

HEARTLAND ALLIANCE HEALTH

HEARTLAND HEALTH OUTREACH, INC

Supportive Treatment for Addiction and Recovery (STAR)

Policies and Procedures for Medications for Addiction Treatment at Heartland Alliance Health

Updated October 2019

Acronyms/Definitions:

AODC: Alcohol and Other Drug Counselors are certified to provide addiction-related counseling services.

BH: Behavioral Health- the Behavioral Health team includes LCSW/LCPCs, AODCs, and Peer Recovery Support Specialists/Recovery Coaches

HAH: Heartland Alliance Health- An FQHC (330H) that services people experiencing homelessness in Chicago, IL

LCSW/LCPC: Licensed Clinical Social Worker/Licensed Clinical Professional Counselors

MA: Medical Assistants room patients, complete vital signs, complete all screening questions in Centricity and schedule follow up visits

Medical Provider: Includes physicians, nurse practitioners, physician assistants

MAT: Medication for Addiction Treatment

STAR: Supportive Treatment for Addiction and Recovery- This HAH team includes all members providing substance use disorder treatment, including counseling, therapy, group sessions, and medication management and monitoring.

The following policies, procedures, and workflows apply to HHO participants who are being assessed for or receiving medications for addiction treatment (MAT) for opioid use disorder (OUD.) This document will be updated every 12 months or more frequently as needed.

Index

1. Definitions	Page 3
2. What is STAR/Criteria and Eligibility..	Page 5
3. Referrals to STAR.....	Page 6
4. Team Member Roles	Page 7
5. Huddles and Meetings	Page 8
6. Opioid Use Disorder Treatment	
Buprenorphine Treatment Workflow.....	Page 9
Buprenorphine Exclusionary and Precautionary Criteria.....	Page 11
Buprenorphine Intake Appointment.....	Page 12
Buprenorphine Follow up Appointment.....	Page 15
Working with Participants with Ongoing Substance Use.....	Page 17
Tapering Buprenorphine.....	Page 18
Provider Quick Texts- Buprenorphine.....	Page 20
Urine Drug Testing Protocol.....	Page 22
Haymarket-HAH Transfer of Care Workflow.....	Page 24
James West-Specific quick texts for buprenorphine.....	Page 25
XR Naltrexone for treatment of OUD- Background.....	Page 26
XR Naltrexone Treatment Workflow.....	Page 27
XR Naltrexone Exclusionary and Precautionary Criteria.....	Page 29
XR Naltrexone Intake Appointment.....	Page 31
XR Naltrexone Follow up Appointment.....	Page 34
Provider Quick Texts- XR Naltrexone.....	Page 37
7. Late Arrival Policy Protocols.....	Page 39
8. Lab Process.....	Page 40
9. Appendices:	
Appendix 1: OUD DSM 5.....	Page 41
Appendix 2: Buprenorphine Agreement.....	Page 42
Appendix 3: Buprenorphine Intake Checklist.....	Page 43
Appendix 4: Vivitrol Agreement.....	Page 45
Appendix 5: Vivitrol Intake Checklist.....	Page 47
Appendix 6: Vivitrol Patient Counseling.....	Page 48

Definitions

Supportive Treatment for Addiction and Recovery (STAR): This HAH team includes all members providing substance use disorder treatment, including counseling, therapy, group sessions, and medication management and monitoring. This document addresses policies and procedures for the STAR team treatment of Opioid Use Disorder (OUD) and Alcohol Use Disorder (AUD). Participants may be involved in substance use counseling services without receiving medication.

Opioid Use Disorder: a problematic pattern of opioid use that leads to serious impairment or distress. To be diagnosed with an opioid use disorder, 2 or more symptoms from the DSM 5 must be positive within the past 12 months.

Medication for Opioid Use Disorder (MOUD): Medication for opioid use disorder involves offering a medication to help a patient to reduce cravings, reduce risk of relapse, and reduce illicit opioid use. When possible this medication is offered in conjunction with counseling/behavioral therapies and other supportive services for the treatment of a substance use disorder. The medications used for treating an opioid use disorder include buprenorphine (trade name for buprenorphine and naloxone combination is Suboxone), extended release (XR) naltrexone (injectable form trade name is Vivitrol), and methadone. HAH does not prescribe methadone, as methadone may only be dispensed from a licensed opioid treatment program. Buprenorphine and XR naltrexone may be prescribed at HAH and in other office-based opioid treatment settings ("OBOT"). Additional training and licensure (DATA Waiver) is required in order to prescribe buprenorphine. Any provider with a valid medical license may prescribe XR naltrexone/Vivitrol. More information available at: <http://www.samhsa.gov/medication-assisted-treatment>

Alcohol Use Disorder: a problematic pattern of alcohol use that leads to serious impairment or distress. To be diagnosed with an opioid use disorder, 2 or more symptoms from the DSM 5 must be positive within the past 12 months.

Medication for Alcohol Use Disorder (MAUD): Medication for alcohol use disorder involve offering a medication to help a patient to reduce cravings, reduce binge drinking, and reduce overall drinking episode among people with alcohol use disorder. When possible, medication is offered in conjunction with counseling/behavioral therapies and other supportive services. The FDA approved medications that have been shown to be effective to treat alcohol use disorder include naltrexone (oral or injectable formulation Vivitrol) and acamprosate. No special licensing is required to prescribe naltrexone or acamprosate.

ASAM Criteria: This is a tool developed by the American Society of Addiction Medicine to assess 6 dimensions – 1) acute intoxication and/or withdrawal potential, 2) biomedical conditions and complications, 3) emotional, behavioral, or cognitive conditions and complications, 4) readiness to change, 5) relapse, continued use, or continues problem potential, and 6) recovery/living environment – in order to inform participant placement recommendations regarding level of care for substance use disorder (SUD).

Prescription Monitoring Program (PMP): Database maintained by the State of Illinois with records of all scheduled substances filled by a participant. Available at: <https://www.ilpmp.org/>.

Medical Provider: Includes physicians, nurse practitioners, physician assistants- anyone who is able to prescribe medications. To be able to prescribe buprenorphine, a provider must have an “X waiver,” which is a special designation assigned by the DEA. To obtain an X waiver providers must complete additional education, apply online, and be certified through the DEA. At HAH, to prescribe buprenorphine, providers must also have privileges to prescribe this medication (through formal privileging form).

LCSW/LCPC: Licensed Clinical Social Worker/Licensed Clinical Professional Counselors are independent licensed providers who are able to make mental health and substance use diagnoses, develop treatment plans, and offer therapy for mental illness and substance use disorders.

AODC: Alcohol and Other Drug Counselors are certified to provide addiction-related counseling services.

Peer Support Specialists/Recovery Coaches are individuals with lived experience who support linkage to a variety of community-based services and who engage with participants based on their own experiences with substance use.

PES: Participant Engagement Specialists check in participants, handle follow up appointments, and calls participants who “no-show.”

MA: Medical Assistants room patients, complete vital signs, complete all screening questions in Centricity, schedule follow up visits, and

What is STAR?

Supportive Treatment for Addiction and Recovery (STAR) is a program for those who have a Substance Use Disorder and are looking for assistance in decreasing their use, improving their health, and improving their quality of life. Participants who have opioid use disorder, alcohol use disorder, or nicotine use disorder may be eligible to receive medication as part of their treatment plan.

STAR uses a harm reduction approach to assist with motivation to change behaviors and improve health and wellness. We support participants in setting their own goals toward improving their health. We do not expect perfection; we hope for progress.

