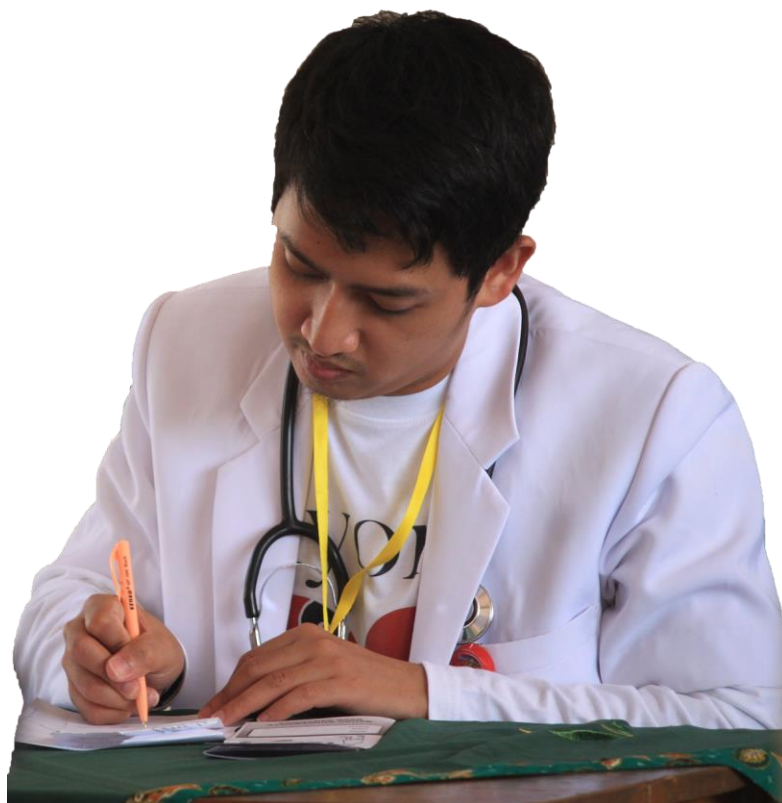




Mindful
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Medication-Assisted Treatment Of Opioid Use Disorder



Opioids are powerful drugs.

Opioids are drugs that slow down the actions of the body, such as breathing and heartbeat. Opioids also affect the brain to increase pleasant feelings. They get their name from opium, a drug made from the poppy plant.

People take opioids for medical reasons.

Doctors prescribe opioid medication to treat pain and sometimes for other health problems such as severe coughing. The medication comes in a pill, a liquid, or a wafer. It also comes in a patch worn on the skin. Examples of prescribed opioid medications include:

- **Codeine**—an ingredient in some cough syrups and in one Tylenol® product
- **Hydrocodone**—Vicodin®, Lortab®, or Lorcet®
- **Oxycodone**—Percocet®, OxyContin®, or Percodan®
- **Hydromorphone**—Dilaudid®
- **Morphine**—MSContin®, MSIR®, Avinza®, or Kadian®
- **Propoxyphene**—Darvocet® or Darvon®
- **Fentanyl**—Duragesic®
- **Methadone.**

People sometimes misuse opioids.

Opioid medications are sometimes misused to self-medicate or to get a good feeling, called a “rush” or “high.” People misuse medications by taking their own prescriptions improperly, stealing medications, going to multiple doctors to get extra, or buying them from drug dealers. Sometimes to get high they drink a large amount of liquid medicine or crush a lot of pills to ingest, snort, or inject. And some people seek a high from heroin, an illegal opioid that can be smoked, snorted, or injected.

Opioids have side effects.

A person who takes opioids can become **tolerant** to them. This means that more of the drug is needed to obtain its effects. It is also possible to become **dependent** on opioids—to feel sick if there are no opioids in the body. This sickness is called **withdrawal**.

Tolerance and dependence are common side effects of prescribed opioid medication. If tolerance is a problem, doctors may adjust the person’s dose or change the medication. People who have become dependent on opioid medication but are ready to stop taking it can **taper off** (take less and less) to avoid withdrawal. This should be done under a doctor’s care.

Tolerance and dependence also occur in people who misuse medications or take heroin. Over time, such people often begin to feel uncomfortable without the opioid. They need to take it just to feel normal.

Opioids can be addictive.

Addiction is a disease that results when the opioid has made changes to the brain. A person using medication properly is not likely to get addicted, but this sometimes happens. Addiction usually occurs through misuse. Some people are at higher risk of addiction because of their genes, temperament, or personal situation. The signs of addiction are:

- **Craving**—The mind develops an overwhelming desire for the drug.
- **Loss of control**—It becomes harder to say no to using the drug. Use is compulsive and continues even when it causes harm.

