	State of Indiana Indiana Department of Correction Division of Youth Services	Effective Date 11/1/2020	Page 1 of 6	Number 2.35Y

HEALTH CARE SERVICES DIRECTIVE-YOUTH
Manual of Policies and Procedures

Title
MEDICATION ASSISTED THERAPY PRE-RELEASE PROGRAM (Vivitrol)

Legal References (includes but is not limited to)	Related Policies/Procedures (includes but is not limited to)	Other References (includes but is not limited to)
IC 11-8-2-5	01-02-101 03-02-113 01-04-101 01-04-105	ACA Standards

I. PURPOSE:

The purpose of this Health Care Services Directive (HCSD) is to provide written guidelines to implement Medication Assisted Therapy (MAT) prior to a youth's release, to lessen chances of relapse or overdose with opioids while a youth is transitioning to addiction recovery treatment in the community. MAT is used in conjunction with behavioral health interventions to treat individuals with substance dependence to alcohol and opioids. To this end, naltrexone (in orally-administered form [Revia] and long-acting injectable form [Vivitrol]) has been approved by the US Food and Drug Administration to treat and prevent relapse, and has been selected as the medication to be used within the MAT Pre-Release Program. Appropriate screening and referrals shall be made for the program, including youth who have demonstrated success within addiction recovery services.

II. PROCEDURE:

A. Criteria for Evaluating Appropriateness for Referral for Vivitrol

1. The youth must have a clinically significant problem with alcohol or opioid use or dependence;

2. The youth must be motivated for treatment;

3. The youth must have successfully completed Addiction Recovery Services (ARS), or be participating in these services and in good standing in the program; and,

4. The youth must be free from active substance use.

Youth shall be provided verbal and written educational material by their assigned Addictions Recovery Services staff regarding the medication(s) and the potential benefits of the medication(s). Youths who express interest and meet the above criteria shall be processed further via completion of the MAT Referral Form. Youth who are appropriate for referral shall review the MAT Information Form. The youth shall be asked to sign the form, indicating agreement to participate in the MAT Pre-Release Program. The referral shall be submitted to the facility Clinician and to the Addiction Recovery Re-Entry Specialist.

B. Recommended Prescribing Indications and Guidelines

1. A diagnosis of alcohol dependence and/or opioid dependence.

2. Intent and ability to abstain (based on clinical judgment) from all alcohol and opioids immediately prior to receiving oral naltrexone or Vivitrol, and be opioid free at least seven to ten (7-10) days prior to starting oral naltrexone or Vivitrol.

3. Testing/Evaluation

   a. A baseline evaluation including physical exam and appropriate lab testing demonstrating adequate hepatic and renal functioning.
   b. An assessment to ensure no signs or symptoms of opioid withdrawal are present.
   c. Negative results on urine pregnancy tests (female).
   d. A urine drug screen negative for all opioids.
   e. Successful naltrexone challenge (1/2 tab of 50mg administered orally with no opioid withdrawal signs present after one [1] hour).

C. Assessment and Scheduling Process

1. Upon completion of the referral form and obtaining the youth's signature on the information form, the referral shall be submitted to the facility Clinician by the Addictions Recovery Services staff.

2. The Addiction Recovery Re-Entry Specialist shall identify a community provider/resource that will allow for continued care following release. Upon identification, the community resource is communicated to the Addictions Recovery Services staff and facility Clinician.

3. An appointment is scheduled with the facility Clinician within two (2) weeks of receipt of referral, at which time the youth is assessed for appropriateness to receive the medication with the assessment including a physical examination. The ultimate decision for a youth continuing with treatment rests with the facility Clinician, who may collaborate with the contracted Regional Medical Director to determine appropriateness.

4. The youth is to be absent from contraindications including:

    a. Youth is receiving opioid analgesics;
    b. Youth is expected to require opioid analgesics for pain;
    c. Current physiological opioid dependence;
    d. Acute opioid withdrawal;
    e. Positive urine drug screen for opioids;
    f. Failed naltrexone challenge;
    g. Hepatotoxicity has been observed with liver function test (LFT) results at a range of three (3) to five (5) times the upper limit of normal;
    h. Testing indicates several renal failure, or moderate to several renal insufficiency;
    i. Acute hepatitis;
    j. Unstable psychiatric illness; and,
    k. Pregnancy.