The two main pillars of STAR are medical management and supportive services. The medical management consists of ongoing visits with a medical provider to address medical needs and if appropriate to prescribe buprenorphine (Suboxone) or XR naltrexone (Vivitrol) for opioid use disorder and naltrexone (oral or injectable) or acamprosate for alcohol use disorder. The supportive services we provide are a combination of individual and group therapies that are led by substance use counselors, (AODC) and licensed therapists (LCSW/LCPC). A recovery coach offers peer support, motivational interviewing, and helps to identify and navigate services (for example housing, transportation, peer support groups (NA, AA, Smart Recovery, etc), and internal and external medical services).

Criteria and Eligibility

STAR is appropriate for a participant who meets the following criteria:

- Has a substance use disorder (SUD),
- Is interested in reducing use and/or reducing risk,
- Is willing to make HAH their primary care provider,
- Meets HRSA definition of homeless (currently living in a shelter, doubling-up, sleeping in public spaces, in a residential treatment facility, in supportive housing, etc.),
- Is willing to engage in services at a frequency recommended by the clinical team in accordance with current guidelines and as determined medically/clinically necessary. This plan will always be discussed with the participant.

Referrals to STAR

Internal referrals:

Each location has one point of contact (and one backup when that individual is out/on leave) who conducts phone screening and sets up intake appointments. When possible, internal referrals should be managed by contacting the site point of contact by phone at the time of the request for services. If the STAR team member does not answer the phone, flag that person in Centricity and include information on how they can reach the participant.

Haymarket referrals:

At James West, Haymarket staff have direct access to provider schedules and will schedule new referrals in new participant slots. STAR leadership will communicate the management of new participant slots with Haymarket team. A new intake packet is sent over by Haymarket by the day of the intake visit. If a provider working at James West identifies someone they think might be appropriate for the STAR team, it is important to talk to the STAR point of contact for James West, who will then communicate with Haymarket to determine appropriateness based on Haymarket's plan.

External and self-referrals:

Each location has one point of contact (and one backup when that individual is out/on leave) who conducts phone screening and sets up intake appointments. Many of our external partners already have this point of contact's phone number. If someone calls the main phone line, the person should be directly linked to the STAR point of contact for that site, or a flag should be sent to that individual.

Team Member Roles

STAR consists of the following team members and their roles:

- PES-Checks participants in at arrival and schedules psychiatry intake/follow up visits as needed.
- MA-Rooms the participant, completes vitals, and assists with labs including urine collection and pregnancy test as needed, schedules primary care/STAR provider follow up visits.
- AODC /Recovery Coach- The point of contact for participants for engagement and follow up. The AODC/Recovery Coach also provides counseling around substance use and harm reduction; uses motivational interviewing to support a participant's recovery; is responsible for providing case management to address social determinants of health including, but not limited to: housing, transportation, food and nutrition, clothing, and referral assistance; provides check-ins (on phone or in person) between visits for their assigned caseload. When a participant misses scheduled appointments the AODC/Recovery Coach will call within 24 hours of missed appointment. The AODC/Recovery Coach works closely with the LCSW/LCPC, the provider, and the participant to develop update treatment plans.
- LCSW/LCPC- Provides individual and group therapy, uses motivational interviewing to support a participant's recovery, and provides case consultations and mental health support including assessing for and adding substance use and mental health diagnoses to medical record.
- RN- Assists with insurance complications and prior authorizations, monitors in-office buprenorphine initiation as needed, can facilitate assessments, lab orders, and/or refills according to policies when prescriber is not available, administers Vivitrol or Sublocade injections, provides harm reduction education and naloxone refills, and answers medication-related questions as appropriate.
- Provider- Provides medical and behavioral assessments, prescribes medications and provides medication monitoring, uses motivational interviewing and other techniques to support participant's recovery.

Huddles and Meetings

A team huddle will occur for the 15 minutes before clinic starts (or time agreed upon by team) to review all participants on the schedule for that clinic, and any relevant updates. The AODC/Recovery Coach, prescriber, and LCSW/LCPC are expected to be present. When possible, the RN and MA should also be present; in the case they are not available, any relevant updates should be provided (examples could include knowledge that participants will be coming early or late, which participants will need urine pregnancy tests or labs; which participants may need vaccines that can be offered prior to the provider visit, etc). Any colleagues who cannot make huddle are expected to share any relevant information with the lead AODC (nurse as backup) prior to the huddle.

There are 1-hour STAR meetings held every other week during which team members can present: 1) challenging cases for case discussion; 2) workflow challenges or other systems-level issues that need to be addressed; 3) quality improvement activities. The Associate Director of Clinical Operations will facilitate meetings and the MAT Director will attend as able/agenda dictates.

Buprenorphine Treatment Workflow

Participant identifies to HAH staff interest in Medication for Opioid Use Disorder (MOUD)

Staff contacts STAR BH point of contact for particular site (ideally through a call but flag in case phone not answered)

STAR BH Pre-Assessment (can be done on phone or in person)

- Vermont TNQ Completed (Centricity)
- Substance use and treatment history documented (Centricity)
- OUD assessment completed (paper- scanned)
- Any concerns or questions addressed

If in-office (or done first time in-office):

- Rapid urine drug test completed & documented
- Complete needed ROI's
- Electronic Communication Agreement
- Participant Buprenorphine Agreement reviewed and signed

Pre-Assessment Form suggests participant is appropriate/interested; Provide naloxone training and give kit and schedule Provider Intake ASAP

Participant is Not Appropriate/interested

Naloxone training and kit given

Assist with outside referral

Provider Assessment (ideally be same day or scheduled for later date if no provider available)

- Review AODC Pre-Assessment & documented treatment history,
- Confirm diagnosis of OUD,
- Confirm current opioid use via utox and AODC notes,
- Review and document review of PMP,
- Complete intake physical (documentation of meds, medical problems, allergies, etc)
- Order labs (HIV, HCV, LFTs, send-out urine toxicology at a minimum; other labs as indicated),
- Urine pregnancy test as applicable,
- Prescribe buprenorphine using home induction protocol (unless methadone or other contraindication),
- Schedule provider follow up visit within one week

STAR team member Follow Up (phone or in-person) within 3 days of first visit

- Check on how first dose went
- Assess issues obtaining medication
- Ensure participant is letting the film melt entirely under tongue
- Assess for side effects: If so- speak with a STAR provider, and remind participant to call/text with any concerns
- Reminder call/text the day before follow up appointment

Participant is Not Interested or appropriate (current/recent opioid use or LFTs >5 times normal range)

Confirm participant has naloxone; if not- training and kit **Assist with outside referral (call to help set up visit and any other assistance needed)

Follow Up Visits

- Participant meets with STAR BH provider for brief check-in
 - STAR team member obtains urine and puts POC urine results into note
- MA checks urine pregnancy test as applicable (monthly for women with a uterus who have not undergone sterilization)
- Provider visit- check PMP, review STAR BH note (see STAR manual for more information and quick texts)
 - Order LFTs, HIV and HCV every 6 months
 - LFTs monitored every 1-2 months for elevation >2 times upper limit of normal

Suggested Follow up Visit Frequency (duration between visits extends as stability increases):

- Visits at least weekly for first month
- If consistently positive for bup, expected bup:norbup ratio, and no other opioid use, can increase visits to every 2 weeks for one month
- If consistently positive for bup, expected bup:norbup ratio, and no other opioid use, extend visits to every 3-4 weeks

Buprenorphine use with no illicit use

- Monthly visits with provider
- Monthly STAR BH visits and more as needed
- Visits may be extended to every 2 months on a case by case basis, taking social circumstances and duration of stability into account

Buprenorphine use with illicit use

- Weekly visits with provider & STAR team member
- Offer higher level of support (i.e. referral to residential, IOP, or OP; increased NA/AA; or increased check-ins with HAH STAR team member)
- Offer harm reduction education and ensure has naloxone

No or Intermittent Buprenorphine use with other opioid use

- Offer higher level of care (i.e. referral to residential, IOP, or OP; increased NA/AA; or increased check-ins with HAH STAR team member)
- Let them know if continually negative for buprenorphine, we can no longer prescribe
- Case discussion with MAT Director and full STAR team
- Offer harm reduction education and ensure has naloxone

