Naltrexone for Opioid Dependence

**Dosage**
- 50 mg/day

**Alternative Dosing Schedules**
- 25 mg daily or twice a day (b.i.d.) with meals to reduce nausea, especially during the first week
- Observed administration improves compliance.
- Full opioid blockade is produced with a schedule of 100 mg on Monday and Wednesday and 150 mg on Friday

**Baseline Evaluation**
- Assure patient completed a naloxone challenge and/or has had at least 7 to 10 days of verified abstinence
- Transaminase levels
- Urine toxicology

**Patient Education**
- Discuss compliance-enhancing procedures.
- Negotiate commitment from the patient regarding monitored ingestion, if necessary.
- Provide patients with wallet cards that indicate use of naltrexone.

**Monitoring**
- Monitor for opioid use at least weekly during early recovery, via urine toxicology.
- Repeat transaminase levels monthly for the first 3 months and every 3 months thereafter.
- Discontinue/reduce naltrexone, if transaminase levels rise significantly.
- Reevaluate patient compliance and progress at least every 3 months and adjust the treatment plan as necessary.
- Continue treatment for 12-24 months, if the patient maintains abstinence.
- Consider reinstating naltrexone if the patient relapses to opioid use after discontinuation of naltrexone.

**Indications for Use**
- Opioid dependence with:
  - Ability to achieve at least 7-10 days of abstinence to rule out the need for opioid detoxification
  - Note: Most effective when the patient is engaged in addiction-focused counseling with monitored administration (e.g., patients in criminal justice system or health care workers with employment-related monitoring).

**Contraindications for Use**
- Pregnancy
- Opioid withdrawal
- Opioid dependence, with use within past week
- Medical condition requiring opioid medication
- Severe hepatic dysfunction (i.e., transaminase levels > 3 times normal, or liver failure)
- Severe renal failure
- Allergy to naltrexone

**Side Effects**
- Common: nausea (~10%)
- Other: headache, dizziness, nervousness, fatigue, insomnia, vomiting, anxiety, and somnolence
- Severe: anaphylaxis, status asthmaticus, respiratory distress

**Drug Interactions**
- Opioid containing medications, including over-the-counter (OTC) preparations
- Thioridazine
- Oral hypoglycemics

**Agonist Therapy for Opioid Dependence**

<table>
<thead>
<tr>
<th>Indications</th>
<th>Opioid Agonist: Methadone and LAAM</th>
</tr>
</thead>
<tbody>
<tr>
<td>Opioid dependence ≥1 year</td>
<td></td>
</tr>
<tr>
<td>2 or more unsuccessful opioid detoxification episodes within a 12-month period</td>
<td></td>
</tr>
<tr>
<td>Relapse to opioid dependence within 2 years from OAT discharge</td>
<td></td>
</tr>
</tbody>
</table>

**Contraindications**
- Allergy to agent
- Concurrent enrollment in another OAT
- Significant liver failure
- Use of opioid antagonists (e.g., naltrexone, naloxone, nalmefene, or naltrexone)
- For LAAM, EKG with QT interval > 0.45 seconds

**Side Effects**
- Common: constipation
- Less common: sexual dysfunction
- QT interval prolongation (LAAM)

**Drug Interactions**
- Drugs that reduce serum methadone level:
  - Rifampicin
  - Barbiturates
  - Alcohol
  - Alcohol dependence with patient education
  - Least every 3 months and adjust the treatment plan as necessary.

