead>
<tr>
<th>Total CIWA-Ar Score</th>
<th>Severity</th>
<th>Treatment Setting</th>
</tr>
</thead>
<tbody>
<tr>
<td>0 to 9 points</td>
<td>Very mild withdrawal</td>
<td>Ambulatory withdrawal management</td>
</tr>
<tr>
<td>10 to 15 points</td>
<td>Mild withdrawal</td>
<td>Inpatient withdrawal management</td>
</tr>
<tr>
<td>16 to 20 points</td>
<td>Modest withdrawal</td>
<td></td>
</tr>
<tr>
<td>21 to 67 points</td>
<td>Severe withdrawal</td>
<td></td>
</tr>
</tbody>
</table>

- **Clients with a CIWA-Ar score of more than 15** should be referred for inpatient medical withdrawal management, including transport to the nearest emergency department, if appropriate. These clients might continue evaluation for possible treatment following completion of the inpatient alcohol withdrawal management program.

- **Clients with a CIWA-Ar score of less than ten** might not need pharmacologic treatment for withdrawal but might need repeat assessment during the first three to four days of alcohol abstinence to monitor for the emergence of additional symptoms.

- **Clients with a CIWA-Ar score of ten to 15** should be assessed for potential ambulatory alcohol withdrawal management treatment.

Clients who meet the following criteria might undergo ambulatory alcohol withdrawal management treatment:
- CIWA-Ar score of ten to 15
- Ability to take oral medications
- Stable housing and a reliable family member or acquaintance who can monitor the client for the first three to four days and get help if symptoms worsen
- No unstable psychiatric or medical condition
- Not pregnant
- No concurrent other substance abuse that might lead to withdrawal symptoms (e.g., narcotic or other sedative withdrawal)
- No history of previous severe alcohol withdrawal episodes (e.g., delirium tremens) or alcohol withdrawal seizures.

Possible treatment for ambulatory alcohol withdrawal management:
- Prescription benzodiazepines or off-label use of anticonvulsants, such as gabapentin.
- Ask client to return to the clinic for reassessment and repeat CIWA-Ar on day three of alcohol abstinence or sooner if symptoms worsen.
Section 2: Prescribing Medications to Clients with Co-AUD

In this section, we review the process for treating identified co-AUD clients with medications in mental health settings. We describe how to discuss these treatments with clients, how to help clients choose the medication(s) that is right for them, and include information on following up through support visits. This section also includes a prescriber summary and co-AUD prescribing strategy.

Discussing Alcohol Use with Clients

After identifying a client with a co-AUD, the clinician should discuss treatment options with the client using a nonjudgmental, nonconfrontational, and motivational approach.

Be mindful that accusing the client or directing them to stop drinking too forcefully risks their defending their drinking behavior.

Tell the client,

- “I am concerned that your drinking is affecting your well-being.”
- “My assessment is that your drinking is causing you or others harm.”
- “I recommend that you consider stopping or cutting down on your drinking.”
- “Ultimately, change is up to you.”
- “I know you can do this and I am happy to help.”
- “Is this something you are willing to try?”

If the client is NOT willing to change their drinking, say,

- “As I said, you are the only one who can change your behavior. I am ready to help if you decide to make a change in the future.”
- “May I see you in the future to discuss this again?”

If the client IS willing to change their drinking, say,

- “There is a medication [I/the psychiatrists here] can prescribe that might help you drink less. I can tell you more about this if you are interested.”
• “I also can give you information on counseling programs available at the clinic and elsewhere, as well as information on self-help groups that other clients of mine have found helpful. Are you interested in these resources?”

The clinician should then discuss the specifics of the medication (see medication-specific information in Part III) or refer the client to see the psychiatrist or other prescribing clinician who can discuss medications for an AUD. The clinician also could recommend specific self-help groups, such as Alcoholics Anonymous and SMART Recovery, and other community-based self-help opportunities.

Clients who are not interested in drinking less should be asked to return in several weeks for additional encouragement to change.

**Helping Clients Choose a Medication**

Excluding medical contraindications or unique clinical concerns, choice of medications is driven primarily by the client’s acceptance of and prospective adherence to the co-AUD pharmacotherapy. Each medication option that is appropriate, given the client’s individual clinical circumstances, should be offered using a shared decisionmaking framework for discussion that includes clear advice about which medication or medication combinations are recommended.

Naltrexone (either oral or long-acting injection) is the most commonly prescribed medication for AUD treatment in mental health settings and generally is recommended as the first-line option (Reus et al., 2018) because of its once-daily or once-monthly dosing. Naltrexone is not appropriate for clients who are using opioids or are expected to need treatment with opioids in the next several months because naltrexone is an opioid antagonist. Naltrexone also is not recommended for clients who report a history of or exhibit signs of severe liver disease. Naltrexone long-acting injection is not recommended in clients with a condition that would preclude safe intragluteal injection.

Naltrexone long-acting injection is the preferred medication option for clients who are already receiving a long-acting injectable medication, for whom long-acting injectable medications are acceptable, and who routinely adhere to long-acting injectable medication treatments. Because naltrexone long-acting injection requires a visit once per month to the clinic as compared with daily oral medication adherence, it is an attractive option for clients who are unlikely to adhere to daily oral medications.
For clients who decline long-acting injectable medications or for whom naltrexone long-acting injection is not otherwise clinically appropriate, offering oral medications is recommended. Once-daily naltrexone usually has better adherence than three-times-per-day acamprosate, so either oral or long-acting injectable naltrexone generally is preferable to acamprosate. However, for clients taking opioids and/or who have liver disease and who find a three-times-per-day medication acceptable, acamprosate is an appropriate option. Additionally, for clients for whom both naltrexone and acamprosate are clinically appropriate and desired by the client, they can be safely combined.

Topiramate is a reasonable off-label medication that is effective for AUD, either on its own or in combination with other medications for AUD, for clients interested in a medication that might mitigate weight gain. Gabapentin, when prescribed for the off-label indication of an AUD, typically is combined with other medications for AUD, although the risk-benefit profile for gabapentin is limited by its overuse potential, particularly in clients with a history of sedative and/or opioid use disorders.

Do not start disulfiram for clients who are likely to continue drinking. Clinical trials support the efficacy of disulfiram in clients who have stopped drinking and when disulfiram is provided in a daily observed dosing program or other specialized setting, but disulfiram does not change drinking behavior for clients in routine outpatient care. For these reasons, we do not discuss disulfiram in this guide.

For clients with no contraindications or other preferences, follow the Co-AUD Prescribing Strategy detailed in the section titled “Prescriber Summary: Medications for Co-AUD.”

**Medication Support Visits**

Clients who are being treated with naltrexone long-acting injection, oral naltrexone, acamprosate, and gabapentin and/or topiramate for AUD should receive a medication support visit to review the risks, benefits, and alternatives for these medications with their prescribing clinician.

Shared decisionmaking is an essential foundation for medication support visits about medications for AUD. The shared-decisionmaking approach elicits which medication options are acceptable to the client; informs which medications have better prospective adherence; and incorporates the client’s values, interests, and perspectives into the
medication-selection process. For example, some clients prefer the convenience of once-per-month long-acting injections to oral medications, which would support the use of naltrexone long-acting injection. For clients who prefer oral medications to long-acting injectable medications, oral medications are more appropriate. Some clients find a once-per-day medication more acceptable than a three-times-per-day medication, which supports once-daily oral naltrexone as compared with three-times-per-day acamprosate. Some clients are interested in medications that might mitigate weight gain, which supports using topiramate; topiramate can be safely combined with naltrexone or other medications for AUD.

**Important things to remember when discussing medications for AUD:**

- Changing alcohol use is a process. Clients who have not stopped drinking but have taken positive steps (e.g., cut down their drinking, attended counseling sessions or self-help meetings) should be validated and encouraged to continue to reduce or discontinue their alcohol use. There is evidence that naltrexone and other medications have a greater effect on reducing heavy drinking than on generating alcohol abstinence (Jonas et al., 2014). Clients who have reduced, but not stopped, alcohol use might be responding to medications for AUD and should be encouraged to continue their treatment.

- Adherence to the medication is critical for success—especially for clients who are not participating in a specialized drug or alcohol psychosocial treatment program.

- Attendance at counseling or self-help programs should be encouraged but not required for clients who are responding to medications for AUD and clinician-delivered medication support visits alone.

- Use a motivational approach and avoid confrontation, which is likely to elicit resistance on the part of the client.

**At each visit,**

- **assess alcohol use since the last visit**
  - Ask permission, e.g., “Can we discuss your alcohol use since our last visit?”
  - Validate clients who did not drink.
  - For clients who did drink, ask,
    - “Were you able to cut down some?”
• “What were the circumstances that led you to drink?”
• “Even though you did drink, it is good that you are here, and I will continue to help you to change your drinking.”
• Help clients to troubleshoot a plan to address their triggers for drinking (e.g., deal with stress; avoid people, places, and things associated with alcohol).

• **assess medication adherence and any medication side effects**
  o Ask, “Clients often tell me they sometimes miss their medication or forget to take it. Does this happen to you?”
  o Address any barriers to medication adherence and side effects.

• **assess participation in counseling or self-help program**
  o Clients who are doing well with medications and medication support visits alone need not be mandated to attend specialized drug or alcohol counseling, peer services, or self-help groups.
  o Clients who are struggling should be encouraged to increase participation in specialized drug or alcohol counseling, peer services, or self-help groups. Encourage clients who are in Alcoholics Anonymous to have a sponsor.
  o **Note:** Some counselors or Alcoholics Anonymous members might discourage clients from taking medications. Advise clients that there is no prohibition against medications in any of the Alcoholics Anonymous fellowships or counseling programs and that taking medication will not conflict with participation in these groups. If necessary, clients should change to a different meeting or program.

**On subsequent visits,**
  o Plan to continue the medications for as long as the client is benefiting from the medication. Clients who have not experienced a serious side effect, are not at risk for precipitated opioid withdrawal (if they are receiving naltrexone), and are making progress in reducing or stopping alcohol use should receive ongoing treatment.
  o If, after several months of treatment, clients are not making progress toward their alcohol use goal, they should be encouraged to enter a treatment setting...
where a higher intensity of treatment can be provided (e.g., specialty outpatient or inpatient alcohol treatment program).
  o To discontinue medications for alcohol use disorders, taper down the doses of oral medications to discontinuation. There are no special procedures for discontinuing naltrexone long-acting injection; simply do not administer any further injections.

