Vivitrol (naltrexone)
Policy Number: C5775-A

CRITERIA EFFECTIVE DATES:

ORIGINAL EFFECTIVE DATE	LAST REVIEWED DATE	NEXT REVIEW DATE
6/1/2014	7/17/2019	7/17/2020
J CODE	**TYPE OF CRITERIA**	**LAST P&T APPROVAL/VERSION**
J2315-Injection, naltrexone, depot form, 1 mg	RxPA	Q3 2019 20190828C5775-A

PRODUCTS AFFECTED:
Vivitrol (naltrexone)

DRUG CLASS:
Opioid Antagonists

ROUTE OF ADMINISTRATION:
Intramuscular

PLACE OF SERVICE:
Specialty Pharmacy
The recommendation is that medications in this policy will be for pharmacy benefit coverage and administered in a place of service that is a non-hospital facility based location (i.e., home infusion provider, provider's office, free-standing ambulatory infusion center)

AVAILABLE DOSAGE FORMS:
Vivitrol SUSR 380MG 1 vials, 1 each Naltrexone 380mg, Powder for suspension for injection

FDA-APPROVED USES:
It is indicated for the treatment of alcohol dependence in patients who are able to abstain from alcohol in an outpatient setting prior to initiation of treatment.
For the prevention of relapse to opioid dependence following opioid detoxification.

COMPENDIAL APPROVED OFF-LABELED USES: None

COVERAGE CRITERIA: INITIAL AUTHORIZATION

DIAGNOSIS: Alcohol dependence, Opioid dependence

REQUIRED MEDICAL INFORMATION:
A. ALL INDICATIONS
1. Member does NOT require prescribed opioid medications for treatment of a medical condition (i.e. for pain management, cough suppressant, etc.)
AND
2. Member is NOT in acute opioid withdrawal
AND
3. Prescriber attests that patient has been Opioid-free (including buprenorphine and methadone) for a minimum of 7-10 days
AND

4. Member does NOT have Acute hepatitis, Active liver disease (AST or ALT > 3 times the upper limit of normal), Severe hepatic impairment (Child-Pugh class C) as evidenced by liver function studies
AND
5. Prescriber attests that patient has had an initial response and tolerates oral naltrexone but is unable to comply with daily dosing

B. ALCOHOL DEPENDENCE(AUD):
1. Documentation prescriber recommends a comprehensive rehabilitation program that includes psychosocial support provided by a program counselor qualified by education, training, or experience to assess the psychological and sociological background of individuals receiving treatment
AND
2. Prescriber attests that patient is able to abstain from alcohol at least 7 days in an outpatient setting prior to treatment initiation
AND
3. Documentation patient has had an initial reponse and tolerate ORAL anti-alcoholic agents [acamprosate or disulfiram (Antabuse®)] or oral naltrexone (Revia®), but is unable to comply with daily dosing.

C. OPIOID DEPENDENCE/OPIOID USE DISORDER (OUD)
1. Diagnosis clinically based on history and physical exam findings that support Diagnostic and Statistical Manual of Mental Disorders, 5th ed. DSM-V-TR criteria for Opiate Abuse and Dependence and/or DSM-IV-TR criteria for opioid dependence
AND
2. (a) FOR STATES WITH PRESCRIPTION DRUG MONITORING PROGRAMS (PDMPs): Prescriber utilized (and will continue to utilize) the applicable State PDMP prior to issuance of a prescription or continuation of therapy request to ensure the member is not concurrently utilizing opioids, benzodiazepines or sedative/hypnotic agents. NOTE: PDMP check is required on date of request and completed within the last 48 hours.
OR
(b) FOR STATES WITHOUT PDMPs: Prescriber agrees to review member's records AND/OR perform drug screens on a periodic basis or as necessary to ensure no abuse or diversion of the buprenorphine/naloxone or buprenorphine
AND
3. Documentation prescriber recommends a comprehensive rehabilitation program that includes psychosocial support provided by a program counselor qualified by education, training, or experience to assess the psychological and sociological background of individuals receiving treatment
AND
4. Prescriber agrees to administer random clinical drug testing a minimum of eight times per year (*or more frequently as appropriate for member) EXCEPTION: If drug screen is POSITIVE for ANY non-prescribed drug of abuse, prescriber must submit an acknowledgement and rationale for requesting continued therapy despite a positive drug screen. Continuation of therapy will not be authorized unless written documentation is submitted for Molina Pharmacy/Medical Director Review
AND
6. Members with Behavioral Health Disorders ONLY: Prescriber agrees to coordinate or oversee ongoing behavioral health care for co-existing behavioral health disorders
AND
7. Prescriber attests that patient has had an initial response and tolerates oral naltrexone but is unable to comply with daily dosing

