Pharmacy Medical Necessity Guidelines:  
**Vivitrol® (naltrexone extended-release injection)**  
*Effective: April 1, 2019*

<table>
<thead>
<tr>
<th>Prior Authorization Required</th>
<th>√</th>
<th>Type of Review – Care Management</th>
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<td>Not Covered</td>
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<td>Type of Review – Clinical Review</td>
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<tr>
<td>Pharmacy (RX) or Medical (MED) Benefit</td>
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<td>Department to Review</td>
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These pharmacy medical necessity guidelines apply to the following:

**Commercial Products**
- Tufts Health Plan Commercial products – large group plans
- Tufts Health Plan Commercial products – small group and individual plans
- Tufts Health Freedom Plan products – large group plans
- Tufts Health Freedom Plan products – small group plans
- CareLinkSM – Refer to CareLink Procedures, Services and Items Requiring Prior Authorization

**Tufts Health Public Plans Products**
- Tufts Health Direct – A Massachusetts Qualified Health Plan (QHP) (a commercial product)
- Tufts Health Together – MassHealth MCO Plan and Accountable Care Partnership Plans
- Tufts Health RITogether – A Rhode Island Medicaid Plan

**Fax Numbers:**  
MM: 888.415.9055

**Note:** This guideline does not apply to Medicare Members (includes dual eligible Members).

**OVERVIEW**

**FOOD AND DRUG ADMINISTRATION-APPROVED INDICATIONS**

**Alcohol Dependence**
Vivitrol (naltrexone extended release injection) 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.

**Opioid Dependence**
Vivitrol (naltrexone extended release injection) is indicated for the prevention of relapse to opioid dependence, following opioid detoxification.

**COVERAGE GUIDELINES**
The plan may authorize coverage of Vivitrol for Members when all of the following criteria are met:

1. The Member has a documented diagnosis of alcohol dependence OR the Member has a documented diagnosis of opioid dependence and has completed opioid detoxification  
   **AND**
2. The Member is currently abstaining from opioids  
   **AND**

Psychosocial support is part of the recommended treatment plan  
**AND**

The Member has tried and failed a trial with oral naltrexone and an allergy to naltrexone been ruled out  
**OR**

The Member has been stable on Vivitrol for a period of at least 3 months prior to this prior authorization request.

**LIMITATIONS**

1. Vivitrol will not be covered for Members who are concurrently taking any opioids. The provider must indicate the recent opioid use was prior to the completion of a recent detoxification in Members found to have pharmacy claims which indicate that the member has received an opioid within the past 30 days or could have used an opioid within the last 10 days.
2. Initial authorization will be limited to one year as follows:
   a. Vivitrol (naltrexone extended release injection) 380 mg: 1 vial per 28 days.
3. Subsequent authorizations will be provided when the following criteria are met:
   a. Psychosocial support is part of the recommended treatment plan  
   **AND**

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Note: This guideline does not apply to Medicare Members (includes dual eligible Members).
Alcohol Dependence: The member is currently abstaining from alcohol and opioids or the provider documented a significant reduction in the amount of drinking or medically related services such as detox or ER visits **OR**

Opioid Dependence: The member currently abstaining from opioid use.

**CODES**

The following HCPCS/CPT code(s) are:

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
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<tr>
<td>J2315</td>
<td>Injection, naltrexone, depot form, 1 mg</td>
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**REFERENCES**


**APPROVAL HISTORY**

May 9, 2017: Reviewed by Pharmacy & Therapeutics Committee.

Subsequent endorsement date(s) and changes made:
1. December 11, 2018: Effective 4/1/19, clarified criteria to indicate that member either needs to have a trial and failure with oral naltrexone or has been stable on Vivitrol for three months. Administrative changes made to template.

**BACKGROUND, PRODUCT AND DISCLAIMER INFORMATION**

Pharmacy Medical Necessity Guidelines have been developed for determining coverage for plan benefits and are published to provide a better understanding of the basis upon which coverage
decisions are made. The plan makes coverage decisions on a case-by-case basis considering the individual member's health care needs. Pharmacy Medical Necessity Guidelines are developed for selected therapeutic classes or drugs found to be safe, but proven to be effective in a limited, defined population of patients or clinical circumstances. They include concise clinical coverage criteria based on current literature review, consultation with practicing physicians in the service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations. The plan revises and updates Pharmacy Medical Necessity Guidelines annually, or more frequently if new evidence becomes available that suggests needed revisions.

For self-insured plans, coverage may vary depending on the terms of the benefit document. If a discrepancy exists between a Pharmacy Medical Necessity Guideline and a self-insured Member’s benefit document, the provisions of the benefit document will govern.

Treating providers are solely responsible for the medical advice and treatment of members. The use of this policy is not a guarantee of payment or a final prediction of how specific claim(s) will be adjudicated. Claims payment is subject to member eligibility and benefits on the date of service, coordination of benefits, referral/authorization and utilization management guidelines when applicable, and adherence to plan policies and procedures and claims editing logic.