**Prescriber Summary: Medications for Co-AUD**

1. **Develop a Shared Treatment Goal**
   Set person-centered goals for alcohol consumption with clients with co-AUD and document these goals in the medical record. Successful treatment strategies can include medications, psychosocial interventions, or a combination of the two. See the introduction to Part I, titled “Using Medications for Co-AUD” for further discussion.

2. **Assess and Address Alcohol Withdrawal Risk**
   Clients who are experiencing withdrawal symptoms should be treated for withdrawal if they plan to abstain from alcohol concurrent with initiating a maintenance medication for AUD treatment. Clients who are medically unstable or have severe alcohol withdrawal symptoms should be referred to the nearest emergency department. Indications of medical instability during alcohol withdrawal include seizures; serious psychiatric features, such as suicidal ideation or new psychotic symptoms; and profound derangements in laboratory studies. Naltrexone and acamprosate do not treat alcohol withdrawal syndrome. See the earlier section on “Discussing Alcohol Use with Clients” for further discussion.

3. **Offer Medications for AUD**
   Review the medications for AUD that are clinically appropriate for the client using shared decisionmaking to reach agreement regarding medication selection. The specific choice of which medications to recommend should be guided by the acceptability of the specific medication or medication combinations, the likelihood of adherence to the medication regimen, and the acceptability of different risk-benefit profiles for individual clients. See the earlier section on “Helping Clients Choose a Medication” for further discussion.

Note: A prescriber summary for naltrexone long-acting injection is included at the end of Part II of this manual. Prescriber summaries for oral naltrexone, acamprosate, gabapentin, and topiramate are included in Part III.
4. **Subsequent Medication Support Visits**

- Plan to continue the medications for as long as the client is benefiting from the medication. Clients who have not experienced a serious side effect, are not at risk for precipitated opioid withdrawal (if they are receiving naltrexone), and are making progress in reducing or stopping alcohol use should receive ongoing treatment.

- If, after several months of treatment, clients are not making progress toward their alcohol use goal, they should be encouraged to enter a treatment setting where a higher intensity of treatment can be provided (e.g., specialty outpatient or inpatient alcohol treatment program).

- To discontinue medications for AUD, taper down the doses of oral medications to discontinuation. There are no special procedures for discontinuing naltrexone long-acting injection; simply do not administer any further injections.
### Medications for Co-AUD

Table 1. Medications for Co-AUD and Pretreatment Indicators

<table>
<thead>
<tr>
<th>Pretreatment Indicators</th>
<th>Medications</th>
<th>Naltrexone Long-Acting Injection</th>
<th>Oral Naltrexone</th>
<th>Acamprosate</th>
<th>Gabapentin</th>
<th>Topiramate</th>
</tr>
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<tbody>
<tr>
<td>Renal failure</td>
<td></td>
<td>A</td>
<td>A</td>
<td>X</td>
<td>C</td>
<td>C</td>
</tr>
<tr>
<td>Active serious liver disease</td>
<td></td>
<td>C</td>
<td>C</td>
<td>A</td>
<td>A</td>
<td>C</td>
</tr>
<tr>
<td>Chronic pain</td>
<td></td>
<td>C</td>
<td>C</td>
<td>A</td>
<td>A</td>
<td>A</td>
</tr>
<tr>
<td>Current opioid use</td>
<td></td>
<td>X</td>
<td>X</td>
<td>A</td>
<td>C</td>
<td>A</td>
</tr>
<tr>
<td>Opioid use disorder in remission</td>
<td></td>
<td>+</td>
<td>+</td>
<td>A</td>
<td>A</td>
<td>A</td>
</tr>
<tr>
<td>Risk factors for poor medication adherence</td>
<td></td>
<td>+</td>
<td>C</td>
<td>C</td>
<td>C</td>
<td>C</td>
</tr>
<tr>
<td>Obesity that precludes intramuscular injection</td>
<td></td>
<td>X</td>
<td>A</td>
<td>A</td>
<td>A</td>
<td>A</td>
</tr>
<tr>
<td>Family history of alcohol use disorder</td>
<td></td>
<td>+</td>
<td>+</td>
<td>A</td>
<td>A</td>
<td>A</td>
</tr>
<tr>
<td>Bleeding/other coagulation disorders</td>
<td></td>
<td>C</td>
<td>A</td>
<td>A</td>
<td>A</td>
<td>A</td>
</tr>
<tr>
<td>Alcohol postacute withdrawal syndrome present</td>
<td></td>
<td>A</td>
<td>A</td>
<td>+</td>
<td>+</td>
<td>A</td>
</tr>
<tr>
<td>Cognitive impairment</td>
<td></td>
<td>A</td>
<td>A</td>
<td>A</td>
<td>C</td>
<td>C</td>
</tr>
</tbody>
</table>

SOURCE: Adapted from Exhibit 6-4 in Center for Substance Abuse Treatment, 2009.
A = Appropriate to use
X = Contraindicated
C = Use with caution
+ = Particularly appropriate
<table>
<thead>
<tr>
<th></th>
<th>Naltrexone Long-Acting Injection</th>
<th>Oral Naltrexone</th>
<th>Acamprosate</th>
<th>Gabapentin</th>
<th>Topiramate</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mechanism of action</td>
<td>Blocks the effects of endogenous opioid peptides to make alcohol use less rewarding and reduce alcohol cravings</td>
<td>Same as naltrexone long-acting injection</td>
<td>Interaction with the glutamate neurotransmitter system</td>
<td>Interaction with voltage-gated calcium channels</td>
<td>Interaction with the glutamate neurotransmitter system</td>
</tr>
<tr>
<td>Examples of drug interactions</td>
<td>Opioid medications, cough/cold medications, antidiarrheal medications</td>
<td>Same as naltrexone long-acting injection</td>
<td>No clinically relevant interactions</td>
<td>Potential sedating effect of sedatives and opioids</td>
<td>Multiple: refer to the product insert for further reference (U.S. Food and Drug Administration, 2012)</td>
</tr>
<tr>
<td>Common side effects</td>
<td>Nausea, reduced appetite, vomiting, anxiety, headache, dizziness, fatigue, somnolence, muscle aches or cramps, injection site pain</td>
<td>Nausea, reduced appetite, vomiting, anxiety, headache, dizziness, fatigue, somnolence</td>
<td>Diarrhea and somnolence</td>
<td>Somnolence, edema, lack of coordination, nausea</td>
<td>Many, including dizziness, confusion, cognitive effects, glaucoma, metabolic acidosis: refer to the product insert for further reference (U.S. Food and Drug Administration, 2012)</td>
</tr>
<tr>
<td>Contraindications</td>
<td>Currently using opioids or in acute opioid withdrawal; anticipated need for opioid analgesics; acute hepatitis or liver failure; inadequate muscle mass for deep intramuscular injection; body mass that precludes deep intramuscular injection; rash or infection at injection site</td>
<td>Currently using opioids or in acute opioid withdrawal; anticipated need for opioid analgesics; acute hepatitis or liver failure</td>
<td>Renal failure</td>
<td>History of allergy to, or overuse of, gabapentin</td>
<td>Metformin contraindicated with topiramate. Can worsen intoxication effects if taken while intoxicated with alcohol. Refer to product insert for further reference (U.S. Food and Drug Administration, 2012)</td>
</tr>
<tr>
<td></td>
<td>Naltrexone Long-Acting Injection</td>
<td>Oral Naltrexone</td>
<td>Acamprosate</td>
<td></td>
<td></td>
</tr>
<tr>
<td>------------------------</td>
<td>-------------------------------------------------------------------------------------------------</td>
<td>--------------------------------------------------------------------------------</td>
<td>--------------------------------------------------------------------------------</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cautions</td>
<td>Renal impairment; chronic pain; hemophilia or other bleeding problems; during pregnancy, the fetal risk cannot be ruled out</td>
<td>Renal impairment; chronic pain; during pregnancy, the fetal risk cannot be ruled out</td>
<td>Dosage might be modified for moderate renal impairment; during pregnancy, the fetal risk cannot be ruled out</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Dosage modified for renal impairment</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Multiple: refer to the product insert for further reference (U.S. Food and Drug Administration, 2012)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Serious adverse reactions</td>
<td>Precipitated opioid withdrawal, rare risk of live inflammation; can rarely worsen depression; rare association with respiratory problems; rare injection site necrosis</td>
<td>Precipitated opioid withdrawal, rare risk of live inflammation; can rarely worsen depression; rare association with respiratory problems</td>
<td>Rare events include severe persistent diarrhea. Rare risk of suicidal ideation</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Can cause psychiatric decompensation including suicidal thoughts, mood swings, and hostile behavior. Can cause Stevens-Johnson syndrome</td>
<td></td>
<td>Can cause suicidal ideation</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Multiple: refer to the product insert for further reference (U.S. Food and Drug Administration, 2012)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**SOURCE:** Adapted from Exhibit 6-5 in Center for Substance Abuse Treatment, 2009.

**NOTES:** The safety and efficacy of naltrexone and acamprosate may not be established for those below 18 years of age. Refer to the respective medication product inserts for pediatric dosing instructions for gabapentin and topiramate. There are no mental health–specific contraindications to the medications for AUD listed in this table.
Part II: Administering Naltrexone Long-Acting Injection to Clients with Co-AUD

A Step-by-Step Guide for Mental Health Clinicians and Providers
Naltrexone Long-Acting Injection

In this part, we present a step-by-step guide to treating clients with co-AUD with naltrexone long-acting injection (trade name: Vivitrol®) in mental health settings.

In this guide, you will find procedures for

- determining whether individuals are appropriate for treatment with naltrexone long-acting injection
- initiating treatment
- assessing side effects and administering follow-up injections.

The first section of this guide provides an overview of the medication and its side effects, as well as quick-reference checklists.

The contents of the guide are as follows:

- **Section 1: “Quick Guide for Administering Naltrexone Long-Acting Injection”** provides an overview of the medication, client eligibility criteria, and side effects. It also contains three procedural checklists for initial and follow-up visits and for explaining the medication to clients.

- **Section 2: “Determining Client Appropriateness for Treatment with Naltrexone Long-Acting Injection: Visit 1”** provides instructions for assessing client appropriateness for the medication.

