

**Medications for Opioid Use Disorder**

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

***UPDATED 2020***

**TREATMENT IMPROVEMENT PROTOCOL**

**TIP 63**

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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.

**TIP Navigation**

Executive Summary

*For healthcare and addiction professionals, policymakers, patients, and families*

Part 1: Introduction to Medications for Opioid Use Disorder Treatment

*For healthcare and addiction professionals, policymakers, patients, and families*

Part 2: Addressing Opioid Use Disorder in General Medical Settings

*For healthcare professionals*

Part 3: Pharmacotherapy for Opioid Use Disorder

*For healthcare professionals*

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

*For healthcare and addiction professionals*

Part 5: Resources Related to Medications for Opioid Use Disorder

*For healthcare and addiction professionals, policymakers, patients, and families*

## Contents

###### EXECUTIVE SUMMARY

**Foreword** ES-iii

**Tip 63 Update** ES-iii

**Introduction** ........................................................... ES-1

**Overall Key Messages** .................................................. ES-1

**Content Overview** ..................................................... ES-3

**Notes** .................................................................. ES-7

**TIP Development Participants** .......................................... ES-9

**Publication Information** ............................................... ES-12

###### PART 1: AN INTRODUCTION TO MEDICATIONS FOR THE TREATMENT OF OPIOID USE DISORDER

#### The Approach to OUD Care 1-1

#### Overview of Medications for OUD 1-3

#### Duration of Treatment With OUD Medication 1-8

#### Treatment Settings 1-9

#### Challenges to Expanding Access to OUD Medication 1-10

**Resources** 1-10

**Notes** 1-11

###### PART 2: ADDRESSING OPIOID USE DISORDER IN GENERAL MEDICAL SETTINGS

#### Scope of the Problem 2-1

**Screening** 2-1

**Assessment** 2-8

#### Treatment Planning or Referral 2-17

**Resources** 2-28

**Appendix** 2-32

**Notes** 2-39

ii

###### PART 3: PHARMACOTHERAPY FOR OPIOID USE DISORDER

#### 4DPQF PG UIF 1SPCMFN 3-1

#### Chapter 3A: Overview of Pharmacotherapy for Opioid Use Disorder 3-5

#### Chapter 3B: Methadone 3-17

#### Chapter 3C: Naltrexone 3-37

#### Chapter 3D: Buprenorphine 3-51

#### Chapter 3E: Medical Management Strategies for Patients

#### Taking OUD Medications in Office-Based Settings 3-83

#### Chapter 3F: Medical Management of Patients Taking OUD Medications

**in Hospital Settings** ......................................

3-103

**Notes** 3-109

###### PART 4: PARTNERING ADDICTION TREATMENT COUNSELORS WITH CLIENTS AND HEALTHCARE PROFESSIONALS

#### Overview and Context 4-1

#### Quick Guide to Medications 4-12

#### Counselor–Prescriber Communications 4-18

#### Creation of a Supportive Counseling Experience 4-20

#### Other Common Counseling Concerns 4-34

**Notes** 4-37

###### PART 5: RESOURCES RELATED TO MEDICATIONS FOR OPIOID USE DISORDER

#### General Resources 5-1

#### Resources for Counselors and Peer Providers 5-10

#### Resources for Clients and Families 5-12

#### Provider Tools and Sample Forms 5-16

#### Glossary of TIP Terminology 5-56

**Notes** 5-59

iii

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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**

**Executive Summary**

***For healthcare and addiction professionals, policymakers, patients, and families***

Part 1: Introduction to Medications for Opioid Use Disorder Treatment

*For healthcare and addiction professionals, policymakers, patients, and families*

Part 2: Addressing Opioid Use Disorder in General Medical Settings

*For healthcare professionals*

Part 3: Pharmacotherapy for Opioid Use Disorder

*For healthcare professionals*

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

*For healthcare and addiction professionals*

Part 5: Resources Related to Medications for Opioid Use Disorder

*For healthcare and addiction professionals, policymakers, patients, and families*

Substance Abuse and Mental Health Services Administration

## Contents

**Foreword** ES-iii

**TIP 63 Update** ES-iii

**Introduction** ........................................................... ES-1

**Overall Key Messages** .................................................. ES-1

**Content Overview** ..................................................... ES-3

Part 1: Introduction to Medications for Opioid Use Disorder Treatment ............. ES-3 Part 2: Addressing Opioid Use Disorder in General Medical Settings ................ ES-4 Part 3: Pharmacotherapy for Opioid Use Disorder ............................... ES-4 Part 4: Partnering Addiction Treatment Counselors With Clients and

