MEDICAL POLICY

POLICY TITLE	TREATMENT OF OPIATE AND ALCOHOL ADDICTION
POLICY NUMBER	MP-2.301

Original Issue Date (Created):	**July 1, 2002**
Most Recent Review Date (Revised):	**March 25, 2014**
Effective Date:	**June 1, 2014**

I. POLICY

Treatment of Opiate Addiction

Methadone

Methadone detoxification treatment may be considered **medically necessary** for opiate addiction in patients who, by history, physical examination, urinalysis or hair sample, demonstrate a current state of physiologic dependence on opiates.

Treatment must be rendered in a U.S. Food and Drug Administration (FDA) approved program. The program must adhere to the following criteria:

- Must dispense and use methadone in oral form only. Methadone products, when used for the treatment of narcotic addiction in detoxification must be provided by approved hospital pharmacies or approved community pharmacies. A methadone product used as an analgesic, and not for the treatment of opiate addiction, may be dispensed in any licensed pharmacy.
- May admit patients under the age of 18 to be detoxified using methadone only under special circumstances, since the safety and effectiveness of methadone in the treatment of adolescents has not been approved by adequate clinical study. The FDA requires that such patients must have a documented history of two or more unsuccessful attempts at detoxification and a documented history of dependence on heroin or other morphine-like drugs beginning two years prior to application for treatment. Under such conditions, a parent, legal guardian, or responsible adult designated by the state authority must complete and sign an FDA "Consent for Methadone Treatment" form.
- Shall include, under FDA requirements, a detoxification treatment not to exceed twenty-one (21) days and not to be repeated earlier than four (4) weeks after completion of the proceeding course. Treatment with methadone over twenty-one (21) days is considered maintenance treatment.

Attention should be directed to women of childbearing age for the potential of addicted babies.

Buprenorphine

Buprenorphine treatment (e.g., Subutex® or Suboxone®) may be considered **medically necessary** for opiate addiction in patients who, by history, physical examination, urinalysis or hair sample, demonstrate a current state of physiologic dependence on opiates.

These medications can only be prescribed by physicians who have waivers to prescribe buprenorphine for the treatment of opioid addiction from the Substance Abuse and Mental Health Services Administration Center for Substance Abuse Treatment (SAMHSA), part of the U.S. Department of Health and Human Services. Buprenorphine should be used by these qualified physicians in combination with psychosocial counseling.

NOTE: Aside from Subutex® and Suboxone®, other forms of buprenorphine (e.g., Buprenex®) are not approved for treatment of opioid addiction2.

Treatment of Alcohol Addiction and Prevention of Relapse to Opioid Dependence

Naltrexone (Vivitrol®)

Injectable naltrexone (Vivitrol) is considered medically necessary for the treatment of alcohol dependence when the individual meets the following criteria:

- Able to abstain from alcohol in an outpatient setting prior to the initiation of treatment.
- Opioid free
- Actively participating in a comprehensive management program that includes psychosocial support

Injectable naltrexone (Vivitrol) is considered medically necessary for the prevention of relapse to opioid dependence following opioid detoxification when the individual meets the following criteria.

- Urine drug screen for opioids is negative **OR**
- Naloxone challenge test is negative.
- Actively participating in a comprehensive management program that includes psychosocial support.

Cross-reference:

MP-2.303 Opioid Antagonists Under Heavy Sedation or General Anesthesia as a Technique of Opioid Detoxification

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II. PRODUCT VARIATIONS

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[N] = No product variation, policy applies as stated
[Y] = Standard product coverage varies from application of this policy, see below

[N] Capital Cares 4 Kids
[N] PPO
[N] HMO
[N] SeniorBlue HMO
[N] SeniorBlue PPO
[N] Indemnity
[N] SpecialCare
[N] POS
[Y] FEP PPO*