Exclusionary and Precautionary Criteria - Buprenorphine

Exclusionary:

- Allergic to Buprenorphine (*this is very rare*)
- Actively suicidal, homicidal, or psychotic and unable to make informed decision (*may be appropriate at later date*)
- Taking Injectable Naltrexone (*must wait until after 28 days since last injection before initiating*)

Precautionary:

- Using Benzodiazepines (*requires coordination with psychiatric provider and plan for co-management; in case of using benzodiazepines on the street will require plan for management going forward*)
- Using alcohol in large volumes to warrant concern for withdrawal and DTs (*may need to consider inpatient medically managed withdrawal from alcohol; afterwards could consider acamprosate for treatment of AUD*)
- Breastfeeding (*small amounts do enter breastmilk*)
- Pregnant (*initiation needs to be planned with OB provider and approach may depend on trimester; use buprenorphine monoprodukt*)
- Chronic pain (*will require comprehensive pain management plan and coordination with outside providers*)
- Elevated liver enzymes greater (*safe to initiate medication if LFTS are within 3-5 times upper limits of normal; if >5 times upper limits, weigh pros and cons of initiating buprenorphine vs. not; explore underlying etiology of elevated LFTS [i.e. active HCV] and consider hepatology consult. If you initiate in someone with elevated liver enzymes, discuss risks with patient and track enzymes more frequently*)

Intake Appointment - Buprenorphine

The **STAR BH intake** is typically completed by the LCSW/LCPC. However, all AODC and recovery coaches on the team are able to do an intake.

If not already completed, then complete the following:

- Vermont TNQ Completed (Centricity)/ if GAIN sent over from Haymarket or other treatment provider, this can take the place of the TNQ
- Substance use and treatment history documented (Centricity)
- OUD assessment completed (done on paper- scanned)
- PMP reviewed in Centricity
- Any participant concerns or questions about HAH process addressed with STAR BH provider
- Rapid urine drug test completed & documented in Centricity
 - We expect for new initiation of buprenorphine, opioids should be positive on the rapid drug screen. Methadone should be negative.
 - If opioids are negative, discuss with participant (remember fentanyl will not show up on our rapid drug screen). Discuss with provider.
 - If methadone is positive, collect information on current dose and last time taken. Discuss with provider.
- Complete needed ROI's (or ask MA to assist)
- Verbally review Electronic Communication Agreement with participant and have them sign- put in scan bin
- Verbally review participant agreement and have them sign- put in scan bin
- Overdose prevention education and naloxone training
- Go through all materials in patient folder:
 - Meds to Avoid
 - Naloxone handout
 - Buprenorphine patient handout

Provider Intake Visit:

- HPI (see quick texts)
 - Review current and past drug use (substances used, amount and frequency of use; much of this can be seen in the STAR BH Intake note)
 - Review current psychiatric symptoms and any current treatment
 - Review past treatment episodes (specifically asking about past experience with medication treatments)
 - Ask about longest period of abstaining from opioids- when was it, for how long, what worked well? (identify participant strengths and what has helped in past)
 - Ask about history of overdoses (discuss naloxone prescription that will be given today)
 - Ask about current goals for treatment and level of motivation for reducing use
- History:
 - Current medications
 - Allergies
 - Medical history (in history tab and in active problem list)- be sure to ask about psychiatric history including hospitalizations and suicide attempts
 - Surgical History

- Family history (be sure to ask about current family involvement; this can be a good way to ask about any open DCFS cases)
- Educational attainment
- Past work history (what types of work have they done in past which opens convo on their plans for work in future)
- Review of systems and physical exam focused on current withdrawal symptoms, signs of hepatitis (jaundice, anicteric sclera, ascites, tenderness to palpation of liver), and mental health stability/insight
- Screening for precautionary and potentially exclusionary criteria:
 - Current methadone use (see document on methadone to buprenorphine transition); AST or ALT > 5 times¹ normal limits; acute hepatitis or liver failure; actively suicidal or homicidal.
 - If concern for hepatic disease, order PT/INR and albumin to assess synthetic function.
- Orders:
 - Labs- use STAR intake lab order set (includes CMP, HIV, Hepatitis panel) *(note- you do not have to have lab results to start buprenorphine. If the participant can't get labs done on day of intake, that is also ok. Not having labs should not lead to delay in initiation of treatment.)*
 - Add additional labs as needed for maintenance of chronic conditions or other STI testing as agreed upon by participant.
 - Review rapid UDS. Send-out is recommended if:
 - Negative for opioids when participant reports use (in this case, send out for fentanyl);
 - Confirmatory testing is needed for any other discrepancies (examples could be prescribed benzos but negative on rapid test; positive for other substances on rapid test that patient denies using)
 - Urine HCG for women of reproductive age who could get pregnant
- Counseling:
 - Counseling regarding contraception for females of reproductive age.
 - Counseling on how the medication works, how to take first dose (importance of letting it melt completely under tongue), and what will happen if taken too soon after using opioids (precipitated withdrawal)
 - Confirm understanding of overdose prevention and how to administer naloxone
- Prescriptions:
 - **Prescribe Naloxone for everyone**
 - **Buprenorphine:**
 - Unless pregnant, prescribe buprenorphine-naloxone combination. In cases where someone is actively using opioids (heroin, fentanyl, etc), usually giving up to 12mg on day 1 and up to 16mg on day 2 is warranted. See patient handout for home induction as needed
 - The buprenorphine monoprodut is still recommended for pregnant women. Consult MAT Director before initiating buprenorphine in pregnancy. In some cases, inpatient monitoring by obstetrics is

¹ <http://pcssmat.org/wp-content/uploads/2014/10/PCSS-MAT-NTX-Liver-Safety-Guideline1.pdf>

recommended. If someone becomes pregnant while on buprenorphine-naloxone, it is safe to transition them to the buprenorphine monopropduct.

- In cases in which someone is leaving detox or incarceration and has no opioids in their system on the day of induction, you can start at a lower dose (usually 2-4mg depending on circumstances). Call MAT Director with any questions.
- Enough medication should be given to last until the follow up visit.
- Follow up visit should be in 1-7 days.

If participant no longer wants to continue with buprenorphine, or wants to engage in Methadone or XR Naltrexone treatment, please consult with team for assistance with finding provider.

Follow-Up Appointments- Buprenorphine

Typical follow up frequency is as follows:

- Visits at least weekly for first month (may be more often if deemed necessary by provider/team)
- If consistently positive for bup, expected bup:norbup ratio, and no other opioid use, can increase visits to every 2 weeks for one month
- If consistently positive for bup, expected bup:norbup ratio, and no other opioid use, extend visits to every 3-4 weeks
- Co-occurring use of other substances will be reviewed on a case-by-case basis. Cocaine, methamphetamine, alcohol and benzodiazepines have all been shown to increase risk of overdose among patients taking opioids. Participants on stable prescribed doses of benzodiazepines who are taking the medications as prescribed have tolerance to the benzodiazepine but should still be monitored for misuse. Marijuana has not been associated with increased risk of overdose, though some participants.

This is meant to be a guide, the provider and team can make adjustments as necessary. Adjustments to this schedule should be documented in Centricity so any cross-covering provider understands the plan

Our goal is that at each visit, one STAR BH team member (Recovery Coach, AODC, or LCSW/LCPC) will see the participant in addition to the provider. During the huddle, the team will go over which team member will see which participant. In some cases, it may be necessary for both a recovery coach/AODC and the LCSW/LCPC to see a participant- particularly in cases where the recovery coach/AODC identifies significant mental health crisis and requests the LCSW/LCPC to see the participant. Similarly, there may be times when there is not adequate staffing or schedules are running behind and no BH team member can see the participant. In these cases, the BH team member should attempt to follow up with the participant by phone/text at some point before the next visit.