- **Section 3: “Administering Naltrexone Long-Acting Injection”** provides guidelines for administering the medication. If possible, complete the necessary assessments to determine the appropriateness for injectable naltrexone and administer the first injection during the same visit.

- **Section 4: “Assessing Treatment Progress and Adverse Events and Administering Additional Medication Doses, If Appropriate”** provides guidelines for assessing progress, side effects, and whether the client should continue the medication.
In this section, we provide an overview of essential information for clinicians treating AUD with naltrexone long-acting injection. Additional details can be found in the subsequent sections of this guide.

**What is naltrexone long-acting injection?**

Naltrexone long-acting injection (Vivitrol®), which is FDA-approved for the treatment of AUD, is an intragluteal injection of an opiate antagonist administered monthly, typically for three to six months, but can be continued indefinitely in clients for whom there is an ongoing benefit that outweighs medication risks. Studies have found similar outcomes when comparing treatment with naltrexone and brief clinician support with specialty alcohol treatment without medication (Anton et al., 2006). As a result, participation in counseling or support services during naltrexone treatment is encouraged but **NOT** mandatory, and naltrexone and clinician support are options for clients who are not interested in other types of treatment or self-help approaches.

**Who is appropriate for treatment with naltrexone long-acting injection?**

Prior to administering the first naltrexone injection, confirm that the client

- has an AUD or has risky drinking and wants to reduce their alcohol consumption
- is motivated to reduce or stop alcohol use and is interested in a medication for AUD
- has received information and/or referrals to counseling and self-help programs (Alcoholics Anonymous, SMART Recovery)
- does **NOT** require inpatient alcohol, benzodiazepine, or other sedative withdrawal management
- is **NOT** currently using opioids (recent review of your state’s Prescription Drug Monitoring Program [PDMP] shows no recent opioid prescriptions and urine drug screen is negative for opioids) and is **NOT** expected to require opioid therapy in the next three months
- does **NOT** have acute hepatitis (AST or ALT more than five times the upper limit of normal) or liver failure. **Note:** Do not withhold naltrexone if liver function
testing has not yet been obtained in a client without signs or symptoms of active liver disease.

- does NOT have previous sensitivity or allergy to naltrexone or components of the diluent (e.g., polylactide-co-glycolide [PLG], carboxymethylcellulose)
- does NOT have a condition that would impede safe intragluteal injection (Springer, 2017)

### Liver Inflammation and Naltrexone

- Despite early reports, research has not found any increased hepatotoxicity associated with receiving naltrexone long-acting injection, even among those living with chronic hepatitis C or HIV infection.
- Expert consensus is that obtaining a liver function panel prior to institution of naltrexone long-acting injection is not warranted, nor is routine monitoring of liver function in all clients receiving naltrexone long-acting injection.
- High doses (more than 100 mg) of oral naltrexone remain associated with an elevated risk of liver inflammation.
- It remains prudent to identify the presence of underlying liver disease and monitor for usual clinical side effects and symptoms in all clients being treated with psychiatric medication.

### What are the most common side effects of naltrexone long-acting injection?

- **mild nausea** (in one-third of clients), which typically resolves within days of injection
- headache
- mild dizziness
- **injection-site reactions**, ranging from mild tenderness to (rarely) cellulitis or abscess: In clinical trials, 3 percent of clients with AUD discontinued naltrexone long-acting injection because of injection-site pain or discomfort (Alkermes, 2019).

**Rare** side effects include

- precipitation of **opioid withdrawal**: Clients should abstain from opioid use prior to and during naltrexone treatment.
- **hepatotoxicity**: Clients with severe acute hepatitis or liver failure should not receive treatment with naltrexone. Mild to moderate elevations in liver enzymes (less than five times the upper limit) are typical in AUD or stable liver diseases
(e.g., chronic hepatitis C infection) and are **NOT** a contraindication to naltrexone treatment. Note that successful naltrexone treatment leads to a reduction in liver enzymes as a result of reduced alcohol use.

- **depression:** Depression is a side effect in 5 percent of clients.

**What assessments should be completed prior to initiating treatment with naltrexone long-acting injection?**

- recent history and mental status examination
- assessment for AUD and need for inpatient alcohol withdrawal management
- assessment for co-occurring drug use and substance use disorders, especially co-occurring opioids or benzodiazepine use disorders
- recent review of your state’s PDMP to determine which controlled substances the client has been prescribed
- the following urine testing should be obtained:
  - urine drug screen for opioids, oxycodone, methadone, and other opioids, if indicated
  - pregnancy (if the client is a woman or transgender man of childbearing age).

It is recommended to offer the following testing to all clients receiving a medication for AUD:

- comprehensive metabolic panel, including blood urea nitrogen (BUN), creatinine, and hepatic enzymes
- complete blood count, including platelet count
- screening of HIV, hepatitis C, hepatitis B, and syphilis infections
- thyroid stimulating hormone (TSH) with reflex to Free T4 and T3
- lipid panel
- hemoglobin A1C
- B12 and folate
- Vitamin D.

It is not necessary to obtain these labs prior to initiating a medication for AUD because waiting for the results limits the opportunity to provide effective treatment.

Indications of liver dysfunction include the client’s report of active liver disease, abnormal swelling of the abdomen, jaundice (yellow eyes or skin), abdominal pain,
nausea, and vomiting. In addition, consider the following tests if the client shows signs of liver dysfunction:

- Prothrombin time (PT) and international normalized ratio (INR).

If vitamin deficiencies are identified, treat these deficiencies. If endocrine, metabolic, hepatic, or hematologic disorders or chronic infections are identified, treat these conditions or offer referral to those with expertise in treatment of these conditions.

**What should a clinician assess prior to administering subsequent naltrexone injections?**

- **Determine whether the client has made progress toward a goal of stopping or reducing alcohol use.** Assess recent alcohol use by asking about the number of drinking days, number of drinks per day, and number of heavy drinking days (at least five drinks per day for men and at least four drinks for women). Signs of progress might include reductions in alcohol intake, participation in counseling or self-help programs, or increases in motivation to change drinking behavior.

- **Discuss side effects, including**
  - injection-site discomfort (injections should alternate buttocks each month; proper intragluteal injection is critical to reduce risk of reactions)
  - nausea
  - acute hepatitis (consider a recheck of the hepatic panel if the client shows signs or symptoms of acute hepatitis or has preexisting liver disease)
  - anhedonia, depression, or suicidality.

**How often should clients be seen during treatment with injectable naltrexone?**

Clients should be seen at least monthly for each injection, or more often in the event of any possible side effects.

**What if a client misses a monthly injection?**

The injection can be administered any time after the typical one-month interval, as long as the client meets the criteria for subsequent injections. In cases of missed injections, be careful to assess for intervening opioid use.

**What if a client requires opioid analgesia during naltrexone treatment?**
High doses of potent opioids are required to achieve analgesia in clients with opioid blockade via naltrexone. Attempts to override naltrexone’s opioid blockade by administering opioids could result in opioid overdose. As a result, **clients requiring opioid analgesics during treatment with injectable naltrexone should be treated by a medical specialist in managing analgesia in a hospital setting.**

**How should injection-site reactions be managed?**

Mild to moderate pain, redness, or swelling at the injection site can be managed with acetaminophen or nonsteroidal anti-inflammatory drugs (NSAIDs), warm or cold compresses, and antibiotics if there are signs of infection. Abscesses, whether sterile or infectious, might require incision and drainage.

**How should naltrexone long-acting injection be discontinued?**

Injectable naltrexone cannot be removed once injected. Discontinuation of treatment is achieved by not administering the next monthly injection.

**What if a client does not participate in counseling or self-help programs?**

Naltrexone long-acting injection with brief clinician support might achieve similar outcomes as specialty alcohol treatment and self-help programs alone. Therefore, participation in counseling or self-help should be encouraged but not mandated.

**What if a client experiences alcohol withdrawal during naltrexone treatment?**

Clients who abruptly stop alcohol use might experience alcohol withdrawal symptoms. Naltrexone does not treat alcohol withdrawal. Clients with severe alcohol withdrawal symptoms or previous episodes of severe alcohol withdrawal should be referred to an inpatient withdrawal management program or the emergency department if necessary. Clients with mild to moderate alcohol withdrawal who are medically and psychiatrically stable and have stable housing may be treated as outpatients (e.g., chlordiazepoxide or off-label gabapentin) and given naltrexone concomitantly.
Section 2: Determining Client Appropriateness for Treatment with Naltrexone Long-Acting Injection: Visit 1

Visit Checklist:

☐ Step 1: Assess the client for an AUD (any clinician)

☐ Step 2: Assess the client for appropriateness for treatment with naltrexone long-acting injection (medical team)

☐ Step 3: Review the handout of potential risks of treatment with the client

Note: Some of these steps might have been completed in a previous visit or by the care coordinator or therapist; check the chart for relevant information.
Step 1: Assess the Client for an AUD

Follow the protocol outlined in Part I, Section I, titled “Identifying Clients with AUD” and use the worksheet in Appendix E to confirm AUD diagnoses.

Step 2: Assess the Client for Appropriateness for Treatment with Naltrexone Long-Acting Injection

Follow the protocol outlined in Part I, Section I, titled “Assess Client Appropriateness for Treatment with Medication” and use the checklist in Appendix A to determine whether a client is appropriate for naltrexone long-acting injection.

From there, assess the following criteria specific to naltrexone long-acting injection.

Assess Current Opioid Use or Upcoming Need for Opiates

Because naltrexone is an opioid blocker, high doses of potent opioids delivered in a monitored setting are required to achieve analgesia in clients on naltrexone. In addition, clients who are currently taking opioids might experience immediate withdrawal effects after receiving naltrexone long-acting injection. To determine past, present, and potential future opioid use,

1. take a thorough history. Ask whether the client is planning any upcoming surgery that will require opioid use. Advise the client that administering naltrexone to a client on opioids would make them very sick (precipitated withdrawal) and, therefore, it is important that they tell their doctor about any and all opioid use.

2. conduct a point-of-care urine toxicology test. All clients should have a urine drug screen immediately prior to treatment with naltrexone. Urine drug screens should detect morphine and morphine derivatives (heroin and codeine), as well as synthetic or semisynthetic opioids (methadone, oxycodone, buprenorphine, hydrocodone, hydromorphone, etc.). Different drug screens test for different opioids. Make sure you are reading the strips correctly: opioids (MOR and OPI), methadone (METHADONE), oxycodone (OXY), and buprenorphine (BUP).

