Manual Prior Criteria

MISSISSIPPI DIVISION OF MEDICAID

Vivitrol® (naltrexone) PA Criteria:

Vivitrol is indicated for the:

1. 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
2. Prevention of relapse to opioid dependence, following opioid detoxification

Vivitrol should be part of a comprehensive management program for opioid dependence or alcohol dependence that includes psychosocial support.

Initial Approval Criteria: ***Initial Authorization is for 6 months***

Alcohol and Opioid Dependence (must meet all)

1. Must be 18 years of age or older, ***and***
2. Diagnosis of one of the following ***(a or b)***:
   a. Alcohol dependence
   b. Opioid dependence
   and
3. Must be abstaining from alcohol consumption at the time of therapy initiation, and
4. Must not currently be taking opioid analgesics (e.g. for pain management), physiologically dependent on opioids, or in acute opioid withdrawal, and
5. If diagnosis is alcohol dependence, upon request a recent alcohol screening test (within past 7 days) confirming or attestation that beneficiary has been alcohol-free, ***and***
6. If diagnosis is opioid dependence, documentation or attestation that a recent naloxone challenge test or urine drug screen (within past 7-10 days) confirms that beneficiary is opioid-free, ***and***
7. Must be abstaining from alcohol consumption at the time of therapy initiation, ***and***
8. Documentation or attestation of patient's tolerability to naltrexone, ***and***
9. Dose does not exceed 380 mg every 4 weeks or once a month.

Continuation of Therapy Criteria: ***Authorization is for 6 months***

1. Have previously met initial approval criteria for Alcohol and Opioid Dependence ***and*** (must be all):
2. Beneficiary is responding to therapy and there continues to be a medical need for the medication, ***and***
3. Beneficiary ***(a or b):***

   a. currently is abstaining from alcohol as documented by attestation upon request

   b. Beneficiary does not have concurrent opioid claims per pharmacy record

   and

4. Evidence of adherence to Vivitrol per pharmacy claims or provider's notes*
   *If not adherent to treatment, beneficiary must meet initial approval criteria.

Contraindications

- Patients receiving opioid analgesics
- Patients with current physiologic opioid dependence
- Patients in acute opioid withdrawal
- Any individual who has failed the naloxone challenge test (naloxone) or has a positive urine screen for opioids
- Patients who have previously exhibited hypersensitivity to naltrexone,polylactide-co-glycolide (PLG), caroboxymethylcellulose, or any other components of the diluent.

Dosing

- Alcohol or Opioid Dependence: 380mg intramuscularly every 4 weeks or once monthly.
- Maximum Dose: 380mg/dose

Dosing Considerations:

Vivitrol must be suspended only in the diluent supplied in the carton and must be administered only with one of the administration needles supplied in the carton. The microspheres, diluent, preparation needle, and an administration needle with needle protection device are required for preparation and administration.

How Supplied

- Each carton contains 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 1/2-inch 20-gauge needles and two 2-inch 20-gauge needles with needle protection devices.