Medications for Opioid Use Disorder

For Healthcare and Addiction Professionals, Policymakers, Patients, and Families

UPDATED 2020

TREATMENT IMPROVEMENT PROTOCOL

TIP 63

SAMHSA
Substance Abuse and Mental Health Services Administration

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TIP 63

MEDICATIONS FOR OPIOID USE DISORDER

Treatment Improvement Protocol 63

For Healthcare and Addiction Professionals, Policymakers, Patients, and Families

This TIP reviews three Food and Drug Administration-approved medications for opioid use disorder treatment—methadone, naltrexone, and buprenorphine—and the other strategies and services needed to support people in recovery.

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TIP 63

MEDICATIONS FOR OPIOID USE DISORDER

Executive Summary

For Healthcare and Addiction Professionals, Policymakers, Patients, and Families

The Executive Summary of this **Treatment Improvement Protocol** provides an overview on the use of the three Food and Drug Administration-approved medications used to treat opioid use disorder—methadone, naltrexone, and buprenorphine—and the other strategies and services needed to support recovery.

TIP Navigation

DEPARTMENT OF HEALTH & HUMAN SERVICES · USA

SAMHSA
Substance Abuse and Mental Health Services Administration

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Foreword

The Substance Abuse and Mental Health Services Administration (SAMHSA) is the U.S. Department of Health and Human Services agency that leads public health efforts to reduce the impact of substance abuse and mental illness on America's communities. An important component of SAMHSA's work is focused on dissemination of evidence-based practices and providing training and technical assistance to healthcare practitioners on implementation of these best practices.

The Treatment Improvement Protocol (TIP) series contributes to SAMHSA's mission by providing science-based, best-practice guidance to the behavioral health field. TIPs reflect careful consideration of all relevant clinical and health services research, demonstrated experience, and implementation requirements. Select nonfederal clinical researchers, service providers, program administrators, and patient advocates comprising each TIP's consensus panel discuss these factors, offering input on the TIP's specific topics in their areas of expertise to reach consensus on best practices. Field reviewers then assess draft content and the TIP is finalized.

The talent, dedication, and hard work that TIP panelists and reviewers bring to this highly participatory process have helped bridge the gap between the promise of research and the needs of practicing clinicians and administrators to serve, in the most scientifically sound and effective ways, people in need of care and treatment of mental and substance use disorders. My sincere thanks to all who have contributed their time and expertise to the development of this TIP. It is my hope that clinicians will find it useful and informative to their work.

Elinore F. McCance-Katz, M.D., Ph.D.
Assistant Secretary for Mental Health and Substance Use
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TIP 63 Update

To ensure that the content of this TIP is as up to date and as useful to readers as possible, SAMHSA, in January 2020, revised certain areas of all five parts. These changes will help provide readers with the latest information needed to understand medications for opioid use disorder. These changes included the following:

- Updating statistics from SAMHSA, the Centers for Disease Control and Prevention, and other health authorities on opioid-related deaths, overdoses, accidents, and hospitalizations.
- Updating the expanded list of other qualifying practitioners who are eligible to apply for a waiver to prescribe buprenorphine (i.e., clinical nurse specialists, certified registered nurse anesthetists, and certified nurse midwives).
- Clarifying that buprenorphine is available in an extended-release injection formulation.
- Adding information about the use of subdermal formulations of buprenorphine (i.e., Probuphine and Sublocade).
- Adding information about possible clinical interactions between formulations of buprenorphine and naltrexone with various other medications and products.
- Improving the language to make clear the importance of testing for HIV and hepatitis C.
- Updating recommendations from the U.S. Preventive Services Task Force on performing drug screening for adults in primary care settings.
- Removing or replacing broken hyperlinks to online resources.

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Executive Summary

The goal of treatment for opioid addiction or opioid use disorder (OUD) is remission of the disorder leading to lasting recovery. Recovery is a process of change through which individuals improve their health and wellness, live self-directed lives, and strive to reach their full potential.[1] This Treatment Improvement Protocol (TIP) reviews the use of the three Food and Drug Administration (FDA)-approved medications used to treat OUD—methadone, naltrexone, and buprenorphine—and the other strategies and services needed to support recovery for people with OUD.

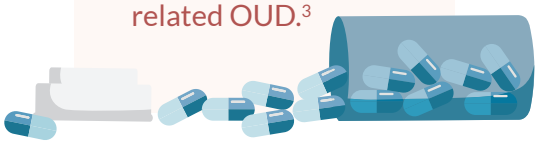
Introduction

Our nation faces a crisis of overdose deaths from opioids, including heroin, illicit fentanyl, and prescription opioids. These deaths represent a mere fraction of the total number of Americans harmed by opioid misuse and addiction. Many Americans now suffer daily from a chronic medical illness called "opioid addiction" or OUD (see the Glossary in Part 5 of this TIP for definitions). Healthcare professionals, treatment providers, and policymakers have a responsibility to expand access to evidence-based, effective care for people with OUD.

Estimated cost of the **OPIOID EPIDEMIC** was **$504 BILLION** in 2015.[2]

An expert panel developed the TIP's content based on a review of the literature and on their extensive experience in the field of addiction treatment. Other professionals also generously contributed their time and commitment to this project.

An estimated **1.7M AMERICANS** have OUD related to opioid painkillers; **526K** have heroin-related OUD.[3]



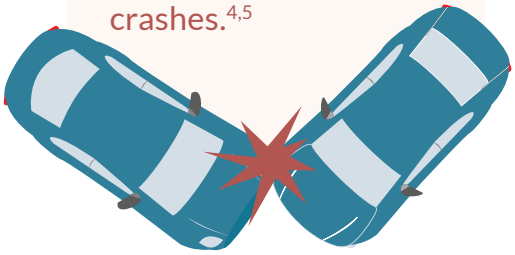
The TIP is divided into parts so that readers can easily find the material they need. Part 1 is a general introduction to providing medications for OUD and issues related to providing that treatment. Some readers may prefer to go directly to those parts most relevant to their areas of interest, but everyone is encouraged to read Part 1 to establish a shared understanding of key facts and issues covered in detail in this TIP.

Following is a summary of the TIP's overall main points and brief summaries of each of the five TIP parts.

Overall Key Messages

Addiction is a chronic, treatable illness. Opioid addiction, which generally corresponds with moderate to severe forms of OUD, often requires continuing care for effective treatment rather than an episodic, acute-care treatment approach.

Opioid overdose caused **46,800 DEATHS** nationwide in 2018—this exceeded the # caused by motor vehicle crashes.[4,5]



General principles of good care for chronic diseases can guide OUD treatment. Approaching OUD as a chronic illness can help providers deliver care that helps patients stabilize, achieve remission of symptoms, and establish and maintain recovery.

Patient-centered care empowers patients with information that helps them make better treatment decisions with the healthcare professionals involved in their care. Patients should receive information from their healthcare team that will help them understand OUD and the options for treating it, including treatment with FDA-approved medication.

Patients with OUD should have access to mental health services as needed, medical care, and addiction counseling, as well as recovery support services, to supplement treatment with medication.

The words you use to describe OUD and an individual with OUD are powerful. This TIP defines, uses, and encourages providers to adopt terminology that will not reinforce prejudice, negative attitudes, or discrimination.

There is no "one size fits all" approach to OUD treatment. Many people with OUD benefit from treatment with medication for varying lengths of time, including lifelong treatment. Ongoing outpatient medication treatment for OUD is linked to better retention and outcomes than treatment without medication. Even so, some people stop using opioids on their own; others recover through support groups or specialty treatment with or without medication.

The science demonstrating the effectiveness of medication for OUD is strong. For example, methadone, extended-release injectable naltrexone (XR-NTX), and buprenorphine were each found to be more effective in reducing illicit opioid use than no medication in randomized clinical trials, which are the gold standard for demonstrating efficacy in clinical medicine.[6,7,8,9,10] Methadone and buprenorphine treatment have also been associated with reduced risk of overdose death.[11,12,13,14,15]

This doesn't mean that remission and recovery occur only through medication. Some people achieve remission without OUD medication, just as some people can manage type 2 diabetes with exercise and diet alone. But just as it is inadvisable to deny people with diabetes the medication they need to help manage their illness, it is also not sound medical practice to deny people with OUD access to FDA-approved medications for their illness.

Medication for OUD should be successfully integrated with outpatient and residential treatment. Some patients may benefit from different levels of care at different points in their lives, such as outpatient counseling, intensive outpatient treatment, inpatient treatment, or long-term therapeutic communities. Patients treated in these settings should have access to OUD medications.

2 MILLION people in the U.S., ages 12 and older, had OUD involving **PRESCRIPTION OPIOIDS, HEROIN,** or both in 2018.[16]

Patients treated with medications for OUD can benefit from individualized psychosocial supports. These can be offered by patients' healthcare providers in the form of medication management and supportive counseling and/or by other providers offering adjunctive addiction counseling, recovery coaching, mental health services, and other services that may be needed by particular patients.

Expanding access to OUD medications is an important public health strategy.[17] The gap between the number of people needing opioid addiction treatment and the capacity to treat them with OUD medication is substantial. In 2012, the gap was estimated at nearly 1 million people, with about 80 percent of opioid treatment programs (OTPs) nationally operating at 80 percent capacity or greater.[18]

Improving access to treatment with OUD medications is crucial to closing the wide gap between treatment need and treatment availability, given the strong evidence of effectiveness for such treatments.[19]

Data indicate that medications for OUD are cost effective and cost beneficial.[20,21]

OPIOID-RELATED
EMERGENCY DEPARTMENT
visits more than doubled from 2005 to 2016.[22,23]

Content Overview

The TIP is divided into parts to make the material more accessible according to the reader's interests.

Part 1: Introduction to Medications for Opioid Use Disorder Treatment

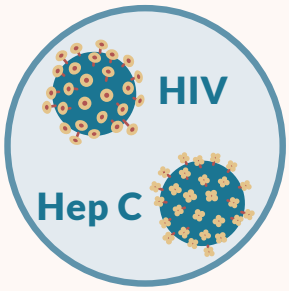
This part lays the groundwork for understanding treatment concepts discussed later in this TIP. The intended audience includes:

- Healthcare professionals (physicians, nurse practitioners, physician assistants, and, until October 1, 2023, clinical nurse specialists, certified registered nurse anesthetists, and certified nurse midwives).
- Professionals who offer addiction counseling or mental health services.
- Peer support specialists.
- People needing treatment and their families.
- People in remission or recovery and their families.
- Hospital administrators.
- Policymakers.

In Part 1, readers will learn that:

- Increasing opioid overdose deaths, illicit opioid use, and prescription opioid misuse constitute a public health crisis.
- OUD medications reduce illicit opioid use, retain people in treatment, and reduce risk of opioid overdose death better than treatment with placebo or no medication.
- Only physicians; nurse practitioners; physician assistants; and, until October 1, 2023, clinical nurse specialists, certified registered nurse anesthetists, and certified nurse midwives can prescribe buprenorphine for OUD. They must get a federal waiver to do so.
- Only federally certified, accredited OTPs can dispense methadone to treat OUD. OTPs can administer and dispense buprenorphine without a federal waiver.
- Any prescriber can offer naltrexone.
- OUD medication can be taken on a short- or long-term basis, including as part of medically supervised withdrawal and as maintenance treatment.
- Patients taking medication for OUD are considered to be in recovery.
- Several barriers contribute to the underuse of medication for OUD.

EVERYONE AGES 15 TO 65 should be tested at least **ONCE** for **HIV**. Persons at **HIGHER RISK**, such as people who use **DRUGS** by injection, should be tested **ANNUALLY**.



Anyone who is injecting or has ever **INJECTED DRUGS**, even **ONCE**, no matter how long ago, should be **TESTED** for **HEPATITIS C**, regardless of their intention to seek **TREATMENT** for SUD.[24,25]

Part 2: Addressing Opioid Use Disorder in General Medical Settings

This part offers guidance on OUD screening, assessment, treatment, and referral. Part 2 is for healthcare professionals working in general medical settings with patients who have or are at risk for OUD.

In Part 2, readers will learn that:

- All healthcare practices should screen for alcohol, tobacco, and other substance misuse (including opioid misuse).
- Validated screening tools, symptom surveys, and other resources are readily available; this part lists many of them.
- When patients screen positive for risk of harm from substance use, practitioners should assess them using tools that determine whether substance use meets diagnostic criteria for a substance use disorder (SUD).
- Thorough assessment should address patients' medical, social, SUD, and family histories.
- Laboratory tests can inform treatment planning.
- Practitioners should develop treatment plans or referral strategies (if onsite SUD treatment is unavailable) for patients who need SUD treatment.

Part 3: Pharmacotherapy for Opioid Use Disorder

This part offers information and tools for healthcare professionals who prescribe, administer, or dispense OUD medications or treat other illnesses in patients who take these medications. It provides guidance on the use of buprenorphine, methadone, and naltrexone by healthcare professionals in:

- General medical settings, including hospitals.
- Office-based opioid treatment settings.
- Specialty addiction treatment programs, including OTPs.

In Part 3, readers will learn that:

- OUD medications are safe and effective when used appropriately.

OPIOID-RELATED inpatient hospital stays **INCREASED 117%** nationally from 2005 to 2016.[26,27]

- OUD medications can help patients reduce or stop illicit opioid use and improve their health and functioning.
- Pharmacotherapy should be considered for all patients with OUD. Opioid pharmacotherapies should be reserved for those with moderate-to-severe OUD with physical dependence.
- Patients with OUD should be informed of the risks and benefits of pharmacotherapy, treatment without medication, and no treatment.
- Patients should be advised on where and how to get treatment with OUD medication.
- Doses and schedules of pharmacotherapy must be individualized.

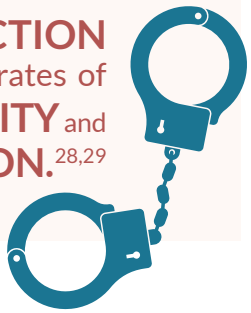
Part 4: Partnering Addiction Treatment Counselors With Clients and Healthcare Professionals

This part recommends ways that addiction treatment counselors can collaborate with healthcare professionals to support client-centered, trauma-informed OUD treatment and recovery. It also serves as a quick guide to medications that can treat OUD and presents strategies for clear communication with prescribers, creation of supportive environments for clients who take OUD medication, and ways to address other common counseling concerns when working with this population.

In Part 4, readers will learn that:

- Many patients taking OUD medication benefit from counseling as part of treatment.
- Counselors play the same role for clients with OUD who take medication as for clients with any other SUD.
- Counselors help clients recover by addressing the challenges and consequences of addiction.
- OUD is often a chronic illness requiring ongoing communication among patients and providers to ensure that patients fully benefit from both pharmacotherapy and psychosocial treatment and support.

OPIOID ADDICTION is linked with high rates of **ILLEGAL ACTIVITY** and **INCARCERATION.**[28,29]



- OUD medications are safe and effective when prescribed and taken appropriately.
- Medication is integral to recovery for many people with OUD. Medication usually produces better treatment outcomes than outpatient treatment without medication.
- Supportive counseling environments for clients who take OUD medication can promote treatment and help build recovery capital.

Part 5: Resources Related to Medications for Opioid Use Disorder

This part has a glossary and audience-segmented resource lists to help medical and behavioral health service providers better understand how to use OUD medications with their patients and to help patients better understand how OUD medications work. It is for all interested readers.

In Part 5, readers will learn that:

- Practice guidelines and decision-making tools can help healthcare professionals with OUD screening, assessment, diagnosis, treatment planning, and referral.
- Patient- and family-oriented resources provide information about opioid addiction in general; the role of medication, behavioral and supportive services, and mutual-help groups in the treatment of OUD; how-tos for identifying recovery support services; and how-tos for locating medical and behavioral health service providers who specialize in treating OUD or other SUDs.

EXHIBIT 1.2. Comparison of Medications for OUD

PRESCRIBING CONSIDERATIONS	METHADONE	NALTREXONE	BUPRENORPHINE
Mechanism of Action at mu-Opioid Receptor	Agonist	Antagonist	Partial agonist
Phase of Treatment	Medically supervised withdrawal, maintenance	Prevention of relapse to opioid misuse, following medically supervised withdrawal	Medically supervised withdrawal, maintenance
Route of Administration	Oral	Oral, intramuscular extended-release	Sublingual, buccal, subdermal implant, subcutaneous extended release injection
Possible Adverse Effects	Constipation, hyperhidrosis, respiratory depression, sedation, QT prolongation, sexual dysfunction, severe hypotension including orthostatic hypotension and syncope, misuse potential, neonatal abstinence syndrome	Nausea, anxiety, insomnia, precipitated opioid withdrawal, hepatotoxicity, vulnerability to opioid overdose, depression, suicidality, muscle cramps, dizziness or syncope, somnolence or sedation, anorexia, decreased appetite or other appetite disorders **Intramuscular:** Pain, swelling, induration (including some cases requiring surgical intervention)	Constipation, nausea, precipitated opioid withdrawal, excessive sweating, insomnia, pain, peripheral edema, respiratory depression (particularly combined with benzodiazepines or other CNS depressants), misuse potential, neonatal abstinence syndrome **Implant:** Nerve damage during insertion/removal, accidental overdose or misuse if extruded, local migration or protrusion **Subcutaneous Injection:** Injection site itching or pain, death from intravenous injection
Regulations and Availability	Schedule II; only available at federally certified OTPs and the acute inpatient hospital setting for OUD treatment	Not a scheduled medication; not included in OTP regulations; requires prescription; office-based treatment or specialty substance use treatment programs, including OTPs	Schedule III; requires waiver to prescribe outside OTPs **Implant:** Prescribers must be certified in the Probuphine Risk Evaluation and Mitigation Strategy (REMS) Program. Providers who wish to insert/remove implants are required to obtain special training and certification in the REMS Program **Subcutaneous Injection:** Healthcare settings and pharmacies must be certified in the Sublocade REMS Program and only dispense the medication directly to a provider for administration

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Notes

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TIP Development Participants

Expert Panelists

Each Treatment Improvement Protocol's (TIP's) expert panel is a group of primarily nonfederal addiction-focused clinical, research, administrative, and recovery support experts with deep knowledge of the TIP's topic. With the Substance Abuse and Mental Health Services Administration's (SAMHSA's) Knowledge Application Program (KAP) team, they develop each TIP via a consensus-driven, collaborative process that blends evidence-based, best, and promising practices with the panel's expertise and combined wealth of experience.