It is not usually possible to taper off an addiction. More help is needed because the cravings are so strong and the fear of withdrawal is so great.



Opioid addiction can be treated.

Opioid addiction is a **chronic disease**, like heart disease or diabetes. A chronic disease is a medical condition for life. It cannot be cured, but it can be managed. A person with addiction can regain a healthy, productive life.

Most people cannot just walk away from addiction. They need help to change addictive behavior into nonaddictive, healthful patterns. They can get this help with **treatment**—with the care of doctors and substance abuse treatment providers.

Treatment helps people stop using the problem drug. It helps them get through withdrawal and cope with cravings. Treatment also helps them move away from other harmful behaviors, such as drinking alcohol or abusing other drugs.

Just as important, treatment helps people address life issues they might have that are tied to the addiction, such as feelings of low self-worth, a bad situation at work or home, or spending time with people who use drugs. In short, treatment helps people move into healthy, addiction-free lifestyles—into a way of living referred to as **recovery**.

Treatment may include medication.

Medication-assisted treatment is treatment for addiction that includes the use of medication along with counseling and other support. Treatment that includes medication is often the best choice for opioid addiction.



If a person is addicted, medication allows him or her to regain a normal state of mind, free of drug-induced highs and lows. It frees the person from thinking all the time about the drug. It can reduce problems of withdrawal and craving. These changes can give the person the chance to focus on the lifestyle changes that lead back to healthy living.

Taking medication for opioid addiction is like taking medication to control heart disease or diabetes. It is NOT the same as substituting one addictive drug for another. Used properly, the medication does NOT create a new addiction. It helps people manage their addiction so that the benefits of recovery can be maintained.

There are three main choices for medication.

The most common medications used in treatment of opioid addiction are **methadone** and **buprenorphine**. Sometimes another medication, called **naltrexone**, is used. Cost varies for the different medications. This may need to be taken into account when considering treatment options.

Methadone and buprenorphine trick the brain into thinking it is still getting the problem opioid. The person taking the medication feels normal, not high, and withdrawal does not occur. Methadone and buprenorphine also reduce cravings.

Naltrexone helps overcome addiction in a different way. It blocks the effect of opioid drugs. This takes away the feeling of getting high if the problem drug is used again. This feature makes naltrexone a good choice to prevent **relapse** (falling back into problem drug use).

All of these medications have the same positive effect: they reduce problem addiction behavior.



All three medications come in pill form. Methadone also comes as a liquid and a wafer. Methadone is taken daily. The other two medications are taken daily at first. After time, buprenorphine is taken daily or every other day, and doses of naltrexone are taken up to 3 days apart.

Methadone to treat addiction is dispensed only at specially licensed treatment centers. Buprenorphine and naltrexone are dispensed at treatment centers or prescribed by doctors. A doctor must have special approval to prescribe buprenorphine. Some people go to the treatment center or doctor's office every time they need to take their medication. People who are stable in recovery may be prescribed a supply of medication to take at home.

Medication is matched to the person.

When a person decides to try medication-assisted treatment, the first step is to meet with a doctor or other medical staff member. This first meeting is called an **assessment**. The person is asked questions such as:

- How long have you been taking the opioid drug?
- Are you taking any other drugs?

- Do you drink alcohol?
- What are your drug-taking and drinking habits and patterns?
- Have you been in treatment before?
- Do you have other health problems?
- Are you taking any medicines?
- Have you ever had reactions to medicines?
- Are you pregnant?
- Do you have any special needs?
- What are your goals for recovery?
- Do you have family or friends to support you through treatment?

During this meeting, the person learns about treatment choices, rules that must be followed to stay in treatment, and what to expect next.

A physical exam also is part of the assessment. This exam finds out about the person's general health. It also checks for diseases that are common to people who have been abusing drugs. The exam often includes a drug test. This is usually a check of urine or saliva.

After the assessment, the doctor or substance abuse treatment provider discusses treatment choices with the person, who may choose to include family or friends in the discussion.

The person agrees to a treatment plan. This covers:

- The goals for treatment
- The decision on which medication to use and the dose level to start
- The schedule for visits to the treatment center
- The plan for counseling

- Other steps to take, such as attending a support group
- How success toward goals will be measured.

The plan describes what happens if it is not followed. The person may be asked to sign a form showing that he or she agrees to follow the plan.

Medication is introduced carefully.

Methadone can be safely taken at the start of recovery. Buprenorphine can be taken once withdrawal has begun. Naltrexone cannot be taken until opioids are completely out of the body, usually 7 to 10 days after withdrawal begins. Taking buprenorphine or naltrexone too soon can make withdrawal worse.