Healthcare Professionals ................................................... ES-5

Part 5: Resources Related to Medications for Opioid Use Disorder .................. ES-5

**Notes** .................................................................. ES-7

**TIP Development Participants** .......................................... ES-9

Expert Panelists ........................................................... ES-9

Scientific Reviewers ....................................................... ES-10

Field Reviewers........................................................... ES-10

**Publication Information** ............................................... ES-12

ES-ii

## 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

U.S. Department of Health and Human Services

Substance Abuse and Mental Health Services Administration

## 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.

ES-i**JJ**

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**TIP 63**

**MEDICATIONS FOR OPIOID USE DISORDER**

# 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 individ- uals 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

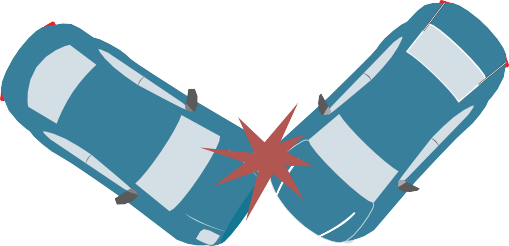
The TIP is divided into parts so that readers can easily find the material they need. Part 1 is a general introduction to providing medications for OUD and issues related to providing that treatment. Some readers may prefer to go directly to those parts most relevant to their areas of interest, but everyone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

ES-1



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 naltrex- one (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

ES-2

**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**

## 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.



**OPIOID-RELATED**

**EMERGENCY**

**DEPARTMENT**

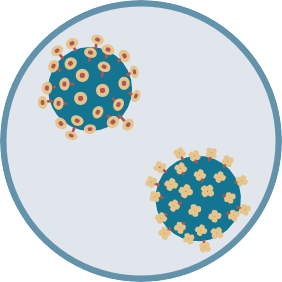
visits more than doubled from 2005 to 2016.22,23

* 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.

ES-3



**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**.

**HIV**

**Hep C**

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**forSUD.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 health- care 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.

ES-4



**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 pharmacothera- pies should be reserved for those with moder- ate-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 pre- scribers, 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 sup- portive 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.

ES-5

### 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 |

*Adapted with permission.30 Copyrighted 2017. UBM Medica. 131265:0917SH*

ES-6

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ES-7

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ES-8

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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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ES-9

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ES-11

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ES-12





**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**  Executive Summary  *For healthcare and addiction professionals, policymakers, patients, and families* | **KEY MESSAGES**   * **Increasing opioid overdose deaths, illicit opioid use, and prescription opioid misuse constitute a public health crisis.** |
| **Part 1: Introduction to Medications for** • **OUD medications reduce illicit opioid use,**  **retain people in treatment, and reduce**  **Opioid Use Disorder Treatment risk of opioid overdose death better than *For healthcare and addiction* treatment with placebo or no medication. *professionals, policymakers,*** • **Only physicians; nurse practitioners;**  ***patients, and families* physician assistants; and, until October 1,**  **2023, clinical nurse specialists, certiﬁed** | |
| Part 2: Addressing Opioid Use Disorder in General Medical Settings  *For healthcare professionals*  Part 3: Pharmacotherapy for Opioid Use Disorder  *For healthcare professionals*  Part 4: Partnering Addiction Treatment Counselors With Clients and Healthcare Professionals  *For healthcare and addiction professionals*  Part 5: Resources Related to Medications for Opioid Use Disorder  *For healthcare and addiction professionals, policymakers, patients, and families* | **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.** |

Substance Abuse and Mental Health Services Administration



**TIP 63**

**MEDICATIONS FOR OPIOID USE DISORDER—Part 1 of 5**

## Contents

#### The Approach to OUD Care 1-1

#### Overview of Medications for OUD 1-3

Benefits 1-3

Effectiveness 1-3

Cost Effectiveness and Cost Benefits 1-7

Requirements and Regulations 1-7

#### Duration of Treatment With OUD Medication 1-8

Maintenance Treatment 1-8

Medication Taper 1-9

Medically Supervised Withdrawal 1-9

#### Treatment Settings 1-9

#### Challenges to Expanding Access to OUD Medication 1-10

**Resources** 1-10

**Notes** 1-11

1-ii



**TIP 63**

**MEDICATIONS FOR OPIOID USE DISORDER**

**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

Estimated cost of the **OPIOID EPIDEMIC** was

**$504**



**BILLION**

###### in 2015.2

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 con- tinuing care also provides, and links to, other medical, behavioral health, and community and recovery support services.