**VA/DoD Pocket Guide**

MANAGEMENT OF SUBSTANCE USE DISORDERS
Module P: Addiction-Focused Pharmacotherapy for Opioid and Alcohol Dependence

1. Patient is opioid dependent.

2. Is opioid agonist therapy (OAT) appropriate for and acceptable to the patient?

3. Is naltrexone therapy appropriate for and acceptable to the patient?

4. Arrange for detoxification if indicated. See Module S - Stabilization and Monitoring.

5. Coordinate with addiction-focused counseling.

6. Patient is alcohol dependent.

7. Is pharmacotherapy for alcohol dependence indicated?

8. Initiate pharmacotherapy for alcohol dependence with patient education and monitoring.

9. Note: Most effective when the patient is engaged in addiction-focused counseling with monitored administration (e.g., patients in criminal justice system or health care workers with employment-related monitoring).
### Pharmacotherapy for Alcohol Dependence

<table>
<thead>
<tr>
<th>Naltrexone</th>
<th>Disulfiram</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Dosage</strong></td>
<td><strong>250 mg/day</strong></td>
</tr>
<tr>
<td><strong>Alternative Dosing Schedules</strong></td>
<td><strong>25 mg daily or b.i.d. with meals to reduce nausea, especially during the first week</strong></td>
</tr>
<tr>
<td></td>
<td><strong>Full therapeutic effect is produced with a schedule of 100 mg on Monday and Wednesday and 150 mg on Friday.</strong></td>
</tr>
<tr>
<td></td>
<td><strong>If a patient taking 250 mg of disulfiram daily drinks alcohol and has no reaction, consider increasing dose to 300 mg daily.</strong></td>
</tr>
<tr>
<td><strong>Baseline Evaluation</strong></td>
<td><strong>Transaminase levels</strong></td>
</tr>
<tr>
<td></td>
<td><strong>Physical assessment</strong></td>
</tr>
<tr>
<td></td>
<td><strong>Psychiatric assessment</strong></td>
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<td></td>
<td><strong>Electrocardiogram</strong></td>
</tr>
<tr>
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<td><strong>Verify abstinence with breath or blood alcohol level.</strong></td>
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<td><strong>Monitoring</strong></td>
<td><strong>Repeat transaminase levels monthly for the first 3 months and every 3 months thereafter, and discontinue if levels significantly rise.</strong></td>
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<td><strong>Continue treatment 3-12 months if the patient is making satisfactory progress towards treatment goals.</strong></td>
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<tr>
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<tr>
<td></td>
<td><strong>Thioridazine</strong></td>
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**Contraindications for Use**

- Pregnancy
- Severe cardiovascular, respiratory, or renal disease
- Severe hepatic dysfunction (i.e., transaminase levels > 3 times upper limit of normal or in liver failure)
- Severe psychiatric disorders, especially psychotic and cognitive disorders and suicidal ideation
- Poor impulse control
- Previous disulfiram-ethanol reaction
- Metronidazole or ketoconazole therapy, which already induces a similar reaction to alcohol
- Allergy to disulfiram

**Side Effects**

- Common (usually mild and self-limiting): somnolence, metallic taste, and headache
- Common (usually mild and self-limiting): somnolence, metallic taste, and headache
- Less common, but more serious: Hepatotoxicity, peripheral neuropathy, psychosis, and delirium

**Drug Interactions**

- Opioid containing medications, including OTC preparations
- Severity of disulfiram-ethanol reaction varies considerably among patients and is generally dose-related, causing vasodilatation, flushing, hypotension, nausea, vomiting, dizziness, tachycardia, cardiac arrhythmias, myocardial infarction/stroke in susceptible patients, and even death from cardiac complications in older patients.
- Drug-drug interactions may occur with phenytoin, warfarin, isoniazid, rifampin, diazepam, chlordiazepoxide, imipramine, desipramine, and oral hypoglycemic agents.

**Baseline Evaluation**

- **Transaminase levels**
- **Physical assessment**
- **Psychiatric assessment**
- **Electrocardiogram**
- **Verify abstinence with breath or blood alcohol level.**

**Patient Education**

- **Discuss compliance-enhancing procedures.**
- **If necessary, negotiate commitment from the patient regarding monitored ingestion.**
- **Provide wallet cards that indicate the use of naltrexone.**
- **Note that side effects, if any, tend to occur early in treatment and can typically be resolved within 1-2 weeks with dose adjustment.**

**Monitoring**

- **Repeat transaminase levels monthly for the first 3 months and every 3 months thereafter, and discontinue if levels significantly rise.**
- **Continue treatment 3-12 months if the patient is making satisfactory progress towards treatment goals.**
- **Consider reinstating naltrexone, if the patient relapses to harmful alcohol use after discontinuation of naltrexone.**

