

**Journey Mental Health Center  
Opiate Recovery Project Treatment Services  
Informed Consent**

**What is the Opiate Recovery Project?**

Dane County and Journey Mental Health Center (JMHC) are offering services for individuals who are completing a jail stay of at least 7-10 days, are a Dane County resident, identified as at risk for relapse with opioid dependence, and willing to participate in treatment services. As part of participating in this project you will be eligible for substance use disorder (SUD) treatment services with monthly medication monitoring and administration of a non-opioid medication called Naltrexone (Vivitrol) on a monthly basis during the course of the project.

Clinicians will conduct a brief SUD assessment with individuals that express interest in order to determine eligibility. You may only meet with clinicians once before receiving an injection due to time constraints, but may meet with them up to 3 times prior to release with subsequent sessions focusing on more thorough assessment and treatment planning. Recovery goals will be established collaboratively between clients and clinicians. You will be responsible for continuing with services following release from Dane County Jail.

**What is this Naltrexone used for?**

Naltrexone is a non-opioid medication that is indicated for the prevention of relapse to opioid dependence, following opioid detoxification. Naltrexone is an opioid receptor antagonist; it binds to opioid receptors, but instead of activating the receptors, it effectively blocks them. Through this action, it prevents opioid receptors from being activated when using opiates such as heroin or prescription painkillers, and thus can help individuals overcome opiate dependence and addiction by blocking the drugs' euphoric effects.

Oral naltrexone has been shown to be most helpful if taken, daily as directed, as part of a treatment program. As it is difficult to always remember to take daily medications, Naltrexone is now available as an extended-release monthly injectable. Both the oral daily form and the monthly injectable monthly extended-release form (Vivitrol®) are FDA approved for treatment of opioid dependence. Vivitrol® was approved by the FDA for this indication in 2010.

**How is the drug Administered and how quickly will the drug start working?**

Naltrexone blocks opioid receptors, blocking euphoric effects of opiates, but does not suppress withdrawal symptoms. Prior to initiating Naltrexone (Vivitrol), an opiate free duration of a minimum of 7-10 days is recommended for individuals in order to avoid opiate withdrawal that may be severe enough to require hospitalization. Some individuals may need to engage in detoxification programs before starting naltrexone.

The extended-release injection is formulated as a single dose 380 mg microsphere formulation and is administered by intramuscular (IM) injection into the gluteal muscle (buttocks) every 4 weeks.

## How long should you take this medication?

Research has not yet established an exact time frame to continue naltrexone. The current recommendation is for continuing naltrexone for an approximately 6 to 12 month period.

## What are warnings, precautions and/or contraindications for Naltrexone (Vivitrol)?

### I. *Vulnerability of Opioid Overdose:*

a. Vivitrol blocks the effects of opioids for approximately 28 days after administration. As the blockade wanes and eventually dissipates completely, individuals who have been treated with Vivitrol may be more sensitive to opioids, even at lower doses of opioid, than previously used, just as they would have shortly after completing detoxification. This could result in potentially life threatening opioid intoxication (respiratory compromise or arrest, circulatory collapse, etc.) if the individual uses previously tolerated doses of opioids.

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b. There is also potential risks for individuals who attempt to overcome the opioid blockade of Naltrexone (Vivitrol) by taking large amounts of opioids while using Naltrexone (Vivitrol), and may lead to life-threatening opioid intoxication or fatal overdose.

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c. Due to the severity of items a and b above, I have been advised to obtain Narcan to be used in the event of an opiate overdose. I have been instructed on where I can get this medication. I will inform those that I live with that I have this medication and where it is being stored in the event that it is needed.

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**Cases of opioid overdose with fatal outcomes have been reported in individuals who used opioids at the end of a dosing interval, after missing a scheduled dose, or after discontinuing treatment.**

### II. *Naltrexone (Vivitrol) is contraindicated in:*

1. Individuals who have received opioid analgesics (e.g., codeine, oxycodone, morphine) in the last 7 to 10 days, or are currently using.
2. Individuals with current physiologic opioid dependence.
3. Individuals in acute opioid withdrawal or are dependent on any opioid (including methadone maintenance).
4. Individuals who have a positive urine screen for opioids.
5. Individuals who have previously exhibited hypersensitivity to naltrexone.
6. Individuals who currently have severe liver disease/liver failure.
7. Individuals who are currently pregnant or breastfeeding.
8. Individuals who have been diagnosed with thrombocytopenia, coagulation disorder.

