



Kentucky Department of Corrections

Substance Abuse Medication Assisted Treatment (SAMAT) Revised 2/18/16

Purpose

The purpose of Substance Abuse Medication Assisted Treatment (SAMAT) is to prevent relapse for inmates with opiate addiction or substance use disorders participating in a substance use program operated or supervised by the Department in compliance with Senate Bill 192. The goal of the program is to facilitate transition of inmate patients into an outpatient substance abuse treatment program which employs a multi-faceted approach to treatment combining the use of FDA-approved extended release VIVITROL, counseling and referral to community based providers upon release.

Goal

To develop a program that satisfies the statutory requirement of SB192 and decreases substance abuse amongst Department of Corrections recovering substance abusers.

The goal of this program is to increase and improve substance abuse treatment post release, decrease drug overdose morbidity and mortality and decrease recidivism related to substance abuse relapses.

The goal is also to conduct a program evaluation that examines the criminal justice and treatment outcomes related to Medication Assisted Treatment administered to inmates prior to release from Kentucky state correctional facilities and transitioning back into the community. This process will be managed by the Kentucky Department of Corrections (KDOC). The University of Kentucky will provide outcome data regarding this population.

Target Population

The target population for the program is residents of the KDOC who have completed the Substance Abuse Program who meet the inclusion criteria and have a documented opioid or alcohol dependence.

Behavioral Health Inclusion Criteria

- Initial CJKTOS intake assessment was positive for substance use disorder related to opioids or alcohol.
- Successfully completed an institutional substance abuse program (SAP).
- Has a mental health code of 0 or 1; Inmates with a mental health code of 2 will be reviewed on an individual basis.
- Anticipated release on mandatory reentry supervision within 60 days
- PED within 60 days or release on parole within 60 days
- Negative drug screen prior to tolerance trial.

- Not currently pregnant.

Medication Assisted Treatment Training

All Substance Abuse Treatment Staff and Medical staff participating in the SAMAT shall receiving training on the methods to educate inmates on the following:

- Opioid Epidemic;
- Overview of Opioid and Alcohol Dependence
- Understanding VIVITROL; and
- Overview of SAMAT

Training will initially be provided by a representative from Alkermes at a central location and then as needed.

Participant Screening, Assessment and Process

All new SAP participants and SAP graduates will be screened by Substance Abuse Staff. Each client will be assessed for drug use using the CJKTOS baseline assessment upon entry into the Substance Abuse Program. All clients will receive education regarding opioid and alcohol dependence, VIVITROL and SAMAT during Substance Abuse Programming. Each client that meets the inclusion criteria will be asked to sign a SAMAT participation form (Attachment B).

If the client is determined to be a candidate for SAMAT and the voluntary participation form has been signed, Substance Abuse Staff shall enter "SAMAT candidate" in the comments field of the current SAP Program Assignment in the Offender Management System for tracking (Prison>Jobs and Programs>Job/Program Assignments).

All participants will be initially screened for behavioral health requirements. Once cleared, the candidate will be referred to the Captain's Office for a urine drug screen.

Target Locations:

Bell County Forestry Camp
Blackburn Correctional Complex
Eastern Kentucky Correctional Complex
Green River Correctional Complex
Kentucky Correctional Institution for Women
Kentucky State Penitentiary
Kentucky State Reformatory
Little Sandy Correctional Complex
Luther Lockett Correctional Complex
Northpoint Training Center
Roederer Correctional Complex
Ross Cash Center
Western Kentucky Correctional Institution

For SAP graduates that are housed at an institution without a SAP Program, the Reentry staff will initiate the SAMAT protocol.

Urine Drug Screen

Prior to the initiation of VIVITROL administration, a urine drug screen (UDS) shall be conducted pursuant to KDOC Policy and Procedure (CPP 15.8). This UDS will include a 14 drug panel assessing for Amphetamines (AMP), Barbiturates (BAR), Benzodiazepines (BZO), Cocaine (COC), Marijuana (THC), Methadone (MTD), Methamphetamine (mAMP), Methylenedioxymethamphetamine (MDMA), Morphine (MO 300 or OPI 300), Opiates (OPI 2000), Propoxyphene (300 NG/ML), Suboxone, Nicotine, Oxycodone. Inmates shall agree to consent to a urine drug screen (UDS) to ensure they have not consumed alcohol or opiates. Once a nonreactive drug screen (clinically negative) has been achieved the first oral dose of Naltrexone will be administered approximately at 60 days from anticipated release on parole or mandatory reentry supervision. Inmates who are found guilty based upon a positive UDS shall be subject to the provisions of Kentucky Corrections Policies and Procedures 15.8 and 15.2, Unauthorized Substance Abuse Testing and Rule Violations and Penalties, and will not be enrolled in SAMAT.