**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 profes- sionals 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.

1-1

**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 Edition4 (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.**

1-2

**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.

## 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 naltrex- one (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.

**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/).

**RESOURCE ALERT**

Methadone and buprenorphine treatment have also been associated with reduced risk of overdose death.13,14,15,16,17

1-3

### 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 |

*Adapted with permission.18 Copyrighted 2017. UBM Medica. 131265:0917SH*

1-4

**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 medica- tions 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 ap- proaches 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.

1-5

##### *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 random- ized trial assigned adult residential treatment patients with OUD to either XR-NTX or bu- prenorphine. 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 partici- pants 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 de- pendence 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 buprenor- phine 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 formu- lation is a monthly subcutaneous injection.

Exhibit 1.2 compares medications for OUD.

1-6

**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 medi- cations 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 medi- cation** 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-assist-](http://www.samhsa.gov/medication-assist-)

ed-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.

1-7

* Physicians BOE PUIFS RVBMJGJFE QSPWJEFST 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 certiﬁ- cation 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 subcutane- ous administration.

**Naltrexone has no regulations beyond those that apply to any prescription pharmaceuti- cal.** 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.

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 depen- dence. 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 med- ication, 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.

1-8

**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](http://www.federalregister.gov/documents/2016/07)

/08/2016-16120/medication-assisted-treatment

-for-opioid-use-disorders

[www.samhsa.gov/sites/default/ﬁles/programs](http://www.samhsa.gov/sites/default/ﬁles/programs)

\_campaigns/medication\_assisted/understanding

-patient-limit275.pdf

**RESOURCE ALERT**

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 buprenor- phine on a short-term basis to reduce physical withdrawal signs and symptoms. Formerly called

Primary care physicians are on the

**front lines of providing ofﬁce-based treatment with medication for OUD.**

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 recommend- ed 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.

## Treatment Settings

**Almost all healthcare settings are appro- priate 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 depart- ments, 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.

1-9

**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 General85 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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1-14





**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**  Executive Summary  *For healthcare and addiction professionals, policymakers, patients, and families*  Part 1: Introduction to Medications for Opioid Use Disorder Treatment  *For healthcare and addiction professionals, policymakers, patients, and families* | **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** |
| **Part 2: Addressing Opioid Use Disorder in harm from substance use, practitioners**  **General Medical Settings should assess them using tools that**  ***For healthcare professionals* determine whether substance use meets**  **diagnostic criteria for a substance use** | |
| Part 3: Pharmacotherapy for Opioid Use Disorder  *For healthcare professionals*  Part 4: Partnering Addiction Treatment Counselors With Clients and Healthcare Professionals  *For healthcare and addiction professionals*  Part 5: Resources Related to Medication for Opioid Use Disorder  *For healthcare and addiction professionals, policymakers, patients, and families* | **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.** |

Substance Abuse and Mental Health Services Administration

## Contents

[Scope of the Problem 2-1](#_TOC_250023)

[Screening 2-1](#_TOC_250022)

[Alcohol Screening 2-3](#_TOC_250021)

[Tobacco Screening 2-5](#_TOC_250020)

[Drug Screening 2-5](#_TOC_250019)

[Assessment 2-8](#_TOC_250018)

[Determine the Need for and Extent of Assessment 2-8](#_TOC_250017)

Set the Stage for Successful Assessment 2-8

[Take a Complete History 2-9](#_TOC_250016)

Conduct a Physical Examination 2-12

[Obtain Appropriate Laboratory Tests 2-13](#_TOC_250015)

[Review the PDMP 2-16](#_TOC_250014)

Determine Diagnosis and Severity of OUD 2-17

Treatment Planning or Referral 2-17

Making Decisions About Treatment 2-17

[Understanding Treatment Settings and Services 2-18](#_TOC_250013)

Outpatient OUD Treatment Settings 2-18

[Determining OUD Service Intensity and Ensuring Follow-Through 2-23](#_TOC_250012)

Preventing Opioid-Related Overdose 2-26

[Resources 2-28](#_TOC_250011)

[Alcohol and Drug Use Screening 2-28](#_TOC_250010)

[Tobacco Screening 2-28](#_TOC_250009)

[Buprenorphine Treatment Locator 2-28](#_TOC_250008)