Medical staff members meet with the person a few hours after the first dose is taken and regularly for a week or two. These meetings are to make sure the medication is working, that side effects are not too uncomfortable, and that the person is taking medication exactly as told. Following directions is important, because taking the medication improperly can lead to overdose or death.



WITHDRAWAL SYMPTOMS

- Yawning and other sleep problems
- Sweating more than normal
- Anxiety or nervousness
- Muscle aches and pains
- Stomach pain, nausea, or vomiting
- Diarrhea
- Weakness

If the medication is not working as expected, the doctor may adjust the dose up or down or prescribe a different medication. The person may feel some symptoms similar to withdrawal as adjustments are made.

Methadone and buprenorphine can cause drowsiness at first. For this reason, a person starting on either medication should not drive or perform other high-risk tasks, to avoid accidents. If drowsiness continues to be a problem, the doctor may adjust dose levels.

The right medication has been found when the person feels normal, has minor or no side effects, does not feel withdrawal, and has cravings under control.

Medication can be taken safely for years.

People can safely take treatment medication as long as needed—for months, a year, several years, even for life. Sometimes people feel that they no longer need the medication and would like to stop taking it. Use of methadone and buprenorphine must be stopped gradually to prevent withdrawal. Stopping naltrexone does not cause withdrawal. Plans to stop taking a medication should ALWAYS be discussed with a doctor.

Counseling can help.

Many people on medication-assisted treatment benefit from **counseling**—from the opportunity to talk with a professional either one-on-one or in a group with others in treatment.

Through counseling, people learn about the disease of addiction. They also learn why the addiction occurred, the problems it has caused, and what they need to change to overcome those problems.

Counseling can provide encouragement and motivation to stick to treatment. It can teach coping skills and how to prevent relapse. And, it can help people learn how to make healthy decisions, handle setbacks and stress, and move forward with their lives.

In **group counseling**, people connect with others in treatment and make new friends who don't use drugs. They can get these benefits from **support groups**, too. These are informal meetings of people facing similar challenges.

Family and friends are important, too.

It is very hard to go through recovery alone. Support from family and friends is very important. Love and encouragement can help a person make the decision to enter treatment and stick with it.

Family and friends can provide help in practical ways—for example, by offering rides to treatment, a safe place to live, or help finding work. Family and friends also can help the person in recovery avoid or overcome setbacks.

Some treatment programs offer counseling for loved ones. They do this because being close to a person with addiction can be very hard and can cause pain and anger or feelings of shame and hopelessness.

Counseling is a useful way for family and friends to learn more about the person's situation, how to help, and how to handle the problems their loved one's addiction has caused them, too. It is a safe place to express feelings and to find out what help is available for them.



There are support groups, too, that are just for family and friends. These are safe places to share information and encourage others who have loved ones who are dealing with addiction.

Many people overcome opioid addiction and regain normal, healthy lives. One way they do this is with medication-assisted treatment. Medication, counseling, and support: together they can help your loved one or your friend.

WARNINGS

- Medications kept at home **must** be locked in a safe place. If children take them by mistake, they can **overdose** or **die**. This is especially true for methadone, because it often comes as a colored liquid. Children can mistake it for a soft drink.
- All three medications have side effects in some people, such as upset stomach and sleep problems. These are usually minor.
- People on any of these medications should be checked by a doctor for liver problems.
- People on any of these medications should talk to their doctor before stopping or starting any other medications.
- Women should let their substance abuse treatment provider know if they are pregnant or breast-feeding. Only methadone is recommended for these women.
- Be aware of the signs of methadone overdose:
 - Trouble breathing or shallow breathing
 - Extreme tiredness or sleepiness
 - Blurred vision
 - Inability to think, talk, or walk normally
 - Feeling faint, dizzy, or confused.

Anyone on methadone who has these symptoms should get medical attention immediately. NOTE: Overdose is less likely with buprenorphine and unlikely with naltrexone. However, to avoid problems, any medication for opioid addiction should be taken exactly as the doctor prescribes.

- People on any of these medications should NOT use other opioid medications or illegal drugs. They should NOT drink alcohol or take sedatives, tranquilizers, or other drugs that slow breathing. Taking any of these substances in large amounts along with the treatment medication can lead to overdose or death.

ADDICTION

WHAT'S TRUE AND WHAT'S NOT

Addiction is a disease. It cannot be cured, but it can be treated with medication, counseling, and support from family and friends. Addiction is NOT a sign of weakness. It is NOT TRUE that all anybody needs to kick addiction is to “be strong.”

