

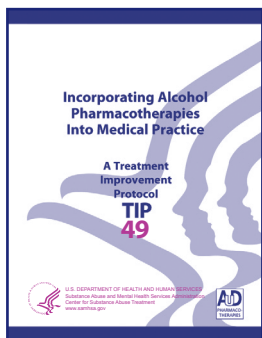
Quick Guide

For Counselors

Based on TIP 49

Incorporating Alcohol Pharmacotherapies Into

Medical Practice



U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
Substance Abuse and Mental Health Services Administration
Center for Substance Abuse Treatment
www.samhsa.gov

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Quick Guide

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Based on TIP 49

Incorporating Alcohol Pharmacotherapies Into Medical Practice

This Quick Guide is based entirely on information contained in TIP 49, published in 2009. No additional research has been conducted to update this topic since publication of TIP 49.

WHY A QUICK GUIDE?

This Quick Guide provides succinct, easily accessible information to substance abuse counselors about the use of medications to help clients achieve and maintain abstinence from alcohol. It is based entirely on *Incorporating Alcohol Pharmacotherapies Into Medical Practice*, number 49 in the Treatment Improvement Protocol (TIP) series.

Users of this Quick Guide are invited to consult the primary source, TIP 49, for more information and a complete list of resources for alcohol use disorder (AUD) pharmacotherapies. To order a copy of TIP 49 or access it online, see the inside back cover of this Guide.

DISCLAIMER

The opinions expressed herein are the views of the consensus panel members and do not necessarily reflect the official position of the Center for Substance Abuse Treatment (CSAT), the Substance Abuse and Mental Health Services Administration (SAMHSA), or the U.S. Department of Health and Human Services (HHS). No official support of or endorsement by CSAT, SAMHSA, or HHS for these opinions or for the instruments or resources described are intended or should be inferred. The guidelines presented should not be considered substitutes for individualized client care and treatment decisions.

WHAT IS A TIP?

The TIP series provides professionals in the substance abuse treatment and related fields with consensus-based, field-reviewed guidelines on substance abuse treatment topics of vital current interest. TIPs are published by CSAT, SAMHSA. The TIP series has been in production since 1991.

TIP 49, *Incorporating Alcohol Pharmacotherapies Into Medical Practice*, presents clinical guidelines on the proper use of four Food and Drug Administration (FDA)-approved medications for treating AUDs:

- Acamprosate (Campral)
- Disulfiram (Antabuse)
- Oral naltrexone (ReVia)
- Extended-release injectable naltrexone (Vivitrol).

INTRODUCTION

TIP 49 is for healthcare practitioners who can prescribe or administer medications for the treatment of AUDs. However, substance abuse counselors also need to know about pharmacotherapy because medications can help some clients achieve and maintain abstinence. The healthcare practitioner and substance abuse counselor should work together as a team to care for the client.

This Quick Guide was written to assist counselors in:

- Answering clients' questions about AUD medications (e.g., how they work, whom they may benefit, side effects)
- Understanding which of their clients may be candidates for pharmacological treatment for AUDs.

Terms Used in This Quick Guide

- **Alcohol use disorder.** Encompasses alcohol *abuse* and *dependence*. TIP 49 uses the term broadly to include the range of alcohol use problems, from intermittent binge drinking to hazardous drinking to chronic alcohol abuse and dependence.
- **Counselors.** Individuals providing specialty substance abuse treatment services.
- **Healthcare practitioners or providers.** Individuals with prescribing privileges, including physicians, physician assistants, and nurse practitioners.

Medication-Assisted Treatment of AUDs

Only a small percentage of U.S. residents being treated for AUDs receives any of the four FDA-approved medications. Medications can improve treatment outcomes for clients with AUDs and are more likely to reduce drinking if used with psychosocial interventions. Medications for AUDs may be used indefinitely or intermittently along with psychosocial interventions.

Benefits of AUD Medications

- Reduce protracted (postacute) withdrawal symptoms that can lead to a return to drinking
- Lessen cravings and urges to drink or use drugs
- Decrease impulsive or situational use of alcohol
- Lengthen periods of abstinence
- Prevent a lapse from becoming a full-blown relapse.

Role of the Counselor

Counselors can help their clients on AUD medication understand:

- Medication benefits and limitations
- Side effects
- How to take the medication
- The importance of taking medication exactly as prescribed
- What to do if a dose is missed or slip or relapse occurs
- The importance of concurrent psychosocial support.

For more detailed information, see TIP 49, Chapter 1—Introduction, pages 1–7.

