Clinical Policy: Naltrexone (Vivitrol)
Reference Number: ERX.SPMN.71
Effective Date: 12/15
Last Review Date: 09/16

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

Policy/Criteria
It is the policy of health plans affiliated with Envolve Pharmacy Solutions® that naltrexone extended-release injectable suspension (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. Alcohol dependence and both of the following:
            i. Has abstained from alcohol in an outpatient setting prior to initiation of treatment with Vivitrol;
            ii. Is not actively drinking at the time of initial Vivitrol administration;
         b. Opioid dependence and:
            i. Member has contraindications to or has failed trials of methadone and Suboxone;
      2. Member has a contraindication to or has failed a trial of oral naltrexone;
      3. Immediately prior to beginning Vivitrol, will have been opioid free for a minimum of 7 days as evidenced by a naloxone challenge test or urine screen for opioids;
      4. 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 ERX.SPMN.16 - Global Biopharm Policy.

II. Continued Approval
   A. Alcohol and Opioid Dependence (must meet all):
      1. Currently receiving medication via health plan benefit or member has previously met all initial approval criteria;
      2. Opioid free as evidenced by a naloxone challenge test or urine screen for opioids within the last 30 days.

   Approval duration: 6 months

   B. Other diagnoses/indications (must meet 1 or 2):
      1. Currently receiving medication via health plan benefit and documentation supports positive response to therapy; or
      2. Refer to ERX.SPMN.16 - 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.

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.

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.

<table>
<thead>
<tr>
<th>HCPCS Codes</th>
<th>Description</th>
<th>Date</th>
<th>Approval Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>J2315</td>
<td>Injection, naltrexone, depot form, 1 mg</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Reviews, Revisions, and Approvals

<table>
<thead>
<tr>
<th>Event Description</th>
<th>Date</th>
<th>Approval Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Policy created.</td>
<td>11/15</td>
<td>12/15</td>
</tr>
<tr>
<td>Policy converted to new template. Added requirement for alcohol abstinence at time of initial request. Added preferring for oral naltrexone for both indications and additional preferring for methadone and Suboxone for opioid dependence (per literature review, naltrexone is a third-line therapy). Removed prescriber restriction, requests for documentation, and requirement for participation in abuse counseling program. Modified approval duration from 12 months to 6 months. Removed specific requirements for treatment beyond 12 months and 18 months.</td>
<td>07/16</td>
<td>09/16</td>
</tr>
</tbody>
</table>
References

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.

This Clinical Policy is not intended to dictate to providers how to practice medicine, nor does it constitute a contract or guarantee regarding payment or results. 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 policy is the property of Envolve Pharmacy Solutions. Unauthorized copying, use, and distribution of this Policy or any information contained herein is strictly prohibited. By accessing this policy, you agree to be bound by the foregoing terms and conditions, in addition to the Site Use Agreement for Health Plans associated with Envolve Pharmacy Solutions.

©2016 Envolve Pharmacy Solutions. All rights reserved. All materials are exclusively owned by Envolve Pharmacy Solutions and are protected by United States copyright law and international copyright law. No part of this publication may be reproduced, copied, modified, distributed, displayed, stored in a retrieval system, transmitted in any form or by any means, or otherwise published without the prior written permission of Envolve Pharmacy Solutions. You may not alter or remove any trademark, copyright or other notice contained herein.