The goal of medication-assisted treatment is to recover from addiction. It does NOT replace one addictive drug with another. It provides a safe, controlled level of medication to overcome the use of a problem opioid.

A substance abuse treatment provider must obtain informed consent (agreement in writing) before sharing information about patients.

There are two exceptions to this privacy rule: (1) if it appears that patients may harm themselves or others and (2) if patients have been ordered into treatment by the courts. To learn more about privacy rights, talk to a substance abuse treatment provider.

Recovery is possible. But it takes work. After treatment is finished, everything is NOT automatically fine again. Recovery takes commitment every day, through treatment and beyond.

GOALS FOR RECOVERY

Goal 1: Withdraw from the problem opioid.

This stage is also called **detoxification** or **detox**.

- _____ Stop taking the opioid drug.
- _____ Work with the doctor to select a medication.
- _____ Reflect on whether use of alcohol or other drugs is interfering with recovery.
- _____ Receive medical treatment to improve overall health.
- _____ Begin counseling to improve health, behavior, and coping skills.

Goal 2: Begin recovery.

- _____ Work with the doctor to adjust the medication and dose as needed.
- _____ Replace unhealthy behaviors with healthy behaviors. For example, join a support group, find a new hobby, or look for a job.
- _____ Work to improve or repair relationships.
- _____ Learn to recognize and avoid **triggers** (places or activities that cause drug cravings to come back).
- _____ Learn how to avoid relapse.

A GOAL FOR ALL STAGES:

Many people in treatment relapse one or more times before getting better and remaining drug free. Each relapse is a setback, but it does not mean failure. People who relapse can continue with treatment and achieve full recovery.

A person can prevent relapse by staying away from triggers, for example, by avoiding former drug-use hangouts and staying away from friends who use drugs.

Another way to prevent relapse is to guard against impatience or overconfidence. A person who makes these statements (or

→ IN MEDICATION-ASSISTED TREATMENT

_____ Learn to take medication at home (if permitted by program, State, and Federal rules).

_____ Get random drug tests.

Goal 3: Stay in recovery.

_____ Keep a normal routine. For example, work or go to school, go to support groups or counseling, build relationships, and have fun.

_____ Schedule regular visits with the doctor to check dose levels and to get refills.

_____ Continue to avoid triggers and relapse.

_____ Get random drug tests.

Goal 4: Live addiction free.

_____ Keep strong habits of healthy behavior.

_____ Check in with the doctor or substance abuse treatment provider every 1 to 3 months.

_____ Continue to draw strength from family, friends, and support groups.

_____ Continue in counseling for other issues, as needed.

→ AVOID RELAPSE AND TRIGGERS

even thinks them) might need to return to an earlier goal for recovery:

“This treatment isn’t working!”

“I thought I wasn’t supposed to feel cravings.”

“I’m cured! I can control it if I only use with my friends.”

“There’s no way I can relapse!”

“I can stay away from drugs by myself.”

“When I got high, I had so much fun! I never had problems.”

Checklist for Prescribing Medication for the Treatment of Opioid Use Disorder

✓ Assess the need for treatment

For persons diagnosed with an opioid use disorder, first determine the severity of patient's substance use disorder. Then identify any underlying or co-occurring diseases or conditions, the effect of opioid use on the patient's physical and psychological functioning, and the outcomes of past treatment episodes.

Your assessment should include:

A patient history

- Ensure that the assessment includes a medical and psychiatric history, a substance use history, and an evaluation of family and psychosocial supports.
- Access the patient's prescription drug use history through the state's prescription drug monitoring program (PDMP), where available, to detect unreported use of other medications, such as sedative-hypnotics or alcohol, that may interact adversely with the treatment medications.

- A physical examination that focuses on physical findings related to addiction and its complications.
- Laboratory testing to assess recent opioid use and to screen for use of other drugs. Useful tests include a urine drug screen or other toxicology screen, urine test for alcohol (ethyl glucuronide), liver enzymes, serum bilirubin, serum creatinine, as well as tests for hepatitis B and C and HIV.

✔ **Educate the patient about how the medication works and the associated risks and benefits; obtain informed consent; and educate on overdose prevention.**

There is a potential for relapse and overdose on discontinuation of the medication. Patients should be educated about the effects of using opioids and other drugs while taking the prescribed medication and the potential for overdose if opioid use is resumed after tolerance is lost.

✔ **Evaluate the need for medically managed withdrawal from opioid**

Naltrexone patients must first be medically withdrawn from opioids.

✓ **Address co-occurring disorders**

Have an integrated treatment approach to meet the substance use, medical and mental health, and social needs of a patient.

