Medications for Opioid Use Disorder

Primary Care Practice Toolkit

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Maryland DEPARTMENT OF HEALTH

Bringing all the pieces together for a healthier community

ACKNOWLEDGMENTS

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DEVELOPMENT TEAM

Marla Oros, RN, MS, FAAN
Chief Executive Officer

Heather Raley, LCPC
Senior Behavioral Health Consultant

Alyssa Thaxton, LCSW
Senior Behavioral Health Consultant

Ajuga, Inc., Graphic Design

ABOUT MOSAIC GROUP

Mosaic Group is nationally recognized for effectively implementing community health and human services strategies to advance health equity. Our primary focuses are:

- Community Solutions for Health Equity
- Complex Planning for Sustainable Change
- Behavioral Health Integration
- Overdose Prevention and Response

Mosaic Group
1122 Kenilworth Drive, Suite 313
Towson, MD 21204
410-852-4263
groupmosaic.com

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Background

According to the CDC, Maryland's overdose rate nearly doubled from 20.9 deaths per 100,000 in 2015 to 44.6 in 2020. While 2022 saw a slight decline compared to 2021, the number of overdose fatalities remains critically high, with overdose deaths continuing to impact Maryland at an alarming rate.

MOUD is a key element in addressing the opioid crisis. When combined with supportive counseling, it has been shown to reduce overdose deaths and opioid use, increase treatment retention, and lower the risk of related health issues, such as infectious diseases. As an evidence-based, first-line approach to opioid use disorder treatment, expanding access to MOUD is essential, particularly in areas with limited resources and high demand.

In 2024, Mosaic Group conducted a comprehensive landscape analysis of MOUD access in Maryland. The analysis revealed that current Opioid Treatment Programs (OTPs) lack sufficient capacity to meet treatment demand, highlighting the need to increase the number of office-based MOUD prescribers within primary care practices.

Purpose

Mosaic Group's "Medications for Opioid Use Disorder Primary Care Practice Toolkit" was created in collaboration with the Maryland Primary Care Program Management Office at the Maryland Department of Health. The primary objective of this partnership is to broaden access to Medications for Opioid Use Disorder (MOUD) in primary care settings. This toolkit provides comprehensive guidance on implementing clinical guidelines and billing practices to effectively integrate MOUD into clinical environments.

While individual practices have received specific clinical protocols for MOUD implementation, the toolkit is designed to support prescribers in adopting MOUD. Its goal is to streamline the integration of MOUD into primary care, improving the quality of care and ease of access to this life-saving treatment, thereby reducing the risk of overdose.

Use

This toolkit is designed to supply resources for providers, staff and patients. Please ensure that the only tools given to patients are the tools where the intended audience is the Patient. The tools that are intended for the Patient may be branded with your practice-specific information. Please see below for a summary of each tool.

TITLE	AUDIENCE	PURPOSE
Getting Started with Buprenorphine	Provider	A comprehensive guide to assist healthcare providers through the continuum of supporting patients interested in Medications for Opioid Use Disorder (MOUD). This tool guides providers through the process of patient assessment and diagnosis, to treatment and follow-up, including the use of diagnostic and billing codes.
Provider Information on MOUD	Provider	A tool for healthcare providers highlighting considerations for each form of MOUD. This tool is designed as a quick reference for the provider to support shared decision-making by providing detailed information on each medication, enabling informed discussions and choices that align with the patient's needs and preferences.
Provider Quick Induction Guide	Provider	This tool, designed specifically for providers, is helpful when initiating a patient on MOUD. It serves as a quick guide for best practice prescribing during initiation.
"How To Take Buprenorphine At Home" Induction Guide	Patient	This tool is a guide for patients to take home and keep in hand during buprenorphine induction. It reviews how to take the medication, possible side effects, and step-by-step instructions on evaluating their withdrawal symptoms to determine the need for additional medication.
Prescriber Resource Guide	Provider/ Practice Staff	This guide lists Maryland-specific resources for patients needing a higher level of substance use or mental health treatment, or having social needs. It also includes prescriber resources for MOUD.
Medical Assistant and Office Staff FAQ	Provider/ Practice Staff	This document will provide support to MAs and additional support staff on questions frequently asked by patients. This reference includes education on opioid withdrawal, scheduling, medication refills and more.
Billing and Coding for Office-Based Treatment	Provider/ Practice Staff	This guide was designed to assist primary care practices while navigating the billing and reimbursement process when delivering care for OUD. It includes guidance on toxicology testing, various forms of appointments, telehealth modifiers and Medicare bundled codes for practices with embedded behavioral health services.
Point of Care Testing in Primary Care	Provider/ Practice Staff	This serves as a comprehensive guide for providers and staff seeking to initiate POCT on site. It walks through considerations for ordering CLIA waived POCT tests and how to become a CLIA waived site.
Precipitated Withdrawal	Provider	This tool covers symptoms of precipitated withdrawal, prevention strategies, and treatment options.
Patient-Provider Agreement	Patient	A sample treatment agreement designed to establish a shared understanding between healthcare providers and patients, outlining safety precautions and programmatic expectations. This customizable agreement can be tailored to meet the specific needs of your practice.
Patient Information on Medication Options	Patient	A patient-facing document detailing all available MOUD options, including the benefits and risks associated with each. This guide is designed to involve patients in the decision-making process and should be reviewed with patients to facilitate shared decision-making that aligns with their individual needs and goals.
MOUD and Pregnancy: A Guide for Providers	Provider	As a PCP, you may see a pregnant patient with Opioid Use Disorder. This tool offers essential information to support decision-making for maternal and fetal health with the use of MOUD.

Getting Started with Buprenorphine

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Quick Reference for MOUD Assessment and Prescribing

This document provides a quick reference guide for assessing, diagnosing, and treating Opioid Use Disorder with buprenorphine. We encourage you to use your clinical judgment when supporting a patient by modifying these steps as needed.

1. Assess

- ☐ Obtain chief complaint and history of presenting illness
- ☐ Conduct History and Physical:
  - Past medical and psychiatric history
  - Substance use history, including:
    - Frequency of use (including last use)
    - Duration of use
    - Type of substances
    - Route of administration
    - Prior treatment attempts (including any medication trials)
  - Evaluation of family and psychosocial supports
  - Physical exam
- ☐ Consider lab testing:
  - Complete blood panel, basic metabolic panel and liver function tests
  - Infectious disease testing (HIV and Hepatitis panel, consider STD/STI panel as appropriate)
  - Urine toxicology testing
  - Pregnancy test

2. Diagnose

- ☐ Confirm patient meets criteria for moderate or severe Opioid Use Disorder diagnosis (see back) within the last 12 months
- ☐ Record any other substance use disorder diagnoses

3. Treat

- ☐ Review prescription drug monitoring database:
  - Identify unreported use of other medications
  - Ensure there isn't a recent prescription of MOUD
  - Be aware of other medications that may interact adversely with MOUD (benzodiazepines, opioid pain medication)
- ☐ Prescribe buprenorphine/naloxone SL 8-2mg
- ☐ Consider prescribing Narcan (Naloxone HCL Nasal Spray, 4mg)
- ☐ Consider pre-exposure prophlyxis (PrEP) based on risk factors
- ☐ Consider antivirals/antiretrovirals based on laboratory findings
- ☐ Review all FDA-approved MOUD options with patient

4. Educate

- ☐ Provide patient education on all prescribed medication
- ☐ Discuss safe storage of medication—secure and out of the reach of others
- ☐ Deliver harm reduction education

5. Support

- ☐ Refer to appropriate behavioral health support, as needed (individual or group counseling, intensive outpatient program, etc.)
- ☐ Discuss the availability of mutual support groups and peer recovery coach support
- ☐ Refer to other community resources (as needed)

6. Follow-up

- ☐ Schedule timely follow-up visits during each stage:
  - Initiation (within first 3-5 days)
  - Stabilization (weekly)
  - Maintenance (monthly)

7. Document

- ☐ Document all screening results, assessments, interventions, and treatment plans
- ☐ Bill for MOUD services (see back)

QUICK REFERENCE

Opioid Use Disorder DSM-5 Criteria

For treatment with MOUD, the patient must meet criteria for moderate (4 or more) or severe (6 or more) Opioid Use Disorder within the last 12 months.

- Opioids taken in a larger amounts or over longer period than intended.
- Desire or unsuccessful efforts to cut down or control opioid use.
- Spending a great deal of time in obtaining, using, and recovering from opioids.
- Craving or strong desire or urge to use opioids.
- Social, occupational, or recreational activities are given up or reduced due to opioid use.
- Recurrent opioid use in situations where it is physically dangerous.
- Continued opioid use despite knowledge of persistent or recurrent physical or psychological problem that is likely to have been caused or exacerbated by the substance.
- Tolerance for opioids.
- Withdrawal symptoms when periods without opioids.

Please note that tolerance and withdrawal alone do not meet criteria for an opioid use disorder.

Diagnostic Codes

OPIOID USE DISORDER CLASSIFICATION	ICD-10 CODE
Moderate (4-5 symptoms)	F11.20
▪ In early remission	F11.21
▪ In sustained remission	F11.21
Severe (6 or more symptoms)	F11.20
▪ In early remission	F11.21
▪ In sustained remission	F11.21

Billing Codes for MOUD

This document offers a quick-reference overview of CPT billing codes for MOUD appointments. For a comprehensive guide, consult the MOUD Billing Guide provided by Mosaic Group.

Key factors for determining the appropriate level of service (LOS) are Time and Complexity of Medical Decision Making (MDM).