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## **What are side effects associated with Naltrexone (Vivitrol)?**

### *I. Common side effects:*

1. Feeling, tired, confusion, depression- this problem usually goes away with time. Use of other drugs that make you drowsy will worsen the problem. Avoid driving a car or operating machinery if drowsiness persists.
2. Nervousness, anxiety, sleep problems- some individuals may feel nervous or have difficulty sleeping for a few days after starting medication.
4. Headache
5. Joint and muscle stiffness
6. Pain, tenderness, itchiness at site of injection; occasionally a lump can be felt.

### *II. Rare side-effects (Contact provider right away if you experience any of the following):*

1. Yellow tinge in the eyes or to the skin; dark-colored (brown) urine
2. Sore mouth, gums, or throat
3. Skin rash and itching, and or swelling of the face
4. Shortness of breath, persistent coughing and wheezing

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## **What do I have to do to participate in the Opiate Recovery Project Treatment Services?**

As a participant in the program you will have to complete the following:

1. You will need to complete an assessment with the Journey Mental Health Center Case Manager to review your eligibility, and complete a mental health, substance abuse, and medical history assessment.
2. You will be requested to sign a release for medical records, to review liver functioning and any medical concerns that would be contraindicated for use of Naltrexone. This will include releases for Correct Care Solutions (CCS, the company that currently contracts with the jail for medical services) and Meriter Laboratories, where you can receive liver function testing. You will be asked to have lab work done to test liver functioning if none have been completed in the past 6 months.
3. Initial Vivitrol injection can occur either in the Dane County Jail, administered by CCS, or at Journey Mental Health Center. This will be determined by multiple factors including prescriber availability and your release date. If injection is to occur after release, you will meet with a Journey psychiatrist and nursing staff to review medical history including liver functioning and receive an injection immediately after this appointment if appropriate. In order to receive your first injection, you must have a negative urine drug screen for opiates, and have not used any form of opiates in the past 7 days.
4. You will attend a weekly Vivitrol group for a minimum of 8 weeks and provide urine drug screens with a goal of sobriety from all substances. You will also complete a 10 group

introductory course required for all clients with SUD issues. Failure to participate in treatment and continued substance use could result in referral to a higher level of care and discontinuation of Vivitrol. You will meet with a counselor at intervals to be determined by the treatment team and agree to follow treatment recommendations, including urine drug screens, and all rights and responsibilities of consumers in Outpatient Services at Journey.

5. You will meet with the Nurse Practitioner every 4 weeks during the program to administer your injection. Urine drug screens will be completed at each appointment with the Nurse practitioner, and a negative urine screen will be required prior to each injection. If you are more than 1 week late for your appointment with the Nurse Practitioner, you will have to have a negative urine drug screen for opiates, and be off opiates for a minimum of 7 days, to resume the injections.

6. In addition to meeting with the prescriber to receive the initial injection (or subsequent injections if the first was administered by the jail) you will be required to attend follow up appointments with the prescriber every 3 months. Failure to do so could result in discontinuation of Vivitrol.

7. If you miss more than 3 appointments with the Nurse Practitioner, you will no longer be eligible to continue in the program.

8. If you relapse on opiates while on naltrexone, you may be a candidate for Suboxone or methadone therapy, and your Case Manager will help coordinate these services if needed.

9. Upon completion of the program, naltrexone (Vivitrol) will be discontinued. For individuals who would like to continue use of the naltrexone, or for individuals that the Nurse Practitioner believes would benefit from ongoing use of Vivitrol, your Case Manager will help coordinate ongoing medication management through Journey Mental Health Center, or another provider in your area, as possible. You and/or your health insurance provider will be responsible for costs of ongoing Naltrexone (Vivitrol) injections or oral medications.

### **Participant Consent:**

By signing below,

-You agree to engage in the Opiate Recovery Project Treatment Services, including regular appointments with your Case Manager and monthly appointments with your Nurse

-You understand you have the right to discontinue treatment at anytime.

-You have been informed of the importance of receiving Narcan and have been instructed how to obtain this medication.

-You agree you have reviewed the above consent form, and have been educated about the risks of Naltrexone (Vivitrol).

Individual Name (print): \_\_\_\_\_ DOB: \_\_\_\_\_

Signature: \_\_\_\_\_ Date: \_\_\_\_\_

Guardian name (print): \_\_\_\_\_

(If applicable)

Signature: \_\_\_\_\_ Date: \_\_\_\_\_

Case Manager Name: \_\_\_\_\_

Signature: \_\_\_\_\_ Date: \_\_\_\_\_