NALTREXONE

DAVID CRABTREE, MD, MPH
TREATMENT OF OPIOID USE DISORDER (OUD)

- Majority of people who develop OUD are not receiving treatment
- Only a small fraction of patients are offered treatment with medications (MAT), despite overwhelming evidence of superior outcomes as compared to psychosocial treatment approach
- All patients should be offered option to be treated with one of the FDA-approved medications, preferably matched to the patient to assure optimal outcome
NALTREXONE

• Antagonist - ligand that binds to the receptor but does not initiate signal transduction
  – Naltrexone & Naloxone act as u-OR antagonists
• Naltrexone binds with the highest affinity of all ligands
  – It will displace all agonists from the receptor
  – It will prevent all agonists from exerting effects
  – At sufficient blood levels, naltrexone fully blocks all opioid effects*
NALTREXONE

- Long acting, high affinity, competitive opioid receptor antagonist with an active metabolite (6-B-naltrexol, also antagonist)
- Tablet is approved for the blockade of exogenously administered opioids
- Injection (Extended release) is approved for “the prevention of relapse to opioid dependence following opioid detoxification” (package insert)
- May be a good choice for patients seeking withdrawal from all opioids as a first stage of treatment
COMPONENTS OF TREATMENT WITH NALTREXONE

• Behavioral component: blockade of the positive reinforcing effects of opioids leads to gradual extinction of craving and compulsive drug use
  – Patients who use opioids while taking naltrexone experience no euphoric effect and usually stop using opioids

• Pharmacological component: naltrexone decreases reactivity to drug conditioned cues thereby minimizing pathological responses contributing to relapse (craving)
  – Patients with a good clinical response to naltrexone usually have no urges to use

• As naltrexone has a different mechanism of action than agonists, it may address limitations related to treatment with agonists, providing another option for patients with OUD
LIMITATIONS

• Requirement of detoxification and a wait period of 7-10 days after the last dose of an opioid before antagonist can be initiated
  – A major barrier for many patients who find difficult to tolerate withdrawal and abstain from opioids

• Difficulty with the induction due to the possibility of precipitated and protracted withdrawal
  – Patients do not feel well at the beginning of the treatment
  – Requirement of close monitoring

• XR preparation of naltrexone is a relatively new medication with limited effectiveness research to date
BRIEF HISTORY OF NALTREXONE-BASED TREATMENT

• First introduced in the 1970s (PO)…disappointing results
  – Difficulty with tx initiation, low patient acceptability and poor adherence
  – Reviews concluded that there was no evidence that naltrexone is effective beyond selected patient groups, which discouraged its use

• New developments in the 1980s
  – Clonidine effective in tx withdrawal
  – Development of naltrexone-assisted withdrawal management protocols
  – Buprenorphine was introduced for withdrawal management which facilitated naltrexone induction
BRIEF HISTORY

• The 1990s-2000s
• Using antagonists during withdrawal management became an opportunity to continue with naltrexone as a relapse prevention agent
• Behavioral therapy was developed to improve adherence to oral naltrexone, including elements of MI/CBT/etc
• Long-acting preparations became available to address non-adherence to PO
EFFICACY OF NALTREXONE: PO VS XR INJECTION

• Retention in treatment rate = 1’ outcome
• Main reason for dropout is relapse
• Majority retained in treatment are abstinent from opioids
• Rate in groups tx’d with XR preparations is twice that of the PO group, appx 50-70% at 6 months
XR VS PLACEBO

- Trials comparing injection of naltrexone vs placebo showed that patients receiving naltrexone have:
  - Better retention
  - Less opioid use
  - Lower craving of opioids
EFFECT OF NALTREXONE: SUMMARY

• XR preparations of naltrexone are more effective than the PO preparation and should be offered over the oral formulation
  – Adherence is a challenge, but it is better with XR preparation
  – Treatment must emphasize adherence
• Better treatment retention, lower opioid use, and lower craving as compared to placebo
• Those retained with XR have low levels of concurrent opioid use
• No direct evidence yet available comparing efficacy of XR naltrexone vs buprenorphine
  – Indirect comparisons show comparable retention with lower level of ongoing opioid use
GOOD CANDIDATES FOR NALTREXONE