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Scientific Reviewers

This TIP's scientific reviewers are among the foremost experts on the three medications discussed in this TIP to treat opioid use disorder. Their role in the collaborative TIP development process was to help the KAP team include current, accurate, and comprehensive information and instructions about the use of each of these medications.

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Field Reviewers

Field reviewers represent each TIP's intended target audiences. They work in addiction, mental health, primary care, and adjacent fields. Their direct front-line experience related to the TIP's topic allows them to provide valuable input on a TIP's relevance, utility, accuracy, and accessibility.

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TIP 63

MEDICATIONS FOR OPIOID USE DISORDER

Part 1: Introduction to Medications for Opioid Use Disorder Treatment

For Healthcare and Addiction Professionals, Policymakers, Patients, and Families

Part 1 of this **Treatment Improvement Protocol (TIP)** will help readers understand key facts and issues related to providing Food and Drug Administration (FDA)-approved medications used to treat opioid use disorder (OUD).

TIP Navigation

KEY MESSAGES

- Increasing opioid overdose deaths, illicit opioid use, and prescription opioid misuse constitute a public health crisis.
- OUD medications reduce illicit opioid use, retain people in treatment, and reduce risk of opioid overdose death better than treatment with placebo or no medication.
- Only physicians; nurse practitioners; physician assistants; and, until October 1, 2023, clinical nurse specialists, certified registered nurse anesthetists, and certified nurse midwives can prescribe buprenorphine for OUD. They must get a federal waiver to do so.
- Only federally certified, accredited opioid treatment programs (OTPs) can dispense methadone to treat OUD. OTPs can administer and dispense buprenorphine without a federal waiver.
- Any prescriber can offer naltrexone.
- OUD medication can be taken on a short- or long-term basis, including as part of medically supervised withdrawal and as maintenance treatment.
- Patients taking medication for OUD are considered to be in recovery.
- Several barriers contribute to the underuse of medication for OUD.

SAMHSA
Substance Abuse and Mental Health Services Administration

Contents

PART 1 of 5

Introduction to Medications for Opioid Use Disorder Treatment

Part 1 of this TIP offers a general introduction to providing medications to address opioid use disorder (OUD). It is for all audiences. Part 1 will help readers understand key facts and issues related to providing FDA-approved medications used to treat OUD. TIP Parts 2 through 5 cover these issues in more detail.

The Approach to OUD Care

According to the Substance Abuse and Mental Health Services Administration (SAMHSA) and the National Institute on Drug Abuse, addiction is a chronic, treatable illness. Opioid addiction, which generally corresponds with moderate to severe forms of OUD (Exhibit 1.1), often requires continuing care for effective treatment rather than an episodic, acute-care treatment approach.

The World Health Organization's (WHO's) principles of good care for chronic diseases can guide OUD care:[1]

- Develop a treatment partnership with patients.
- Focus on patients' concerns and priorities.
- Support patient self-management of illness.
- Use the five A's at every visit (assess, advise, agree, assist, and arrange).
- Organize proactive follow-up.
- Link patients to community resources/support.
- Work as a clinical team.
- Involve "expert patients," peer educators, and support staff in the health facility.
- Ensure continuity of care.

Chronic care management is effective for many long-term medical conditions, such as diabetes and cardiovascular disease, and it can offer similar benefits to patients with substance use disorders (SUDs); for example, it can help them stabilize, achieve remission of symptoms, and establish and maintain recovery. Good continuing care also provides, and links to, other medical, behavioral health, and community and recovery support services.

Estimated cost of the **OPIOID EPIDEMIC** was **$504 BILLION** in 2015.[2]

A noticeable theme in chronic disease management is patient-centered care. Patient-centered care empowers patients with information that helps them make better treatment decisions with the healthcare professionals involved in their care. Patients should receive information from their healthcare team that will help them understand OUD and the options for treating it, including treatment with FDA-approved medications. Healthcare professionals should also make patients aware of available, appropriate recovery support and behavioral health services.

EXHIBIT 1.1. Key Terms

Addiction: As defined by the American Society of Addiction Medicine, "a primary, chronic disease of brain reward, motivation, memory, and related circuitry."[3] It is characterized by inability to consistently abstain, impairment in behavioral control, craving, diminished recognition of significant problems with one's behaviors and interpersonal relationships, and a dysfunctional emotional response. Like other chronic diseases, addiction often involves cycles of **relapse** and **remission.** The *Diagnostic and Statistical Manual of Mental Disorders,* Fifth Edition[4] (DSM-5), does not use the term for diagnostic purposes, but it commonly describes the more severe forms of OUD.

Medically supervised withdrawal (formerly called detoxification): Using an opioid agonist (or an alpha-2 adrenergic agonist if an opioid agonist is not available) in tapering doses or other medications to help a patient discontinue illicit or prescription opioids.

Opioid misuse: The use of prescription opioids in any way other than as directed by a prescriber; the use of any opioid in a manner, situation, amount, or frequency that can cause harm to self or others.[5]

Opioid receptor agonist: A substance that has an affinity for and stimulates physiological activity at cell receptors in the central nervous system (CNS) that are normally stimulated by opioids. Mu-opioid receptor full agonists (e.g., methadone) bind to the mu-opioid receptor and produce actions similar to those produced by the endogenous opioid beta-endorphin. Increasing the dose increases the effect. Mu-opioid receptor partial agonists (e.g., buprenorphine) bind to the mu-opioid receptor. Unlike with full agonists, increasing their dose may not produce additional effects once they have reached their maximal effect. At low doses, partial agonists may produce effects similar to those of full agonists.

Opioid receptor antagonist: A substance that has affinity for opioid receptors in the CNS without producing the physiological effects of opioid agonists. Mu-opioid receptor antagonists (e.g., naltrexone) can block the effects of exogenously administered opioids.

Opioids: All natural, synthetic, and semisynthetic substances that have effects similar to morphine. They can be used as medications having such effects (e.g., methadone, buprenorphine, oxycodone).

Opioid treatment program (OTP): An accredited treatment program with SAMHSA certification and Drug Enforcement Administration registration to administer and dispense opioid agonist medications that are approved by FDA to treat opioid addiction. Currently, these include methadone and buprenorphine products. Other pharmacotherapies, such as naltrexone, may be provided but are not subject to these regulations. OTPs must provide adequate medical, counseling, vocational, educational, and other assessment and treatment services either onsite or by referral to an outside agency or practitioner through a formal agreement.[6]

Opioid use disorder (OUD): Per DSM-5, a disorder characterized by loss of control of opioid use, risky opioid use, impaired social functioning, tolerance, and withdrawal. Tolerance and withdrawal do not count toward the diagnosis in people experiencing these symptoms when using opioids under appropriate medical supervision. OUD covers a range of severity and replaces what DSM-IV termed "opioid abuse" and "opioid dependence." An OUD diagnosis is applicable to a person who uses opioids and experiences at least 2 of the 11 symptoms in a 12-month period. (See Exhibit 2.13 in Part 2 for full DSM-5 diagnostic criteria for OUD.)

Recovery: A process of change through which individuals improve their health and wellness, live self-directed lives, and strive to reach their full potential. Even individuals with severe and chronic SUDs can, with help, overcome their SUDs and regain health and social function. Although abstinence from all substance misuse is a cardinal feature of a recovery lifestyle, it is not the only healthy, prosocial feature. Patients taking FDA-approved medication to treat OUD can be considered in recovery.

Relapse: A process in which a person with OUD who has been in **remission** experiences a return of symptoms or loss of remission. A relapse is different from a **return to opioid use** in that it involves more than a single incident of use. Relapses occur over a period of time and can be interrupted. Relapse need not be long lasting. The TIP uses relapse to describe relapse prevention, a common treatment modality.

Remission: A medical term meaning a disappearance of signs and symptoms of the disease.[7] DSM-5 defines remission as present in people who previously met OUD criteria but no longer meet any OUD criteria (with the possible exception of craving).[8] Remission is an essential element of **recovery.**

Return to opioid use: One or more instances of **opioid misuse** without a return of symptoms of OUD. A return to opioid use may lead to **relapse.**

As is true for patients undergoing treatment for any chronic medical condition, patients with OUD should have access to medical, mental health, addiction counseling, and recovery support services that they may need to supplement treatment with medication. Medical care should include preventive services and disease management. Patients with OUD who have mental disorders should have access to mental health services.

Treatment and support services should reflect each patient's individual needs and preferences. Some patients, particularly those with co-occurring disorders, may require these treatments and services to achieve sustained remission and recovery.

The words you use to describe both OUD and an individual with OUD are powerful and can reinforce prejudice, negative attitudes, and discrimination. Negative attitudes held by the public and healthcare professionals can deter people from seeking treatment, make patients leave treatment prematurely, and contribute to worse treatment outcomes. The TIP expert panel recommends that providers always use medical terms when discussing SUDs (e.g., positive or negative urine sample, not dirty or clean sample) and use person-first language (e.g., a person with an SUD, not a user, alcoholic, or addict). Exhibit 1.1 defines some key terms. A full glossary is in Part 5 of this TIP.

RESOURCE ALERT

Shared Decision Making

SAMHSA's shared decision-making tool is helpful for educating patients and their families about OUD. The information this tool provides can help patients make informed decisions about their care (https://mat-decisions-in-recovery.samhsa.gov/).

Overview of Medications for OUD

There is no "one size fits all" approach to OUD treatment. Many people with OUD benefit from treatment with medication for varying lengths of time, including lifelong treatment. Ongoing outpatient medication treatment for OUD is linked to better retention and outcomes than treatment without medication. Even so, some people stop using opioids on their own; others recover through support groups or specialty outpatient or residential treatment with or without medication. Still, FDA-approved medication should be considered and offered to patients with OUD as part of their treatment.

Benefits

The three FDA-approved medications used to treat OUD improve patients' health and wellness by:

- Reducing or eliminating withdrawal symptoms: methadone, buprenorphine.
- Blunting or blocking the effects of illicit opioids: methadone, naltrexone, buprenorphine.
- Reducing or eliminating cravings to use opioids: methadone, naltrexone, buprenorphine.

See Exhibit 1.2 for further comparison between these medications.

Effectiveness

The science demonstrating the effectiveness of medication for OUD is strong. For example, methadone, extended-release injectable naltrexone (XR-NTX), and buprenorphine were each found to be more effective in reducing illicit opioid use than no medication in randomized clinical trials,[9,10,11,12] which are the gold standard for demonstrating efficacy in clinical medicine. Methadone and buprenorphine treatment have also been associated with reduced risk of overdose death.[13,14,15,16,17]

EXHIBIT 1.2. Comparison of Medications for OUD

PRESCRIBING CONSIDERATIONS	METHADONE	NALTREXONE	BUPRENORPHINE
Mechanism of Action at mu-Opioid Receptor	Agonist	Antagonist	Partial agonist
Phase of Treatment	Medically supervised withdrawal, maintenance	Prevention of relapse to opioid misuse, following medically supervised withdrawal	Medically supervised withdrawal, maintenance
Route of Administration	Oral	Oral, intramuscular extended-release	Sublingual, buccal, subdermal implant, subcutaneous extended release injection
Possible Adverse Effects	Constipation, hyperhidrosis, respiratory depression, sedation, QT prolongation, sexual dysfunction, severe hypotension including orthostatic hypotension and syncope, misuse potential, neonatal abstinence syndrome	Nausea, anxiety, insomnia, precipitated opioid withdrawal, hepatotoxicity, vulnerability to opioid overdose, depression, suicidality, muscle cramps, dizziness or syncope, somnolence or sedation, anorexia, decreased appetite or other appetite disorders **Intramuscular:** Pain, swelling, induration (including some cases requiring surgical intervention)	Constipation, nausea, precipitated opioid withdrawal, excessive sweating, insomnia, pain, peripheral edema, respiratory depression (particularly combined with benzodiazepines or other CNS depressants), misuse potential, neonatal abstinence syndrome **Implant:** Nerve damage during insertion/removal, accidental overdose or misuse if extruded, local migration or protrusion **Subcutaneous Injection:** Injection site itching or pain, death from intravenous injection
Regulations and Availability	Schedule II; only available at federally certified OTPs and the acute inpatient hospital setting for OUD treatment	Not a scheduled medication; not included in OTP regulations; requires prescription; office-based treatment or specialty substance use treatment programs, including OTPs	Schedule III; requires waiver to prescribe outside OTPs **Implant:** Prescribers must be certified in the Probuphine Risk Evaluation and Mitigation Strategy (REMS) Program. Providers who wish to insert/remove implants are required to obtain special training and certification in the REMS Program **Subcutaneous Injection:** Healthcare settings and pharmacies must be certified in the Sublocade REMS Program and only dispense the medication directly to a provider for administration

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This doesn't mean that remission and recovery occur only through medication. Some people achieve remission without OUD medication, just as some people can manage type 2 diabetes with exercise and diet alone. But just as it is inadvisable to deny people with diabetes the medication they need to help manage their illness, it is also not sound medical practice to deny people with OUD access to FDA-approved medications for their illness.

Medication for OUD should be successfully integrated with outpatient and residential treatment. Some patients may benefit from different levels of care during the course of their lives. These different levels include outpatient counseling, intensive outpatient treatment, inpatient treatment, or long-term therapeutic communities. Patients receiving treatment in these settings should have access to FDA-approved medications for OUD.

Patients treated with OUD medications can benefit from individualized psychosocial supports. These can be offered by patients' healthcare providers in the form of medication management and supportive counseling and/or by other providers offering adjunctive addiction counseling, contingency management, recovery coaching, mental health services, and other services (e.g., housing supports) that particular patients may need.

> **The TIP expert panel strongly recommends informing all patients with OUD about the risks and benefits of treatment of OUD with all FDA-approved medications. Alternatives to these treatments and their risks and benefits should be discussed. Patients should receive access to such medications if clinically appropriate and desired by the patients.**

Expanding access to FDA-approved medications is an important public health strategy.[19] A substantial gap exists between the number of people needing OUD treatment and the capacity to treat those individuals with OUD medication. In 2012, the gap was estimated at nearly 1 million people, with approximately 80 percent of OTPs nationally operating at 80 percent capacity or greater.[20] Blue Cross Blue Shield reported a 493 percent increase in members diagnosed with OUD from 2010 to 2016 but only a 65 percent increase in the use of medication for OUD.[21] **Improving access is crucial to closing the wide gap between the need for treatment with OUD medications and the availability of such treatment,** given the strong evidence of OUD medications' effectiveness.[22]

Methadone

Methadone retains patients in treatment and reduces illicit opioid use more effectively than placebo, medically supervised withdrawal, or no treatment, as numerous clinical trials and meta-analyses of studies conducted in many countries show.[23,24,25] Higher methadone doses are associated with superior outcomes.[26,27] Given the evidence of methadone's effectiveness, WHO lists it as an essential medication.[28]

Methadone treatment has by far the largest, oldest evidence base of all treatment approaches to opioid addiction. Large multisite longitudinal studies from the world over support methadone maintenance's effectiveness.[29,30,31] Longitudinal studies have also found that it is associated with:[32,33,34,35,36,37,38,39,40]

- Reduced risk of overdose-related deaths.
- Reduced risk of HIV and hepatitis C infection.
- Lower rates of cellulitis.
- Lower rates of HIV risk behavior.
- Reduced criminal behavior.

Naltrexone

XR-NTX reduces illicit opioid use and retains patients in treatment more effectively than placebo and no medication, according to findings from randomized controlled trials.[41,42,43]

In a two-group random assignment study of adults who were opioid dependent and involved in the justice system, all participants received brief counseling and community treatment referrals. One group received no medication, and the other group received XR-NTX. During the 6-month follow-up period, compared with the no-medication group, the group that received the medication demonstrated:[44]

- Longer time to return to substance use (10.5 weeks versus 5.0 weeks).
- A lower rate of return to use (43 percent versus 64 percent).
- A higher percentage of negative urine screens (74 percent versus 56 percent).

