I. Medication Description:
Naltrexone is an oral opiate receptor antagonist. It is derived from thebaine and is very similar in structure to oxymorphone. Like parenteral naloxone, naltrexone is a pure antagonist (i.e., agonist actions are not apparent), but naltrexone has better oral bioavailability and a much longer duration of action than naloxone. Clinically, naltrexone is used to help maintain an opiate-free state in patients who are known opiate abusers. Naltrexone is of greatest benefit in patients who take the drug as part of a comprehensive occupational rehabilitative program or other compliance-enhancing program. Unlike methadone or LAAM, naltrexone does not reinforce medication compliance and will not prevent withdrawal.

Naltrexone supports abstinence, prevents relapse, and decreases alcohol consumption in patients treated for alcoholism. Naltrexone is not beneficial in all alcoholic patients and may only provide a small improvement in outcome when added to conventional therapy. The FDA approved Vivitrol, a once-monthly intramuscular naltrexone formulation used to help control cravings for alcohol in April 2006, and then in October 2010, the FDA approved Vivitrol for the prevention of relapse to opioid dependence after opioid detoxification.

II. Length of Authorization:
Coverage will be for 6 months and is eligible for renewal

III. Review Criteria:
- Patient must be 18 years old or over; **AND**
- Patient does not have acute hepatitis or liver failure; **AND**

Alcohol dependence:
- Documented participation in a comprehensive management program including psychosocial support; **AND**
- Patient has failed oral naltrexone (Revia), Antabuse® (disulfiram), or Campral® (acamprosate) therapy; **AND**
- Patient has not had an alcoholic drink for 7 days prior to initiation with Vivitrol; **AND**
- Patient is not taking any opioid medications as evidenced by a urine screen

Opioid dependence:
- Patient is in a comprehensive rehabilitation program; **AND**
IV. **Renewal Criteria:**
- Documented continued clinical benefit to the Patient as defined by complete abstinence from or reduction in the use of alcohol/opioids; **AND**
- Documented participation in a comprehensive management program including psychosocial support; **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include the following: symptoms or signs of acute hepatitis; severe injection site reactions; eosinophilic (allergic) pneumonia; hypersensitivity reactions, including anaphylaxis; development of depression or suicidal thinking.

V. **Dosage/Administration:**

<table>
<thead>
<tr>
<th>Indication</th>
<th>Dose</th>
</tr>
</thead>
<tbody>
<tr>
<td>All indications</td>
<td>380mg administered IM every 4 weeks</td>
</tr>
</tbody>
</table>

VI. **Billing/Code Information:**

**JCode:**
- J2315 – Vivitrol (Alkermes) 380mg injection: 1mg = 1 billable unit

**NDC:**
- Vivitrol 380 mg vial: 65757-0300-xx (Alkermes)

**Max Units (per dose and over time):**
- 380 billable units every 28 days

**Quantity Limits:**
- 1 syringe (380mg) every 28 days

**Covered Diagnosis:**

<table>
<thead>
<tr>
<th>ICD-9 Codes</th>
<th>Diagnosis</th>
</tr>
</thead>
<tbody>
<tr>
<td>303.00</td>
<td>Acute alcoholic intoxication in alcoholism, unspecified</td>
</tr>
<tr>
<td>303.01</td>
<td>Acute alcoholic intoxication in alcoholism, continuous</td>
</tr>
<tr>
<td>303.02</td>
<td>Acute alcoholic intoxication in alcoholism, episodic</td>
</tr>
<tr>
<td>303.03</td>
<td>Acute alcoholic intoxication in alcoholism, in remission</td>
</tr>
<tr>
<td>303.90</td>
<td>Other and unspecified alcohol dependence, unspecified</td>
</tr>
<tr>
<td>303.91</td>
<td>Other and unspecified alcohol dependence, continuous</td>
</tr>
<tr>
<td>303.92</td>
<td>Other and unspecified alcohol dependence, episodic</td>
</tr>
<tr>
<td>303.93</td>
<td>Other and unspecified alcohol dependence, in remission</td>
</tr>
<tr>
<td>304.00</td>
<td>Opioid type dependence, unspecified</td>
</tr>
<tr>
<td>304.01</td>
<td>Opioid type dependence, continuous</td>
</tr>
</tbody>
</table>
VII. **Centers for Medicare and Medicaid Services (CMS):**
Medicare coverage for outpatient (Part B) drugs is outlined in the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals. In addition, National Coverage Determination (NCD) and Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. They can be found at: [http://www.cms.gov/medicare-coverage-database/search/advanced-search.aspx](http://www.cms.gov/medicare-coverage-database/search/advanced-search.aspx). Additional indications may be covered at the discretion of the health plan.

VIII. **Criteria Exclusions:**
- Treatment for diagnoses not FDA approved
- All indications not described in Section III Review criteria are not covered and may be considered experimental or investigational.

IX. **Black Box Warnings/Contraindications:**
**Contraindications:**
- Hypersensitivity to naltrexone or any component of the formulation
- Narcotic dependence or current use of opioid analgesics
- Failure to pass naloxone challenge or positive urine screen for opioids
- Acute hepatitis
- Liver failure

X. **References:**