

Market Applicability													
Market	DC	FL & FHK	FL MMA	FL LTC	GA	KY	MD	NJ	NV	NY	TN	TX	WA
Applicable	NA	X	NA	NA	NA	X	X	NA	X	X	NA	NA	NA

*FHK- Florida Healthy Kids

Vivitrol (naltrexone)

Override(s)	Approval Duration
Prior Authorization	1 year

****New York Medicaid – See State Specific Mandates below***

Medications
Vivitrol (naltrexone) Intramuscular Injection

APPROVAL CRITERIA

Requests for Vivitrol (injectable naltrexone) **for the treatment of alcohol dependence (alcohol use disorder)** may be approved if the following criteria are 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. Vivitrol is used as a part of a substance use disorder treatment program to include counseling and psychosocial support.

Requests for Vivitrol (injectable naltrexone) **for the treatment of opioid dependence (opioid use disorder)** may be approved if the following criteria are met:

- I. Individual is being treated for opioid dependence (opioid use disorder); **AND**
- II. Individual has successfully completed an opioid detoxification program; **AND**
- III. Individual has been opioid-free (including buprenorphine and methadone) for at least 7 days prior to initiating treatment with naltrexone (Vivitrol) injection; **AND**.
- IV. Vivitrol is used as a part of a substance use disorder treatment program to include counseling and psychosocial support.

Requests for Vivitrol (injectable naltrexone) may **not** be approved if the following criteria are met:

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.

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- I. Individual is currently on opioid analgesics for pain management; **OR**
- II. Individual is currently on opioid agonists for the treatment of opioid dependence (opioid use disorder) (for example, buprenorphine and methadone); **OR**
- III. Individual is physiologically dependent on opioids; **OR**
- IV. Individual is currently in acute opioid withdrawal; **OR**
- V. Individual has a positive urine screen for opioids; **OR**
- VI. Individual has a failed naloxone challenge test; **OR**
- VII. Individual has acute hepatitis; **OR**
- VIII. Individual has liver failure; **OR**
- IX. Individual has previous hypersensitivity to naltrexone, 75:25 polylactide-co-glycolide (PLG), carboxymethylcellulose or any other component of the diluent.

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:

1. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2018. URL: <http://www.clinicalpharmacology.com>. Updated periodically.
2. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. <http://dailymed.nlm.nih.gov/dailymed/about.cfm>. Accessed: June 14, 2018.
3. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
4. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2018; Updated periodically.

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5. Substance Abuse and Mental Health Services Administration (SAMHSA). Behavioral health trends in the United States: Results from the 2014 National Survey on Drug Use and Health; 2014. Available at: <http://www.samhsa.gov/data/sites/default/files/NSDUH-FRR1-2014/NSDUH-FRR1-2014.pdf>. Accessed on June 30, 2017.
6. 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. 2015a. Available at: <http://store.samhsa.gov/shin/content/SMA14-4892/SMA14-4892.pdf>. Accessed on June 30, 2017.
7. Substance Abuse and Mental Health Services Administration (SAMHSA). Medication for the treatment of alcohol use disorder: A brief guide. 2015b. Available at: <http://store.samhsa.gov/shin/content/SMA15-4907/SMA15-4907.pdf>. Accessed on June 30, 2017.

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