SUBJECT: MEDICATION – ASSISTED TREATMENT FOR SUBSTANCE USE DISORDERS

EFFECTIVE DATE: 05/21/2021

I. PURPOSE:

Provide clinical guidance to health care staff for the assessment and treatment with Naltrexone Extended Release for Injection Suspension (Vivitrol®) for inmates who have a primary diagnosis of alcohol dependence and/or opioid dependence disorder.

These standards and responsibilities apply to both Department staff, contracted treatment staff and Comprehensive Health Care Contractor (CHCC) staff.

II. DEFINITIONS:

A. **Comprehensive Health Care Contractor (CHCC)** refers to contracted staff that has been designated by the Department to provide medical, dental, and mental health services at designated institutions within a particular region.

B. **Contracted Treatment Staff** refers to contracted staff that have been designated by the Department to provide substance use treatment at designated institutions within a particular region.

III. GENERAL INFORMATION:

Naltrexone Extended Release for Injection Suspension (Vivitrol®), https://www.vivitrol.com, is a medication that must be used with other alcohol or drug recovery programs such as counseling. Inmates identified as candidates for treatment may voluntarily participate in the medication assisted treatment at designated site and will also receive substance use counseling services.

The program shall include inmates who are at least six (6) months from their tentative release dates and who meet the program requirements. Inmates nearing their release date shall receive no more than 4 months of Naltrexone Extended Release for Injection Suspension (Vivitrol®).
Substance Use Treatment Services staff shall identify inmates who have a primary diagnosis of alcohol dependence and/or opioid dependence and provide a referral to medical staff.

Mental Health staff shall provide Intake Mental Health Screening at Reception Centers and Outpatient Mental Health Services in accordance with 15.05.17 and 15.05.18.

Medical clinicians shall perform an assessment; physical examination; laboratory testing; provide education; medication administration (if inmate is eligible for treatment and consents to treatment); and ongoing evaluation.

IV. PROGRAM REQUIREMENTS:

Naltrexone Extended Release for Injection Suspension (Vivitrol®) is indicated for use in adults (eighteen years or older) who meet the following criteria:

A. A primary diagnosis of alcohol dependence and/or opioid dependence disorder;
B. Intent and ability to abstain (in the clinician's judgment) from alcohol and all opioids immediately prior to receiving the Naltrexone Extended Release for Injection Suspension (Vivitrol®) dose and opioid-free (including Tramadol) at least 7-10 days before starting Naltrexone Extended Release for Injection Suspension (Vivitrol®);
C. A baseline evaluation which includes a physical exam, and, where that indicates likelihood of hepatic disease or injury or diminished renal function, appropriate laboratory testing such as liver transaminase levels and bilirubin within normal limits, or creatinine clearance (estimated or measured) 50ml/min or greater;
D. Negative results on urine beta-HCG (human chorionic gonadotropin) pregnancy test for females;
E. A urine drug screen negative for all opioids, a negative Naloxone/Narcan IV or IM challenge (for patients with opioid addiction) immediately prior to first injection; and, if the Naloxone Challenge is negative, an oral Naltrexone Challenge (a half tab of 50mg administered orally) with no opioid withdrawal present after 1 hour.
F. No signs or symptoms of opioid withdraw.
G. New commitment inmate with sentence of 3 years or less.
H. Re-Entry inmate within 6 months of release.

V. CONTRAINDICATIONS AND PRECAUTIONS/WARNINGS:

Contraindications for Naltrexone Extended Release for Injection Suspension (Vivitrol®) administration include (see https://www.vivitrol.com/):

A. Patient receiving opioid analgesics;
B. Patient is expected to require opioid analgesics for pain management;
C. Patient with current physiologic opioid dependence;
D. Patient in acute opioid withdrawal;
E. Patient has positive urine screen for opioids; Patient failed Naloxone Challenge or Naltrexone Challenge;
F. Patient has hypersensitivity to Naltrexone or any ingredients in Naltrexone Extended Release for Injection Suspension (Vivitrol®) and the liquid used to mix it;
G. Hepatotoxicity (acute hepatitis and clinically significant liver dysfunction) are observed (i.e., transaminase levels >3 times normal and abnormal bilirubin);
H. Testing indicates severe renal failure or moderate to severe renal insufficiency;
I. Testing indicates pregnancy;
J. Medication Alerts Must be communicated to outside hospitals when inmate is transferred for outside care, either routine or emergent due to the potential for interaction with other medications, particularly opioids.