**Drug Interactions**

- Opioid containing medications, including OTC preparations
- Severity of disulfiram-ethanol reaction varies considerably among patients and is generally dose-related, causing vasodilatation, flushing, hypotension, nausea, vomiting, dizziness, tachycardia, cardiac arrhythmias, myocardial infarction/stroke in susceptible patients, and even death from cardiac complications in older patients.
- Drug-drug interactions may occur with phenytoin, warfarin, isoniazid, rifampin, diazepam, chlordiazepoxide, imipramine, desipramine, and oral hypoglycemic agents.
**ACUTE INTOXICATION**

- The most common signs and symptoms involve disturbances of perception, wakefulness, attention, thinking, judgment, psychomotor behavior, and interpersonal behavior.
- Patients should be medically observed at least until the blood alcohol level (BAC) is decreasing and clinical presentation is improving.
- Highly tolerant individuals may not show signs of intoxication. For example, patients may appear “sober” even at BACs well above the legal limit (e.g., 80 or 100 mg percent).
- Consider withdrawal risk for each substance when using multiple substances.

**Hazardous Alcohol Use**

<table>
<thead>
<tr>
<th>Typical Drinks per week</th>
<th>Standard Drinks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Male: 14</td>
<td>2.5 fluid ounces of absolute alcohol</td>
</tr>
<tr>
<td>Female: 12</td>
<td>2.5 fluid ounces of beer</td>
</tr>
<tr>
<td>5 fluid ounces of wine</td>
<td>2.5 fluid ounces of 80-proof spirits</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Maximum drinks per occasion</th>
<th>Male: 6</th>
<th>Female: 4</th>
</tr>
</thead>
<tbody>
<tr>
<td>May vary depending on age, etiology, medical and psychiatric co-morbidity, pregnancy, and other risk factors.</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**RISK OF RELAPSE**

A simple and brief patient inquiry will often suffice, such as “Have you had any ‘close calls’ with drinking or other drug use?”

**DSM-IV Criteria (APA, 1994)**

**Substance Abuse**

1. A maladaptive pattern of substance use leading to clinically significant impairment or distress, as manifested by one or more of the following, occurring within a 12-month period:
   - Repeated substance use resulting in failure to fulfill major role obligations at work, school, or home (e.g., repeated absences or poor work performance, failure to meet academic obligations, or neglect of children);
   - Substantial time spent in activities necessary to obtain the substance or recover from its effects;
   - Important social, occupational, or recreational activities are given up or reduced because of substance use;
   - Continued substance use despite knowledge of having a persistent or recurrent physical or psychological problem (e.g., recurrent ulcers or depression) that is likely to have been caused or exacerbated by the substance.

**Substance Dependence**

A maladaptive pattern of substance use leading to clinically significant impairment or distress, as manifested by one or more of the following, occurring within any time in the same 12-month period:

1. Tolerance, as defined by either of the following:
   - A need for markedly increased amounts of the substance to achieve intoxication or desired effect.
   - Markedly diminished effect with continued use of the same amount of the substance.
2. Withdrawal, as defined by either of the following:
   - A characteristic withdrawal syndrome (for the substance refer to DSM-IV for further details).
   - The same or a closely related substance is taken to relieve or avoid withdrawal symptoms.
3. The substance is often taken in larger amounts or over a longer period than was intended.
4. There is persistent desire to cut down or control substance use.
5. A great deal of time is spent in activities necessary to obtain the substance (e.g., visiting multiple doctors or driving long distances to see one’s drug dealer, or chain smoking), or recover from its effects.
6. Important social, occupational, or recreational activities are given up or reduced because of substance use.
7. The substance use is continued despite knowledge of having a persistent or recurrent physical or psychological problem (e.g., recurrent ulcers or depression) that is likely to have been caused or exacerbated by the substance (e.g., current cocaine use despite recognition of cocaine-induced depression or continued drinking despite recognition that an ulcer was made worse by alcohol consumption).