Discuss Urine Toxicology with Clients

For clients who are reluctant to participate in urine toxicology testing, provide reassurance that this testing is being offered for their safety and to support their well-being. Many clients have experience with toxicology testing as a forensic tool to catch unreported substance use. Reassure clients that the purpose of urine toxicology testing
is to support their treatment and is not a punitive tool. Point-of-care urine toxicology testing is recommended prior to administering naltrexone long-acting injection because of the safety concern that naltrexone might precipitate acute opioid withdrawal in clients who are currently physically dependent on opioids.

Assess for Physical Conditions Contraindicated for Treatment with Naltrexone Long-Acting Injection

Prior to administering naltrexone long-acting injection, check that the client does not have the following:

- acute hepatitis or hepatic impairment
- previous sensitivity or allergy to naltrexone, PLG, carboxymethylcellulose, or any other components of the diluent
- body habitus or a skin condition that would impede safe intragluteal injection
- pregnancy in women and transgender men of childbearing age.

Laboratory Testing

The following point-of-care urine testing should be obtained:

- urine drug screen for opioids, oxycodone, methadone, and buprenorphine
- if the client is a woman or transgender man of childbearing age, also obtain a point-of-care pregnancy test.

It is recommended to offer the following testing to all clients receiving a medication for AUD:

- comprehensive metabolic panel, including BUN, creatinine, and hepatic enzymes
- complete blood count, including platelet count
- screening of HIV, hepatitis C, hepatitis B, and syphilis infections
- TSH with reflex to Free T4 and T3
- lipid panel
- hemoglobin A1C
- B12 and folate
- Vitamin D.

Labs

Following completion of the assessment and potential management of alcohol withdrawal, order or review the results of the following lab tests:

- hepatic panel
- creatinine
- platelet count
- PT/INR
- pregnancy test (for females and transgender men)

NOTES: Lab results might already be in the client’s chart.

Do not withhold naltrexone if labs have not yet been obtained in a client without signs or symptoms of liver disease.
However, it is not necessary to obtain these labs prior to initiating a medication for an AUD, because waiting for the results limits the opportunity to provide effective treatment for AUD.¹

Indications of liver dysfunction include the client’s report of active liver disease, abnormal swelling of the abdomen, jaundice (yellow eyes or skin), abdominal pain, nausea, and vomiting. In addition to the above, consider the following tests if the client shows signs of liver dysfunction:

- PT
- INR.

If vitamin deficiencies are identified, treat these deficiencies. If endocrine, metabolic, hepatic, or hematologic disorders or chronic infections are identified, treat these conditions or offer referral to those with expertise in treatment of these conditions.

**Interpretation of Lab Results**

- **Pregnancy test:** To our knowledge, there are no studies assessing the safety and efficacy of naltrexone for an AUD in pregnancy. Pregnant clients with AUD should be referred for specialty treatment.

- **Hepatic panel:** Mild to moderate transaminitis (AST/ALT less than or equal to five times the upper limit of normal) is common in clients with AUD and in conditions often co-morbid with AUD, such as hepatitis C and HIV infections, and are NOT a contraindication to treatment with naltrexone. Hepatocellular injury rarely occurs with treatment with naltrexone, and clients should be evaluated for liver injury if they develop the signs or symptoms of hepatic dysfunction, such as jaundice, abdominal pain, nausea, and vomiting. Clients with severe liver disease or acute hepatitis should not be treated with naltrexone, but do not withhold naltrexone if these labs have not yet been obtained in a client without signs or symptoms of active liver disease.

- **Creatinine:** Use caution in clients with an estimated glomerular filtration rate (GFR) of less than 50, as the safety of injectable naltrexone has not been established in this population. Do not withhold naltrexone if labs have not yet been obtained in a client without signs or symptoms of renal disease.

- **Platelet count and PT/INR:** Naltrexone long-acting injection requires a deep intramuscular injection, and therefore caution is recommended in clients with a

¹ See Springer, 2017, for a discussion supporting the safety of administering naltrexone prior to acquiring baseline labs.
severe coagulopathy (platelet count less than 50,000 or INR more than two) or in clients treated with anticoagulant medications (except aspirin or standard NSAID treatment). Do not withhold naltrexone if these labs have not yet been obtained in a client without signs or symptoms of active thrombocytopenia or coagulopathies.

**Step 3: Review the Client Handout Concerning Potential Risks of Treatment**

Refer to Appendix B to review risks and benefits of naltrexone with the client.
Section 3: Administering Naltrexone Long-Acting Injection

Visit Checklist:

☐ Step 1: Administer the first injection of naltrexone long-acting injection.

☐ Step 2: Monitor the client, schedule the next visit, and provide counseling and support referrals.
Step 1: Administer the First Injection of Naltrexone Long-Acting Injection

If the client is appropriate for the medication, a licensed health care professional should prepare and administer the injection. (See Appendix C for step-by-step instructions.)

To ensure proper dosing, it is important to follow the following preparation and administration instructions:

- **dose**—The recommended dose is 380 mg, delivered intramuscularly every four weeks or once per month.

- **injection**—The injection should be administered by a health care professional as an intramuscular gluteal injection, alternating buttocks for each subsequent injection, using the carton components provided (details below). Naltrexone long-acting injection must not be administered intravenously or subcutaneously.

- **needles and suspension**—The needles provided in the carton are customized. Naltrexone long-acting injection must not be injected using any other needle.
  - Two thin-walled, 1.5-inch needles with needle protection devices are provided in the clinical drug cartons for intramuscular administration.
  - In addition, longer (2-inch) thin-walled needles with needle-protection devices are provided as ancillary supplies. For clients with a larger amount of subcutaneous tissue overlying the gluteal muscle, the administering health care professional might utilize the supplied 2-inch needle with needle-protection device to ensure that the injectate reaches the intramuscular mass.
  - Both 1.5-inch and 2-inch administration needles are provided to accommodate varying body habitus. A spare administration needle of each size is provided in case of clogging. Do not substitute any other components for the components of the carton.
  - The needle lengths (either 1.5 or 2 inches) might not be adequate in every client because of body habitus. Body habitus should be assessed prior to each injection for each client to ensure that needle length is adequate for intramuscular administration. Health care professionals should ensure that the naltrexone long-acting injection is given correctly and should consider alternate treatment for those clients whose body habitus...
precludes an intramuscular gluteal injection with one of the provided needles.
  o Naltrexone long-acting injection must be suspended only in the diluent supplied in the carton and must be administered only with one of the administration needles supplied in the carton. The microspheres, diluent, preparation needle, and administration needle with needle-protection device are required for preparation and administration.

- **Preparing the injection.** Prior to preparation, allow the drug to reach room temperature (approximately 45 minutes). Parenteral products should be visually inspected for particulate matter and discoloration prior to administration. A properly mixed suspension will be milky white, will not contain clumps, and will move freely down the wall of the vial. Prepare and administer the naltrexone long-acting injection suspension using aseptic technique.

  **Pretreatment with oral naltrexone is not required before administering naltrexone long-acting injection.**

<table>
<thead>
<tr>
<th>Proper Storage of Naltrexone Long-Acting Injection</th>
</tr>
</thead>
<tbody>
<tr>
<td>The entire carton should be stored in the refrigerator (2–8 °C, 36–46 °F). Unrefrigerated, naltrexone long-acting injection microspheres can be stored at temperatures not exceeding 25 °C (77 °F) for no more than seven days prior to administration. Do not expose unrefrigerated product to temperatures above 25 °C (77 °F). Naltrexone long-acting injection should not be frozen.</td>
</tr>
</tbody>
</table>

**Detailed, step-by-step instructions for the preparation and injection** of naltrexone long-acting injection are provided in Appendix C.
Step 2: Monitor the Client, Schedule the Next Visit, and Provide Counseling and Support Referrals

After the client has received an injection, the following steps should be taken:

1. Give the client a wallet card (see Appendix G) with notification and warning to health care providers that the client is under opioid blockade on one side and information for the client regarding who to contact in case of questions regarding side effects on the other.
2. Schedule the client to return to the clinic in four weeks for the next injection.
3. Provide local counseling and support resources.
Section 4: Assessing Treatment Progress and Adverse Events and Administering Additional Medication Doses, If Appropriate

Follow-Up Visit Checklist:

☐ Step 1: Assess the client’s drinking since the last visit (therapist or physician).

☐ Step 2: Assess the client’s involvement in counseling and support services (therapist or physician).

☐ Step 3: Assess and manage any potential medication side effects (physician).

☐ Step 4: Assess and manage any interruptions in treatment and opioid use (physician).

☐ Step 5: If appropriate, administer the next injection of naltrexone long-acting injection (physician or nurse).

A typical course of treatment with naltrexone long-acting injection for AUD involves three to six monthly injections. Reasons to discontinue naltrexone long-acting injection include intolerable side effects, clinical deterioration, or client preference.

Because the optimal duration of therapy with naltrexone long-acting injection has not been established definitively, a reasonable approach is to plan for an initial course of three monthly injections, with the decision to continue beyond three months made by the prescribing clinician and the client on a case-by-case basis.
**Step 1: Assess the Client’s Drinking Since the Last Visit**

Ask the client about their drinking status since the last visit and about any opioid use or other drug use and attendance at mutual-support groups (e.g., Alcoholics Anonymous, SMART Recovery). Allow for some open-ended discussion of the client’s current concerns about drinking or treatment with naltrexone long-acting injection. Reward any positive steps the client has made toward reducing or stopping alcohol use. Do not gloss over any problems, but attempt to stay positive and provide the client with optimism that they can recover. The client is more likely to respond to a motivational approach than a confrontational one. If the client used Drinking Tracker Cards (National Institutes of Health, undated a), these can assist with the discussion of drinking behavior.

**Possible prompts:**
- How have you been since the last visit?
- How well were you able to reduce or stop your drinking?
- What was difficult? What went well?

**For clients who did drink:**
- What were the circumstances when you drank? Remember, this is hard; change happens through small steps. It’s a good sign that you are here at your visit and still trying hard at this. Keep trying and don’t get too discouraged!
- How strong was your desire to drink? Did you have strong cravings or urges?

**If the client did drink but has experienced fewer cravings since starting treatment:**
- Reductions in your cravings are a sign that the treatment is working and that you are beginning the process of change!