Buprenorphine Training, Mentorship,

and Waivers 2-28

[Medication Treatment for OUD 2-29](#_TOC_250007)

[Syringe Exchange 2-29](#_TOC_250006)

[Opioid-Related Overdose Prevention 2-29](#_TOC_250005)

[Opioid Withdrawal Scales 2-30](#_TOC_250004)

[Patient and Family Education on Medications To Treat OUD 2-30](#_TOC_250003)

[Referral and Treatment Locators 2-30](#_TOC_250002)

[Screening, Assessment, and Drug Testing Resources 2-30](#_TOC_250001)

[Treatment Planning 2-31](#_TOC_250000)

2-ii

**Appendix** 2-32

Stable Resource Toolkit 2-32

Drug Abuse Screening Test (DAST-10) 2-34

DSM-5 Opioid Use Disorder Checklist 2-35

TAPS Tool Part I 2-36

TAPS Tool Part 2 2-37

**Notes** 2-39

2-iii

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**TIP 63**

**MEDICATIONS FOR OPIOID USE DISORDER**

**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.

2-1

**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 Edition4 (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*

2-2

**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

2-3

**EXHIBIT 2.2. Substance Misuse and SUD Screening**

**Substance misuse screening**

**Negative**

**Positive**

**Reinforce healthy behavior**

**Assess substance use and comorbidities**

**Substance misuse**

**Substance use disorder**

**Brief counseling**

**Brief counseling and treatment referral**

**Monitoring/follo**-**w up**

**Consider pharmacotherapy**

**If misuse continues, negotiate a plan and refer to treatment**

**Ongoing assessment and support**

*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 in- formation 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 pharmacothera- py and referral to counseling for people with AUD.** The three FDA-approved medications to treat AUD—acamprosate, disulﬁram, and naltrex- one (oral and extended-release injectable nal- trexone [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

2-4

**EXHIBIT 2.3. NIAAA Single-Item Screener**

**How many times in the past year have you** One or more times constitutes a positive

**had ﬁve or more drinks in a day (four drinks** screen. Patients who screen positive

**for women and all adults older than age 65)?** 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 conse-

quences 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 Dependence26 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.

2-5

### EXHIBIT 2.4. AUDIT Screener

|  |  |
| --- | --- |
| 1. **How often do you have a drink containing alcohol?**    1. Never *[Skip to Questions 9–10]*    2. Monthly or less    3. 2 to 4 times a month    4. 2 to 3 times a week    5. 4 or more times a week | 1. **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?**    1. Never    2. Less than monthly    3. Monthly    4. Weekly    5. Daily or almost daily |
| 1. **How many drinks containing alcohol do you have on a typical day when you are drinking?**    1. 1 or 2    2. 3 or 4    3. 5 or 6   (3) 7, 8, or 9  (4) 10 or more | 1. **How often during the last year have you had a feeling of guilt or remorse after drinking?**    1. Never    2. Less than monthly    3. Monthly    4. Weekly    5. Daily or almost daily |
| 1. **How often do you have six or more drinks on one occasion?**    1. Never    2. Less than monthly    3. Monthly    4. Weekly    5. Daily or almost daily   *Skip to Questions 9 and 10 if total score for Questions 2 and 3 = 0* | 1. **How often during the last year have you been unable to remember what happened the night before because you had been drinking?**    1. Never    2. Less than monthly    3. Monthly    4. Weekly    5. Daily or almost daily |
| 1. **How often during the last year have you found that you were not able to stop drinking once you had started?**    1. Never    2. Less than monthly    3. Monthly    4. Weekly    5. 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 |
| 1. **How often during the last year have you failed to do what was normally expected from you because of drinking?**    1. Never    2. Less than monthly    3. Monthly    4. Weekly    5. Daily or almost daily | **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).

2-6

**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*

**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

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.

Resources” section for a link to a modiﬁed version of the ASSIST.)

**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*

**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 V1.042,43 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

2-7

## 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.

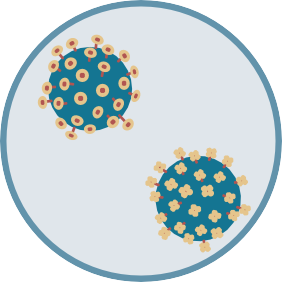
The extent of assessment depends on a provider’s ability to treat patients directly.

**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 assess- ment, 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**.

**HIV**

**Hep C**

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**forSUD.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, respect- ful, and empathetic.** Many patients with OUD are reluctant to discuss their opioid use in

2-8

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 phar- macotherapy. 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.