There are two studies comparing XR-NTX to sublingual buprenorphine. A multisite randomized trial assigned adult residential treatment patients with OUD to either XR-NTX or buprenorphine. Patients randomly assigned to buprenorphine had significantly lower relapse rates during 24 weeks of outpatient treatment than patients assigned to XR-NTX.[45] This finding resulted from challenges in completing XR-NTX induction, such that a significant proportion of patients did not actually receive XR-NTX. However, when comparing only those participants who started their assigned medication, no significant between-group differences in relapse rates were observed. Because dose induction was conducted with inpatients, findings may not be generalizable to dose induction in outpatient settings, where most patients initiate treatment. A 12-week trial among adults with opioid dependence in Norway who were opioid abstinent at the time of random assignment found that XR-NTX was as effective as buprenorphine in retaining patients in treatment and in reducing illicit opioid use.[46]

Oral naltrexone is also available, but it has not been found to be superior to placebo or to no medication in clinical trials.[47] Nonadherence limits its use.

Buprenorphine

Buprenorphine in its sublingual form retains patients in treatment and reduces illicit opioid use more effectively than placebo.[48] It also reduces HIV risk behaviors.[49,50] A multisite randomized trial with individuals addicted to prescription opioids showed that continued buprenorphine was superior to buprenorphine dose taper in reducing illicit opioid use.[51] Another randomized trial showed that continued buprenorphine also improved treatment retention and reduced illicit prescription opioid use compared with buprenorphine dose taper.[52] Long-term studies of buprenorphine show its effectiveness outside of clinical research protocols.[53,54] Naloxone, a short-acting opioid antagonist, is also often included in the buprenorphine formulation to help prevent diversion to injected misuse. Because of the evidence of buprenorphine's effectiveness, WHO lists it as an essential medication.[55] Buprenorphine is available in "transmucosal" (i.e., sublingual or buccal) formulations.

Buprenorphine implants can be effective in stable patients. FDA approved implants (Probuphine) after a clinical trial showed them to be as effective as relatively low-dose (i.e., 8 mg or less daily) sublingual buprenorphine (Suboxone equivalents) for patients who are already clinically stable.[56] More research is needed to establish implants' effectiveness outside of research studies, but findings to date are promising.[57,58]

FDA approved buprenorphine extended-release injection (Sublocade) in November 2017 to treat patients with moderate or severe OUD who have first received treatment with transmucosal buprenorphine for at least 1 week. This buprenorphine formulation is a monthly subcutaneous injection.

Exhibit 1.2 compares medications for OUD.

Cost Effectiveness and Cost Benefits

Cost-effectiveness and cost-benefit analyses can further our understanding of OUD medications' effectiveness.

Data indicate that medications for OUD are cost effective. Cost-effectiveness analyses compare the cost of different treatments with their associated outcomes (e.g., negative opioid urine tests). Such analyses have found that:

- Methadone and buprenorphine are more cost effective than OUD treatment without medication.[59]
- Counseling plus buprenorphine leads to significantly lower healthcare costs than little or no treatment among commercially insured patients with OUD.[60]
- Treatment with any of the three OUD medications this TIP covers led to lower healthcare usage and costs than treatment without medication in a study conducted in a large health plan.[61]

Relatively few cost-benefit analyses have examined addiction treatment with medication separately from addiction treatment in general.[62] Cost-benefit studies compare a treatment's cost with its benefits. The treatment is cost beneficial if its benefits outweigh its cost. These benefits can include:

- Reduced expenditures because of decreased crime.
- Reduced expenditures related to decreases in the use of the justice system.
- Improved quality of life.
- Reduced healthcare spending.
- Greater earned income.

Methadone treatment in OTPs can reduce justice system and healthcare costs.[63,64]

Requirements and Regulations

Following is a summary of regulations and requirements that apply to the three OUD medications. Part 3 of this TIP discusses the pharmacology and dosing of these medications.

Only federally certified and accredited OTPs can dispense methadone for the treatment of OUD. Methadone is typically given orally as a liquid.[65]

OTPs can dispense buprenorphine under OTP regulations without using a federal waiver.

Individual healthcare practitioners can prescribe buprenorphine in any medical setting, as long as they apply for and receive waivers of the special registration requirements defined in the Controlled Substances Act. Several laws and regulations contain information about which healthcare practitioners are eligible to apply for a waiver and how to qualify (https://www.samhsa.gov/medication-assisted-treatment/training-materials-resources/apply-for-practitioner-waiver). This information is summarized below.

- Eligible physicians, nurse practitioners, physician assistants, and other qualifying practitioners (clinical nurse specialists, certified registered nurse anesthetists, and certified nurse midwives) can apply for a waiver.
- At present, clinical nurse specialists, certified registered nurse anesthetists, and certified nurse midwives are only eligible to apply for a waiver until October 1, 2023.
- For the first year of waiver use, **all providers** can treat up to 30 patients at one time. However, providers who satisfy additional practice and reporting requirements, and physicians who are board certified in addiction psychiatry or addiction medicine, may request to treat up to 100 patients at a time in the first year of waiver use. Additionally, practitioners who provide MAT in "qualified practice settings," as defined in title 42, section 8.615 of the Code of Federal Regulations, may also request to treat up to 100 patients within the first year.
- After the first year of waiver use, **all providers** may request to increase their patient limit to 100.

- Physicians and other qualified providers who are board certified in addiction psychiatry or addiction medicine or who satisfy additional practice and reporting requirements may apply to increase their patient limit to 275 after a year at the 100-patient limit.

Prescribing buprenorphine implants requires Probuphine REMS Program certification. Providers who wish to insert or remove implants must obtain live training and certification in the REMS Program.

Healthcare settings and pharmacies must get Sublocade REMS Program certification to dispense this medication and can only dispense it directly to healthcare providers for subcutaneous administration.

Naltrexone has no regulations beyond those that apply to any prescription pharmaceutical. Any healthcare provider with prescribing authority, including those practicing in OTPs, can prescribe its oral formulation and administer its long-acting injectable formulation.

The Controlled Substances Act contains a few exceptions from the requirement to provide methadone through an OTP or buprenorphine through an OTP or a waivered practitioner.

RESOURCE ALERT

OUD Medication Treatment Limits and Reporting Requirements

The following websites provide information about (1) the Department of Health and Human Services' final rule to increase patient access to medication for OUD and (2) associated reporting requirements:

www.federalregister.gov/documents/2016/07/08/2016-16120/medication-assisted-treatment-for-opioid-use-disorders

www.samhsa.gov/sites/default/files/programs_campaigns/medication_assisted/understanding-patient-limit275.pdf

These include (1) administering (not prescribing) an opioid for no more than 3 days to a patient in acute opioid withdrawal while preparations are made for ongoing care and (2) administering opioid medications in a hospital to maintain or detoxify a patient as an "incidental adjunct to medical or surgical treatment of conditions other than addiction."[66]

Duration of Treatment With OUD Medication

Patients can take medication for OUD on a short-term or long-term basis. However, patients who discontinue OUD medication generally return to illicit opioid use. Why is this so, even when discontinuation occurs slowly and carefully? Because the more severe form of OUD (i.e., addiction) is more than physical dependence. Addiction changes the reward circuitry of the brain, affecting cognition, emotions, and behavior. Providers and their patients should base decisions about discontinuing OUD medication on knowledge of the evidence base for the use of these medications, individualized assessments, and an individualized treatment plan they collaboratively develop and agree upon. Arbitrary time limits on the duration of treatment with OUD medication are inadvisable.

Maintenance Treatment

The best results occur when a patient receives medication for as long as it provides a benefit. This approach is often called "maintenance treatment."[67,68] Once stabilized on OUD medication, many patients stop using illicit opioids completely. Others continue to use for some time, but less frequently and in smaller amounts, which reduces their risk of morbidity and overdose death.

OUD medication gives people the time and ability to make necessary life changes associated with long-term remission and recovery (e.g., changing the people, places, and things connected with their drug use), and to do so more safely. Maintenance treatment also minimizes cravings and withdrawal symptoms.

And it lets people better manage other aspects of their life, such as parenting, attending school, or working.

Medication Taper

After some time, patients may want to stop opioid agonist therapy for OUD through gradually tapering doses of the medication. Their outcomes will vary based on factors such as the length of their treatment, abstinence from illicit drugs, financial and social stability, and motivation to discontinue medication.[69] Longitudinal studies show that most patients who try to stop methadone treatment relapse during or after completing the taper.[70,71] For example, in a large, population-based retrospective study, only 13 percent of patients who tapered from methadone had successful outcomes (no treatment reentry, death, or opioid-related hospitalization within 18 months after taper).[72] A clinical trial of XR-NTX versus treatment without medication also found increased risk of returning to illicit opioid use after discontinuing medication.[73]

Adding psychosocial treatments to taper regimens may not significantly improve outcomes compared with remaining on medication. One study randomly assigned participants to methadone maintenance or to 6 months of methadone treatment with a dose taper plus intensive psychosocial treatment. The maintenance group had more days in treatment and lower rates of heroin use and HIV risk behavior at 12-month follow-up.[74] Patients wishing to taper their opioid agonist medication should be offered psychosocial and recovery support services. They should be monitored during and after dose taper, offered XR-NTX, and encouraged to resume treatment with medication quickly if they return to opioid use.

Medically Supervised Withdrawal

Medically supervised withdrawal is a process in which providers offer methadone or buprenorphine on a short-term basis to reduce physical withdrawal signs and symptoms. Formerly called detoxification, this process gradually decreases the dose until the medication is discontinued, typically over a period of days or weeks. Studies show that most patients with OUD who undergo medically supervised withdrawal will start using opioids again and won't continue in recommended care.[75,76,77,78,79,80,81,82,83] Psychosocial treatment strategies, such as contingency management, can reduce dropout from medically supervised withdrawal, opioid use during withdrawal, and opioid use following completion of withdrawal.[84] Medically supervised withdrawal is necessary for patients starting naltrexone, which requires at least 7 days without short-acting opioids and 10 to 14 days without long-acting opioids.

Patients who complete medically supervised withdrawal are at risk of opioid overdose.

> **Primary care physicians are on the front lines of providing office-based treatment with medication for OUD.**

Treatment Settings

Almost all healthcare settings are appropriate for screening and assessing for OUD and offering medication onsite or by referral. Settings that offer OUD treatment have expanded from specialty sites (certified OTPs, residential facilities, outpatient addiction treatment programs, and addiction specialist physicians' offices) to general primary care practices, health centers, emergency departments, inpatient medical and psychiatric units, jails and prisons, and other settings.

> **Sustained public health efforts are essential to address the urgent need for OUD treatment and the risk of related overdose, HIV, and hepatitis C virus epidemics. These efforts must remove barriers and increase access to OUD medication.**

OUD medications should be available to patients across all settings and at all levels of care—as a tool for remission and recovery. Because of the strength of the science, a 2016 report from the Surgeon General[85] urged adoption of medication for OUD along with recovery supports and other behavioral health services throughout the healthcare system.

Challenges to Expanding Access to OUD Medication

Despite the urgent need for treatment throughout the United States, only about 21.5 percent of people with OUD received treatment from 2009 to 2013.[86] The Centers for Disease Control and Prevention lists more than 200 U.S. counties as at risk for an HIV or a hepatitis C virus outbreak related to injection drug use.[87]

Resources

Patient success stories are inspirational. They highlight the power of OUD medication to help people achieve remission and recovery. See the "Patient Success Stories" section in Part 5 of this TIP.

Part 5 of this TIP also contains community resources and advocacy resources. The community resources are for OTP, addiction treatment, and office-based providers. The advocacy resources can help patients and others advocate for OUD medication for themselves and in their communities.

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TIP 63

MEDICATIONS FOR OPIOID USE DISORDER

Part 2: Addressing Opioid Use Disorder in General Medical Settings

For Healthcare Professionals

Part 2 of this **Treatment Improvement Protocol (TIP)** will guide practitioners' efforts to identify, assess, and treat or refer patients with opioid use disorder (OUD) in general medical settings.

TIP Navigation

KEY MESSAGES

- All healthcare practices should screen for alcohol, tobacco, and other substance misuse (including opioid misuse).
- Validated screening tools, symptom surveys, and other resources are readily available; this part lists many of them.
- When patients screen positive for risk of harm from substance use, practitioners should assess them using tools that determine whether substance use meets diagnostic criteria for a substance use disorder (SUD).
- Thorough assessment should address patients' medical, social, SUD, and family histories.
- Laboratory tests can inform treatment planning.
- Practitioners should develop treatment plans or referral strategies (if onsite SUD treatment is unavailable) for patients who need SUD treatment.

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Contents

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PART 2 of 5

Addressing Opioid Use Disorder in General Medical Settings

Part 2 of this TIP is for healthcare professionals who work in general medical settings* and care for patients who misuse opioids or have OUD. Healthcare professionals in such settings address most personal healthcare needs, develop sustained partnerships with patients, and practice in the context of family and community. Thus, they have a good basis from which to understand patients' needs related to OUD screening, assessment, and treatment (or referral to specialty treatment).

Scope of the Problem

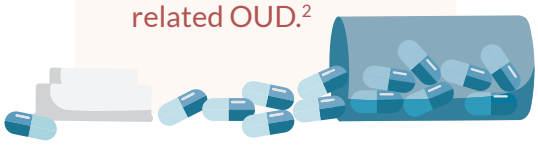
The number of patients presenting with OUD in medical clinics, community health centers, and private practices is increasing. Healthcare professionals in these general settings are in an important position to identify, assess, and treat OUD or to refer patients for treatment. Moreover, patients who are medically and mentally stable can benefit from receiving OUD medications in integrated care settings, where they often have already established therapeutic relationships with their healthcare providers.

Exhibit 2.1 defines key terms in Part 2. For more definitions, see the glossary in Part 5 of this TIP.

Screening

Screening can identify patients who may have diseases or conditions related to their substance use. Health care in general medical settings routinely includes screening for common, treatable conditions such as cancer that are associated with significant morbidity and mortality. Screening for SUDs is important, as misuse of alcohol, tobacco, and other substances is common among patients in medical settings (Exhibit 2.2).[1]

An estimated **1.7M AMERICANS** have OUD related to opioid painkillers; **526K** have heroin-related OUD.[2]



Screening can identify substance misuse in patients who wouldn't otherwise discuss it or connect it with the negative consequences they're experiencing. Some patients may spontaneously reveal their substance use and ask for help. This is more likely when they're experiencing harmful consequences of substance use. However, screening may identify unhealthy substance use (e.g., binge drinking) and SUDs

> **The TIP expert panel recommends that healthcare professionals screen patients for alcohol, tobacco, prescription drug, and illicit drug use at least annually.**

*In this TIP, the term "general medical setting" includes medical clinics, community health centers, and private practices.

EXHIBIT 2.1. Key Terms

Addiction: As defined by the American Society of Addiction Medicine (ASAM),[3] "a primary, chronic disease of brain reward, motivation, memory, and related circuitry." It is characterized by inability to consistently abstain, impairment in behavioral control, craving, diminished recognition of significant problems with one's behaviors and interpersonal relationships, and a dysfunctional emotional response. Like other chronic diseases, addiction often involves cycles of **relapse** and **remission.** The *Diagnostic and Statistical Manual of Mental Disorders,* Fifth Edition[4] (DSM-5), does not use the term for diagnostic purposes, but it commonly describes the more severe forms of OUD.

Healthcare professionals: Physicians, nurse practitioners (NPs), physician assistants (PAs), and other medical service professionals who are eligible to prescribe medications for and treat patients with OUD (i.e., until October 1, 2023, clinical nurse specialists, certified registered nurse anesthetists, certified nurse midwives). The term **"prescribers"** also refers to these healthcare professionals.

Maintenance treatment: Providing medications to achieve and sustain clinical remission of signs and symptoms of OUD and support the individual process of recovery without a specific endpoint (as with the typical standard of care in medical and psychiatric treatment of other chronic illnesses).

Medically supervised withdrawal (formerly called detoxification): Using an opioid agonist (or an alpha-2 adrenergic agonist if an opioid agonist is not available) in tapering doses or other medications to help a patient discontinue illicit or prescription opioids.

Medical management: Process whereby healthcare professionals provide medication, basic brief supportive counseling, monitoring of drug use and medication adherence, and referrals, when necessary, to addiction counseling and other services to address the patient's medical, mental health, comorbid addiction, and psychosocial needs.

Office-based opioid treatment (OBOT): Providing medication for OUD in outpatient settings other than certified opioid treatment programs (OTPs).

Opioid misuse: The use of prescription opioids in any way other than as directed by a prescriber; the use of any opioid in a manner, situation, amount, or frequency that can cause harm to self or others.[5]

Opioid receptor agonist: A substance that has an affinity for and stimulates physiological activity at cell receptors in the central nervous system that are normally stimulated by opioids. **Mu-opioid receptor full agonists** (e.g., methadone) bind to the mu-opioid receptor and produce actions similar to those produced by the endogenous opioid beta-endorphin. Increasing the dose increases the effect. **Mu-opioid receptor partial agonists** (e.g., buprenorphine) bind to the mu-opioid receptor. Unlike with full agonists, increasing their dose may not produce additional effects once they have reached their maximal effect. At low doses, partial agonists may produce effects similar to those of full agonists.

Opioid receptor antagonist: A substance that has an affinity for opioid receptors in the central nervous system without producing the physiological effects of opioid agonists. Mu-opioid receptor antagonists (e.g., naltrexone) can block the effects of exogenously administered opioids.

