



Expected Practices

Specialty: Addiction Medicine

Subject: Medication Management of Opioid Use Disorder in
Ambulatory Care Settings

Date: October 28, 2019

Purpose: To promote treatment of Opioid Use Disorder (OUD) in ambulatory care settings

Target Audience: Primary and Specialty Care Outpatient Providers

Expected Practice: OUD is defined as “a problematic pattern of opioid use leading to clinically significant impairment or distress” by the Diagnostic and Statistical Manual of Mental Disorders (DSM 5). Two or more of the 11 criteria must be met to make the diagnosis (See **Appendix A**).

- All patients diagnosed with OUD should be offered medications for OUD.
 - Patients should be provided with education on medications for opioid use disorder. Patient handouts are available in **Appendix B**
- When clinically appropriate and desired, patients with OUD can be linked to psychosocial treatments.
 - Medications for OUD should not be delayed while or contingent upon arranging psychosocial treatments.
- **Naloxone** (e.g. Narcan®), should be prescribed as per California state law to all patients with OUD, regardless of whether they also accept a medication for OUD.

This *Expected Practice* was developed by a DHS Specialty-Primary Care Work Group to fulfill the DHS mission to ensure access to high-quality, patient-centered, and cost-effective health care. SPC Work Groups, composed of specialist and primary care provider representatives from across LA County DHS, are guided by 1) real-life practice conditions at our facilities, 2) available clinical evidence, and 3) the principle that we must provide equitable care for the entire population that LA County DHS is responsible for, not just those that appear in front of us. It is recognized that in individual situations a provider’s clinical judgment may vary from this *Expected Practice*, but in such cases compelling documentation for the exception should be provided in the medical record.

MEDICATIONS FOR OPIOID USE DISORDER

The FDA has approved three classes of medications for the treatment of OUD, including buprenorphine-based medications, naltrexone long-acting injection, and methadone. Only the first two classes should be used to treat opioid use disorder in DHS ambulatory care settings. Buprenorphine is the preferred medication for treating OUD while naltrexone can be prescribed to those who have failed or have a contraindication to buprenorphine containing regimen such as an allergic reaction, worsened opioid use while taking buprenorphine, non-adherence to buprenorphine, or history of significant diversion. Specialized OUD treatment centers do not have higher rates of OUD remission than comprehensive primary care in community settings. ¹

1) Buprenorphine is a Schedule III controlled medication that requires the prescribing provider to have obtained a DEA waiver (“X license”) that authorizes them to prescribe buprenorphine for OUD. The information in this EP is an adjunct to the X-waiver training for providers. Buprenorphine is a high-affinity, partial agonist opioid with a favorable safety profile and high efficacy for treating OUD. For non-pregnant patients, the preferred formulation is buprenorphine co-formulated with naloxone (e.g. Suboxone®). Pregnant patients and those confirmed to have a verified oral naloxone intolerance should be treated with buprenorphine mono-formulations (e.g. Subutex®).

- Buprenorphine should be started at soonest opportunity, and absent any clinical imperative to warrant an abbreviated supply, the patient should be prescribed a one to two-week supply of buprenorphine (e.g. 60-120 tabs of 2mg/0.5mg buprenorphine/naloxone or 14-28 tabs of 8mg/2mg buprenorphine/naloxone, assuming a maintenance dose of 16mg of buprenorphine/day), depending upon their clinical stability. Because discontinuing buprenorphine is associated with increased mortality risks in patients with opioid use disorder, patients should be provided with sufficient supply of buprenorphine to ensure that they can reasonably adhere to treatment.
- A return visit should be scheduled no later than two weeks after the start date to discuss ongoing dosing and symptoms. If this visit is performed by another clinical team member, they should inform the prescribing provider of the patient’s progress. Providers may conduct a telephone visit 3-4 days after the buprenorphine start date for early dose adjustments.
- Buprenorphine/naloxone should be self-administered by the patient at home once they are in at least mild opioid withdrawal. Mild opioid withdrawal is more likely to be present 12 hours after the patient’s last use of a short-acting opioids (e.g. hydrocodone [Norco®], heroin), 24 hours after the last use of long-acting opioids (extended-release morphine [MS Contin®]), and 72 hours after the last use of methadone.
- Once mild opioid withdrawal symptoms are noted, the patient should place buprenorphine/naloxone under the tongue until fully dissolved. The starting dose and titration should be individualized for the patient. The usual dose of buprenorphine on the first day usually does not exceed 16mg/2mg.
- On day 2 and onwards, patient should take the total dose from the day prior, with additional doses as needed based on the presence of opioid cravings and withdrawal symptoms. The dose for the second day usually does not exceed 24mg/4mg.
- Additional Considerations
 - Check the California prescription drug monitoring program (Controlled Substance Utilization, Review and Evaluation System [CURES] -

