

Vivitrol® (naltrexone extended-release injection)



When requesting Vivitrol® (naltrexone extended-release injection), the individual requiring treatment must be diagnosed with one of the following FDA-approved indications and meet the specific coverage guidelines and applicable safety criteria for the covered indications.

FDA-approved indications

- Vivitrol® (naltrexone) is indicated for the treatment of alcohol dependence in individuals who are able to abstain from alcohol in an outpatient setting prior to initiation of treatment with Vivitrol®(naltrexone).
- Vivitrol® (naltrexone) is indicated for the prevention of relapse to opioid dependence, following opioid detoxification.

Approved Off-label Compendial use

- No off-label uses meet evidence standards

Coverage Guidelines

For all approved indications, the individual meets **ALL** of the following criteria:

- Has been opioid-free for a minimum of 7 days
- Is NOT currently receiving opioid analgesics
- Is NOT currently experiencing physiologic opioid dependence
- Is NOT currently in acute opioid withdrawal
- Has NOT failed the naloxone challenge test or has a negative urine screen for opioids
- Has NOT previously exhibited hypersensitivity to naltrexone, polylactide-co-glycolide, carboxymethylcellulose, or any other components of the diluent
- Is currently participating in a comprehensive management program that includes psychosocial support
- Is NOT a candidate for or has failed oral agent(s) (e.g., acamprosate, oral naltrexone, buprenorphine)
- Does NOT have acute hepatitis

For Treatment of Alcohol Dependence

The individual must meet **all** of the following criteria for approval:

- Has a diagnosis of alcohol dependence
- Is currently abstaining from alcohol

For Prevention of Relapse to Opioid Dependence

The individual must meet **all** of the following criteria for approval:

- Has a diagnosis of opioid dependence
- Has completed an opioid detoxification program

Approval duration: 12 months

Additional Information for Prescribers

Our prescribers are alerted to the following safety concerns as educational points/reminders:

- Following treatment with Vivitrol® (naltrexone), opioid tolerance is reduced from pre-treatment baseline. Individuals are vulnerable to potentially fatal overdoses at the end of a dosing interval, after missing a dose, or after discontinuing treatment with Vivitrol® (naltrexone).
- Individuals should be opioid-free before starting treatment with Vivitrol® (naltrexone). An opioid-free duration of a minimum of 7-10 days is recommended for individuals to avoid precipitation of opioid withdrawal that may be severe enough to require hospitalization.

References

1. Vivitrol® prescribing information. Waltham, MA: Alkermes; December 2015. Accessed February 14, 2017. <https://www.vivitrol.com/content/pdfs/prescribing-information.pdf>
2. Klasco RK (Ed): DRUGDEX® system. Thomson Micromedex, Greenwood Village, CO. Accessed February 14, 2017. <https://www.micromedexsolutions.com>.
3. Comer S, Cunningham C, Fishman MJ, et al. American Society of Addiction Medicine. The National Practice Guideline. For the Use of Medications in the Treatment of Addiction Involving Opioid Use. <http://www.asam.org/docs/default-source/practice-support/guidelines-and-consensus-docs/asam-national-practice-guideline-supplement.pdf?sfvrsn=24> Accessed on April 07, 2017.
4. National Institute for Health and Care Excellence. Alcohol-use disorders: diagnosis, assessment and management of harmful drinking and alcohol dependence. Published: 23 February 2011. <https://www.nice.org.uk/guidance/cg115/resources/alcohol-use-disorders-diagnosis-assessment-and-management-of-harmful-drinking-and-alcohol-dependence-35109391116229> . Accessed on April 07, 2017.