

COUNTY OF LOS ANGELES - DEPARTMENT OF MENTAL

HEALTH OFFICE OF THE MEDICAL DIRECTOR

**3.10 PARAMETERS FOR THE USE OF MEDICATIONS FOR ADDICTION TREATMENT IN
INDIVIDUALS WITH CO-OCCURRING SUBSTANCE USE DISORDERS**

October 2017

I. Introduction:

- A. The proper use of select medications can help treat specific substance use disorders, and is referred to as medications for addiction treatment (MAT).
- B. Individuals offered MAT should also be offered other appropriate psychosocial treatment interventions, as MAT does not substitute for psychosocial treatment.
- C. Prescribers who treat individuals with co-occurring substance use disorders should be familiar with, and include, the use of selected medications recognized as potentially useful for treatment of substance use disorders;. Familiarity should include knowledge of proper use of each medication, including proper elements of assessment and management.
- D. These parameters do not address the use of medications to ameliorate symptoms of substance intoxication or withdrawal, nor do they address methadone treatment for opioid use disorder.
- E. Use of MAT in individuals below 18 years of age should be associated with documentation in the medical record of the benefits outweighing the risks in this these populations.

II. Purpose:

To describe those situations in which MAT should be used to treat co-occurring substance use disorders in LAC DMH programs.

III. Alcohol Use Disorder:

- A. Individuals being treated for mental illness, who have comorbid alcohol use disorder that has not responded to DMH psychosocial interventions during one year's time, and do not have contraindications for MAT, should be offered treatment trials of oral naltrexone, naltrexone Long-Acting Injectable (LAI), acamprosate, disulfiram, gabapentin, or topiramate. The order of the trails should be based upon clinical presentation.
- B. The medications, excepting those that are contraindicated or refused, should be offered sequentially until one or more of these medications has been found to be effective or the entire series has been tried. Combinations of these agents may be offered when clinical evidence supports this approach and there is clinical documentations supporting this decision.
- C. For individuals that have been unsuccessfully treated for more than one year by DMH for comorbid alcohol use disorder without use of MAT, documentation must be provided to explain why the use of MAT is not indicated.

IV. Opioid Use Disorder:

Individuals being treated for mental illness, who have comorbid opioid use disorder and do not have contraindications for MAT, should be offered buprenorphine/naloxone or naltrexone LAI. The selection of buprenorphine/naloxone or naltrexone LAI shall be based upon an individual's clinical characteristics and preferences. Individuals who are pregnant or with other validated contraindications to buprenorphine/naloxone shall be offered buprenorphine monotherapy when buprenorphine/naloxone is otherwise indicated.

- A. For individuals who have been unsuccessfully treated for more than one year for comorbid opioid use disorder, without the use of MAT, the associated medical record must include documentation that justifies why MAT has not been initiated.

V. Medication-Specific Parameters:

A. Acamprosate

In the absence of contraindications, acamprosate should be preferentially selected in lieu of other MAT for maintenance of abstinence in individuals with alcohol use disorder who are relatively stable and in early stages of recovery.

B. Buprenorphine and Buprenorphine/naloxone

Buprenorphine or buprenorphine/naloxone should be prescribed for treatment of opioid use disorder by prescribers with the federal waiver authorizing their use of Schedule III, IV, or V medications FDA-approved for the treatment of opioid use disorder. See Section VII, Reference 1.

C. Gabapentin

Gabapentin should be reserved for treatment of alcohol use disorder in instances in which acamprosate and naltrexone are ineffective, contraindicated, or there is a co-occurring mental disorder that requires gabapentin for treatment.

D. Naltrexone

- 1. In the absence of contraindications, naltrexone should be preferentially selected over other MAT for situations involving efforts to reduce ongoing alcohol consumption or significant craving.

E Topiramate

Topiramate should be reserved for treatment of alcohol use disorder only when acamprosate and naltrexone are ineffective or contraindicated, or in the presence of a co-morbid disorder that requires topiramate for treatment.

VI. Attachments

- 1. GUIDELINES FOR THE USE OF NALTREXONE LONG ACTING INJECTION (NLAI)

VII. References

- 1. GUIDELINES FOR THE USE OF BUPRENORPHINE / NALOXONE AND BUPRENORPHINE:
<http://pcssmat.org/mat-basics/buprenorphine/>

LOS ANGELES COUNTY DEPARTMENT OF MENTAL HEALTH
GUIDELINES FOR THE USE OF NALTREXONE LONG ACTING INJECTION (NLAI)

September 2017

I. Program Implementation: Consultation regarding administrative and clinical requirements for the use of NLAI in DMH programs is available through the DMH Pharmacy Bureau at (213) 738-4725.