Opioid treatment program (OTP): An accredited treatment program with Substance Abuse and Mental Health Services Administration (SAMHSA) certification and Drug Enforcement Administration (DEA) registration to administer and dispense opioid agonist medications that are approved by the Food and Drug Administration (FDA) to treat opioid addiction. Currently, these include methadone and buprenorphine products. Other pharmacotherapies, such as naltrexone, may be provided but are not subject to these regulations. OTPs must provide adequate medical, counseling, vocational, educational, and other assessment and treatment services either onsite or by referral to an outside agency or practitioner through a formal agreement.[6]

Continued on next page

EXHIBIT 2.1. Key Terms (continued)

Opioid use disorder (OUD): Per DSM-5,[7] a disorder characterized by loss of control of opioid use, risky opioid use, impaired social functioning, tolerance, and withdrawal. Tolerance and withdrawal do not count toward the diagnosis in people experiencing these symptoms when using opioids under appropriate medical supervision. OUD covers a range of severity and replaces what the *Diagnostic and Statistical Manual of Mental Disorders,* Fourth Edition, termed "opioid abuse" and "opioid dependence." An OUD diagnosis is applicable to a person who uses opioids and experiences at least 2 of the 11 symptoms in a 12-month period. (See Exhibit 2.13 and the Appendix in Part 2 for full DSM-5 diagnostic criteria for OUD.)

Recovery: A process of change through which individuals improve their health and wellness, live a self-directed life, and strive to reach their full potential. Even individuals with severe and chronic SUDs can, with help, overcome their SUDs and regain health and social function. Although abstinence from all substance misuse is a cardinal feature of a recovery lifestyle, it is not the only healthy, prosocial feature. Patients taking FDA-approved medication to treat OUD can be considered in recovery.

Relapse: A process in which a person with OUD who has been in **remission** experiences a return of symptoms or loss of remission. A relapse is different from a **return to opioid use** in that it involves more than a single incident of use. Relapses occur over a period of time and can be interrupted. Relapse need not be long lasting. The TIP uses relapse to describe relapse prevention, a common treatment modality.

Remission: A medical term meaning a disappearance of signs and symptoms of the disease.[8] DSM-5 defines remission as present in people who previously met OUD criteria but no longer meet any OUD criteria (with the possible exception of craving).[9] Remission is an essential element of **recovery.**

Return to opioid use: One or more instances of **opioid misuse** without a return of symptoms of OUD. A return to opioid use may lead to **relapse.**

Tolerance: Alteration of the body's responsiveness to alcohol or other drugs (including opioids) such that higher doses are required to produce the same effect achieved during initial use. See also **medically supervised withdrawal.**

before patients connect their substance use with their presenting complaint. Screening is also helpful when patients feel ashamed or afraid to reveal their concerns spontaneously.

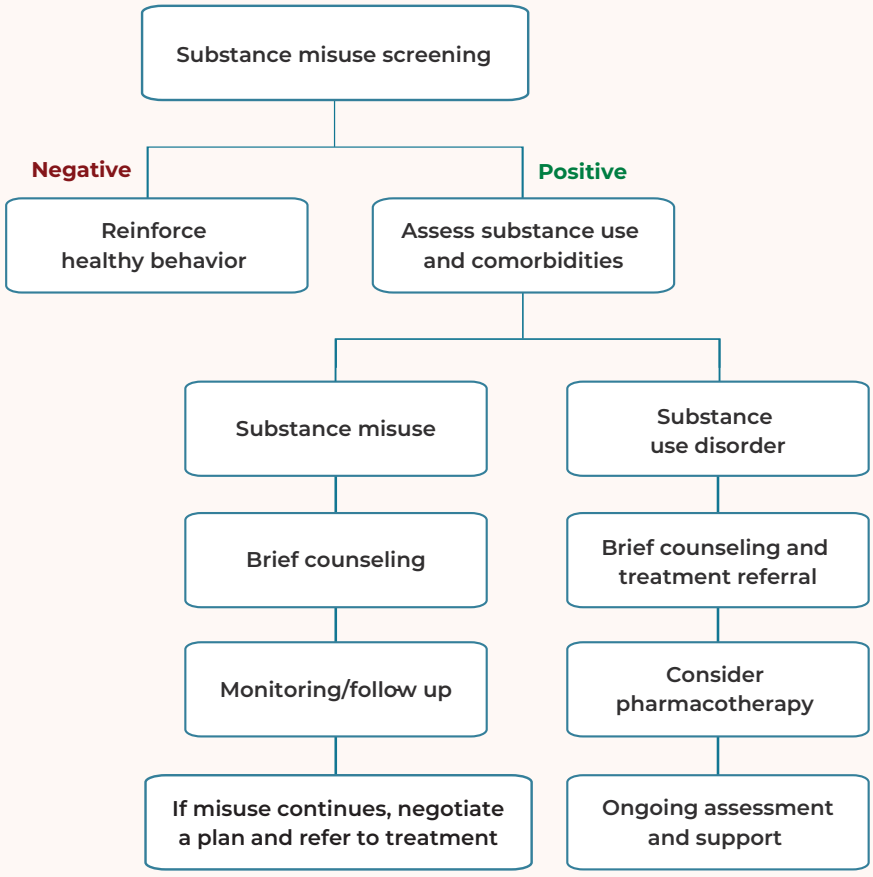
Every medical practice should determine which screening tools to use and when, how, and by whom they will be administered. Each practice should also identify steps to take when a patient screens positive. One efficient workflow strategy is to have clinical assistants or nurses administer the screening instrument in an interview or provide patients with a paper or computer tablet version for self-administration. (Self-administration is generally as reliable as interviewer administration.)[10] Providers should be nonjudgmental and rely on established rapport when discussing screening results with patients.

The following sections summarize reliable screening tools. (See Part 5 for more resources.)

Alcohol Screening

Screening for alcohol misuse can identify patients at increased risk for opioid use. When screening patients for opioid misuse, providers should also screen for alcohol misuse and alcohol use disorder (AUD), which cause considerable morbidity and mortality.[11] Providers should warn patients who use opioids that alcohol may increase opioid overdose risk.[12] The U.S. Preventive Services Task Force (USPSTF) recommends screening adults for alcohol misuse, including risky drinking and AUD. USPSTF also recommends brief counseling for patients with risky drinking.[13,14]

EXHIBIT 2.2. Substance Misuse and SUD Screening



Adapted with permission.[15]

USPSTF recommends the following alcohol screeners:

- **The single-item National Institute on Alcohol Abuse and Alcoholism (NIAAA) Screener** is the briefest tool available (Exhibit 2.3). It can help distinguish at-risk patients who require further screening from those not at risk for AUD. Encourage patients in the latter category to maintain healthy behavior.
- **The Alcohol Use Disorders Identification Test (AUDIT)[16] or its briefer version, the AUDIT-Consumption,**[17] can elicit more information from patients who screen positive on the single-item screener. The full AUDIT tool (Exhibit 2.4) and its briefer version have demonstrated acceptable reliability in AUD screening.[18] Assess patients with positive screens for AUD.

Practitioners should consider pharmacotherapy and referral to counseling for people with AUD. The three FDA-approved medications to treat AUD—acamprosate, disulfiram, and naltrexone (oral and extended-release injectable naltrexone [XR-NTX])—can be prescribed in general medical and specialty SUD treatment settings. (For more information on AUD treatment, see the SAMHSA/NIAAA publication *Medication for the Treatment of Alcohol Use Disorder: A Brief Guide*.)[19]

EXHIBIT 2.3. NIAAA Single-Item Screener

How many times in the past year have you had five or more drinks in a day (four drinks for women and all adults older than age 65)?

→ One or more times constitutes a positive screen. Patients who screen positive should have an assessment for AUD.

Adapted with permission.[20]

Tobacco Screening

More than 80 percent of patients who are opioid dependent smoke cigarettes.[21] Understanding of the major health consequences and risks associated with tobacco use has grown significantly over the past 50 years. Among preventable causes of premature death, smoking remains most prevalent, with more than 480,000 deaths per year in the United States.[22] In addition, more than 40 percent of all people who smoke are mentally ill or have SUDs.[23,24]

USPSTF recommends that primary care providers screen for tobacco use, advise patients to quit, and provide counseling and FDA-approved medications for tobacco cessation.[25] The six-item Fagerström Test for Nicotine Dependence[26] assesses cigarette use and nicotine dependence. The maximum score is 10; the higher the total score, the more severe the patient's nicotine dependence. The two-item Heaviness of Smoking Index (Exhibit 2.5) is also useful.[27]

Drug Screening

Screening for illicit drug use and prescription medication misuse is clinically advantageous. USPSTF's position is that adults ages 18 and older (including those who are pregnant) should be routinely screened in primary care for illicit drug use and prescription medication misuse when services for accurate diagnosis, effective treatment, and appropriate care can be offered or referral can be provided.[28] Identifying misuse of prescription or illegal drugs can prevent harmful drug interactions, lead to adjustments in prescribing practices, improve medical care adherence, and increase the odds of patients getting needed interventions or treatment.[29]

Brief screening instruments for drug use can determine which patients need further assessment. Providers should reinforce healthy behaviors among patients who report "no use" and direct those who report "some use" for further screening and assessment to obtain a diagnosis.

Several brief screening instruments for drug use can help primary care practitioners identify patients who use drugs.[30,31] For example, a single-item screen is available for the general public (Exhibit 2.6).[32] A two-item valid screener is available for use with U.S. veterans (Exhibit 2.7).[33]

Brief drug screens don't indicate specific types of drugs used (nor does the longer Drug Abuse Screening Test; see the Part 2 Appendix).[34] If providers use nonspecific screens, they need to assess further which substances patients use and to what degree.

> **The TIP expert panel recommends universal OUD screening.** Given the high prevalence of SUDs in patients visiting primary care settings and the effectiveness of medications to treat OUD specifically, the TIP expert panel recommends screening all patients for opioid misuse.

EXHIBIT 2.4. AUDIT Screener

1. How often do you have a drink containing alcohol?

(0) Never *[Skip to Questions 9–10]*
(1) Monthly or less
(2) 2 to 4 times a month
(3) 2 to 3 times a week
(4) 4 or more times a week

2. How many drinks containing alcohol do you have on a typical day when you are drinking?

(0) 1 or 2
(1) 3 or 4
(2) 5 or 6
(3) 7, 8, or 9
(4) 10 or more

3. How often do you have six or more drinks on one occasion?

(0) Never
(1) Less than monthly
(2) Monthly
(3) Weekly
(4) Daily or almost daily

Skip to Questions 9 and 10 if total score for Questions 2 and 3 = 0

4. How often during the last year have you found that you were not able to stop drinking once you had started?

(0) Never
(1) Less than monthly
(2) Monthly
(3) Weekly
(4) Daily or almost daily

5. How often during the last year have you failed to do what was normally expected from you because of drinking?

(0) Never
(1) Less than monthly
(2) Monthly
(3) Weekly
(4) Daily or almost daily

6. How often during the last year have you needed an alcoholic drink first thing in the morning to get yourself going after a night of heavy drinking?

(0) Never
(1) Less than monthly
(2) Monthly
(3) Weekly
(4) Daily or almost daily

7. How often during the last year have you had a feeling of guilt or remorse after drinking?

(0) Never
(1) Less than monthly
(2) Monthly
(3) Weekly
(4) Daily or almost daily

8. How often during the last year have you been unable to remember what happened the night before because you had been drinking?

(0) Never
(1) Less than monthly
(2) Monthly
(3) Weekly
(4) Daily or almost daily

9. Have you or someone else been injured as a result of your drinking?

(0) No
(2) Yes, but not in the last year
(4) Yes, during the last year

10. Has a relative, friend, doctor, or another health professional expressed concern about your drinking or suggested you cut down?

(0) No
(2) Yes, but not in the last year
(4) Yes, during the last year

Note: Add up the points associated with answers. A score of 8 or more is considered a positive test for unhealthy drinking.

Adapted from material in the public domain.[35] Available online (http://auditscreen.org).

EXHIBIT 2.5. Heaviness of Smoking Index

Ask these two questions of current or recent smokers:

1. How soon after waking do you smoke your first cigarette?
   - Within 5 minutes (3 points)
   - 5–30 minutes (2 points)
   - 31–60 minutes (1 point)
   - 61 or more minutes (no points)
2. How many cigarettes a day do you smoke?
   - 10 or less (no points)
   - 11–20 (1 point)
   - 21–30 (2 points)
   - 31 or more (3 points)

Total score:
1–2 points = very low dependence
3 points = low to moderate dependence
4 points = moderate dependence
5 or more points = high dependence

Adapted with permission.[36]

EXHIBIT 2.6. Single-Item Drug Screener

How many times in the past year have you used an illegal drug or a prescription medication for nonmedical reasons?

(A positive screen is 1 or more days.)

Reprinted with permission.[39]

EXHIBIT 2.7. Two-Item Drug Use Disorder Screener for Primary Care Clinics Serving U.S. Veterans

Question 1: How many days in the past 12 months have you used drugs other than alcohol? (A positive screen is 7 or more days.) If fewer than 7, proceed with Question 2.

Question 2: How many days in the past 12 months have you used drugs more than you meant to? (A positive screen is 2 or more days.)

Adapted with permission.[40]

The Alcohol, Smoking, and Substance Involvement Screening Test (ASSIST) screens patients for all categories of substance misuse, including alcohol and tobacco. This World Health Organization (WHO) screener also assesses substance-specific risk. The ASSIST's length and rather complex scoring system have hindered its adoption, but a computerized version and a briefer hard copy version (ASSIST-lite) make its use more efficient.[37,38] (See the "Screening, Assessment, and Drug Testing Resources" section for a link to a modified version of the ASSIST.)

The TIP expert panel does not recommend routine universal drug testing with urine, blood, or oral fluids in primary care. Still, drug testing can confirm recent drug use in patients receiving diagnostic workups for changes in mental status, seizures, or other disorders. Conduct drug testing before patients start OUD medication and during treatment for monitoring.

Follow up any positive one-question screen with a brief assessment. An example of a two-step screening and brief assessment is the Tobacco, Alcohol, Prescription Medications, and Other Substance Use (TAPS Tool; see Part 2 Appendix), developed and tested in primary care settings.[41] This tool is based on the National Institute on Drug Abuse (NIDA) Quick Screen V1.0[42,43] and a modified WHO ASSIST-lite.[44]

The TAPS Tool screens for clinically relevant heroin and prescription opioid misuse (meeting one or more DSM-5 SUD criteria) and misuse of an array of other substances in primary care patients. However, it may also detect SUDs only for the most often-used substances (i.e., alcohol, tobacco, and marijuana). Patients with positive screens for heroin or prescription opioid misuse need more indepth assessment.[45]

Assessment

Determine the Need for and Extent of Assessment

Assess patients for OUD if:

- They screen positive for opioid misuse.
- They disclose opioid misuse.
- Signs or symptoms of opioid misuse are present.

The extent of assessment depends on a provider's ability to treat patients directly.

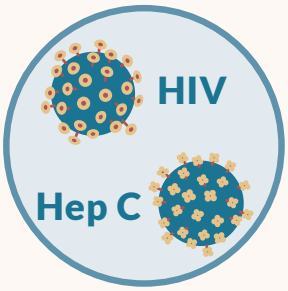
If a provider does not offer pharmacotherapy, the focus should be on medical assessment, making a diagnosis of OUD, and patient safety. This allows the provider to refer patients to the appropriate level of treatment. The provider can also conduct:

- Assessment and treatment for co-occurring medical conditions or mental disorders (including HIV and hepatitis C [anti-HCV]).
- Motivational brief interventions to promote safer behavior and foster effective treatment engagement.
- Overdose prevention education and provide a naloxone prescription.
- Education for patients who inject drugs on how to access sterile injecting equipment.
- An in-person follow-up, regardless of referral to specialty treatment.

If the provider offers pharmacotherapy, the patient needs more comprehensive assessment, including:

- A review of the prescription drug monitoring program (PDMP).
- A history, including a review of systems.
- A targeted physical exam for signs of opioid withdrawal, intoxication, injection, and other medical consequences of misuse.
- Determination of OUD diagnosis and severity.
- Appropriate laboratory tests in addition to those recommended by the nontreating provider (e.g., urine or oral fluid drug tests, liver function tests, hepatitis B test).[46]

EVERYONE AGES 15 TO 65 should be tested at least **ONCE** for **HIV**. Persons at **HIGHER RISK**, such as people who use **DRUGS** by injection, should be tested **ANNUALLY**.



Anyone who is injecting or has ever **INJECTED DRUGS**, even **ONCE**, no matter how long ago, should be **TESTED** for **HEPATITIS C**, regardless of their intention to seek **TREATMENT** for SUD.[47,48]

A comprehensive assessment is intended to:

- Establish the diagnosis of OUD.
- Determine the severity of OUD.
- Identify contraindicated medications.
- Indicate other medical conditions to address during treatment.
- Identify mental and social issues to address.

Set the Stage for Successful Assessment

The medical setting should create a welcoming environment that is nonjudgmental, respectful, and empathetic. Many patients with OUD are reluctant to discuss their opioid use in

Open-ended, thought-provoking questions encourage patients to explore their own experiences. Ask questions like "In what ways has oxycodone affected your life?" or "What could you do to prevent infections like this in the future?" Closed-ended questions with yes/no answers—like "Has oxycodone caused your family trouble?"—can seem judgmental to patients who already feel ashamed and defensive. Closed-ended questions don't help patients become aware of and express their own circumstances and motivations, nor do they encourage patients to identify what they see as the consequences of their substance use.

medical settings.[49] A welcoming environment can help patients feel safe disclosing facts they may find embarrassing.[50] Motivational interviewing strategies, such as asking open-ended questions, foster successful assessment.[51] (Refer to TIP 34, *Brief Interventions and Brief Therapies for Substance Abuse*, for more specific examples of interview questions and responses.)[52]

Staff should explore patients' ambivalence and highlight problem areas to help them find motivations for change. Almost all patients have some ambivalence about their opioid use. They will find some aspects pleasant and beneficial, but others problematic, painful, or destructive. By exploring that ambivalence and highlighting problem areas, providers can help patients discover their own motivations for change. *Motivational Interviewing: Helping People Change*[53] discusses specific applications of motivational interviewing in health care.

