



## Prior Authorization Criteria

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### **VIVITROL® (naltrexone) PA CRITERIA for Alcohol Dependence:**

VIVITROL® (naltrexone) is an opioid antagonist indicated for:

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

Prior authorization is required for VIVITROL® when used for alcohol dependence. Prior authorization approval will be considered when the following criteria are met. Along with the Universal PA Form, please submit any supporting clinical documentation.

#### **Initial Authorization:** 6 Months

1. The patient must meet the minimum age and weight requirements recommended by the package insert for FDA approved indication; **AND**
2. The patient has a diagnosis of alcohol dependence; **AND**
3. The patient must be abstaining from alcohol consumption at the time of therapy initiation; **AND**
4. The patient must not currently be taking opioid analgesics (e.g., for pain management), physiologically dependent on opioids, or in acute opioid withdrawal; **AND**
5. Documentation or attestation of the patient's tolerability to naltrexone; **AND**
6. Prescribed dose does not exceed 380 mg monthly.

#### **Re-Authorization:** 12 Months

1. Patient continues to meet initial authorization criteria; **AND**
2. Prescribed dose does not exceed 380 mg monthly; **AND**
3. Positive clinical response to therapy.

**VIVITROL® Dosing:** 380 mg intramuscularly every 4 weeks or once monthly.

**Formulation:** VIVITROL® is available as a carton containing one 380-mg vial of VIVITROL® microspheres, one vial containing 4 mL (to deliver 3.4 mL) of diluent for the suspension of VIVITROL®, one 5-mL prepackaged syringe, one 1-inch 20-gauge needle, two 1 ½ -inch 20-gauge needles, and two 2-inch 20-gauge needles with needle protection devices.