Medication Assisted Treatment—Naltrexone

Collaborative Practice Agreement

Statement of Need

Opioid overdose continues to be a significant public health concern in America. Misuse of prescription opioids (hydrocodone, morphine, hydromorphone, oxycodone, etc) as well as illicit substances such as heroin have resulted in increased opioid-related poisoning deaths. Indian Country is not immune to this medical crisis. The 2013 National Survey on Drug Use and Health (NSDUH) survey suggests a health disparity regarding past year nonmedical use of pain relievers among persons aged 12 and older between person identifying as 'not Hispanic American Indian or Alaska Native' (7.8% vs. 4.8%)[1]. This data suggests increased use prevalence in our communities. Additionally, the CDC has reported an all-population doubling of drug overdose death between 1999 and 2013—with 51.8% related to pharmaceuticals (71% involving opioid analgesics and 31% involving benzodiazepines)[1,2,3].

[Insert Local data, trends, needs]

Background

Long-acting Naltrexone is an extended-release injectable suspension of the opiate antagonist naltrexone. Long-acting Naltrexone is indicated for the prevention of relapse to both opioid or alcohol dependence in patients able to abstain from these substances for a period of time prior to initial Long-acting Naltrexone administration. Long-acting Naltrexone is intended to be part of a comprehensive management program that includes psychosocial support. Naltrexone blocks the mu opioid receptor in order to reduce cravings in patients with history of alcohol or opioid dependence. Some studies have shown that a monthly IM injection of Long-acting Naltrexone helps patients maintain complete abstinence through treatment for both alcohol and opioids.

Long-acting Naltrexone is contraindicated in patients receiving chronic opioid therapy for pain management. Attempts to overcome the opioid blockade may lead to fatal overdose. Patients must be opioid free for a minimum of 7-10 days or alcohol free for 3-5 days before initial injection of Long-acting Naltrexone. Long-acting Naltrexone is contraindicated in acute hepatitis or liver failure. Its use in patients with active liver disease must be carefully considered in light of its potential hepatotoxic effects.

Purpose and Goals:

The intent of this protocol is to

- Increase awareness of a medication option for opioid and/or alcohol dependent patients
- To initiate Long-acting Naltrexone therapy safely in carefully selected patients in order to help them achieve sobriety in conjunction with outpatient drug and alcohol treatment
- To improve care and quality of life for patients with substance use disorders
- The multidisciplinary collaboration between medical, behavioral health, and chemical health departments is critical for the safety and success of this treatment option.

Clinic Information:

Eligibility:

To be eligible for Long-acting Naltrexone treatment, patients must:

1. Have an active diagnosis of alcohol or opioid dependence disorder
2. Not be intoxicated or be at risk for developing severe withdrawal symptoms at treatment initiation
3. Have abstained from opioid use within the previous 7 days
4. Demonstrate willingness to participate in a comprehensive integrated recovery program that includes medical management through the outpatient clinic, psychosocial support through the Behavioral Health program, as well as participation in Chemical Health recovery programs as part of a holistic treatment program.
5. Be actively enrolled in the Red Lake Chemical Health drug and alcohol treatment program. Patients are expected to participate in Chemical Health programming as outlined in their individual treatment plan.
6. Participate with Behavioral Health counseling as directed by treatment plan.

Contraindications:

- Pregnancy
- Chronic opioid analgesics for chronic pain syndromes
- Acute hepatitis or liver failure

Referral Process

Patients must have an active referral from a Red Lake provider for pharmacist managed naltrexone.

- Patients must have a medical screening exam that includes an updated history and physical; risks and benefits of naltrexone; baseline urine drug screen; baseline lab assessment; comprehensive treatment plan
- Signed release of information for medical, behavioral health, and chemical health records
- Signed MAT consent form
- Completed detoxification or self-report last use of opioid >7-14 days.

Referral to PCP Criteria:

If the patient refuses to participate in pharmacist management or is non-compliant with the treatment plan (including, but not limited to, having UDS positive for substances of abuse), the pharmacist will request a meeting of the treatment team including behavioral health and medical providers. The team will determine if higher level of care is needed for stabilization, options including inpatient treatment or combination halfway house. It will be the medical provider's clinical discretion whether the patient should continue on Long-acting Naltrexone. The provider will need to weigh the risk of continuing the medication against the dangers of relapse on opioids or alcohol.