Take a Complete History

Staff should prioritize medical, mental health, substance use, and SUD treatment histories. When obtaining patient histories, staff should address these domains before starting treatment. As providers and staff build trust over future visits, they can get into more detailed elements of the assessment.

Medical history

Taking a complete medical history of patients with OUD is critical, as it is for patients with any other medical condition treatable with pharmacotherapy. Asking about patients' medical/surgical history can:

- Reveal medical effects of substance use (e.g., endocarditis, soft tissue infection, hepatitis B or C, HIV infection) that may need treatment.
- Highlight consequences that motivate change.
- Identify medical issues (e.g., severe liver disease) that contraindicate or alter dosing approaches for OUD pharmacotherapies.
- Reveal chronic pain issues.
- Help providers consider interactions among various medications and other substances.

Exhibit 2.8 lists medical problems associated with opioid misuse.

Mental health history

Assessing for comorbid mental illness is critical. Mental illness is prevalent among people with SUDs; it can complicate their treatment and worsen their prognosis. In one study, nearly 20 percent of primary care patients with OUD had major depression.[54] SUDs can also mimic or induce depression and anxiety disorders. Although substance-induced depression and anxiety disorders may improve with abstinence, they may still require treatment in their own right after a period of careful observation.[55] Take a history of the relationship between a patient's psychiatric symptoms and periods of substance use and abstinence. Treatment for mental disorders and SUDs can occur concurrently.

Substance use history

Substance use histories can help gauge OUD severity, inform treatment planning, clarify potential drug interactions, and highlight the negative consequences of patients' opioid use.

To help determine the severity of patients' substance use, explore historical features of their use, like:

- Age at first use.
- Routes of ingestion (e.g., injection).
- History of tolerance, withdrawal, drug mixing, and overdose.

Histories should also explore current patterns of use,[56] which inform treatment planning and include:

- Which drugs patients use.
- Comorbid alcohol and tobacco use.
- Frequency, recency, and intensity of use.

EXHIBIT 2.8. Medical Problems Associated With Opioid Misuse[57]

CATEGORY	POSSIBLE COMPLICATIONS
Cancer	**Injection drug use:** Hepatocellular carcinoma related to hepatitis C
Cardiovascular	**Injection drug use:** Endocarditis, septic thrombophlebitis
Endocrine/metabolic	**Opioids:** Osteopenia, hypogonadism, erectile dysfunction, decreased sperm motility, menstrual irregularity including amenorrhea, infertility
Hematologic	**Injection drug use/sharing intranasal use equipment:** Hematologic consequences of liver disease from hepatitis C, hepatitis C-related cryoglobulinemia and purpura
Hepatic	**Injection drug use/sharing intranasal use equipment:** Hepatitis B, C, D; infectious and toxic hepatitis
Infectious	**Opioids:** Aspiration pneumonia, sexually transmitted infections **Injection drug use:** Endocarditis, cellulitis, necrotizing fasciitis, pneumonia, septic thrombophlebitis, mycotic aneurysm, septic arthritis (unusual joints, such as sternoclavicular), osteomyelitis (including vertebral), epidural and brain abscess, abscesses and soft tissue infections, mediastinitis, malaria, tetanus, hepatitis B, hepatitis C, hepatitis D, HIV, botulism
Neurologic	**Opioids:** Seizure (overdose and hypoxia), compression neuropathy (following overdose), sleep disturbances
Nutritional	**Opioids:** Protein malnutrition
Other gastrointestinal	**Opioids:** Constipation, ileus, intestinal pseudo-obstruction, sphincter of Oddi spasm, nausea
Pulmonary	**Opioids:** Respiratory depression/failure, bronchospasm, exacerbation of sleep apnea, noncardiogenic pulmonary edema, bullae **Injection drug use:** Pulmonary hypertension, talc granulomatosis, septic pulmonary embolism, pneumothorax, emphysema, needle embolization
Renal	**Opioids:** Rhabdomyolysis, acute renal failure (not direct toxic effect of opioids but secondary to central nervous system depression and resulting complications), factitious hematuria **Injection drug use:** Focal glomerular sclerosis (HIV, heroin), glomerulonephritis from hepatitis or endocarditis, chronic renal failure, amyloidosis, nephrotic syndrome (hepatitis C)

To diagnose an SUD, assess patients' negative consequences of use, which can affect:

- Physical health.
- Mental health.
- Family relationships.
- Work/career status.
- Legal involvement.
- Housing status.

Buprenorphine and methadone can cause complications for patients who misuse or have SUDs involving alcohol or benzodiazepines. Providers should take specific histories on the use of these substances.

SUD treatment history

Information about a patient's past efforts to get treatment or quit independently can inform treatment planning. The same is true for details about the events and behaviors that led to a patient's return to substance use after periods of abstinence and remission of SUD. Similarly, identifying the features of successful quit attempts can help guide treatment plan decisions. Such features may involve:

- Specific treatment settings.
- Use of support groups.
- Previous responses to OUD medications.

Social history

Information about a patient's social environments and relationships can aid treatment planning. Social factors that may influence treatment engagement and retention, guide treatment planning, and affect prognosis include:

- Transportation and child care needs.
- Adequacy and stability of housing.
- Criminal justice involvement.
- Employment status and quality of work environment.
- Close/ongoing relationships with people with SUDs.
- Details about drug use from people the patient lives or spends time with (obtained with patient's consent).

Understanding patients' motivations for change can be more useful than assessing "readiness" for change. Patients coerced into treatment—such as through parole and probation or drug courts—are as likely to succeed in treatment as patients engaging voluntarily. Readiness fluctuates and depends on context. Helping patients explore why they want to change their drug use can motivate them and prepare their providers to support them during assessment and treatment.

- Sexual orientation, identity, and history, including risk factors for HIV/sexually transmitted infections.
- Safety of the home environment. Substance misuse substantially increases the risk of intimate partner violence; screen all women presenting for treatment for domestic violence.[58]

Family history

Learn the substance use histories of patients' parents, siblings, partners, and children. One of the strongest risk factors for developing SUDs is having a parent with an SUD. Genetic factors, exposure to substance use in the household during childhood, or both can contribute to the development of SUDs.[59]

EXHIBIT 2.9. Signs of Opioid Intoxication

Physical findings

Drowsy but arousable
Sleeping intermittently ("nodding off")
Constricted pupils

Mental status findings

Slurred speech
Impaired memory or concentration
Normal to euphoric mood

PATIENT TESTIMONY

Opioid Withdrawal

"Severe opioid withdrawal isn't something I'd wish on my worst enemy. The last time I went cold turkey, I was determined to come off all the way. The physical symptoms were just the tip of the iceberg. My mind was a nightmare that I thought I would never wake up from. There were times when I was almost convinced that dying would be better than what I was feeling. I did not experience a moment of ease for the first 3 months, and it was 6 months until I started to feel normal."

Conduct a Physical Examination

Perform a physical exam as soon as possible if recent exam records aren't accessible. Assess for:

- Opioid intoxication or withdrawal.
- Physical signs of opioid use.
- Medical consequences of opioid use.

Exhibit 2.9 provides an overview of physical and mental status findings for opioid intoxication.

Opioid withdrawal

Opioid withdrawal can be extremely uncomfortable. Symptoms are similar to experiencing gastroenteritis, severe influenza, anxiety, and dysphoria concurrently.

Severity of withdrawal can indicate a patient's level of physical dependence and can inform medication choices and dosing decisions. The duration of withdrawal depends on the specific opioid from which the patient is withdrawing and can last 1 to 4 weeks. After the initial withdrawal phase is complete, many patients experience a prolonged phase of dysphoria, craving, insomnia, and hyperalgesia that can last for weeks or months.

EXHIBIT 2.10. Physical Signs of Opioid Withdrawal and Time to Onset

STAGE	GRADE	PHYSICAL SIGNS/ SYMPTOMS
Early withdrawal Short-acting opioids: 8–24 hours after last use Long-acting opioids: Up to 36 hours after last use	Grade 1	Lacrimation, rhinorrhea, or both Diaphoresis Yawning Restlessness Insomnia
Early withdrawal Short-acting opioids: 8–24 hours after last use Long-acting opioids: Up to 36 hours after last use	Grade 2	Dilated pupils Piloerection Muscle twitching Myalgia Arthralgia Abdominal pain
Fully developed withdrawal Short-acting opioids: 1–3 days after last use Long-acting opioids: 72–96 hours after last use	Grade 3	Tachycardia Hypertension Tachypnea Fever Anorexia or nausea Extreme restlessness
Fully developed withdrawal Short-acting opioids: 1–3 days after last use Long-acting opioids: 72–96 hours after last use	Grade 4	Diarrhea, vomiting, or both Dehydration Hyperglycemia Hypotension Curled-up position

Total duration of withdrawal:

- Short-acting opioids: 7–10 days
- Long-acting opioids: 14 days or more

Assess opioid withdrawal in the physical exam by noting physical signs and symptoms (Exhibit 2.10). Structured measures (e.g., Clinical Opiate Withdrawal Scale [COWS]; Clinical Institute

Narcotic Assessment Scale for Withdrawal Symptoms) can help standardize documentation of signs and symptoms to support diagnosis, initial management, and treatment planning. See the "Resources" section for links to standardized scales. Part 3 of this TIP covers withdrawal symptom documentation for pharmacotherapy initiation.

The physical signs of opioid misuse vary depending on the route of ingestion:

- Patients who primarily smoke or sniff ("snort") opioids or take them orally often have few physical signs of use other than signs of intoxication and withdrawal. However, snorting can cause congestion and damage nasal mucosa.
- Patients who inject opioids may develop:
  - Sclerosis or scarring of the veins and needle marks, or "track marks," in the arms, legs, hands, neck, or feet (intravenous use).
  - Edema in the foot, hand, or both (common in injection use, but may occur in oral use).
  - Abscesses or cellulitis.
  - Jaundice, caput medusa, palmar erythema, spider angiomata, or an enlarged or hardened liver secondary to liver disease.
  - Heart murmur secondary to endocarditis.

Obtain Appropriate Laboratory Tests

Urine or oral fluid drug testing

Urine or oral fluid drug testing is useful before initiating OUD pharmacotherapy. Testing establishes a baseline of substances the patient has used so that the provider can monitor the patient's response to treatment over time. Testing for a range of commonly used substances helps confirm patient histories, facilitates discussion of recent drug use and symptoms, and aids in diagnosing and determining severity of SUDs. Drug testing is an important tool in the diagnosis and treatment of addiction. A national

> **During ongoing pharmacotherapy with buprenorphine or methadone, drug testing can confirm medication adherence.**

EXHIBIT 2.11. Patient–Provider Dialog: Talking About Drug Testing

Frame drug testing in a clinical, nonpunitive way. For example, before obtaining a drug test, ask the patient, "What do you think we'll find on this test?" The patient's response is often quite informative and may make the patient less defensive than confrontation with a positive test result.

SCENARIO: A provider discusses urine drug testing with a patient being assessed for OUD treatment with medication.

Provider: When we assess patients for medication for opioid addiction, we always check urine samples for drugs.

Patient: I'll tell you if I used. You don't need to test me.

Provider: Thank you, I really appreciate that. The more we can talk about what's going on with you, the more I can help. I'm not checking the urine to catch you or because I don't trust you. I trust you. I can see how motivated you are. But I don't trust the addiction because I know how powerful addiction can be, too. To monitor your safety on medication and help determine what other services you may need, it's important for us to test you periodically and discuss the results. Does that sound okay?

Patient: Yeah, that makes sense.

guideline on the use of drug testing is available from ASAM.[60] Exhibit 2.11 provides guidance on talking with patients about drug testing.

To assess and manage patients with OUD properly, providers must know which tests to order and how to interpret results. There are many drug testing panels; cutoffs for positive results vary by laboratory. One widely used panel, the NIDA-5, tests for cannabinoids, cocaine, amphetamines, opiates, and phencyclidine. Additional testing for benzodiazepines, the broader category of opioids, and specific drugs commonly used in the patient's locality may be warranted. The typical opioid immunoassay will only detect morphine, which is a metabolite of heroin, codeine, and some other opioids. The typical screen will not detect methadone, buprenorphine, or fentanyl and may not detect hydrocodone, hydromorphone, or oxycodone. Specific testing is needed to identify these substances.

Co-occurring SUDs require separate, specific treatment plans.

Testing for substances that can complicate OUD pharmacotherapy is essential. Testing for cocaine, benzodiazepines, and methamphetamine is clinically important because these and other substances (and related SUDs, which may require treatment in their own right), especially benzodiazepines, can complicate pharmacotherapy for OUD. Benzodiazepine and other sedative misuse can increase the risk of overdose among patients treated with opioid agonists. When assessing benzodiazepine use, note that typical benzodiazepine urine immunoassays will detect diazepam but perhaps not lorazepam or clonazepam. Providers must specifically request testing for these two benzodiazepines. Exhibit 2.12 shows urine drug testing windows of detection.

EXHIBIT 2.12. Urine Drug Testing Window of Detection[61,62]

DRUG	POSITIVE TEST	WINDOW OF DETECTION*	COMMENTS
Amphetamine; methamphetamine; 3,4-methylenedioxy-methamphetamine	Amphetamine	1–2 days	False positives with bupropion, chlorpromazine, desipramine, fluoxetine, labetalol, promethazine, ranitidine, pseudoephedrine, trazadone, and other common medications. Confirm unexpected positive results with the laboratory.
Barbiturates	Barbiturates	Up to 6 weeks	N/A
Benzodiazepines	Benzodiazepines	1–3 days; up to 6 weeks with heavy use of long-acting benzodiazepines	Immunoassays may not be sensitive to therapeutic doses, and most immunoassays have low sensitivity to clonazepam and lorazepam. Check with your laboratory regarding sensitivity and cutoffs. False positives with sertraline or oxaprozin.

*Detection time may vary depending on the cutoff.

Continued on next page

EXHIBIT 2.12. Urine Drug Testing Window of Detection (continued)

DRUG	POSITIVE TEST	WINDOW OF DETECTION*	COMMENTS
Buprenorphine	Buprenorphine	3–4 days	Will screen negative on opiate screen. Tramadol can cause false positives. Can be tested for specifically.
Cocaine	Cocaine, benzoylecgonine	2–4 days; 10–22 days with heavy use	N/A
Codeine	Morphine, codeine, high-dose hydrocodone	1–2 days	Will screen positive on opiate immunoassay.
Fentanyl	Fentanyl	1–2 days	Will screen negative on opiate screen. Can be tested for specifically. May not detect all fentanyl-like substances.[63]
Heroin	Morphine, codeine	1–2 days	Will screen positive on opiate immunoassay. 6-monoacetylmorphine, a unique metabolite of heroin, is present in urine for about 6 hours. Can be tested for specifically to distinguish morphine from heroin, but this is rarely clinically useful.
Hydrocodone	Hydrocodone, hydromorphone	2 days	May screen negative on opiate immunoassay. Can be tested for specifically.
Hydromorphone	May not be detected	1–2 days	May screen negative on opiate immunoassay. Can be tested for specifically.
Marijuana	Tetrahydrocannabinol	Infrequent use of 1–3 days; chronic use of up to 30 days	False positives possible with efavirenz, ibuprofen, and pantoprazole.
Methadone	Methadone	2–11 days	Will screen negative on opiate screen. Can be tested for specifically.
Morphine	Morphine, hydromorphone	1–2 days	Will screen positive on opiate immunoassay. Ingestion of poppy plant/seed may screen positive.
Oxycodone	Oxymorphone	1–1.5 days	Typically screens negative on opiate immunoassay. Can be tested for specifically.

*Detection time may vary depending on the cutoff.

Positive opioid tests can confirm recent use. Document recent use before starting patients on buprenorphine or methadone. Positive methadone or buprenorphine tests are expected for patients receiving these treatments. **Positive opioid tests contraindicate starting naltrexone.**

Negative opioid test results require careful interpretation. A patient may test negative for opioids despite presenting with opioid withdrawal symptoms if he or she hasn't used opioids for several days. A negative opioid test in the absence of symptoms of opioid withdrawal likely indicates that the patient has little or no opioid tolerance, which is important information for assessment and treatment planning. Consider that the opioid the patient reports using may not be detected on the particular immunoassay.