- **Time-based coding** differs between new and established patients (see table at right) and includes both face-to-face and non-face-to-face time spent by the provider on the day of the appointment. Document the time spent per encounter in the medical record.
- **MDM-based coding** includes the following three elements—at least two of these elements must meet the complexity threshold:
  - Number of possible diagnoses and/or management options
  - Amount and/or complexity of data to be obtained and reviewed
  - Risk of complications, morbidity, and/or mortality

BILLING CODE	TIME-BASED CODING	MDM-BASED CODING
New Patient		
99202	15-29 mins	Straightforward
99203	30-44 mins	Low
99204	45-59 mins	Moderate
99205	60-74 mins	High
Established Patient		
99211	N/A (minimal needs)	N/A (minimal needs)
99212	10-19 mins	Straightforward
99213	20-29 mins	Low
99214	30-39 mins	Moderate
99215	40-54 mins	High

REFERENCES

SAMHSA. (2021.) Treatment Improvement Protocol (TIP) 63. *Medication for Opioid Use Disorder.*

SAMHSA. (2021.) *Practical Tools for Prescribing and Promoting Buprenorphine in Primary Care Settings.*

American Psychiatric Association. (2022). *Diagnostic and Statistical Manual of Mental Disorders. DSM-S-TR.*

MEDICATIONS FOR OPIOID USE DISORDER

Provider Information On Medications

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This tool is designed to support your shared decision-making process when discussing medication options for opioid use disorder with your patients. During these conversations, it's essential to engage in a thorough discussion of the risks and benefits of each medication, including potential side effects, the risk of dependence, and available alternatives.

Currently, three medications are approved for the treatment of opioid use disorder: methadone, buprenorphine, and naltrexone.

While methadone is typically administered in specialized treatment settings, buprenorphine and naltrexone can be prescribed or administered by primary care providers in office-based settings.

Encourage patients to actively participate in the decision-making process to ensure the treatment aligns with their needs and goals.

BRAND NAME *(GENERIC NAME)*	METHOD OF ADMINISTRATION	GETTING STARTED	MEDICATION CONSIDERATIONS
Buprenorphine Products			
Suboxone™ *Buprenorphine/ Naloxone*	▪ **Method of Administration:** Sublingual Film or Tablet ▪ **Frequency:** Daily ▪ **Dosage Forms:** Four dosage forms available—most common is 8 mg buprenorphine/2 mg naloxone ▪ **Dosing Flexibility:** Ease of modified dosing with ability to cut strips/split pills	▪ Opioid-dependent patients must be in at least moderate withdrawal. Assess using the COWS in-office or through a self-assessment for home induction. ▪ Opioid naïve patients with a history of OUD will not be in withdrawal.	▪ **Addresses Opioid Withdrawal:** Effective in managing withdrawal symptoms. ▪ **Efficacy:** Effective in reducing opioid cravings and withdrawal symptoms. ▪ **Benefits:** Widely available, lower cost with generic options, higher safety profile due to respiratory ceiling effect. ▪ **Risks:** Causes physical dependence. ▪ **Opioid Intolerance:** Can create an environment for fatal overdose if misuse occurs. ▪ **Consultation:** Consider in consultation with a board-certified addiction physician or nurse practitioner. ▪ **Pharmacy:** Widely available at most pharmacies. ▪ **Authorization:** Typically covered by most formularies.
Zubsolv™ *Buprenorphine/ Naloxone*	▪ **Method of Administration:** Sublingual Tablet ▪ **Frequency:** Daily ▪ **Dosage Forms:** Six dosage forms available—most common is 5.7 mg buprenorphine/1.4 mg naloxone ▪ **Dosing Flexibility:** Ease of modified dosing with ability to cut tablets	▪ Opioid-dependent patients must be in at least moderate withdrawal. Assess using the COWS in-office or through a self-assessment for home induction. ▪ Opioid naïve patients with a history of OUD will not be in withdrawal.	▪ **Addresses Opioid Withdrawal:** Effective in managing withdrawal symptoms. ▪ **Efficacy:** Similar to Suboxone with effective craving and withdrawal symptom management. ▪ **Benefits:** Preferred by some for taste and quicker dissolution. ▪ **Risks:** Causes physical dependence. ▪ **Opioid Intolerance:** Can create an environment for fatal overdose if misuse occurs. ▪ **Consultation:** Consider in consultation with a board-certified addiction physician or nurse practitioner. ▪ **Pharmacy:** Variable formulary coverage; may require prior authorization. ▪ **Authorization:** May require prior authorization or may not be covered.
Sublocade™ *Buprenorphine (Extended Release)*	▪ **Method of Administration:** Subcutaneous Injection ▪ **Frequency:** Monthly ▪ **Dosage Forms:** Injection for subcutaneous use at 100 mg-300 mg ▪ **Injection Sites:** Injected only into the abdomen ▪ **Special Requirements:** ▪ Requires preparation and administration by a healthcare provider. ▪ Requires refrigeration and storage in compliance with manufacturer, DEA and state regulations.	▪ Treatment initiation requires a minimum of 7 days of sublingual buprenorphine use prior to starting Sublocade. ▪ **Black Box Warning:** Medication must be prepared and administered by a healthcare provider, requires REMS registration.	▪ **Addresses Opioid Withdrawal:** Effective in managing withdrawal symptoms. ▪ **Efficacy:** Effective in maintaining opioid dependence management with a built-in taper. ▪ **Benefits:** Provides stable plasma concentrations; may have less frequent dosing. ▪ **Risks:** Causes physical dependence; added risk of injection site reactions. ▪ **Opioid Intolerance:** Creates an environment for fatal overdose if misuse occurs. ▪ **Consultation:** Consider in consultation with a board-certified addiction physician or nurse practitioner. ▪ **Pharmacy:** Available through specialty pharmacies or 'buy and bill' process. ▪ **Authorization:** Requires prior authorization, variable coverage, and copays; copay assistance may be available.

BRAND NAME *(GENERIC NAME)*	METHOD OF ADMINISTRATION	GETTING STARTED	MEDICATION CONSIDERATIONS
Brixadi™ *Buprenorphine*	▪ **Method of Administration:** Subcutaneous Injection ▪ **Frequency:** Weekly or Monthly ▪ **Dosage Forms:** · Weekly: 8 mg/16 mg/32 mg · Monthly: 64 mg/96 mg/128 mg ▪ **Injection Sites:** May be injected into the abdomen, upper arm, or thigh	▪ No waiting period required after the last use of sublingual buprenorphine. ▪ Treatment may begin when the patient is in withdrawal after a single dose of oral buprenorphine.	▪ **Addresses Opioid Withdrawal:** Effective in managing withdrawal symptoms. ▪ **Efficacy:** Effective in managing opioid dependence. ▪ **Benefits:** Provides sustained release and effective management. ▪ **Risks:** Causes physical dependence. ▪ **Opioid Intolerance:** Creates an environment for fatal overdose if misuse occurs. ▪ **Consultation:** Consider in consultation with a board-certified addiction physician or nurse practitioner. ▪ **Pharmacy:** Available through specialty pharmacies or 'buy and bill' process. ▪ **Authorization:** Requires prior authorization, variable coverage, and copays; copay assistance may be available.
Naltrexone Products			
ReVia™, Depade™ *Naltrexone*	▪ **Method of Administration:** Oral Tablet ▪ **Frequency:** Daily ▪ **Dosage Forms:** Single dosage form available—typically 50 mg tablet	▪ Requires a 7-10 day period of full agonist opioid abstinence for opioid-dependent patients to safely initiate treatment.	▪ **Addresses Opioid Withdrawal:** Not primarily used for managing withdrawal; focuses on relapse prevention and blocking opioid effects. ▪ **Efficacy:** Limited data; effectiveness may vary based on patient history and adherence to prior treatment. ▪ **Benefits:** May be more safely considered after an extensive period of sobriety on agonist MOUD. ▪ **Risks:** Increased risk of fatal overdose; creates an environment for fatal overdose if dose is missed, delayed, stopped, or overridden due to opioid intolerance. ▪ **Opioid Intolerance:** Increased risk of fatal overdose; use is strongly discouraged due to opioid intolerance. ▪ **Consultation:** Consider only in consultation with a board-certified addiction physician or nurse practitioner. ▪ Initiation Requirements: Requires a 7-10 day period of full agonist opioid abstinence for those dependent on opioids to safely initiate. ▪ **Pharmacy:** Variable; often requires specialized handling. ▪ **Authorization:** Often requires prior authorization.
Vivitrol™ *Naltrexone (Extended Release)*	▪ **Method of Administration:** Deep Intramuscular Gluteal Injection ▪ **Frequency:** Monthly ▪ **Dosage Forms:** Injectable suspension 380 mg/vial ▪ **Special Requirements:** · Requires preparation and administration by a healthcare provider. · Requires refrigeration and storage in compliance with manufacturer, DEA and state regulations. · Needs to rise to room temp for at least 45 minutes prior to injection.	▪ Requires a 7-10 day opioid-free interval for opioid-dependent patients to safely initiating treatment.	▪ **Addresses Opioid Withdrawal:** Not primarily used for withdrawal; focuses on relapse prevention. ▪ **Efficacy:** Variable impact on cravings; mainly used for relapse prevention. ▪ **Benefits:** Non-controlled substance, may be beneficial after extensive sobriety on agonist MOUD. ▪ **Risks:** Increased risk of fatal overdose if dose is missed or overdose occurs due to opioid intolerance. ▪ **Opioid Intolerance:** Creates an environment for fatal overdose if dose is missed or overridden. ▪ **Consultation:** Must be considered in consultation with a board-certified addiction physician or nurse practitioner. ▪ **Pharmacy:** Typically ordered through specialty pharmacies; may be available at retail pharmacies depending on health plan. ▪ **Authorization:** Often requires prior authorization.
Methadone Products			
Dolophine™ *Methadone*	▪ **Method of Administration:** Oral Tablet, Liquid, or Wafer ▪ **Frequency:** Daily ▪ **Dosage Forms:** Tablets (not used for those with OUD in OTP settings), Liquid, Wafer ▪ **Dosing Flexibility:** Limited flexibility; tablets not used for OUD in OTP settings, but other forms can be adjusted	▪ May only be dispensed by a certified opioid treatment program. ▪ Patient must be willing and able to attend opioid treatment program daily when beginning treatment.	▪ **Addresses Opioid Withdrawal:** Effective in managing withdrawal symptoms and cravings. ▪ **Efficacy:** Effective in managing opioid dependence with a structured dosing regimen. ▪ **Benefits:** Provides increased structure with daily dosing; covered by many insurance plans. ▪ **Risks:** Causes physical dependence; risk of QTc prolongation; requires gradual dose titration. ▪ **Opioid Intolerance:** Creates an environment for fatal overdose if misuse occurs. ▪ **Consultation:** Risk/benefit discussion required between patient and opioid treatment program. ▪ **Pharmacy:** Often covered by Medicare, Medicaid, and private insurance. ▪ **Authorization:** Generally covered but may involve specific program requirements.