The Substance Abuse Treatment Team shall coordinate the collection of the urine drug screen with the facility's Captain's Office, who shall be responsible for the collection and testing of urine specimens. The Captain's Office or designee shall collect the urine specimen and immediately test pursuant to procedures outlined in KDOC Policy and Procedure. Results of the urine drug screen shall be immediately communicated with the Substance Abuse Treatment Staff. Once the urine drug screen is completed and results are determined to be negative, the inmate shall be referred to medical by electronic referral to the institutional Health Services Administrator (see Attachment C).

Medical Evaluation

The onsite medical provider will meet with the inmate, prior to starting VIVITROL therapy to discuss whether VIVITROL therapy is appropriate. The medical evaluation/testing shall include an assessment of Liver Function Tests and a Hepatitis Panel (blood work). If the inmate is cleared by the medical provider, the inmate will sign the KY DOC VIVITROL Therapy Consent form (see Attachment D). The provider will order the three (3) day Naltrexone tolerance trial. If no adverse reactions occur, the provider will order the VIVITROL injections to be given by the nursing staff.

The Health Service Administrator will notify the designated Substance Abuse Treatment staff when an inmate is cleared or disqualified for therapy.

VIVITROL Medication Guidelines:

The following represent indications for use of VIVITROL to be reviewed by the medical provider with the patient:

- For the prevention of relapse to opioid dependence, following opioid detoxification

- For the treatment of alcohol dependence in patients who are able to abstain from alcohol in an outpatient setting prior to initiation of treatment with VIVITROL. Patients should not be actively drinking at the time of initial VIVITROL administration.
- As part of a comprehensive program that includes psychosocial support.

Contraindications for the use of VIVITROL to be reviewed by the medical provider with the patient are:

- Patients receiving opioid analgesics.
 - Exceptions include short term use for acute injury or illness.
- Patients with current physiological opioid dependence.
- Patients in acute opioid withdrawal.
 - COWS greater than 7.
- Any individual who has failed the Naltrexone challenge test or has a positive urine screen for opioids.
- Patients who have previously exhibited hypersensitivity to naltrexone, polylactide-co-glycolide (PLG), carboxymethylcellulose, or any other components of the diluent.
- Patients with unstable mental health conditions.

The following must be reviewed by the medical provider with the patient:

WARNINGS AND PRECAUTIONS

- **Vulnerability to Opioid Overdose:** Following VIVITROL treatment opioid tolerance is reduced from pretreatment baseline, and patients are vulnerable to potentially fatal overdose at the end of a dosing interval, after missing a dose, or after discontinuing VIVITROL treatment. Attempts to overcome blockade may also lead to fatal overdose.
- **Injection Site Reactions:** In some cases, injection site reactions may be very severe. Some cases of injection site reactions required surgical intervention.
- **Precipitation of Opioid Withdrawal:** Opioid-dependent and opioid-using patients, including those being treated for alcohol dependence, should be opioid-free before starting VIVITROL treatment, and should notify healthcare providers of any recent opioid use. An opioid-free duration of a minimum of 7-10 days is recommended for patients to avoid precipitation of opioid withdrawal that may be severe enough to warrant hospitalization.
- **Hepatotoxicity:** Cases of hepatitis and clinically significant liver dysfunction were observed in association with VIVITROL treatment during the clinical development program and in the post marketing period. Discontinue use in the event of symptoms or signs of acute hepatitis.
- **Depression and Suicidality:** Monitor patients for the development of depression or suicidal thinking.
- **When Reversal of VIVITROL Blockade Is Required for Pain Management:** In an emergency situation in patients receiving VIVITROL, suggestions for pain management include regional analgesia or use of non-opioid analgesics.

ADVERSE REACTIONS

The adverse events seen most frequently in association with VIVITROL therapy in opioid-dependent patients (i.e. those occurring in $\geq 5\%$ and at least twice as frequently with VIVITROL than placebo) were hepatic enzyme abnormalities, injection site pain, nasopharyngitis, insomnia, and toothache.

The adverse events seen most frequently in association with VIVITROL therapy for alcohol dependence (i.e. those occurring in $\geq 5\%$ and at least twice as frequently with VIVITROL than placebo) include nausea, vomiting, injection site reactions (including induration, pruritus, nodules and swelling), muscle cramps, dizziness or syncope, somnolence or sedation, anorexia, decreased appetite or other appetite disorders.