III. DESCRIPTION/BACKGROUND

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Methadone Hydrochloride is a synthetic narcotic analgesic with multiple actions similar to those of morphine. Its principal use is detoxification or maintenance in opiate addiction (heroin or other morphine-like drugs). Maintenance programs must be approved by the FDA and the designated state authority (usually the Department of Health). The FDA further states that "If methadone is administered for treatment of heroin dependence for more than three weeks, the procedure passes from treatment of the acute withdrawal syndrome (detoxification) to maintenance therapy. Maintenance treatment is permitted to be undertaken only by approved methadone programs. This does not preclude the maintenance treatment of an addict who is hospitalized for medical conditions other than addiction and who requires temporary maintenance during the critical period of his stay or whose enrollment has been verified in a program which has been approved for maintenance treatment with methadone."

Buprenorphine, a partial agonist analgesic, is an antagonist at the κ-opioid receptor but is a partial agonist at the μ-opioid receptor. Buprenorphine may precipitate withdrawal effects in those dependent on morphine-like drugs, but to a lesser degree than mixed agonist-antagonists (pentazocine, butorphanol, and nalbuphine). Buprenorphine produces less psychotomimetic effects that are seen with mixed agonist-antagonists.

The induction phase of buprenorphine treatment is typically initiated as observed therapy in a physician's office and may be carried out using either Subutex® or Suboxone®. Following induction, Suboxone®, because of the presence of naloxone, is preferred when clinical use includes unsupervised administration. Because of the long half-life of buprenorphine, it is sometimes possible to switch patients to alternate-day dosing once stabilization has been achieved. The length of time of the maintenance phase is individualized for each patient and may be indefinite. The alternative to going into (or continuing) a maintenance phase, once stabilization has been achieved, is medically supervised withdrawal.

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In October 2002, the U.S. Food and Drug Administration (FDA) approved buprenorphine monotherapy product, Subutex®, and a buprenorphine/naloxone combination product, Suboxone®, for use in opioid addiction treatment. Suboxone® is designed to decrease the potential for abuse by injection. Buprenex®, the parenteral form of buprenorphine, is FDA-approved for the relief of moderate to severe pain and is not FDA-approved for use in opioid addiction treatment.

Vivitrol® (naltrexone for extended-release injectable suspension), is an opioid antagonist with highest affinity for the μ-opioid receptor. The neurobiological mechanisms responsible for the reduction in alcohol consumption observed in patients with alcohol dependence treated with naltrexone are not entirely understood. Preclinical data suggest that occupation of the opioid receptors by Vivitrol may result in the blockade of the neurotransmitters in the brain that are believed to be involved with alcohol dependence. This blockade may result in the reduction in alcohol consumption observed in patients taking Vivitrol. The drug also blocks any pain-relieving actions of opioid medications.

A single injection of Vivitrol delivers naltrexone for a month using a proven technology called Medisorb®. This technology encapsulates naltrexone in microspheres made of a biodegradable polymer called poly(d,l-lactide-co-glycolide) or PLG1 The PLG polymer has a history of safe use in humans in the form of absorbable sutures, abdominal mesh, bone plates, and other extended-release pharmaceuticals. With this technology, naltrexone is steadily released as the polymer breaks down. The recommended dose of Vivitrol is 380 mg delivered intramuscularly every 4 weeks or once a month. The injection should be administered by a healthcare professional as an intramuscular (IM) gluteal injection, alternating buttocks for each subsequent injection, using the carton components provided. It must not be administered intravenously or subcutaneously due to risk of severe injection site reactions including tissue necrosis if inadvertently given subcutaneously.

Vivitrol was approved by the FDA in 2006 for the treatment of alcohol dependence. It was approved by the FDA October 2010 for the prevention of relapse to opioid dependence following opioid detoxification. It is the first and only non-narcotic, non-addictive, once monthly medication for both alcohol and opioid dependence. Vivitrol should be used as part of a comprehensive management program that includes psychosocial support.