MEDICATIONS FOR OPIOID USE DISORDER

Provider Quick Induction Guide

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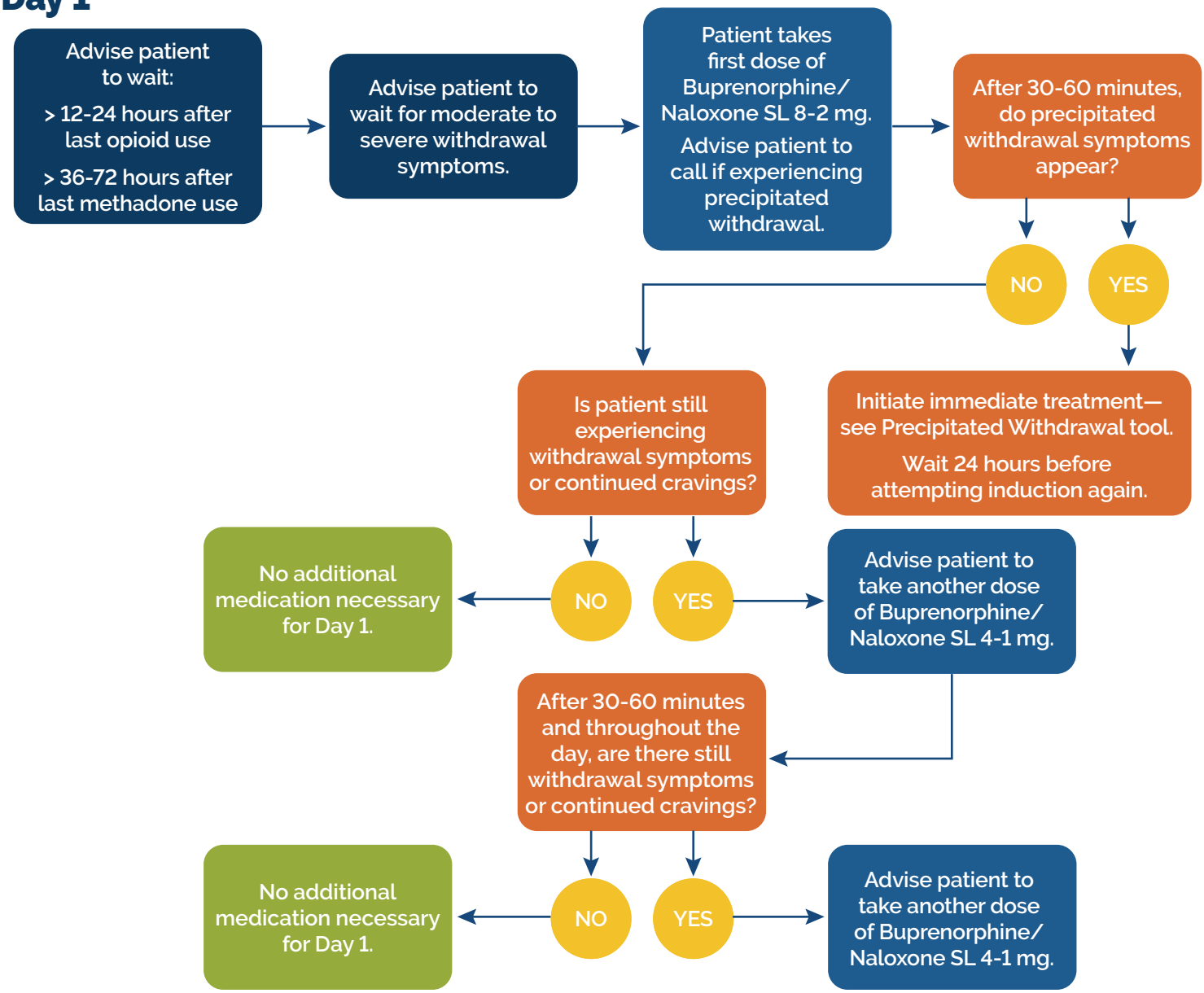
This guide aims to equip prescribers with the essential knowledge and best practices for initiating buprenorphine effectively and safely. Whether you are new to prescribing buprenorphine or looking to refine your approach, this guide offers practical recommendations to support your practice in combating the opioid epidemic.

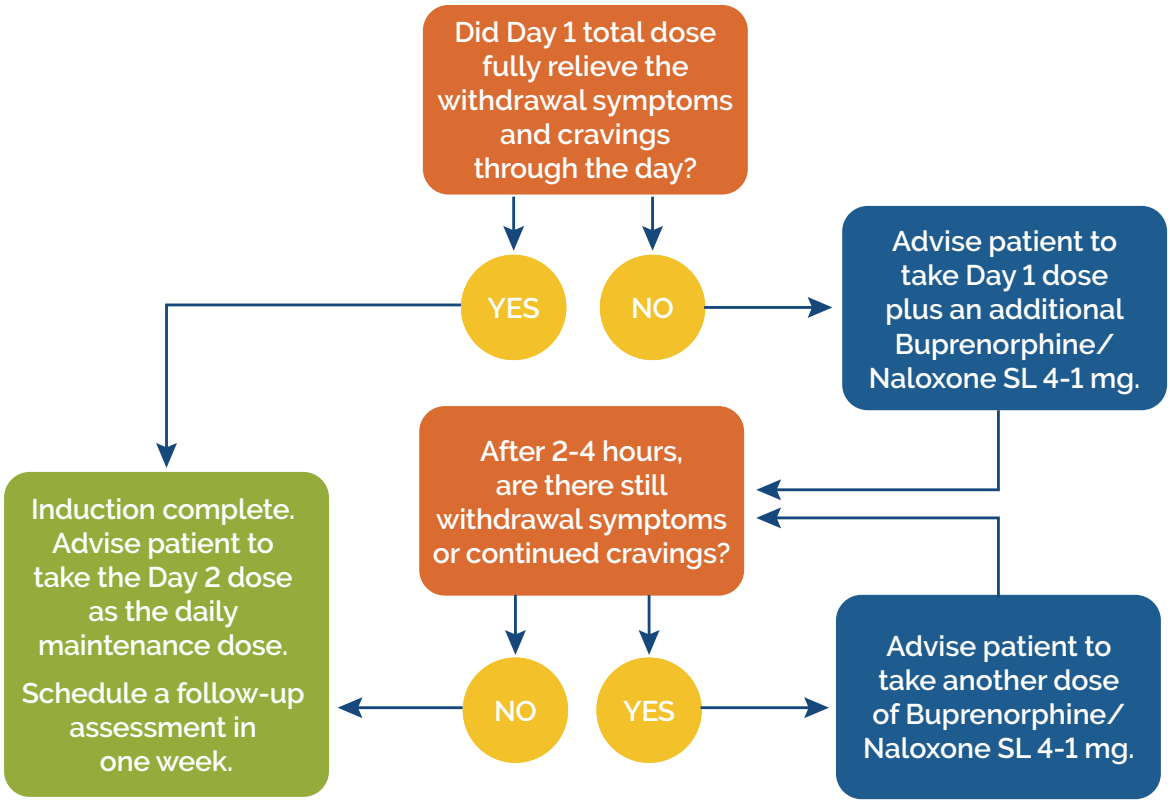
This tool is intended to be utilized when reviewing initial dosing with a patient or when a call is received from a patient that is not yet on a stable dose. It includes the maximum dosage each day to quickly reference when e-prescribing 1, 2, or 3 days worth of buprenorphine/naloxone.

Day 1



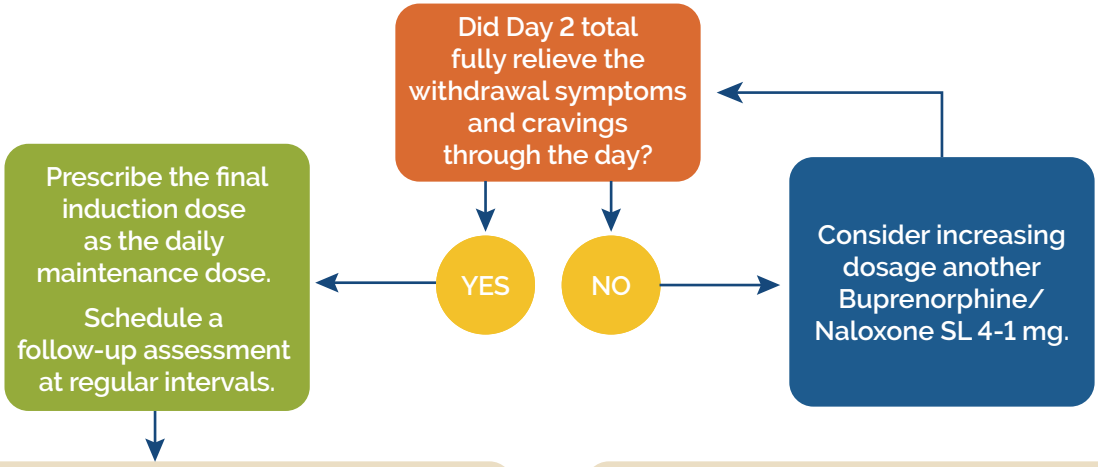
Maximum total daily dose: Buprenorphine/Naloxone SL 16-4 mg.

Day 2



Maximum total daily dose: Buprenorphine/Naloxone SL 24-6 mg.