**If the client’s desire to drink was strong but he or she didn’t drink:**
- Congratulations on choosing not to drink when you really wanted to. You have taken an important step toward your recovery!

**If the client did not drink:**
- Congratulations for staying abstinent. You are demonstrating your determination to change. You are making great progress toward your recovery!

These prompts are adapted from Pettinati et al., 2004.
Step 2: Assess the Client's Involvement in Counseling and Support Services

If the client attended any counseling or self-help or support meetings, provide them with positive feedback and encourage continued attendance. For clients who are not attending these services, ask whether there are any practical problems, such as coordinating the schedule of visits or transportation, so the client can attend both types of treatment. If this is a problem, work with the client to ensure that they can continue to attend both types of treatment.

Clients have better responses when they are motivated and participate in AUD treatment. Therefore, for clients willing to participate in but ambivalent about counseling and/or self-help support meetings, clinicians should explore the reasons for the client’s ambivalence and make specific suggestions to overcome common barriers to treatment acceptability, such as encouraging clients to find alternative psychosocial treatment options if they had an initial negative response to a specific meeting, counselor, or treatment approach. Specific resources for clients interested in psychosocial treatment can be found on the “Rethinking Drinking” webpage (National Institutes of Health, undated b).

Step 3: Assess and Manage Any Potential Medication Side Effects

Injection-site reactions

Ask the client about pain, redness, swelling, or irritation at the previous injection site. Mild to moderate pain and tenderness for the first several days after the injection can be treated conservatively with NSAIDs or acetaminophen, and with ice. Clients with signs or symptoms of cellulitis (e.g., fever, chills, warmth, erythema) should receive a course of treatment with antibiotics. Rarely, clients develop an abscess that might require incision and drainage. Clients with mild injection-site reactions who respond to conservative treatment can continue to receive naltrexone long-acting injection.

Hepatitis

Routine repeat liver-function tests (LFTs) are not required unless the client presents with any signs or symptoms suggestive of hepatitis (e.g., jaundice, dark urine, right upper-quadrant abdominal pain) or if the client’s initial medical history suggests that further monitoring is required (e.g., chronic hepatitis C infection). Clients who develop
severe hepatitis while on naltrexone should discontinue naltrexone (either injectable or oral).

**Depression and Suicidality**

**Mild to moderate depressed mood during treatment for a co-AUD is common.** Mood usually improves during the first two to three weeks of alcohol abstinence for most clients. These clients might be managed by explaining that their mood will likely improve and by providing additional support in the meantime. For a client whose mood does not improve during initial alcohol abstinence or who is troubled by the symptoms, treatment for depression is appropriate.

Insomnia is also a common symptom associated with problem alcohol use and with early abstinence from alcohol in clients with an AUD. These effects are usually best managed with reassurance and sleep hygiene, and clients also can be appropriately prescribed brief courses of nonbenzodiazepine and nonhypnotic sedating medications to aid in reducing insomnia.

Clients with severe depressive symptoms or serious suicidal ideation or behavior should be referred through the procedures specific to the prescriber’s state. Naltrexone long-acting injection should be discontinued in these clients if the depression seems related to the client’s treatment with naltrexone long-acting injection, although significant worsening of mental health symptoms in response to naltrexone is rare.

**Eosinophilic Pneumonia**

Eosinophilic pneumonia is a rare complication but should be considered in clients who develop progressive dyspnea and hypoxemia during treatment.

**Step 4: Assess and Manage Any Interruptions in Treatment and Opioid Use**

The greatest concern for precipitating opioid withdrawal among clients receiving ongoing treatment with naltrexone long-acting injection involves clients whose treatment has been interrupted (more than four weeks since the last injection). **Prior to any naltrexone injection, clients should be assessed for opioid use and should be** reminded that the administration of naltrexone to someone who is using opioids might precipitate severe opioid withdrawal symptoms. Clients who have used opioids while under continuous naltrexone blockade are unlikely to experience precipitated opioid withdrawal.
### Clients Requiring Opioid Analgesia

In an emergency situation requiring pain control among clients receiving naltrexone long-acting injection, suggestions for pain management include regional analgesia or use of nonopioid analgesics. If opioid therapy is required as part of anesthesia or analgesia, clients should be monitored continuously in an anesthesia care setting by qualified medical personnel. The opioid therapy must be provided by individuals trained in the use of anesthetic drugs and the management of the respiratory effects of potent opioids, specifically the establishment and maintenance of a patent airway and assisted ventilation. Irrespective of the drug chosen to reverse naltrexone opioid blockade, the client should be monitored closely by appropriately trained personnel in a hospital emergency or intensive care setting equipped and staffed for cardiopulmonary resuscitation.
Step 5: If Appropriate, Administer the Next Injection of Naltrexone Long-Acting Injection

Clients who have not experienced a serious side effect, are not at risk for precipitated opioid withdrawal, and are making progress in reducing or stopping alcohol use should receive the next injection of naltrexone long-acting injection. Use the checklist in Appendix D to guide this assessment.

If, after several months of treatment, clients are not making progress toward stopping or reducing their alcohol use, they should be encouraged to enter a treatment setting where a higher intensity of treatment can be provided (e.g., specialty outpatient or inpatient alcohol treatment program).

It is important to note that reductions in alcohol use short of complete alcohol abstinence might be reasonable signs of progress, especially early in the treatment course and among clients who are otherwise motivated and engaged in the treatment process. In clinical trials, naltrexone significantly reduced heavy drinking days (at least five drinks per day for men and at least four drinks per day for women [Jonas et al., 2014]). Clients reducing heavy drinking days without achieving abstinence also will experience reductions in the negative health and social consequences of heavy drinking.

There are no special procedures for discontinuing naltrexone long-acting injection; simply do not administer any further injections.
Prescriber Summary: Naltrexone Long-Acting Injection

- Naltrexone is dosed at 380 mg per month and injected into the alternating gluteal muscle each month.
- Naltrexone can be administered safely to clients who are actively drinking alcohol.
- Review your state’s PDMP for the presence of any recently prescribed prescription opioids.
- Obtain a point-of-care urine toxicology test that includes opioids (morphine/codeine derivatives), oxycodone, methadone, and buprenorphine.
- Order the following labs and trend if needed:
  - hepatic panel
  - creatinine
  - platelet count
  - PT/INR
  - pregnancy test (for women and transgender men).
  Do not withhold naltrexone if these labs have not yet been obtained in a client without signs or symptoms of pregnancy, active renal disease, or active liver disease.
- Verify that there are no contraindications.
  - The client is not physiologically opioid dependent, is not currently using opioids, is not exhibiting signs or symptoms of opioid intoxication or withdrawal, and is not expected to require opioid medications in the next three months. The client must have recent opioid abstinence verified by point-of-care urine toxicology.
  - Do not withhold naltrexone if baseline labs have not yet been obtained in a client without signs or symptoms of pregnancy, active renal disease, or active liver disease.
    - Pregnancy: The safety of naltrexone during pregnancy has not been established and it should be used only if the expected benefits outweigh the risks associated with naltrexone exposure during pregnancy.
    - The client should not have signs or symptoms of acute hepatitis (AST or ALT more than five times the upper limit of normal) or liver failure.
    - The client should not have known severe renal impairment (use caution if the estimated GFR is less than 50).
    - The client should not have known severe thrombocytopenia (platelet count less than 50,000) or coagulopathy (INR more than two).
  - The client does not have previous sensitivity or allergy to naltrexone, PLG, carboxymethylcellulose, or any other components of the diluent.
The client does not have an obese body habitus that prevents safe injection into the gluteal muscle or a skin condition that would impede safe intragluteal injection.

- Common side effects include headache, nausea, and injection site soreness. Naltrexone long-acting injection is known to cause anhedonia and symptoms that mimic mild opioid withdrawal immediately following the initial injection. Each of these side effects is likely to resolve with ongoing naltrexone administrations. Naltrexone can rarely cause liver inflammation, and the risk-benefit profile of naltrexone supports ongoing naltrexone treatment in clients without known severe liver inflammation (defined as LFTs more than five times the upper limit of normal [ULN]).

- Naltrexone can be administered safely to clients who received naltrexone long-acting injection within the past 28 days, even if the client has tried using opioids on top of naltrexone long-acting injection.
Part III: Prescribing Oral Medications for Clients with Co-AUD
Oral Medications for AUD

In this part, we provide information on screening recommendations, dosing instructions, and follow-up procedures for treating clients with co-AUD using various oral medications in mental health settings. We also provide prescriber summaries for each medication.

In this guide, you will find information on the following medications:

- oral naltrexone
- acamprosate
- gabapentin
- topiramate.

The remainder of the guide and the appendixes provide detailed recommendations and tools to facilitate treatment.
Information Sheet: Oral Naltrexone

Oral naltrexone (brand name: ReVia®) is a medication that can and should be prescribed for clients who are actively drinking and who wish to receive an oral medication to help them reduce their drinking. Oral naltrexone is effective in reducing heavy alcohol use in clients who are adherent (Jonas et al., 2014; Jonas and Bradley, 2014).

Assess for reduced drinking after one or two months and discontinue if the medication does not reduce drinking volume or frequency after three months at full dose. Do not continue to prescribe these medications indefinitely to clients who have not experienced a response. Assess one or two months after discontinuation of the medication to determine the client’s stability off medication. A retrial of the medication is appropriate if drinking resumes or worsens.

Contraindication with Opioid Use
Oral naltrexone is an opioid antagonist and will precipitate withdrawal in clients who are currently taking or have recently taken opioids. Thus, it is contraindicated in anyone who is currently taking any opioids or who is in opioid withdrawal. Naltrexone can be prescribed if the client has been verified (by self-report, a recent PDMP report that shows no recent opioid prescriptions, and point-of-care urine toxicology) to be free from such short-acting opioids as morphine, oxycodone, hydrocodone, and hydromorphone for at least seven days; such extended-release opioids as morphine sulfate extended-release or oxycodone extended-release for at least ten days; and such long-acting opioids methadone and buprenorphine for at least 14 days.

Screening
- It is not necessary to obtain baseline or trend liver function tests prior to prescribing naltrexone because this might limit the opportunity to provide treatment to those in need. Naltrexone is associated with a very low risk of medication-induced hepatitis and should not be withheld from clients whose LFT results have not been obtained or are moderately elevated at less than five times ULN.
- Clients with symptoms of medication-induced hepatitis from naltrexone or another AUD medication should be evaluated for the risks and benefits of the potentially offending medications and for discontinuing the offending medication if the risk does not outweigh the benefit.