To report SUSPECTED ADVERSE REACTIONS, contact Alkermes, Inc. at 1-800-VIVITROL (1-800-848-4876) and/or email: usmedinfo@alkermes.com or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

DRUG INTERACTIONS

Naltrexone antagonizes the effects of opioid-containing medications, such as cough and cold remedies, antidiarrheal preparations, and opioid analgesics.

USE IN SPECIFIC POPULATIONS

- VIVITROL pharmacokinetics have not been evaluated in subjects with severe hepatic impairment.
- Caution is recommended in administering VIVITROL to patients with moderate to severe renal impairment (GFR ≤ 50).

The medical evaluation/testing shall include an assessment of overall health and Liver Function Tests and Hepatitis Panel (Blood Lab) prior to starting VIVITROL. All forms must be properly executed in order for the inmate to participate in the program. Screening shall be completed within (30) to (60) days of release/anticipated release.

At the conclusion of the meeting, the inmate shall be given the opportunity to sign the SAMAT Consent form consenting to participate in the medical screen/testing and acknowledging the requirements of the medication-assisted treatment.

The Health Services Administration designee shall notify KDOC Substance Abuse Staff if the inmate has been determined to be eligible for the program and has executed all required consent forms.

Upon said notification, Substance Abuse Staff shall enter a comment "SAMAT participant" in the comments field of the current SAP Program Assignment in the Offender Management System for tracking (Prison>Jobs and Programs>Job/Program Assignments).

Additionally, the Health Services Administration designee shall notify KDOC Substance Abuse Staff if an inmate rescinds his consent to participate.

Naltrexone Tolerance Trial

Eligible VIVITROL therapy candidates will participate in a three (3) day Naltrexone tolerance test to evaluate for possible side effects and/or adverse reactions. The inmate will receive Naltrexone 50 mg daily prior to beginning VIVITROL injections at least six weeks before release/PED. When the tolerance test is initiated, nursing staff will issue the inmate a red medical alert card to be attached to their state identification badge.

VIVITROL Ordering

Oral Naltrexone and VIVITROL injection prescriptions will be entered into the inmate electronic health record. Review packing insert, upon receiving the medication from Diamond Pharmacy, for medication storage instructions.

Initiation of VIVITROL Treatment

Inmates participating in SAMAT shall receive the first injection of VIVITROL approximately five (5) weeks prior to release/PED. The medical provider will prescribe the medications for those who are approved and voluntarily consent to therapy. VIVITROL will be stored according to the manufacturers' instructions.

Discharge Planning

After the second injection of VIVITROL is given, the medical staff will provide the inmate (at no cost) a copy of their Medication Administration Record (MAR) to take with them upon discharge. The MAR(s) shall include documentation of the Naltrexone tolerance test and both VIVITROL injections.

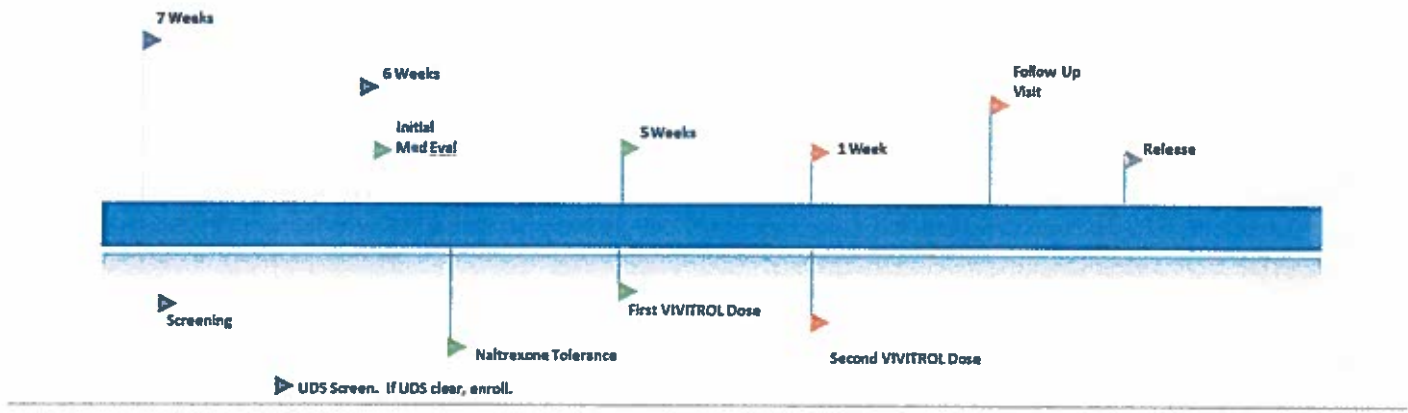
Inmates who have been determined to be enrolled in SAMAT will be discharged in accordance with KDOC policy. Participation in SAMAT shall be included on the inmate's Substance Abuse Program discharge summary. Each participant shall be referred by Institutional Substance Abuse Treatment Staff to a Community Social Service Clinician (SSC) who will provide bridging services to community-based substance abuse treatment.