2-9

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

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

* Age at ﬁrst use. • Which drugs patients use.
* Routes of ingestion (e.g., injection). • Comorbid alcohol and tobacco use.
* History of tolerance, withdrawal, drug mixing, and overdose.
* Frequency, recency, and intensity of use.

### EXHIBIT 2.8. Medical Problems Associated With Opioid Misuse57

|  |  |
| --- | --- |
| **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) |

2-10

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 environ- ments 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 transmit- ted 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

2-11

**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 uncom- fortable.** 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.

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

**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

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

Total duration of withdrawal:

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

2-12

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 dis- cussion 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.

2-13

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 phencycli- dine. 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.

**EXHIBIT 2.12. Urine Drug Testing Window of Detection61,62**

\*Detection time may vary depending on the cutoff.

*Continued on next page*

Co-occurring SUDs require separate, speciﬁc treatment plans.

**Testing for substances that can complicate OUD pharmacotherapy is essential.** Testing for cocaine, benzodiazepines, and methamphet- amine is clinically important because these and other substances (and related SUDs, which may require treatment in their own right), especially benzodiazepines, can complicate pharmacother-

apy 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 clonaz- epam. Providers must speciﬁcally request testing for these two benzodiazepines. Exhibit 2.12 shows urine drug testing windows of detection.

|  |  |  |  |
| --- | --- | --- | --- |
| **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. |

2-14

### 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** | Tetrahydrocan- nabinol | 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.

2-15

**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 opportu- nity to discuss results with patients immedi- ately.** 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 naltrex- one 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 pregnancy67 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 aminotransfer- ase, 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](http://www.pdmpassist.org/content)

/state-proﬁles).

2-16

**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

**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/](http://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%20 MH%20and%20Addiction%20Treatment/MAT/ SMA14-4443.pdf?ver=2018-11-26-113004-157).

**RESOURCE ALERT**

or ﬁve criteria have moderate OUD, and those meeting six or more criteria have severe OUD.71 A printable checklist of DSM-572 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.

### EXHIBIT 2.13. DSM-5 Criteria for OUD73

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:
    1. A need for markedly increased amounts of opioids to achieve intoxication or desired effect
    2. A markedly diminished effect with continued use of the same amount of an opioid
11. Withdrawal,\* as manifested by either of the following:
    1. The characteristic opioid withdrawal syndrome
    2. 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

2-17

* 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 signif- icant weight when making decisions.** Patient characteristics can’t reliably predict greater likeli- hood 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 understand- ing, 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.

2-18

### 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 placebo74 | Higher than treatment without OUD medication and treatment with placebo75 | 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*

2-19

### 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/diver- sion 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 respira- tory 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.*

2-20

|  |  |
| --- | --- |
| **POSSIBLE TREATMENT**  **MEDICATION 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

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

a buprenorphine waiver can provide buprenor- phine. Any healthcare professional with a pre- scribing 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 nal- trexone 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 require- ments 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.

2-21

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

**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](http://www.samhsa.gov/)

/medication-assisted-treatment/physician

-program-data/treatment-physician-locator).

**RESOURCE ALERT**

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.

**Maintaining Conﬁdentiality**

**RESOURCE ALERT**

**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](http://www.samhsa.gov/)

/about-us/who-we-are/laws-regulations/conﬁden tiality-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.

2-22

### 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 patient80 (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 pre- scribers 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

**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.](http://www/) williamwhitepapers.com/pr/CSAT%20 Mutual%20Support%20Groups%202008.pdf).

**RESOURCE ALERT**

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 condi- tions 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.

2-23

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

Is the patient willing to engage in additional behavioral health

therapies?

**Yes**

**No**

Is the patient entering an OTP for methadone or

intensive treatment?

Offer best advice and ongoing motivational interviewing; revisit offer for behavioral

health therapies.

**Yes**

**No**

Counseling, peer support, and case management will likely be provided

through the OTP.

Identify speciﬁc needs, and refer appropriately to one or more of

the following:

Counseling: Individual, family,

and/or group

Peer support groups: Alcoholics Anonymous, Narcotics Anonymous, SMART Recovery,

buprenorphine groups

Case

management

Vocational

training

Housing, transportation,

food, legal, and other

support programs

**Guidance on Providing Integrated Care**

**RESOURCE ALERT**

Fragmented healthcare services are less likely to meet all patient needs. Integrated medical and behavioral healthcare delivery can effectively provide patient-focused, comprehensive treat- ments 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).](http://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).