Warning or precautions for Naltrexone Extended Release for Injection Suspension (Vivitrol®) (see https://www.vivitrol.com) **administration (requiring clinical judgment) include:**

K. Precipitate withdrawal may result for as long as two weeks for patients transitioning from buprenorphine or methadone;
L. Stable chronic hepatitis, e.g., in Hepatitis C infection, may be treated with XR-NTX, based on clinical judgment and ongoing liver function test monitoring;
M. Intramuscular injections should be used with caution in patients with thrombocytopenia or coagulation disorders;
N. Depression and/or suicidality develop as a result of taking Naltrexone Extended Release for Injection Suspension (Vivitrol®).

VI. PROCEDURE:

A. The clinician shall review the inmate patient's medical record and confirm alcohol and/or opioid use disorder based on the referral provided to medical staff by the Substance Use Treatment Services staff and then conduct a thorough health assessment, immediately prior to the first injection of Naltrexone Extended Release for Injection Suspension (Vivitrol®), the clinician shall perform the following:

1. Determine, based upon the inmate patient's self-report and any other available information, that the inmate patient is interested in remaining abstinent from alcohol and/or opioids and ready to begin trying to do so.
2. Document alcohol and/or opioid use disorder on the DC4-730, Problem List.
3. Perform urine drug screen for opiates (11 panel, on-site drug screen) for natural and synthetic opiates to detect all possible opioids patient may have used.
4. If any significant doubt remains about the assessment of the inmate patient's opioid status or the veracity of the inmate patient's self-reporting, the Naloxone Challenge should be administered for patients with opioid addiction because it minimizes the duration of severe withdrawal. In regions known to have significant prevalence of buprenorphine diversion, the Naltrexone Challenge should also be administered, following Naloxone Challenge, because Naloxone does not displace buprenorphine whereas naltrexone does.

    a. The Naltrexone Challenge Test involves oral administration of 25mg of Naltrexone (i.e., half of a 50mg tablet), and is negative if no withdrawal signs or symptoms are apparent after 1 hour.

5. If any clinical concern is raised by history or physical exam of either hepatic or renal status, liver function tests/ with transaminase levels and bilirubin should be performed and results should be within normal limits and/or creatinine clearance (estimated or measured) 50ml/min or greater.
6. Perform urine beta-HCG pregnancy test for females

7. The clinician shall
   a. Explain to the client the benefits and risks/possible side effects
      (1) If inmate patient is a candidate for treatment and wants to participate in treatment the clinician shall complete form DC4-545V, *Informed Consent for Vivitrol* and have inmate patient sign the form once explained.
   b. Provide the inmate patient with medication support information.
   c. Evaluate the client based on the above reference criteria and prescribe Naltrexone Extended Release for Injection Suspension (Vivitrol®), as indicated.

8. If liver function tests were checked at baseline, these shall be checked again at time intervals appropriate to the inmate patient's underlying clinical condition(s).

B. Naltrexone Extended Release for Injection Suspension (Vivitrol®) ADMINISTRATION:

1. Remove carton from refrigeration, open the box, and allow Naltrexone Extended Release for Injection Suspension (Vivitrol®) to reach room temperature (approximately 45 minutes) prior to injection.
2. The inmate patient will lie face down and the gluteal muscle must be relaxed prior to injection.
3. The injection shall be given intramuscularly using a 11/2 inch or 2 inch 20-gauge needle into the upper, outer quadrant of the buttock.
4. Aspirate for blood prior to injection, and if blood is withdrawn, abort the injection in that site and move to another site in same side buttock quadrant.
5. Injection site will rotate monthly from right to left, document injection on the DC4-701A, *Medication and Treatment Record*.
6. The first injection should always be in the right gluteal muscle.
7. Monitor the injection site for any problems (redness, infection, swelling and/or itching at the injection site that gets worse over time), observe the inmate patient for any adverse reactions, and monitor the inmate patient for effectiveness and side effects over time.
8. Injection site side effects that develop any signs of allergic reaction shall be reported immediately to the clinician.