✓ **Integrate pharmacologic and nonpharmacologic therapies**

All medications for the treatment of the opioid use disorder should be prescribed as part of a comprehensive individualized treatment plan that includes counseling and other psychosocial therapies, as well as social support through participation in Narcotics Anonymous and other mutual-help programs.

✓ **Refer patients for higher levels of care, if necessary**

Refer the patient for more intensive or specialized services if office-based treatment with buprenorphine or naltrexone is not effective or the clinician does not have the resources to meet a particular patient's needs. Providers can find programs in their areas or throughout the United States by using SAMHSA's Behavioral Health Treatment Services Locator at www.findtreatment.samhsa.gov.

Medications Approved in the Treatment of Opioid Use Disorder*

► Frequency of Administration

Extended Release Injectable Naltrexone	Methadone	Buprenorphine
Monthly†	Daily	Daily (also alternative dosing regimens)

► Route of Administration

Extended Release Injectable Naltrexone	Methadone	Buprenorphine
Intramuscular (IM) injection into the gluteal muscle by a physician or other health care professional.†	Orally as liquid concentrate, tablet or oral solution of diskette or powder.	Oral tablet or film is dissolved under the tongue.

► Who May Prescribe or Dispense

Extended Release Injectable Naltrexone	Methadone	Buprenorphine
<p>Any individual who is licensed to prescribe medicines (e.g., physician, physician assistant, nurse practitioner) may prescribe and/or order administration by qualified staff.</p>	<p>SAMHSA-certified Opioid Treatment Programs dispense methadone for daily administration either on site or, for stable patients, at home.</p>	<p>Physicians must have board certification in addiction medicine or addiction psychiatry and/or complete special training to qualify for the federal waiver to prescribe buprenorphine, but any pharmacy can fill the prescription.</p> <p>There are no special requirements for staff members who dispense buprenorphine under the supervision of a waived physician.</p>

*Table highlights some properties of each medication. It does not provide complete information and is not intended as a substitute for the package inserts or other drug reference sources used by clinicians (see www.dailymed.nlm.nih.gov for current package inserts). For patient information about these and other drugs, visit the National Library of Medicine's MedlinePlus (www.medlineplus.gov). Whether a medication should be prescribed and in what amount are matters to be discussed between an individual and his or her health care provider. The prescribing information provided here is not a substitute for the clinician's judgment, and the National Institutes of Health and SAMHSA accept no liability or responsibility for use of the information in the care of individual patients.

†Naltrexone hydrochloride tablets (50 mg each) are also available for daily dosing.

► Pharmacologic Category

Extended Release Injectable Naltrexone

Opioid antagonist

Naltrexone displaces opioids from receptors to which they have bound. This can precipitate severe, acute withdrawal symptoms if administered in persons who have not completely cleared opioid from their system. Patients who have been treated with extended-release injectable naltrexone will have reduced tolerance to opioids. Subsequent exposure to previously tolerated or even smaller amounts of opioids may result in overdose.

Methadone

Opioid agonist

Patients starting methadone should be educated about the risk of overdose during induction onto methadone, if relapse occurs, or substances such as benzodiazepines or alcohol are consumed. During induction, a dose that seems initially inadequate can be toxic a few days later because of accumulation in body tissues. For guidance on methadone dosing for all phases of MAT consult: TIP 43 (<http://store.samhsa.gov/product/TIP-43-Medication-Assisted-Treatment-for-Opioid-Addiction-in-Opioid-Treatment-Programs/SMA12-4214>)

Buprenorphine

Opioid partial agonist

Buprenorphine's partial agonist effect relieves withdrawal symptoms resulting from cessation of opioids. This same property will induce a syndrome of acute withdrawal in the presence of long-acting opioids or sufficient amounts of receptor-bound full agonists. Naloxone, an opioid antagonist, is sometimes added to buprenorphine to make the product less likely to be abused by injection.

► Clinical Uses/Ideal Candidates

Extended Release Injectable Naltrexone	Methadone	Buprenorphine
<p>Prevention of relapse to opioid use disorder following opioid detoxification; studies suggest benefits for patients who are experiencing increased stress or other relapse risks (e.g., visiting places of previous drug use, loss of spouse, loss of job).</p> <p>Appropriate for patients who have been detoxified from opioids and who are being treated for a co-occurring alcohol use disorder.</p> <p>Extended-release naltrexone should be part of a comprehensive management program that includes psychosocial support.</p> <p>Other good candidates include persons with a short or less severe addiction history or who must demonstrate to professional licensing boards or criminal justice officials that their risk of opioid use is low.</p>	<p>Detoxification and maintenance treatment of opioid addiction.</p> <p>Patients who are motivated to adhere to the treatment plan and who have no contraindications to methadone therapy.</p> <p>Methadone should be part of a comprehensive management program that includes psychosocial support.</p>	<p>Treatment of opioid dependence.</p> <p>Patients who are motivated to adhere to the treatment plan and who have no contraindications to buprenorphine therapy.</p> <p>Buprenorphine should be part of a comprehensive management program that includes psychosocial support.</p>

► Contraindications

Extended Release Injectable Naltrexone

Contraindicated in patients receiving long-term opioid therapy.