Dose
- To help with tolerability, the recommended starting dose is 25 mg daily for three days, and then 50 mg daily thereafter.
• Naltrexone is dosed at 50 mg once daily. It can be increased to 200 mg or more taken by mouth daily in clients who have experienced a positive partial response at lower doses.

Recommended Follow-Up

• Clients who start medications for AUD should be seen by a coordinator, clinician, or provider no less frequently than monthly for the first three months. Busy clinic settings can use nonlicensed community health workers or care coordinators, and/or alternate modalities like telephonic or telemedicine to support visit frequency.

• A client missing an appointment is not a reason to withhold medications. All efforts should be made to continue medications for a full three-month trial because the benefits of these medications usually outweigh the risks and withholding medications for AUD limits the opportunity to provide treatment to those in need.
**Prescriber Summary: Oral Naltrexone**

- Oral naltrexone is dosed at 25 mg daily for three days, then 50 mg daily thereafter. It can be increased to 200 mg or higher taken by mouth daily in clients who have experienced a positive partial response at lower doses.
- Naltrexone can be safely prescribed to clients who are actively drinking alcohol.
- Review your state’s PDMP for the presence of any recently prescribed prescription opioids.
- Verify that there are no contraindications:
  - The client is not physiologically opioid dependent, is not currently using opioids, is not exhibiting signs or symptoms of opioid intoxication or withdrawal, and is not expected to require opioid medications in the next three months.
  - Pregnancy: The safety of naltrexone during pregnancy has not been established and it should be used only if the expected benefits outweigh the risks associated with naltrexone exposure during pregnancy.
  - The client should not have signs or symptoms of acute hepatitis (AST or ALT more than five times the upper limit of normal) or liver failure.
  - The client should not have known severe renal impairment (use caution if the estimated GFR is less than 50).
- Do not withhold naltrexone if baseline labs have not yet been obtained in a client without signs or symptoms of pregnancy, active renal disease, or active liver disease.
  - Order the following labs and trend if needed:
    - hepatic panel
    - creatinine
    - pregnancy test (for women and transgender men).
- Common side effects include headache and nausea. These side effects are likely to resolve with maintaining a lower initial dose (25 mg daily for more than three days) and ongoing naltrexone adherence. Naltrexone can rarely cause liver inflammation, and the risk-benefit profile of naltrexone supports ongoing naltrexone treatment in clients without known severe liver inflammation (defined as LFTs more than five times ULN).
Acamprosate (brand name: Campral®) is a medication that can and should be prescribed for clients with an AUD who are not appropriate for alternative medications and who desire an oral medication. The mechanism of action of acamprosate for alcohol abstinence is not understood but might interact with the glutamate and gamma-aminobutyric acid (GABA) neurotransmitter systems.

Assess for reduced drinking after one or two months and discontinue if the medication is not effective to maintain abstinence after three months at full dose. Do not continue to prescribe these medications indefinitely to clients who have not experienced a response. Assess one or two months after discontinuation of the medication to determine the client’s stability off medication. A retrial of the medication is appropriate if drinking resumes or worsens.

Screening
- This medication is contraindicated in clients who have severe renal impairment (creatinine clearance less than or equal to 30 mL per minute), and requires reduced dosing with moderate renal impairment (creatinine clearance 30–50 mL per minute). There is no need to withhold acamprosate from clients without a history of renal disease where a baseline kidney function (GFR) has not been obtained, but it is recommended to assess kidney function prior to prescribing acamprosate in a client with renal insufficiency or failure.
- It is not necessary to obtain baseline or trend liver function tests when prescribing acamprosate because this might limit the opportunity to provide treatment to those in need.

Dose
- Initiate one 333 mg tablet three times daily for three days before proceeding to the maintenance dose.
- The recommended maintenance dose is two 333 mg tablets (each dose should total 666 mg) taken three times daily.
- For those with moderate renal impairment, a dose of one 333 mg tablet taken three times daily is recommended.
- Although dosing can be done without regard to meals, dosing with meals during clinical trials appeared to aid adherence in clients who regularly eat three meals daily.
Recommended Follow-Up

- Clients who start medications for AUD should be seen by a clinician, counselor, psychiatrist, nurse, or nurse practitioner no less frequently than monthly for the first three months. Alternate modalities (like telephonic or telemedicine) can support visit frequency.

- A client missing an appointment is not a reason to withhold medications. All efforts should be made to continue medications for a full three-month trial because the benefits of these medications usually outweigh risks and withholding medications for AUD limits the opportunity to provide treatment to those in need.
Prescriber Summary: Acamprosate

- Acamprosate is dosed at 333 mg three times per day for three days, then 666 mg three times per day thereafter.
- Acamprosate can be safely prescribed to clients who are actively drinking alcohol.
- It can be safely used in clients who take opioids and in clients with acute hepatic disease.
- There are few contraindications, but the client should not have known severe renal impairment (use caution if estimated GFR is less than 30) or be pregnant.
- Do not withhold acamprosate if baseline labs have not yet been obtained in a client without signs or symptoms of pregnancy or severe renal impairment.
  - Order the following labs and trend if needed:
    - creatinine
    - pregnancy test (for women and transgender men).
- Common side effects include nausea and diarrhea. These side effects are likely to resolve with maintaining a lower initial dose (333 mg three times per day) for more than three days and with ongoing acamprosate adherence.
- There is no evidence of benefit when adding acamprosate to the medication regimen of clients who adhere to naltrexone.
Gabapentin and topiramate are medications that can and should be prescribed to clients who are actively drinking, who want to take an oral medication, and for whom naltrexone or acamprosate are contraindicated or ineffective.

Assess for reduced drinking after one or two months and discontinue these medications if they do not reduce drinking volume or frequency after three months at full dose. Do not continue to prescribe these medications indefinitely to clients who have not experienced a response. Assess one or two months after discontinuation of these medications to determine the client’s stability off medications.

A retrial of these medications is appropriate if drinking resumes or worsens.

**Screening**
- It is not necessary to obtain baseline or trend liver function tests prior to prescribing gabapentin or topiramate because this might limit the opportunity to provide treatment to those in need.
- Clients with symptoms of medication-induced hepatitis should be evaluated for the risk or benefit of the potentially offending medications and for discontinuing the offending medication if the risk does not outweigh the benefit.
- Gabapentin has an overuse potential that is higher in individuals with a sedative use disorder and/or an opioid use disorder.

**Dose**
Gabapentin or topiramate should be considered as a second line for clients who do not tolerate or improve on naltrexone. Consider a trial of either
- gabapentin at doses of 300–600 mg by mouth three times daily. Dosing often is titrated by an additional 300 mg per day every three to seven days as tolerated. The maximum dose is 2,400 mg per day.
- topiramate at doses of 200–300 mg by mouth daily. Usually start at 50 mg by mouth daily and titrate by 50 mg every week. The maximum dose is 400 mg per day.

If a client has a contraindication to gabapentin or topiramate, providers can consider acamprosate.

**Recommended Follow-Up**
- Clients who start medications for AUD should be seen by a clinician, counselor, psychiatrist, nurse, or nurse practitioner no less frequently than monthly for the
first three months. Alternate modalities (like telephonic or telemedicine) can support visit frequency.

- A client missing an appointment is not a reason to withhold medications. All efforts should be made to continue medications for a full three-month trial because the benefits of these medications usually outweigh the risks and withholding medications for AUD limits the opportunity to provide treatment to those in need.
Prescriber Summary: Gabapentin

- Gabapentin is dosed at 300 mg three times per day initially. For clients who can tolerate the adverse effects of gabapentin, the prescriber can increase the dose to a maximum of 2,400 mg three times per day. Prescribers can consider doses of gabapentin near the maximum if they are attempting to mitigate the risk of an alcohol withdrawal seizure.
- Gabapentin can be safely prescribed to clients who are actively drinking alcohol.
- Gabapentin can be safely used in clients who take opioids and in clients with acute hepatic disease.
- It is relatively contraindicated if the client has a history of inappropriate overuse of gabapentin.
- The dose should be adjusted if there is renal impairment present.
- Common adverse effects include sedation, edema, nausea, ataxia, nystagmus, and overuse.

Prescriber Summary: Topiramate

- Topiramate is dosed at 50 mg daily and can be increased, if tolerated, to a maximum dose of 400 mg daily.
- Topiramate can be safely prescribed to clients who are actively drinking alcohol.
- It can be safely used in clients who take opioids and in clients with acute hepatic disease.
- The dose should be adjusted if there is renal impairment present.
- Common adverse effects include sedation, confusion, fever, impaired cognition, loss of appetite and weight loss, and metabolic acidosis. More-rare adverse effects include liver inflammation; glaucoma; renal impairment; and skin inflammation, such as Stevens-Johnson syndrome.
Appendix A: Pre-Injection Checklist for Appropriateness for Naltrexone Long-Acting Injection

Pre-Injection Checklist for Appropriateness for Naltrexone Long-Acting Injection

Client name: _________________________________________________________________
Date: _________________________________