DURATION OF APPROVAL: Initial authorization may be authorized up to 3 months (3 injections per authorization period). Continuation of therapy: 12 months

QUANTITY:
Quantity limit: One vial per 28 days of Vivitrol (naltrexone) 380 mg strength. Each IM injection (no more than 380mg/injection) must be given by a physician or nurse once every 4 weeks

PRESCRIBER REQUIREMENTS: None

AGE RESTRICTIONS:
18 years of age or older

GENDER:
Male and female

CONTINUATION OF THERAPY:
A. ALL INDICATIONS:

1. Prescriber attests to Adherence to plan of treatment as prescribed and verified by Prescriber
   AND
2. A clinical rationale for continued treatment for the prevention of relapse: Improvement in opioid and/or alcohol dependence evidenced by a decrease or cessation of use/abuse of alcohol and/or opioids
   AND
3. Active participation in at least monthly formal behavioral health counseling, substance abuse counseling, or an addiction recovery program as determined appropriate for individual patient by the Prescriber. If member is not on continued counseling program, Prescriber to submit documentation of reason counseling has been discontinued for this member.
   AND
4. Prescriber agrees to continue to administer random clinical drug testing a minimum of eight times per year (*or more frequently as appropriate for member) EXCEPTION: If drug screen is POSITIVE for ANY non-prescribed drug of abuse, prescriber must submit an acknowledgement and rationale for requesting continued therapy despite a positive drug screen. Continuation of therapy will not be authorized unless written documentation is submitted for Molina Pharmacy/Medical Director Review

CONTRAINDICATIONS/EXCLUSIONS/DISCONTINUATION:
All other uses that are not an FDA-approved indication or not included in the 'Coverage Criteria' section of this policy are considered experimental/investigational or not a covered benefit of this policy. This subject to change based on research and medical literature, or at the discretion of Molina Healthcare.

OTHER SPECIAL CONSIDERATIONS: None

BACKGROUND:
Vivitrol- extended-release, injectable Naltrexone- is an opioid antagonist that binds to the opioid receptors, blocking the euphoric effects of exogenous opioids in those who are opioid dependent. The neurobiological mechanism by which it reduces alcohol consumption in alcohol dependent individuals is not entirely understood, but clinical data suggests that there is involvement of the

endogenous opioid system. Vivitrol is approved for the treatment of alcohol dependency for individuals who are able to abstain from alcohol in an outpatient setting prior to initiation of treatment with Vivitrol. Vivitrol is also approved for preventing opioid dependence relapse, following opioid detoxification. Vivitrol is administered via intramuscular injection and generally produces a sustained effect for 30 days.

APPENDIX: None

REFERENCES:

1. Vivitrol [Product information], Cambridge, MA. Alkermes, Inc.; December 01, 2015.
2. Lobmaier PP, Kunoe N, Gossop M, Waal H. Naltrexone depot formulations for opioid and alcohol dependence: a systematic review. CNS Neurosci Ther. 2011; 17(6):629-636.
3. Naltrexone Monograph. Lexicomp® Online, American Hospital Formulary Service® (AHFS®) Online, Hudson, Ohio, Lexi-Comp., Inc.
4. Substance Abuse and Mental Health Services Administration. Clinical Use of Extended-Release Injectable Naltrexone in the Treatment of Opioid Use Disorder: A Brief Guide. HHS Publication No. (SMA) 14-4892R. Rockville, MD: Substance Abuse and Mental Health Services Administration, 2015