<http://cures.doj.ca.gov/siteminderagent/forms/DOJOBlogin.fcc>) before prescribing buprenorphine. Use similar considerations for diversion or misuse as you would for other schedule III-controlled substances.

- If the patient has concomitant pain, the total daily dose can be split into TID or QID doses to maximize pain control.
- Providers interested in obtaining “X-waiver” can inquire more about trainings at <https://pcssnow.org/medication-assisted-treatment/>
- There is a cap on the total number of patients that X-waivered clinicians can treat with buprenorphine for opioid use disorder at one time. DHS Pharmacy can provide a list of buprenorphine prescriptions for DHS prescribing clinicians who wrote buprenorphine prescriptions to DHS patients at a DHS facility. Prescribing clinicians also working at locations outside of DHS can maintain a buprenorphine patient log. An example log is available via <https://30qkon2g8eif8wrj03zeh041-wpengine.netdna-ssl.com/wp-content/uploads/2015/03/Bup-Patient-Log.pdf>

2) **Naltrexone Long-Acting Injection (LAI)** is an injectable depot formulation of naltrexone, an opioid antagonist, and is given monthly through a dorsogluteal injection at a dose of 380mg.

- Naltrexone is indicated for patients who do not want to be on any opioids. Providers are not required to have an x-waiver to prescribe naltrexone LAI, and patients will not experience withdrawal symptoms on discontinuation of the medication.
- Naltrexone LAI should be prescribed for pick up by the patient or nursing staff. Naltrexone LAI is on the DHS formulary and requires a Prior Authorization in ORCHID. The prior authorizations requirements for the indication of opioid use disorder are:
 - Patient has been opioid free for at least seven days from short-acting opioids and fourteen days from long-acting opioids
 - Naltrexone is contraindicated in anyone who has taken opioids over the past week, who is likely to require opioid pharmacotherapy, or who is actively in opioid withdrawal. Naltrexone can be prescribed if the patient has been verified, by self-report and CURES collateral and, if available, toxicology, to be free from short acting opioids (such as morphine, oxycodone, hydrocodone, and hydromorphone) for at least seven days, extended release opioids (such as morphine sulfate extended-release or oxycodone extended-release) for at least ten days, and long-acting opioids (such as methadone and buprenorphine) for at least 14 days.
 - Patient has failed or has contraindications to Buprenorphine containing regimen (Buprenorphine or Buprenorphine/Naloxone), such as an allergic reaction, worsened opioid use while taking buprenorphine, or history of significant diversion or non-adherence to buprenorphine
- Relative contraindications for naltrexone LAI include BMI >40 (injection unable to reach gluteal muscle) and severe coagulopathy or thrombocytopenia (risk of injection site hematoma).

- A licensed nurse or provider administers the IM dorsogluteal injection in clinic in a sterile approach and monitors the patient for 10 minutes after the injection for any adverse effects.
- Provide the patient with a wallet-sized medication safety card (see **Appendix C**) or bracelet.
- A return appointment for repeat injection in the contralateral gluteus should be scheduled 1 month afterwards.

