Premier Health Plan

POLICY AND PROCEDURE

POLICY TITLE: ***Vivitrol (naltrexone extended release injection)***
DEPARTMENT: **Clinical Pharmacy Services- Utilization Management**
ORIGINAL DATE: ***Month Year (as adopted from UPMC Health Plan)***

Last P & T Committee Approval Date: *February 2018*

Product Applicability: *mark all applicable products below:*

COMMERCIAL	[ ] HMO [ ] PPO *Products*: [ ] Small [ ] Indiv. [ ] Large *Exchange*: [ ] Shop [ ] Indiv. [x] All
OTHER	[x] Self-funded/ASO

PURPOSE

The purpose of this policy is to define the prior authorization process for Vivitrol (naltrexone extended release injection).

Vivitrol (Naltrexone ER injection) 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 with naltrexone ER injection (Vivitrol). Patients should not be actively drinking at the time of initial naltrexone ER injection (Vivitrol) administration. Naltrexone ER injection (Vivitrol) is also indicated for prevention of relapse to opioid dependence, following opioid detoxification.

DEFINITIONS

Addiction Specialist- a physician certified by the American Board of Addiction Medicine (ABAM) and/or psychiatrist certified by the American Board of Psychiatry and Neurology (ABPN) who has demonstrated by education, experience, and examination the requisite knowledge and skills to provide prevention, screening, intervention, and treatment for substance use and addiction.

POLICY

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It is the policy of the Health Plan to maintain a prior authorization process that promotes appropriate utilization of specific drugs with potential for misuse or limited indications. This process involves a review using Food and Drug Administration (FDA) criteria to make a determination of Medical Necessity, and approval by the Pharmacy & Therapeutics Committee of the criteria for prior authorization, as described in RX.002 Pharmacy and Therapeutics Committee and RX.003-Prior Authorization Process.

The drug, Vivitrol (Naltrexone ER injection)m, is subject to the prior authorization process.

PROCEDURE

Initial Authorization Criteria:

Must meet all of the criteria listed below:

- Must have a diagnosis of alcohol dependence or opioid dependence
- Must be prescribed by an addiction specialist
- Must not have acute hepatitis or liver failure
- Must have evidence of tolerability to oral naltrexone
- Must not be in acute opioid withdrawal
- Must not be on concurrent therapy with opioids. The member's pharmacy claim history is reviewed for any attempted fills for opioid prescriptions.
- Must be opioid-free for a minimum of 7-10 days before starting treatment with naltrexone ER injection (Vivitrol)
- Must have a negative urine drug screen for opioids. Documentation of urine drug screen is required.
- Must have documentation of an initial evaluation or scheduled appointment by a licensed Drug & Alcohol provider to determine the recommended level of care.

Reauthorization Criteria:

All prior authorization renewals are reviewed on a 6-month basis to determine the Medical Necessity for continuation of therapy. Authorization may be extended at 6-month intervals based upon chart documentation from the prescriber that the member's disease course has stabilized or improved based on the prescriber's assessment while on therapy. In addition, for continuation:

- Must have documentation of a negative urine drug screen for opioids
- Must not be on concurrent therapy with opioids. The member's pharmacy claims are reviewed for attempts to fill any opioid prescriptions.
- Must be participating in counseling as follows:
    - For members approved initially for 3 months (1st reauthorization only):
        - Must have chart documentation confirming completion of evaluation with a licensed D&A provider which indicates the recommended level of care and have begun treatment in a licensed drug and alcohol treatment program
        - Must have chart documentation showing participation in formal behavioral health counseling and/or substance abuse counseling that is consistent with the level of care recommended at the initial evaluation.
    - For members approved previously for 6 months:
        - Must have documentation of participation with a licensed D&A at the recommended level of care until completion of the program AND
        - Must have chart documentation showing participation of at least monthly formal behavioral health counseling, substance abuse counseling, or an addiction recovery program as indicated in the initial D&A evaluation. After a period of 1 year, less formal programs would be allowed as participation.
    - An annual evaluation by a licensed D&A provider is required.

Limitations:

Length of Authorization (if above criteria met)	
Initial Authorization	• Member who is referred to or has a D&A appointment scheduled but has not yet been evaluated: up to 3 months • Member who has been evaluated by a D&A provider which indicates the recommended level of care and has begun treatment in a licensed D&A program: up to 6 months
Reauthorization	Up to 6 months

If the established criteria are not met, the request is referred to a Medical Director for review.

REFERENCES

1. Vivitrol [package insert]. Waltham, MA: Alkermes, Inc.; October 2010.

RECORD RETENTION

Records Retention for Evolent Health documents, regardless of medium, are provided within the Evolent Health records retention policy and as indicated in CORP.028.E Records Retention Policy and Procedure.

REVIEW HISTORY

DESCRIPTION OF REVIEW / REVISION	DATE APPROVED
Annual review	*02/17, 02/18*