2-24

**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

1. 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](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.

##### *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.

* + Housing. Every visit is a chance to help patients begin
  + Transportation.
  + Legal assistance.

**healthy changes and move toward treatment and recovery.** Patients may not be ready to change right away. Successfully quitting drug use

2-25

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 infor- mation 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 preven- tion education and a naloxone prescription.92**

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

#### Overdose risk Overdose identiﬁcation

* + - Using heroin (possibly mixed with illicitly • Fingernails or lips are blue or purple. manufactured fentanyl or fentanyl analogs) • Breathing or heartbeat is slow or stopped.
    - 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.
* 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.
  + Don’t use drugs when you are alone. • Put the person in the “recovery position,” on his
  + 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,

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.

and **any use may be fatal.** *Adapted from material in the public domain.93*

2-26

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.

2-27

## 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](http://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](http://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](http://www.apna.org/i4a/pages)

/index.cfm?pageID=6150

* + **U.S. Department of Health and Human Services’ Be Tobacco Free:** Provides infor- mation 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](http://www.cdc.gov/tobacco)

/index.htm and [www.cdc.gov/tobacco/basic](http://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 buprenor- phine. [www.samhsa.gov/medication-assisted](http://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-assist-](http://www.samhsa.gov/medication-assist-)

ed-treatment/training-materials-resources/ apply-for-practitioner-waiver

* + **SAMHSA, Buprenorphine Training for Physicians:** Provides links to organizations that train physicians on buprenor-

phine treatment. https://www.samhsa. gov/medication-assisted-treatment/ training-materials-resources/

apply-for-practitioner-waiver

2-28

* + **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-assist-](http://www.samhsa.gov/medication-assist-) ed-treatment/training-materials-resources/ apply-for-practitioner-waiver
  + **PCSS-MAT:** Provides buprenorphine waiver training and mentorship for healthcare pro- fessionals (physicians, NPs, PAs, clinical nurse specialists, certiﬁed registered nurse anesthe- tists, 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/](http://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](http://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 regis- tered 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://prescribeto](http://prescribeto/) prevent.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/dru-](http://www.cdc.gov/dru-) goverdose/prevention/index.html

2-29

* + **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](http://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.WhatEveryIndividualNeeds ToKnow.pdf?1435165554

* + **ASAM Resources:** Provides patient and family education tools about addiction in general and OUD speciﬁcally.
* Patient Resources. [www.asam.org](http://www.asam.org/)

/resources/patientresources

* *Opioid Addiction Treatment: A Guide for Patients, Families, and Friends.* https:// [www.asam.org/docs/default-source](http://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.](http://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.uspreven- tiveservicestaskforce.org/Page/Document/ draft-recommendation-statement/drug-use- in-adolescents-and-adults-including-pregnant- women-screening

2-30

### 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

2-31

## 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

|  |  |  |
| --- | --- | --- |
|  | **MEN1** | **WOMEN2** |
| **≥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

|  |  |  |
| --- | --- | --- |
|  | **MEN1** | **WOMEN2** |
| **≥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.
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*Continued on next page*

2-32

**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.*

*Reprinted from material in the public domain.99* Available online ([https://www](http://www.queri.research.va.gov/tools/alcohol-misuse/).queri.r[esearch.va.gov/tools/alcohol-misuse/](http://www.queri.research.va.gov/tools/alcohol-misuse/) alcohol-faqs.cfm#3).

2-33

### 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), tran- quilizers (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*

2-34

### DSM-5 Opioid Use Disorder Checklist102

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. |  |  |
| 1. Tolerance,\* as deﬁned by either of the following:    1. a need for markedly increased amounts of opioids to achieve intoxication or desired effect    2. markedly diminished effect with continued use of the same amount of an opioid |  |  |
| 1. Withdrawal,\* as manifested by either of the following:    1. the characteristic opioid withdrawal syndrome    2. 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:

2-35

### 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

2-36

### 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?
  + Did you usually smoke within 30 minutes after waking?
* Yes **□** No
* Yes **□** No

1. **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?
  + Has anyone expressed concern about your drinking?
* Yes **□** No
* Yes **□** No

1. **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

1. **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

1. **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

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

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*

2-37

### 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 | **□** Yes | **□** No |
|  | a week or more often?   * 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 | **□** Yes | **□** No |
|  | more often?   * 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*

2-38

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2-43