Pharmacist management

Pharmacists practicing in the MAT program will:

- Order laboratory tests (including but not limited to LFT, UDS, others as needed to monitor drug therapy).
- Interpret laboratory tests
- Perform limited physical assessment
- Assess Vitals
- Document LMP
- Administer screenings including: PHQ-2, PHQ-9, Tobacco Assessment, Alcohol Assessment, Intimate Partner Violence.
- Complete comprehensive intake including opioid use within last 7-10 days or alcohol within past 3-5 days. Patient must have negative UDS and be displaying no signs/ symptoms of opioid withdrawal before initial administration.
- Prescribe medications per the protocol.
    1. Naltrexone 380mg IM (gluteal) every 4 weeks
    2. Naltrexone 50mg oral x1—with observation for 20 minutes for signs and symptoms of opioid withdrawal.
- Following the 20 minute observation period following the initial injection:
    1. Patient will complete the Subjective Opiate Withdrawal Scale (SOWS)
    2. Clinician will complete the Clinical Opiate Withdrawal Scale (COWS)

Important Notes:

- Any precipitation of withdrawal due to naltrexone tablet or injection will be managed in the ED according to opiate withdrawal protocol (attached).
- If the test is positive, do not initiate Long-acting Naltrexone. Repeat the challenge in 24 hours.

- Provide and document patient education
- Medication options with patients, use, expectations, and risks involved in treatment plan.
- Provide follow-up of the patient and assist with coordination of the treatment plan elements.

Outcomes

A report of clinical outcomes will be provided to the Medical Staff semi-annually. Report will include:

1. Number of patients referred to MAT clinic
2. Number of patients discharged for non-compliance with treatment plan and categorization
3. Number of patients discharged as completed treatment course
4. Number of patients experiencing an opioid overdose while in MAT program

Performance Improvement

In addition to the above outcome reporting, privileged pharmacists will undergo semi-annual peer review analysis that will include review of inclusion criteria, clinical documentation, and patient education. OPPE will be provided to the Clinical Director semi-annually.

Training and Local Certification

- Medical and behavioral health staff will become familiar with the use, contraindications, and risks associated with Long-acting Naltrexone treatment. Patient and provider information is available at www.long-acting Naltrexone.com.
- Complete PCSS-MAT (or other agency defined) training:
    1. Managing Acute and Chronic Pain with Opioid Analgesics in Patients on MAT-- http://pcssmat.org/wp-content/uploads/2015/12/Alford-Acute-Chronic-Pain-MAT-FINAL2-12-22-15.pdf
    2. Medication Assisted Treatment of Opioid Use Disorders: Progress and Challenges http://pcssmat.org/event/medication-assisted-treatment-of-opioid-use-disorders/

References

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Chen LH, Hedegaard H, Warner M. Drug-poisoning deaths involving opioid analgesics: United States, 1999–2011. NCHS data brief, no 166. Hyattsville, MD: National Center for Health Statistics. 2014. (http://www.cdc.gov/nchs/data/databriefs/db166.htm)

Content source: Centers for Disease Control and Prevention, National Center for Injury Prevention and Control, Division of Unintentional Injury Prevention

MN Department of Human Services, HCRQ, DAANES (01/2015 & 01/2014)

https://www.long-acting Naltrexone.com/Content/pdf/prescribing_info.pdf

Substance Abuse and Mental Health Services Administration. *Clinical Use of Extended-Release Injectable Naltrexone in the Treatment of Opioid Use Disorder: A Brief Guide.* HHS Publication No. (SMA) 14-4892. Rockville, MD: Substance Abuse and Mental Health Services Administration, 2015.

Center for Substance Abuse Treatment.Detoxification and Substance Abuse Treatment. Treatment Improvement Protocol(TIP) Series, No. 45. HHS Publication No.(SMA) 15-4131. Rockville, MD: Center for Substance Abuse Treatment, 2006.

Comprehensive Treatment Plan Components:

The medical provider will receive bi-monthly progress notes from Chemical Health counselors. Progress notes will include patient compliance with treatment plan including UDS results. The patient should meet with their medical provider/pharmacist monthly to evaluate effectiveness and safety of Long-acting Naltrexone treatment and receive monthly injection if appropriate to continue.

Pharmacy staff will set up a tracking system/ calendar for injection dates of patients actively receiving monthly Long-acting Naltrexone injections. There will be coordinated effort of nursing staff, pharmacists, and Chemical Health staff to ensure that patients schedule appointments for timely monthly injections. Transportation will be available through Chemical Health.

Patients will work with a case manager and/or recovery coach to overcome external barriers to their long-term recovery. All patients will fully participate with the treatment plan (which may include mental health counseling) and follow all recommendations to continue in the program.

The expectation is for patients to be maintained on Long-acting Naltrexone for 6 months. The medical provider may choose to continue Long-acting Naltrexone treatment for an additional 4-6 months where appropriate. Patients may receive Long-acting Naltrexone treatment for no longer than 12 months. Patients are expected to continue in Chemical Health and Behavioral Health program for 4-6 months following last Long-acting Naltrexone injection for recovery support.

