Clinical Policy: Naltrexone (Vivitrol)

Reference Number: CP.PHAR.96
Effective Date: 03.01.12
Last Review Date: 02.26
Line of Business: Commercial, HIM, Medicaid

Coding Implications
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

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 health plans affiliated with Centene Corporation® that Vivitrol is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria*

*For members in **Nevada**, medical management techniques, including quantity management, beyond step therapy is not allowed.

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. Member meets one of the following (a or b):
   a. Member is currently hospitalized or is being treated in a residential addiction treatment facility, and request is for Vivitrol treatment post-hospital or facility discharge;
   b. Member meets both of the following (i and ii):
      i. If diagnosis is alcohol dependence, member has abstained from drinking prior to Vivitrol therapy;
      ii. Member meets one of the following (1 or 2):
         1) Recent naloxone challenge test or urine drug screen (within past 7 days) confirms that member is opioid-free;
         2) Member is currently being treated at an addiction treatment center or outpatient facility (e.g., physician's office, outpatient clinic), and chart

note documentation is submitted demonstrating daily treatment with oral naltrexone;

3. Dose does not exceed 380 mg every 4 weeks or once a month.

Approval duration:
Medicaid/HIM – 12 months
Commercial – 6 months or to the member's renewal date, whichever is longer

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

1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):
   a. For drugs on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the no coverage criteria policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.33 for health insurance marketplace, and CP.PMN.255 for Medicaid; or
   b. For drugs NOT on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the non-formulary policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.103 for health insurance marketplace, and CP.PMN.16 for Medicaid; or
2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace, and CP.PMN.53 for Medicaid.

II. Continued Therapy*

*For members in **Nevada**, medical management techniques, including quantity management, beyond step therapy is not allowed.

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

1. Member meets one of the following (a or b):
   a. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
   b. Member is currently receiving medication and is enrolled in a state and product with continuity of care regulations (*refer to state specific addendums for CC.PHARM.03A and CC.PHARM.03B);*
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:
Medicaid/HIM – 12 months
Commercial – 6 months or to the member's renewal date, whichever is longer

B. Other diagnoses/indications (must meet 1 or 2)**:**
1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):
   a. For drugs on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the no coverage criteria policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.33 for health insurance marketplace, and CP.PMN.255 for Medicaid; or
   b. For drugs NOT on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the non-formulary policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.103 for health insurance marketplace, and CP.PMN.16 for Medicaid; or
2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace, and CP.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 – CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace, and CP.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.; January 2024. Available at http://www.vivitrol.com. Accessed November 6, 2026.
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):358;367.
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.
6. Center for Substance Abuse Treatment. Medications for opioid use disorder. Rockville (MD): Substance Abuse and Mental Health Services Administration (US); July 2021. (Treatment Improvement Protocol (TIP) Series, No. 63) Available from: https://store.samhsa.gov/product/TIP-63-Medications-for-Opioid-Use-Disorder-Full-Document/PEP20-02-01-006. Accessed November 6, 2025.
7. Center for Substance Abuse Treatment. Medication-assisted treatment for opioid addiction in opioid treatment programs. Treatment improvement protocol (TIP) series 43. DHHS Publication No. (SMA) 05-4048. Rockville, MD: Substance Abuse and Mental Health Services Administration, 2005. Available at: https://www.ncbi.nlm.nih.gov/books/NBK64164/. Accessed November 19, 2026.

8. Center for Substance Abuse Treatment. Detoxification and substance abuse treatment. Treatment improvement protocol (TIP) series, No. 45. HHS Publication No. (SMA) 15-4131. Rockville, MD: Center for Substance Abuse Treatment, 2006. Available at: https://store.samhsa.gov/product/TIP-45-Detoxification-and-Substance-Abuse-Treatment/SMA15-4131. Accessed November 19, 2026.
9. Cunningham C, Edlund MJ, Gordon AJ et al. The ASAM national practice guideline for the treatment of opioid use disorder: 2020 focused update. Available from: https://www.asam.org/quality-care/clinical-guidelines/national-practice-guideline. Accessed November 6, 2025.

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	P&T Approval Date
1Q 2022 annual review: no significant changes; references reviewed and updated.	11.22.21	02.22
Template changes applied to other diagnoses/indications and continued therapy section.	10.12.22	
1Q 2023 annual review: no significant changes; references reviewed and updated.	11.16.22	02.23
1Q 2024 annual review: no significant changes; references reviewed and updated.	10.19.23	02.24
Added disclaimer that medical management techniques, including quantity management, beyond step therapy is not allowed for members in NV per SB 439.	05.30.24	
For alcohol dependence, removed requirement for alcohol screening test and revised to "member has abstained from drinking prior to Vivitrol therapy".	07.12.24	11.24
1Q 2025 annual review: expanded treatment settings to include outpatient facility (e.g., physician's office, outpatient clinic) with chart note documentation submitted demonstrating daily treatment with oral naltrexone; added standard approval language to Commercial line of business to continued therapy; references reviewed and updated.	11.01.24	02.25
1Q 2026 annual review: no significant changes; for Medicaid, extended initial approval duration from 6 to 12 months for this maintenance medication for a chronic condition; for Commercial,	11.06.25	02.26

Reviews, Revisions, and Approvals	Date	P&T Approval Date
revised approval duration to standard language for injectables; references reviewed and updated.		

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. The Health Plan 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. "Health Plan" means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan's affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions, and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment, or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

Note: For Medicaid members, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.