Day 3+



Initial Management Plan:

- Conduct regular drug screenings initially, transitioning to random screenings over time.
- Regularly check the Prescription Drug Monitoring Program (PDMP).
- Encourage consistent attendance at counseling and support groups.
- If cravings or withdrawal symptoms persist beyond a dose of Buprenorphine/Nalxone SL 32-8 mg, consider consulting an addiction specialist for further evaluation.

Long-Term Management:

- Once the patient is stable on the medication, assess their readiness for transitioning to monthly appointments.
- Continue monitoring and adjusting the dose based on cravings or withdrawal symptoms.
- If cravings or withdrawal symptoms persist beyond a dose of Buprenorphine/Nalxone SL 32-8 mg, consider consulting an addiction specialist for further evaluation.

Maximum total daily dose Day 3: Buprenorphine/Naloxone SL 24-7 mg.
Maximum total daily dose Days 4, 5: Buprenorphine/Naloxone SL 32-8 mg.

PATIENT INSTRUCTIONS

How To Take Buprenorphine At Home

Starting Medication for Opioid Use Disorder (MOUD)

The goal of MOUD is to reduce cravings and withdrawal symptoms quickly. Follow these instructions closely to avoid worsening symptoms.

Before You Begin

- **A step-by-step guide** is provided on the reverse side to help you start your medication.
- **Start with Step 1** if you are NOT currently using buprenorphine.
- **If you are currently using buprenorphine,** skip Step 1 and go directly to Step 2.

General Guidelines

- If possible, **have a family member or trusted friend with you** during your first dose to help monitor how you're feeling and assist if needed.
- **Avoid alcohol and sedative medications like benzodiazepines** (e.g., Xanax) while taking buprenorphine.
- **Wait until you experience severe withdrawal symptoms before taking your first dose**. Waiting for these severe symptoms ensures that buprenorphine will work effectively. These symptoms include:
  - Intense muscle pain
  - Severe anxiety
  - Vomiting or diarrhea
  - Rapid heartbeat

Warning: Precipitated Withdrawal

Taking buprenorphine too soon after using opioids like heroin, fentanyl, or pain pills can cause precipitated withdrawal—a sudden worsening of symptoms within 30-60 minutes. Unlike common side effects, these symptoms are severe and require medical attention. precipitated withdrawal symptoms include:

- Intense muscle pain or cramping
- Severe nausea, vomiting, or diarrhea
- Sweating, chills, or worsening goosebumps
- Sudden anxiety, agitation, or feeling very unwell
- Enlarged pupils, uncontrollable shaking, or fast heartbeat

If you experience these symptoms after your first dose, **call your doctor immediately**.

Common Side Effects

You may experience side effects after your first dose. These are normal and should improve as your body adjusts to the medication. They include:

- Headache
- Mild dizziness
- Numbness or tingling
- Drowsiness or trouble sleeping (insomnia)
- Stomach pain, vomiting, or constipation
- Redness, pain, or numbness in your mouth
- Feeling "drunk" or intoxicated
- Trouble concentrating

Keep out of reach of children. If a child consumes this medication or you begin to feel worse or have adverse reactions, visit your local hospital emergency department or call Poison Control toll-free at (800) 222-1222.

Step-by-Step Guide for Taking Buprenorphine

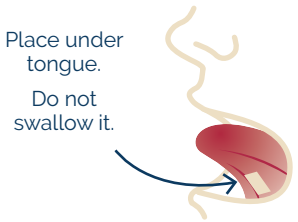
1

Start here if you are NOT currently using buprenorphine.
If you are currently using buprenorphine, skip this step and start on Step 2.

- **Do NOT take buprenorphine if your symptoms are mild or just starting.**
- **Wait until you have multiple severe withdrawal symptoms**, such as:
  - ☐ Achy joints or bones
  - ☐ Fast heartbeat
  - ☐ Anxiety or irritability
  - ☐ Flu-like symptoms (runny nose, watery eyes)
  - ☐ Nausea, diarrhea, or vomiting
  - ☐ Uncontrollable shaking
  - ☐ Yawning
  - ☐ Loss of appetite

2

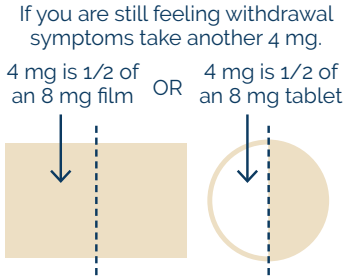
First Dose: Take an 8 mg buprenorphine film or tablet.



- **Take everything out of your mouth** (gum, food, drinks).
- **Wet your mouth with water**, then swallow or spit it out.
- **Place the 8 mg film or tablet under your tongue and let it dissolve.**
  - Do not suck on or swallow the film/tablet. If you swallow it, it will not work.
  - Do not eat, drink, or talk for 3-5 minutes while it dissolves.
  - You may spit out your saliva once the medicine is fully dissolved.

3

Wait 30-60 Minutes.



- **Check how you feel after 30-60 minutes:**
  - **If you feel better**, do not take more medication.
  - **If you still have symptoms**, take 4 mg more (half a film or tablet).
  - **If your symptoms get worse quickly** after the first dose, you may be experiencing precipitated withdrawal. Call your doctor immediately.
- **Do not exceed 16 mg total on Days 1-3.**

4

Keep Track of Your Daily Dose.

- **Make a note of your total daily dosage:**
  - ☐ I took 8 mgs (1 whole film or tablet) in total today.
  - ☐ I took 12 mgs (1 and 1/2 films or tablets) in total today.
  - ☐ I took 16 mgs (2 whole films or tablets) in total today.
- **If you still have withdrawal symptoms after 16 mg in 24 hours,** please call your doctor to discuss a higher dose.

5

Day 2 Onward.

- **Take the same amount you took in total on Day 1** as your daily dose.
- **If you still feel moderate to severe symptoms after 30-60 minutes**, take another 4 mg.
- **Do not exceed 16 mg total per day** without speaking to your doctor.
- **Plan to see your provider within the next ____ days.**

MEDICATION FOR OPIOID USE DISORDERS

Prescriber Resources

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As a primary care provider, your patients often have multi-dimensional and ever-changing needs. Whether you have a specific question or are looking to enhance your knowledge, improve patient outcomes, or stay updated on the latest advancements, these resources provide valuable insights and practical tools for healthcare professionals committed to delivering high-quality care.

Maryland Resources

Maryland Addiction Consultation Services (MACS)

MACS is a free resource provided by addiction specialists at the University of Maryland School of Medicine. It offers guidance on MOUD, co-occurring mental health conditions, harm reduction, and pain management. MACS also provides free resources, including clinical toolkits, patient education materials, and training opportunities for healthcare providers in Maryland. Prescribers can access support through a warm line or by scheduling a consultation on the website.

- **Website:** https://www.marylandmacs.org
- **Call:** 1-855-337-MACS (6227)

MACS for MOMs

MACS for MOMs, a division of MACS, provides free support, resources, and training for providers treating **pregnant and postpartum individuals**. It offers guidance on issues such as use of MOUD while pregnant or breastfeeding, neonatal abstinence syndrome (NAS), relapse prevention, and perinatal mental health.

- **Website:** https://www.medschool.umaryland.edu/macsformoms
- **Call:** 1-855-337-MACS (6227)

Maryland's Office of Overdose Response

Maryland's Office of Overdose Response provides information in English and Spanish for providers and community members to obtain Naloxone, learn about opioid medication drop-off, syringe exchange, overdose prevention, and more.

- **Website:** https://stopoverdose.maryland.gov/resources

988 Suicide & Crisis Lifeline

988 is a nationwide substance use, mental health and suicide prevention support line. Patients can call (or text or chat) 9-8-8 to talk and to connect with services when they need immediate support or are in crisis.

- **Website:** https://health.maryland.gov/bha/Pages/988md.aspx
- **Call or Text:** 988

211 Maryland

211 Maryland is a statewide network that connects individuals to local resources for various needs, including substance use, mental health, housing, and more. It's available in English and Spanish, and people can seek help for themselves, a family member, or a friend.

- **Website:** https://211md.org
- **Call:** 211

MDHope

MDHope is part of the 211 Maryland network of resources. By texting "MDHOPE" to 898-211, individuals can sign up to receive local resources based on their zip code. The system asks questions about whether the service is for the person texting, a friend/family member, or a client/patient, and then provides relevant information such a treatment centers, overdose reversal medication information, safe disposal sites, prevention support and much more.

- **Website:** https://211md.org/resources/substance-use/mdhope
- **Text:** "MDHOPE" to 898-211
- **Call:** 211

Prescribing Tools

SAMHSA TIP 63: Medications for Opioid Use Disorder

This Treatment Improvement Protocol (TIP) for healthcare professionals reviews the use of the three FDA-approved medications used to treat OUD: methadone, naltrexone, and buprenorphine. It also covers other strategies and services needed to support recovery for people with OUD.

- **Website:** https://store.samhsa.gov/product/tip-63-medications-opioid-use-disorder/pep21-02-01-002

SAMHSA Practical Tools for Prescribing and Promoting Buprenorphine in Primary Care Settings

This resource provides information to primary care providers and practices on how to implement OUD treatment using buprenorphine. It identifies common barriers and strategies to overcome them. It documents step-by-step tactics to support buprenorphine implementation.

- **Website:** https://www.samhsa.gov/resource/ebp/practical-tools-prescribing-buprenorphine-primary-care

Boston Medical Center MOUD Quick Start APP

This mobile or online application offers helpful branching logic to guide providers through the initiation or maintenance of medications for opioid use disorder (MOUD), including naltrexone and buprenorphine. It also contains numerous tools and resources to assist providers in managing MOUD treatment.

- **Apple App Store:** https://apps.apple.com/us/app/bmc-mat-quick-start/id1524468581
- **Google Play Store:** https://play.google.com/store/apps/details?id=org.bmcobat.app

Other Community Resources to Address Health-related Social Needs

FindHelp.org

FindHelp is an online, searchable resource that allows users to find free or reduced-cost resources like food, housing, financial assistance, health care, and more. Resources can be filtered by location and service type.

