

SPECIALTY GUIDELINE MANAGEMENT

VIVITROL (naltrexone for extended-release injectable suspension)

POLICY

I. INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indications

- A. Vivitrol is 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. Patients should not be actively drinking at the time of initial Vivitrol administration.
- B. Vivitrol is indicated for the prevention of relapse to opioid dependence, following opioid detoxification.

All other indications are considered experimental/investigational and not medically necessary.

II. CRITERIA FOR INITIAL APPROVAL

A. Alcohol Dependence

Authorization of 24 months may be granted for treatment of alcohol dependence.

B. Opioid Dependence

Authorization of 24 months may be granted for prevention of relapse to opioid dependence.

III. CONTINUATION OF THERAPY

All members (including new members) requesting authorization for continuation of therapy must meet all initial authorization criteria.

IV. REFERENCES

1. Vivitrol [package insert]. Waltham, MA: Alkermes, Inc.; December 2015.