

Market Applicability/Effective Date														
Market	FL & FHK	FL MMA	FL LTC	GA	KS	KY	LA	MD	NJ	NV	NY	TN	TX	WA
Applicable	X	N/A	N/A	X	N/A	X	X	N/A	X	X	N/A	N/A	N/A	N/A

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Vivitrol (naltrexone)

CG-DRUG-21

Override(s)	Approval Duration
Prior Authorization	6 months

Medications	Quantity Limit
Vivitrol (naltrexone) Intramuscular Injection	N/A

**Please see State Specific Mandates for NY

APPROVAL CRITERIA

Injectable naltrexone (Vivitrol) may be approved for the treatment of alcohol dependence (alcohol use disorder) when the following criteria have been met:

- I. Individual is being treated for alcohol dependence (alcohol use disorder); **AND**
- II. Individual is not actively drinking at the time of initial injectable naltrexone (Vivitrol) administration; **AND**
- III. Individual is able to abstain from alcohol for at least 7 days in an outpatient setting prior to treatment initiation; **AND**
- IV. Individual actively participates in a comprehensive rehabilitation program that includes psychosocial support; **AND**
- V. Individual is not:
 - A. Currently on opioid analgesics for pain management; **OR**
 - B. Currently on opioid agonists for the treatment of opioid dependence (opioid use disorder) (for example, buprenorphine and methadone); **OR**
 - C. Physiologically dependent on opioids; **OR**
 - D. Currently in acute opioid withdrawal**AND**
- VI. Individual does not have:
 - A. Failed the naloxone challenge test; **OR**
 - B. A positive urine screen for opioids; **OR**
 - C. Acute hepatitis; **OR**
 - D. Liver failure; **OR**
 - E. Previous hypersensitivity to naltrexone, 75:25 polylactide-co-glycolide (PLG), carboxymethylcellulose or any other component of the diluent

Injectable naltrexone (Vivitrol) may be approved for the prevention of relapse to opioid dependence (opioid use disorder) following detoxification when the individual:

- I. Is being treated for opioid dependence (opioid use disorder); **AND**
- II. Has successfully completed an opioid detoxification program; **AND**

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This policy does not apply to health plans or member categories that do not have pharmacy benefits, nor does it apply to Medicare. Note that market specific restrictions or transition-of-care benefit limitations may apply.

WEB-PEC-0618-17

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- III. Has been opioid-free (including buprenorphine and methadone) for at least 7 days prior to initiating treatment with naltrexone (Vivitrol) injection; **AND**.
- IV. Actively participates in a comprehensive rehabilitation program that includes psychosocial support; **AND**
- V. Is not:
 - A. Currently on opioid analgesics for pain management; **OR**
 - B. Currently in acute opioid withdrawal; **OR****AND**
- VI. Does not have:
 - A. A positive urine screen for opioids; **OR**
 - B. A failed naloxone challenge test; **OR**
 - C. Acute hepatitis; **OR**
 - D. Liver failure; **OR**
 - E. Previous hypersensitivity to naltrexone, 75:25 polylactide-co-glycolide (PLG), carboxymethylcellulose or any other component of the diluent.

May not be approved:

Injectable naltrexone (Vivitrol) **may not be approved** for the treatment of alcohol dependence (alcohol use disorder) or opioid dependence (opioid use disorder) when the criteria above are not met.

Injectable naltrexone (Vivitrol) **may not be approved** for the treatment of diagnoses other than alcohol dependence (alcohol use disorder) and opioid dependence (opioid use disorder).

State Specific Mandates		
NY MCD	8/11/16	Vivitrol will no longer require a Prior Authorization Per changes to Social Services Law section 364j, and Public Health Law section 273, prior authorization is not allowable for initial or renewal prescriptions for preferred or formulary buprenorphine or injectable naltrexone when used for detoxification or maintenance treatment of opioid addiction. Food and Drug Administration (FDA) and Compendia supported frequency, quantity and/or duration limits may continue to be applied.
WA MCD	2/15/17	PA removal.

Key References:

Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2016. URL: <http://www.clinicalpharmacology.com>. Updated periodically.

DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. <http://dailymed.nlm.nih.gov/dailymed/about.cfm>.

DrugPoints® System (electronic version). Truven Health Analytics, Greenwood Village, CO. Updated periodically.

Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2016; Updated periodically.

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