3) Methadone is a full agonist that can be used to treat OUD at outpatient Opioid Treatment Programs (OTP). OTPs can be considered for patients who desire a more structured setting where they can take either buprenorphine or methadone. County-contracted OTPs can be identified through <https://sapccis.ph.lacounty.gov/sbat>

- Medically hospitalized patients with OUD can receive methadone from the inpatient pharmacy of a DHS hospital facility to treat opioid withdrawal symptoms and to continue a verified methadone maintenance treatment.

4) Naloxone (e.g. Narcan ®), or other opioid reversal agent, should be offered as per California state law to all patients with OUD, regardless of whether they also accept a medication for OUD. Naloxone reduces risk of overdose deaths in community settings.

LABORATORY TESTING

- No laboratory testing is required to start or continue buprenorphine.
 - Urine drug screens can be obtained to support the initial diagnosis of OUD and to monitor response to buprenorphine, but urine toxicology results are not themselves diagnostic, and buprenorphine should be given if there is other clinical evidence to support that the patient would benefit. If possible, obtain a pregnancy test for women of child-bearing age to determine if a patient is appropriate for buprenorphine monotherapy instead of buprenorphine/naloxone.
- Prior to starting naltrexone LAI, obtain a pregnancy test for women of child-bearing age. Liver function testing/monitoring is not required prior to initiation or during/after treatment with naltrexone LAI (<https://pcssnow.org/wp-content/uploads/2014/10/PCSS-MAT-NTX-Liver-Safety-Guideline1.pdf>), however if there is suspicion of hepatic disease this can be ordered. Also obtain urine toxicology screen to exclude opioids, oxycodone, methadone, and buprenorphine. Confirm recent opioid abstinence in discussion with patient.
- Order in ORCHID U **Pain Management, Opiates Expanded, Quantitative-SO** which includes codeine, hydrocodone, hydromorphone, morphine, norhydrocodone, noroxycodone, oxycodone, and oxymorphone. In DHS sites where this order is masked, a provider should order using the manual form to order [Quest 16298](#) or contacting their facility's laboratory by phone for information on how to order this test.
- Order in ORCHID U **Pain Management, Methadone Metabolite, w/out Confirmation-SO**, which tests for methadone.
- Order in ORCHID U **Pain Management, Buprenorphine, Quant-SO**, which tests for buprenorphine. Buprenorphine will remain positive in the urine for three days after administration.

- Once medication is initiated, consider ongoing urine testing for opioids, oxycodone, methadone, and buprenorphine. Medication should not be withheld in the absence of this testing. All efforts should be made to engage patients in continued treatment.
 - Urine testing can support monitoring for ongoing abstinence from other opioids (one element of a therapeutic response to medications for OUD).
 - Urine testing can evaluate for other substances or support confirmation that patient is taking prescribed medications such as buprenorphine.

PSYCHOSOCIAL THERAPY FOR OUD

- No engagement in concurrent psychosocial services is required to begin or continue treatment of OUD with these medications.
- Patients with OUD should be offered linkage to psychosocial treatment if they are interested in participating in these services, even if they decline to take a medication for opioid use disorder.
- DHS clinics with Clinical Social Work (clinical social worker, medical caseworker, and/or substance abuse counsellor) on site should order in ORCHID “Specialty request to Social Work” with “Substance abuse” drop down.
- See LINKAGE AND REFERRAL for discussion of linking patients to psychosocial treatments for OUD.

RECOMMENDED FOLLOW-UP

- After follow-up for medication initiation within the first two weeks, no minimum set of visit frequency is required to continue medication for treatment.
- All patients with OUD should be offered routine follow-up and monitoring at least quarterly, even if they are not participating in or interested in OUD treatment
- For patients receiving medications for OUD, it is recommended to offer follow-up visits at least monthly during the first three months. For new patients or in high-risk social situations, follow up can occur more frequently through a combination of phone calls, social worker, community health worker, pharmacist, or nursing visits.
- See individual medication descriptions above for more detailed follow up instructions.