II. DMH Program requirements for NLAI use

A. Directly-operated programs:

1. Appropriate knowledge by each program staff participating in NLAI-associated services.
 - a. DMH Parameters for Medications for Addiction Treatment.
 - b. FDA prescribing and monitoring requirements for Naltrexone long-acting injection (NLAI).
2. Standardized procedure for acquisition of NLAI dose from pharmacy.
3. Proper storage facilities procedures for NLAI.
4. Availability of supplies and facilities for on-site urine testing.

B. Contract agency programs: Programs operated by agencies under contract to LACDMH should also meet the requirements outlined in this document before prescribing NLAI. Monitoring of adherence to these requirements and liability is the responsibility of the contract agency. On request, LACDMH staff is available for consultation to contract agencies to assist in meeting the requirements.

III. Client Selection for NLAI

- A. Should be between ages 18 and 65, unless specifically approved by supervising psychiatrist.
- B. If female, should be cautioned about unknown effect of Naltrexone in pregnancy, and have signed an informed consent form (DMH Outpatient Medication Review-MH 566).
- C. Should currently meet DHCS medical necessity criteria for co-morbid specialty mental health services and DSM criteria for Alcohol or Opioid Use Disorders.
- D. If Opioid Use Disorder is present, the client should have recently received detoxification from opioids and should be opioid-free for a minimum of 7 days.
- E. Any client with the following conditions should not be started on NLAI therapy:
 1. Opioid analgesics
 2. Current physiologic opioid dependence
 3. In acute opioid withdrawal
 4. Unreliable history of being opioid free for at least 7 days
 5. Positive urine screen for opioids
 6. Fails a naloxone challenge test
 7. Known previous allergic response to Naltrexone or NLAI
 8. Acute hepatitis or liver failure
- F. Special Populations
 1. Pregnancy: NLAI is a *Pregnancy Category C* drug. There are no adequate or well controlled studies of either Naltrexone or NLAI in pregnant women. *Clients should sign a consent* documenting that they have been informed of NLAI's pregnancy category status.

2. Labor and Delivery: The potential effects on labor and delivery are unknown, and clients should be advised to inform their obstetrical provider if they are taking NLAI.
3. Nursing Mothers: Naltrexone should not be prescribed to nursing mothers without specific approval from the responsible supervising psychiatrist.
4. Pediatric Use: Naltrexone should not be used, as the efficacy and safety has not been established for any individuals under the age of 18.
5. Geriatric Use: Naltrexone should not be used, as the efficacy and safety has not been established for the geriatric population (>65 years old).

IV. Screening Requirements

- A. Clients should meet the DSM criteria for alcohol and/or opioid use disorder.
- B. **Medical History:** Should include current and past drug and alcohol use, allergies, psychiatric, legal, medical, surgical, family, and previous drug treatment history, recorded properly in the DMH clinical record.
- C. **Physical Assessment:** A targeted physical assessment should include specific assessment for signs of addiction. Clients with identified primary medical conditions should be referred to primary care or other medical specialists.
- D. **Laboratory Screening**
 1. All clients should be assessed for the absence of recent opioid use with physiologic opioid tolerance prior to administration each injection. This can be assessed through the use of on-site toxicology negative for opioids, and may also include a verified history of naltrexone long acting injection within the prior thirty days, a verified history of recent containment in an opioid-free environment such as residential addiction treatment, and verified tolerance to oral naltrexone.
 2. All clients receiving NLAI should be offered laboratory testing that includes a liver function panel at baseline, and re-checking liver function at month one, three, six, twelve, and annually thereafter. If the patient has risk factors for infectious Hepatitis, Hep A, B, & C laboratory testing may be considered. See reference 1 for additional discussion regarding laboratory monitoring.

V. Informed consent

- A. Clients should be documented to have stated their understanding of the risks, benefits, and alternatives to NLAI treatment and their consent to treatment with NLAI.

VI. Dosage, Administration, and Storage

- A. The standard FDA-approved dose is 380 mg delivered intramuscularly every 28-31 days.
- B. The injection should be administered as an intramuscular (IM) gluteal injection, alternating buttocks for each subsequent injection, using carton provided components only.
- C. NLAI MUST NOT BE ADMINISTERED INTRAVENOUSLY OR SUBCUTANEOUSLY
- D. NLAI must be kept refrigerated (36-46 degrees F) and not frozen. It should not be exposed to temperatures over 77 degrees F.
- E. NLAI should not be stored at home by clients, or in any other off-site location.

VII. Provision of other services

- A. Clients who are receiving NLAI therapy should be offered all other relevant clinical services, including both psychotherapy and medication services.

VIII. Treatment Monitoring and Duration

- A. NLAI treatment should continue only when ongoing monitoring and associated documentation supports the determination that client is tolerating and responding to NLAI and there continues to be a medical need for further use.
- B. NLAI treatment should be offered alongside a comprehensive treatment program for opioid or alcohol use dependence that should include psychosocial support.

References

1. <http://pcssmat.org/wp-content/uploads/2014/10/PCSS-MAT-NTX-Liver-Safety-Guideline1.pdf>