Special considerations:

Patients receiving Long-acting Naltrexone injections will be required to wear an identification bracelet/ necklace revealing Long-acting Naltrexone treatment. This is necessary for emergency health care providers (such as EMS and ED physicians) in cases where the patient is unable to communicate their Long-acting Naltrexone therapy. Medical treatment with opioid analgesics for pain management in emergency situations could lead to fatal overdose with opioid doses required to overcome blockade.

Patients will be encouraged to choose a method of birth control while on Long-acting Naltrexone. Patients who decline birth control will be required to indicate declination of birth control on the patient consent form. Patients who are pregnant will not be eligible to participate in the Long-acting Naltrexone program.

Naltrexone place in therapy:

Clinical recommendations:

- Patient features predictive of success with naltrexone injection:
    - Patients who have not had treatment success with methadone or buprenorphine
    - Patients who have a high degree of motivation for abstinence
    - Patients who have been successful on opioid agonists who wish to discontinue agonist therapy.

Predictive Patient Precautions

1. Patients who do not tolerate extended opioid-free periods
2. Patients who are unable to complete withdrawal
3. Patients whose psychiatric symptoms worsen during withdrawal
4. Patients whose chronic pain requires treatment with opioid analgesics
5. Patients who have advanced liver disease or acute hepatitis

APPENDIX 1
Clinical Opiate Withdrawal Scale

For each item, circle the number that best describes the patient's signs or symptom. Rate on just the apparent relationship to opiate withdrawal. For example, if heart rate is increased because the patient was jogging just prior to assessment, the increase pulse rate would not add to the score.

Patient's Name:_____ Date and Time ____/____/____:_____

Reason for this assessment:_____

Resting Pulse Rate: _____beats/minute *Measured after patient is sitting or lying for one minute* 0 pulse rate 80 or below 1 pulse rate 81-100 2 pulse rate 101-120 4 pulse rate greater than 120	**GI Upset**: *over last 1/2 hour* 0 no GI symptoms 1 stomach cramps 2 nausea or loose stool 3 vomiting or diarrhea 5 multiple episodes of diarrhea or vomiting
Sweating: *over past 1/2 hour not accounted for by room temperature or patient activity.* 0 no report of chills or flushing 1 subjective report of chills or flushing 2 flushed or observable moistness on face 3 beads of sweat on brow or face 4 sweat streaming off face	**Tremor** *observation of outstretched hands* 0 no tremor 1 tremor can be felt, but not observed 2 slight tremor observable 4 gross tremor or muscle twitching
Restlessness *Observation during assessment* 0 able to sit still 1 reports difficulty sitting still, but is able to do so 3 frequent shifting or extraneous movements of legs/arms 5 unable to sit still for more than a few seconds	**Yawning** *Observation during assessment* 0 no yawning 1 yawning once or twice during assessment 2 yawning three or more times during assessment 4 yawning several times/minute
Pupil size 0 pupils pinned or normal size for room light 1 pupils possibly larger than normal for room light 2 pupils moderately dilated 5 pupils so dilated that only the rim of the iris is visible	**Anxiety or Irritability** 0 none 1 patient reports increasing irritability or anxiousness 2 patient obviously irritable or anxious 4 patient so irritable or anxious that participation in the assessment is difficult
Bone or Joint aches *If patient was having pain previously, only the additional component attributed to opiates withdrawal is scored* 0 not present 1 mild diffuse discomfort 2 patient reports severe diffuse aching of joints/muscles 4 patient is rubbing joints or muscles and is unable to sit still because of discomfort	**Gooseflesh skin** 0 skin is smooth 3 piloerrection of skin can be felt or hairs standing up on arms 5 prominent piloerrection
Runny nose or tearing *Not accounted for by cold symptoms or allergies* 0 not present 1 nasal stuffiness or unusually moist eyes 2 nose running or tearing 4 nose constantly running or tears streaming down cheeks	Total Score _____ The total score is the sum of all 11 items Initials of person completing assessment: _____

Score: 5-12 = mild; 13-24 = moderate; 25-36 = moderately severe; more than 36 = severe withdrawal

This version may be copied and used clinically.

Source: Wesson, D. R., & Ling, W. (2003). The Clinical Opiate Withdrawal Scale (COWS). *J Psychoactive Drugs*, 35(2), 253–9.

Subjective Opiate Withdrawal Scale (SOWS)

Instructions: Answer the following statements as accurately as you can. Circle the answer that best fits the way you feel now.