PRIMARY CARE OF PATIENTS WITH OUD

- Co-occurring medical and psychological conditions and other substance use disorders also need to be assessed and addressed.
- *Concurrent use of stimulants, antidepressants, and/or anxiolytics are not a contraindication to buprenorphine.*
- Co-occurring Alcohol Use Disorder should be addressed through pharmacotherapy, referral to support group and/or medication. If appropriate, IM naltrexone is an effective therapy for both AUD and OUD.
- Chronic pain can co-exist with OUD. Buprenorphine has analgesic effects and can be used to treat chronic pain when the total daily dose requirement is split into TID or QID dosing. Do not prescribe other opioids to patients taking buprenorphine for chronic, non-terminal, and non-acute pain. Consider acetaminophen or NSAIDs and non-pharmacologic approaches (e.g. physical therapy, acupuncture) for additional support.
- Housing, safe shelter, and food security should be addressed for patients experiencing homelessness, domestic violence, and food insecurity.

- Patients with a history of injection drug use:
 - screen for HIV and Hepatitis B/C
 - Offer hepatitis A and B vaccination in accordance with existing *DHS Expected Practices on Screening and Vaccination for Adults for Hepatitis A, B, and C*. Consider providing the first dose of the hepatitis A and/or B vaccine at the time of screening if follow up is not assured.
 - Offer HIV pre-exposure prophylaxis (PrEP). Please refer to the *DHS Clinical Care Library for Pre-Exposure Prophylaxis (PrEP) for HIV Prevention*.
 - Provide information on syringe services programs.
 - Offer long-acting contraception
 - Offer sexually transmitted infection screening.

LINKAGE AND REFERRAL

- Walk-in buprenorphine services are available to all DHS-responsible patients at LAC+USC Urgent Care.
 - DHS provider should make every effort to initiate and continue patients' treatment with medications for opioid use disorder without interruption, so even when appointments are not available, missed, or rescheduled, the benefit to risk ratio heavily favors of treating OUD with medications. Similarly, positive urine drugs screens should be considered opportunities for discussion rather than reasons for treatment discontinuation.
- Providers who have diagnosed OUD and are unable to prescribe appropriate medications are encouraged to send DHS patients to LAC+USC Urgent Care or to other DHS sites for initiation of buprenorphine for OUD.
- In situations where patients want more psychosocial services than available with local resources, patients can be referred to the Department of Public Health Substance Abuse Prevention and Control system of care using the DPH-SAPC Service and Bed Availability Tool: <https://sapccis.ph.lacounty.gov/sbat>. The patient can also be provided the 24/7 call-in number for the Substance Abuse Service Helpline (SASH): 844-804-7500
- In situations where a Medi-Cal beneficiary would benefit from community health worker-provided care navigation and care transition, the patient can contact the WPC-LA Helpline via (844) 804-5200 to discuss the available support for transitions in care and referrals to psychosocial services.
- Opioid Treatment Programs (available through the LINKAGE and REFERRAL to Department of Public Health Substance Abuse Prevention and Control system of care) are options for patients who are unable to follow up in DHS.

WHEN TO SUBMIT AN eCONSULT

- Any clinician who is considering initiating a medication for OUD in any DHS setting is advised to seek consultation via the **Addiction Medicine** eConsult portal if they have any questions related to this treatment or are looking for DHS sites with buprenorphine waived providers. Please note that this is an advice-only portal.
- Submit an Addiction Medicine eConsult if there are questions about an appropriate level of care for a patient that can't be addressed by on-site behavioral health clinicians, if these clinicians are available.

Appendix A: Diagnostic Criteria for Opioid Use Disorder:

- A. A problematic pattern of opioid use leading to clinically significant impairment or distress, as manifested by at least two of the following, occurring within a 12-month period:
1. Opioids are often taken in larger amounts or over a longer period than was intended.
 2. There is a persistent desire or unsuccessful efforts to cut down or control opioid use.
 3. A great deal of time is spent in activities necessary to obtain the opioid, use the opioid, or recover from its effects.
 4. Craving, or a strong desire or urge to use opioids.
 5. Recurrent opioid use resulting in a failure to fulfill major role obligations at work, school, or home.
 6. Continued opioid use despite having persistent or recurrent social or interpersonal problems caused or exacerbated by the effects of opioids.
 7. Important social, occupational, or recreational activities are given up or reduced because of opioid use.
 8. Recurrent opioid use in situations in which it is physically hazardous.
 9. Continued opioid use despite knowledge of having a persistent or recurrent physical or psychological problem that is likely to have *been* caused or exacerbated by the substance.
 10. Tolerance, as defined by either of the following:
 - a. A need for markedly increased amounts of opioids to achieve intoxication or desired effect.
 - b. A markedly diminished effect with continued use of the same amount of an opioid.