Contraindicated in patients who are engaged in current opioid use (as indicated by self-report or a positive urine drug screen) or who are on buprenorphine or methadone maintenance therapy, as well as in those currently undergoing opioid withdrawal.

Contraindicated in patients with a history of sensitivity to polylactide-co-glycolide, carboxymethylcellulose, or any components of the diluent.

Should not be given to patients whose body mass precludes IM injection with the 2-inch needle provided; inadvertent subcutaneous injection may cause a severe injection site reaction.

Should not be given to anyone allergic to naltrexone.

Methadone

Contraindicated in patients who are hypersensitive to methadone hydrochloride or any other ingredient in methadone hydrochloride tablets, diskettes, powder or liquid concentrate.

Contraindicated in patients with respiratory depression (in the absence of resuscitative equipment or in unmonitored settings) and in patients with acute bronchial asthma or hypercarbia.

Contraindicated in any patient who has or is suspected of having a paralytic ileus.

Buprenorphine

Contraindicated in patients who are hypersensitive to buprenorphine or naloxone.

► Warnings

Extended Release Injectable Naltrexone

Use with caution in patients with active liver disease, moderate to severe renal impairment, and women of childbearing age.

Discontinue in the event of symptoms or signs of acute hepatitis.

As with any IM injection, extended-release injectable naltrexone should be used with caution in patients with thrombocytopenia or any coagulation disorder (e.g., hemophilia, severe hepatic failure); such patients should be closely monitored for 24 hours after naltrexone is administered.

Patients may become sensitive to lower doses of opioids after treatment with extended-release injectable naltrexone. This could result in potentially life-threatening opioid intoxication and overdose if previously tolerated larger doses are administered.

Clinicians should warn patients that overdose may result from trying to overcome the opioid blockade effects of naltrexone.

Methadone

Methadone should be used with caution in elderly and debilitated patients; patients with head injury or increased intracranial pressure; patients who are known to be sensitive to central nervous system depressants, such as those with cardiovascular, pulmonary, renal, or hepatic disease; and patients with comorbid conditions or concomitant medications that may predispose to dysrhythmia or reduced ventilatory drive.

Methadone should be administered with caution to patients already at risk for development of prolonged QT interval or serious arrhythmia.

The label includes a warning about somnolence that may preclude driving or operating equipment.

Buprenorphine

Caution is required in prescribing buprenorphine to patients with polysubstance use and those who have severe hepatic impairment, compromised respiratory function, or head injury.

Significant respiratory depression and death have occurred in association with buprenorphine, particularly administered intravenously or in combination with benzodiazepines or other central nervous system depressants (including alcohol).

Buprenorphine may precipitate withdrawal if initiated before patient is in opioid withdrawal, particularly in patients being transferred from methadone.

The label includes a warning about somnolence that may preclude driving or operating equipment.

► Use in Pregnant and Postpartum Women

Extended Release Injectable Naltrexone

Pregnancy: FDA pregnancy category C[†]

Nursing: Transfer of naltrexone and 6 β -naltrexol into human milk has been reported with oral naltrexone. Because animal studies have shown that naltrexone has a potential for tumorigenicity and other serious adverse reactions in nursing infants, an individualized treatment decision should be made whether a nursing mother will need to discontinue breastfeeding or discontinue naltrexone.

Methadone

Pregnancy: FDA pregnancy category C[†]

Methadone has been used during pregnancy to promote healthy pregnancy outcomes for more than 40 years. Neonatal abstinence syndrome may occur in newborn infants of mothers who received medication-assisted treatment with methadone during pregnancy. No lasting harm to the fetus has been recognized as a result of this therapy but individualized treatment decisions balancing the risk and benefits of therapy should be made with each pregnant patient.

Nursing: Mothers maintained on methadone can breastfeed if they are not HIV positive, are not abusing substances, and do not have a disease or infection in which breastfeeding is otherwise contraindicated.