0=not at all
1=a little
2=moderately
3=quite a bit
4=extremely

	Not at all	A little	Moderately	Quite a bit	Extremely		How long after your last dose did THIS symptom begin? (hours)
1 I feel anxious.	0	1	2	3	4		
2 I feel like yawning.	0	1	2	3	4		
3 I'm perspiring.	0	1	2	3	4		
4 My eyes are tearing.	0	1	2	3	4		
5 My nose is running.	0	1	2	3	4		
6 I have goose flesh.	0	1	2	3	4		
7 I am shaking.	0	1	2	3	4		
8 I have hot flashes.	0	1	2	3	4		
9 I have cold flashes.	0	1	2	3	4		
10 My bones and muscles ache.	0	1	2	3	4		
11 I feel restless.	0	1	2	3	4		
12 I feel nauseous.	0	1	2	3	4		
13 I feel like vomiting.	0	1	2	3	4		
14 My muscles twitch.	0	1	2	3	4		
15 I have cramps in my stomach.	0	1	2	3	4		
16 I feel like shooting up now.	0	1	2	3	4		

The Subjective Opiate Withdrawal Scale (SOWS) consist of 16 symptoms rated in intensity by patients on a 5-point scale of intensity as follows: 0=not at all, 1=a little, 2=moderately, 3=quite a bit, 4=extremely. The total score is a sum of item ratings, and ranges from 0 to 64.

Mild Withdrawal is considered to be a score of 1 - 10.
Moderate withdrawal is considered to be a score of 11 - 20
Severe withdrawal is considered to be 21 - 30.

Source : Reprinted from Handelsman et al. 1987, p. 296, by courtesy of Marcel Dekker, Inc.

Other Sources : Gossop 1990; Bradley 1987.

Opioid Withdrawal Symptom Management Guideline

The purpose of this guideline is to provide an evidence-based approach to the management of acute opioid withdrawal. Detoxification in itself does not constitute complete substance abuse treatment. Detoxification services generally encompass three areas: evaluation, stabilization, fostering readiness for patient to enter into substance abuse treatment. This guideline is not meant to manage opioid withdrawal in pregnant women.

Opiate Withdrawal

Clinical Information	1) Assess withdrawal severity utilizing the Clinical Opiate Withdrawal Scale (COWS- objective; completed by nurse or provider) **AND** Subjective Opiate Withdrawal Scale (SOWS- subjective; completed by patient); documents to be sent to medical records department to be scanned into the patient EMR profile. 2) Confirm presence of opiate with a blood or urine drug toxicology lab test; ******Methadone and Buprenorphine require special lab order 3) Opiate withdrawals are extremely uncomfortable but NOT life-threatening- symptoms typically start within 12 hours of last Heroin usage (shortest acting opiate) and within 30 hours of last Methadone exposure (longest acting opiate) 4) Symptom Timeline: a) **Early Phase Symptoms (~6-12 hours)**: agitation, anxiety, myalgia (muscle aches), hyperlacrimation (increased tearing), insomnia, rhinorrhea (runny nose), diaphoresis (sweating), yawning b) **Late Phase Symptoms (~48-72 hours)**: abdominal cramping, diarrhea, mydriasis (dilated pupils), horripilation (goose bumps), nausea, vomiting
Pharmacological Intervention **+** ***Support Measures:*** **recommend brief daily clinic (nurse, pharmacist, or behavioral health counselor) visits for duration of withdrawal (2-10 days) for vital sign assessment, brief interview to identify menacing symptoms and apprehensions, and/or provide reassurance and support. These measures are targeted to mitigate psychological obstacles and may significantly increase success of detoxification completion and initial extended release naltrexone (XR-NXT) injection.	• **Symptom**: Anxiety/Insomnia/Restlessness/Agitation 1. *Mild to Moderate* a. Clonidine 0.1mg or 0.3mg: 1 PO Q6-8H PRN #QS i. *Contraindications* 1. Heart Rate ≤ 60 bpm 2. Hypotension (as defined by Mayo Clinic) a. Blood Pressure ≤ 90/60 mmHg b. Hydroxyzine 25mg or 50mg: 1 PO QID PRN (assists with rhinorrhea) c. Gabapentin 100mg 1-2 caps up to TID and QHS 2. *Severe* a. Clonidine **and/or** Gabapentin **and/or** Hydroxyzine **AND** b. Lorazepam 1mg: 1 PO Q6-8H and HS PRN Qty# 10-45 i. minimal use if possible due to addictive properties(C-IV) • **Symptom**: Nausea/Vomiting 1. Mild to Moderate a. Prochlorperazine 5 or 10 mg: 1 PO Q6-8H PRN **OR** Promethazine 25mg: 1 PO Q4-6h PRN **OR** Ondansetron 4mg: 1 PO Q8H PRN 2. Severe a. Ondansetron Oral Disintegrating (ODT) 4 to 8mg: 1 SL Q8H PRN • **Symptom**: Diarrhea 1. Mild to Moderate a. Loperamide 2mg: 4mg PO x 1 dose, then 2 mg after each loose stool for a maximum of 16mg/24hrs 2. Severe a. Diphenoxylate/Atropine 2.5/0.025mg: 1-2 PO BID to QID PRN max of 8 tabs/24hrs • **Symptom**: Rhinorrhea (runny nose)

