



**PHARMACY PRIOR AUTHORIZATION
Clinical Guideline - Opioid Antagonist
Vivitrol™[®] (Naltrexone for extended-release injectable suspension)**

FDA Indications

- For the treatment of alcohol dependence in patients who are able to abstain from alcohol in an outpatient setting prior to initiation of treatment
- For the prevention of relapse to opioid dependence, following opioid detoxification

Dosage Forms

380 mg powder for injection

Dosage

380 mg injected intramuscularly (IM) every 4 weeks or once a month

- **Must be prepared and administered by a healthcare professional**
- **Must be injected using the customized needles provided.** Must not be injected using any other needle
- **Must be administered IM.** Must not be administered intravenously or subcutaneously.
- **Renal Impairment:** Dosage adjustment is not needed for mild to moderate renal impairment (CrCl 50-80ml/min). Specific guidelines for dosage adjustment in patients with moderate to severe renal impairment are not available
- **Hepatic Impairment:** Dosage adjustment is not needed for mild to moderate hepatic impairment (Child-Pugh Group A and B). Specific guidelines for dosage adjustment in patients with severe hepatic impairment are not available. Contraindicated for use in acute hepatitis or liver failure.

Authorization Guidelines

Prior authorization personnel will review the request for prior authorization and apply the clinical guidelines to assess the medical necessity of the request for a prescription for Vivitrol. If the guidelines are met, the reviewer will prior authorize the prescription. If the guidelines are not met, the prior authorization request will be referred to a physician reviewer for a medical necessity determination. Such a request for prior authorization will be approved when, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the recipient.

For patients who meet all of the following:

- Must be at least 18 years of age
- No hypersensitivity naltrexone or any components of the commercially available product
- Patient does not have acute hepatitis or hepatic failure (Black Box Warning)
- Not experiencing acute opiate agonist withdrawal
- Not receiving opioid analgesics (e.g.; must pass naloxone challenge test or negative urine drug screen for opiates)
- Must be enrolled in and compliant with a substance abuse treatment program or psychosocial support plan
- Must be and remain abstinent from using all substances of abuse (as verified by random urine drug testing)

In Addition:

For Treatment of Alcohol Dependence:

- Medical records support diagnosis of alcohol dependence
- Must be abstinent from alcohol for at least 7 days in an ambulatory setting prior to the initiation of treatment
- If also opioid-dependent, must be opioid-free for a minimum of 7-10 days before starting treatment in order to prevent unintentional withdrawal.
- Clinical documentation supports trial and failure of, intolerance to, or non-compliance with oral naltrexone, Campral and/or disulfiram, or a rationale is provided to support the necessity of Vivitrol injections

For the Prevention of Relapse to Opioid Dependence:

- Medical records support diagnosis of opioid dependence
- Must be opioid-free for a minimum of 7-10 days prior to the initiation of treatment in order to prevent unintentional withdrawal
- Clinical documentation supports trial and failure of, intolerance to, or non-compliance with oral naltrexone and/or oral buprenorphine with or without naloxone (Subutex or Suboxone), or a rationale is provided to support the necessity of Vivitrol injections.

Prior Authorization Requirements

Initial Approval

90 days

Renewal

90 days at a time, to a maximum of 1 year :

- Compliant with a substance abuse treatment program or psychosocial support plan
- Remains abstinent from using all substances of abuse (as verified by random urine drug testing)
- Review of Rx history for compliance

Additional Information

This medication has not been studied in direct comparison with other agents used for these conditions.

There are no data to specifically address treatment re-initiation in patients who stopped therapy, or the switch from oral naltrexone to IM naltrexone

Pregnancy Category C: Reproduction and developmental studies have not been conducted for naltrexone injection. Use naltrexone during pregnancy only if the potential benefit justifies the potential risk to the fetus

Lactation: Transfer into human milk has been reported with oral naltrexone. Because of the potential for tumorigenicity shown for naltrexone in animal studies, and due to the potential for serious adverse reactions in breast-feeding infants from naltrexone, naltrexone is not recommended for use in this patient population.

References

1. Vivitrol [package insert]. Waltham, MA: Alkermes, Inc; April 2011.
2. Vivitrol. Clinical Pharmacology. Clinical Pharmacology [database online]. 2011. Available at <http://www.clinicalpharmacology.com>. Accessed April 4, 2011
3. National Institute on Alcohol Abuse and Alcoholism. Helping Patients Who Drink Too Much: A Clinician's Guide. October 2008 Update. Available at: www.niaaa.nih.gov/guide
4. Nicholls L, Bragaw L, Ruetsch C. Opioid Treatment and Guidelines. J Manage Care Pharm. 2010;16(1-b): S14-S21