**Remission**

Dependence exists on a continuum of severity. Remission requires a period of at least 30 days without meeting full diagnostic criteria and is specified as Early (first 12 months) or Sustained (beyond 12 months) and Partial (some continued criteria met) versus Full (no criteria met).

**Care Management**

Care management is a clinical approach to the management of chronic SUDs where full remission (e.g., abstinence) is not a realistic goal or one the patient endorses. Conceptionally, the care management approach is similar to managing other chronic illnesses, such as diabetes or schizophrenia. Practically, the care management framework provides specific strategies designed to enhance motivation to change, relieve symptoms and improve function where possible, and monitor progress towards goals. Care management is a flexible approach that may be integrated into medical and psychiatric care in any setting. In some cases, care management will lead to remission of the SUD or referral for specialty care rehabilitation, while in other cases it serves a more palliative function.

**Care Management Components**

**Include the following:**

- Determine specific substance use at each contact by patient report (e.g., number of drinking or substance-using days in the past month, typical and maximum number of drinks per occasion).
- Monitor and discuss biological indicators (e.g., transaminase levels and urinalysis results).
- Encourage reduction or cessation of use at each visit and support motivation to change.
- Address or refer for social, financial, and housing problems.
- Coordinate treatment with other care providers.
- Recommend self-help groups.
- Provide episodic care or in primary care.
- Summarize and educate the patient about the problem.

**Follow-Up**

- Monitor substance use and encourage continued reduction or abstinence.
- Educate about substance use and associated problems.
- For DoD active duty, keep the commanding officer informed of progress, or lack thereof.

**Regarding DoD Active Duty**

Referral to addictions specialty care for assessment is required for all active duty patients in an incident involving/suspected to involve legal/legal substances.
**ALCOHOL USE DISORDERS**

**IDENTIFICATION TEST (AUDIT)**

The AUDIT can be administered by interview or self-report.

1. How often do you have a drink containing alcohol?
2. How many drinks containing alcohol do you have on a typical day when you are drinking?
3. How often do you have six or more drinks on one occasion?
4. How often during the last year have you found that you were not able to stop drinking once you had started?
5. How often during the last year have you felt you had to do something you were normally expected not to do because you wanted to cut down or control drinking?
6. Have you ever felt very guilty or ashamed about your drinking?
7. Have you ever felt you needed a drink first thing in the morning to steady your nerves or to get rid of a hangover (Eyes opener)?
8. How effectively do you feel your personal life has been affected by your drinking?
9. How often during the last year have you been unable to remember what happened the night before because you had been drinking?
10. Have you or someone else been injured as a result of your drinking?

**BRIEF INTERVENTION**

- Give feedback about screening results, relating the risks of negative health effects to the patient's presenting health concerns.
- Inform the patient about safer consumption limits and offer advice about change.
- Offer to involve family members (or, for DoD active duty, commanders or PMs/BCs) in this process to educate them and solicit their input (consent is required for family members).
- Assess patient’s degree of readiness for change (e.g., “How willing are you to consider reducing your use at this time?”).
- Schedule initial follow-up appointment in two to four weeks.

**NEGOTIATE AND SET GOALS WITH THE PATIENT**

- Negotiate treatment goals.
- Review results of previous efforts at self-change and formal treatment experiences, including treatments for treatment dropout.
- Use non-confrontational motivational enhancement techniques.
- Consider bringing the addiction specialist into your office to assist with referral decisions.
- Consider referring to social work services for assistance in addressing barriers to treatment engagement.

**REFERRAL TO SPECIALTY CARE**

- Assess patient’s needs, past treatment responses, readiness for change, motivational level, and patient goals.
- When acceptable to the patient, a specialty care rehabilitation plan is generally indicated.
- Care management is likely to be a more acceptable and effective alternative when one of the following applies:
  - The patient resists referral to rehabilitation but continues to seek some services, especially medical and/or psychiatric services.
  - The patient has serious co-morbidity that precludes participation in available rehabilitation programs.