• Patients who are not interested or able to be on agonist med
  – Highly motivated for abstinence from all opioids
  – In professions where treatment w/ agonist med is controversial (health care, pilots, etc)
• Patients who are abstinent from opioids but remain at risk for relapse
  – Released from a controlled setting (prison, residential program)
    • Moving back to neighborhood w/ greater exposure to drugs
• Patients who failed prior treatment w/ agonist
  – Continued cravings and use of illicit opioids, non-adherence w/ agonist med, diverting/misusing agonists
CONTINUED

• Less severe forms of OUD
• Young adults living with involved parents who can supervise tx
• Young adults unwilling to commit to longer-term agonist therapy
• Individuals who use opioids sporadically and are at risk or progression to daily use
• Patients successful on agonist therapy who wish to DC med and seek alternative tx
PATIENT-TREATMENT MATCHING

• No evidence, only clinical experience
• Good response to PO Naltrexone:
  – Highly motivated pt
  – Older pt w/ long hx of use and multiple relapses
  – Pt w/ long periods of abstinence between relapses
IS THE PATIENT READY?

• Naltrexone WILL precipitate severe and prolonged withdrawal in those who are physically dependent on opioids or have large amount of opioids in their system

• Always confirm absence of opioids and physical dependence prior to the first dose
  – UDS must be negative for all opioids, but remember not all opioids will be detected (Kratom, loperamiide)
  – Naloxone challenge if unsure of the abstinence and the absence of physiological dependence
  – Patient must understand the risks of precipitated withdrawal if underreporting
INITIATING XR-NALTREXONE

• Give immediately after confirming absence of physical dependence or passing the challenge
• May give PO challenge (12.5-25 mg x 1) at least 1-2 hours before the injection, to ensure tolerability
• Alternatively, may do this for a few days, then inject
  – Residential setting
  – Give XR ASAP to minimize risks of non-adherence to PO
NALOXONE CHALLENGE

- Short acting opioid antagonist used to reverse overdose AND to detect physiological dependence
- Will precipitate withdrawal that usually emerges within 5-10 min and dissipates within 30 min
  - COWS to measure withdrawal
  - Severity of withdrawal proportional to the level of physical dependence and dose of naloxone
  - Any change from baseline = Positive test (wait a day, repeat)
- Naloxone IM (deltoid)
  - 2 stages to minimize withdrawal: 0.4 mg then 0.8 mg
  - Negative test → full dose naltrexone can be started
INDUCTION: CLINICAL SCENARIOS

• Abstinent, after opioid withdrawal
  – XR most easily started this way
  – Not in acute withdrawal, no use of opioids for 7+ days
  – Confirm absence of opioids and physical dependence
  – Administer injection

• Sporadic use of opioids
  – Individuals who started using after a period of abstinence, high risk intermittent users of opioids
  – Require 2-3 days of abstinence and confirm absence of physical dependence
  – Neg UDS and neg naloxone challenge
  – Administer injection
INDUCTION: CLINICAL SCENARIOS

- Use of daily low amounts
  - Misuse of opioids in the context of pain-treatment (<100 MME)
  - Low amount of heroin (1-3 bags/day)
  - Must complete withdrawal (outpatient w/ daily visits)
  - Confirm absence of physical dependence (neg Utox, neg challenge)
  - Administer injection
INDUCTION: CLINICAL SCENARIOS

• Use of daily large amounts
  – Short or long acting, IN or IV
  – >5 bags heroin, oxycodone, fentanyl, methadone
  – Often use of other substances (etoh, sedatives, simulants)
  – Consider agonist as a first line tx
  – If patient wants naltrexone, consider inpatient withdrawal management (10-14 days)
  – Confirm absence of physical dependence (neg Utox, neg challenge)
  – Administer injection BEFORE discharge
THE PATIENT DISCONTINUING METHADONE OR BUPRENORPHINE