MA:

- Conducts “normal” triage- vital signs, screening questions, requests ROI for any recent ED visits or hospitalizations, etc.
- Obtains pregnancy test if requested by provider

AODC/Recovery Coach or LCSW/LCPC:

- Obtain rapid urine drug screen from participant and record results in Centricity
- Meet with participant for brief check-in and document note in Centricity
- Assist with any needed resources (housing/recovery homes, locations and times of meetings, transportation, job training/opportunities, legal aid, etc.)
- Provide any additional support needed (peer support, addiction counseling, or mental health counseling (LCSW/LCPC))

Provider:

- HPI:
 - Confirm participant was able to get medication without problem (including naloxone; it is good to confirm intermittently whether they still have it and if not re-prescribe)
 - Ask about drug use since last visit
 - Ask about new or ongoing stressors

- Ask about any progress made on goals
- Ask about any side effects from buprenorphine (headaches are common during first days/weeks of treatment; constipation can come at any point)
- Ask about mood and sleep- these can significantly contribute to relapse potential
- Address any primary care needs as able (*the goal is to manage primary care/preventive care during these visits, but in cases where SUD is too complex or primary care needs are too complex- you can either have participant follow up on another day to focus on just PC needs, or in rare cases, having them see another PCP may be warranted*)
- Review of Systems can focus on physical symptoms of withdrawal, mood, constipation, headaches (common side effects)
- Physical exam should include at a minimum general appearance, mood, and insight
- Review PMP
- Review urine drug screen results
- Review any recent lab results with participant
- Orders:
 - Send out buprenorphine confirmatory test to get bup:norbup breakdown
 - Send out other toxicology tests as needed (*see urine drug screen protocol for more information*)
 - LFTs, HIV, HCV (if not known to be positive) should be redrawn every 6 months, or in the case of elevated LFTs more frequently
- Assessment and Plan:
 - Document current dose and any dose adjustments made (most participants will stabilize somewhere between 12mg-24mg; note that there is lower protective affect against overdose at doses less than 12mg)
 - Document frequency of visits (this is helpful in case of cross-cover- is participant on weekly, bi-weekly or monthly follow up schedule)
 - Document any items that need follow up at next visit (examples could include anything not able to be addressed at this visit, upcoming labs, other primary care needs, etc- this is also helpful for cross-cover)
 - Be sure to prescribe enough medication to last until the next visit.

Working with Participants with Ongoing Substance Use While on Buprenorphine:

Most participants will continue to have some substance use (opioid and non-opioid) during early weeks and months of treatment. Some may reduce/abstain from opioid use, but continue to use other substances. It is important to remember that buprenorphine is only treating opioid use disorder. It will not help with other substance use disorders.

When participants have ongoing substance use, it is important to consider:

- Would a higher level of care be more appropriate?
- What other factors may be contributing to continued use (ongoing homelessness, family and social stressors, “people, places, and things”). What can we do to help them address these factors?
- Is participant open to a higher level of care? If so, what would be acceptable to them? (Methadone, residential, IOP, etc)
- How can we increase the intensity of the services we offer (more frequent visits with BH staff, shorter duration of prescriptions)?
- How can we support them to engage in other community-based services that support pro-social, sober behaviors that may contribute to their sense of purpose, and sense of connection to other people? (examples could be meetings, church, volunteering, spending time with family, etc)

It is appropriate to continue buprenorphine as long as:

- There is evidence participant is taking it (i.e. buprenorphine and norbuprenorphine toxicology is positive at least most of the time)
- Participant reports they want to continue to work toward reducing opioid use

In cases in which buprenorphine or norbuprenorphine are negative:

- Confirm that the last prescription should have lasted until today’s visit (for example, if the participant missed the last visit and has been out of medication for a week, we would not expect buprenorphine to be in the urine; in these cases clearly document that participant was out of prescribed medication)
- Talk to participant about findings- be open and transparent. We are not trying to “catch” people and want to build trust.
- Be transparent by letting them know that we cannot continue to prescribe buprenorphine if they are not routinely taking the medication.
 - If this continues, use a revised treatment agreement.
 - If it still continues, discontinuation of medication is appropriate.
 - Support linkage to other treatment (residential, methadone, etc) as participant is willing.
 - Ensure participant has naloxone.

Tapering Buprenorphine

Participants have many reasons for wanting to taper buprenorphine. They often include, but are not limited to:

- External pressures (from family, friends, AA/NA community) about continuing to use a medication as part of treatment. People may feel they are “not really in recovery” if using a medication.
- Challenges with getting to/from the office because of competing priorities such as work.
- Side effects related to the medication (constipation is the most common, but could also include things like erectile dysfunction and irregular periods, etc)
- A desire to not have to take a medication daily/personal desires to be “drug-free.”

When a participant asks about tapering, it is important that we share the following information to allow them to make an informed decision, recognizing that the decision to take a medication is always up to the participant:

- Research has shown that people taking buprenorphine for less than one year have high rates of relapse.
- People who take medications longer have lower rates of relapse (i.e. people on medication for 5 years have lower rate of relapse compared to those who have taken it for one year).
- People who use medications as part of their recovery ARE still in recovery. It sometimes help to ask participant about their symptoms of addiction (loss of control around use; compulsive behaviors; continued use in spite of negative consequences) before initiating treatment, then to reflect on whether they have those symptoms now. If not, then they are not in active addiction.
- We recommend that people who are interested tapering have the following:
 - STABLE housing (ask about length of time they can remain in current environment- especially if recovery home setting where stay is time limited)
 - STABLE support network (network of individuals who are supportive of participant’s recovery and whose relationship does not involve drugs or alcohol)
 - STABLE source of income (disability, job, etc)
*The reason we recommend this is because we have seen that lack of these circumstances often increases risk of relapse. Losing housing or not having stable income are very destabilizing factors and often lead people back into environments where drugs are prevalent.

If participant decides they want to taper buprenorphine, it is important to discuss:

- That we want to be supportive and want the taper process to be participant-driven. There is no set schedule we have to follow for tapering.
- When we start decreasing the dose, we will rely on the participant to update us on symptoms (increased cravings, resumed use, etc) to dictate the speed at which we taper dose. It is a not a

“one way street.” We can slow down the taper at any time, or even increase dose again if needed.

- We generally recommend a slow taper- often 4mg reduction per month until at 4mg daily dose (after that down to 2mg daily then to 2mg every other day). If the participant prefers a more rapid taper, we recommend seeing them every 1-2 weeks to adjust dose and check in on how things are going. This allows us to decide to stay at any particular dose if a participant feels they need more time to stabilize.
- The reductions at the lowest doses are often the most difficult for people- 4mg to 2mg and 2mg to going off the medication can be very challenging for people. It is ok if people want to stay at these doses for months. (Also important to remember these very low doses do little in the way of overdose prevention)
- Injectable XR naltrexone can be an option to assist with relapse prevention if the participant is interested in this option. See section on XR naltrexone for more information.
- Always ensure the participant has naloxone!

Provider Quick Texts- Buprenorphine

.bupnew

{PATIENT.FIRSTNAME} {PATIENT.LASTNAME} is a {PATIENT.FORMATTEDAGE} year old {PATIENT.SEX} here today for initiation of buprenorphine maintenance.

Current living situation:

Opioid of choice:

Hx of IDU:

Other drugs of use:

Previous treatment history:

Longest period of abstaining from opioids:

What was helpful during that time:

Previous use of buprenorphine/methadone/XR naltrexone:

Any previous overdoses:

Any current psychiatric symptoms:

Family involvement:

Motivation for engaging in treatment:

Goals for treatment:

(*Be sure to fill out history pages to include medical, surgical history, as well as educational attainment, past work history, etc)

.bupnew (to be used in provider “assessment” notes on the first visit ONLY)

The following information was reviewed with participant at this visit:

FDA handout on how medication works

Buprenorphine agreement was reviewed and signed

“Meds to avoid” list

Importance of making it to scheduled appointments, and letting us know when phone/address changes occur

Naloxone education and Rx for naloxone

Follow up in one week

.buppi (use this one in the patient information box that is printed on their visit summary- be sure to change name of LCSW/LCPC and AODC/Recovery Coach as appropriate!)