Note: This criterion is not considered to be met for those taking opioids solely under appropriate medical supervision.
 11. Withdrawal, as manifested by either of the following:
 - a. The characteristic opioid withdrawal syndrome (refer to Appendix D).
 - b. Opioids (or a closely related substance) are taken to relieve or avoid withdrawal symptoms.

Note: This criterion is not considered to be met for those individuals taking opioids solely under appropriate medical supervision.

The presence of 2 or more symptoms indicates a diagnosis of opioid use disorder.

Mild:	2-3 symptoms
Moderate:	4-5 symptoms
Severe:	6 or more symptoms

A Guide for Patients Beginning Buprenorphine Treatment at Home

Before you begin you want to feel very sick from your withdrawal symptoms

<p>It should be at least ...</p> <ul style="list-style-type: none"> • 12 hours since you used heroin/fentanyl • 12 hours since snorted pain pills (Oxycontin) • 16 hours since you swallowed pain pills • 48-72 hours since you used methadone 	<p>You should feel at least three of these symptoms ...</p> <ul style="list-style-type: none"> • Restlessness • Heavy yawning • Enlarged pupils • Runny nose • Body aches • Tremors/twitching • Chills or sweating • Anxious or irritable • Goose pimples • Stomach cramps, nausea, vomiting or diarrhea
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Once you are ready, follow these instructions to start the medication

DAY 1: 8-12mg of buprenorphine

Most people feel better the first day after 8-12mg. (Dosing depends on how early on the first day you started)

<p>Step 1.</p> <p>Take the first dose</p> <p>4mg</p> <p>Wait 45 minutes</p> <p>45 minutes</p> <ul style="list-style-type: none"> • Put the tablet or strip under your tongue • Keep it there until fully dissolved (about 15 min.) • Do NOT eat or drink at this time • Do NOT swallow the medicine 	<p>Step 2.</p> <p>Still feel sick? Take next dose</p> <p>4mg</p> <p>Wait 6 hours</p> <p>6 hours</p> <p>Most people feel better after two doses = 8mg</p>	<p>Step 3.</p> <p>Still uncomfortable? Take last dose</p> <p>4mg</p> <p>Stop</p> <ul style="list-style-type: none"> • Stop after this dose • Do not exceed 12mg on Day 1 	<p>DAY 2: 16mg of buprenorphine</p> <p>Take one 16mg dose</p> <p>Most people feel better with a 16mg dose</p> <p>16mg</p> <p>Repeat this dose until your next follow-up appointment</p> <p>Max 24mg/4mg per day</p>
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If you develop worsening symptoms while starting buprenorphine before your scheduled outpatient appointment return to the emergency department

Una guía para pacientes que empiezan tratamiento con Buprenorfina en casa

Antes de empezarlo tiene que sentirse muy afectado por los síntomas de abstinencia

- Deben haber pasado por lo menos . . .
- 12 horas desde que usó heroína o fentanilo
 - 12 horas desde que inhaló pastillas para el dolor (Oxycontin)
 - 16 horas desde que ingirió pastillas para el dolor
 - 48-72 horas desde que se usó metadona
- Debe sentir al menos tres de estos síntomas . . .
- Inquietud
 - Bostezos fuertes
 - Pupilas engrandecidas
 - secreción nasal
 - Dolor corporal
 - Temblor/contracciones
 - Escalofríos o sudores
 - Ansiedad o irritabilidad
 - Piel de gallina
 - Cólicos estomacales, náusea, vómito o diarrea