Recommended Interventions: Mindful CBT (awareness), Talk Therapy, Breathing Exercises, ACT therapy (abbreviated)	1. Diphenhydramine 25mg: 1-2 PO Q4-6H PRN (sedative effect beneficial) 2. Cetirizine 10mg: 1 PO QD PRN • **Symptom**: Myalgias (muscle aches/pains) 1. Meloxicam 15mg: 1 PO QD with food **OR** 2. Diclofenac Sodium ER 75mg: 1 PO BID with food • **Symptom:** Insomnia 1. Trazodone 50-100mg QHS up to 1 year
Non-Pharmacological	• **Symptom**: Dehydration (from diarrhea/vomiting/malnutrition) 1. NS 0.09% IV; monitor electrolyte imbalances/kidney fxn with chem.-7 lab
Relapse Prevention	1) Immediate referral to behavioral health for in-patient/out-patient rehabilitation; *After-care*: continued follow-up with Behavioral Health 2) Consider Extended Release Injectable Naltrexone (Vivitrol) injections monthly for minimum of 12 months and continued Clonidine (tablets) PRN for anxiety.

References:

1. Miller, Norman, and Mark Gold. "Management of Withdrawal Syndromes and Relapse Prevention in Drug and Alcohol Dependence." *American Family Physician*. 1998 Jul1; 58(1): 139-146.
2. Myrick, Hugh, and Raymond Anton. "Treatment of Alcohol Withdrawal" *Alcohol Health & Research World*. 1998; 22(1): 38-43.
3. Bayard, Max, et al. "Alcohol Withdrawal Syndrome." *American Family Physician*. 2004 Mar 15; 69(6): 1444-1450.
4. "Addiction Medicine Essentials Clinical Institute Withdrawal Assessment of Alcohol Scale, Revised (CIWA-AR)." *American Society of Addiction Medicine.* 2001 Jan-Feb; Supplement 16(1).
5. Babor, Thomas, et al. "AUDIT: The Alcohol Use Disorders Identification Test Guidelines for Use in Primary Care, Second Edition." *World Health Organization*. 2001.
6. "Detoxification if Chemically Dependent Inmates Federal Bureau of Prisons Clinical Practice Guidelines." *Federal Bureau of Prisons*. 2009 Aug.
7. Longo, Lance, and Brian Johnson. "Addiction: Part I. Benzodiazepines- Side Effects, Abuse Risk and Alternatives." American Family Physician. 2000 Apr 1; 61(7); 2121-2128.
8. Ockert, David, et al. "A Nonopiod Procedure for Outpatient Opioid Detoxification." Journal of Addiction Medicine. 2011 June; 5(2); 110-114.

Vivitrol Treatment Consent and Agreement

I. Vivitrol Medication Guide:

VIVITROL® (viv-i-trol) (naltrexone for extended-release injectable suspension)

Read this Medication Guide before you start receiving Vivitrol injections and each time you receive an injection. There may be new information. This information does not take the place of talking to your healthcare provider about your medical condition or your treatment.

What is the **most important information** I should know about Vivitrol?

Vivitrol can cause serious side effects, including:

1. Risk of opioid overdose. You can accidentally overdose in two ways.

•Vivitrol blocks the effects of opioids, such as heroin or opioid pain medicines. Do not take opioids, including opioid containing medicines, such as heroin or prescription pain pills, to try to overcome the opioid blocking effects of Vivitrol. This can lead to serious injury, coma, or death.

•After you receive a dose of Vivitrol, its blocking effect slowly decreases and completely goes away over time. If you have used opioid street drugs or opioid-containing medicines in the past, using opioids in amounts that you used before treatment with Vivitrol can lead to overdose and death. You may also be more sensitive to the effects of lower amounts of opioids:

- ◦ after you have gone through detoxification
- ◦ when your next Vivitrol dose is due
- ◦ if you miss a dose of Vivitrol
- ◦ after you stop Vivitrol treatment

It is important that you tell your family and the people closest to you of this increased sensitivity to opioids and the risk of overdose. You or someone close to you should get emergency medical help right away if you:

- •have trouble breathing
- •become very drowsy with slowed breathing
- •have slow, shallow breathing (little chest movement with breathing)
- •feel faint, very dizzy, confused, or have unusual symptoms

2. Severe reactions at the site of the injection (injection site reactions).

Some people on Vivitrol have had severe injection site reactions, including tissue death (necrosis). Some of these injection site reactions have required surgery. Call your healthcare provider right away if you notice any of the following at any of your injection sites:

- intense pain
- blisters
- a dark scab
- the area feels hard
- an open wound
- lumps
- large area of swelling

Tell your healthcare provider about any reaction at an injection site that concerns you, gets worse over time, or does not get better by two weeks after the injection.

