Prior Authorization Review Panel

CHC-MCO Policy Submission

A separate copy of this form must accompany each policy submitted for review.
Policies submitted without this form will not be considered for review.

Plan: PA Health & Wellness	**Submission Date**: **7/31/2018**
Policy Number: PA.CP.PHAR.96	**Effective Date: 01/2018** **Revision Date: 07/18/2018**
Policy Name: Naltrexone (Vivitrol)	**HC Approval Date:**

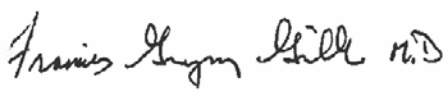
Type of Submission – Check all that apply:

- ☐ **New Policy**
- ☐ **Revised Policy***
- ☐ **Annual Review – No Revisions**
- ☐ **Attestation of HC PARP Policy –** *This option should only be used during Readiness Review for Community HealthChoices. The policy must be identical to the PARP approved policy for the HealthChoices Program, with the exception of revisions/clarifications adding the term "Community HealthChoices" to the policy.*

***All revisions to the policy must be highlighted using track changes throughout the document.**

Please provide any changes or clarifying information for the policy below:

This policy is being retired and will no longer require Prior Authorization.

Name of Authorized Individual (Please type or print): **Francis G. Grillo, MD**	**Signature of Authorized Individual:** 

Clinical Policy: Naltrexone (Vivitrol)

Reference Number: PA.CP.PHAR.96
Effective Date: 01/18
Last Review Date: 03/17

Coding Implications
Revision Log

Description
The intent of the criteria is to ensure that patients follow selection elements established by Pennsylvania Health and Wellness ® clinical policy for naltrexone extended-release injectable suspension (Vivitrol®).

Policy/Criteria
It is the policy of Pennsylvania Health and Wellness 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. Member will participate in psychosocial treatment while on Vivitrol;
5. Prescribed dose of Vivitrol does not exceed 380 mg every 4 weeks or once a month.

Approval Duration: 6 months

B. Other diagnoses/indications: Refer to PA.CP.PHAR.57 - Global Biopharm Policy.

II. Continued Approval

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

1. Currently receiving medication via Pennsylvania Health and Wellness benefit or member has previously met initial approval criteria or the Continuity of Care policy applies (see PA.LTSS.PHAR.01);
2. Documentation of positive response to therapy;
3. Member does not have concurrent opioid claims per pharmacy record;
4. Member will participate in psychosocial treatment while on Vivitrol;
5. Evidence of adherence to Vivitrol per pharmacy claims record or provider's notes;
   **If not adherent to treatment, member must meet initial approval criteria*
6. Prescribed dose of Vivitrol 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 Pennsylvania Health and Wellness benefit or member has previously met initial approval criteria or the Continuity of Care policy applies (PA.LTSS.PHAR.02) and documentation supports positive response to therapy; or
2. Refer to PA.CP.PHAR.57 - Global Biopharm Policy**.**

Background

Description/Mechanism of Action:

Vivitrol (naltrexone for extended-release injectable suspension) is supplied as a microsphere formulation of naltrexone for suspension, to be administered by intramuscular injection. Naltrexone is an opioid antagonist with little, if any, opioid agonist activity; its highest affinity is for the mu opioid receptor. Naltrexone has few, if any, intrinsic actions besides its opioid blocking properties. However, it does produce some pupillary constriction, by an unknown mechanism.

Formulations

Vivitrol is an injectable suspension containing 380 mg of naltrexone in a microsphere formulation and 4 mL diluent.

FDA Approved Indications:

Vivitrol is an opioid antagonist /single-use intramuscular injection suspension indicated for:

- 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.*

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

Safety Information

Warnings and Precautions:

- Vulnerability to Opioid Overdose: Following Vivitrol treatment, opioid tolerance is reduced from pretreatment baseline, and patients are vulnerable to potentially fatal overdose at the end of a dosing interval, after missing a dose, or after discontinuing Vivitrol treatment. Attempts to overcome blockade may also lead to fatal overdose.
- Injection Site Reactions: In some cases, injection site reactions may be very severe. Some cases of injection site reactions required surgical intervention.
- Precipitation of Opioid Withdrawal: 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.
- Hepatotoxicity: Cases of hepatitis and clinically significant liver dysfunction were observed in association with Vivitrol treatment during the clinical development program

and in the postmarketing period. Discontinue use of Vivitrol in the event of symptoms or signs of acute hepatitis.

- Depression and Suicidality: Monitor patients for the development of depression or suicidal thinking.
- When Reversal of Vivitrol Blockade Is Required for Pain Management: In an emergency situation in patients receiving Vivitrol, suggestions for pain management include regional analgesia or use of non-opioid analgesics.

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	Approval Date
This policy is being retired and will no longer require Prior Authorization.	7/18	

References
1. Vivitrol Prescribing Information. Waltham, MA: Alkermes, Inc.; December 2015. Available at http://www.vivitrol.com. Accessed February 13, 2017.
2. Kampman K, Jarvis M. American Society of Addiction Medicine (ASAM) National Practice Guideline for the use of medication sin 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 Psychiatic 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. Johnson BA. Pharmacotherapy for alcohol use disorder. In: UpToDate, Waltham, MA: Walters Kluwer Health; 2016. Available at UpToDate.com. Accessed February 14, 2017.
6. Strain E. Pharmacotherapy for opioid use disorder. In: UpToDate, Waltham, MA: Walters Kluwer Health; 2016. Available at UpToDate.com. Accessed February 13, 2017.