5. The facility Clinician shall discuss the course of treatment with the youth, complete State Form 55923 “Consent for Vivitrol Administration” to include youth’s signature, and enter orders for laboratory testing to be completed within two (2) weeks following the visit with the facility Clinician. The laboratory tests shall include:

    a. Urine Pregnancy Test (females);
    b. CMP;
    c. HIV antibody test (HIV Ab);
    d. Hepatitis B Surface Antigen (HBsAG); and,
    e. Hepatitis C Antibody (HCV Ab).

6. Nursing staff shall follow the facility Clinician's order for the administration of the laboratory draw. The facility Clinician shall sign off lab results via the electronic medical record (EMR).

7. After review of the lab results and examination, the facility Clinician shall order a naltrexone challenge to occur twenty-four (24) hours prior to the start of oral naltrexone, as well as a sixty (60) day course of oral naltrexone to begin sixty (60) days prior to release. The challenge protocol is a single 25mg dose of naltrexone by mouth to ensure the youth has no adverse effects from the medication and is fully opiate free. The naltrexone challenge shall occur in the Health Services Unit, where the youth shall be observed for one (1) hour for withdrawal signs and symptoms. Nursing staff shall use the Clinical Opiate Withdrawal Scale (COWS) assessment to document findings of the naltrexone challenge.

8. Upon clearance from the naltrexone challenge being documented, the nursing staff shall follow the Clinician's order for sixty (60) days of oral naltrexone. The medication is recommended at 50mg daily.

9. The Clinician shall order a urine drug screen to occur five (5) to seven (7) days prior to release, and upon the screen being negative, order one (1) Vivitrol 4cc deep intramuscular injection to be administered the same day of the urine screen. Upon the injection being administered, the order for oral naltrexone can be discontinued if not already ended.

10. At two (2) weeks prior to release the Addiction Recovery Re-Entry Specialist shall confirm that an appointment has been made with a community provider to allow for continued services following release. The Re-Entry Specialist shall confirm with Case Management/Unit Team staff that insurance has been secured and a referral to Recovery Works has been provided.

11. Should the youth's release not occur when originally scheduled, the facility Clinician shall determine whether Vivitrol is continued, or if an alternative plan of care is appropriate dependent upon the outcome of an updated release date.

D. Storage of Vivitrol

1. Vivitrol shall be ordered by facility pharmacy coordinators from the approved vendor, pursuant to the appropriate order form to maintain a stock consistent with the needs of the population.

2. Vivitrol shall be stored under specific temperature-controlled conditions to ensure proper delivery and patient safety.

3. Vivitrol shall be refrigerated at 2 degrees to 8 degrees Celsius (36-46 degrees Fahrenheit). It shall not be frozen.

4. Vivitrol shall be stored separately from food.

5. The product shall be appropriately disposed after the expiration date printed on the container.

E. Preparation of Vivitrol:

1. Vivitrol is supplied in single-use cartons.

2. Remove carton from refrigeration, open carton, and allow Vivitrol to reach room temperature (approximately 45 minutes) prior to injection.

3. The products shall be visually inspected for particulate matter and discoloration prior to administration.

4. Vivitrol shall be suspended only in the diluent supplied and must be administered only with one (1) of the needles supplied.

5. Select needle length based on the youth's body size. Consider using the 2-inch needle with protection device for youth with a large amount of subcutaneous tissue overlying the gluteal muscle. Alternative treatment shall be considered for youth whose body type precludes an intramuscular injection with one of the provided needles.

6. Warm the diluent vial to near body temperature by rolling it in the hand until no longer cool to the touch.

7. After preparation, a properly mixed suspension will be milky white, will not contain clumps, and moves freely down the walls of the vial.

8. Vivitrol MUST NOT be administered intravenously, subcutaneously, or into adipose. It must be injected into deep muscle tissue to minimize risk of adverse injection site reaction.

III. APPLICABILITY:

This HCSD is applicable to all facilities housing youth.

_____signature on file_____ _____

Kristen Dauss, MD Date

Chief Medical Officer