VII. STAFF RESPONSIBILITIES:

This program requires communication among an interdisciplinary team that is made up of Substance Use Treatment Services staff, Security Staff, Mental and Physical health staff and Community Providers to provide continuity of service for the inmate patient receiving treatment for alcohol and/or opioid addiction.

A. **Substance Use Treatment Services staff** will identify inmates who are potentially eligible for Medication Assisted Treatment and refer to the facility Chief Health Officer and provide substance use counseling.

B. **Mental Health** shall provide necessary mental health services in accordance with identified clinical needs as determined by a qualified mental health professional. While substance use disorders are addressed through the Department's Bureau of Substance Use, provisions are in place allowing mental health and substance use staff to coordinate services as outlined in HSB 15.05.18.

C. **Clinician shall**:
1. Confirm alcohol and/or opioid substance use disorder diagnosis;
2. Complete thorough health assessment;
3. Order laboratory testing listed in section VI. on DC4-714B, Clinician's Order Sheet;
4. Provide education and obtain inmate's signature on DC4-545V;
5. Evaluate inmate patient monthly;
6. Identify one person accountable for maintaining clinical documentation for reporting to Transition & Substance Use Treatment Services as outlined in section VIII.

D. Nursing staff shall:
1. Store Naltrexone Extended Release for Injection Suspension (Vivitrol®) per manufacturer guidelines and maintain an accurate inventory;
2. Administer medication per manufacturer instructions (see https://www.vivitrol.com);
3. Document medication administration on DC4-701A and report no shows or refusals to clinician the same day;
4. Coordinate care as clinically indicated.

VIII. DOCUMENTATION REQUIREMENTS:

A. Medication Utilization Reports for Naltrexone Extended Release for Injection Suspension (Vivitrol®) may be requested from the Chief of Pharmaceutical Services . Monthly inmate patient data program activities and outcomes reports will include, but will not be limited to:

1. Number of inmate patients screened and educated on the use, benefits, and risks of Naltrexone Extended Release for Injection Suspension (Vivitrol®). Substance Use staff will track this information.
2. Number of inmate patients assessed (by physical exam and/or lab work) for use of Naltrexone Extended Release for Injection Suspension (Vivitrol®). Health services staff will track this information.

3. Number of inmate patients who received one or more doses of Naltrexone Extended Release for Injection Suspension (Vivitrol®); Health services staff will track this information.

4. Number of inmate patients screened, educated, and/or assessed who did not receive one or more doses of Naltrexone Extended Release for Injection Suspension (Vivitrol®) and reason for not receiving; Information provided by Substance Use and Health services staff.
5. Demographics of individuals served (first, middle, and last name; date of birth; race; ethnicity; gender; DC number); Substance use staff will track this information.
6. Inmate patient outcomes including, urge to drink alcohol and/or use opiates; number days in the month that client drank alcohol or used opiates; number of admissions to inpatient treatment; number of days client participated in treatment; increase or decrease in observed or reported symptoms; and changes in social and occupational function. Substance use staff will track this information.
7. Number of clients who received at least one dose of Naltrexone Extended Release for Injection Suspension (Vivitrol®) and completed the prescribed course of treatment with the total number of doses received by inmate patient. Substance use staff will track this information.
8. Number of inmate patients who received at least one dose of Naltrexone Extended Release for Injection Suspension (Vivitrol®) and did not complete the prescribed course of treatment with the total number of doses received by client. Substance use staff will track this information.
9. Average number of doses for alcohol users and average number of doses received by client. Substance use staff will track this information.

IX. RELEVANT FORMS AND DOCUMENTS:

A. DC4-545V, *Informed Consent for Vivitrol* ®
B. DC4-701A, *Medication and Treatment Record*
C. DC4-714B, *Clinician's Order Sheet*
D. DC4-730, *Problem List*
E. HSB 15.05.17, *Intake Mental Health Screening at Reception*
F. HSB 15.05.18, *Outpatient Mental Health Services*

Health Services Director Date

This Health Services Bulletin Supersedes:

HSB 15.01.04 dated 8/5/93 AND 4/18/05
HSB 15.01.02 dated 12/1/96
HSB 15.06.01 dated 9/18/00 AND 1/12/12
HSB 15.02.03 dated 9/21/16 06/26/2019, AND 07/10/2020