Screening tests are not definitive; false positive and false negative test results are possible. Confirmatory testing should follow all unexpected positive screens. Urine drug testing will detect metabolites from many prescription opioids but miss others, so it is easy to misinterpret results in patients taking these medications.[64] False positives are also common in amphetamine testing.[65]

Point-of-service testing provides the opportunity to discuss results with patients immediately. However, cutoffs for positive screens are not standardized across point-of-service tests. Know the specifications of the screens used.[66]

Other laboratory tests

Patients with OUD, particularly those who inject drugs, are at risk for liver disease and blood-borne viral infections. Pregnancy is another important consideration in determining treatment course. **Recommended laboratory tests for patients with OUD include:**

Pregnancy testing, which is important because:

- It is not advisable for patients to start naltrexone during pregnancy.
- Pregnant women treated for active OUD typically receive buprenorphine or methadone.
- The American College of Obstetricians and Gynecologists and a recent SAMHSA-convened expert panel on the treatment of OUD in pregnancy[67] recommend that pregnant women with OUD receive opioid receptor agonist pharmacotherapy.[68]
- Providers should refer pregnant women to prenatal care or, if qualified, provide it themselves.

Liver function tests (e.g., aspartate aminotransferase, alanine aminotransferase, bilirubin), which can:

- Guide medication selection and dosing.
- Rule out severe liver disease, which may contraindicate OUD medication (see Part 3 of this TIP).

Hepatitis B and C serology, which can indicate:

- Patients with positive tests (evaluate for hepatitis treatment).
- The need to administer hepatitis A and B and tetanus vaccines, if appropriate.

HIV serology, which can help identify:

- Patients who are HIV positive (evaluate for antiretroviral treatment).
- Patients who are HIV negative (evaluate for preexposure prophylaxis and targeted education).

Review the PDMP

Before initiating OUD medication, providers should check their states' PDMPs to determine whether their patients receive prescriptions for controlled substances from other healthcare professionals. Using the PDMP improves the ability to manage the risks of controlled substances and to identify potentially harmful drug interactions.[69] Although OTPs are not permitted to report methadone treatment to PDMPs, pharmacies that dispense buprenorphine and other controlled substances do report to PDMPs. Medications that need monitoring and required frequency of updates vary by state (for more information about state PDMPs, visit www.pdmpassist.org/content/state-profiles).

Determine Diagnosis and Severity of OUD

Use DSM-5 criteria to make an OUD diagnosis (Exhibit 2.13).[70] Patients who meet two or three criteria have mild OUD. Those meeting four or five criteria have moderate OUD, and those meeting six or more criteria have severe OUD.[71] A printable checklist of DSM-5[72] criteria is available in the Part 2 Appendix.

Treatment Planning or Referral

Making Decisions About Treatment

Start by sharing the diagnosis with patients and hearing their feedback. Patients with OUD need to make several important treatment decisions:

- Whether to begin medication to treat OUD.
- What type of OUD medication to take.

RESOURCE ALERT

Shared Decision-Making Tool for Patients and Family Members

SAMHSA's online shared decision-making tool for patients is a good information source for patients to review before their visit or in the office (https://www.samhsa.gov/brss-tacs/recovery-support-tools/shared-decision-making). In addition, providers can suggest that family, friends, and other potential recovery supports (e.g., 12-Step program sponsors, employers, clergy) read educational material tailored for them. See *Medication-Assisted Treatment for Opioid Addiction: Facts for Families and Friends* (https://mha.ohio.gov/Portals/0/assets/HealthProfessionals/About%20MH%20and%20Addiction%20Treatment/MAT/SMA14-4443.pdf?ver=2018-11-26-113004-157).

EXHIBIT 2.13. DSM-5 Criteria for OUD[73]

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

1. Opioids are often taken in larger amounts or over a longer period of time than was intended.
2. There is a persistent desire or unsuccessful efforts to cut down or control opioid use.
3. A great deal of time is spent in activities to obtain the opioid, use the opioid, or recover from its effects.
4. Craving, or a strong desire or urge to use opioids.
5. Recurrent opioid use resulting in a failure to fulfill major role obligations at work, school, or home.
6. Continued opioid use despite having persistent or recurrent social or interpersonal problems caused by or exacerbated by the effects of opioids.
7. Important social, occupational, or recreational activities are given up or reduced because of opioid use.
8. Recurrent opioid use in situations in which it is physically hazardous.
9. Continued opioid use despite knowledge of having a persistent or recurrent physical or psychological problem that's likely to have been caused or exacerbated by the substance.
10. Tolerance,* as defined by either of the following:
    a. A need for markedly increased amounts of opioids to achieve intoxication or desired effect
    b. A markedly diminished effect with continued use of the same amount of an opioid
11. Withdrawal,* as manifested by either of the following:
    a. The characteristic opioid withdrawal syndrome
    b. The same—or a closely related—substance is taken to relieve or avoid withdrawal symptoms

*This criterion is not met for individuals taking opioids solely under appropriate medical supervision.
Severity: mild = 2–3 symptoms; moderate = 4–5 symptoms; severe = 6 or more symptoms

- Where and how to access desired treatment.
- Whether to access potentially beneficial mental health, recovery support, and other ancillary services, whether or not they choose pharmacotherapy.

Offer information to patients about the various treatments for OUD and collaborate with them to make decisions about treatment plans or referrals (Exhibit 2.14). Consider discussing:

- Indications, risks, and benefits of medications and alternatives to pharmacotherapy.
- Types of settings that deliver medications (including healthcare professionals' own practice locations, if applicable).
- Availability of and accessibility to treatment (i.e., transportation).
- Alternative treatments without medication (e.g., residential treatment, which often offers medically supervised opioid withdrawal).
- Costs of treatment with OUD medication, including insurance coverage and affordability.

Give patients' expressed preferences significant weight when making decisions. Patient characteristics can't reliably predict greater likelihood of success with one approved medication or another. For detailed information on medications to treat OUD, refer to Part 3 of this TIP.

Strategies to engage patients in shared decision making include:

- Indicating to patients a desire to collaborate with them to find the best medication and treatment setting for them.
- Including family members in the treatment planning process, if possible (and only with patients' consent).
- Exploring what patients already know about treatment options and dispelling misconceptions.
- Offering information on medications and their side effects, benefits, and risks (Exhibit 2.14; Part 3).

> **Part 1 of this TIP gives an overview of the three FDA-approved medications used to treat OUD. Part 3 covers the details of their use.**

- Informing patients of the requirements of the various treatment options (e.g., admission criteria to an OTP; frequency of visits to an OBOT or OTP).
- Offering options, giving recommendations after deliberation, and supporting patients' informed decisions.

Understanding Treatment Settings and Services

Support patient preferences for treatment settings and services. Some patients prefer to receive OUD medication via physicians' offices. Others choose outpatient treatment programs that provide opioid receptor agonist treatment for medically supervised withdrawal (with or without naltrexone) or for ongoing opioid receptor agonist maintenance treatment. Still others may want OUD treatment in a residential program with or without pharmacotherapy (Exhibit 2.15).

Many patients initially form a preference for a certain treatment without knowing all the risks, benefits, and alternatives. Providers should ensure that patients understand the risks and benefits of all options. Without this understanding, patients can't give truly informed consent.

Outpatient OUD Treatment Settings

Refer patients who prefer treatment with methadone or buprenorphine via an OTP and explain that:

- They will have to visit the program from 6 to 7 times per week at first.
- Additional methadone take-home doses are possible at every 90 days of demonstrated progress in treatment.
- Buprenorphine take-home doses are not bound by the same limits as methadone.

EXHIBIT 2.14. Comparison of OUD Medications To Guide Shared Decision Making

CATEGORY	BUPRENORPHINE	METHADONE	NALTREXONE
Appropriate patients	Typically for patients with OUD who are physiologically dependent on opioids	Typically for patients with OUD who are physiologically dependent on opioids and who meet federal criteria for OTP admission	Typically for patients with OUD who are abstinent from short-acting opioids for 7 days and long-acting opioids for 10–14 days
Outcome: Retention in treatment	Higher than treatment without medication and treatment with placebo[74]	Higher than treatment without OUD medication and treatment with placebo[75]	Treatment retention with oral naltrexone is no better than with placebo or no medication;[76] for XR-NTX, treatment retention is higher than for treatment without OUD medication and treatment with placebo;[77,78] treatment retention is lower than with opioid receptor agonist treatment
Outcome: Suppression of illicit opioid use	Effective	Effective	Effective
Outcome: Overdose mortality	Lower for people in treatment than for those not in it	Lower for people in treatment than for those not in it	Unknown
Location/ frequency of office visits	**Office/clinic:** Begins daily to weekly, then tailored to patient's needs **OTP:** Can treat with buprenorphine 6–7 days/ week initially; take-homes are allowed without the time-in-treatment requirements of methadone	**OTP only:** 6–7 days/week initially; take-homes are allowed based on time in treatment and patient progress	**Office/clinic:** Varies from weekly to monthly
Who can prescribe/ order?	Physicians, NPs,* PAs, and, until October 1, 2023, clinical nurse specialists, certified registered nurse anesthetists, and certified nurse midwives possessing a federal waiver can prescribe and dispense; also can be dispensed by a community pharmacy or an OTP	OTP physicians order the medication; nurses and pharmacists administer and dispense it	Physicians, NPs,* PAs, and, until October 1, 2023, clinical nurse specialists, certified registered nurse anesthetists, and certified nurse midwives

*NPs, PAs, clinical nurse specialists, certified registered nurse anesthetists, and certified nurse midwives should check with their state to determine whether prescribing buprenorphine, naltrexone, or both is within their allowable scope of practice.

Continued on next page

EXHIBIT 2.14. Comparison of OUD Medications To Guide Shared Decision Making (continued)

CATEGORY	BUPRENORPHINE	METHADONE	NALTREXONE
Administration	Sublingual/buccal; injection; implant by specially trained provider, and only for stabilized patients	Oral	Oral or intramuscular (Note: Oral naltrexone is less effective than the other OUD medications.)
Misuse/diversion potential	Low in OTPs or other settings with observed dose administration; moderate for take-home doses; risk can be mitigated by providing take-homes to stable patients only and having a diversion control plan for the practice or program. Appropriate patients may be transitioned to a depot formulation of buprenorphine if and when it is appropriate.	Low in OTPs with directly observed therapy; moderate for take-home doses; risk can be mitigated by a diversion control plan	None
Sedation	Low unless concurrent substances are present (e.g., alcohol, benzodiazepines)	Low unless dose titration is too quick or dose is not adjusted for the presence of concurrent substances (e.g., alcohol, benzodiazepines)	None
Risk of medication-induced respiratory depression	Very rare; lower than methadone	Rare, although higher than buprenorphine; may be elevated during the first 2 weeks of treatment or in combination with other sedating substances	None
Risk of precipitated withdrawal when starting medication	Can occur if started too prematurely after recent use of other opioids	None	Severe withdrawal is possible if period of abstinence is inadequate before starting medication
Withdrawal symptoms on discontinuation	Present; lower than methadone if abruptly discontinued	Present; higher than buprenorphine if abruptly discontinued	None
Most common side effects	Constipation, vomiting, headache, sweating, insomnia, blurred vision	Constipation, vomiting, sweating, dizziness, sedation	Difficulty sleeping, anxiety, nausea, vomiting, low energy, joint and muscle pain, headache, liver enzyme elevation XR-NTX: Injection site pain, nasopharyngitis, insomnia, toothache

D. Coffa, December 2017 (personal communication). Adapted with permission.

EXHIBIT 2.15. Treatment Setting Based on Patient's Choice of OUD Medication

MEDICATION	POSSIBLE TREATMENT SETTING
Buprenorphine	Office-based treatment, outpatient or residential SUD treatment programs (prescriber must have a federal waiver), OTP. REMS program participation is required for use of depot formulations.
Methadone	OTP
Naltrexone	Office-based treatment, outpatient or residential SUD treatment programs, OTP

- Counseling and drug testing are required parts of OTP treatment.
- Some programs also offer case management, peer support, medical services, mental disorder treatment, and other services.

Try to arrange OTP intake appointments for patients before they leave the office. If no immediate openings are available, consider starting buprenorphine as a bridge or alternative to the OTP.

Gauge the appropriate intensity level for patients seeking non-OTP outpatient treatment for OUD. These programs range from low intensity (individual or group counseling once to a few times a week) to high intensity (2 or more hours a day of individual and group counseling several days a week). Appropriate treatment intensity depends on each patient's:[79]

- Social circumstances.
- Severity of addiction.
- Personal preferences.
- Psychiatric/psychological needs.
- Ability to afford treatment at a given intensity.

Outpatient medical settings

Healthcare professionals cannot provide methadone in their clinics. Only those with a buprenorphine waiver can provide buprenorphine. Any healthcare professional with a prescribing authority can provide naltrexone.

Once providers obtain the necessary waiver, they should offer buprenorphine treatment to all patients who present with OUD if such treatment is available and appropriate. Referring them to treatment elsewhere will likely result in delay or lack of patient access to care. Develop a treatment plan to determine where patients will receive continuing care (see the "Treatment Planning" section). Continue to provide naltrexone for patients who were already receiving it from some other setting (e.g., a prison, a specialty addiction treatment program) or for patients who meet opioid abstinence requirements and wish to take a medication for relapse prevention.

Residential drug treatment settings

Patients who have OUD, concurrent other substance use problems, unstable living situations, or a combination of the three may be appropriate candidates for residential treatment, which can last from a week to several weeks or more. Inform patients about the services and requirements typical of this treatment setting.

Some patients taking buprenorphine (or methadone) who have other SUDs, such as AUD or cocaine use disorder, can benefit from residential treatment. If such treatment is indicated, determine whether the residential program allows patients to continue their opioid receptor agonist medication while in treatment. Some residential programs require patients to discontinue these medications to receive residential treatment, which could destabilize patients and result in opioid overdose.

Residential treatment programs typically provide:

- Room and board.
- Recovery support.
- Counseling.
- Case management.
- Medically supervised withdrawal (in some programs).
- Starting buprenorphine or naltrexone (in some programs).
- Onsite mental health services (in some cases).
- Buprenorphine or methadone continuation for patients already enrolled in treatment prior to admission if their healthcare professionals have waivers or their OTP permits.

Transitioning out of residential settings requires careful planning. During a patient's stay in residential treatment, plan for his or her transition out of the program. A good transition plan maximizes the likelihood of continuity of care after discharge. Plans should also address overdose risk. Patients who are no longer opioid tolerant are at heightened risk of opioid overdose if they don't get OUD medication at discharge. Providing XR-NTX, buprenorphine, or methadone during treatment and continuing the medication after discharge can help prevent return to opioid use after discharge. Providing a naloxone prescription and overdose prevention information is appropriate.

RESOURCE ALERT

Treatment and Provider Locator

SAMHSA's Behavioral Health Treatment Services Locator (https://findtreatment.samhsa.gov) provides information on drug and alcohol treatment programs across states. Another SAMHSA tool identifies the locations of buprenorphine providers (www.samhsa.gov/medication-assisted-treatment/physician-program-data/treatment-physician-locator).

RESOURCE ALERT

Maintaining Confidentiality

Providers who treat patients with addiction must know substance use-related disclosure rules and confidentiality requirements. SAMHSA's webpage lists frequently asked questions on substance use confidentiality and summarizes federal regulations about disclosure and patient records that federal programs maintain on addiction treatment (https://www.samhsa.gov/about-us/who-we-are/laws-regulations/confidentiality-regulations-faqs). Key points include:

- Confidentiality regulations prohibit specialty SUD treatment programs from sharing information with healthcare professionals about patients' SUD treatment without specific consent from patients.
- Referrals to other behavioral health services require consent for sharing information on treatment progress.
- Healthcare professionals should discuss confidentiality and consent with patients during the referral process.
- OUD pharmacotherapy prescribers may consider requiring patient consent for communicating with treatment programs as a condition of receiving OUD treatment.

Treatment program staff members can help identify returns to substance use, or risk of such, before the prescriber and can work with the prescriber to stabilize patients.

Determining OUD Service Intensity and Ensuring Follow-Through

Use ASAM placement criteria for guidance on selecting the right level of OUD treatment. ASAM criteria define the level of care and key features that may make a given level (e.g., residential, intensive outpatient, standard outpatient) appropriate for a patient[80] (see the "Treatment Planning" section). To help patients select programs, note that some focus on specific populations (e.g., gender-specific programs; parents with children; lesbian, gay, bisexual, transgender, and questioning populations).

Make an appointment with the referral program during the patient's visit rather than giving the patient a phone number to call. Follow up with the patient later to determine whether he or she kept the appointment. Doing so increases the chances of a successful referral.

Referring patients to behavioral health and support services

Discuss patients' potential need for behavioral health, peer support, and other ancillary services, like:

- Drug and alcohol counseling.
- Mental health services.
- Case management.
- Mutual-help groups.
- Peer recovery support services.

Offer referrals to counseling and tailored psychosocial support to patients receiving OUD medication (Exhibit 2.16).

Drug Addiction Treatment Act of 2000 legislation requires that buprenorphine prescribers be able to refer patients to counseling, but making referrals is not mandatory.[81] Many patients benefit from referral to mental health services or specialized addiction counseling and recovery support services. However, four randomized trials found no extra benefit to adding adjunctive counseling to well-conducted medical management visits delivered by the buprenorphine prescriber. There is evidence of benefits to adding contingency management to pharmacotherapy.[82,83,84,85,86]

Make referrals to mutual-help groups. Patients may wish to participate in mutual-help groups (e.g., Alcoholics Anonymous, Narcotics Anonymous, Methadone Anonymous, Medication-Assisted Recovery Services, SMART Recovery) in addition to or instead of specialized treatment. These programs can be highly supportive, but they may pressure patients to stop taking OUD medication. If possible, refer patients to groups that welcome patients who take OUD medication.