Cuando ya esté listo, siga estas instrucciones para empezar el medicamento

DÍA 1:
De 8 a 12mg de buprenorfina

La mayoría de personas se sienten mejor desde el primer día al tomar de 8 a 12mg. (la dosis depende de que tan temprano empezó el primer día)

Paso 1.		Paso 2.		Paso 3.		DÍA 2: 16mg de buprenorfina
Tome la primera dosis	Espere 45 minutos	¿Todavía se siente mal? Tome la siguiente dosis	Espere 6 horas	¿Todavía se siente incómodo? Tome la última dosis	Pare	Tome una dosis de 16mg La mayoría de personas se sienten mejor con una dosis de 16mg
4mg	45 minutos	4mg	6 Horas	4mg	Pare	
<ul style="list-style-type: none"> • Coloque la tableta o tira debajo de su lengua • Manténgala ahí hasta que se disuelva completamente (aproximadamente 15 min.) • NO coma, ni beba durante este tiempo • NO se trague (no ingiera) el medicamento 		La mayoría de personas se sienten mejor después de dos dosis = 8mg		<ul style="list-style-type: none"> • Pare después de esta dosis • No exceda 12mg el día 1 		Repita esta dosis hasta su próxima cita de seguimiento Máx 24mg/4mg por día

Si sus síntomas empeoran al empezar la buprenorfina antes de su próxima cita programada debe regresar a la sala de emergencia.

Appendix C: Naltrexone Long-Acting Injection Instructions

PCSS XR Naltrexone Step by Step Guide

http://pcssnow.org/wp-content/uploads/2017/02/Naltrexone_Step-by-Step_Virtual_Brochure-1.pdf

SAMHSA Clinical use of ER IM Naltrexone for OUD: A Brief Guide

<https://store.samhsa.gov/system/files/sma14-4892r.pdf>

Appendix D: Opioid Withdrawal

The symptoms of opioid withdrawal syndrome are described here:

<https://www.drugabuse.gov/sites/default/files/files/ClinicalOpiateWithdrawalScale.pdf>

Appendix E: Patient Resources

English FAQs:

https://lacounty-my.sharepoint.com/:b:/g/personal/bhurley_dhs_lacounty_gov/EbJkpf6T1SVPq3IMBNStWYMBWvyzJDc8A2phMQbg4rBYZA?e=wHoEk0

Spanish FAQs:

https://lacounty-my.sharepoint.com/:b:/g/personal/bhurley_dhs_lacounty_gov/Ebk9au-wOVMmHgARyjym9wBvDz6ywnmprFxb3NCN1nBXw?e=A2qWH9

SOURCES:

National Council for Behavioral Health. Implementing Care for Alcohol & Other Drug Use in Medical Settings: An Extension of SBIRT. March 2018. National Council for Behavioral Health. https://www.thenationalcouncil.org/wp-content/uploads/2018/03/021518_NCBH_ASPTReport-FINAL.pdf

SUMMIT Procedures for Medications for Alcohol and OUDs:

https://www.rand.org/content/dam/rand/pubs/tools/TL100/TL148-1/RAND_TL148-1.pdf

SAMHSA TIP 63: Medications for OUD: <https://store.samhsa.gov/product/TIP-63-Medications-for-Opioid-Use-Disorder-Full-Document-Including-Executive-Summary-and-Parts-1-5-/SMA18-5063FULLDOC>

Treating Addiction in the Primary Care Safety Net Program Resources Page: <https://tapcprogram.com>

American Psychiatric Association. (2013). *Diagnostic and statistical manual of mental disorders (DSM-5®)*.

American Psychiatric Pub. Hans-Ulrich Wittchen, et al; Feasibility and outcome of substitution treatment of heroin-dependent patients in specialized substitution centers and primary care facilities in Germany: A naturalistic study in 2694 patients, *Drug and Alcohol Dependence*, Volume 95, Issue 3, 2008, Pages 245-257, ISSN 0376-8716, <https://doi.org/10.1016/j.drugalcdep.2008.01.015>.