Treatment Plan: Continue to take your medication as prescribed. Follow up at scheduled visits with me.

Please remember that it is very important to keep your scheduled visit. If you miss a visit, it is very likely you will run out of medication and will go through symptoms of withdrawal. I am only in clinic on

Thursday afternoons. If you need to miss an appointment, please call Megan or Tony right away so we can make alternate arrangements and find a time for you to follow up. You can reach Megan at 708 298 2502 and Tony at 312 914 0273. If you are not able to make it to your visit, or if you have any problems getting your medication or need other support, please call or text Megan or Tony.

.bupfu (to be used for any follow up visits in HPI portion of note)

{PATIENT.FIRSTNAME} {PATIENT.LASTNAME} is a {PATIENT.FORMATTEDAGE} year old {PATIENT.SEX} here today for follow up on buprenorphine maintenance treatment.

Living situation:

Cravings:
Drug or Alcohol Use:
Constipation:
Headaches:
Support:
Participation in therapy or groups:
Sleep:
Mood:
Challenges since last visit:
Positives since last visit:
Goals:

.bupplan (use this one to put in the medical provider box only- it helps for cross-coverage)

PMP reviewed, Utox ordered

Current Dose:

Follow up frequency:

To address at next visit:

.buppi (use this one in the patient information box that is printed on their visit summary- be sure to change name of LCSW/LCPC and AODC/Recovery Coach as appropriate!)

Treatment Plan: Continue to take your medication as prescribed. Follow up at scheduled visits with me. Please remember that it is very important to keep your scheduled visit. If you miss a visit, it is very likely you will run out of medication and will go through symptoms of withdrawal. I am only in clinic on Thursday afternoons. If you need to miss an appointment, please call Megan or Tony right away so we can make alternate arrangements and find a time for you to follow up. You can reach Megan at 708 298 2502 and Tony at 312 914 0273. If you are not able to make it to your visit, or if you have any problems getting your medication or need other support, please call or text Megan or Tony.

STAR Urine Drug Testing Protocol

Urine Drug Testing (UDT) is specifically recommended for monitoring individuals with opioid use disorder, especially in the case we are prescribing controlled substances (i.e. buprenorphine). It is recommended to be used as one objective measure of recovery, but is NOT the only measure for how someone is doing in their recovery. UDT can be used randomly, though in our setting we have had a hard time doing random call-ins (because of lack of phone access, lack of transportation, difficulty with being able to leave jobs, etc) so have typically defaulted to using UDT at every visit, or at least most visits the participant is being seen by the clinical team. UDT is often used to help determine the frequency of follow up visits as a form of contingency management. UDT is recommended when prescribing XR naltrexone to ensure no opioid use, and can be used in counseling and monitoring of other substance use disorders.

- Every patient coming for STAR clinic for medical management will be given a rapid urine drug test, and ideally have given urine and have the tests result BEFORE the provider visit. This is listed in the OUD order set as “POC UDS.” (Point of care UDS)
 - The STAR team member will be responsible for adding the results into the chart in the “Urine Drug Screen” form in Centricity in the provider chart (this should be in the provider note, not the STAR team member note for faster/easier reference. STAR team member should “sign” the form so it’s clear who read the results).
 - If the STAR team member notes any positive result, that should be discussed with the participant and documented in the chart, and the provider should be alerted before entering the room.
 - Remember: the rapid cups are not 100% accurate. If a participant says that they did not use, just reassure them that we will do a send out which is much more accurate; ensure the provider is aware that a confirmation test should be ordered.
- The provider will order “Pain management, BUPRENORPHINE, with confirmation” (the confirmatory buprenorphine test) for every patient on buprenorphine. This is done because we are looking for both the presence of norbuprenorphine and the ratio of buprenorphine: norbuprenorphine. This is in the OUD order set.

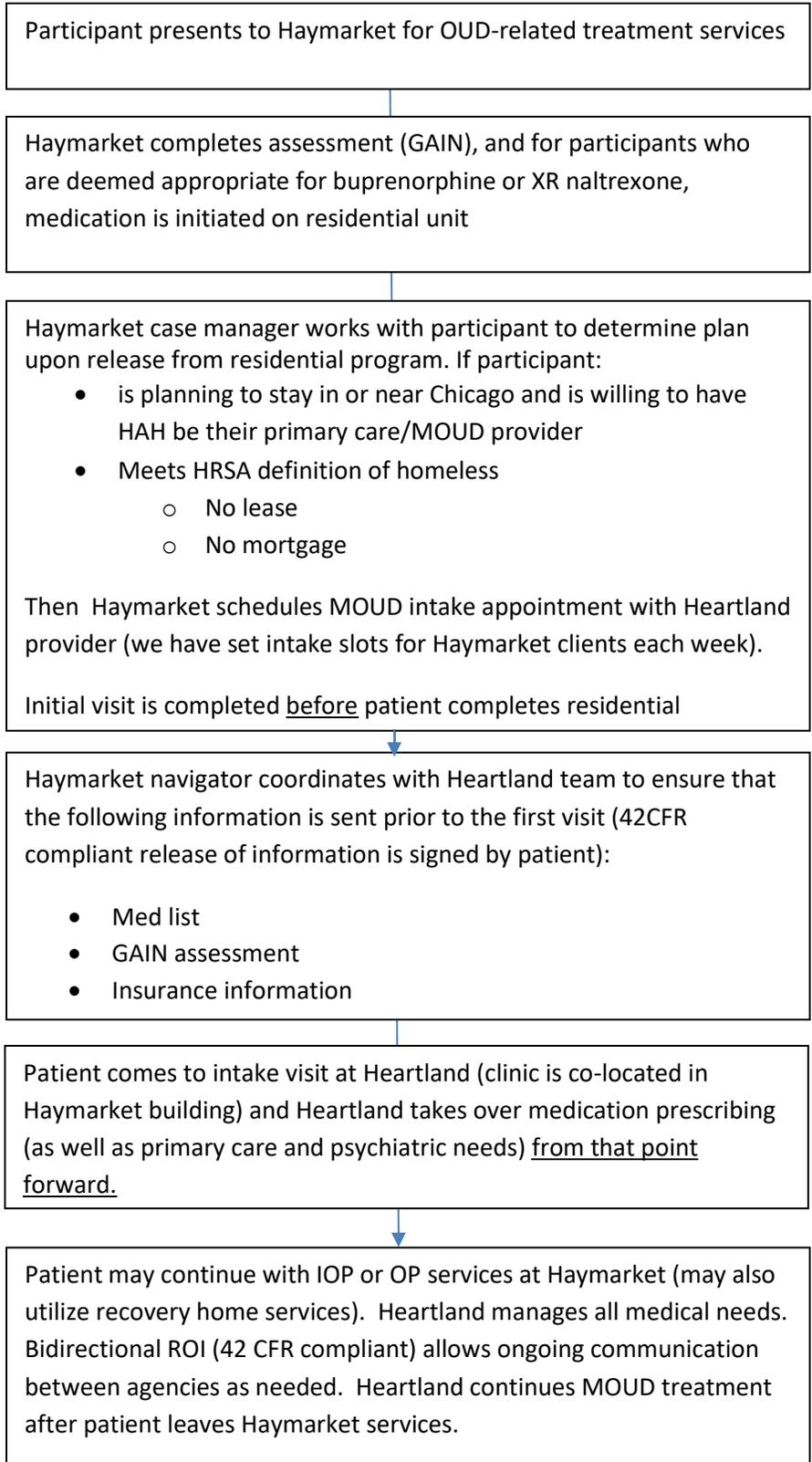
In the case that we do not have rapid cups in clinic, use the “pain management” send out in addition to the Pain management, buprenorphine with confirmation”.