Make referrals to medical and mental health services. Respectful, consistent medical care can support patients' efforts to recover from OUD and all other SUDs. As for any patient, providers should make appropriate referrals for patients with OUD to receive medical or mental health services beyond the providers' own scope of practice.

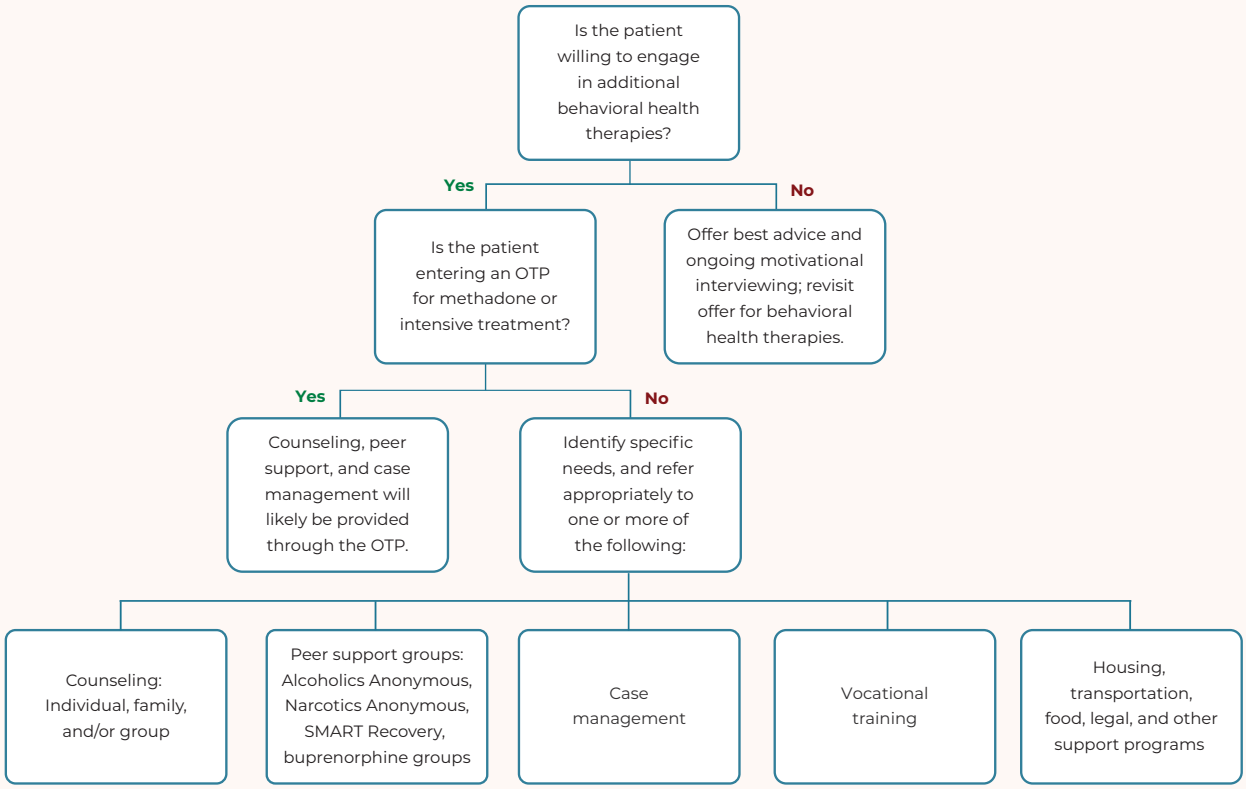
Patients with depression, anxiety disorders, and other mental disorders may be more likely to succeed in addiction treatment if those conditions are managed.[87] If the severity or type of a patient's psychiatric comorbidity is beyond a provider's scope of practice, the provider should refer the patient to mental health services as appropriate.

RESOURCE ALERT

Mutual-Support Groups

For an introduction to mutual-support groups, see SAMHSA's *Substance Abuse in Brief*, "An Introduction to Mutual Support Groups for Alcohol and Drug Abuse" (http://www.williamwhitepapers.com/pr/CSAT%20Mutual%20Support%20Groups%202008.pdf).

EXHIBIT 2.16. Referring Patients Who Receive OUD Pharmacotherapy to Behavioral Health Therapies



RESOURCE ALERT

Guidance on Providing Integrated Care

Fragmented healthcare services are less likely to meet all patient needs. Integrated medical and behavioral healthcare delivery can effectively provide patient-focused, comprehensive treatments that address the full range of symptoms and service needs patients with OUD often have.[88] The key components of integration should be in place to make sure that SUD treatment in a primary care setting works. For more information about how to provide integrated services for individuals taking medication for OUD, see:

- **The Agency for Healthcare Research and Quality's report** *Medication-Assisted Treatment Models of Care for Opioid Use Disorder in Primary Care Settings.* (www.ncbi.nlm.nih.gov/books/NBK402352).
- **The Agency for Healthcare Research and Quality's Academy for Integrating Behavioral Mental Health and Primary Care.** (https://integrationacademy.ahrq.gov).

OPPORTUNITY ALERT

Becoming an OUD Medication Treatment Provider

SAMHSA strongly urges physicians, NPs, PAs, and, until October 1, 2023, clinical nurse specialists, certified registered nurse anesthetists, and certified nurse midwives to obtain waivers that will qualify them to offer buprenorphine pharmacotherapy. They can become qualified to use buprenorphine to taper appropriate patients with OUD off illicit or prescription opioids or to provide long-term OUD treatment.

Only healthcare professionals with a federal waiver may prescribe buprenorphine for the treatment of OUD. To get waivers, providers must meet set criteria, complete buprenorphine training (online or in person), and apply for a waiver from SAMHSA. Waivered prescribers are assigned an additional DEA registration number (usually their existing number with an added "X").

NPs, PAs, clinical nurse specialists, certified registered nurse anesthetists, and certified nurse midwives need to meet additional criteria for waivers.[89] Check with the state licensing board about restrictions and requirements at the state level before applying for a waiver.

Wavier training: ASAM, the American Academy of Addiction Psychiatry, the American Psychiatric Association, and the American Osteopathic Academy of Addiction Medicine all provide the waiver training courses for physicians. Providers' Clinical Support System for Medication Assisted Treatment (PCSS-MAT) provides the required 8-hour OUD medication waiver course for physicians and 24-hour waiver course for NPs, PAs, clinical nurse specialists, certified registered nurse anesthetists, and certified nurse midwives for free (https://pcssnow.org/medication-assisted-treatment/). Other providers also provide NP, PA, clinical nurse specialist, certified registered nurse anesthetist, and certified nurse midwife courses.

New prescribers can benefit from mentorship from experienced providers in their practice or community. Mentorship is available for free from PCSS-MAT (http://pcssmat.org/mentoring).

For detailed information on prescribing OUD medications, review Part 3 of this TIP.

Make referrals to ancillary services. Besides medical care and mental health services, OUD patients, like patients with other illnesses, may need more support in some areas, including ancillary services such as:

- Case management.
- Food access.
- Vocational training.
- Housing.
- Transportation.
- Legal assistance.

Helping patients who are not ready to engage in OUD treatment

Help reluctant patients be safer and approach readiness. Patients may seem unwilling to discuss their drug use if they're ashamed or fear being judged. Accepting, nonjudgmental attitudes help patients overcome shame and discuss concerns honestly while also instilling hope.

Every visit is a chance to help patients begin healthy changes and move toward treatment and recovery. Patients may not be ready to change right away. Successfully quitting drug use

can take many attempts. Returns to substance use, even after periods of remission, are expected parts of the recovery process.

Patients with OUD are much more likely to die than their peers,[90,91] and HIV, hepatitis C, and skin and soft tissue infections are common among this population. **Help reduce these OUD-related risks by testing patients for HIV and hepatitis and by educating patients** about:

- Using new syringes.
- Avoiding syringe sharing.
- Avoiding sharing other supplies during the injection process.
- Preventing opioid overdose (see the "Preventing Opioid-Related Overdose" section).
- Obtaining overdose prevention information and resources (e.g., *SAMHSA Opioid Overdose Prevention Toolkit* [https://store.samhsa.gov/product/Opioid-Overdose-Prevention-Toolkit/SMA18-4742]).
- Obtaining naloxone and instructions for its use.

Refer patients to syringe exchange sites. The North American Syringe Exchange Network provides options (see the "Syringe Exchange" section).

Preventing Opioid-Related Overdose

Every patient who misuses opioids or has OUD should receive opioid overdose prevention education and a naloxone prescription.[92]

EXHIBIT 2.17. Opioid Overdose: Risk, Prevention, Identification, and Response

Overdose risk

- Using heroin (possibly mixed with illicitly manufactured fentanyl or fentanyl analogs)
- Using prescription opioids that were not prescribed
- Using prescription opioids more frequently or at higher doses than prescribed
- Using opioids after a period of abstinence or reduced use (e.g., after medically supervised withdrawal or incarceration)
- Using opioids with alcohol, benzodiazepines, or both

Overdose prevention

- Don't use opioids that were not prescribed.
- Take medications only as prescribed.
- Don't use drugs when you are alone.
- Don't use multiple substances at once.
- Have naloxone available and make sure others know where it is and how to use it.
- Use a small "test dose" if returning to opioid use after a period of abstinence, if the substance appears altered, or if it has been acquired from an unfamiliar source. Beware: This doesn't guarantee safety; illicitly manufactured fentanyl or other substances may be present in the drug, and **any use may be fatal.**

Overdose identification

- Fingernails or lips are blue or purple.
- Breathing or heartbeat is slow or stopped.
- The person is vomiting or making gurgling noises.
- The person can't be awakened or is unable to speak.

Overdose response

- Call 9-1-1.
- Administer naloxone (more than one dose may be needed to restore adequate spontaneous breathing).
- Perform rescue breathing. If certified to provide cardiopulmonary resuscitation, perform chest compressions if there is no pulse.
- Put the person in the "recovery position," on his or her side and with the mouth facing to the side to prevent aspiration of vomit, if he or she is breathing independently.
- Stay with the person until emergency services arrive. Naloxone's duration of action is 30–90 minutes. The person should be observed after this time for a return of opioid overdose symptoms.

Adapted from material in the public domain.[93]

The United States is experiencing a death epidemic related to opioid overdose. Opioids (including prescription opioids and heroin) killed 47,600 people in 2017, more than in any prior year. In 2018, the number of all opioid overdose deaths was 46,800. Less than one-third of overdose deaths involved prescription opioids. From 2010 to 2018, heroin-related overdose deaths rose about fivefold.[94,95] Overdose deaths from illicit fentanyl have also risen sharply.[96]

Healthcare professionals should educate patients and their families about overdose risk, prevention, identification, and response (Exhibit 2.17). FDA has approved an autoinjectable naloxone device (Evzio) and a naloxone nasal spray (Narcan) for use by patients and others. For information about all forms of naloxone, prescribing, and patient and community education, see the *SAMHSA Opioid Overdose Prevention Toolkit* (https://store.samhsa.gov/product/Opioid-Overdose-Prevention-Toolkit/SMA18-4742).

Municipalities with community-based naloxone distribution programs have seen substantial decreases in opioid overdose death rates.[97,98] Many syringe exchange programs also dispense naloxone. For information and resources on prescribing naloxone for overdose prevention, including educational patient handouts and videos, see the "Opioid-Related Overdose Prevention" section.

Resources

The following selected resources address key content presented in Part 2. Part 5 of this TIP includes comprehensive resources on topics pertaining to substance misuse and medications to treat OUD.

Alcohol and Drug Use Screening

- **American Academy of Addiction Psychiatry:** Provides Performance in Practice Clinical Modules for screening of tobacco use and AUD. https://www.aaap.org/clinicians/education-training/grants/pcssprojects/aaap-sponsored-pcss-resources/aaap-sponsored-pcss-modules/
- **NIAAA, Professional Education Materials:** Provides links to screening, treatment planning, and general information for clinicians in outpatient programs. www.niaaa.nih.gov/publications/clinical-guides-and-manuals
- **NIDA, Medical and Health Professionals:** Provides resources for providers to increase awareness of the impact of substance use on patients' health and help identify drug use early and prevent it from escalating to misuse or addiction. www.drugabuse.gov/nidamed-medical-health-professionals

Tobacco Screening

- **American Psychiatric Nursing Association, Tobacco & Nicotine Use Screening Tools and Assessments:** Provides the Fagerström screening tools for nicotine dependence and smokeless tobacco and a screening checklist for tobacco use. www.apna.org/i4a/pages/index.cfm?pageID=6150
- **U.S. Department of Health and Human Services' Be Tobacco Free:** Provides information for individuals struggling with nicotine addiction and links for clinicians that provide guidance on caring for patients with nicotine addiction. https://betobaccofree.hhs.gov/
- **U.S. Department of Health and Human Services' Million Hearts Initiative:** Provides templates for developing and guidance on implementing tobacco cessation programs and guidance on implementing them as part of clinical care. https://millionhearts.hhs.gov/tools-protocols/protocols.html
- **Centers for Disease Control and Prevention (CDC):** Offers resources and information for patients and clinicians; includes a webpage with resource links for clinicians on treating tobacco dependence. www.cdc.gov/tobacco/index.htm and www.cdc.gov/tobacco/basic_information/related_links/index.htm

Buprenorphine Treatment Locator

- **SAMHSA, Buprenorphine Treatment Practitioner Locator:** Provides a state-by-state list of providers who offer buprenorphine. www.samhsa.gov/medication-assisted-treatment/physician-program-data/treatment-physician-locator

Buprenorphine Training, Mentorship, and Waivers

- **SAMHSA, Buprenorphine Waiver Management:** Provides information on buprenorphine waivers with links to waiver applications; explains waiver processes, requirements, and recordkeeping. https://www.samhsa.gov/medication-assisted-treatment/training-materials-resources/apply-for-practitioner-waiver
- **SAMHSA, Buprenorphine Training for Physicians:** Provides links to organizations that train physicians on buprenorphine treatment. https://www.samhsa.gov/medication-assisted-treatment/training-materials-resources/apply-for-practitioner-waiver

- **SAMHSA, Qualify for a Practitioner Waiver:** Provides information for NPs, PAs, clinical nurse specialists, certified registered nurse anesthetists, and certified nurse midwives about the buprenorphine waiver training, with links to trainings and the application process. https://www.samhsa.gov/medication-assisted-treatment/training-materials-resources/apply-for-practitioner-waiver
- **PCSS-MAT:** Provides buprenorphine waiver training and mentorship for healthcare professionals (physicians, NPs, PAs, clinical nurse specialists, certified registered nurse anesthetists, and certified nurse midwives); includes updates and other resources about medication for OUD. https://pcssnow.org/

Medication Treatment for OUD

- **SAMHSA, *Advisory,* Sublingual and Transmucosal Buprenorphine for Opioid Use Disorder: Review and Update:** Summarizes information on the use of buprenorphine to treat OUD. https://store.samhsa.gov/product/Advisory-Sublingual-and-Transmucosal-Buprenorphine-for-Opioid-Use-Disorder-/SMA16-4938
- **SAMHSA, *Clinical Use of Extended-Release Injectable Naltrexone in the Treatment of Opioid Use Disorder: A Brief Guide:*** Provides a brief review of the use of XR-NTX. https://store.samhsa.gov/product/Clinical-Use-of-Extended-Release-Injectable-Naltrexone-in-the-Treatment-of-Opioid-Use-Disorder-A-Brief-Guide/SMA14-4892R
- **ASAM, *The ASAM National Practice Guideline for the Treatment of Opioid Use Disorder. 2020 Focused Update:*** Provides national practice guidelines for the use of medications to treat OUD. https://www.asam.org/docs/default-source/quality-science/npg-jam-supplement.pdf?sfvrsn=a00a52c2_2
- **Department of Veterans Affairs/ Department of Defense, *VA/DoD Clinical Practice Guideline for the Management of Substance Use Disorders:*** Provides substance use disorder practice guidelines. www.healthquality.va.gov/guidelines/MH/sud/VADoDSUDCPGRevised22216.pdf
- **PCSS-MAT:** Provides training and mentorship for healthcare professionals (physicians, NPs, PAs, clinical nurse specialists, certified registered nurse anesthetists, and certified nurse midwives) on medications for OUD treatment including buprenorphine, naltrexone, and methadone. https://pcssnow.org/

Syringe Exchange

- **North American Syringe Exchange Network:** Provides a national directory of syringe exchange programs in the United States. https://nasen.org/directory

Opioid-Related Overdose Prevention

- **Prescribe To Prevent:** Provides information about naloxone prescribing for overdose prevention, including educational patient handouts and videos. http://prescribetoprevent.org
- ***SAMHSA Opioid Overdose Prevention Toolkit:*** Provides healthcare professionals, communities, and local governments with material to develop practices and policies to help prevent opioid-related overdoses and deaths. It addresses issues for healthcare professionals, first responders, treatment providers, and those recovering from opioid overdose as well as their families. https://store.samhsa.gov/product/Opioid-Overdose-Prevention-Toolkit/SMA18-4742
- **CDC—Overdose Prevention:** Provides links and tools for clinicians to help prevent opioid overdose deaths. https://www.cdc.gov/drugoverdose/prevention/index.html

- **NIDA, Opioid Overdose Reversal with Naloxone (Narcan, Evzio):** Provides naloxone information for providers. www.drugabuse.gov/related-topics/opioid-overdose-reversal-naloxone-narcan-evzio