• Those maintained with good response may be considered for transition onto naltrexone
• Patient should be able to tolerate gradual agonist dose reduction
  – Those on methadone should go onto buprenorphine
  – All should remain stable on buprenorphine 2-4 mg for at least one month before discontinuation
  – Use adjuncts after stopping buprenorphine to alleviate withdrawal
  – Initiate w/ PO followed by XR injection
    • Waiting for neg Utox (bup) is not necessary if starting low naltrexone dose
OPIOID WITHDRAWAL

• Approaches, not to be discussed in detail
  – Agonist assisted opioid withdrawal
  – Symptomatic only care
  – Rapid withdrawal using antagonist
    • Naltrexone added 2-3 days after the last dose, start low (3-6 mg), use adjuncts to minimize discomfort
  – Ultra Rapid withdrawal under anesthesia
Administering naltrexone during the first week after stopping heroin will precipitate withdrawal with the severity depending on the time and dose.

Administering low doses of naltrexone 2-3 days after last dose of heroin will NOT produce intolerable withdrawal but will accelerate time to reach the full dose of naltrexone.
- Two phases of treatment: 1) acute withdrawal, 2) naltrexone induction
- Current FDA-sanctioned method involves 7-10 days “washout” period between the last dose of opioid and first dose of naltrexone (NTX)

- Not using agonist during withdrawal, shortens duration of induction

- Two phases of treatment: 1) acute withdrawal, 2) naltrexone induction
- Withdrawal and naltrexone induction can occur at the same time: rapid withdrawal/naltrexone induction
- Introducing low-doses of naltrexone during withdrawal accelerates the process of induction (i.e., readiness for XR-naltrexone)
### Naltrexone Induction Algorithms (Sigmon et al, 2012)

#### Severity (physical dependence/anticipated withdrawal)

<table>
<thead>
<tr>
<th>Setting</th>
<th>NONE</th>
<th>MILD</th>
</tr>
</thead>
<tbody>
<tr>
<td>Buprenorphine Dose</td>
<td>None</td>
<td>None or 4mg, day 1</td>
</tr>
<tr>
<td>Clonidine</td>
<td>None</td>
<td>0.1-0.2 mg TID to QID</td>
</tr>
<tr>
<td>Clonazepam</td>
<td>None</td>
<td>0.5 mg BID</td>
</tr>
<tr>
<td>Ancillary medications</td>
<td>None</td>
<td>Sleep, pain (e.g. NSAID)</td>
</tr>
<tr>
<td>Hydration</td>
<td>Routine</td>
<td>Aggressive oral hydration</td>
</tr>
<tr>
<td>Time to first NTX dose</td>
<td>Day 1</td>
<td>Day 3</td>
</tr>
<tr>
<td>Initial oral NTX dose</td>
<td>25-50 mg</td>
<td>12.5 mg QD</td>
</tr>
<tr>
<td>Time to XR-NTX Injection</td>
<td>Days 1-2</td>
<td>Day 4; (or Day 5-6 after titrating oral naltrexone to 25-50mg QD)</td>
</tr>
</tbody>
</table>

### Rapid Naltrexone Induction Algorithm (continued)

#### Severity (physical dependence/anticipated withdrawal)

<table>
<thead>
<tr>
<th>Setting</th>
<th>MODERATE</th>
<th>SEVERE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Buprenorphine Dose</td>
<td>4-8 mg, day 1 or 2</td>
<td>8 mg, day 1 or 2, or &gt;8 mg as needed</td>
</tr>
<tr>
<td>Clonidine</td>
<td>0.2 mg (TID to QID)</td>
<td>0.2-0.3 mg QID</td>
</tr>
<tr>
<td>Clonazepam</td>
<td>1.0-2.0 mg (TID to QID)</td>
<td>1.0-2.0 mg QID</td>
</tr>
<tr>
<td>Ancillary medications</td>
<td>Sleep, pain, GI distress</td>
<td>Sleep, pain, GI distress</td>
</tr>
<tr>
<td>Hydration</td>
<td>Aggressive oral hydration</td>
<td>Aggressive oral or IV hydration</td>
</tr>
<tr>
<td>Time to first NTX dose</td>
<td>Days 3-4</td>
<td>Day 4-5 (later if needed)</td>
</tr>
<tr>
<td>Initial oral NTX dose</td>
<td>6 mg BID</td>
<td>3-6 mg QD-BID</td>
</tr>
<tr>
<td>Time to XR-NTX Injection</td>
<td>Days 4-5; or days 5-7 after titrating oral naltrexone to 25-50 mg QD</td>
<td>Day 5-6; (or Day 6-7 after titrating oral naltrexone to 25-50mg QD)</td>
</tr>
</tbody>
</table>

