



Clinical Edit Criteria Proposal

Drug/Drug Class: Vivitrol® Clinical Edit

Date: April 10, 2009

Prepared for:

Prepared by: MO HealthNet

New Criteria

Revision of Existing Criteria

Executive Summary

Purpose: Ensure appropriate utilization of Vivitrol® (naltrexone for extended-release injectable suspension).

Why was this Issue Selected: Vivitrol® is a branded new drug product containing extended-release naltrexone. It is a once monthly intramuscular gluteal injectable indicated for the treatment of alcohol dependence for patients who are able to abstain from alcohol in an outpatient setting prior to initiation of treatment. This opioid antagonist has a high affinity for the mu-opioid receptor. Naltrexone blocks the effects of opioids by competitively binding at opioid receptors. Vivitrol is not aversive therapy and does not cause disulfiram-like reaction as a result of opioid use or ethanol ingestion. Treatment with naltrexone injections should be part of a comprehensive management program that includes psychosocial support.

Program-specific information:	Drug	Cost/Claim
	• Vivitrol Injection	\$764.50/mo
	• Revia 50mg Tabs	\$139.74/mo
	• Naltrexone Tabs	\$50.60/mo

Setting & Population: Patients 18 years of age and older

Type of Criteria:

<input type="checkbox"/> Increased risk of ADE	<input type="checkbox"/> Non-Preferred Agent
<input checked="" type="checkbox"/> Appropriate Indications	<input type="checkbox"/>

Data Sources:

<input type="checkbox"/> Only administrative databases	<input checked="" type="checkbox"/> Databases + Prescriber-supplied
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Setting & Population

- Drug for review: Vivitrol® (naltrexone extended-release injectable suspension)
- Age range: Patients 18 years of age and older
- Gender: Male and female

Approval Criteria

- Prior Diagnosis of alcohol, opiate, or poly substance abuse or dependence
 - See attached Appendix A
 - May be subject to clinical review
- **Patient currently enrolled in CSTAR**
- OR
- **Substance abuse program or mental health treatment services recognized by the Department of Mental Health Division of Alcohol and Drug Abuse**
 - **See attached Appendix B**
- Adequate trial on oral naltrexone therapy
 - Identified as one claim
- Claims history free of opiate prescriptions in most recent 45 days
- No pre-scheduled surgeries

Denial Criteria

- Lack of approval criteria
- Claims for patients under 18 years of age
- **Pregnancy**

References

1. Facts and Comparisons, pg. 383 – 385b. 2008.
2. USPDI, Micromedex, 2008.
3. Lippincott, Williams, Wilkins. PDR Electronic Library, Montvale NJ; 2008.
4. Cephalon Inc., “Vivitrol AMCP Dossier Submission”, Frazer, PA. September 2006.

Appendix A

Substance abuse diagnosis codes for Clinical Consultant Review :

Condition	Submitted ICD-9 Diagnoses	History Date Range
Alcohol-induced Mental Disorders	291 – 291.9	730 days
Drug-induced Mental Disorders	292 – 292.9	730 days
Alcohol Dependence Syndrome	303 – 303.9	730 days
Drug Dependence	304 – 304.9	730 days
Alcohol Abuse	305.0	730 days
Cannabis Abuse	305.2	730 days
Hallucinogen Abuse	305.3	730 days
Sedative, Hypnotic or Anxiolytic Abuse	305.4	730 days
Opioid Abuse	305.5	730 days
Cocaine Abuse	305.6	730 days
Amphetamine Abuse	305.7	730 days
Other or Unspecified Drug Abuse	305.9	730 days

Appendix B

Substance Abuse or Mental Health Treatment Services HCPCS or Procedure Codes for Clinical Consultant Review :

Condition	Submitted HCPCS or Procedure Codes	History Date Range
Behavioral Health Counseling & Therapy (15 min)	H0004	730 days
Alcohol & or Drug Services; Group	H0005	730 days
Behavioral Health Day Treatment (per hour)	H2012	730 days
Alcohol & or Substance Abuse Services (Family/Couples)	T1006	730 days
Individual Psychotherapy (Office or Outpt Facility) 20-30 min	90804	730 days
Individual Psychotherapy (Office or Outpt Facility) 45-50 min	90806	730 days
Family Psychotherapy (with patient present)	90847	730 days
Group Psychotherapy (Other than of a multiple-family group)	90853	730 days
Individual Psychotherapy (Inpt or Partial Hosp or Res Care Setting) 20-30 min	90816	730 days
Individual Psychotherapy (Inpt or Partial Hosp or Res Care Setting) 45-50 min	90818	730 days
Individual Psychotherapy (Office or Outpt Facility) 20-30 min w/ Medical Eval & Mgmt Services	90805	730 days
Individual Psychotherapy (Office or Outpt Facility) 45-50 min w/ Medical Eval & Mgmt Services	90807	730 days
Individual Psychotherapy (Inpt or Partial Hosp or Res Care Setting) 20-30 min w/ Medical Eval & Mgmt Services	90817	730 days
Individual Psychotherapy (Inpt or Partial Hosp or Res Care Setting) 45-50 min w/ Medical Eval & Mgmt Services	90819	730 days