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.

A. FDA-Approved Indications
- 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.

- Vivitrol is indicated for the prevention of relapse to opioid dependence, following opioid detoxification.

All other indications are considered experimental/investigational and are not a covered benefit.

II. EXCLUSIONS

A. Members with current physical opioid dependence
B. Members with acute opioid withdrawal

III. CRITERIA FOR APPROVAL

A. Alcohol Dependence

Authorization of 12 months may be granted to members who are not actively drinking at the time of initiation of Vivitrol therapy for the treatment of alcohol dependence when both of the following criteria is met:

1. The member meets one of the following:
   a. Member had an inadequate treatment response to orally-administered therapies (e.g., naltrexone, acamprosate, or disulfiram) for alcohol dependence
   b. Member has a clinical reason that prevents the first-line use of an orally-administered therapy (e.g., inability to comply with daily dosing).
2. The member has been opioid free for at least 7 days

B. Opioid Dependence

Authorization of 12 months may be granted for the prevention of relapse to opioid dependence when both of the following criteria are met:

1. The member meets one of the following:
   i. The member had an inadequate treatment response to oral naltrexone
   ii. The member has a clinical reason that prevents the first-line use of oral naltrexone (e.g., inability to comply with daily dosing)
2. The member meets one of the following:
   i. The member has been opioid free for at least 7 days
   ii. The member is transitioning from an opioid agonist therapy taper (e.g., Suboxone) and will be closely monitored for precipitated withdrawal

IV. CONTINUATION OF THERAPY

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

V. DOSAGE AND ADMINISTRATION

Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines.

A. Dosing Limits

The following dosing limits apply: 380 mg per 28 days

VI. REFERENCES

1. Vivitrol [package insert]. Waltham, MA: Alkermes, Inc.; December 2015.
2. Institute for Clinical and Economic Review. Management of patients with opioid dependence: a review of clinical, delivery system, and policy options. http://icer-review.org/wp-content/uploads/2014/04/CEPAC-Opioid-Dependence-Final-Report-For-Posting-July-211.pdf. Accessed 05/26/2016.