

Clinical Policy: Naltrexone (Vivitrol)

Reference Number: CP.PHAR.96

Effective Date: 03.01.12

Last Review Date: 02.21

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

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 (12 months for New Hampshire)

B. Other diagnoses/indications

1. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace, and CP.PMN.53 for Medicaid.

II. Continued Therapy

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

1. Currently receiving medication via Centene 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 Centene 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 for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): 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.; July 2020. Available at <http://www.vivitrol.com>. Accessed December 2, 2020.
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.
6. Center for Substance Abuse Treatment. Medications for opioid use disorder. Rockville (MD): Substance Abuse and Mental Health Services Administration (US); 2020. (Treatment Improvement Protocol (TIP) Series, No. 63) Available from: <https://store.samhsa.gov/product/TIP-63-Medications-for-Opioid-Use-Disorder-Full-Documents/PEP20-02-01-006>. Accessed December 2, 2020.
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.asam.org/docs/advocacy/samhsa_tip43_matforopioidaddiction.pdf?sfvrsn=0. Accessed December 3, 2020.

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://www.samhsa.gov/search-samhsa/featured/tip-45>. Accessed December 3, 2020.
9. American Society of Addiction Medicine (ASAM). National Practice Guideline for the Use of Medications in the Treatment of Addiction Involving Opioid Use. Available at: <https://www.asam.org/docs/default-source/practice-support/guidelines-and-consensus-docs/asam-national-practice-guideline-supplement.pdf>. Accessed December 3, 2020.

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
Added participation in psychosocial treatment while on Vivitrol to initial and continued criteria. Removed abstaining from alcohol in an outpatient setting and not actively drinking at the time of initial Vivitrol administration and replaced with a requirement for alcohol screening test. Extended initial approval to 6 months and continued approval to 12 months. Added a time period for which naloxone challenge test/urine drug screen is valid. Certain conditions representing potential contraindications to therapy and other safety criteria removed. Formulations added.	02.17	03.17
1Q18 annual review: - Removed requirement related to participation in psychosocial treatment while on Vivitrol from initial and continued approval criteria. - Modified initial approval duration from 6 to 12 months. - References reviewed and updated.	11.10.17	02.18
1Q 2019 annual review: no significant change; shortened initial approval duration from 12 months to 6 months; references reviewed and updated.	10.15.18	02.19
1Q 2020 annual review: no significant changes; added HIM line of business; references reviewed and updated.	11.27.19	02.20
Initial approval duration expanded to 12 months for New Hampshire per regulations.	09.17.20	

Reviews, Revisions, and Approvals	Date	P&T Approval Date
1Q 2021 annual review: added Commercial line of business; references to HIM.PHAR.21 revised to HIM.PA.154; references reviewed and updated.	12.02.20	02.21

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.

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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.

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