### Naltrexone initiation during withdrawal: Rapid Naltrexone Induction Procedure

<table>
<thead>
<tr>
<th>Day 1</th>
<th>Day 2</th>
<th>Day 3</th>
<th>Day 4</th>
<th>Day 5</th>
<th>Day 6</th>
<th>Day 7</th>
</tr>
</thead>
<tbody>
<tr>
<td>Buprenorphine admission</td>
<td>4 mg bid</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Naltrexone</td>
<td>3 mg</td>
<td>6 mg</td>
<td>25 mg</td>
<td>50 mg po 380 mg im</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Supportive medications</td>
<td>clonidine 0.1-0.2 mg qid, clonazepam 0.5-1.0 mg bid, prochlorperazine, zopidem, trazodone</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

- Protocol may be modified depending on the level of physiological dependence
- Low starting doses of naltrexone (1-3 mg) will minimize precipitated withdrawal while accelerating time to the full dose
  - At present, low-dose naltrexone is only available from compounding pharmacies
- Approximately 70% of patients complete inpatient and 60% complete outpatient procedure and accept naltrexone injection
# Buprenorphine Bridge (after heroin) prior to Rapid Naltrexone Induction

<table>
<thead>
<tr>
<th></th>
<th>Day 1</th>
<th>Day 2</th>
<th>Day 3</th>
<th>Day 4</th>
<th>Day 5</th>
<th>Day 6</th>
<th>Day 7</th>
</tr>
</thead>
<tbody>
<tr>
<td>Buprenorphine</td>
<td>8 mg</td>
<td>6 mg</td>
<td>4 mg</td>
<td>3 mg</td>
<td>2 mg</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Naltrexone</td>
<td>1-3 mg</td>
<td>6-9 mg</td>
<td>12-25 mg</td>
<td>380 mg im</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Supportive medications**: clonidine 0.1-0.2 mg qid, clonazepam 0.5-1.0 mg tid, zolpidem, trazodone

- An outpatient procedure appropriate for patients with severe use disorder (e.g., injecting large doses of heroin) and those who are not able to tolerate more rapid transition onto naltrexone
- A period of treatment with buprenorphine allows patients to stabilize (stop) their drug use first prior to undergoing opioid withdrawal

---

# Transition from Buprenorphine Maintenance to Naltrexone

<table>
<thead>
<tr>
<th></th>
<th>Day 1</th>
<th>Day 2</th>
<th>Day 3</th>
<th>Day 4</th>
<th>Day 5</th>
<th>Day 6</th>
<th>Day 7</th>
</tr>
</thead>
<tbody>
<tr>
<td>Buprenorphine</td>
<td>2 mg qd</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Naltrexone</td>
<td>1-3 mg</td>
<td>6 mg</td>
<td>25 mg</td>
<td>50 mg po</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Supportive medications</td>
<td>clonidine 0.1-0.2 mg qid, clonazepam 0.5-1.0 mg tid, Prochlorperazine, zolpidem, trazodone</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

- Many people who are unable to taper off buprenorphine may have a greater sensitivity to withdrawal symptoms or an anxiety disorder both of which can benefit from ancillary medications and support
- Some of patients who stop buprenorphine maintenance experience protracted withdrawal (anxiety, low energy, or amotivation) that may benefit from symptomatic treatment
NALTREXONE “FLU”

- Patients who start naltrexone right after withdrawal commonly experience a “flu-like” symptoms (low-grade withdrawal)
  - Somatic complaints: insomnia, GI distress, hyperalgesia, anergia
  - Anxiety, irritability, dysphoria, anhedonia
  - Symptom severity correlated with naltrexone dose and timing
  - Severity may be lower if naltrexone initiation is postponed (but relapse risk)