The FDA label includes a black box warning for hepatotoxicity. Naltrexone has the capacity to cause heptocellular injury when given in excessive doses and is contraindicated in acute hepatitis or liver failure. Use of Vivitrol should be discontinued in the event of symptoms or signs of acute hepatitis.

A patient beginning Vivitrol treatment should be enrolled in the Touchpoints program. Touchpoints, Vivitrol Information for Patients and Healthcare Providers, is a confidential service designed to comply with federal privacy regulations, which offers enrollment of patients and providers in the Touchpoints program, identification and coordination of healthcare providers for injections, coordination of product delivery, adherence services and reimbursement support services.

IV. RATIONALE

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Methadone

For nearly three decades, methadone hydrochloride (6-dimethylamino-4, 4-diphenyl-3-heptanone hydrochloride) has been the primary means of treating opiate addiction. Approved by the Food and Drug Administration (FDA) in 1947 for analgesic and antitussive uses, methadone was shown to be effective in treating opiate addiction in the mid-1960s and was approved by FDA for this use in late 1972. Pharmacologically, methadone is a weak-acting opiate agonist (that is, it imitates the action of an opiate, such as heroin) that does not generate the euphoria of an opiate but does reduce symptoms of opiate withdrawal. Today, an estimated 115,000 individuals receive methadone treatment for opiate addiction, and thousands more have benefited from it in the past.

The effectiveness of methadone treatment of opiate addicts has been established in many studies conducted over three decades. Methadone-maintained patients show improvement in a number of outcomes, after an adequate dose (usually 60–120 mg per day) is established. Consumption of all illicit drugs, especially heroin, declines. The prescribing information does not contain information related to clinical studies.

Buprenorphine (buprenorphine)

Clinical data on the safety and efficacy of buprenorphine HCl sublingual tablets were derived from studies of buprenorphine sublingual tablet formulations, with and without naloxone, and from studies of sublingual administration of a more bioavailable ethanolic solution of buprenorphine.

Buprenorphine HCl tablets were studied in 1834 patients; buprenorphine and naloxone tablets in 575 patients, and buprenorphine sublingual solutions in 2470 patients. A total of 1270 women received buprenorphine in those clinical trials.

Dosing recommendations are based on data from one trial of both tablet formulations and two trials of the ethanolic solution. All trials used buprenorphine in conjunction with psychosocial counseling as part of a comprehensive addiction treatment program. There were no clinical studies conducted to assess the efficacy of buprenorphine as the only component of treatment.

In a double-blind placebo- and active-controlled study, 326 heroin-addicted subjects were randomly assigned to either buprenorphine and naloxone sublingual tablets, 16/4 mg per day; buprenorphine HCl sublingual tablets, 16 mg per day; or placebo sublingual tablets. For subjects randomized to either active treatment, dosing began with one 8 mg buprenorphine HCl sublingual tablets on Day 1, followed by 16 mg (two 8 mg tablets) of buprenorphine HCl sublingual tablets on Day 2.

On Day 3, those randomized to receive buprenorphine/naloxone sublingual tablets were switched to the combination tablet. Subjects randomized to placebo received one placebo tablet on Day 1 and two placebo tablets per day thereafter for four weeks. Subjects were seen daily in the clinic (Monday through Friday) for dosing and efficacy assessments. Take-home doses were provided for weekends. Subjects were instructed to hold the medication under the tongue for approximately 5 to 10 minutes until completely dissolved. Subjects received counseling regarding HIV infection and up to one hour of individualized counseling per week. The primary study comparison was to assess the efficacy of buprenorphine and naloxone sublingual tablets and buprenorphine HCl sublingual tablets individually against placebo sublingual tablet. The percentage of thrice-weekly urine samples that were negative for non-study opioids was statistically higher for both buprenorphine and naloxone sublingual tablets and buprenorphine HCl sublingual tablets than for placebo sublingual tablets.

