



## Vivitrol (Extended-Release Injectable Naltrexone) Protocol Matrix

### Criteria and Referral Process

Indicated Diagnosis	Alcohol Use Disorder (AUD) Opioid Use Disorder (OUD)
Referral Source	<ul style="list-style-type: none"> <li>• Patients with</li> </ul>
Criteria for Vivitrol Referral	<ul style="list-style-type: none"> <li>• Patient must have a primary care physician at one of the five FHCCGLA site</li> <li>• Diagnosis of alcohol dependence and/or opioid dependence disorder</li> <li>• Intent and ability to abstain (in the clinical judgement) from all opioids and alcohol immediately prior to receiving VIVITROL dose</li> <li>• Opioid-free (including Tramadol) at least 7-10 days before starting VIVITROL; Please note: Long acting opioids such as buprenorphine (Suboxone) and methadone can require additional time and care.</li> </ul>
Contraindications	<ul style="list-style-type: none"> <li>• &lt;18 or &gt;65 years old (must consult supervising MD and document risk/benefit ratio must be well documented if used) -Patient does not require inpatient alcohol detox or opioid detoxification</li> <li>• Acute hepatitis or liver failure</li> <li>• On opioid analgesics</li> <li>• In acute opiate withdrawal</li> <li>• Positive UDS for opioids</li> <li>• Unreliable history of being opiate free for at least 7 days</li> <li>• Fails naloxone challenge test</li> <li>• Known previous allergic response to naltrexone or LAIN</li> <li>• Pregnancy/Nursing: special consent documenting they are aware that there are no well controlled studies for oral or injectable Naltrexone (category C) – with supervising MD approval only; Must notify OB prior to administering as Labor and Delivery effects are unknown</li> </ul>

With Caution	<ol style="list-style-type: none"> <li>1. Bleeding disorders: Use intramuscular (IM) injection with caution in patient's thrombocytopenia or any bleeding disorder (including hemophilia and severe hepatic failure), or patients on anticoagulant therapy; bleeding/hematoma may occur from IM administration.</li> <li>2. Hepatocellular injury: Dose-related hepatocellular injury is possible; the margin of separation between the apparent safe and hepatotoxic doses appears to be <math>\leq 5</math>-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.</li> </ol>
Patient Education and/or handout	<ul style="list-style-type: none"> <li>• For patients who meet criteria for Vivitrol, provide Patient Education Material provided by Vivitrol Representative (Nancy Hovey/Senior Territory Business Manager-Los Angeles.) to the patient.</li> <li>• If patient is interested, refer patient to the MAT</li> </ul>
How to Refer Patients for Vivitrol	<ul style="list-style-type: none"> <li><input type="checkbox"/> Enter a Referral for MAT program.</li> <li><input type="checkbox"/> Specify whether the referral is for alcohol dependence and/or opioid dependence on your progress note</li> <li><input type="checkbox"/> Recommended labs prior to referral/injection: Liver Function Test, BUN/Creatinine, Hepatitis Panel, HIV, STI</li> <li><input type="checkbox"/> Referral to behavioral health therapist (LCSW)</li> <li><input type="checkbox"/> Patient should have had one visit with LCSW prior as part of the preassessment for Vivitrol therapy.</li> </ul>
Behavioral Health Assessments <b>(To be done prior to the Vivitrol Injection Appointment)</b>	<p>Full behavioral health assessment to include current and past drug/alcohol use, allergies, psych history, legal history, medical history, surgical history, family history, previous drug treatment history well documented within past year in medical record</p> <ul style="list-style-type: none"> <li>- Alcohol and Drug Use Screen using standardized assessment tools</li> </ul>

INITIAL ASSESSMENT	
Medical Assistant	<ol style="list-style-type: none"> <li>1. Review schedule and prepare Vivitrol by taking Vivitrol out of the refrigerator minimum of 40 minutes before the scheduled appointment.</li> <li>2. Complete Vitals and Intake as per normal clinic protocol</li> <li>3. Perform urine drug test and record results</li> <li>4. Administer PHQ, AUDIT Questionnaire, CAGE</li> </ol>

