Use of Injectable Naltrexone (Vivitrol®) for Treatment of Alcohol Dependence

Subject: Use of Injectable Naltrexone (Vivitrol®) for Treatment of Alcohol Dependence
Guideline #: CG-DRUG-21
Status: New
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Description

Alcohol dependence can be treated by rehabilitation and medication. Three oral medications, naltrexone (Depade®, Revia®), acamprosate (Campral®) and disulfiram (Antabuse®) are currently approved to treat alcohol dependence. In some cases, oral medication does not achieve optimum therapeutic effect and in some cases this may be related to poor compliance in taking an oral drug. An injectable, long-acting form of naltrexone (Vivitrol®) has been approved by the FDA for use when the desired clinical effect is not attained with oral medication.

Clinical Indications

Medically Necessary:
Injectable naltrexone (Vivitrol®) is medically necessary for the treatment of alcohol dependence when:
- The individual is being treated for alcohol dependence; and
- The individual has had an initial response and tolerates oral naltrexone (Revia®) but is unable to comply with daily dosing; and
- The individual is able to abstain from alcohol for at least 7 days in an outpatient setting prior to treatment initiation; and
- The individual is not actively drinking at the time of initial Vivitrol® administration; and
- The individual actively participates in a comprehensive rehabilitation program that includes psychosocial support; and
- The individual is not:
  - Currently on opioid analgesics; or
  - Physiologically dependent on opioids; or
  - Currently in acute opioid withdrawal.
- The individual does not have:
  - A positive urine screen for opioids; or
  - A failed naloxone challenge test; or
  - Acute hepatitis; or
  - Liver failure; or
  - Previous hypersensitivity to naltrexone, 75:25 polyactide-co-glycolide (PLG), carboxymethylcellulose or any other component of the diluent.

Place of Service

Place of Service: Ambulatory
Coding

The following codes for treatments and procedures applicable to this UM guideline are included below for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

HCPCS
J2315 Injection, naltrexone, depot form, 1 mg (Vivitrol®)

ICD-9 Diagnosis
291.0-291.9 Alcohol induced mental disorders
303.00-303.03 Acute alcoholic intoxication
303.90-303.93 Other and unspecified alcohol dependence
V11.3 Personal history of mental disorder; alcoholism

Discussion/General Information

The efficacy of Vivitrol® was evaluated in a 24-week, placebo-controlled, multi-center, double-blind, randomized trial of alcohol dependent outpatients. Subjects were treated with an injection every 4 weeks of Vivitrol® 190 mg, Vivitrol® 380 mg, or placebo. Subjects who were abstinent from alcohol for the week prior to initiating treatment with Vivitrol® 380 mg demonstrated a statistically significant 25% reduction in heavy drinking days than those treated with placebo (Garbutt, 2006). Both treatment and placebo groups received psychosocial intervention in addition. In contrast, the effect was not evident in those who were actively drinking at the start of treatment. Vivitrol® is marketed as providing increased compliance as compared to the oral formulation of naltrexone. However, there are no trials to substantiate the claim that increased compliance leads to better outcomes through either increased rates of abstinence or increased time to first heavy drinking day. Heavy drinking is defined by self-report as 5 or more standard drinks consumed on a given day for male patients and 4 or more standard drinks for female patients. The monthly method of administration addresses non compliance with the oral medication regimen and would reduce first-pass hepatic metabolism as compared to oral naltrexone.

Alcoholism is divided into 2 categories: dependence and abuse. Alcohol dependence, the most severe alcohol disorder, is an interrelated cluster of psychological symptoms, such as craving; physiological signs, such as tolerance and withdrawal; and behavioral indicators, such as the use of alcohol to relieve withdrawal discomfort. Alcohol abuse implies alcohol use that causes either physical or mental damage in the absence of dependence.

Nearly 14 million Americans meet diagnostic criteria for alcohol use disorders. For many of these individuals, oral medication and rehabilitation successfully treat their dependence. The oral medications work in different ways:
- naltrexone (Depade®, Revia®): acts within the brain to reduce craving for alcohol after alcohol intake has stopped;
- acamprosate (Campral®): is thought to work by reducing symptoms that follow lengthy abstinence, such as anxiety and insomnia;
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- disulfiram (Antabuse®): discourages drinking by inducing a ‘sick’ feeling, much like a hangover, after alcohol intake; may have significant risks and side effects.

When an individual who is on oral medication therapy, fails to achieve and maintain alcohol abstinence, Vivitrol®, the injectable form of naltrexone (Depade®, Revia®) is an option. Vivitrol® is injected monthly by a healthcare provider. The monthly injections are combined with ongoing rehabilitation.

Definitions

First-pass hepatic metabolism: when an oral medication undergoes passage through the gut and liver before reaching the systemic circulation; the concept provides information about the therapeutic effect of an orally administered drug versus administration via intramuscular or intravenous injection

References


Web Sites for Additional Information

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acamprosate
Antabuse®
Campral®
Depade®
disulfiram
naltrexone
Revia®
Vivitrol®

The use of specific product names is illustrative only. It is not intended to be a recommendation of one product over another, and is not intended to represent a complete listing of all products available.

Policy History

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<th>Status</th>
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<tr>
<td>New</td>
<td>05/17/2007</td>
<td>Medical Policy &amp; Technology Assessment Committee (MPTAC) review. Initial guideline development.</td>
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Federal and State law, as well as contract language, including definitions and specific contract provisions/exclusions, and Medical Policy take precedence over Clinical UM Guidelines and must be considered first in determining eligibility for coverage. The member’s contract benefits in effect on the date that services are rendered must be used. Clinical UM Guidelines, which addresses medical efficacy, should be considered before utilizing medical opinion in adjudication. Medical technology is constantly evolving, and we reserve the right to review and update Clinical UM Guidelines periodically.

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