Post Release Treatment

SAMAT participants on supervision will be monitored as an Intensive Management Caseload by the Community SSC's for the duration of their treatment. The Community SSC will assist with their enrollment with Medicaid upon release, referral to an appropriate community provider to continue VIVITROL treatment and referral to community substance abuse treatment. SAMAT participants shall also be subject to random monthly urine drug screens as determined by the assigned SSC.

Attachment A

Recommended timeline for SAMAT
(Begins at 7 weeks prior to anticipated release/PED)



Attachment B



Name:

DOC #:

Date:

I have been advised by my SAP Counselor of the opportunity to participate in the Substance Abuse Medication Assisted Treatment (SAMAT) Program offered by the Kentucky Department of Corrections. I further understand that the use of the medication VIVITROL (Naltrexone) is strictly voluntary.

I have also been advised that should I choose to participate, I will be referred to the Institutional Medical Department for screening, medical information and final determination to participate.

I agree to participate.

I choose not to participate.

Offender signature/date

Counselor signature/date

Kentucky Department of Corrections - Vivitrol Therapy Consent Form

I, _____, do hereby voluntarily apply and consent to participate in the Substance Abuse Medication Assisted Treatment (SAMAT) Program offered by the Kentucky Department of Corrections. I am requesting Vivitrol (Naltrexone extended release injection) therapy as a treatment for alcohol and opioid dependence. I understand that, as far as possible, precautions will be taken to prevent any complications or ill effects on my health. I further understand that it is my responsibility to tell the medical provider in the program as much as I can about my current health status. It is my responsibility to seek medical attention immediately if any drug reaction occurs to Vivitrol or if any changes occur in my health status. As a participant, I freely and voluntarily agree to adhere to the treatment protocol as follows by initialing and signing below:

_____ I understand that medication (Vivitrol) alone is not sufficient treatment for managing my substance dependence. After I am released, I agree to participate in an outpatient treatment program offered by the designated community clinic.

_____ I understand that Vivitrol (naltrexone extended release injection) is being prescribed as part of a comprehensive treatment plan for my opioid dependence.

_____ I agree to keep, and be on time, for my scheduled appointment at the community clinic. If I cannot keep the appointment, I will call in advance to cancel and reschedule.

_____ I agree to have a blood specimen taken for assessment of liver function prior to beginning Vivitrol therapy.

_____ I agree to submit to urine drug screenings as required.

_____ I understand that urine toxicology screenings shall be conducted and that any positive results could result in disciplinary or criminal action.

_____ I agree to participate in two (2) verbal assessments assessing my level of motivation and level of risk relating to my substance dependence. Verbal assessments to be administered by the Substance abuse staff and a medical provider.

_____ I agree to actively participate in individual counseling sessions prior to beginning Vivitrol therapy.

_____ I understand that I will be prescribed Naltrexone (the pill form of Vivitrol) for up to 3 days prior to beginning Vivitrol injectable therapy. The purpose of this trial is to assess for any

adverse effects from the medication. I understand that I am to inform the medical staff if I experience any side effects during this time.

___ I understand that I will receive the first injection of Vivitrol therapy approximately 4-5 weeks prior to my release. And the second injection will be given during the week of release.

___ I understand that Vivitrol is well tolerated in the recommended doses, but it may cause liver injury when taken in excess or in people who develop liver disease from other causes.

___ If I experience excessive tiredness, unusual bleeding or bruising, pain the upper right part of my stomach that lasts more than a few days, light-colored bowel movements, dark urine, or yellowing of the skin or eyes, I will stop taking Vivitrol immediately and see my medical provider as soon as possible.

___ I agree to take Vivitrol only as directed by a prescriber.

___ I understand that I must inform any medical provider treating me that I am receiving Vivitrol therapy.

___ I attest that I am not using opiates at this time and understand that I cannot use opiates within 10 days of the administration of Naltrexone/Vivitrol.

___ I understand that I should not take Vivitrol if I am pregnant or if I am planning on becoming pregnant. It is not known if Vivitrol will harm your unborn baby.

___ I understand that the community clinic offering follow-up treatment may terminate my treatment at any time if I do not comply with treatment guidelines.

___ I understand it is my responsibility to maintain active health insurance coverage, so that I do not have difficulty receiving Vivitrol injections.