In a double-blind, double-dummy, parallel-group study comparing buprenorphine ethanolic solution to a full agonist active control, 162 subjects were randomized to receive the ethanolic sublingual solution of buprenorphine at 8 mg/day (a dose which is roughly comparable to a dose of 12 mg per day of buprenorphine HCl sublingual tablets), or two relatively low doses of active control, one of which was low enough to serve as an alternative to placebo, during a 3 to 10 day induction phase, a 16-week maintenance phase and a 7-week detoxification phase. Buprenorphine was titrated to maintenance dose by Day 3; active control doses were titrated more gradually.
Maintenance dosing continued through Week 17, and then medications were tapered by approximately 20% to 30% per week over Weeks 18 to 24, with placebo dosing for the last two weeks. Subjects received individual and/or group counseling weekly.

Based on retention in treatment and the percentage of thrice-weekly urine samples negative for non-study opioids, buprenorphine was more effective than the low dose of the control, in keeping heroin addicts in treatment and in reducing their use of opioids while in treatment. The effectiveness of buprenorphine, 8 mg per day was similar to that of the moderate active control dose, but equivalence was not demonstrated. In a dose-controlled, double-blind, parallel-group, 16-week study, 731 subjects were randomized to receive one of four doses of buprenorphine ethanolic solution: 1 mg, 4 mg, 8 mg, and 16 mg. Buprenorphine was titrated to maintenance doses over 1 to 4 days and continued for 16 weeks. Subjects received at least one session of AIDS education and additional counseling ranging from one hour per month to one hour per week, depending on site.

Based on retention in treatment and the percentage of thrice-weekly urine samples negative for non-study opioids, the three highest tested doses were superior to the 1 mg dose. Therefore, this study showed that a range of buprenorphine doses may be effective. The 1 mg dose of buprenorphine sublingual solution can be considered to be somewhat lower than a 2 mg tablet dose. The other doses used in the study encompass a range of tablet doses from approximately 6 mg to approximately 24 mg.

Naltrexane (Vivitrol)

