DEPARTMENT OF PUBLIC HEALTH & HUMAN SERVICES
Mountain Pacific INNOVATING BETTER HEALTH
Mailing Address: P.O. Box 5119 | Helena, MT 59604
Phone: 406.443.6002 | Toll-free: 1.800.395.7961
Fax: 406.513.1928 | Toll-free: 1.800.294.1350

Montana Healthcare Programs
Physicians Administered Drugs (PAD) Criteria
Interim Criteria
Vivitrol® (naltrexone extended-release injection)

I. Medication Description

Vivitrol® contains naltrexone, an opioid antagonist, and is indicated for:

- 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.
- Prevention of relapse to opioid dependence, following opioid detoxification.

II. Position Statement

Coverage is determined through a prior authorization process **that must include** supporting clinical documentation for each request.

III. Initial Coverage Criteria

Alcohol Dependence:

Member must meet all of the following criteria:

- Be 18 years of age or older.
- Assessment/screening supports a diagnosis of alcohol dependence.
- Has demonstrated tolerability to oral naltrexone.

Prescriber requirements:

- Must be a Montana Healthcare Programs enrolled provider.
- Must provide clinical rationale documenting necessity to switch to injectable product.
- Prescriber attests to the following:
  - Member has been opioid free for 7 to 10 days or demonstrated negative naloxone or naltrexone challenge.
  - Vivitrol® will NOT be used for the treatment of methamphetamine use disorder. (Vivitrol® has not been U.S. Food and Drug Administration [FDA]-approved for methamphetamine use disorder).

Opioid Use Disorder:

Member must meet all the following criteria:

- Be 18 years of age or older.
- Assessment/screening supports a diagnosis of opioid use disorder (DSM-V).
- Has demonstrated tolerability to oral naltrexone.

Prescriber requirements:

- Must be a Montana Healthcare Programs-enrolled provider.
- Must perform an overdose risk assessment and recommend naloxone if appropriate.
- Must provide clinical rationale documenting why buprenorphine containing products are not appropriate for member. Must provide clinical rationale documenting necessity to switch to injectable product.
- Prescriber attests to the following:
  - Member has been opioid free for 7 to 10 days or demonstrated negative naloxone or naltrexone challenge.
  - Vivitrol® will NOT be used for the treatment of methamphetamine use disorder. (Vivitrol® has not been FDA-approved for methamphetamine use disorder).

Limitations: Dosed per package labeling

IV. Renewal Coverage Criteria

Member must meet all the following criteria:

- Has documentation of positive clinical response to therapy.

Prescriber requirements:

- Must be a Montana Healthcare Programs-enrolled provider.

V. Quantity Limits

Maximum dose = 380 mg IM every four weeks.

VI. Coverage Duration

Initial approval: 12 months

Renewal approval duration: 12 months