Clinical Policy: Naltrexone (Vivitrol)

Reference Number: LA.PHAR.96
Effective Date:
Last Review Date: 01.21 — **Coding Implications**
Line of Business: Medicaid — **Revision Log**

See Important Reminder at the end of this policy for important regulatory and legal information.

Description

Naltrexone (Vivitrol®) is an opioid antagonist.

FDA Approved Indication(s)

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***
- **For the prevention of relapse to opioid dependence, following opioid detoxification***

Vivitrol should be part of a comprehensive management program that includes psychosocial support.

Policy/Criteria

Prior authorization is required. Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

It is the policy of Louisiana Healthcare Connections that Vivitrol is medically necessary when the following criteria are met:

I. Initial Approval Criteria

A. Alcohol and Opioid Dependence (must meet all):

1. **Diagnosis of one of the following (a or b):**
   a. **Alcohol dependence;**
   b. **Opioid dependence;**
2. **If diagnosis is alcohol dependence, recent alcohol screening test (within past 7 days) confirms that member has been alcohol-free;**
3. **Recent naloxone challenge test or urine drug screen (within past 7 days) confirms that member is opioid-free;**
4. **Dose does not exceed 380 mg every 4 weeks or once a month.**

Approval duration: 6 months

B. Other diagnoses/indications

1. **Refer to the off-label use policy if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): LA.PMN.53 for Medicaid.**

II. Continued Therapy

A. Alcohol and Opioid Dependence (must meet all):

1. **Currently receiving medication via Louisiana Healthcare Connections benefit or member has previously met initial approval criteria;**
2. **Member is responding positively to therapy;**
3. **Member does not have concurrent opioid claims per pharmacy record;**
4. **Evidence of adherence to Vivitrol per pharmacy claims record or provider's notes;**
   If not adherent to treatment, member must meet initial approval criteria
5. **If request is for a dose increase, new dose does not exceed 380 mg every 4 weeks or once a month.**

Approval duration: 12 months

B. Other diagnoses/indications (must meet 1 or 2):

1. **Currently receiving medication via Louisiana Healthcare Connections benefit and documentation supports positive response to therapy.**
   Approval duration: Duration of request or 6 months (whichever is less); or
2. **Refer to the off-label use policy if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): LA.PMN.53 for Medicaid.**

III. Diagnoses/Indications for which coverage is NOT authorized:

A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policy – LA.PMN.53 for Medicaid, or evidence of coverage documents.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key
FDA: Food and Drug Administration

Appendix B: Therapeutic Alternatives
Not applicable

Appendix C: Contraindications/Boxed Warnings

- **Contraindication(s):**
  - **Patients receiving opioid analgesics;**
  - **Patients with current physiologic opioid dependence;**
  - **Patients in acute opioid withdrawal;**
  - **Any individual who has failed the naloxone challenge test or has a positive urine screen for opioids;**
  - **Patients who have previously exhibited hypersensitivity to naltrexone, polylactide-co-glycolide (PLG), carboxymethylcellulose, or any other components of the diluent.**
- **Boxed warning(s): none reported**

Appendix D: General Information

- **Opioid-dependent and opioid-using patients, including those being treated for alcohol dependence, should be opioid-free before starting Vivitrol treatment, and should notify healthcare providers of any recent opioid use. An opioid-free duration of a minimum of 7-10 days is recommended for patients to avoid precipitation of opioid withdrawal that may be severe enough to require hospitalization.**
- **Although the safety and efficacy of Vivitrol have not been established in the pediatric population, the consensus opinion of the American Society of Addiction Medication (ASAM) national practice guideline committee is that opioid agonists (methadone and buprenorphine) and antagonists (naltrexone) may be considered for treatment of opioid use disorder in adolescents. The American Academy of Pediatrics recommends that pediatricians consider offering medication-assisted treatment to their adolescent and young adult patients with severe opioid use disorders or discuss referrals to other providers for this service.**

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
Alcohol and opioid dependence	380 mg IM every 4 weeks or once a month	380 mg/dose

VI. Product Availability

Injectable suspension (vial): 380 mg naltrexone microspheres and 4 mL diluent

VII. References

1. Vivitrol Prescribing Information. Waltham, MA: Alkermes, Inc.; September 2019. Available at http://www.vivitrol.com. Accessed November 27, 2019.
2. Kampman K, Jarvis M. American Society of Addiction Medicine (ASAM) National Practice Guideline for the use of medications in the treatment of addiction involving opioid use. J Addict Med. 2015 Sept/Oct; 9(5).
3. Kleber HD, Weiss RD, Anton RF et al. Practice guidelines for the treatment of patients with substance use disorders, second addition. American Psychiatric Association. Am J Psychiatry. 2006 Aug;163(8 Suppl):5-82.
4. Practice guideline for the treatment of patients with substance use disorders: alcohol, cocaine, opioids. American Psychiatric Association. Am J Psychiatry. 1995 Nov;152(11 Suppl):1-59.
5. AAP Committee on Substance Use and Prevention. Medication-Assisted Treatment of Adolescents With Opioid Use Disorders. Pediatrics. 2016;138(3):e20161893.

Coding Implications

Codes referenced in this clinical policy are for informational purposes only. Inclusion or exclusion of any codes does not guarantee coverage. Providers should reference the most up-to-date sources of professional coding guidance prior to the submission of claims for reimbursement of covered services.

HCPCS Codes	Description
J2315	Injection, naltrexone, depot form, 1 mg

Reviews, Revisions, and Approvals	Date
Converted corporate to local policy.	1/2021

Important Reminder
This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. LHCC makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved.

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