- **Website:** https://www.findhelp.org

FindTreatment.gov

This online, searchable resource provided by SAMHSA to help identify mental health and substance use treatment services. Resources can be filtered by location and service type.

- **Website:** https://www.findtreatment.gov

MEDICATIONS FOR OPIOID USE DISORDER

Medical Assistant & Office Staff Frequently Asked Questions (FAQ)

mosaic GROUP

We recognize that treating patients with opioid use disorder might be new for your practice and staff. Our aim is to support you through this transition. We hope that this guide, along with the training provided, will deepen your understanding of the disease and equip you with the tools and confidence needed to deliver effective care. Your commitment to expanding your knowledge is crucial in making a positive impact on your patients' lives.

Opioid Use Disorder (OUD)

Q. What are opioids?

A. Opioids are a type of drug that affects the brain, often providing pain relief. Some opioids, like Fentanyl, Percocet, Oxycontin, and Vicodin, are legal when used as prescribed by a healthcare provider. When they're misused or bought illegally, they can be dangerous. On the other hand, drugs like heroin are always illegal. While opioids can ease pain, they can also cause a euphoric 'high,' especially in larger doses. Even a small amount can lead to an overdose, and opioids are involved in over 80% of fatal overdoses.

Q. What is opioid use disorder?

A. Opioid use disorder is a chronic and often deadly disease that millions of Americans experience. OUD is typically diagnosed when a person is physically dependent on opioids and experiences loss of control of their use, negative consequences from their use and/or increased time spent using or inability to cut down their use. The course of the disease is different for everyone; however, it is chronic, progressive, and if left untreated, may be fatal.

Q. What are the common symptoms of opioid withdrawal?

A. Agitation, muscle aches, restlessness, anxiety, increased tearing, runny nose, excessive sweating, inability to sleep, yawning often, diarrhea, abdominal cramping, nausea and vomiting, skin goose bumps, dilated pupils, rapid heartbeat and high blood pressure.

Q. What does it feel like to be in opioid withdrawal?

A. Withdrawal symptoms may vary widely from person to person, as may the intensity and timeline for these symptoms. Opioid withdrawal typically starts with anxiety and a sick feeling in the pit of the stomach. Stomach problems and muscle cramping soon follow. Patients experiencing muscle cramping report extreme tensing of muscles and feeling locked up and unable to move. Nausea, vomiting and diarrhea and the feeling of "bones wanting to rip out of the body" may be experienced next. Patients have reported that they feel like they have been run over by a truck and their mind is racing, only able to focus on making it stop. Patients may not be able to get comfortable, making sleep almost impossible. Patients report self-loathing and extreme body pain and because of this, the brain knows obtaining or resuming use will immediately end this feeling. While opioid withdrawal is most often not fatal, a person experiencing it will report they are in agony.

Q. Can't people just stop using opioids? Why do they need medication?

A. OUD has both psychological and physical components resulting from changes in the brain chemistry. It should be thought of like any other chronic illness—like high blood pressure or diabetes. Treatment recommendations for all chronic illnesses often involve lifestyle changes AND medication to reduce or eliminate symptoms. Medication significantly increases the chances that a patient will maintain sobriety and makes the recovery process safer. Contrary to myth, MOUD is not 'replacing one addiction with another'. Patients are replacing the illicit use of a harmful substance with a prescribed and monitored medication.

Scheduling

Q. When the provider determines that they are going to initiate MOUD treatment with a patient, how frequently should I schedule follow-ups?

A. This will depend on the length of time the patient has been on MOUD and the provider's preference. Typically, in the induction stage, and until the patient is on a stable (within the first 5-7 days), they may be seen weekly. Once the patient is in the maintenance stage, visits are spaced out to biweekly and then they would typically be seen monthly for a follow-up. The visit frequency and duration may vary based on your specific practice's provider preference and workflow, however, if a patient is taking their medication as prescribed and abstaining from illicit substances, they often are seen less frequently. If a provider believes they may not be taking their medication as prescribed or is continuing to struggle with illicit substance use, the provider may request they be seen more frequently.

Q. How long are the appointments?

A. This may vary by practice so please clarify with your provider. In general, initial assessments may require 45–60-minute appointments. Follow-up appointments are often 15 minutes but may vary.

Q. What should we do if a patient misses an appointment?

A. Administrative staff should call the patient to make sure they're ok and assess for barriers to maintaining scheduled appointments. If patient answers and engages, you should schedule follow-up appointment as soon as possible—ideally that same day or the following morning (you may use Sick Visit time slots for this, consider telehealth visit as an option if practice is equipped to do so). Patients will more than likely be out of medication at this time, so the provider may consider a bridge prescription for 1-3 days to get them through to their next appointment. It will be important to find out if they are out of medication (or how much they have left) and confirm their pharmacy. Alternatively, the call can be transferred to a MA/RN to obtain these details.

Q. What should I do if a patient calls and reports that they lost their medication or it was stolen?

A. Immediately notify the provider. Confirm date/time last dose taken and pharmacy. Anticipate scheduling the patient for same/next day follow up.

Labs and Specimen Samples

Q. How often does a patient need to complete a urine drug screen and/or labs?

A. Urine drug screens are often taken at each visit at the beginning of MOUD treatment, and then may continue to be scheduled or at random. Labs may be taken on initial visits and then monthly or less frequently. They should be anticipated as part of the care, generally. Front office staff may want to clarify with a provider ahead of the patient's visit, if they should notify the patient that they need a urine sample or lab upon arrival. Office staff may anticipate collecting urine at initial visits. If the provider deems a urine sample may be necessary, it's helpful to notify the patient so that they may let you know if they need to use the restroom.

Q. Do I need to observe a urine sample?

A. Observed urine samples are not often recommended for a variety of reasons. If there are concerns about the validity of the sample provider, let your provider know. There are alternative testing options (saliva) and there are ways to assess a urine for validity (temperature, color) and if you have any discrepancies.

Q. What other testing may be needed?

A. At the initial appointment, the provider may want to collect urine samples for pregnancy (if female) and a drug panel. Initial labs may include screening for HIV and Hepatitis, a CBC and CMP, Hepatic panel, and others as the provider deems appropriate. A hepatic panel (LFTs) is recommended approximately every 6 months or at intervals decided by the provider.

Medication Refills

Q. What should I do if a patient misses an appointment and calls for medication refill?

A. Confirm date/time last dose taken, how much they have left and pharmacy. A message must be sent to provider urgently as it will likely need same day review. If the provider is out of the office, this will need to be escalated to the covering provider.

Conduct

Q. How do we proceed with patients who appear to be under the influence or become disruptive in the practice?

A. It's rare that this will happen.. If a patient appears to be under the influence, first assess the situation to determine if there is an immediate safety risk to the patient, staff, or others in the office. In a healthcare office, it's important to have a clear and consistent protocol for handling situations where a patient appears to be under the influence or becomes disruptive in general, not strictly for patients being treated for MOUD.

Q. How should we respond if a patient requests early refills?

A. Please notify the provider immediately and request that they review this request the same day. While this is concerning behavior, the provider may consider a short prescription (3-5 days) and request that the patient be scheduled for an appointment as soon as possible.

Q. What should we tell other patients or staff members who might have concerns about patients on MOUD?

A. Educating and promoting a whole-health approach often fosters understanding. MOUD is a proven and effective treatment for people who are managing their recovery. You may let them know that you believe in providing a supportive environment for all our patients as they work towards better health. Your practice's priority is to ensure that every patient receives the care they need to live a healthy life. This includes treating various health conditions, such as opioid use disorder, which, like many other conditions, requires medical management. However, it's important to be mindful of confidentiality and state that every patient's medical treatment is private and confidential. Your practice should ask that everyone respects the privacy and dignity of others

Billing and Coding for Office-Based Treatment

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This tool is designed to assist primary care practices with navigating the coding and reimbursement process by providing clear guidance on the appropriate use of CPT and ICD-10 codes when delivering care for OUD. It includes guidance on coding for various aspects of OUD treatment, including Medications for Opioid Use Disorder (MOUD), urine drug testing, and Medicare bundled codes for practices with embedded behavioral health services.

Billing Codes for Treating OUD

Office-based treatment of Opioid Use Disorder (OUD) may be integrated into primary care practices by licensed medical professionals (MD, DO, PA, APRN). Standard billing procedures and codes, used for typical E/M visits, may be utilized for these services.

Service codes used to bill for OUD are often the same as codes for other primary care visits.

Primary Care Billing for SUD Services

As for other primary care visits, the key components to select the appropriate level of service (LOS) are time and/or Complexity of Medical Decision-Making (MDM). Providers may use CPT codes for OUD treatment that they are accustomed to using for outpatient evaluation and management (E/M).

BILLING CODE	TIME-BASED CODING	MDM-BASED CODING
New Patient		
99202	15-29 mins	Straightforward
99203	30-44 mins	Low
99204	45-59 mins	Moderate
99205	60-74 mins	High
Established Patient		
99211	N/A (minimal needs)	N/A (minimal needs)
99212	10-19 mins	Straightforward
99213	20-29 mins	Low
99214	30-39 mins	Moderate
99215	40-54 mins	High

- **New Patient (99202-99205)**
  - MOUD treatment initiation visits often meet criteria for 99204 and it is not unusual for visits to be billed at 99205.
- **Established Patient (99212-99215)**
- **Prolonged Visit (+99415 and +99416)**
  - Add when time extends at least 30 minutes beyond standard visit length—beyond 75 minutes for new patients or beyond 55 minutes for established patients (e.g., in-office buprenorphine initiation or observation after an injection).
  - 30-74 minutes: Add (+99415)
  - 75-104 minutes: Add (+99415 and +99416)
  - 105+ minutes: Add (+99416) for each additional 30 minutes

Other CPT codes that may be relevant to OUD treatment include:

- **Drug Test (80305)** (e.g., immunoassay)
  - Can be billed once per day and can be used in conjunction with an E/M visit. However, it's essential to ensure it is appropriately documented as part of the patient's evaluation and treatment plan during the E/M visit. The E/M service should be separately identifiable and well-documented to avoid issues with bundling.
- **Therapeutic Injection (96372)** (e.g., naltrexone or buprenorphine)
  - Can be billed in conjunction with an E/M visit, however the E/M service must be separately identifiable from the injection service.
  - This code is typically used when the injection is administered by a healthcare provider other than the physician, or when the physician's work involved the injection itself and not other significant services.
  - When billing with an E/M code, use modifier (25) with the E/M code to indicate that a significant, separately identifiable E/M service was performed on the same day as the injection.
- **Telehealth "Modifier" Codes**
  - **Interactive Audio and Video (95 or GT),** preference for 95 or GT may vary by payor.
  - **Place of Service Code (02)** should be used to specify the service was provided via telehealth.
  - These modifier codes are added to the CPT codes noted above.