___ I understand that a positive urine drug screen for alcohol and/or opiates, such as heroin, methadone or Suboxone, may result in termination of Vivitrol therapy, because these drugs, if taken, may be lethal.

___ I agree to sign a Release of Medical Records authorizing the release of relevant medical/treatment information to the designated Outpatient Treatment Centers to facilitate the continuation of my post-release treatment in the community.

___ I understand and agree that violating any of these conditions is grounds for termination from participation in Vivitrol therapy.

___ I have received verbal/written information and understand the indications, contraindications, warnings, precautions and adverse reactions pertaining to Vivitrol injections.

The Vivitrol indications, contraindications, warnings, precautions and adverse reactions to be reviewed by the medical provider with the patient are listed below:

Indications

- For the prevention of relapse to opioid dependence, following opioid detoxification.
- As part of a comprehensive management program that includes psychosocial support.

Contraindications

- Patients receiving opioid analgesics
- Patients with current physiological opioid dependence
- Patients in acute opioid withdrawal
- Any individual who has failed the naltrexone challenge test
- Any individual who has a positive urine drug screen
- Any individual who is allergic to Naltrexone or any of the ingredients in Vivitrol or the liquid used to mix Vivitrol
- Any individual with Acute Hepatitis
- Moderate to Severe Renal Impairment ($GFR \leq 50$)
- Abnormal LFTs (AST/ALT value > than 3 times the upper limit of normal)
- Pregnancy

Warnings and Precautions

Vulnerability to Opioid Overdose: Following Vivitrol treatment opioid tolerance is reduced from pretreatment baseline, and patients are vulnerable to potentially fatal overdose at the end of a dosing interval, after missing a dose, or after discontinuing Vivitrol treatment. Attempts to overcome blockade may also lead to fatal overdose.

Injection Site Reactions: In some cases, injection site reactions may be severe. Notify your provider right away if you notice any of the following symptoms: intense pain, the area feels hard, swelling, lumps, blisters or an open wound. Some cases of injection site reactions required surgical intervention.

Precipitation of Opioid Withdrawal: Opioid-dependent and opioid-using patients, including those being treated for alcohol dependence, should be opioid-free before starting Vivitrol treatment, and should notify their healthcare provider of any recent opioid use. An opioid-free duration of a minimum of 7-10 days is recommended for patients to avoid precipitation of opioid withdrawal that may be severe enough to require hospitalization.

Hepatotoxicity: Cases of hepatitis and clinically significant liver dysfunctions were observed in association with Vivitrol treatment during the clinical development program and in the post marketing period. Discontinue use of Vivitrol in the event of symptoms or signs of acute hepatitis.

Depression and Suicidality: Monitor patients for the development of depression or suicidal thinking. Sometimes Vivitrol leads to suicidal thoughts and behavior. Notify your provider if you have the following symptoms of depression: feel sad or have crying spells, No longer interested in seeing your friends or do things you used to enjoy, sleeping a lot more OR a lot less than usual, feel hopeless or helpless or feel more irritable, angry, or aggressing than usual.

When Reversal of Vivitrol Blockade is required for Pain Management: In an emergency situation in patients receiving Vivitrol, suggestions for pain management include regional analgesia or use of non-opioid analgesics.

Adverse Reactions

Adverse reactions seen most frequently in association with Vivitrol therapy include nausea, vomiting, injection site reactions (including induration, puritis, nodules and swelling), muscle cramps, dizziness or syncope, somnolence or sedation, anorexia, decreased appetite or other appetite disorders. Other serious side effects of Vivitrol may include: Pneumonia (a certain type of pneumonia that is caused by an allergic reaction) and Serious Allergic Reactions (skin rash, swelling of face, eyes, mouth, tongue, trouble breathing, chest pain, dizziness or feel faint).

WARNING: IF I ATTEMPT TO USE LARGE DOSES OF ALCOHOL, HEROIN OR ANY OTHER NARCOTIC WHILE ON VIVITROL, I MAY DIE OR SUSTAIN SERIOUS INJURY, INCLUDING COMA.

Inmate Signature

Date

I, the undersigned, have defined and fully explained the above information to this individual.

Medical Provider Signature

Date

Nursing staff to review this informed consent again prior to administering the first dose.

Medication Administration Nurse

Date

Attachment D



SAMAT Candidate – Referral to HSA

Date:

To: Institutional HSA

From: _____, Substance Abuse Staff

Offender Name:

DOC Number:

_____ Successfully completed SAP

_____ Signed voluntary participation form

_____ Negative UDS results confirmed

_____ Release date within 60 days
Anticipated release date/PED: _____

Please notify Substance Abuse Staff when inmate is cleared or disqualified for participation.