<table>
<thead>
<tr>
<th>YES</th>
<th>NO</th>
<th>Criteria</th>
</tr>
</thead>
<tbody>
<tr>
<td>☐</td>
<td>☐</td>
<td>Client meets DSM-5 criteria for AUD</td>
</tr>
<tr>
<td>☐</td>
<td>☐</td>
<td>Client does <strong>NOT</strong> require inpatient alcohol withdrawal management (no current signs of severe alcohol withdrawal; no history of requiring hospitalization for severe alcohol withdrawal, seizures, or delirium tremens)</td>
</tr>
<tr>
<td>☐</td>
<td>☐</td>
<td>Client is motivated to reduce or stop alcohol use</td>
</tr>
<tr>
<td>☐</td>
<td>☐</td>
<td>Client is <strong>NOT</strong> physiologically opioid dependent, is <strong>NOT</strong> currently using opioids, and is <strong>NOT</strong> exhibiting signs or symptoms of opioid intoxication or withdrawal</td>
</tr>
<tr>
<td>☐</td>
<td>☐</td>
<td>Urine drug screen negative for opioids</td>
</tr>
<tr>
<td>☐</td>
<td>☐</td>
<td>Client is <strong>NOT</strong> expected to require opioid medications in the next three months</td>
</tr>
<tr>
<td>☐</td>
<td>☐</td>
<td>Client does <strong>NOT</strong> have signs or symptoms of acute hepatitis (AST or ALT more than five times upper limit of normal) or liver failure. <strong>Do not withhold naltrexone if these labs have not yet been obtained in a client without signs or symptoms of active liver disease.</strong></td>
</tr>
<tr>
<td>☐</td>
<td>☐</td>
<td>Client does <strong>NOT</strong> have known severe renal impairment (use caution if estimated glomerular filtration rate [GFR] is less than 50). <strong>Do not withhold naltrexone if these labs have not yet been obtained in a client without signs or symptoms of active renal disease.</strong></td>
</tr>
<tr>
<td>☐</td>
<td>☐</td>
<td>Client does <strong>NOT</strong> have known severe thrombocytopenia (platelet count less than 50,000) or coagulopathy (INR more than two). <strong>Do not withhold naltrexone if these labs have not yet been obtained in a client without signs or symptoms of active thrombocytopenia or coagulopathies.</strong></td>
</tr>
<tr>
<td>☐</td>
<td>☐</td>
<td>Client does <strong>NOT</strong> have previous sensitivity or allergy to naltrexone, polylactide-co-glycolide (PLG), carboxymethylcellulose, or any other components of the diluent.</td>
</tr>
</tbody>
</table>

**IF YES TO ALL CRITERIA ABOVE, ADMINISTER FIRST INJECTION**
Appendix B: Risks of Naltrexone Long-Acting Injection Worksheet (English and Spanish Versions)

Naltrexone Long-Acting Injection Client Handout

What is naltrexone long-acting injection?
It is a monthly shot that might help you to stop or reduce your alcohol use.

Important: Please tell your doctor before you start treatment if . . .
- you use drugs (for example, morphine, Vicodin, methadone, Suboxone, oxycodone, heroin)
  - Do NOT use opioid drugs for the first two to three weeks after stopping treatment; it could result in an overdose.
- you are going to have surgery or medical treatment that might include pain medications
- you have any liver disease(s)
- you are pregnant, intend to get pregnant, or are breastfeeding.
  - You should NOT get any treatment shots if you are pregnant or breastfeeding.

Side effects and complications of naltrexone long-acting injection
- The most common side effect is mild nausea, which usually goes away within days after the shot.
- You might experience a little pain at the location of the shot.
  - You may use over-the-counter pain medications, such as Tylenol or Advil.
- You might feel sad; if you have thoughts about hurting or killing yourself, notify your doctor RIGHT AWAY.
- Some might experience an allergic reaction.
- It might harm your liver or cause hepatitis in some individuals.

Notify your doctor RIGHT AWAY if . . .
- you have bad pain at the site of the shot
- the location of the shot feels hard, is red, or if there is a bump or blister
- there is an open cut at the site of the shot
- you have stomach pain lasting longer than a few days
- you have dark urine
- the area around your eyes is yellow
- you feel really tired
- you are having a hard time breathing
- you are coughing and it does not go away
- you have a skin rash
- swelling of your face, eyes, mouth, or tongue happens
- you feel chest pain
- you feel dizzy or weak.

If you experience any side effects or complications, please contact your doctor immediately.
La Naltrexona Inyectable de Liberación Prolongada
Folleto para el Paciente

¿Qué es la naltrexona inyectable de liberación prolongada?
Es una inyección mensual que puede ayudle a dejar o reducir su consumo del alcohol.

Importante: Por favor, informe a su médico antes de comenzar el tratamiento si . . .
- Utiliza drogas (por ejemplo, Morfina, Vicodina, Metadona, Suboxone, la Oxicodona, Heroína)
  - No consuma este drogas durante las primeras dos o tres semanas después de suspender el tratamiento, dado que puede resultar en una sobredosis.
- Usted va a tener una cirugía o tratamiento médico que puede necesitar medicamentos para el dolor
- Tiene alguna enfermedad(es) del hígado
- Está embarazada, piensa quedar embarazada o está amamantando
  - NO debe tener tratamientos de vacunas si está embarazada o está amamantando.

Efectos secundarios y complicaciones de la naltrexona inyectable de liberación prolongada:
- El efecto secundario más común es la náusea leve, por lo general desaparece a los pocos días después de la inyección
- Un poco de dolor en el lugar de la inyección
  - Usted puede usar los medicamentos para el dolor sin receta, como Tylenol o Advil
- Es posible que se sienta triste. Si tiene pensamientos de hacerse daño o suicidarse, avise a su médico inmediatamente
- Algunas personas pueden tener una reacción alérgica
- Puede dañar el hígado o causar hepatitis en algunas personas.

Informe a su médico de inmediato si . . .
- tiene dolor fuerte en el sitio de la inyección
- el sitio de la inyección se siente duro, hay un bulto, una ampolla o está rojo
- tiene una herida abierta en el sitio de la inyección
- tiene dolor de estómago que dura más de unos pocos días
- tiene orina oscura
- el área alrededor de los ojos está amarilla
- se siente muy cansado
- está teniendo dificultad cuando respira
- tiene tos y no se le quita
- tiene sarpullido
- tiene hinchazón de la cara, los ojos, la boca o la lengua
- siente dolor de pecho
- se siente mareado o débil.

Si usted siente alguno de los efectos secundarios o complicaciones, por favor póngase en contacto con su médico inmediatamente.
Appendix C: Step-by-Step Instructions for the Preparation and Injection of Naltrexone Long-Acting Injection

Injections should be administered by a physician or a nurse. Proper intragluteal injection is important to minimize the chance of injection-site reactions. Naltrexone must NOT be administered subcutaneously or intravenously. Note: These instructions and figures are from the Vivitrol® package insert.

1. Remove the carton from refrigeration. Prior to preparation, allow drug to reach room temperature (approximately 45 minutes).
2. To ease mixing, firmly tap the VIVITROL Microspheres vial on a hard surface, ensuring the powder moves freely (see Figure B).
3. Remove flip-off caps from both vials. DO NOT USE IF FLIP-OFF CAPS ARE BROKEN OR MISSING.
4. Wipe the vial tops with an alcohol swab.
5. Place the 1-inch preparation needle on the syringe and withdraw 3.4 mL of the diluent from the diluent vial. Some diluent will remain in the diluent vial (see Figure B).
Inject the 3.4 mL of diluent into the VIVITROL Microsphere vial (see Figure C).

Mix the powder and diluent by vigorously shaking the vial for approximately 1 minute (see Figure D). Ensure that the dose is thoroughly suspended prior to proceeding to Step E.

A PROPERLY MIXED SUSPENSION WILL BE MILKY WHITE, WILL NOT CONTAIN CLUMPS, AND WILL MOVE FREELY DOWN THE WALLS OF THE VIAL.

1. Immediately after suspension, withdraw 4.2 mL of the suspension into the syringe using the same preparation needle (see Figure E).
2. Select the appropriate needle for an intramuscular injection based on client’s body habitus:
   a. 1.5-inch TERUMO® Needle
   b. 2-inch NEEDLE-PRO® Needle
1. Remove the preparation needle and replace with appropriately selected administration needle for immediate use.

2. Peel the blister pouch of the selected administration needle open halfway. Grasp sheath using the plastic pouch. Attach the Luer connection to the syringe with an easy clockwise twisting motion (see Figure F).

3. Seat the needle firmly on the protection device with a push and clockwise twist.

---

1. Pull the sheath away from the needle—do not twist the sheath because it could result in loosening the needle.

2. Prior to injecting, tap the syringe to release any air bubbles, then push gently on the plunger until 4 mL of the suspension remains in the syringe (see Figure G).

**THE SUSPENSION IS NOW READY FOR IMMEDIATE ADMINISTRATION.**

---

1. Administer the suspension by deep intramuscular (IM) injection into a gluteal muscle, alternating buttocks per monthly injection. Remember to aspirate for blood before injection (see Figure H).

2. If blood aspirates or the needle clogs, do not inject. Change to the spare needle provided in the carton and administer into an adjacent site in the same gluteal region, again aspirating for blood before injection.

3. Inject the suspension in a smooth and continuous motion.

**VIVITROL must NOT be given intravenously or subcutaneously.**
After the injection is administered, cover the needle by pressing the needle-protection device against a flat surface using a one-handed motion away from self and others (see Figure I).

Visually confirm needle is fully engaged into the needle-protection device (see Figure J).

DISPOSE OF USED AND UNUSED ITEMS IN PROPER WASTE CONTAINERS.
# Appendix D: Follow-Up Visit Pre-Injection Checklists

## Naltrexone Long-Acting Injection Follow-Up Visit Pre-Injection Checklist

**Client name:**

**Date:**

<table>
<thead>
<tr>
<th>Yes</th>
<th>No</th>
<th>Criteria</th>
</tr>
</thead>
<tbody>
<tr>
<td>☐</td>
<td>☐</td>
<td>Client is making sufficient progress toward goal of alcohol abstinence</td>
</tr>
<tr>
<td>☐</td>
<td>☐</td>
<td>Potential side effects have been assessed and managed—e.g.,</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• injection site reactions</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• nausea</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• acute hepatitis (consider recheck of hepatic panel if there are signs and symptoms of hepatitis)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• depression or suicidality</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• eosinophilic pneumonia</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• need for opioid analgesia.</td>
</tr>
<tr>
<td>☐</td>
<td>☐</td>
<td>Interruptions of naltrexone opioid blockade and any intervening opioid use have been assessed.</td>
</tr>
<tr>
<td>☐</td>
<td>☐</td>
<td>There is no indication that treatment with opioid analgesics is likely in the next month.</td>
</tr>
</tbody>
</table>

**IF YES TO ALL CRITERIA ABOVE, ADMINISTER NEXT INJECTION**

**Completed by:** _____________________________________________________________

**MD name:** ________________________________________________________________

**MD signature:** _____________________________________________________________

**Date:** __________________________________
# Appendix E: DSM-5 AUD Diagnosis Worksheet

<table>
<thead>
<tr>
<th>Client's name:</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Worksheet for DSM-5 criteria for diagnosis of AUD</strong></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Diagnostic criteria*</th>
</tr>
</thead>
<tbody>
<tr>
<td>(Current diagnosis requires meeting two or more criteria in the PAST 12 MONTHS)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Meets criteria?</th>
<th>Notes/supporting information</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
<td>No</td>
</tr>
</tbody>
</table>

| (1) Alcohol often is taken in larger amounts or over a longer period than was intended. | |