ACAMPROSATE

Trade name: Campral.

How taken: Two delayed-release tablets by mouth three times per day, with or without food (a lower dose may be effective with some clients and *must* be prescribed for those with impaired renal function).

How supplied: Enteric-coated 333 mg tablets.

How Acamprosate Works

Acamprosate's mechanism of action is not clearly understood, but it seems to reduce symptoms of protracted withdrawal such as sleep and mood disturbances, which may trigger relapse.

Who May Benefit From Acamprosate

Acamprosate may be most effective for clients who, at treatment onset, are motivated to achieve complete abstinence rather than decrease drinking. Because it does not interfere with opioids, this medication may be appropriate for clients who are:

- Receiving opioid maintenance therapy
- At risk of relapsing to opioid use
- Taking opioids for chronic or acute pain.

Who Should Not Take Acamprosate

- Clients with hypersensitivity to acamprosate or its components
- Clients with severe kidney impairment.

Acamprosate should be prescribed with caution for:

- Pregnant women (the benefits must outweigh the potential harm to the fetus) or nursing women
- Adults ages 65 and older
- Children or adolescents.

Women of childbearing age need to use an effective form of birth control while taking acamprosate.

Safety

Acamprosate has a good safety profile:

- Clients will not develop tolerance to or dependence on acamprosate.
- Acamprosate appears to have no potential for abuse.
- It has virtually no overdose risk.
- Most side effects are mild and temporary.
- Acamprosate can be continued safely if a client relapses to drinking and then requires detoxification.
- There are no clinically significant drug interactions, so it is safe for clients who have multiple medical issues and are taking several medications.

Acamprosate:

- Is typically started 5 days after drinking stops
- Reaches full effectiveness in 5 to 8 days
- Does not interact with benzodiazepines or other medications used in medical detoxification
- Can be started during medically supervised withdrawal
- Should be taken even if a client relapses
- Should not be crushed or broken when it is taken

- Should not be discontinued by the healthcare practitioner if the client has returned to alcohol use.

Some clients may have trouble remembering to take acamprosate three times per day. Tips to support adherence are on page 25.

Acamprosate has advantages over other medications for AUDs:

- It is not metabolized by the liver and can be used safely by clients with severe liver disease.
- It can be used with clients receiving opioid maintenance therapy or opioids for acute or chronic pain.
- It can be continued safely if a client returns to drinking and subsequently requires detoxification.

Side Effects

- Diarrhea
- Drowsiness.

These side effects are usually mild, lessening or disappearing within the first few weeks of treatment. However, for some people diarrhea is severe or persistent:

- Recommend that the client report the condition to the healthcare practitioner (Acamprosate may need to be reduced or discontinued if diarrhea remains intolerable.)
- Suggest use of Imodium or Pepto-Bismol and appropriate dietary changes for diarrhea.

Clients experiencing daytime drowsiness should take acamprosate at bedtime.

Suicide Risk

Suicidal ideation or suicide attempts are a very uncommon but serious side effect of substance use disorders, with or without acamprosate use. If a client experiences suicidal ideation or attempts suicide:

- Call 911 if the client is in imminent danger
- Notify the supervisor on call
- Contact the healthcare practitioner immediately and confer (The client may be advised by the healthcare practitioner to discontinue acamprosate.)
- Monitor the client for onset or worsening of depression
- Obtain a psychiatric consult for possible antidepressant medication or admittance to an inpatient psychiatric facility, if necessary.

For more detailed information, see TIP 49, Chapter 2—Acamprosate, pages 9–14.

DISULFIRAM

Trade name: Antabuse.

How taken: Tablet by mouth once daily (also may be crushed and mixed with water, coffee, tea, milk, soft drink, or fruit juice).

How supplied: 250 mg or 500 mg tablets.

How Disulfiram Works

Disulfiram causes a toxic physical reaction when mixed with alcohol—even when the alcohol is disguised in foods, medications, or other substances. The toxic reaction serves as an aversive. Awareness of this reaction can motivate clients to abstain from alcohol.

The reaction:

- Varies from client to client
- Typically begins about 10 to 30 minutes after alcohol is ingested
- Is generally proportional to the amounts of disulfiram and alcohol ingested
- May occur for up to 14 days after the last ingested dose of disulfiram
- Can range from moderate to severe.

Who May Benefit From Disulfiram

Disulfiram is most appropriate for clients who:

- Are motivated for treatment and committed to total abstinence
- Have undergone detoxification or are in the beginning stage of abstinence

- Understand the consequences of drinking alcohol while taking disulfiram
- Maintain abstinence during treatment.