3. Sudden opioid withdrawal.

Anyone who receives a Vivitrol injection must not use any type of opioid (must be opioid-free) including street drugs, prescription pain medicines, cough, cold, or diarrhea medicines that contain opioids, or opioid dependence treatments, buprenorphine or methadone, for at least 7 to 14 days before starting Vivitrol. Using opioids in the 7 to 14 days before you start receiving Vivitrol may cause you to suddenly have symptoms of opioid withdrawal when you get the Vivitrol injection.

Sudden opioid withdrawal can be severe, and you may need to go to the hospital. You must be opioid-free before receiving Vivitrol unless your healthcare provider decides that you don't need to go through detox first. Instead, your doctor may decide to give your Vivitrol injection in a medical facility that can treat you for sudden opioid withdrawal.

4. Liver damage or hepatitis. Naltrexone, the active ingredient in Vivitrol, can cause liver damage or hepatitis. Tell your healthcare provider if you have any of the following symptoms of liver problems during treatment with Vivitrol:

- yellowing of the whites of your eyes
- dark urine
- stomach area pain lasting more than a few days
- tiredness

Your healthcare provider may need to stop treating you with Vivitrol if you get signs or symptoms of a serious liver problem.

What is Vivitrol?

Vivitrol is a prescription injectable medicine used to:

- Treat alcohol dependence. You should stop drinking before starting Vivitrol.
- Prevent relapse to opioid dependence, after opioid detoxification. This means that if you take opioids or opioid containing medicines, you must stop taking them before you start receiving Vivitrol.

To be effective, treatment with Vivitrol must be used with other alcohol or drug recovery programs such as counseling.

Vivitrol may not work for everyone.

Who should not receive Vivitrol?

Do not receive Vivitrol if you:

• **Are using or have a physical dependence on opioid-containing medicines or opioid street drugs.** To see whether you have a physical dependence on opioid-containing medicines or opioid street drugs, your healthcare provider may give you a small injection of a medicine called naloxone. This is called a naloxone challenge test. If you get symptoms of opioid withdrawal after the naloxone challenge test, do not start treatment with Vivitrol at that time. Your provider may repeat the test after you have stopped using opioids to see whether it is safe to start Vivitrol.

• **Are having opioid withdrawal symptoms.** Opioid withdrawal symptoms may happen when you have been taking opioid-containing medicines or opioid street drugs regularly and then stop.

Symptoms of opioid withdrawal may include: anxiety, sleeplessness, yawning, fever, sweating, teary eyes, runny nose, goose bumps, shakiness, hot or cold flushes, muscle aches, muscle twitches, restlessness, nausea and vomiting, diarrhea, or stomach cramps. Tell your healthcare provider if you have any of these symptoms before taking Vivitrol.

• are allergic to naltrexone or any of the ingredients in Vivitrol or the liquid used to mix Vivitrol (diluent).

What should I tell my healthcare provider before receiving Vivitrol?

Before you receive Vivitrol, tell your provider if you:

• have liver problems • have kidney problems • use or abuse street (illegal) drugs

• have bleeding problems • have any other medical conditions

• are pregnant or plan to become pregnant. It is not known if Vivitrol will harm your unborn baby.

• are breastfeeding. It is not known if Vivitrol passes into your milk, and if it can harm your baby. Naltrexone, the active ingredient in Vivitrol, is the same active ingredient in tablets taken by mouth that contain naltrexone. Naltrexone from tablets passes into breast milk. Talk to your doctor about whether you will breastfeed or take Vivitrol. You should not do both.

Tell your healthcare provider about all the medicines you take, including prescription and non-prescription medicines, vitamins, and herbal supplements. Especially tell

your healthcare provider if you take any opioid containing medicines for pain, cough or colds, or diarrhea. If you are being treated for alcohol dependence but also use or are addicted to opioid-containing medicines or opioid street drugs, it is important that you tell your healthcare provider before starting Vivitrol to avoid having sudden opioid withdrawal symptoms when you start Vivitrol treatment. Know the medicines you take. Keep a list of them to show your healthcare provider and pharmacist when you get a new medicine.

How will I receive Vivitrol?

• Vivitrol is injected by a healthcare provider, about 1 time each month.

• Vivitrol is given as an injection into a muscle in your buttocks using a special needle that comes with Vivitrol.

• After Vivitrol is injected, it lasts for a month and it cannot be removed from the body.

• If you miss your appointment for your Vivitrol injection, schedule another appointment as soon as possible.

• Whenever you need medical treatment, be sure to tell the treating healthcare provider that you are receiving Vivitrol injections and mention when you got your last dose. This is important because Vivitrol can also block the effects of opioid-containing medicines that might be prescribed for you for pain, cough or colds, or diarrhea.

• Carry written information with you at all times to alert healthcare providers that you are taking Vivitrol, so that they can treat you properly in an emergency. Ask your healthcare provider how you can get a wallet card to carry with you.