Additional Testing (done on case by case basis):

- Positive test results the participant denies: In the case that a rapid urine drug screen is positive for a substance (i.e. amphetamine or benzodiazepines often have false positives), the provider will order confirmatory testing and reassure participant that we will get a more accurate test. (This is called “Pain management Profile 5, with conf, urine” and is in the OUD order set. There are more specific tests for benzodiazepines if needed). If on the other hand, the rapid test is positive for cocaine and the participant confirms cocaine use, no further testing needed.
- Reproductive age female able to get pregnant (I.e. no hysterectomy): Order a point of care urine HCG at least once a month. This is in the OUD order set and is listed as “Urine pregnancy test”.

- Patient with co-occurring alcohol use: Alcohol metabolites can be added to other urine drug testing.
- Fentanyl Testing: Fentanyl is not tested for in either the rapid or the standard send out drug screen. If a participant reports “heroin” use but the opioid test is negative, you may consider adding fentanyl to the orders. There may be other cases (for example a participant thinks they may have been exposed to fentanyl during heroin use) in which this information can be helpful to the participant to increase their awareness about the drugs they’ve consumed.

Haymarket- Heartland Alliance Health Workflow



Quick Texts Specific to James West/Haymarket Transfers

Bup transition at James West

.bupjw (used for new intakes from Haymarket in HPI section)

{PATIENT.FIRSTNAME} {PATIENT.LASTNAME} is a {PATIENT.FORMATTEDAGE} year old

{PATIENT.SEX} here today for transition of buprenorphine maintenance from Haymarket.

Current Unit at Haymarket:

How much longer on this unit:

Plan when leaving Haymarket:

Current Medication Dose:

Cravings on current dose:

Constipation:

Headaches:

Any other side effects:

Previous treatment history:

Opioid of choice:

Hx of IDU:

Other drugs of use:

Current psychiatric symptoms:

Family involvement:

Motivation for engaging in treatment:

Goals for treatment:

XR Naltrexone (Vivitrol) for Opioid Use Disorder - Background

Naltrexone is available in two formulations- oral and XR injectable (Vivitrol). Although oral naltrexone is FDA-approved for treatment of OUD, subsequent studies have not found it to be efficacious, so it is not recommended as treatment for OUD. Injectable XR naltrexone is FDA-approved for treatment of OUD and has been found to be more effective than placebo or counseling alone to reduce illicit opioid use and increase retention in treatment. The one available US-based study comparing buprenorphine and injectable XR naltrexone found that the greatest challenge was being able to initiate people on XR naltrexone because of the required 10 day period of opioid abstinence (most people had resumed use before being able to initiate. Once people initiated treatment, the two groups had comparable outcomes over the 6 month trial period.²

It is important to note that no study to date has shown that injectable XR naltrexone is associated with reduction in mortality (methadone and buprenorphine are both associated with mortality reduction).^{3,4} It is important to counsel participants on the increased risk of overdose with resumed use because of loss of tolerance while on XR naltrexone.

“A multisite randomized trial in the United States started in residential treatment programs found that buprenorphine treatment was associated with lower rates of return to use during 24 weeks of post-discharge outpatient treatment compared with XR-NTX,³ given the significant proportion of patients who did not actually receive XR-NTX because of challenges related to XR-NTX induction. The same study found no significant between-group differences in rates of return to use when data were analyzed based solely on patients who did begin assigned medications. Study findings may not generalize to outpatient settings, where naltrexone induction may be more difficult than in residential treatment settings.”

-SAMHSA Tip 63, page 3-32

It is critical when counseling someone about their interest in XR naltrexone that they understand that they will need to undergo medically managed withdrawal (“detox”) and wait at least 7-10 days without opioids in their system. If we give injectable XR naltrexone (Vivitrol) too soon, there is risk for severe precipitated withdrawal- with case reports of individuals requiring hospitalization and ICU stays.

For more information on how XR naltrexone works and evidence base behind it, please see SAMHSA Tip 63: Mediations for Opioid Use Disorder (available as pdf for free online).

² Lee, J. D., Nunes, E. V., Jr., Novo, P., Bachrach, K., Bailey, G. L., Bhatt, S., ... Rotrosen J. (2017, November 14). Comparative effectiveness of extended-release naltrexone versus buprenorphine-naloxone for opioid relapse prevention (X:BOT): A multicentre, open-label, randomised controlled trial. *Lancet*. Advance online publication. doi:10.1016/S0140-6736(17)32812-X

³ LaRochelle et al. Medications for Opioid Use Disorder After Nonfatal Opioid Overdose and Association with Mortality. *Annals of Internal Medicine*. August 2018.

⁴ Sordo et al. Mortality risk during and after opioid substitution treatment: systematic review and metaanalysis of cohort studies. *British Medical Journal*. 2017; 357:j1550.

XR Naltrexone for OUD- Workflow

Participant identifies to HAH staff interest in Medication for Opioid Use Disorder (MOUD)

Staff contacts STAR BH point of contact for particular site (ideally through a call but flag in case phone not answered)

STAR BH Pre-Assessment (can be done on phone or in person)

- Vermont TNQ Completed (Centricity)
- Substance use and treatment history documented (Centricity)
- OUD assessment completed (paper- scanned)
- PMP reviewed and printed/scanned
- Ensure participant understands must be opioid-free for 10-14 days prior to injection

If in-office (or done first time in-office):

- Rapid urine drug test completed & documented
- Complete needed ROI's
- Electronic Communication Agreement
- Participant Vivitrol agreement reviewed and signed

Pre-Assessment Form suggests participant is appropriate/interested; Alert STAR RN who will start order process for Vivitrol; provider visit to be scheduled when Vivitrol is available; give naloxone

Participant is Not Appropriate/ interested

Naloxone training and kit given

Assist with outside referral

Provider Assessment (ideally be same day or scheduled for later date if no provider available)

- Review AODC Pre-Assessment & documented treatment history,
- Confirm diagnosis of OUD,
- Confirm last opioid use (no use in past 10 days, or 14 days for long acting); confirm via utox no opioids in system
- Review and document review of PMP,
- Complete intake physical (documentation of meds, medical problems, allergies, etc)
- Order labs (HIV, HCV, LFTs, at a minimum; other labs as indicated), urine pregnancy test as applicable, Naloxone challenge as indicated
- Administer injectable naltrexone (or STAR RN if available) and give naloxone bracelet/card,
- Schedule follow-up visit within 28 days (sooner if additional primary care needs),
- Counseling services are recommended- these can be at HAH or external,
- Prescribe naloxone for OD prevention if doesn't already have.