---

**CAGE QUESTIONNAIRE**

C. Have you ever felt you should Cut down on your drinking?
A. Have people Annoyed you by criticizing your drinking?
G. Have you ever felt Guilty about your drinking?
E. Have you ever had a Drink first thing in the morning to steady your nerves or to get rid of a hangover (Eyes opener)?

**SCORING**

Item responses on the CAGE are scored 0 (No) or 1 (Yes). A total score of 2 or greater is considered clinically significant.
**TREATMENT OF CO-OCCURRING DISORDERS**

- Prioritize and address other coexisting biopsychosocial problems (e.g., Medical, Psychiatric, Family, Vocational, And/Or Legal) with services targeted to these areas, rather than increasing drug and alcohol counseling alone.
- Identify and treat concurrent psychiatric disorders consistent with VA/DoD clinical practice guidelines (e.g., Major Depressive Disorder or Psychoses) including concurrent pharmacotherapy.
- Identify and treat other compulsive behaviors (e.g., gambling or spending).
- Identify and treat nicotine dependence.
- Provide multiple services in the most accessible setting to promote engagement and coordination of care.
- Monitor and address deferred problems and emerging needs through ongoing treatment plan updates.

**INDICATIONS FOR PHARMACOTHERAPY FOR ALCOHOL DEPENDENCE**

<table>
<thead>
<tr>
<th>Naltrexone</th>
<th>Disulfiram</th>
</tr>
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<tbody>
<tr>
<td>Alcohol dependence with:</td>
<td>Alcohol dependence with:</td>
</tr>
<tr>
<td>- Ability to achieve at least 3-5 days of abstinence to rule out the need for detoxification</td>
<td>- Abstinence &gt; 24 hours and BAL equal to 0</td>
</tr>
<tr>
<td>- Drinking within the past 30 days and/or reports of craving</td>
<td>- Combined cocaine and alcohol dependence</td>
</tr>
<tr>
<td>- Most effective when the patient is engaged in addiction-focused counseling</td>
<td>- Failure of or contraindication to naltrexone</td>
</tr>
<tr>
<td></td>
<td>- Previous response to disulfiram</td>
</tr>
<tr>
<td></td>
<td>- Patient preference</td>
</tr>
<tr>
<td></td>
<td>- Capacity to appreciate risks and benefits and to consent to treatment</td>
</tr>
</tbody>
</table>

Note: Most effective with monitored administration (e.g., in clinic or with spouse or probation officer).

**BIOPSYCHOSOCIAL ASSESSMENT OF SUDS**

1. Patient’s demographics and identifying information, including housing, legal, and occupational status
2. Patient’s chief complaint and history of the presenting complaint
3. Recent substance use and severity of substance-related problems
4. Lifetime and family history of substance use
5. Co-morbid psychiatric conditions and psychiatric history
6. Social and family context
7. Developmental and military history
8. Current medical status and history, including risk for HIV or hepatitis C
9. Mental status and physical examinations
10. Patient’s perspective on current problems and treatment goals or preferences

**MOTIVATIONAL ENHANCEMENT TECHNIQUES**

- **Feedback:** Provide personalized feedback based on patient report of substance-related harm.
- **Responsibility:** Emphasize patient responsibility and freedom of choice for changing behavior.
- **Advice:** Provide clear and direct advice about the importance of change and availability of help.
- **Menu:** Acknowledge and discuss alternative strategies for change.
- **Empathy:** Maintain a patient-centered approach and accurately reflect patient statements and feelings.
- **Self-Efficacy:** Emphasize the role of patient self-efficacy in their ability to make needed change and convey optimism in their potential to be successful.

