



Prior Authorization Approval Criteria

Vivitrol (naltrexone)

Generic name:	naltrexone
Brand name:	Vivitrol
Medication class:	Opioid antagonist
FDA-approved uses:	Treatment of alcohol dependence in patients who are able to abstain from alcohol in an outpatient setting prior to initiation of treatment with naltrexone injection. Prevention of relapse to opioid dependence, following opioid detoxification

Available dosage forms: 380 mg intramuscular injection

Usual dose: 380 mg IM once a month in the doctor's office

Duration of therapy: 6 months (safety and tolerability beyond 6 months has not been established)

Approximate monthly cost: \$834.00
(based on AWP 2006)

Criteria for use for alcohol dependence*(bullet points below are all inclusive unless otherwise noted):*

- Patient must be 18 years old or over
- Patient must have already abstained from drinking alcohol.
- Must be part of a comprehensive treatment program for alcohol dependence that should include a psychosocial support system.
- Failed/intolerant to oral naltrexone
- Failed/intolerant to Campral*

* Campral requires a prior authorization and the criteria that must be met for approval are available at fchp.org.

Criteria for use for opioid dependence *(bullet points below are all inclusive unless otherwise noted):*

- Patient must be 18 years old or over
- Patient must be opioid free for a minimum of 7-10 days
- Patient must not have a current need for opioid analgesics
- Must be part of a comprehensive treatment program for opioid dependence that should include a psychosocial support system.
- Failed/intolerant to oral naltrexone
- Failed/intolerant to Suboxone and Subutex

Contraindications:

- Should not be administered to patients in opioid withdrawal.
- Acute hepatitis or liver failure.
- Patients allergic to naltrexone, or any inactive ingredient of Vivitrol powder or diluent.

Not approved if:

- Does not meet the above stated criteria.
- Have any contraindications to the use of Vivitrol.

Special considerations:

- Alternative to daily doses of oral naltrexone.
- Expected to work the same as oral naltrexone.
- No head to head trials with other medications for alcohol dependence.
- No head to head trials with other medications for opioid dependence.
- High incidence of nausea that may decrease with subsequent doses.
- Patients at risk of opioid overdose after stopping therapy and restarting prior opioid dose.

Patients are advised to wear a medical alert bracelet so they get proper pain management in case of an emergency. If an opioid must be used in the ER or hospital, the dose must be carefully titrated to give enough to overcome the naltrexone, but not too much to cause respiratory depression.

FCHP Pharmacy and Therapeutics Committee approval: _____

Date: _____