Vivitrol (Extended-release Injectable Naltrexone)

Iowa Medicaid Program:	Prior Authorization	**Effective Date:** 10/20/2017
Revision Number:		**Last Review Date:** 10/20/2017
Reviewed By:	Medicaid Clinical Advisory Committee	**Next Review Date:** 10/2018
Approved By:	Medicaid Medical Director	**Approved Date:** 11/27/2017

Naltrexone is an oral opiate receptor antagonist. It is derived from thebaine and is very similar in structure to oxymorphone. Like parenteral naloxone, naltrexone is a pure antagonist (i.e., agonist actions are not apparent); however, naltrexone has better oral bioavailability and a much longer duration of action than naloxone. Clinically, naltrexone is used to help maintain an opiate-free state in patients who are known opiate abusers. Naltrexone is of greatest benefit in patients who take the drug as part of a comprehensive occupational rehabilitative program or other compliance-enhancing program. Unlike methadone or LAAM, naltrexone does not reinforce medication compliance and will not prevent withdrawal.

Naltrexone supports abstinence, prevents relapse, and decreases alcohol consumption in patients treated for alcoholism. Naltrexone is not beneficial in all alcoholic patients and may only provide a small improvement in outcome when added to conventional therapy. The FDA approved Vivitrol, a once-monthly intramuscular naltrexone formulation used to help control cravings for alcohol in April 2006, and then in October 2010, the FDA approved Vivitrol for the prevention of relapse to opioid dependence after opioid detoxification.

Criteria: Injectable naltrexone is approvable when **ALL** criteria are met. Prior authorization can be cancelled at any time if there is evidence of opioid or narcotic use. Approval of criteria provides coverage for six months.

1. The member is at least 18 years of age; AND
2. The prescriber must be a behavioral health provider or demonstrate expertise and training in management of substance abuse; AND
3. The member is not currently on opioid analgesics, physiologically dependent on opioids, or in acute opioid withdrawal; AND
4. The member does not have acute hepatitis or liver failure.
5. The dosing schedule of 380 mg IM is given every four weeks.

Additional criteria specific for a diagnosis of opioid dependence:

1. The member has a diagnosis of opioid dependence and/or addiction; AND
2. The member has active participation in a comprehensive drug abuse management program with psychosocial support; AND
3. There is documentation the member has been opioid free for a minimum of 7 to 10 days prior to initiation of therapy. Documentation is provided with relevant laboratory testing which may include urine drug screen for opioids or a naloxone challenge; AND
4. Evidence the member tolerates naltrexone in any form.

Criteria specific for a diagnosis of alcohol dependence:

1. The member has a diagnosis of alcohol dependence; AND
2. The member is actively participating in a comprehensive program addressing alcohol abuse with psychosocial support; AND
3. There is documentation the member is not actively consuming alcohol at the start of therapy; AND
4. There is documentation the member is opioid free demonstrated with a urine drug screen or naloxone challenge test; AND
5. The member has failed oral naltrexone, disulfiram (Antabuse), or acammprosate (Campral); AND
6. Evidence the member tolerates naltrexone in any form.

Reauthorization criteria:

1. Claims history documenting compliance with Vivitrol; AND
2. Documentation of compliance with comprehensive management program with psychosocial support; AND
3. Documentation the member has remained abstinent of substances of abuse.

Codes:
NDC: 65757-300-01
HCPCS: J2315

References Used:
Vivitrol [package insert]. Waltham, MA: Alkermes, Inc.; Dec 2015.

Substance Abuse and Mental Health Services Administration (SAMHSA). Clinical use of extended-release injectable naltrexone in the treatment of opioid use disorder: a brief guide. 2014.

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;9(5):358-67.

The ASAM National Practice Guideline. http://www.asam.org/docs/default-source/practicesupport/guidelines-and-consensus-docs/asam-national-practice-guideline-supplement.pdf?sfvrsn=24. Accessed online: November 21, 2016.

Development of utilization management criteria may also involve research into other state Medicaid programs, other payer policies, consultation with experts and review by the Medicaid Clinical Advisory Committee (CAC). These sources may not be referenced individually unless they are specifically published and are otherwise applicable to the criteria at issue.

Change History:

Change Date:	Changed By:	Description of Change:	New Version Number:

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