



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.

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

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

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For healthcare professionals

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



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Foreword

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

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

The talent, dedication, and hard work that TIP panelists and reviewers bring to this highly participatory process have helped bridge the gap between the promise of research and the needs of practicing clinicians and administrators to serve, in the most scientifically sound and effective ways, people in need of care and treatment of mental and substance use disorders.

U.S. Department of Health and Human Services
Substance Abuse and Mental Health Services Administration

TIP 63 Update

As a reflection of SAMHSA's commitment to ensuring that people with substance use disorders receive timely, relevant, high-quality care, SAMHSA in May 2021 revised certain areas of all five parts of this TIP to bring the content up to date and make it as useful to readers as possible. These changes will help provide readers with the latest information needed to understand medications for opioid use disorder. These changes include 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 qualifications of 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) to include exceptions under the latest buprenorphine practice guidelines on obtaining a waiver.
- Where needed, clarifying whether references to naltrexone refer to the oral formulation or the extended-release injectable formulation.
- Adding recent citations that support induction onto extended-release naltrexone of people with positive urine tests for opioids so long as they pass the naloxone challenge.
- Clarifying that naltrexone can result in decreased opioid cravings.
- Removing or replacing broken hyperlinks to online resources.

Executive Summary

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

Introduction

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



Estimated cost of the **OPIOID EPIDEMIC** was **\$504 BILLION** in 2015.²

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

An estimated **1.4M AMERICANS** have OUD related to opioid painkillers; **438K** 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.

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

Part 4: Bringing Together Addiction Treatment Counselors, Clients, and Healthcare Professionals

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

In Part 4, readers will learn that:

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

OPIOID ADDICTION
is linked with high rates of
ILLEGAL ACTIVITY and
INCARCERATION.^{28,29}



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

Part 5: Resources Related to Medications for Opioid Use Disorder

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

In Part 5, readers will learn that:

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



EXHIBIT 1.2. Comparison of Medications for OUD

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

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Notes

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TIP Development Participants

Expert Panelists

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

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This TIP's scientific reviewers are among the foremost experts on the three medications discussed in this TIP to treat opioid use disorder. Their role in the collaborative TIP development process was to help the KAP team include current, accurate, and comprehensive information and instructions about the use of each of these medications. (Note that affiliations reflect those relevant at the time of the individual's review.)

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Field reviewers represent each TIP's intended target audiences. They work in addiction, mental health, primary care, and adjacent fields. Their direct front-line experience related to the TIP's topic allows them to provide valuable input on a TIP's relevance, utility, accuracy, and accessibility. (Note that affiliations reflect those relevant at the time of the individual's review.)

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Disclaimer

The views, opinions, and content expressed herein are the views of the consensus panel members and do not necessarily reflect the official position of SAMHSA or HHS. No official support of or endorsement by SAMHSA or HHS for these opinions or for the instruments or resources described is intended or should be inferred. The guidelines presented should not be considered substitutes for individualized client care and treatment decisions.

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