- Partially alleviated with aggressive symptomatic treatment,
  - Insomnia (v. frequent, often severe): zolpidem, trazodone, quetiapine
  - GI distress: H2 blockers
  - Anxiety/hyperarousal: clonazepam, clonidine, gabapentin

- Most of these symptoms remit by 2-4 weeks
  - True prolonged symptoms are rare and likely reflect additional psychopathology
SIDE EFFECTS

• Infrequent, first month, related to withdrawal
  – Nausea, Tiredness, Headache, Dizziness, Vomiting, Decreased Appetite, Painful Joints, Muscle Cramps, Insomnia

• Injection Site Reactions (inflammation, Tissue Damage)
  – Local tenderness, small bump is common, resolves 1-3 days
  – Serious Site Reaction If Administered Into FAT TISSUE

• Rare
  – Depressed mood, suicidal behavior
  – Allergic Eosinophilic Pneumonitis
  – Systemic Allergic Reaction
CLINICAL CHALLENGES: TESTING THE BLOCKADE

• Approximately a third of patients will “test” blockade, often within 1-2 days after receiving XR-naltrexone
  ▪ As blood level may be low the first 24hrs, oral supplementation may be considered on the first day

• Most commonly, patients will “test” 1-2 times with small amounts of opioid during the first week of treatment, after which they are “reassured” that blockade works and do not continue use

• Some patients will use large amounts, for 1-3 weeks, but very few will persist in the use if they receive full blocking doses of the medication
  ▪ Very few patients try intentionally to “override the blockade”
“Blocked” vs. “unblocked” use

• The narcotic “blockade” wears off 2-3 days after oral and 5-6 weeks after injectable doses of naltrexone
  ▪ Patients who use while still “blocked” (3-5 weeks post-injection) most often do not become re-dependent and can receive subsequent naltrexone doses and remain in treatment
  ▪ Many patients who use while “blocked” prefer to remain on the medication
  ▪ “Unblocked use” will rapidly progress to relapse and puts patient at risk for overdose
• Continuous blockade prevents patients from relapsing to physical dependence
Clinical Challenges: Managing Relapse (1)

- Occasionally patients report increased craving 3-4 weeks after the injection
  - It may be a pharmacological effect (blood level of the medication drops below a therapeutic level) or the expectancy effect (knowing that the blockade may be "wearing off")

- In patients who report increase in craving before the next scheduled dose may consider more frequent injections (e.g., every 3 weeks – off label) or supplementation with oral naltrexone (in weeks 3-4)

Clinical Challenges: Managing Relapse (2)

- Most commonly, the first sign of relapse is new episode of opioid use and missing naltrexone doses/injections
- This warrants an immediate response to prevent destabilization:
  - Increase frequency and intensity of behavioral treatment and support groups
  - When appropriate, involving family/significant other/friends in treatment to improve adherence
  - Residential treatment/sober house
  - Patients who become re-dependent may require inpatient stabilization and another attempt at antagonist treatment
- If unable to stabilize, consider transition onto agonist
Clinical Challenges: Missing Doses

- Naltrexone non-adherence is often seen with oral preparation but also happens with injection and is a frequent reason for treatment failure

- Naltrexone non-adherence often occurs at treatment outset
  - Long-acting preparation should be chosen over oral preparation because it significantly reduces the risk of non-adherence
  - Injection naltrexone should be administered as soon as available; little/no advantage of an oral naltrexone “trial” prior to the injection

- If the patient is late for the next injection, contact the patient/family to advise oral doses (100-150 mg every 2-3 days)
  - Involve family in monitoring/supervising medication administration

- Verify that the patient is not physically dependent before administering “late” injection (similar to induction procedures)
Managing Severe Pain

Commonly used prescription opioid analgesics will not be effective in patients on therapeutic doses of naltrexone
- Patients should wear medical bracelet or carry a “wallet card”

Alternative approaches to manage pain
- Non-opioid therapies: acetaminophen, NSAID’s (ketorolac iv), ketamine, clonidine, muscle relaxants (baclofen), anticonvulsant (gabapentin)
- Non-pharmacologic therapies: peripheral and neuraxial nerve blocks, local anesthetic infiltration

