



Behavioral Health Services (BHS)

Adult and Older Adult Behavioral Health
Physicians Manual and Practice Guidelines

Quick Guide: Medications for Addiction
Treatment (MAT) - Guidelines for the Use of
Naltrexone Long-Acting Injection (NLAI)

2021



Quick Guide

Medications for Addiction Treatment (MAT) - Guidelines for the Use of Naltrexone Long-Acting Injection (NLAI)

I. Program requirements for NLAI use:

- A. Appropriate knowledge by each program staff participating in NLAI-associated services.
 - 1. Indications for Medications for Addiction Treatment (MAT).
 - 2. FDA prescribing and monitoring requirements for naltrexone long-acting injection (NLAI).
- B. Proper storage facilities for NLAI.
- C. Availability of supplies and facilities for on-site urine testing.
- D. Beneficiary/Client participation in a comprehensive SUD counseling program.

II. Beneficiary/Client Selection for NLAI

- A. Should be between ages 18 and 65, unless provider specifically documents clinical reasoning why NLAI is offered to beneficiary/client outside of this age range.
- B. If female, beneficiary/client should be cautioned about unknown effect of naltrexone in pregnancy. The beneficiary/client should also sign an informed medication consent form with specific discussion of risks/benefits/alternatives for NLAI use in pregnancy.
- C. Should currently meet DSM criteria for Alcohol or Opioid Use Disorders.
- D. If Opioid Use Disorder is present, the beneficiary/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. Taking opioid analgesics for pain condition.



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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 (for concern that client possibly not opioid free for 7 days as required to start NLAI)
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. Beneficiary/clients should sign a medication consent documenting that they have been informed of NLAI's pregnancy category status and the risks/benefits/alternatives of NLAI use in pregnancy.
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. Coordination of care should also take place directly between the MAT and obstetrical provider.
3. Nursing Mothers: Naltrexone should not be prescribed to nursing mothers without specific discussion of risks/benefits/alternatives for NLAI use in breastfeeding clients.
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).



III. Screening Requirements

- A. Beneficiaries/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 BHS clinical record.
- C. Physical Assessment: A targeted physical assessment should include specific assessment for signs of addiction. Beneficiaries/clients with identified primary medical conditions should be referred to primary care or other medical specialists.
- D. Laboratory Screening
 - 1. All beneficiaries/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 beneficiaries/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, Hepatitis A, B, & C laboratory testing should be considered. See reference 1 for additional discussion regarding laboratory monitoring.

IV. Informed consent

- A. Documentation should state the beneficiary's/client's understanding of the risks, benefits, and alternatives to NLAI treatment and their consent to treatment with NLAI.

V. Dosage, Administration, and Storage

- A. The standard FDA-approved dose is 380 mg delivered intramuscularly every 28-31 days.



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- 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.

VI. Provision of other services

- A. Beneficiaries/clients who are receiving NLAI therapy should be participating in a comprehensive substance use counseling program with coordination of care between MAT and counseling providers.

VII. 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.

References:

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