Opioid Withdrawal Scales

- ***WHO Guidelines for the Psychosocially Assisted Pharmacological Treatment of Opioid Dependence: Annex 10:*** Provides COWS and other opioid withdrawal scales. www.ncbi.nlm.nih.gov/books/NBK143183
- **The Clinical Institute Narcotic Assessment Scale for Withdrawal Symptoms:** Provides a scale that measures signs and symptoms observed in patients during withdrawal. www.ncpoep.org/wp-content/uploads/2015/02/Appendix_7_Clinical_Institute_Narcotic_Assessment_CINA_Scale_for_Withdrawal_Symptoms.pdf

Patient and Family Education on Medications To Treat OUD

- **SAMHSA Store:** Provides patient and family educational resources about OUD and medication treatment for OUD; some resources are available in multiple languages, including Spanish. https://store.samhsa.gov
  - Buprenorphine. https://store.samhsa.gov/product/The-Facts-about-Buprenorphine-for-Treatment-of-Opioid-Addiction/SMA15-4442
  - Methadone. https://roar.nevadaprc.org/system/documents/3100/original/NPRC.168.WhatEveryIndividualNeedsToKnow.pdf?1435165554
- **ASAM Resources:** Provides patient and family education tools about addiction in general and OUD specifically.
  - Patient Resources. www.asam.org/resources/patientresources
  - *Opioid Addiction Treatment: A Guide for Patients, Families, and Friends.* https://www.asam.org/docs/default-source/publications/asam-opioid-patient-piece_-5bopt2-5d_3d.pdf

Referral and Treatment Locators

- **SAMHSA, OTP Directory:** Provides a state-by-state directory of methadone OTPs. https://dpt2.samhsa.gov/treatment/directory.aspx
- **SAMHSA, Behavioral Health Treatment Services Locator:** Provides a directory of treatment facilities. https://findtreatment.samhsa.gov
- **SAMHSA, Behavioral Health Treatment Services Locator—Self-Help, Peer Support, and Consumer Groups:** Provides a directory for mutual-help groups. https://findtreatment.samhsa.gov/

Screening, Assessment, and Drug Testing Resources

- **NIDA, Screening Tools and Prevention:** Provides an evidence-based screening tool chart for adolescents and adults, drug use screening tool support materials, and a clinician resource and quick reference guide for drug screening in general medical settings, including the NIDA-Modified ASSIST (NM ASSIST) www.drugabuse.gov/nidamed-medical-health-professionals/tool-resources-your-practice/additional-screening-resources
- **ASAM, *The ASAM Appropriate Use of Drug Testing in Clinical Addiction Medicine:*** Discusses appropriate use of drug testing in identifying, diagnosing, and treating people with or at risk for SUDs. https://www.asam.org/Quality-Science/quality/drug-testing
- **USPSTF, *Draft Recommendation Statement on Unhealthy Drug Use Screening:*** Discusses updated recommendations about screening for illicit drug use and prescription medication misuse in adults in primary care settings. At the time of this publication, only the draft (not the final) recommendation statement is available. https://www.uspreventiveservicestaskforce.org/Page/Document/draft-recommendation-statement/drug-use-in-adolescents-and-adults-including-pregnant-women-screening

Treatment Planning

- **SAMHSA, Decisions in Recovery—Treatment for Opioid Use Disorder:** Provides an online interactive tool to support people with OUD in making informed decisions about their care. https://mat-decisions-in-recovery.samhsa.gov/

  An accompanying handbook is also available. https://store.samhsa.gov/product/Decisions-in-Recovery-Treatment-for-Opioid-Use-Disorders/SMA16-4993

- **SAMHSA, TIP 42, *Substance Abuse Treatment for Persons With Co-Occurring Disorders:*** Provides comprehensive treatment guidance for individuals with co-occurring mental and substance use disorders. https://store.samhsa.gov/product/TIP-42-Substance-Abuse-Treatment-for-Persons-With-Co-Occurring-Disorders/SMA13-3992

Appendix

Stable Resource Toolkit

Audit-C – Overview

The AUDIT-C is a 3-item alcohol screen that can help identify persons who are hazardous drinkers or have active alcohol use disorders (including alcohol abuse or dependence). The AUDIT-C is a modified version of the 10 question AUDIT instrument.

Clinical Utility

The AUDIT-C is a brief alcohol screen that reliably identifies patients who are hazardous drinkers or have active alcohol use disorders.

Scoring

The AUDIT-C is scored on a scale of 0-12.

Each AUDIT-C question has 5 answer choices. Points allotted are:
a = 0 points, **b** = 1 point, **c** = 2 points, **d** = 3 points, **e** = 4 points

- **In men,** a score of 4 or more is considered positive, optimal for identifying hazardous drinking or active alcohol use disorders.
- **In women,** a score of 3 or more is considered positive (same as above).
- However, when the points are all from Question #1 alone (#2 & #3 are zero), it can be assumed that the patient is drinking below recommended limits and it is suggested that the provider review the patient's alcohol intake over the past few months to confirm accuracy.[3]
- Generally, the higher the score, the more likely it is that the patient's drinking is affecting his or her safety.

Psychometric Properties

For identifying patients with heavy/hazardous drinking and/or Active-DSM alcohol abuse or dependence

	MEN[1]	WOMEN[2]
≥3	Sens: 0.95 / Spec. 0.60	Sens: 0.66 / Spec. 0.94
≥4	Sens: 0.86 / Spec. 0.72	Sens: 0.48 / Spec. 0.99

For identifying patients with active alcohol abuse or dependence

	MEN[1]	WOMEN[2]
≥3	Sens: 0.90 / Spec. 0.45	Sens: 0.80 / Spec. 0.87
≥4	Sens: 0.79 / Spec. 0.56	Sens: 0.67 / Spec. 0.94

1. Bush K, Kivlahan DR, McDonell MB, et al. The AUDIT Alcohol Consumption Questions (AUDIT-C): An effective brief screening test for problem drinking. *Arch Internal Med. 1998* (3): 1789-1795.
2. Bradley KA, Bush KR, Epler AJ, et al. Two brief alcohol-screening tests from the Alcohol Use Disorders Identification Test (AUDIT): Validation in a female veterans affairs patient population. *Arch Internal Med Vol 165,* April 2003: 821-829.
3. Frequently Asked Questions guide to using the AUDIT-C can be found via the website: https://www.queri.research.va.gov/tools/alcohol-misuse/alcohol-faqs-print.cfm

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AUDIT-C Questionnaire

Patient Name: _____ **Dates of Visit:** _____

1. **How often do you have a drink containing alcohol?**
   - ☐ a. Never
   - ☐ b. Monthly or less
   - ☐ c. 2-4 times a month
   - ☐ d. 2-3 times a week
   - ☐ e. 4 or more times a week

2. **How many standard drinks containing alcohol do you have on a typical day?**
   - ☐ a. 1 or 2
   - ☐ b. 3 or 4
   - ☐ c. 5 or 6
   - ☐ d. 7 to 9
   - ☐ e. 10 or more

3. **How often do you have six or more drinks on one occasion?**
   - ☐ a. Never
   - ☐ b. Less than monthly
   - ☐ c. Monthly
   - ☐ d. Weekly
   - ☐ e. Daily or almost daily

AUDIT-C is available for use in the public domain.

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Drug Abuse Screening Test (DAST-10)

General Instructions

"Drug use" refers to (1) the use of prescribed or over-the-counter drugs in excess of the directions, and (2) any nonmedical use of drugs. The various classes of drugs may include cannabis (i.e., marijuana, hashish), solvents (e.g., paint thinner), tranquilizers (e.g., Valium), barbiturates, cocaine, stimulants (e.g., speed), hallucinogens (e.g., LSD), or narcotics (e.g., heroin). The questions do not include alcoholic beverages.

Please answer every question. If you have trouble with a question, then choose the response that is mostly right.

Segment: _____ Visit Number: _____ Date of Assessment: _____/_____/_____

These questions refer to drug use in the past 12 months. Please answer No or Yes.

1.	**Have you used drugs other than those required for medical reasons?**	☐ No	☐ Yes
2.	**Do you use more than one drug at a time?**	☐ No	☐ Yes
3.	**Are you always able to stop using drugs when you want to?**	☐ No	☐ Yes
4.	**Have you had "blackouts" or "flashbacks" as a result of drug use?**	☐ No	☐ Yes
5.	**Do you ever feel bad or guilty about your drug use?**	☐ No	☐ Yes
6.	**Does your spouse (or parents) ever complain about your involvement with drugs?**	☐ No	☐ Yes
7.	**Have you neglected your family because of your use of drugs?**	☐ No	☐ Yes
8.	**Have you engaged in illegal activities to obtain drugs?**	☐ No	☐ Yes
9.	**Have you ever experienced withdrawal symptoms (i.e., felt sick) when you stopped taking drugs?**	☐ No	☐ Yes
10.	**Have you had medical problems as a result of your drug use (e.g., memory loss, hepatitis, convulsions, bleeding)?**	☐ No	☐ Yes

Comments:

Scoring

Score 1 point for each "Yes," except for question 3, for which a "No" receives 1 point.

DAST Score: _____

Interpretation of Score:

Score	Degree of Problems Related to Drug Abuse	Suggested Action
0	No problems reported	None at this time
1–2	Low level	Monitor, reassess at a later date
3–5	Moderate level	Further investigation
6–8	Substantial level	Intensive assessment
9–10	Severe level	Intensive assessment

Adapted with permission.[100,101]

DSM-5 Opioid Use Disorder Checklist[102]

Patient's Name: _____ Date of Birth: _____

Worksheet for DSM-5 Criteria for Diagnosis of Opioid Use Disorder

DIAGNOSTIC CRITERIA (Opioid use disorder requires that at least 2 criteria be met within a 12-month period.)	MEETS CRITERIA? Yes OR No	NOTES/SUPPORTING INFORMATION
1. Opioids are often taken in larger amounts or over a longer period of time than intended.		
2. There is a persistent desire or unsuccessful efforts to cut down or control opioid use.		
3. A lot of time is spent in activities necessary to obtain the opioid, use the opioid, or recover from its effects.		
4. Craving, or a strong desire to use opioids.		
5. Recurrent opioid use resulting in failure to fulfill major role obligations at work, school, or home.		
6. Continued opioid use despite having persistent or recurrent social or interpersonal problems caused or exacerbated by the effects of opioids.		
7. Important social, occupational, or recreational activities are given up or reduced because of opioid use.		
8. Recurrent opioid use in situations in which it is physically hazardous.		
9. Continued use despite knowledge of having a persistent or recurrent physical or psychological problem that is likely to have been caused or exacerbated by opioids.		
10. Tolerance,* as defined by either of the following: (a) a need for markedly increased amounts of opioids to achieve intoxication or desired effect (b) markedly diminished effect with continued use of the same amount of an opioid		
11. Withdrawal,* as manifested by either of the following: (a) the characteristic opioid withdrawal syndrome (b) the same (or a closely related) substance is taken to relieve or avoid withdrawal symptoms		

*This criterion is not met for individuals taking opioids solely under appropriate medical supervision.

Severity: mild = 2–3 symptoms; moderate = 4–5 symptoms; severe = 6 or more symptoms

Signed: _____ Date: _____

TAPS Tool Part I

Directions: The TAPS Tool Part 1 is a 4-item screening for tobacco use, alcohol use, prescription medication misuse, and illicit substance use in the PAST YEAR. Question 2 should be answered by males, and Question 3 should be answered by females. Each of the four multiple-choice items has five possible responses to choose from. Check the box to select your answer.

In the PAST 12 MONTHS:

1. How often have you used any tobacco product (for example, cigarettes, ecigarettes, cigars, pipes, or smokeless tobacco)?

   ☐ Never ☐ Less than monthly ☐ Monthly ☐ Weekly ☐ Daily or almost daily

2. How often have you had 5 or more drinks containing alcohol in 1 day? One standard drink is about 1 small glass of wine (5 oz), 1 beer (12 oz), or 1 single shot of liquor. *(Note: This question should only be answered by males.)*

   ☐ Never ☐ Less than monthly ☐ Monthly ☐ Weekly ☐ Daily or almost daily

3. How often have you had 4 or more drinks containing alcohol in 1 day? One standard drink is about 1 small glass of wine (5 oz), 1 beer (12 oz), or 1 single shot of liquor. *(Note: This question should only be answered by females.)*

   ☐ Never ☐ Less than monthly ☐ Monthly ☐ Weekly ☐ Daily or almost daily

4. How often have you used any drugs including marijuana, cocaine or crack, heroin, methamphetamine (crystal meth), hallucinogens, or ecstasy/MDMA?

   ☐ Never ☐ Less than monthly ☐ Monthly ☐ Weekly ☐ Daily or almost daily

5. How often have you used any prescription medications just for the feeling, more than prescribed, or that were not prescribed for you? Prescription medications that may be used this way include opiate pain relievers (for example, OxyContin, Vicodin, Percocet, or methadone), medications for anxiety or sleeping (for example, Xanax, Ativan, or Klonopin), or medications for ADHD (for example, Adderall or Ritalin).

   ☐ Never ☐ Less than monthly ☐ Monthly ☐ Weekly ☐ Daily or almost daily

TAPS Tool Part 2

Directions: The TAPS Tool Part 2 is a brief assessment for tobacco use, alcohol use, illicit substance use, and prescription medication misuse in the PAST 3 MONTHS ONLY. Each of the following questions and subquestions has two possible answers, yes or no. Check the box to select your answer.

In the PAST 3 MONTHS:

1. **Did you smoke a cigarette containing tobacco?** ☐ **Yes** ☐ **No**

   If "Yes," answer the following questions:

   - Did you usually smoke more than 10 cigarettes each day? ☐ Yes ☐ No
   - Did you usually smoke within 30 minutes after waking? ☐ Yes ☐ No

2. **Did you have a drink containing alcohol?** ☐ **Yes** ☐ **No**

   If "Yes," answer the following questions:

   - Did you have 4 or more drinks containing alcohol in a day?* ☐ Yes ☐ No
     (Note: This question should only be answered by females.)
   - Did you have 5 or more drinks containing alcohol in a day?* ☐ Yes ☐ No
     (Note: This question should only be answered by males.)
   - Have you tried and failed to control, cut down, or stop drinking? ☐ Yes ☐ No
   - Has anyone expressed concern about your drinking? ☐ Yes ☐ No

3. **Did you use marijuana (hash, weed)?** ☐ **Yes** ☐ **No**

   If "Yes," answer the following questions:

   - Have you had a strong desire or urge to use marijuana at least once a week or more often? ☐ Yes ☐ No
   - Has anyone expressed concern about your use of marijuana? ☐ Yes ☐ No

4. **Did you use cocaine, crack, or methamphetamine (crystal meth)?** ☐ **Yes** ☐ **No**

   If "Yes," answer the following questions:

   - Did you use cocaine, crack, or methamphetamine (crystal meth) at least once a week or more often? ☐ Yes ☐ No
   - Has anyone expressed concern about your use of cocaine, crack, or methamphetamine (crystal meth)? ☐ Yes ☐ No

5. **Did you use heroin?** ☐ **Yes** ☐ **No**

   If "Yes," answer the following questions:

   - Have you tried and failed to control, cut down, or stop using heroin? ☐ Yes ☐ No
   - Has anyone expressed concern about your use of heroin? ☐ Yes ☐ No

6. **Did you use a prescription opiate pain reliever (for example, Percocet or Vicodin) not as prescribed or that was not prescribed for you?** ☐ **Yes** ☐ **No**

   If "Yes," answer the following questions:

   - Have you tried and failed to control, cut down, or stop using an opiate pain reliever? ☐ Yes ☐ No
   - Has anyone expressed concern about your use of an opiate pain reliever? ☐ Yes ☐ No

*One standard drink is about 1 small glass of wine (5 oz), 1 beer (12 oz), or 1 single shot of liquor.

Continued on next page

TAPS Tool Part 2 (continued)

7.	**Did you use medication for anxiety or sleep (for example, Xanax, Ativan, or Klonopin) not as prescribed or that was not prescribed for you?**	☐ **Yes**	☐ **No**
	If "Yes," answer the following questions:		
	• Have you had a strong desire or urge to use medications for anxiety or sleep at least once a week or more often?	☐ Yes	☐ No
	• Has anyone expressed concern about your use of medication for anxiety or sleep?	☐ Yes	☐ No
8.	**Did you use medication for ADHD (for example, Adderall or Ritalin) not as prescribed or that was not prescribed for you?**	☐ **Yes**	☐ **No**
	If "Yes," answer the following questions:		
	• Did you use a medication for ADHD (for example, Adderall or Ritalin) at least once a week or more often?	☐ Yes	☐ No
	• Has anyone expressed concern about your use of medication for ADHD (for example, Adderall or Ritalin)?	☐ Yes	☐ No
9.	**Did you use any other illegal or recreational drugs (for example, ecstasy, molly, GHB, poppers, LSD, mushrooms, special K, bath salts, synthetic marijuana ["spice"], or whip-its)?**	☐ **Yes**	☐ **No**
	If "Yes," answer the following question:		
	• What were the other drug(s) you used? (write in response)		

The complete tool is available online (https://cde.drugabuse.gov/instrument/29b23e2e-e266-f095-e050-bb89ad43472f).
Adapted from material in the public domain.[103]

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