APPENDIX C

Administrative Bulletin

Division of Mental Health and Addiction Services

November 30, 2010

Subject: Vivitrol Injectable Guidelines

Introduction

The FDA approved the use of Naltrexone in the injectable formulation of Vivitrol for the use in treatment of Alcohol Dependence (2006) and Opiate Dependence (2010). Vivitrol is approved for use in Alcohol and Opiate maintenance therapy in conjunction with a full treatment experience which includes psychological counseling and aftercare programs. ***Opioid dependent patients, including those being treated for alcohol dependence, must be opioid free for a minimum of seven (7) days at the time of initial VIVITROL administration.***

Vivitrol is indicated for use in patients who are abstinent from use of alcohol and who have undergone detoxification from opioid use. Patients should not use Vivitrol while they are actively using alcohol or opioids or are detoxifying from either substance.

Primary and Aftercare Counseling

Primary counseling providers need to accept Vivitrol injectable therapy as adjunctive to addiction treatment, just as outpatient treatment programs (OTPs) accept methadone treatment as adjunctive and not contrary to the concept of effective treatment for opioid dependence. Treatment professionals will need **initial and ongoing education** to effect this significant change in treatment philosophy. Those patients who are receiving Vivitrol therapy ***should not be in segregated groups***. Currently those individuals in treatment with co-occurring disorders are not routinely segregated for primary and continuing care therapy, and those patients receiving Vivitrol should not be segregated either. **Patients on Vivitrol therapy should be permitted to participate alongside patients not receiving Vivitrol therapy in primary and aftercare substance abuse counseling.**

1. Screening Tools:

All patients admitted to licensed substance use disorders treatment facilities need to meet the established admission criteria as per DMHAS regulations. **All patients must meet DSM-IV-TR criteria for Opiate or Alcohol Dependence.**

Those persons presenting for substance use disorders treatment must undergo a screening process to determine their diagnosis, severity of illness, and the selection of the appropriate level of care for rehabilitation counseling. The American Society of Addiction Medicine Patient Placement Criteria-2R **(ASAM PPC-2R)** is the only peer reviewed beta instrument currently available for patient placement assessment. Licensed substance use disorders treatment agencies should select and use consistently a screening tool for each and every patient (e.g., **CAGE, COWS, CAGE-AID**, Narcotic Withdrawal Scale, or CIWA.)

2. Complete History and Physical Examination:

All patients admitted to licensed substance use disorders treatment facilities will undergo a complete history and physical examination, including blood work (LFT). The history should include current and past drug and alcohol use, allergies, psychiatric, legal, medical, surgical, family, and previous drug treatment. Patients should also be screened for Hep A & B. The physical examination should be comprehensive and be specific for signs of addiction. In addition, patients should undergo a neurological and mental status evaluations. **All patients that are to be treated with Vivitrol must meet DSM-IV-TR criteria for Opioid or Alcohol Dependence. All patients must meet ASAM PPC-2R Criteria for Level I or Level II treatment.**

3. Comprehensive Patient Management and Referrals:

All patients must be referred for follow-up for primary medical conditions not being addressed in the licensed substance use disorders treatment facility to primary care or other medical specialists as may be warranted.

All patients with major psychiatric diagnoses must be referred to a Psychiatrist, or licensed mental health facility, qualified to manage patients with addictions.

4. Signed Informed Consent to Treatment of Vivitrol must be obtained by a physician explaining the risks and benefits of Vivitrol.

Patient Selection

Patients who currently meet DSM criteria for Alcohol or Opioid Dependence are eligible for Vivitrol therapy. These patients must have recently received detoxification from opioids and should be ***opioid-free for a minimum of 7 days***.

Patient Exclusion

Any patient with the following conditions should not be started on Vivitrol therapy:

1. Patients with acute hepatitis or liver failure
2. Patients receiving opioid analgesics
3. Patients with current opioid dependence
4. Patients in acute opioid withdrawal
5. Patients with positive urine screens for opioids
6. Patients with a known previous allergic response to naltrexone or Vivitrol
7. Patients who fail a naloxone challenge test

Dosage and Administration

The FDA approved and recommended dose is **380mg (plus 4mg diluent)** delivered **intramuscularly every 4 weeks, or once a month**. The injection is to be administered by a **healthcare professional** as an **intramuscular (IM) gluteal injection**, alternating buttocks for each subsequent injection, **using carton provided components, only**.

VIVITROL MUST NOT BE ADMINISTRED INTRAVENOUSLY OR SUBCUTANEOUSLY!

Vivitrol must be kept refrigerated (36-46 degrees F) and not frozen. Do not expose to temperatures over 77 degrees.

Vivitrol is to be given in a hospital or clinic and should not be stored at home by patients.

Pretreatment with oral Naltrexone is not required.

Warnings and Precautions

1. **Hepatotoxicity**: Naltrexone can cause hepatotoxicity when given in excessive dosages. It is contraindicated in patients in acute hepatitis and liver failure, and its use in patients with active liver disease must be carefully considered in light of its hepatotoxic effects.

2. **Injection Site Reactions**: Naltrexone injections may be followed by pain, tenderness, induration, swelling, local erythema, bruising, or pruritus. Severe reactions such as ***prolonged induration, hematoma, cellulitis, abscess, sterile abscess, and necrosis may require a surgical consult and intervention***.

3. **Eosinophilic Pneumonia**: Eosinophilic pneumonia requires hospitalization and treatment with steroids and antibiotics.

4. **Hypersensitivity Reactions Including Anaphylaxis**: Cases of urticarial, angioedema, and anaphylaxis have occurred with Vivitrol injections. Patients should seek ***immediate medical attention and should not continue with Vivitrol therapy***.

5. **Unintended Precipitation of Opioid Withdrawal**: This can occur when providers are unaware of patient opioid use, or in instances where a naloxone challenge test was not performed.

6. **Opioid Overdosage**: Opioid overdoses can occur after patients attempt to use (abuse) opioids after being on Vivitrol following an injection period, or immediately thereafter.

7. **Depression and Suicidality**: Alcohol and opioid dependent patients should be screened and monitored for the development of depression or suicidal thinking. These patients require psychiatric evaluations and treatment for their depression.

8. **Reversal of Vivitrol Blockade for Pain Management**: In emergency situations when Vivitrol treated patients develop pain, ***regional analgesia or use of non-narcotic analgesics*** is recommended. If opioid medication is required, the patient should be managed in a ***hospital setting*** or a setting that can provide ***cardio-pulmonary resuscitation services***.

Special Populations

1. **Pregnancy**: Vivitrol is a ***Pregnancy Category* C** drug. There are no adequate or well controlled studies of either naltrexone or Vivitrol in pregnant women. ***Patients should sign a waiver*** documenting that they have been informed of Vivitrol's pregnancy category status.

2. **Labor and Delivery**: The potential effects on labor and delivery are unknown.

3. **Nursing Mothers**: Naltrexone has been reported to be found in the milk of nursing mothers. A decision needs to be made regarding avoiding breast feeding or discontinuation of Vivitrol. Tumorigenicity has been found in animal studies.

4. **Pediatric Use**: The efficacy and safety has not been established for any individuals under the age of 18.

5. **Geriatric Use**: Vivitrol has not been evaluated in the geriatric population (>65 years old).

Clinical Guideline References

CSAT TIP #28, 43, 45, 49

MANUFACTURER'S MEDICATION GUIDE

www.vivitrol.com

1-800-VIVITROL