High potency opioids (e.g., alfentanil) can override the naltrexone blockade but should be done under anesthesia monitoring
Naltrexone and Overdose

- Therapeutic doses of naltrexone protect against overdose however there is a significant risk of overdose if patient decides to stop taking naltrexone and resumes opiate use
  - Due to the absence of pharmacological blockade, absence of tolerance, and possibly increased sensitivity to opioids

To mitigate this risk, provide a detailed description of risks at treatment outset (e.g., treatment agreement) and discuss it during treatment, especially in patients who continue use

Overdose Risk

- Risk of overdose is present following completed opioid withdrawal or discontinuation of agonist maintenance.
- Treatment with agonist or antagonists reduces mortality as compared to drug-free treatment
- The risk of overdose is comparable among patients in active MAT (adherent to naltrexone oral/XR, buprenorphine, or methadone)
- Mortality rates differ among patients who discontinue MAT
  - Higher in patients treated with oral naltrexone as compared to methadone
  - Higher in patients treated with oral as compared to XR-naltrexone
  - Comparable in patients treated with XR-naltrexone and methadone
- The long “tail” on the serum XR-naltrexone curve may provide protection in patients who discontinue MAT, which is often marked by an elevated mortality
Depression and Suicide Risk

There are concerns whether treatment with naltrexone increases risk of depression and suicidality through blocking of endogenous opioid activity

- Though theoretically plausible, there is no systematic clinical evidence that naltrexone increases depression in this population
- Depressive symptoms usually improve during early abstinence from opioids
- However, some patients may have increased depressive symptoms, usually brief and occurring during the first few weeks of treatment

Opioid Use Disorder is a risk factor for suicide: 10% vs. 1.3% in the general population

Depression and suicidality warning is included in the package insert for Vivitrol

- Suicidality was reported in 5% of patients treated with Vivitrol (10% in oral naltrexone) in open-label long-term US safety study
- No such warning on buprenorphine package insert
Injectable Naltrexone: Ordering and Storage

- Medication needs to be ordered in advance through specialty pharmacy services
  - It is reimbursed under medical rather than pharmacy benefits
  - Medication is shipped directly to the medical office
  - Because it may take 1-2 weeks for the office to receive medication, patients may be treated with oral preparation until then
  - Most of the time patients with insurance do not have out-of-pocket expenses (vivitrolcopay.com)

- Once received, medication needs to be stored in the refrigerator (36-46°F) but should not be frozen
  - Medication has to reach room temperature prior to injection (30-40 min at RT)
  - Can be out of the fridge for up 7 days prior to injection, but it can be put back if not administered within this time
• Medication comes with a syringe and two sets of needles (different lengths)

• Additional supplies needed: alcohol/betadine swabs, gauze, band aids, medical pads (chux), sharps container

• Injection technique: standing up vs. lying down vs. bending over
  ▪ Lying down is preferred to minimize muscle tension

• It is preferable, but not essential, to have nurse or other staff present, as the patient is partially undressed for the injection

Medication powder and diluent have to be mixed (by hand or with a vortex shaker) and suspension should be injected immediately to minimize the risk of needle clogging

  ▪ Occasionally the needle clogs, if that happens, withdraw the syringe and change the needle (included in the set)

The recommended dose of VIVITROL is 380 mg or 4 mL of the suspension to be delivered as a single deep IM injection into the gluteal muscle every 4 weeks or once monthly

  ▪ Alternate site (L/R) with each injection

Dorsogluteal side is preferred for injection but providers may consider a ventrogluteal injection side (from the side) if it provides better access to the muscle
1. Using the circular motion clean the injection site with the alcohol swab

2. Quickly insert the full length of the needle

3. Aspirate for blood before injecting the suspension

4. Inject the suspension in a smooth and continuous motion (approx. 30s)

- Administer injection into the outer upper quadrant of a gluteal muscle
- Administer deeply into the muscle tissue, avoid injecting to adipose tissue
- Alternate site (L/R) for each injection
INJECTABLE NALTREXONE PRIOR AUTHORIZATION