Buprenorphine

Pregnancy: FDA pregnancy category C[†]

Neonatal abstinence syndrome may occur in newborn infants of mothers who received medication-assisted treatment with buprenorphine during pregnancy. No lasting harm to the fetus has been recognized as a result of this therapy but individualized treatment decisions balancing the risk and benefits of therapy should be made with each pregnant patient.

Nursing: Buprenorphine and its metabolite norbuprenorphine are present in low levels in human milk and infant urine. Available data are limited but have not shown adverse reactions in breastfed infants.

► Potential for Abuse and Diversion

Extended Release Injectable Naltrexone	Methadone	Buprenorphine
No	Yes	Yes

‡Animal studies have shown an adverse effect on the fetus and there are no adequate, well-controlled studies in humans, but potential benefits may warrant use of the drug in some pregnant women despite potential risks.



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Clinical Opiate Withdrawal Scale

This tool can be used in both inpatient and outpatient settings to reproducibly rate common signs and symptoms of opiate withdrawal and monitor these symptoms over time.

Resting Pulse Rate: _____ beats/minute

Measured after patient is sitting or lying for one minute.

- 0 pulse rate 80 or below
- 1 pulse rate 81-100
- 2 pulse rate 101-120
- 4 pulse rate greater than 120

Sweating: *Over past 1/2 hour not accounted for by room temperature or patient activity.*

- 0 no report of chills or flushing
- 1 subjective report of chills or flushing
- 2 flushed or observable moistness on face
- 3 beads of sweat on brow or face
- 4 sweat streaming off face

Restlessness: *Observation during assessment.*

- 0 able to sit still
- 1 reports difficulty sitting still, but is able to do so
- 3 frequent shifting or extraneous movements of legs/arms
- 5 unable to sit still for more than a few seconds

GI (Gastrointestinal) Upset: *Over last 1/2 hour.*

- 0 no GI symptoms
- 1 stomach cramps
- 2 nausea or loose stool
- 3 vomiting or diarrhea
- 5 multiple episodes of diarrhea or vomiting

Tremor: *Observation of outstretched hands.*

- 0 no tremor
- 1 tremor can be felt, but not observed
- 2 slight tremor observable
- 4 gross tremor or muscle twitching

Yawning: *Observation during assessment.*

- 0 no yawning
- 1 yawning once or twice during assessment
- 2 yawning three or more times during assessment
- 4 yawning several times/minute

Pupil Size:

- 0 pupils pinned or normal size for room light
- 1 pupils possibly larger than normal for room light
- 2 pupils moderately dilated
- 5 pupils so dilated that only the rim of the iris is visible

Bone or Joint Aches: *If patient was having pain previously, only the additional component attributed to opiates withdrawal is scored.*

- 0 not present
- 1 mild diffuse discomfort
- 2 patient reports severe diffuse aching of joints/muscles
- 4 patient is rubbing joints or muscles and is unable to sit still because of discomfort

Runny Nose or Tearing: *Not accounted for by cold symptoms or allergies.*

- 0 not present
- 1 nasal stuffiness or unusually moist eyes
- 2 nose running or tearing
- 4 nose constantly running or tears streaming down cheeks

Anxiety or Irritability:

- 0 none
- 1 patient reports increasing irritability or anxiousness
- 2 patient obviously irritable or anxious
- 4 patient so irritable or anxious that participation in the assessment is difficult

Gooseflesh Skin:

- 0 skin is smooth
- 3 piloerection of skin can be felt or hairs standing upon arms
- 5 prominent piloerection

TOTAL SCORE: _____

The total score is the sum of all 11 items.

- **SCORE:** 5-12 = mild; 13-24 = moderate; 25-36 = moderately severe; more than 36 = severe withdrawal

Initials of person completing assessment: _____

Appendix A: Certification of Opioid Treatment Programs (OTPs)

Opioids are medications that relieve pain. In the United States, the treatment of opioid dependence with medications is governed by the [Certification of Opioid Treatment Programs, 42 Code of Federal Regulations \(CFR\) 8](#). This regulation created a system to accredit and certify opioid treatment programs (OTPs). OTPs provide medication-assisted treatment (MAT) for people diagnosed with an opioid-use disorder. MAT patients also must receive counseling, which can include different forms of behavioral therapy. Learn more about [medication and counseling treatment](#) for [substance use disorders](#).

[SAMHSA's Division of Pharmacologic Therapies \(DPT\)](#), part of the [SAMHSA Center for Substance Abuse Treatment \(CSAT\)](#), oversees the certification of OTPs. OTPs must be certified by SAMHSA and accredited by an independent, SAMHSA-approved accrediting body to dispense opioid treatment medications. All OTPs also must be licensed by the state in which they operate and must register with the Drug Enforcement Administration (DEA), through a local DEA office.

