Vivitrol (naltrexone for extended-release injectable suspension)
Policy Number: C5775-A

CRITERIA EFFECTIVE DATES:

ORIGINAL EFFECTIVE DATE	LAST REVIEWED DATE	NEXT REVIEW DUE BY OR BEFORE
06/2014	12/16/2020	1/26/2022
HCPCS CODING	**TYPE OF CRITERIA**	**LAST P&T APPROVAL/VERSION**
J2315-injection, naltrexone, depot form, 1mg	RxPA	Q1 2021 20210127C5775-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. Prescriber attests to all of the following:
   (a) that member does NOT require prescribed opioid medications for treatment of a medical condition (i.e. for pain management, cough suppressant, etc.)
   AND
   (b) member is NOT in acute opioid withdrawal
   AND
   (c) member has been opioid-free (including buprenorphine and methadone) for a minimum of 7-10

days
AND
(d) 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
(e) Member has had an initial response and tolerates oral naltrexone but is unable to comply with daily dosing

B. ALCOHOL DEPENDENCE (AUD):

1. Prescriber attestation of counseling member regarding 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 response and tolerate ORAL anti-alcoholic agents [acamprosate or disulfiram (Antabuse®)] or oral naltrexone (Revia®) but is unable to comply with daily dosing.
   AND
4. Prescriber agrees to administer random clinical drug testing a minimum of twice per year (*or more frequently as appropriate for member)

C. OPIOID DEPENDENCE/OPIOID USE DISORDER (OUD)

1. Documented diagnosis of opioid use disorder or opioid dependence
   AND
2. (a) FOR STATES WITH PRESCRIPTION DRUG MONITORING PROGRAMS (PDMPs): Prescriber attestation that they utilized (and will continue to utilize) the applicable State PDMP prior to issuance of a prescription or continuation of therapy request
   OR
   (b) FOR STATES WITHOUT PDMPs: Prescriber attestation that they will review member's records on a periodic basis or as necessary to ensure no abuse or diversion
   AND
3. Prescriber attestation of counseling member regarding 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 twice per year (*or more frequently as appropriate for member) [MOLINA NOTE]- EXCEPTION: If drug screen is POSITIVE for ANY non-prescribed drug of abuse or NEGATIVE for prescribed drug, 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 Clinical Review
   AND
5. Members with co-existent Behavioral Health Disorders ONLY: Prescriber agrees to coordinate or oversee
   ongoing behavioral health care for co-existing behavioral health disorders
   AND
6. 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

CONTINUATION OF THERAPY:
A. ALL INDICATIONS:
1. Compliance with Vivitrol (naltrexone for extended-release injectable suspension) therapy since previous authorization [VERIFIED BY PRESCRIBER SUBMITTED DOCUMENTATION OR PHARMACY CLAIMS DATA]
AND
2. Prescriber attestation of monitoring that member has adhered to any recommendations regarding 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
3. Prescriber agrees to administer random clinical drug testing a minimum of twice per year (*or more frequently as appropriate for member) [MOLINA NOTE]- EXCEPTION: If drug screen is POSITIVE for ANY non-prescribed drug of abuse or NEGATIVE for prescribed drug, 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 Clinical 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:

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

Documentation Requirements:

Molina Healthcare reserves the right to require that additional documentation be made available as part of its coverage determination; quality improvement; and fraud; waste and abuse prevention processes. Documentation required may include, but is not limited to, patient records, test results and credentials of the provider ordering or performing a drug or service. Molina Healthcare may deny reimbursement or take additional appropriate action if the documentation provided does not support the initial determination that the drugs or services were medically necessary, not investigational or experimental, and otherwise within the scope of benefits afforded to the member, and/or the documentation demonstrates a pattern of billing or other practice that is inappropriate or excessive.

REFERENCES:

1. Vivitrol (naltrexone) [prescribing information]. Waltham, MA: Alkermes, Inc; September2019.
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