What should I avoid while receiving Vivitrol? Do not drive a car, operate machinery, or do other dangerous activities until you know how Vivitrol affects you. Vivitrol may make you feel dizzy and sleepy.

What are the possible side effects of Vivitrol?

Vivitrol can cause serious side effects, including:

• Depressed mood. Sometimes this leads to suicide, or suicidal thoughts, and suicidal behavior. Tell your family members and people closest to you that you are taking Vivitrol. You, a family member, or the people closest to you should call your healthcare provider right away if you

become depressed or have any of the following symptoms of depression, especially if they are new, worse, or worry you:

- You feel sad or have crying spells.
- You feel hopeless or helpless.
- You have trouble paying attention
- You feel tired or sleepy all the time
- You are more irritable, angry, or aggressive than usual.
- You are no longer interested in seeing your friends or doing things you used to enjoy.
- You are sleeping a lot more or a lot less than usual.
- You are more or less hungry than usual or notice a big change in your body weight.
- You have thoughts about hurting yourself or ending your life.

• **Pneumonia.** Some people receiving Vivitrol treatment have had a certain type of pneumonia that is caused by an allergic reaction. If this happens to you, you may need to be treated in the hospital. Tell your healthcare provider right away if you have any of these symptoms during treatment with Vivitrol:

- shortness of breath or wheezing
- coughing that does not go away

• **Serious allergic reactions.** Serious allergic reactions can happen during or soon after an injection of Vivitrol. Tell your provider or get medical help right away if you have any of these symptoms of a serious allergic reaction.

- skin rash
- chest pain
- trouble breathing or wheezing
- feeling dizzy or faint
- swelling of your face, eyes, mouth, or tongue

Common side effects of Vivitrol may include:

• Nausea may happen after your first Vivitrol injection and usually improves within a few days. Nausea is less likely with future injections of Vivitrol.

- sleepiness
- headache
- dizziness
- trouble sleeping
- decreased appetite
- toothache
- painful joints
- muscle cramps
- cold symptoms
- vomiting

Tell your healthcare provider if you have any side effect that bothers you or that does not go away. These are not all the side effects of Vivitrol. For more information, ask your provider or pharmacist. Call your doctor for medical advice about side effects. You may report side effects

to FDA at 1-800-FDA-1088. **General information about Vivitrol:** For more information about Vivitrol, call 1-800-848-4876, Option #1 or go to **www.vivitrol.com.**

What are the ingredients in Vivitrol? Active ingredient: naltrexone Inactive ingredient: polylactide-co-glycolide (PLG)

Diluent ingredients: carboxymethylcellulose sodium salt, polysorbate 20, sodium chloride, and water for injection.

II. Vivitrol Patient Treatment Counseling and Treatment Agreement:

Patient Initial Each Item:

_____1. I understand that I need to follow my comprehensive treatment plan. My treatment plan will change as I progress in my recovery. I must call 24 hours prior to canceling an appointment. If I miss an appointment with my provider, I may be asked to return for more frequent visits, may not have my medication refilled until I am seen again, and I may be discharged from the clinic. I understand that if I am not seen in the office as requested by my provider, I will be unable to obtain my prescription since the injection is coordinated with monthly visits.

_____3. I agree not to take any **other medications** with Vivitrol without discussing first with my provider.

_____4. I understand that **goal of treatment** for opioid dependency is to learn to live without abusing alcohol and drugs. Vivitrol injections should continue as long as necessary to prevent relapse and then stopped

_____5. I will submit a **urine specimen** (my own urine) for drug screen (narcotic, pot, cocaine, amphetamine, PCP, alcohol, benzodiazepine, and others) upon my providers' request as often as directed. My provider may ask that a clinical staff member observe my providing the appropriate specimen. If my drug screen indicates the presence of illegal/inappropriate substances, I may be discharged from the clinic.

_____6. I understand that if I have previously used opioids, I may be more **sensitive to lower doses of opioids** and at risk of accidental overdose if I use opioids when my next dose is due, if I miss a dose, or after Vivitrol treatment is discontinued. It is important that I inform family members and people close to me of this increased sensitivity to opioids and the risk of overdose. I understand that because Vivitrol can block the effects of opioids. I may not perceive any effect if I self-administer heroin or any other opioid drug in small does while on Vivitrol. Further, I understand that administration of doses of heroin or any other opioid to try to bypass the blockade and get high while on Vivitrol may lead to serious injury, coma, or death. I understand that overdose deaths have occurred in the cases where opioid tolerant patients have tried to "override" the blocking action of Vivitrol with larger doses of opioids (even at doses previously tolerated).

_____7. I understand that I may not experience the expected effect from **opioid-containing** pain medication, diarrhea, or other cough medications.