Disulfiram–Alcohol Aversive Reaction

Moderate aversive effects:

- Sweating
- Warmth and flushing, particularly on upper chest and face
- Difficulty breathing or hyperventilation
- Acetaldehyde breath odor
- Blurred vision
- Head and neck throbbing
- Thirst
- Nausea/vomiting
- Chest pain, palpitations, very fast heart beat
- Hypotension (low blood pressure)
- Vertigo or syncope (fainting)
- Feeling of marked uneasiness
- Confusion
- Weakness.

Severe aversive effects:

- Respiratory depression
- Severe cardiac problems including heart attack, acute congestive heart failure, or cardiovascular collapse (in people with preexisting coronary artery disease)
- Arrhythmia (abnormal heartbeat)
- Seizures
- Death.

Who Should Not Take Disulfiram

- Clients with hypersensitivity to rubber derivatives, sulfur, or nickel
- Clients with a history of coronary artery disease
- Clients with significant liver disease
- Women who are nursing.

Disulfiram should be prescribed with caution to:

- Clients with a history of cardiac disease, diabetes mellitus, hypothyroidism, epilepsy, cerebral damage, chronic or acute nephritis, hepatic cirrhosis, hepatic insufficiency, or hepatitis C
- Adults ages 61 and older
- Children and adolescents
- Clients who have severely impaired judgment, have unstable psychosis, or are very impulsive from a severe mental illness or cognitive impairment.

Safety

- Disulfiram has been used to treat AUDs for almost 60 years.
- Liver toxicity is a concern in some clients.
- Disulfiram should be avoided by pregnant women.

Encourage clients to:

- Let healthcare practitioners know they are taking disulfiram
- Carry a medical alert card indicating that they are taking disulfiram, symptoms of possible disulfiram–alcohol aversive reaction, and medical

emergency contact information that includes the name of the healthcare practitioner who prescribed the disulfiram.

Side Effects

The following minor side effects typically occur during the first 2 weeks of therapy and wane either spontaneously or after a decrease in the disulfiram dosage:

- Mild drowsiness
- Metallic taste in mouth
- Dermatitis
- Headache
- Impotence.

For more detailed information, see TIP 49, Chapter 3—Disulfiram, pages 15–26.

ORAL NALTREXONE

Trade name: ReVia.

How taken: Tablet by mouth once daily.

How supplied: 50 mg tablets.

How Oral Naltrexone Works

It is a long-lasting opioid antagonist (blocker) that reduces both the rewarding effects of alcohol and the craving for it. It is typically prescribed to:

- Help clients abstain from drinking
- Reduce heavy drinking in those who drink.

Naltrexone can be taken for up to 3 months to treat AUDs.

Who May Benefit From Oral Naltrexone

Naltrexone's opioid antagonist properties make it a good treatment option for individuals who, in addition to having an AUD, have a history of opioid abuse/dependence and are abstinent from opioids.

Who Should Not Take Naltrexone

- Individuals using legal or illegal opioids or buprenorphine
- Clients anticipating the need for opioids for pain within 7 days
- Clients on methadone maintenance therapy for opioid dependence
- Clients undergoing acute opioid withdrawal
- Clients with acute hepatitis or liver failure.

Safety

- Naltrexone has a low incidence of common adverse events.
- FDA-approved label contains a black-box warning about liver toxicity.
- Naltrexone precipitates withdrawal; clients must be fully withdrawn from all opioids before beginning naltrexone treatment.

Naltrexone should be prescribed with caution with clients who:

- Have active liver disease
- Have moderate to severe kidney impairment
- Are women of childbearing age (Birth control is recommended while taking naltrexone.)
- Have chronic pain syndromes with acute or recurring need for opioid analgesics.

Side Effects

The following side effects are generally mild and often diminish over time:

- Nausea/vomiting
- Headache
- Dizziness
- Fatigue
- Drowsiness.

Pain Management

Pain management for clients taking oral naltrexone can be complicated because the medication blocks the effects of opioid analgesics. See page 19 for details.

For more detailed information, see TIP 49, Chapter 4—Oral Naltrexone, pages 27–35.

EXTENDED-RELEASE INJECTABLE NALTREXONE

Trade name: Vivitrol.

How taken: Intramuscular (IM) injection once every 4 weeks.

How supplied: Single-use carton containing 380 mg vial of Vivitrol microspheres, 4 mL vial of diluent, 5 mL syringe, 20-gauge ½-inch needle, and two 20-gauge 1½-inch needles.