Medicare Bundled Payments for Office-Based SUD Treatment Services

The Medicare Physician Fee Schedule (PFS) includes coding and payment for a monthly bundle of office-based services for SUD treatment that includes overall management, care coordination, individual and group psychotherapy, substance use counseling and an add-on code for extraordinary circumstances requiring additional treatment and resources. Primary care practices with embedded behavioral health services may utilize bundled codes and should consider individual vs bundled reimbursement to determine which benefits the practice the most.

- **Initial Month of Treatment (G2086)**—includes intake activities, development of a treatment plan, assessments to aid in the development of the treatment plan, care coordination, individual therapy, group therapy and counseling. It requires at least 70 minutes in the first calendar month.
- **Subsequent Months of Treatment (G2087)**—includes care coordination, individual therapy, group therapy, and counseling. It requires at least 60 minutes in a subsequent calendar month.
- **Extraordinary Circumstances (G2088)**—can be billed in circumstances when effective treatment requires additional resources for a patient that subsequently exceed the resources included in the base codes. The add-on code would address extraordinary circumstances that are not contemplated by the bundled code. It can be used for each additional 30 minutes beyond the first 120 minutes and should be listed separately in addition to the primary code for primary procedure.

These codes are not limited to any particular physician or non-physician practitioner (NPP) specialty, but CMS recommends that practitioners furnishing OUD treatment services should consult with addiction specialists, as clinically appropriate.

These codes may be billed in addition to the E/M codes that are reported for E/M services.

At least one psychotherapy service must be furnished in order to bill for G2086 or G2087, as their payment rate incorporates the resource costs involved in furnishing psychotherapy.

CMS recognizes that stable patients may not require monthly psychotherapy and encourages clinicians to use existing codes that describe care management services (CPT Codes 99484, 99492, 99493, and 99494) and E/M services rather than the codes for SUD service bundles for patients who do not require at least monthly psychotherapy.

Medicare SUD bundle codes are not applicable for FQHCs or RHCs. Instead, these organizations can use CCM, CoCM, and BHI billing codes to cover these services.

Diagnostic Codes

The use of ICD-10 diagnostic codes for Opioid Use Disorder (OUD) is a critical component in the accurate identification, treatment, and billing for services related to opioid addiction. Utilizing the various types and severities of opioid dependence in billing and coding allows for increased precision in diagnosing and treating OUD.

- **Opioid Dependence, Uncomplicated (F11.20)**—A person has not developed additional significant physical or psychological complications from opioid use.
- **Opioid Dependence, in Remission (F11.21)**—A period of 3 months or more of successfully managing their condition.
- **Opioid Dependence, with Intoxication (F11.22)**—A condition of body-wide symptoms making the patient feel ill and impaired.
- **Opioid Dependence with Withdrawal (F11.23)**—Withdrawal symptoms may include cravings, sweating, nausea, vomiting, diarrhea, lack of appetite, tremors, watery eyes, runny nose, yawning, and/or muscle pain.

Medicare CPT Payment Summary 2023

CPT CODE	DESCRIPTION	PAYMENT/PATIENT NON-FACILITIES	PAYMENT/PATIENT FACILITIES
G2086	▪ Office-based treatment for substance use disorder. ▪ Includes development of the treatment plan, care coordination, individual therapy, group therapy, counseling. ▪ At least 70 minutes in the first calendar month.	$378.54	$278.37
G2087	▪ Office-based treatment for substance use disorder. ▪ Includes care coordination, individual therapy, group therapy, counseling. ▪ At least 60 minutes in a subsequent calendar month.	$343.82	$296.22
G2088	▪ Office-based treatment for substance use disorder. ▪ Includes care coordination, individual therapy, group therapy, counseling. ▪ For each additional 30 minutes beyond the first 120 minutes. ▪ List separately in addition to code for primary procedure.	$59.18	$34.38

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Providers Clinical Support System. (2021). *Reimbursement Toolkit.* https://pcssnow.org/wp-content/uploads/2021/07/Reimbursement-Toolkit.pdf

AIMS Center. (2023). *Quick Guide: CMS SUD 2023.* https://aims.uw.edu/wordpress/wp-content/uploads/2023/11/Quick-Guide-CMS-SUD-2023.pdf

MEDICATIONS FOR OPIOID USE DISORDER

Point of Care Testing in Primary Care

mosaic GROUP

The purpose of this tool is to help you and your practice become familiar with best practices for point-of-care testing (POCT) for urine toxicology screening and hCG testing related to the initiation and maintenance of medications for opioid use disorder (MOUD).

It offers crucial information for those interested in providing POCT on-site and obtaining CLIA-waived lab status, which is a federal requirement when offering such testing.

While POCT can be advantageous for initiating and maintaining patients on MOUD, it is not mandatory. Many practices choose to use traditional, send-out lab testing and send specimens to external laboratories as needed.

It is important to note that CLIA-waived POCT urine toxicology testing is a screening test and all unexpected or contested results should be sent for confirmation testing. Regardless of methodology, toxicology testing results should be considered one of several elements used in clinical decision-making.

POCT is inexpensive, simple to perform, and provides qualitative positive or negative results. Additionally, POCT can provide immediate insight into substances used including amphetamines, cocaine, benzodiazepines, many opioids, buprenorphine and THC depending on the choice of test used.

A listing of all waived tests can be found on the FDA website's list of waived analytes: https://www.cdc.gov/labquality/waived-tests.html.

POCT can be used in a primary care setting for patients initiating or maintaining MOUD as:

- Part of the initial assessment of a patient being evaluated for and treatment of opioid use disorder (OUD).
- A tool to objectively assess illicit substance and medication intake to prevent potential adverse effects of pharmacotherapy (e.g., opioid screen prior to starting naltrexone) and ensure safety.
- An accountability component of OUD treatment.
- Means to provide immediate access to outcomes including pregnancy results and/or toxicology panels to support timely clinical decision making.

Clinical Laboratory Improvement Amendments (CLIA) Certification

It can be advantageous when managing multiple patients on medications for opioid use disorder (MOUD) to incorporate on-site lab testing. CLIA-waived point-of-care (POC) urine drug tests can provide immediate insights into the presence or absence of substances, prompting meaningful discussions with patients to determine the most appropriate next steps.

Common POC tests that are particularly beneficial for patients on MOUD include urine drug panels and pregnancy tests.

What is a CLIA Waived Test?

As defined by CLIA, waived tests are categorized as "simple laboratory examinations and procedures that have an insignificant risk of an erroneous result."[1] The FDA determines which tests meet these criteria when reviewing a manufacturer's application for test system waiver.

To determine if your supplier's tests are eligible for use with a waiver, visit the **CLIA - Clinical Laboratory Improvement Amendments - Currently Waived Analytes** page on the FDA website: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfClia/analyteswaived.cfm.

Clinical Laboratory Improvement Amendments of 1988 (CLIA)

All practice sites and facilities in the United States that perform laboratory testing on human specimens for health assessment or the diagnosis, prevention, or treatment of disease are regulated under the Clinical Laboratory Improvement Amendments of 1988 (CLIA). Waived tests include test systems cleared by the FDA for home use and those tests approved for waiver under the CLIA criteria. Once a waived POCT is selected for use, the office utilizing the POCT must have, or must apply for a Certificate of Waiver (COW).

Obtaining a CLIA Certificate of Waiver

You can enroll your testing site in the CLIA program by completing an application available on the CMS CLIA website: **How to Apply for a CLIA Certificate, Including International Laboratories** at https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Downloads/HowObtainCertificateofWaiver.pdf.

As of September 2024, turnaround time for obtaining a CLIA waiver is typically 4 to 6 weeks after submission, which is subject to change. There is a fee associated with the application for obtaining a CLIA waiver. The fee varies based on the type of laboratory and the volume of testing it performs. For most practices, the fee for a CLIA waiver is typically $180 every two years. It is important to note that this fee covers the cost of the certificate, and administrative expenses associated with the CLIA program. If the practice is considering conducting more complex testing, additional fees and requirements may apply.

The application for CLIA Certification is **Form CMS-116, CLIA Application for Certification:** https://www.cms.gov/Medicare/CMS-Forms/CMS-Forms/Downloads/CMS116.pdf.

Completed applications and associated fees are submitted to the identified state agency, and practice sites may be subject to inspection by the state.

1 Centers for Medicare & Medicaid Services. (2023). How to obtain a CLIA certificate of waiver. U.S. Department of Health and Human Services. https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Downloads/HowObtainCertificateofWaiver.pdf

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U.S. Food and Drug Administration. (2023). *List of waived analytes.* U.S. Department of Health and Human Services. https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfClia/analyteswaived.cfm

Precipitated Withdrawal

Defining Precipitated Withdrawal

Precipitated withdrawal refers to the rapid onset of opioid withdrawal symptoms immediately after administering a partial opioid agonist (e.g., buprenorphine) or an opioid antagonist (e.g., naltrexone, naloxone).