The provisions of 42 CFR 8 enable DPT to focus its oversight efforts on improving treatment rather than solely ensuring that OTPs are meeting regulatory criteria. The regulation also preserves states' authority to regulate OTPs. Oversight of treatment medications used in MAT remains a multilateral system involving states, SAMHSA, the Department of Health and Human Services (HHS), and DEA. Learn more about the [federal legislation, regulations, and guidelines](#) that apply to OTPs and MAT.

OTP Certification

To become certified, an OTP must successfully complete the certification and accreditation process and meet other requirements outlined in [42 CFR 8](#). A program may apply to SAMHSA for provisional (initial) certification while it is working towards accreditation with a SAMHSA-approved accrediting body. Provisional certification is temporary, lasting for only one year. An OTP must become accredited during this one-year timeframe.

A program may also seek provisional certification while it works to gain state and DEA approvals. However, provisional certification will not be granted until state and DEA approvals have been obtained.

After an OTP receives accreditation, SAMHSA determines if the program can be certified to provide treatment under 42 CFR 8. This work is carried out by SAMHSA's regional [OTP Compliance Officers](#).

Once an OTP is certified, its certification must be renewed annually or every three years depending on the accreditation timeframe awarded.

[Apply for OTP certification.](#)

OTP Accreditation

Accreditation is a peer-review process that evaluates an OTP against SAMHSA's opioid treatment standards and the accreditation standards of SAMHSA-approved accrediting bodies. The accreditation process includes site visits by specialists with experience in opioid treatment medications and related treatment activities. The purpose of site visits is to ensure that OTPs meet specific, nationally accepted standards for MAT.

OTP accreditation:

- Enhances community confidence
- Improves medical staff recruitment
- Fulfills most state licensure requirements
- Meets certain Medicare certification requirements
- Influences liability insurance premiums

OTP Accreditation Technical Assistance

SAMHSA offers technical assistance to help programs meet accreditation standards. Support services include identifying potential deficiencies and providing the resources to help make the necessary adjustments. If your OTP needs technical assistance, or you would like to learn more about resources available to help you through the accreditation process, contact DPT at 240-276-2700 or otp-extranet@opioid.samhsa.gov (link sends e-mail).

To help OTPs achieve regulatory compliance, SAMHSA also has developed [Federal Guidelines for Opioid Treatment Programs – 2015](#).

OTPs applying for accreditation must comply with any applicable state laws and regulations. Contact your local opioid treatment authority using the [State Opioid Treatment Authorities Directory](#).

Patient Exception Requests

Sometimes patients taking medications for opioid treatment may need exceptions from federal opioid treatment standards. Common reasons include transportation hardships, conflicts with employment or vacation, and medical disabilities. In these instances, the physician must submit an “exception request” to SAMHSA and (where applicable) the state opioid treatment authority for approval to change the patient care regimen from federal opioid standards.

Learn more about [submitting patient exception requests](#).

Buprenorphine

SAMHSA is also responsible for implementing the Drug Addiction Treatment Act of 2000 (DATA 2000), which expanded the clinical context of medication-assisted opioid addiction treatment. DATA 2000 allows physicians to dispense or prescribe buprenorphine (a medication with a lower risk for abuse than some medications used in MAT) along with other medications approved by the Food and Drug Administration (FDA) to treat opioid use disorders in treatment settings other than OTPs. Buprenorphine also can be dispensed through OTPs. Learn more about [buprenorphine](#).

In addition, DATA 2000 reduces the regulatory burden on physicians who choose to prescribe or dispense buprenorphine. It permits qualified physicians to apply for and receive waivers for the special registration requirements defined in the [Controlled Substances Act](#). OTPs are not required to apply for a waiver, but they must be SAMHSA-certified. They also are not subject to patient limits as physicians. Learn more about SAMHSA’s [buprenorphine waiver management program](#).

To provide approved buprenorphine products, OTPs should modify their registration with DEA to add Schedule III narcotics to their registration certificates. OTPs providing approved buprenorphine products for opioid maintenance or detoxification treatment must conform to the federal opioid treatment standards under the [Federal Opioid Treatment Standards, 42 CFR 8.12](#). These regulations

require that OTPs provide medical services, counseling, drug abuse testing, and other services to patients admitted to treatment.

Source: Substance Abuse and Mental Health Services Administration, 9/28/15

<http://www.samhsa.gov/medication-assisted-treatment/opioid-treatment-programs>





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"This course was developed from the public domain document: Medication-Assisted Treatment of Opioid Use Disorder: Facts for Families and Friends - Substance Abuse and Mental Health Services Administration SAMHSA."