_____8. I understand that a **reaction at the site of Vivitrol injection** may occur. Reactions include pain, tenderness, induration, swelling, redness, bruising and itching. Serious injection

site reactions including tissue death may occur. Some of these injection site reactions have required surgery. I should seek medical attention for worsening skin reactions.

_____9. I understand that I need to be off all opioids, including opioid-containing medicines, for at least 7-14 days before starting Vivitrol in order to avoid precipitation of **opioid withdrawal**. I understand that withdrawal caused by an opioid antagonist (Vivitrol) may be severe enough to require hospitalization if I have not been opioid-free for a sufficient number of days, and the withdrawal is different from the experience of spontaneous withdrawal that occurs with discontinuation of opioids in a dependent individual. I am not to take Vivitrol if I have any symptoms of opioid withdrawal. I understand that I need to tell my provider about any recent alcohol or drug use prior to Vivitrol injection.

_____10. I understand that Vivitrol may cause **liver injury** and I need to notify my healthcare provider if I develop symptoms and or signs of liver disease.

_____11. I understand that I may experience **depression** while taking Vivitrol. It is important that I inform family members and people close to me that I am taking Vivitrol and that they should call a doctor right away if I become depressed or experience symptoms of depression.

_____12. I understand that Vivitrol may cause an allergic **pneumonia**. I should immediately notify my physician if I develop signs and symptoms of pneumonia, including shortness of breath, coughing or wheezing.

_____13. I understand that I may experience **nausea/vomiting** following the initial injection of Vivitrol. These episodes of nausea tend to be mild and subside within a few days post-injection. Nausea is less likely with subsequent injections. I may also experience tiredness, headache, vomiting, decreased appetite, painful joints and muscle cramps. A copy of the potential side effects has been given to me.

_____14. I understand that **dizziness or fainting** may occur with Vivitrol treatment and I should avoid driving or operating heavy machinery until I have determined how Vivitrol affects me.

_____15. I understand **other side effects** include muscle cramps, somnolence or sedation, anorexia, decreased appetite or other appetite disorder, difficulty sleeping, and toothache.

_____16. I understand that Vivitrol **should be avoided** in individuals with acute hepatitis or liver failure, fulminant AIDS, opioid positive drug screens and any individual who have previously had a drug allergy to naltrexone.

_____17. I understand that once Vivitrol is injected, it is **not possible to remove it from my body.**

_____18. I understand that the use of Vivitrol is a form of **Medication Assisted Treatment** (MAT) helping me stay sober while I participate in my long term recovery program. Vivitrol has

been shown to treat alcohol and opioid dependence only when used as part of a treatment program that includes counseling and support. I will be required to participate fully with my treatment program.

_____19. I understand that I am to notify my provider if I am **breast-feeding**, if I **become pregnant**, if I think I might be pregnant, or if I am thinking about becoming pregnant. I understand that I should choose a reliable form of birth control if I am of child-bearing age. A prescription or appointment with my provider has been established for this reason.

_____20. I allow my provider to **communicate with other providers** regarding my medical care, consistent with HIPAA guidelines. Treatment disclosure may include, but is not limited to, discussing my medications with the pharmacist. I understand that records released may contain information pertaining to psychiatric treatment and/or treatment for alcohol and/or drug dependence. These records may contain confidential information about communicable diseases including Hepatitis, HIV(AIDS) or related illnesses.

_____24. I understand that **rude or disrespectful treatment of staff** is not tolerated and may result in my discharge. (Ex: using profanity, raising my voice, making vulgar or inappropriate comments).

_____25. I understand that I must provide a good **contact** phone number at all times (and will update the office of any changes) or my provider may not prescribe medications.

_____26. I understand the **commitment** to the program and the many appointments, therefore transportation cannot be an issue or a reason for short notice cancellations or no show appointments.

_____28. Regarding **opioids:** I understand that I must be **opioid drug free (detoxed) for 7 days and for 14 days detoxed from Methadone and Buprenorphine**. If I am not detoxed than the Vivitrol injection will precipitate immediate and sometimes severe opioid withdrawal (to include but not limited to nausea, vomiting, muscle cramps, tremors, headache and sweating).

_____29. I understand that I need to **carry documentation** to alert medical personnel to the fact that I am taking Vivitrol. This is important information if I need to obtain medical treatment in an emergency and am unable to tell other health care providers that I am on Vivitrol. I agree to wear a medical alert (card, bracelet).

I have read and understand all the information about Vivitrol treatment. I have received answers to any questions I have. I agree that I am responsible to abide by these instructions. I wish to be treated with Vivitrol.

Name_____ Date of Birth_____

Pharmacy: Red Lake Hospital Pharmacy_

Primary Care Provider_____

Patient Signature_____ Patient Initials:_____ Date _____

I, the Provider, have reviewed Vivitrol risks and side effects with the patient.

Provider Signature _____ Date _____

One copy of this form is given to the patient after signing.