How Injectable Naltrexone Works

Extended-release injectable naltrexone is a microsphere formulation of the opioid antagonist medication naltrexone. It has the same effect as oral naltrexone (see page 14). The injected medication is slowly released into the blood stream, and the effects last approximately 4 weeks.

Who May Benefit From Injectable Naltrexone

- Clients who are motivated to maintain abstinence or to reduce their drinking
- Clients who have not responded to other pharmacological and behavioral treatments
- Clients who have problems adhering to other treatments
- Clients who have means to cover its considerable cost, compared with oral naltrexone.

Who Should Not Be Prescribed Injectable Naltrexone

- Clients using opioids or anticipating the need for opioid analgesics within 30 days
- Clients on methadone maintenance therapy for opioid dependence
- Clients undergoing acute opioid withdrawal
- Clients with acute hepatitis or liver failure
- Obese clients (for whom a 1½-inch needle precludes IM injection)
- Clients with insufficient muscle mass for IM injection
- Clients who are sensitive to polylactide glycolide polymers, carboxymethylcellulose, or any components of the diluent
- Clients with a bleeding disorder that prevents them from receiving a deep IM injection
- Clients anticipating surgery or who have a condition, such as chronic pain, for which opioid analgesics may be required.

Safety

- Injectable naltrexone appears to be well tolerated.
- FDA-approved label contains a black-box warning about liver toxicity.
- Naltrexone precipitates withdrawal; clients must be fully withdrawn from all opioids before beginning naltrexone treatment.

Side Effects

- Injection-site reactions
- Nausea/vomiting
- Headache
- Dizziness
- Fatigue
- Back pain
- Upper abdominal pain
- Decreased appetite.

Injection-site reactions are common and can be severe. Clients should seek immediate medical attention if:

- Skin at the injection site becomes painful, red, and swollen.
- Injection-site reaction does not improve within 1 week.

Naltrexone and Pain Management

Taking opioids or opioid medications while on naltrexone increases the risk of overdose, respiratory arrest, coma, and death. Clients on naltrexone should avoid using:

- Illicit opioid drugs
- Opioid maintenance medication (methadone and buprenorphine)
- Opioid pain medications (e.g., codeine, morphine, oxycodone, hydrocodone).

Clients with pain are advised to:

- Talk to their healthcare practitioner about medications for pain

- Know about other options for pain medication
- Know about risks of opioid use while on naltrexone
- Tell all healthcare practitioners (e.g., dentists, pharmacists) that they are receiving naltrexone
- Carry a medical alert card that states they are taking naltrexone, indicates whether it is taken orally or by injection, and lists the physician or institution to contact in an emergency.

Clients who must use opioid analgesics for surgery or other medical procedure should discuss their use of naltrexone with their healthcare practitioner and:

- Stop treatment with oral naltrexone for at least 3 days (conservatively, 7 days) before the procedure
- Wait 30 days after last injection of naltrexone before the procedure.

Pain management options for clients on naltrexone include:

- Aspirin
- Acetaminophen
- Nonsteroidal anti-inflammatory drugs (e.g., ibuprofen, naproxen sodium)
- Local anesthetics (e.g., lidocaine, general nonopioid anesthetics) and procedures (e.g., regional nerve block).

Clients who have taken naltrexone for a period and then stop taking it may be more sensitive to lower doses of opioids and at greater risk of overdose if they take opioids.

Naltrexone may block the effects of antidiarrheal or cough/cold medications that contain opioids.

For more detailed information, see TIP 49, Chapter 5—Extended-Release Injectable Naltrexone, pages 37–44.

CLIENT MANAGEMENT

With the client's permission, counselors and healthcare practitioners should work together to help the client achieve and maintain abstinence. Healthcare practitioners base their decision for prescribing a medication for an AUD on many factors.

Elements of Client Assessment by the Healthcare Practitioner

Before a client starts a medication to treat an AUD, his or her healthcare practitioner should have:

- Diagnosed the client with an AUD
- Conducted a thorough physical exam
- Conducted laboratory tests for:
 - Legal and illegal drug use
 - Biomarkers for AUD
 - Liver function
 - Kidney function
 - Anemia
 - Vitamin deficiencies
 - Pregnancy
- Assessed the client for co-occurring mental disorders, such as depression
- Obtained a social history
- Assessed motivation to change
- Educated the client about treatment options.

Choosing a Medication

Healthcare practitioners use their clinical judgment regarding which medication may be most helpful and the client's:

- Experience with AUD medications, if any
- Level of motivation for abstinence
- Medical status and contraindications for each medication
- History of medication adherence.