STAR BH team member Follow Up (phone or in-person) within 1 week of first visit

- Check on how first dose went
- Ask about any site reaction: if so- speak with STAR RN or provider
- Assess for side effects: If so- speak with a STAR provider, and remind participant to call/text with any concerns
- Reminder call/text the day before follow up appointment

STAR RN to order next injectable naltrexone dose to be delivered in time for follow up visit (on day 28 from date of last injection)

Follow Up Visits

- Participant meets with STAR BH provider for brief check-in
 - STAR team member obtains urine and puts POC urine results into note
 - Offers support around recovery as appropriate
- MA checks urine pregnancy test as applicable (monthly for women with a uterus who have not undergone sterilization)
- Provider visit- check PMP, review STAR BH note (see STAR manual for more information and quick texts)
 - Order LFTs, HIV and HCV every 6 months
 - LFTs monitored every 1-2 months for elevation >2 times upper limit of normal

Suggested Follow up Visit Frequency (duration between visits extends as stability increases):

- Provider visits at least monthly
- Behavioral health support is recommended based on participant stability (could be IOP or OP, could be weekly check-in visits with HAH team, or could be other identified external supports (i.e. NA, AA, Smart Recovery)
- Current recommendations (SAMHSA Tip 63) support continued use of injectable naltrexone as long as patient sees benefit and no contraindications

Exclusionary and Precautionary Criteria – XR Naltrexone⁵

Indication:

XR-NTX is indicated for the prevention of return to opioid use following medically supervised opioid withdrawal. Appropriate patients should have an adequate period of abstinence with no signs of opioid withdrawal before XR-NTX administration. Patients must be willing to receive monthly IM injections. Become acquainted with the FDA label for XR-NTX, which is available online (<https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=cd11c435-b0f0-4bb9-ae78-60f101f3703f>).

Contraindications

Contraindications to receiving XR-NTX (as well as to receiving oral naltrexone, with the exception of hypersensitivity to the XR-NTX suspension and diluent) include:

- Current pain treatment with opioid analgesics.
- Current physiological opioid dependence.
- Current acute opioid withdrawal.
- Severe hepatic impairment.
- Naloxone challenge (Exhibit 3C.1) or oral naltrexone dose causing opioid withdrawal symptoms.
- Positive urine opioid screen for morphine, methadone, buprenorphine, oxycodone, fentanyl, or other opioids.
- History of hypersensitivity to naltrexone, polylactide-co-glycolide, carboxymethylcellulose, or any other components of the diluent.

Precautions and warnings

- **Discuss the risks and benefits of continuing naltrexone with patients who become pregnant while receiving naltrexone treatment and whose OUD is in remission.** Unlike methadone and buprenorphine, naltrexone has been little researched in pregnant populations.
- **Patients are vulnerable to opioid overdose death** after completing the every-4-weeks or once monthly dosing period, missing a dose, or stopping treatment. Trying to override opioid blockade with high opioid doses may cause overdose.
- **Patients may experience injection site reactions** including pain, tenderness, induration, swelling, erythema, bruising, or pruritus. Severe injection site reactions may occur (e.g., cellulitis, hematoma, abscess, sterile abscess, necrosis). Some cases may require surgical intervention and may result in significant scarring. (See the Chapter 3C Appendix for techniques to reduce injection site reactions). As with any IM injection, use caution in patients with thrombocytopenia or a coagulation disorder.
- **Precipitated opioid withdrawal can occur in patients who used illicit opioids recently or switched from an opioid agonist medication.** Symptoms may be severe enough for hospitalization. To avoid precipitated withdrawal from either formulation, patients should typically stop use of short-acting opioid agonists for 7 to 10 days and long-acting agonists for 10 to 14 days. There is active research on approaches to initiate XR-NTX more quickly for patients physically dependent on opioid agonists.
- **Hepatitis has been associated with XR-NTX**, often in the presence of other potential causes of hepatic toxicity (e.g., alcohol liver disease, viral hepatitis). Monitor liver function tests during

⁵ All information taken directly from SAMHSA Tip 63, page 3-33 through 3-34

treatment. Stop naltrexone in the presence of acute hepatitis and severe liver disease. Initiate or refer patients to treatment for hepatitis.

- **Use cautiously in patients with moderate-to-severe renal impairment**, because the medication is eliminated primarily through the kidneys.
- **Hypersensitivity reactions** can occur, including rash, urticaria, angioedema, and anaphylaxis.

XR Naltrexone Intake Appointment

Ideally the XR naltrexone should have been ordered in advance of the intake visit. As shown in the XR naltrexone workflow, at the time when the STAR BH POC at each site is notified that a participant is interested in XR naltrexone, the STAR RN should be notified and initiate the workflow to order XR naltrexone. Some plans allow participants to pick up the medication at the pharmacy (they should do this and bring the medication to the first visit) and other plans require specialty pharmacy to deliver to the clinic. The STAR RN manages this process and works with the provider to order the medication in advance of the initial visit. In the case that the medication hasn't been ordered in advance of the visit, the intake visit happens as normal, but the participant has to come back on another day to receive the injection.

The **STAR BH intake** is typically completed by the LCSW/LCPC. However, all AODC and recovery coaches on the team are able to do an intake.

If not already completed, then complete the following:

- Vermont TNQ Completed (Centricity)/ if GAIN sent over from Haymarket or other treatment provider, this can take the place of the TNQ
- Substance use and treatment history documented (Centricity)
- OUD assessment completed (done on paper- scanned)
- Any participant concerns or questions about HAH process addressed with STAR BH provider
- Confirmation of last opioid use/dose (7-10 days abstinence of short-acting opioids and 10-14 days for long acting opioids like buprenorphine or methadone)
- Rapid urine drug test completed & documented in Centricity
 - Urine drug screen should be negative for all opioids (buprenorphine, methadone, oxycodone, opiates, etc)
 - Alert provider if any opioids are positive- participant will not be able to receive injection if they have opioids in their system
- Complete needed ROI's (or ask MA to assist)
- Verbally review Electronic Communication Agreement with participant and have them sign- put in scan bin
- Verbally review participant Vivitrol Agreement and have them sign- put in scan bin
- Overdose prevention education and naloxone training
- Go through all materials in patient folder:
 - Naloxone handout
 - Vivitrol patient handout
 - Give Vivitrol card and bracelet (if we have them available)

Provider Intake Visit:

- HPI (see quick texts)
 - Review current and past drug use (substances used, amount and frequency of use; much of this can be seen in the STAR BH Intake note)
 - Review current psychiatric symptoms and any current treatment
 - Review past treatment episodes (specifically asking about past experience with medication treatments)
 - Ask about longest period of abstaining from opioids- when was it, for how long, what worked well? (identify participant strengths and what has helped in past)

- Ask about history of overdoses (discuss naloxone prescription that will be given today)
- Ask about current goals for treatment and level of motivation for reducing use
- History:
 - Current medications
 - Allergies
 - Medical history (in history tab and in active problem list)- be sure to ask about psychiatric history including hospitalizations and suicide attempts
 - Surgical History
 - Family history (be sure to ask about current family involvement; this can be a good way to ask about any open DCFS cases)
 - Educational attainment
 - Past work history (what types of work have they done in past which opens convo on their plans for work in future)
- Review of systems and physical exam focused signs of hepatitis (jaundice, anicteric sclera, ascites, tenderness to palpation of liver), and mental health stability/insight
- Screening for precautionary and potentially exclusionary criteria:
 - Any recent use of opioids (risk for severe precipitated withdrawal)
 - If participant has known elective surgery coming up that would likely involve general anesthesia, counsel around the fact this will block opioids
 - AST or ALT > 5 times⁶ normal limits; acute hepatitis or liver failure; actively suicidal or homicidal.
 - If concern for hepatic disease, order PT/INR and albumin to assess synthetic function.
- Orders:
 - Labs- use STAR intake lab order set (includes CMP, HIV, Hepatitis panel) *(note- you do not have to have lab results to start XR naltrexone. If the participant can't get labs done on day of intake, that is also ok. Not having labs should not lead to delay in initiation of treatment.)*
 - Add additional labs as needed for maintenance of chronic conditions or other STI testing as agreed upon by participant.
 - Review rapid UDS- should be negative for opioids, but remember this only gives information on last 3 days.
 - Urine HCG for women of reproductive age who could get pregnant. (Current guidelines do not support XR naltrexone as first line in pregnancy)
- Counseling:
 - Review of all three MAT options for opioid use disorder, risks and benefits, and serious risk of overdose if use opioid after abstinence with naltrexone, given loss of tolerance.
 - Counseling regarding contraception for females of reproductive age.
 - Tobacco use counseling, if applicable.
 - Encourage PCP engagement and facilitate appointment if indicated.
 - Provide counseling on how the medication works, risk of precipitated withdrawal in case of any recent use (past 7-14 days depending on type of opioid)