	<ol style="list-style-type: none"> <li>5. Have patient sign Vivitrol Consent Form</li> <li>6. Print and Fax Vivitrol Referral form to Olive Branch or VM pharmacy</li> </ol>
<p>Provider</p>	<ol style="list-style-type: none"> <li>1. See patient as per clinic protocol</li> <li>2. For AOD Review AUDIT Score. Score/Required action range 0-40: <ol style="list-style-type: none"> <li>1. <input type="checkbox"/> 0-7 Encouragement</li> <li>2. <input type="checkbox"/> 8-19 Brief Intervention</li> <li>3. <input type="checkbox"/> 20+ Brief Intervention/ Referral to Behavioral Health</li> </ol> </li> <li>3. Provide Diagnosis of AOD or OUD using screening tool meeting DSM-5 criteria.</li> <li>4. Order/ review pertinent labs regarding liver function, BUN/Creatinine and Urine Drug Screen</li> <li>5. Write prescription for Vivitrol as per clinic protocol <ol style="list-style-type: none"> <li>1. <b>Vivitrol 380mg- Inject 380mg IM every 4 weeks, Maximum of 6 Refills as indicated</b></li> <li>2. <b>Write in Comment: Please deliver to Clinic (Specify which clinic to deliver to)</b></li> <li>3. <b>Send RX to VM or Olive Branch Pharmacy</b></li> </ol> </li> <li>6. Complete Vivitrol Referral in Next Gen. Referral must include the following diagnoses: <ol style="list-style-type: none"> <li>1. Alcohol dependency (F10.20); and/or</li> <li>2. Uncomplicated or Opioid dependency; in remission (F11.21)</li> </ol> </li> </ol>
<p>Behavioral Health Worker</p>	<ol style="list-style-type: none"> <li>1. Utilize motivational interviewing techniques to explore ambivalence, build motivation (OARS), and explore treatment options with patient.</li> <li>2. Give Vivitrol education, which can include verbal description, handouts and/or brochures.</li> <li>3. Referral <ol style="list-style-type: none"> <li>a. To specialist outside the scope of substance abuse counseling (i.e. mental health, homelessness, co-occurring medical problems, legal problems etc.)</li> <li>b. Back to PCP for MAT treatment assessment</li> <li>c. Both concurrently</li> </ol> </li> <li>4. Provides counseling and psychosocial support <ol style="list-style-type: none"> <li>a. To provide patients with multidisciplinary care through comprehensive evaluations, treatment planning, case conferencing and referral services</li> <li>b. To achieve housing stabilization and development of drug free social support</li> <li>c. Establish short term goals (1-3 months)</li> <li>d. Establish long term goals (6+ months)</li> <li>e. Establish and monitor any trigger or possible problem that may hinder patient's success in treatment</li> <li>f. Increase Patient's early recovery and relapse prevention skills</li> </ol> </li> <li>5. Recommend group support and meetings in patient's area</li> </ol>

### Beginning Treatment and Routine

Medical Assistant	<ol style="list-style-type: none"> <li>1. Drug Screen             <ol style="list-style-type: none"> <li>a. Order UA Cups as per clinic protocol</li> <li>b. Collect urine specimen for POCT urine drug screen (see separate SOP for collection and performance of POCT urine drug screen).</li> <li>c. Enter results of urine drug screen in medical record.</li> <li>d. Flag any positive results and/or inconsistencies.</li> </ol> </li> <li>2. Take Vivitrol box out of refrigeration for 45 minutes or more before injection. See medication procedure.</li> <li>3. Have Patient sign Vivitrol Consent to Treatment form.</li> <li>4. When patient has seen the provider and Vivitrol injection is ordered, refer to injection instructions.</li> <li>5. Vivitrol should be administered on alternating buttocks</li> <li>6. Upon discharge, schedule patient 2-week follow-up with Behavioral health. 4-week follow-up with Provider for next injection.</li> <li>7. Patients to be given information cards and or bracelets indicating they are currently on Vivitrol.</li> </ol>
Provider	<ol style="list-style-type: none"> <li>1. Medication Review and Reconciliation             <ol style="list-style-type: none"> <li>a. Review current medications and document any changes</li> <li>b. Flag any concerns or inconsistencies</li> <li>c. Check CURES prior to injection</li> </ol> </li> <li>2. Co-Prescribe Narcan for Overdose, if indicated.</li> <li>3. Address any questions, concerns or side effects per clinic protocol</li> </ol>
Behavioral Health Therapist	<ol style="list-style-type: none"> <li>1. Continue to see patient throughout duration of treatment addressing any new barriers, relapse prevention and psychosocial support and counseling.</li> <li>2. Counseling session at least every 2-weeks (recommended) or more depending on patient and provider recommendation.</li> <li>3. Address non-adherence to program (i.e. missing appointments, positive drug screens) through recommendations by SAMHSA Harm Reduction Model.</li> </ol>
Managing injection site reactions	<ul style="list-style-type: none"> <li>-Pain, tenderness, induration, swelling, local erythema, bruising or pruritus may occur.</li> <li>-MD to check injection site at each visit and document any noticeable reactions</li> <li>-Severe reactions such as prolonged induration, hematoma, cellulitis, abscess, sterile abscess, necrosis may require surgical consult and intervention</li> </ul>
Discontinuing treatment	<ul style="list-style-type: none"> <li>-Typically after 6 months, can extend to 1 year at physician discretion (contact physician supervisor if extending past 6 months)</li> </ul>

### Delivery and Storage of Treatment

Medical Assistant/Receptionist

1. Medication will be received, signed and logged by Receptionist when delivered by carrier.
2. Receptionist will immediately take to any available Medical Assistant, since medication has to be refrigerated until this is administered to patient. (Receptionist should specify on Log Sheet the name of Medical Assistant)
3. Medical assistant will log and store medication according to training specifications given by Nancy Hovey/Senior Territory Business Manager- Los Angeles.
4. Medical assistant will immediately inform and Task Ordering Provider about treatment being delivered to clinic.
5. For donated medication, fax receipt to manufacturer