Clients need ongoing monitoring of pharmacotherapy by the healthcare practitioner to ensure that the treatment plan remains appropriate.

Elements of Client Education About Pharmacotherapy

Before taking an AUD medication, the client should be educated about:

- What to expect in early recovery, including symptoms of postacute withdrawal
- Possible benefits of a particular medication
- The medication itself:
 - How and when to take it and the importance of adhering to the regimen
 - When the medication will become fully effective
 - Possible common side effects and their expected duration
 - Under what conditions to immediately call the practitioner

- Any cautions regarding daily activities
- Medication interactions
- The importance for women of childbearing age to use an effective birth control method
- What to do if a slip or relapse occurs after a period of abstinence
- The importance of concurrent psychosocial treatment and mutual- or self-help programs
- Followup plans.

Developing a Treatment Plan

A comprehensive pharmacotherapy treatment plan for a client with an AUD should include:

- The medication to be used and a rationale for its use
- Initial and maintenance dosages
- A schedule for followup office visits and laboratory testing for monitoring health status and progress
- Criteria for discontinuing the medication
- A referral and followup plan for concurrent specialty substance abuse treatment, psychiatric treatment, and/or family therapy
- A plan for mutual- or self-help group attendance
- Clarification of family or significant other involvement in treatment
- A plan for treating alcohol-related or other concurrent medical or mental health conditions.

Promoting Adherence to Treatment

To help clients remember to take medications as directed, counselors may suggest that clients:

- Wear a reminder bracelet so they take their medications on time
- Set a watch alarm
- Start a recovery-oriented ritual around taking the medication
- Use a special pillbox
- Ask their prescriber for the medication in blistercard packs, if available
- Involve their family members or trusted individuals in helping them adhere to treatment, such as by asking them to observe dosing
- Get social support from a friend or family member.

Modifying the Treatment Plan

Clients receiving pharmacological treatment for AUDs may relapse. If this occurs, the counselor and healthcare practitioner may consider:

- Increasing monitoring of medication adherence
- Increasing the dose of the medication
- Changing the medication
- Increasing or changing the intensity of psychosocial treatments to include referring the client to more intensive specialty care
- Examining social, medical, or behavioral factors that contribute to alcohol consumption.

Discontinuing Pharmacotherapy

Because an AUD is a chronic disorder, clients may need long-term medication or more than one episode of pharmacotherapy. Ideally, the client, healthcare practitioner, and counselor will decide together to discontinue pharmacotherapy, such as when the client:

- Reports substantially diminished craving
- Has maintained stable abstinence over a sustained period
- Feels ready to discontinue the medication
- Has established a sound plan and support for ongoing recovery
- Is engaged in ongoing recovery, including community supports (such as attendance at mutual-help group meetings).

Clients may:

- Stop taking the medication on their own
- Want to discontinue a medication because of side effects
- Need to discontinue medication because of significant negative changes in laboratory findings or physical health status
- Persistently not adhere to the medication regimen.

The medications discussed in this Quick Guide are not associated with withdrawal syndrome, and they do not need to be tapered.

Some clients may benefit from restarting one of these medications along with behavioral interventions later in recovery to help them through particularly stressful

periods or in situations that may lead to relapse, such as holidays, vacations, personal losses, and major life changes.

For more detailed information, see TIP 49, Chapter 6—Patient Management, pages 45–61.

Ordering Information

TIP 49

Incorporating Alcohol Pharmacotherapies Into Medical Practice

TIP 49-Related Products

KAP Keys for Clinicians Based on TIP 49
(SMA) 10-4544

Quick Guide for Physicians Based on TIP 49
(SMA) 10-4543

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Three Ways to Obtain FREE Copies of All TIP Products

1. Call SAMHSA's Health Information Network (SHIN) at **1-877-SAMHSA-7 (1-877-726-4727)** (English and Español).
2. Visit SHIN's Web site at **<http://www.samhsa.gov/shin>**.
3. Access products online at **<http://www.kap.samhsa.gov>**.



Other SAMHSA products that are relevant to this Quick Guide:

TIP 45: *Detoxification and Substance Abuse Treatment (SMA) 08-4131*

TIP 48: *Managing Depressive Symptoms in Substance Abuse Clients During Early Recovery (SMA) 08-4353*

TIP 50: *Addressing Suicidal Thoughts and Behaviors in Substance Abuse Treatment (SMA) 09-4381*

See the inside back cover for ordering information for all TIPs and related products.