Monterey County Behavioral Health
Policy and Procedure

Policy Number	508
Policy Title	Administration of VIVITROL
References	None
Form	FDA regulations handout: http://www.fda.gov/downloads/Drugs/DrugSafety/UCM206669.pdf
Effective	November 25, 2015

Policy

This is the policy, protocol and procedures to administer VIVITROL. VIVITROL is an FDA approved injectable medication used in the treatment of opiate and alcohol addiction. VIVITROL must be administered within federal and state guidelines. VIVITROL is used along with counseling and other social supports to help individuals to subsequently cease and/or decrease opiate or alcohol use.

Procedure

VIVITROL is indicated for use in adults (18 years or older) who meet the following criteria:

1) A diagnosis of alcohol dependence and/or opioid dependence disorder;

2) Intent and ability to abstain (in the clinical judgement) from all opioids and alcohol immediately prior to receiving VIVITROL dose and opioid-free (including Tramadol) at least 7-10 days before starting VIVITROL;

3) Required labs prior to injection:

A. Liver function tests
B. Urine toxicology
C. BUN/creatinine

Contraindications:

1. Reported history of opioid use (including tramadol) within 7 to 10 days of injection, with the exception of methadone and buprenorphine, which require a minimum of 14 drug-free days

2. Failure to tolerate oral Naloxone

3. Positive urine screen for opioids

4. Hypersensitivity to Naltrexone or any component of the formulation

5. Pregnancy

6. Breast feeding

7. Severe renal failure, as VIVITROL has not been studied in this population

8. Severe hepatic impairment, as VIVITROL has not been studied in this population

Use with caution:

1. Bleeding disorders: Use intramuscular (IM) injection with caution in patients thrombocytopenia or any bleeding disorder (including hemophilia and severe hepatic failure), or patients on anticoagulant therapy; bleeding/hematoma may occur from IM administration.

2. Hepatocellular injury: Dose-related hepatocellular injury is possible; the margin of separation between the apparent safe and hepatotoxic doses appears to be ≤5-fold. Discontinue therapy if signs/symptoms of acute hepatitis develop. Clinicians should note that elevated transaminases may be a result of pre-existing alcoholic liver disease, hepatitis B and/or C infection, or concomitant use of other hepatotoxic drugs; abrupt opioid withdrawal may also lead to acute liver injury.

Administration Instructions:

Administer IM VIVITROL into the upper outer quadrant of the gluteal area; must inject dose using one of the provided needles for administration. Use either the 1.5-inch needle (for very lean patients) or the 2-inch needle (for patients with a larger amount of subcutaneous tissue overlying the gluteal muscle). Either needle may be used for patients with average body habitus. Avoid inadvertent injection into a blood vessel; do not administer IV, SubQ, or into fatty tissue (the risk of serious injection site reaction is increased if given incorrectly as a SubQ injection or into fatty tissue instead of the gluteal muscle). Injection should alternate between the 2 buttocks. Do not substitute any components of the dose-pack

Informed Consent:

Please provide informed consent, including warning that opiate use after VIVITROL can cause fatal overdose, as the opiate receptors may be sensitized.

The following document should be provided and discussed with the patient. The FDA regulations handout: http://www.fda.gov/downloads/Drugs/DrugSafety/UCM206669.pdf