Precipitated Withdrawal Symptoms

- Myalgia
- Nausea and vomiting
- Diarrhea
- Abdominal cramps
- Yawning
- Agitation and restlessness
- Rhinorrhea/lacrimation
- Piloerection
- Mydriasis

This condition can occur when transitioning to MOUD too soon after the last opioid use, particularly with buprenorphine.

Challenges with Fentanyl

The presence of fentanyl, a potent synthetic opioid, complicates buprenorphine initiation:

- Fentanyl binds strongly to opioid receptors.
- Buprenorphine, as a partial agonist, has a higher receptor affinity and displaces fentanyl.
- This displacement can trigger severe withdrawal symptoms.
- Fentanyl is fat-soluble and stored in fatty tissues, making it difficult to predict when it is safe to begin buprenorphine.

Avoiding Precipitated Withdrawal

Timing Guidelines

- Delay buprenorphine initiation for at least 24 hours after last use of fentanyl.
- Delay for 36-48 hours after last use of methadone.

Patient Counseling

- Advise patients to wait until they are in moderate to severe withdrawal before taking buprenorphine.
- Explain the slow-release properties of fentanyl to emphasize the need for delay.

Naltrexone (Vivitrol)

- Patients should be completely abstinent from any opioids or MOUD for a minimum of 7 days before starting.

Treating Precipitated Withdrawal

If a patient experiences precipitated withdrawal, advise them to contact you immediately.

Treatment Options

- **Increase buprenorphine dosage:** Administer repeat doses of 4 mg - 8 mg every 15-30 minutes until symptoms subside.
- **Prescribe Clonidine** (0.1 mg every 8 hours; caution regarding hypotension).
- **Provide an antiemetic for nausea.**
- **Recommend NSAIDs** for joint and muscle pain.
- **Revert to full opioid agonists:** Discontinue buprenorphine and consider immediate warm handoff to a community-based opioid treatment program offering methadone.

Reassurance and Symptomatic Medication

- Not advised due to minimal effectiveness and overdose risk.

Medications for Opioid Use Disorder (MOUD) Patient-Provider Agreement

[SAMPLE]

I understand the following information has been discussed with me to ensure my safety and I have had opportunity to participate in shared decision making, including asking any questions I may have:

1. **I will keep my medication in a secure place** away from children (e.g., in a lock box). I will immediately report any lost/stolen/missing medication to my provider. I understand that a higher level of care or additional stabilization may be discussed if my provider deems appropriate.
2. **I will take the medication as prescribed.** If I want to change my medication dose, I will speak with the provider first. I understand changing my dose or ingesting it in ways other than prescribed may necessitate referral to a higher level of care for my safety.
3. **I will keep my provider informed of all my medications** (including herbs and vitamins) and medical problems. I understand it is important for me to discuss any plans to engage in any other opioid treatment while under this provider's care for same.
4. **If I am going to have a medical procedure that will cause pain**, I will let my primary care provider, the provider conducting the medical procedure, and any other provider involved in my healthcare know in advance so that my pain can be adequately treated.
5. **I understand that I may be asked to provide scheduled or random drug screens** to determine if the treatment protocol is beneficial for me. I will discuss any concerns around this with my provider.
6. **I understand that I could be called at random times to bring my medication to the office for a medication count.**
7. **I understand my provider will work with me to develop an individualized treatment plan.** This may involve weekly, twice a month or monthly visits depending on my stability and disease severity.
8. **I understand that people have died by mixing buprenorphine with other drugs** like alcohol and benzodiazepines (drugs like Valium®, Klonopin® or Xanax®). I agree that I will avoid alcohol or take any benzodiazepines not prescribed while prescribed buprenorphine by my provider.
9. **I understand that treatment of opioid use disorder may involve additional modalities beyond medication.** I will remain open-minded to these discussions with my provider and consider how they may benefit my well-being.
10. **I understand that there is no fixed time for being on buprenorphine** and that the goal of treatment is to stop using all illicit drugs and become successful in all aspects of my life.
11. **I understand that I will develop a physiological dependence on buprenorphine**, meaning I will need to take the medication every day. I will experience opioid withdrawal symptoms and cravings when I go off buprenorphine, and I will discuss with my provider a plan to minimize these symptoms.
12. **I have been educated about other options** of FDA-approved medications for opioid use disorder treatment, methadone and naltrexone. Together with my provider, we have agreed that at this time, buprenorphine is the best option for me.
13. **If biologically female and of child-bearing years,**
    - **I have been educated about the increased chance of pregnancy** when stopping illicit opioid use and starting buprenorphine treatment and offered methods for preventing pregnancy.
    - **I have been educated about the effects of MOUD during pregnancy** and how these things can adversely affect my health and my current or future fetus/newborn's health. I understand that neonatal abstinence syndrome can occur when taking illicit opioids and that neonatal opioid withdrawal syndrome (NOWS) is less severe, but can still occur, when methadone or buprenorphine is taken during pregnancy, even if taken as prescribed/dispensed in substance use disorder treatment.
14. Other specific items unique to my treatment include:

_____

_____	_____	_____
PATIENT NAME (PRINT)	PATIENT SIGNATURE	DATE
_____	_____	_____
PROVIDER NAME (PRINT)	PROVIDER SIGNATURE	DATE

Adopted from Providers Clinical Support System (PCSS), Patient Agreement, 2024.

Medications for Opioid Use Disorder (MOUD) Patient Information on Medication Options

[SAMPLE]

This guide will help you understand medicines that can help recover from opioid use disorder. These medicines, called Medications for Opioid Use Disorder (MOUD), are important for your recovery.

There are three main types of medications used:

- Buprenorphine
- Naltrexone
- Methadone

Buprenorphine and naltrexone can be given by your regular health care provider during your visits. Methadone is only available at special places called Opioid Treatment Programs (OTPs) or "Methadone Clinics." If methadone is right for you, your health care provider will refer you to one of these clinics.

This guide will explain each medication, including where to get them, how to use them, how they work, and their benefits and risks. Be sure to talk with your health care provider to make sure the treatment fits your needs and goals. It's important to ask questions and be involved in making decisions about your treatment.

Overview of Buprenorphine Medications

BRAND NAME (GENERIC NAME)	HOW DO I TAKE IT?	GETTING STARTED	INFORMATION TO CONSIDER
Suboxone™ (Buprenorphine/ Naloxone) **Zubsolv™** (Buprenorphine/ Naloxone) **Subutex** (Buprenorphine)	▪ **Forms:** You can get it as a film or a tablet ▪ **How to Take:** Sublingual—place it under the tongue and let it dissolve ▪ **How Often:** Daily ▪ **Dosing Changes:** You can adjust the dose by cutting the film or splitting the pills if directed to do so by your health care provider	▪ If you are using opioids, you need to wait until your withdrawal symptoms are strong or really uncomfortable before starting to take this medication. ▪ If you're already taking buprenorphine, you don't need to wait for withdrawal symptoms to start.	▪ These medications are the most common choice for patients who are starting MOUD. ▪ These medications cost less and are often covered by most insurance plans, including Medicare and Medicaid. ▪ You can find this medication at most pharmacies. You can get a prescription and take it at home. ▪ You do not need to visit a clinic each day as you do with other medication options. ▪ If you take Suboxone or Zubsolv, you won't feel the effects of opioids if you use them afterward. ▪ Some patients prefer Zubsolv over Suboxone because they like the taste better. It also seems to dissolve faster than Suboxone. ▪ These medications can cause physical dependence, which means you can't just stop taking them on your own. You need to work with your health care provider to slowly lower the amount you take.
Sublocade™ (Buprenorphine Extended Release) **Brixadi™** (Buprenorphine Extended Release)	▪ **Forms:** Administered as an injection (shot) ▪ **How to Take:** The injection is given under your skin by a medical provider. Sublocade can only be injected into your stomach, while Brixadi may be injected into your stomach, upper arm or buttocks. ▪ **How Often:** Either weekly or monthly—your health care provider will determine how often you will get the injection	▪ **For Sublocade:** You must be taking buprenorphine tablets/strips for at least 7 days before starting this medication. ▪ **For Brixadi:** You may begin to take this medication when you are start to feel withdrawal symptoms after 1 dose of Suboxone.	▪ These medications give you a steady amount of buprenorphine over time. ▪ **Warning:** It is very dangerous to try to give yourself these injections. Only trained medical staff should do it. ▪ These medications are NOT available in regular pharmacies. ▪ Your insurance company must approve these medications before Before your health care provider can prescribe them. ▪ Your health insurance might not pay for the full cost. Ask your health care provider how much you might need to pay for each prescription. ▪ These medications can cause physical dependence, which means you can't just stop taking them on your own. You need to work with your health care provider to slowly lower the amount you take.

Overview of Naltrexone Medications

BRAND NAME *(GENERIC NAME)*	METHOD OF ADMINISTRATION	GETTING STARTED	MEDICATION CONSIDERATIONS
ReVia,™ Depade™ (Naltrexone)	▪ **Forms:** Comes as an oral tablet (taken by mouth) ▪ **How Often:** Daily	▪ Requires 7-10 day period of absolutely no opioid use for those currently using opioids in order to start safely. ▪ Increased risk of fatal overdose—strongly discouraged for those not yet consistently opioid-free.	▪ ReVia/Depade are not as effective in reducing cravings as buprenorphine and methadone. They are typically used to help manage cravings and maintain long-term abstinence from opioids, rather than for starting treatment. ▪ Your health care provider may refer you to an addiction specialist to make sure this medication is safe for you. ▪ It's important to take this medication exactly as prescribed; missing doses, delaying them, or stopping suddenly can increase the risk of a dangerous overdose. ▪ This medication is usually considered after you have been on another medication for a while and have gradually reduced or stopped using it. ▪ This medication does not cause dependence or withdrawal symptoms when stopped.
Vivitrol™ (Naltrexone Extended Release)	▪ **Forms:** Administered as a deep intramuscular injection (shot in the buttocks) ▪ **How to Take:** The shot is given in your buttocks by trained medical staff at your health care provider's office ▪ **How Often:** You will get the injection once a month	▪ Must be free of all opioids for 7-10 days before starting this medication.	▪ Vivitrol is not as effective as buprenorphine and methadone at reducing cravings. They are typically used to help manage cravings and maintain long-term abstinence from opioids, rather than for starting treatment. ▪ Your health care provider may refer you to an addiction specialist to make sure this medication is safe for you. ▪ It's often not available at regular pharmacies and is usually ordered through a specialty pharmacy, though some health plans might allow it to be filled at a regular pharmacy. ▪ Your insurance company must approve this medication before your health care provider can prescribe it. ▪ This medication does not cause dependence or withdrawal symptoms when stopped. It is not a controlled substance. However, you should not stop taking them on your own. You need to work with your health care provider to slowly lower the amount you take.