**EVIDENCE-BASED PSYCHOSOCIAL INTERVENTIONS**

- Behavioral marital therapy
- Cognitive-behavioral coping skills training
- Community reinforcement and other contingency-based approaches
- Individual and group drug counseling
- Motivational enhancement
- Twelve-Step facilitation training
CONTINUING CARE
- Modify treatment plans individually based on changes in a patient’s clinical and psychosocial condition rather than imposing uniform treatment plans.
- Discuss relapse as a signal to reevaluate the treatment plan rather than evidence that the patient cannot succeed or was not sufficiently motivated.
- Consider care management for patients with persistently sub-optimal response, rather than routinely intensifying rehabilitation or discharging.
- Coordinate follow-up with the patient’s primary medical or behavioral health provider during transitions to less intensive levels of care in order to reinforce progress and improve monitoring of relapse risks.
- For DoD active duty patients, addiction-focused treatment follow-up may be mandated for a period of 6-12 months from the time of initial referral (this may be referred to as “aftercare” in the DoD community).

SPECIALTY CARE DISCHARGE PLANNING
- Schedule primary care follow-up within 90 days of specialty discharge to reinforce recovery progress.
- Encourage patients to re-contact specialty treatment providers for additional help to prevent or promptly interrupt relapse.

<table>
<thead>
<tr>
<th>Types of Housing</th>
<th>Indications</th>
<th>ASAM Level Of Care</th>
<th>Examples</th>
</tr>
</thead>
<tbody>
<tr>
<td>Intensive Medical Management or Monitoring</td>
<td>• Medical or psychiatric instability requiring hospitalization (includes severe intoxication or withdrawal)</td>
<td>III.3 &amp; IV</td>
<td>• Inpatient medical bed section</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• Inpatient addiction/psychiatry bed section</td>
</tr>
<tr>
<td>Professional Monitoring</td>
<td>• Medical or psychiatric instability requiring 24-hour professional monitoring, but not of sufficient severity to require hospitalization</td>
<td>III.3-III.5</td>
<td>• Social detoxification setting</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• VA Substance Abuse Residential Rehabilitation Treatment Programs (SARRTP) and VA Domiciliaries (professional staff present 24-hours/day)</td>
</tr>
<tr>
<td>24-Hour Supervision</td>
<td>• Conditions requiring supervision that may be provided by paraprofessionals, volunteers, or patients in advanced stages of treatment</td>
<td>III.1-III.2</td>
<td>• Halfway houses</td>
</tr>
<tr>
<td></td>
<td>• Demonstrated inability to remain abstinent in unsupervised setting</td>
<td></td>
<td>• Sober houses or safe houses</td>
</tr>
<tr>
<td></td>
<td>• Lacking own social support system, such as family members willing and able to assist, or homeless</td>
<td></td>
<td>• Use of hospital bed space for lodging purposes (e.g., self-care wards in DoD &amp; lodger status in VA)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• VA SARRTP and VA Domiciliaries (staffed only by non-professionals at least part of the day or night)</td>
</tr>
<tr>
<td>Non-Supervised Housing</td>
<td>• Lives at too great a distance to travel to outpatient program</td>
<td>I, II.1, or II.3</td>
<td>• Patient’s own home</td>
</tr>
<tr>
<td></td>
<td>• Able to care for self, including use of medications</td>
<td></td>
<td>• Transitional living facility</td>
</tr>
<tr>
<td></td>
<td>• Able to remain abstinent in an unsupervised setting</td>
<td></td>
<td>• Temporary housing provided on-site or in the community</td>
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</tbody>
</table>

OPTIMAL GOALS OF REHABILITATION
- Complete and sustained remission of all SUDs
- Resolution of, or significant improvement in, all coexisting biopsychosocial problems and health-related quality of life

INTERMEDIATE GOALS OF REHABILITATION
- Short- to intermediate-term remission of SUDs or partial remission of SUDs for a specified period of time
- Resolution or improvement of at least some coexisting problems and health-related quality of life

GOALS OF CARE MANAGEMENT
- Engagement in the treatment process, which may continue for long periods of time or indefinitely
- Continuity of care
- Enhanced motivation to change
- Improvement in SUDs, even if temporary or partial
- Improvement in coexisting medical, psychiatric, and social conditions
- Improvement in quality of life
- Reduction in the need for high-intensity health care services
- Maintenance of progress
- Reduction in the rate of illness progression