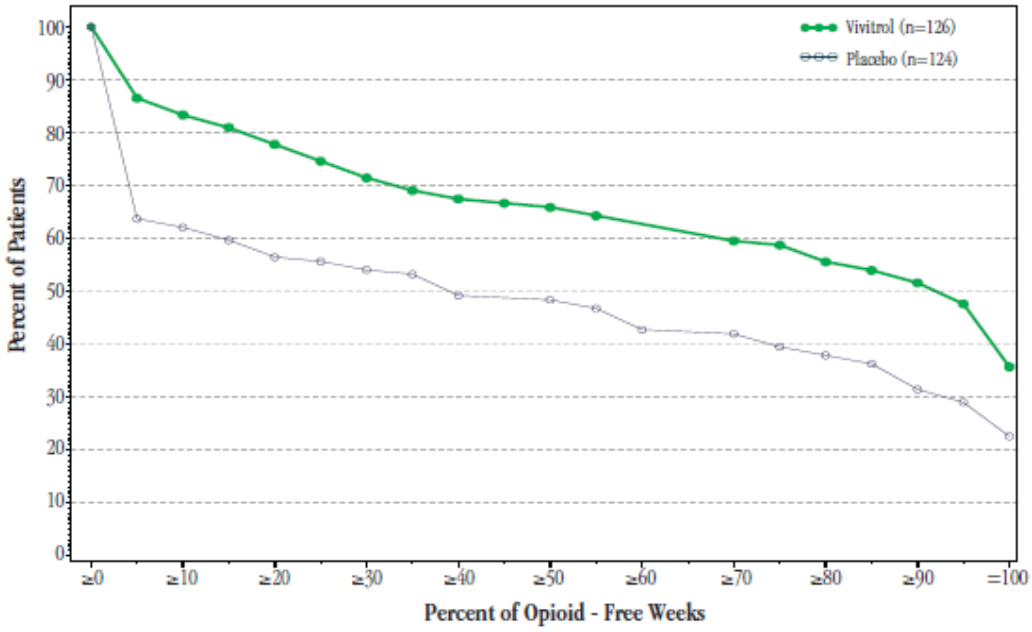
Alcohol Dependence

The efficacy of VIVITROL in the treatment of alcohol dependence was evaluated in a 24-week, placebo-controlled, multi-center, double-blind, randomized trial of alcohol-dependent (DSM-IV criteria) outpatients. Subjects were treated with an injection every 4 weeks of VIVITROL 190 mg, VIVITROL 380 mg or placebo. Oral naltrexone was not administered prior to the initial or subsequent injections of study medication. Psychosocial support was provided to all subjects in addition to medication. Subjects treated with VIVITROL 380 mg demonstrated a greater reduction in days of heavy drinking than those treated with placebo. Heavy drinking was defined as self-report of 5 or more standard drinks consumed on a given day for male patients and 4 or more drinks for female patients. Among the subset of patients (n=53, 8% of the total study population) who abstained completely from drinking during the week prior to the first dose of medication, compared with placebo-treated patients, those treated with VIVITROL 380 mg had greater reductions in the number of drinking days and the number of heavy drinking days. In this subset, patients treated with VIVITROL were also more likely than placebo-treated patients to maintain complete abstinence throughout treatment. The same treatment effects were not evident among the subset of patients (n=571, 92% of the total study population) who were actively drinking at the time of treatment initiation.

Opioid Dependence

The efficacy of VIVITROL in the treatment of opioid dependence was evaluated in a 24-week, placebo-controlled, multi-center, double-blind, randomized trial of opioid-dependent (DSM-IV) outpatients, who were completing or had recently completed detoxification. Subjects were treated with an injection every 4 weeks of VIVITROL 380 mg or placebo. Oral naltrexone was not administered prior to the initial or subsequent injections of study medication. Standardized, manual-based psychosocial support was provided on a biweekly basis to all subjects in addition to medication. Figure 1, below, displays the cumulative percentage of subjects with opioid-free weeks ranging from no visits (0%) to all visits (100%). An opioid-free week was one in which urine drug test results were negative for opioids and self-reported opioid use was also zero. An initial period of engagement in treatment was permitted during which opiate use, if it occurred, was not considered in the analysis. Subjects discontinuing from the trial were assumed to have had opioid-use weeks for the weeks after dropout. The cumulative percentage of subjects achieving each observed percentage of opioid-free weeks was greater in the VIVITROL group compared to the placebo group. Complete abstinence (opioid-free at all weekly visits) was sustained by 23% of subjects in the placebo group compared with 36% of subjects in the VIVITROL group from Week 5 to Week 24.

Figure 1: Subjects Sustaining Varying Percentages of Opioid-Free Weeks



A greater percentage of subjects in the VIVITROL group remained in the study compared to the placebo group.

V. DEFINITIONS

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DETOXIFICATION is the process of removing the physiological effects of a drug or substance from an addicted individual.

SYNTHETIC refers to being artificially prepared.

VI. BENEFIT VARIATIONS

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The existence of this medical policy does not mean that this service is a covered benefit under the member's contract. Benefit determinations should be based in all cases on the applicable contract language. Medical policies do not constitute a description of benefits. A member's individual or group customer benefits govern which services are covered, which are excluded, and which are subject to benefit limits and which require preauthorization. Members and providers should consult the member's benefit information or contact Capital for benefit information.

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VII. DISCLAIMER

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Capital's medical policies are developed to assist in administering a member's benefits, do not constitute medical advice and are subject to change. Treating providers are solely responsible for medical advice and treatment of members. Members should discuss any medical policy related to their coverage or condition with their provider and consult their benefit information to determine if the service is covered. If there is a discrepancy between this medical policy and a member's benefit information, the benefit information will govern. Capital considers the information contained in this medical policy to be proprietary and it may only be disseminated as permitted by law.