**Possible prompts:**
- *Are you unable to have just one drink?*

| (2) There is a persistent desire or are unsuccessful efforts to cut down or control alcohol use. | |

**Possible prompts:**
- *Can you stop when you want to?*

| (3) A great deal of time is spent in activities necessary to obtain alcohol, use alcohol, or recover from its effects. | |

**Possible prompts:**
- *Do you spend a great deal of your time drinking, getting alcohol, or recovering from drinking [hangovers]?*

| (4) Craving, or a strong desire or urge to use alcohol. | |

| (5) Recurrent alcohol use resulting in a failure to fulfill rote obligations at work, school, or home. | |

| (6) Continued alcohol use despite having persistent or recurrent social or interpersonal problems caused or exacerbated by the effects of alcohol. | |
### Client’s name:

### Worksheet for DSM-5 criteria for diagnosis of AUD

<table>
<thead>
<tr>
<th>Diagnostic criteria*</th>
<th>Meets criteria?</th>
<th>Notes/supporting information</th>
</tr>
</thead>
<tbody>
<tr>
<td>(Current diagnosis requires meeting two or more criteria in the PAST 12 MONTHS)</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>(7) Important social, occupational, or recreational activities are given up or reduced because of alcohol use.</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Possible prompt:**
- *Does your drinking get in the way of doing other things that don't involve alcohol? For example, do you miss work because of drinking or spend less time with family or friends who do not drink?*

| (8) Recurrent alcohol use in situations in which it is physically hazardous. |  |  |
| (9) Alcohol use is continued despite knowledge of having a persistent or recurrent physical or psychological problem that is likely to have been caused or exacerbated by alcohol. |  |  |

**Possible prompts:**
- *Have any bad things happened as a result of your drinking—to you or other people?*
- *Do you continue to drink even though your drinking is causing harm?*

| (10) Tolerance, as defined by either of the following: |  |  |
| a. a need for markedly increased amounts of alcohol to achieve intoxication or desired effect. |  |  |
| b. a markedly diminished effect with continued use of the same amount of alcohol. |  |  |
### Client’s name:

**Worksheet for DSM-5 criteria for diagnosis of AUD**

<table>
<thead>
<tr>
<th>Diagnostic criteria* (Current diagnosis requires meeting two or more criteria in the PAST 12 MONTHS)</th>
<th>Meets criteria?</th>
<th>Notes/supporting information</th>
</tr>
</thead>
<tbody>
<tr>
<td>(11) Withdrawal, as manifested by either of the following:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>a. the characteristic withdrawal syndrome for alcohol (see Appendix F)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>b. alcohol (or a closely related substance, such as a benzodiazepine) is taken to relieve or avoid withdrawal symptoms.</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Possible prompt:**

- *Do you have symptoms, such as anxiety or “the shakes,” when you don’t drink?*
Appendix F: CIWA-Ar Worksheet

<table>
<thead>
<tr>
<th>Clinical Institute Withdrawal Assessment of Alcohol Scale, Revised (CIWA-Ar)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Patient:</strong> ______________________ <strong>Date:</strong> ___________ <strong>Time:</strong> ___________ <em>(24 hour clock, midnight = 00:00)</em></td>
</tr>
<tr>
<td><strong>Pulse or heart rate, taken for one minute:</strong> ___________ <strong>Blood pressure:</strong> ___________</td>
</tr>
<tr>
<td><strong>NAUSEA AND VOMITING</strong> — Ask “Do you feel sick to your stomach? Have you vomited?” Observation.</td>
</tr>
<tr>
<td>0 no nausea and no vomiting</td>
</tr>
<tr>
<td>1 mild nausea with no vomiting</td>
</tr>
<tr>
<td>2</td>
</tr>
<tr>
<td>3</td>
</tr>
<tr>
<td>4 intermittent nausea with dry heaves</td>
</tr>
<tr>
<td>5</td>
</tr>
<tr>
<td>6</td>
</tr>
<tr>
<td>7 constant nausea, frequent dry heaves and vomiting</td>
</tr>
<tr>
<td><strong>TACTILE DISTURBANCES</strong> — Ask “Have you any itching, pins and needles sensations, any burning, any numbness, or do you feel bugs crawling on or under your skin?” Observation.</td>
</tr>
<tr>
<td>0 none</td>
</tr>
<tr>
<td>1 very mild itching, pins and needles, burning or numbness</td>
</tr>
<tr>
<td>2 mild itching, pins and needles, burning or numbness</td>
</tr>
<tr>
<td>3 moderate itching, pins and needles, burning or numbness</td>
</tr>
<tr>
<td>4 moderately severe hallucinations</td>
</tr>
<tr>
<td>5 severe hallucinations</td>
</tr>
<tr>
<td>6 extremely severe hallucinations</td>
</tr>
<tr>
<td>7 continuous hallucinations</td>
</tr>
<tr>
<td><strong>TREMOR</strong> — Arms extended and fingers spread apart Observation.</td>
</tr>
<tr>
<td>0 no tremor</td>
</tr>
<tr>
<td>1 not visible, but can be felt fingertip to fingertip</td>
</tr>
<tr>
<td>2</td>
</tr>
<tr>
<td>3</td>
</tr>
<tr>
<td>4 moderate, with patient's arms extended</td>
</tr>
<tr>
<td>5</td>
</tr>
<tr>
<td>6</td>
</tr>
<tr>
<td>7 severe, even with arms not extended</td>
</tr>
<tr>
<td><strong>AUDITORY DISTURBANCES</strong> — Ask “Are you more aware of sounds around you? Are they harsh? Do they frighten you? Are you hearing anything that is disturbing to you? Are you hearing things you know are not there?” Observation.</td>
</tr>
<tr>
<td>0 not present</td>
</tr>
<tr>
<td>1 very mild harshness or ability to frighten</td>
</tr>
<tr>
<td>2 mild harshness or ability to frighten</td>
</tr>
<tr>
<td>3 moderate harshness or ability to frighten</td>
</tr>
<tr>
<td>4 moderately severe hallucinations</td>
</tr>
<tr>
<td>5 severe hallucinations</td>
</tr>
<tr>
<td>6 extremely severe hallucinations</td>
</tr>
<tr>
<td>7 continuous hallucinations</td>
</tr>
<tr>
<td><strong>PAROXYSMAL SWEATS</strong> — Observation.</td>
</tr>
<tr>
<td>0 no sweat visible</td>
</tr>
<tr>
<td>1 barely perceptible sweating, palms moist</td>
</tr>
<tr>
<td>2</td>
</tr>
<tr>
<td>3</td>
</tr>
<tr>
<td>4 beads of sweat obvious on forehead</td>
</tr>
<tr>
<td>5</td>
</tr>
<tr>
<td>6</td>
</tr>
<tr>
<td>7 drenching sweats</td>
</tr>
<tr>
<td><strong>VISUAL DISTURBANCES</strong> — Ask “Does the light appear to be too bright? Is its color different? Does it hurt your eyes? Are you seeing anything that is disturbing to you? Are you seeing things you know are not there?” Observation.</td>
</tr>
<tr>
<td>0 not present</td>
</tr>
<tr>
<td>1 very mild sensitivity</td>
</tr>
<tr>
<td>2 mild sensitivity</td>
</tr>
<tr>
<td>3 moderate sensitivity</td>
</tr>
<tr>
<td>4 moderately severe hallucinations</td>
</tr>
<tr>
<td>5 severe hallucinations</td>
</tr>
<tr>
<td>6 extremely severe hallucinations</td>
</tr>
<tr>
<td>7 continuous hallucinations</td>
</tr>
<tr>
<td><strong>ANXIETY</strong> — Ask “Do you feel nervous?” Observation.</td>
</tr>
<tr>
<td>0 no anxiety, at ease</td>
</tr>
<tr>
<td>1 mild anxious</td>
</tr>
<tr>
<td>2</td>
</tr>
<tr>
<td>3</td>
</tr>
<tr>
<td>4 moderately anxious, or guarded, so anxiety is inferred</td>
</tr>
<tr>
<td>5</td>
</tr>
<tr>
<td>6</td>
</tr>
<tr>
<td>7 equivalent to acute panic states as seen in severe delirium or acute schizophrenic reactions</td>
</tr>
<tr>
<td><strong>HEADACHE, FULLNESS IN HEAD</strong> — Ask “Does your head feel different? Does it feel like there is a band around your head?” Do not rate for dizziness or lightheadedness. Otherwise, rate severity.</td>
</tr>
<tr>
<td>0 not present</td>
</tr>
<tr>
<td>1 very mild</td>
</tr>
<tr>
<td>2 mild</td>
</tr>
<tr>
<td>3 moderate</td>
</tr>
<tr>
<td>4 moderately severe</td>
</tr>
<tr>
<td>5 severe</td>
</tr>
<tr>
<td>6 very severe</td>
</tr>
<tr>
<td>7 extremely severe</td>
</tr>
</tbody>
</table>
AGITATION -- Observation.
0 normal activity
1 somewhat more than normal activity
2
3
4 moderately fidgety and restless
5
6
7 paces back and forth during most of the interview, or constantly thrashes about

ORIENTATION AND CLOUDING OF SENSORIUM -- Ask
“What day is this? Where are you? Who am I?”
0 oriented and can do serial additions
1 cannot do serial additions or is uncertain about date
2 disoriented for date by no more than 2 calendar days
3 disoriented for date by more than 2 calendar days
4 disoriented for place/or person

Total CIWA-Ar Score
Rater’s Initials
Maximum Possible Score 67

The CIWA-Ar is not copyrighted and may be reproduced freely. This assessment for monitoring withdrawal symptoms requires approximately 5 minutes to administer. The maximum score is 67 (see instrument). Patients scoring less than 10 do not usually need additional medication for withdrawal.

Appendix G: Wallet Cards

Important Information For Emergency Pain Management
I am currently taking naltrexone for extended-release injectable suspension, an opioid antagonist. Please see the back of this card for important information about pain management.

My name: ________________
Emergency contact name: ________________
My doctor: ________________
My doctor’s number: ________________
Call 1-888-835-8008
For Full Prescribing Information, including brand warnings visit www.tao-armedinfo.com

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My doctor: ________________
My doctor’s number: ________________
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