- [https://www.vivitrolhcp.com/content/pdfs/vivitrol2gether-enrollment-form.pdf](https://www.vivitrolhcp.com/content/pdfs/vivitrol2gether-enrollment-form.pdf)

- Or Google “touchpoints Vivitrol”
- Make sure patient signs consent and opts for co-pay assistance
- You choose diagnosis and choose length of prescription
- Fax the form in, expect 2-4 weeks for approval
Patient Enrollment

1. Prescriber or Facility Information
   - Prescriber Name
   - State License #
   - DEA #
   - Prescriber Phone #
   - NPI #
   - Facility Name
   - Fax #
   - Address
   - City
   - State
   - ZIP Code
   - Staff Contact Name
   - Staff Contact Phone #
   - Staff Contact E-mail

2. Patient Information
   - Name (First)
   - Name (Last)
   - Date of Birth
   - Gender
   - Male
   - Female
   - Address
   - City
   - State
   - ZIP Code
   - Home Phone #
   - Mobile Phone #
   - Best Number to Call
   - Home
   - Mobile
   - Best Day to Call
   - M
   - T
   - W
   - Th
   - F
   - Best Time to Call
   - Morning
   - Afternoon
   - Evening
   - E-mail Address

   INSTRUCT PATIENT TO LIST ALTERNATE CONTACTS ON PAGE 2.

3. Patient Diagnosis—Please complete the diagnosis code(s) you would like to use by filling in the additional digits.
   - Alcohol Dependence
   - Opioid Dependence
   - ICD-10
   - P10.
   - F11.
   - P10.
   - Other
   - Patient has tried and failed the following medication(s):
   - Please list any known allergies to medications or other substances:
   - Patient’s concurrent medications:

4. Injection Provider/Specialty Pharmacy Information
   - Will your patient receive ongoing injections at your location?
   - Yes, patient will receive all injections at this location.
   - Complete steps A and B of this section.
   - No, patient will transition to a new provider after the first dose.
   - Complete steps A and B of this section.
   - A. Injecting provider
   - B. A new provider is unknown; need assistance from Vivitrol2gether to locate one
   - Vivitrol2gether should contact provider below to coordinate ongoing care for this patient
   - Provider Name
   - Phone #
   - Provider Address
   - Shipping Details
   - Patient needs Vivitrol delivered by (date)
   - Preferred pharmacy (if applicable)
   - Special shipping instructions/ restrictions

5. Patient Insurance Information
   - A. Payment Method
   - Insured
   - Paying out-of-pocket
   - B. ATTACH A COPY OF BOTH SIDES OF THE PATIENT’S INSURANCE CARD(S).
   - C. IF YOU ELECT NOT TO ATTACH AN INSURANCE CARD, COMPLETE SECTIONS BELOW.
   - PRIMARY INSURANCE / MEDICAL INSURANCE
   - Insurance Type
   - Commercial
   - Medicaid
   - Medicare
   - QHP
   - Carrier Name
   - Policyholder Name
   - PA # (if obtained)
   - Relationship to Patient
   - Carrier Phone #
   - Policyholder Employer Name
   - Policy #
   - Group ID #
   - Policy Type
   - HMO
   - PPO
   - Other
   - PHARMACY BENEFIT PLAN (PBM)
   - PBM Name
   - PBM Phone #
   - Policyholder Name
   - Policy #
   - Relationship to Patient
   - Policyholder Employer Name
   - Rx 
   - Rx BIN #
   - Rx PCN
   - Co-pay Card Number (if already obtained)

6. Prescription Information and Attestation
   - PRESCRIBER SIGNATURE MUST BE THE SAME AS THE PRESCRIBER NAME ABOVE
   - Patient Name
   - Vivitrol 380 mg is 1 unit inject 380 mg in every 4 weeks or every 1 month
   - Provider State License #
   - Provider License #
REFERENCES

• https://www.samhsa.gov/medication-assisted-treatment/treatment/naltrexone
• https://pcssnow.org/education-training/training-courses/naltrexone-treatment-opioid-use-disorder-training-clinicians-part-2/