VIII. CODING INFORMATION

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Note: This list of codes may not be all-inclusive, and codes are subject to change at any time. The identification of a code in this section does not denote coverage as coverage is determined by the terms of member benefit information. In addition, not all covered services are eligible for separate reimbursement.

Covered when medically necessary:

CPT Codes®								

HCPCS Code	Description
J2315	VIVITROL (Naltrexone) depot form, 1 mg
H0020	ALCOHOL AND/OR DRUG SERVICES; METHADONE ADMINISTRATION AND/OR SERVICE (PROVISION OF THE DRUG BY A LICENSED PROGRAM)
S0109	METHADONE, ORAL, 5MG

ICD-9-CM Diagnosis Code*	Description
292.0	DRUG WITHDRAWAL
303.0	ACUTE ALCOHOLIC INTOXICATION, UNSPECIFIED DRUNKENESS
303.1	ACUTE ALCOHOLIC INTOXICATION, CONTINUOUS DRUNKENESS
303.2	ACUTE ALCOHOLIC INTOXICATION, EPISODIC DRUNKENNESS
303.3	ACUTE ALCOHOLIC INTOXICATION, IN REMISSION
303.90	OTHER AND UNSPECIFIED ALCOHOL DEPENDENCE, UNSPECIFIED DRUNKENNESS
303.91	OTHER AND UNSPECIFIED ALCOHOL DEPENDENCE, CONTINUOUS DRUKENNESS

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ICD-9-CM Diagnosis Code*	Description
303.92	OTHER AND UNSPECIFIED ALCOHOL DEPENDENCE, EPISODIC DRUKENNESS
304.00	OPIOID TYPE DEPENDENCE, UNSPECIFIED ABUSE
304.01	OPIOID TYPE DEPENDENCE, CONTINUOUS ABUSE
304.02	OPIOID TYPE DEPENDENCE, EPISODIC ABUSE

*If applicable, please see Medicare LCD or NCD for additional covered diagnoses.

The following ICD-10 diagnosis codes will be effective October 1, 2015:

ICD-10-CM Diagnosis Code*	Description
F10.20	Alcohol dependence, uncomplicated
F10.120	Alcohol abuse with intoxication, uncomplicated
F10.129	Alcohol abuse with intoxication, unspecified
F10.220	Alcohol dependence with intoxication, uncomplicated
F10.229	Alcohol dependence with intoxication, unspecified
F11.2Ø	Opioid dependence, uncomplicated
F11.220	Opioid dependence with intoxication, uncomplicated
F11.221	Opioid dependence with intoxication delirium
F11.222	Opioid dependence with intoxication with perceptual disturbance
F11.229	Opioid dependence with intoxication, unspecified
F11.23	Opioid dependence with withdrawal
F11.24	Opioid dependence with opioid-induced mood disorder
F11.93	Opioid use, unspecified with withdrawal
F11.250	Opioid dependence with opioid-induced psychotic disorder with delusions
F11.251	Opioid dependence with opioid-induced psychotic disorder with hallucinations
F11.259	Opioid dependence with opioid-induced psychotic disorder, unspecified
F11.281	Opioid dependence with opioid-induced sexual dysfunction
F11.282	Opioid dependence with opioid-induced sleep disorder
F11.288	Opioid dependence with other opioid-induced disorder
F11.29	Opioid dependence with unspecified opioid-induced disorder

*If applicable, please see Medicare LCD or NCD for additional covered diagnoses.

IX. REFERENCES

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X. POLICY HISTORY

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MP 2.301	**CAC 03/30/04**
	CAC 5/31/05
	CAC 7/26/05
	CAC 9/27/05
	CAC 9/26/06
	CAC 11/27/07
	CAC 11/25/08
	CAC 11/24/09 Consensus Review
	CAC 01/25/11 Minor Revision. Changed Title, Vivitrol information added
	4/2012 Consensus, no changes, references updated.
	CAC 6/4/13 Consensus list review. Administrative code review complete**.**
	CAC 3/25/14 Consensus. No change to policy statements. References updated.

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