Overview of Methadone Medications

BRAND NAME *(GENERIC NAME)*	METHOD OF ADMINISTRATION	GETTING STARTED	MEDICATION CONSIDERATIONS
Dolophine™ (Methadone)	▪ **Forms:** Comes as an oral tablet, liquid, or wafer ▪ **How to Take:** Your health care provider can't prescribe this medication. You must go to a clinic with an Opioid Treatment Program (OTP) to get it every day. ▪ **How to Often:** Daily ▪ **Dosing Changes:** The clinic staff will gradually increase your dose over a few weeks to find the right amount for you.	▪ You must be willing and able to attend an OTP or methadone clinic every day when starting your treatment.	▪ This medication might be a good choice if you still crave opioids or use illegal opioids and want to stop, especially after trying buprenorphine or naltrexone. ▪ Most clinics with OTPs are open very early in the morning, but some also offer afternoon hours. ▪ After showing that you've been going to the clinic daily and have a safe place to store the medication, you might be allowed to take some doses home. ▪ Methadone is often covered by Medicare, Medicaid, and private insurance, and it usually costs less than other options. It also often includes counseling and other support for recovery. ▪ This medication causes cause physical dependence, which means you can't just stop taking them on your own. You need to work with your health care provider to slowly lower the amount you take.

MEDICATION FOR OPIOID USE DISORDER

MOUD and Pregnancy: A Guide for Providers

mosaic GROUP

As a primary care provider, you may see a pregnant patient with Opioid Use Disorder (OUD). Here, we offer essential information to support decision-making for maternal and fetal health with the use of Medications for Opioid Use Disorder (MOUD).

Recommendations for MOUD in Pregnancy

The American College of Obstetricians and Gynecologists (ACOG) and the Substance Abuse and Mental Health Services Administration (SAMHSA) recommend MOUD over supervised withdrawal during pregnancy, as it offers better health outcomes and reduces the risk of return to opioid use.[1] Abrupt discontinuation or tapering of opioids during pregnancy can lead to severe complications, including preterm labor, fetal distress, and maternal and fetal mortality. Informing patients about these risks is essential.

Benefits and Considerations for MOUD in Pregnancy

MOUD, such as buprenorphine or methadone, provides unique benefits for pregnant patients, including:

- Increased engagement in prenatal care
- Stabilization of opioid use, minimizing withdrawal risks for both mother and fetus
- Lowered return-to-use rates, promoting maternal health and pregnancy stability
- Potentially reducing Child Protective Services (CPS) involvement through a well-coordinated care plan and evidence-based prenatal care (consult hospital, state, and local policies on CPS involvement as needed)

Key Considerations for Providers

Pregnancy and Medication Considerations

CONSIDERATIONS	BUPRENORPHINE
Starting Dose	4-8 mgs with presence of withdrawal symptoms.
Target Dose	16 mgs is the most common daily dosage; however, an optimal target dose will be individually determined by regular assessment of the individual and their response to treatment.
Dose Increase Interval During Initiation	Daily, with presence of withdrawal symptoms, after patient assessment.
Need for Periodic Dose Adjustment	Dose stability is critical for maternal and fetal health. Discuss possible dose increases needed in 2nd and 3rd trimesters due to metabolism and blood volume increase.

It is important to note that many patients struggle with the suggestion to increase their medication dosage through pregnancy, so it's helpful to have educational conversations about this directly.

Educate patients about the potential need for adjustments dosage or frequency during the second and third trimesters, as increased blood volume can affect medication levels. Emphasize the importance of these adjustments in preventing withdrawal symptoms and cravings to help address any concerns about dose changes.

Providers may consider both increasing the dose as well as adjusting the frequency of dosing. Patients should be made aware that increased dose does not increase the likelihood of Neonatal Opioid Withdrawal Syndrome (NOWS). Dose stability is corollary to maternal and fetus wellbeing. MOUD should be maintained throughout and following delivery.

Neonatal Opioid Withdrawal Syndrome (NOWS) Considerations

Approximately 50% of neonates exposed to opioids require treatment for Neonatal Opioid Withdrawal Syndrome (NOWS), meaning there is a significant possibility that the newborn may not experience NOWS at all. Furthermore, when NOWS occurs, it is generally milder in cases where the mother was treated with buprenorphine compared to full mu-opioid agonists, such as most opioid analgesics and methadone.

It is recommended to discuss NOWS with patients to set realistic expectations. Educate patients on the importance of understanding the NOWS protocols at the delivering hospital, including the possibility of a precautionary observation period of 5-7 days for neonates exposed to opioids or MOUD.

NOWS symptoms, such as irritability and poor feeding, can vary based on opioid type, exposure duration, and additional factors. Evidence shows that non-pharmacologic methods like rooming-in and skin-to-skin contact can significantly decrease NOWS severity. Additionally, breastfeeding can help, as low levels of buprenorphine or methadone in breast milk can provide a gradual taper for the newborn, shortening hospital stays and fostering bonding.

Discussing MOUD with Pregnant Patients

When discussing MOUD with opioid-using pregnant patients, primary care providers should adopt a compassionate, trauma-informed approach that focuses on patient empowerment and evidence-based care. It's essential to explain that MOUD is a highly effective treatment that improves maternal and fetal outcomes by way of harm reduction, significantly reducing the risk for overdose and withdrawal, as well as lowering the likelihood of return to use during pregnancy.

Providers should also emphasize that untreated withdrawal during pregnancy may increase the risk of miscarriage. Ongoing illicit opioid use can lead to additional adverse outcomes, including miscarriage, complications from infectious diseases and maternal overdose. A clear, nonjudgmental explanation of these risks, combined with support for harm reduction strategies, can help patients make informed and confident decisions.

It is highly likely that there will be child protective services (CPS) involvement once the child is born. When discussing potential CPS involvement, providers should adopt a transparent, compassionate, and supportive approach. Start by acknowledging the patient's concerns and explaining that CPS involvement varies by jurisdiction and often depends on whether the parent demonstrates active engagement in prenatal care and substance use treatment, such as MOUD. It is critical to emphasize that being on buprenorphine under medical supervision is considered a best-practice treatment for opioid use disorder during pregnancy and can be viewed favorably by CPS as part of a responsible plan to ensure maternal and fetal health. Providers should reassure patients that maintaining treatment and participating in additional supportive services, such as counseling or prenatal care, can significantly reduce the risk of adverse outcomes, including negative perceptions by CPS. Open, nonjudgmental communication about the patient's rights, the role of CPS, and the provider's advocacy for the patient's well-being can help build trust and empower the patient to remain engaged in care.

Developing Collaborative Relationships

Establishing strong, collaborative partnerships with a patient's prenatal healthcare provider is critical for enhancing care and support for pregnant patients receiving MOUD. Effective coordination ensures continuity and quality of care across healthcare settings. Optimal care is delivered by a multidisciplinary team, including OB/GYNs, substance use disorder (SUD) specialists, case managers, and peer recovery coaches, working together to address the comprehensive needs of the patient. If a patient is not yet connected with an OB/GYN or fetal medicine specialist, consultation and a warm handoff is recommended. Additionally, behavioral interventions may need to be adjusted or intensified to mitigate the risk of return to use. Referring patients to counseling or SUD specialty care, in conjunction with MOUD, fosters adherence to treatment, builds coping mechanisms, and reduces the likelihood of substance use recurrence during pregnancy.

Return to Use During Pregnancy

Given that return to use is a common occurrence with OUD, especially early in treatment when medication is being stabilized, doing so should not be viewed as a setback or failure, but as an indication of the need to reassess the patient and adjust the treatment plan.

A pregnant patient who returns to opioid use should have the effectiveness of the medication reevaluated. A medication taper is not recommended after returning to use, and MOUD should not be interrupted. Instead, an increase in dose may be warranted to relieve cravings and possible withdrawal symptoms. Additionally, it might be beneficial to refer to a higher level of care, up to and including residential treatment (if MOUD is continued) to provide increased support and accountability.

Clinical Complexity and Referral to a Higher Level of Care

When determining whether to continue prescribing buprenorphine to a pregnant patient or refer to a higher level of care, primary care providers should assess several factors including:

- Patient's stability in treatment
- Adherence to prescribed medication
- Engagement in recommended behavioral health or prenatal services

If the patient demonstrates consistent attendance, adherence to treatment, and an ability to manage their recovery effectively, the provider may feel confident keeping them on their caseload. However, signs of clinical complexity, such as polysubstance use, significant psychosocial stressors, unmanaged psychiatric comorbidities, or frequent relapses, may indicate the need for a referral to a higher level of care, including an Opioid Treatment Program or Residential Care.

Labor and Delivery

MOUD providers should deliver patient education around pain management during labor and following delivery in anticipation of both vaginal and cesarean section deliveries. Additionally, the patient can be encouraged to have an anesthesia consult to discuss options should a vaginal birth be contra-indicated. Modalities of pain management reviewed should include both pharmacological and non-pharmacological options including:

- Oral, intravenous or intramuscular opioids
- OTC non-opioid analgesics
- Spinal analgesia
- Nitrous oxide
- Massage
- Hydrotherapy
- Ice/heat
- TENS and breathing techniques.

RESOURCES

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Notes

mosaic
GROUP

1122 Kenilworth Drive, Suite 313
Towson, MD 21204
410-852-4263
groupmosaic.com