⁶ <http://pcssmat.org/wp-content/uploads/2014/10/PCSS-MAT-NTX-Liver-Safety-Guideline1.pdf>

- Counseling around the fact that the medication will wear off around day 28. Cravings are likely to resume without subsequent injection so it's important to come to follow up appointment.
- Counseling regarding risk of overdose in case of resumed use (use less opioids if to resume use)
- Confirm understanding of overdose prevention and how to administer naloxone
- Prescriptions:
 - **Prescribe Naloxone for everyone**
 - **Vivitrol:** Naltrexone 380mg
- **Follow up in 28 days**

Naltrexone Administration (done by STAR RN if available; if not provider to administer):

- If there is any concern that participant may experience precipitated withdrawal (unclear timeline on last use, etc), a naloxone challenge is recommended.
 - **Subcutaneous Administration**
 - Inject 0.8 mg naloxone subcutaneously.
 - Wait 20 minutes while checking vital signs and observing for signs and symptoms of opioid withdrawal.
 - If withdrawal signs and symptom are present, stop the naloxone challenge, and treat symptomatically. The test can be repeated in 24 hours or the patient can be considered for opioid agonist treatment.
 - If no withdrawal signs and symptoms are present administer XR naltrexone.
- XR Naltrexone administration
 - Review package insert before giving injection
 - There are youtube videos showing exactly how and where to administer naltrexone
 - Administer in the alternate glut from the last injection
 - Document which glut the injection was given; update the XR Naltrexone card if the participant has it

XR Naltrexone follow up appointment

Our goal is that at each visit, one STAR BH team member (Recovery Coach, AODC, or LCSW/LCPC) will see the participant in addition to the provider. During the huddle, the team will go over which team member will see which participant. In some cases, it may be necessary for both a recovery coach/AODC and the LCSW/LCPC to see a participant- particularly in cases where the recovery coach/AODC identifies significant mental health crisis and requests the LCSW/LCPC to see the participant. Similarly, there may be times when there is not adequate staffing or schedules are running behind and no BH team member can see the participant. In these cases, the BH team member should attempt to follow up with the participant by phone/text at some point before the next visit. When possible the STAR RN will also meet all participants, and will specifically facilitate the ordering/delivery of XR naltrexone and will give the injections.

MA:

- Conducts “normal” triage- vital signs, screening questions, requests ROI for any recent ED visits or hospitalizations, etc.
- Obtains pregnancy test if ordered by provider

AODC/Recovery Coach or LCSW/LCPC:

-
- Obtain rapid urine drug screen from participant and record results in Centricity
- Meet with participant for brief check-in and document note in Centricity
- Assist with any needed resources (housing/recovery homes, locations and times of meetings, transportation, job training/opportunities, legal aid, etc.)
- Provide any additional support needed (peer support, addiction counseling, or mental health counseling (LCSW/LCPC))

Provider:

- HPI:
 - Confirm participant was able to get medication without problem (including naloxone; it is good to confirm intermittently whether they still have it and if not re-prescribe)
 - Ask about drug use since last visit
 - Ask about new or ongoing stressors
 - Ask about any progress made on goals
 - Ask about any side effects from XR naltrexone (insomnia, injection site pain, hepatic enzyme elevation, nasopharyngitis, and GI symptoms)
 - Ask about mood and sleep- these can significantly contribute to relapse potential. Initially there were concerns that XR naltrexone could exacerbate depression, but subsequent studies have not found this to be common.
 - Address any primary care needs as able (*the goal is to manage primary care/preventive care during these visits, but in cases where SUD is too complex or primary care needs are too complex- you can either have participant follow up on another day to focus on just PC needs, or in rare cases, having them see another PCP may be warranted*)
- Review of Systems can focus on common side effects
- Physical exam should include at a minimum general appearance, mood, and insight
- Review PMP

- Review urine drug screen results and address use of any substances (including non-opioids)
- Review any recent lab results with participant
- Orders:
 - Send out other toxicology tests as needed (*see urine drug screen protocol for more information*)
 - LFTs, HIV, HCV (if not known to be positive) should be redrawn every 6 months, or in the case of elevated LFTs more frequently
- Assessment and Plan:
 - Re-counsel regarding loss of tolerance with naltrexone and risk of overdose
 - Importance of follow up at 28 days
 - LFTs to be re-checked at 8-12 weeks after first dose and then quarterly. Order if indicated
 - Tobacco counseling and PCP engagement, if indicated.
 - Refill XR naltrexone and flag to STAR RN to ensure specialty pharmacy used if needed.

Naltrexone Administration (done by STAR RN if available; if not provider to administer):

- If there is any concern that participant may experience precipitated withdrawal (unclear timeline on last use, etc), a naloxone challenge is recommended.
 - **Subcutaneous Administration**
 - Inject 0.8 mg naloxone subcutaneously.
 - Wait 20 minutes while checking vital signs and observing for signs and symptoms of opioid withdrawal.
 - If withdrawal signs and symptom are present, stop the naloxone challenge, and treat symptomatically. The test can be repeated in 24 hours or the patient can be considered for opioid agonist treatment.
 - If no withdrawal signs and symptoms are present administer XR naltrexone.
- XR Naltrexone administration
 - Review package insert before giving injection
 - There are youtube videos showing exactly how and where to administer naltrexone
 - Administer in the alternate glut from the last injection
 - Document which glut the injection was given; update the XR Naltrexone card if the participant has it

In the case that the provider is not available on the day that the participant comes for the injection, the **STAR RN** can offer an RN visit and administer the injection in the following circumstances:

- Participant is within 28 day window for injection (if outside of 28 day window, verbal consultation with STAR provider required)
- Participant's rapid urine drug screen is negative for all opioids
- A STAR provider is aware that the participant is coming in for the injection

STAR RN:

- Review naloxone training and confirm participant has naloxone (if not, order refill to pharmacy or give kit if available on-site).
- Order today's labs: rapid urine drug screen and pregnancy test (for female of reproductive age who is able to become pregnant)
 - If pregnant, contact provider and do not give injection. Do not give naloxone challenge)

- Assesses for any recent opioid use. If concern for recent opioid use, naloxone challenge may be administered (see above).
- Administer 380mg IM naltrexone, documenting location (R or L gluteal muscle) of injection. Injection site to be alternated between L and R gluteal muscle every 4 weeks

Follow Up Frequency:

- At the beginning of treatment, we typically recommend following up with AODC/recovery coach at least every 2 weeks (can be weekly if participant is interested/available).
- Rapid urine drug screen to be completed at each visit (ordered ahead of time by nurse or provider).
- Not participating in counseling at HAH will not lead to discharge from program, but we do need to support participant to identify external supports.
- Follow up appointment with provider every 4 weeks for injection visit; recovery coach, AODC or LCSW/LCPC will check in with participant at these visits as well.
- If a participant misses a dose, they should come in as soon as possible for dose administration so long as they have not had recent opioid use; if they report resumed opioid use, we should again discuss all 3 medication options (methadone, buprenorphine, and XR naltrexone) and if still interested in XR naltrexone, coordinate medically managed withdrawal (detox) as appropriate.
- Consult provider lead re: discontinuing medication. Length of treatment shall be decided on an individual basis.

XR Naltrexone Discontinuation

Discourage patients who are not yet stable from discontinuing treatment, because of the high rate of return to illicit opioid use and the increased chance of overdose death.

Signs that a patient may be ready to discontinue medication include:

- Sustaining illicit drug abstinence over time.
- Having stable housing and income.
- Having no legal problems.
- Having substantially reduced craving.
- Attending counseling or mutual-help groups.

Patients who discontinue should have a recovery plan that may include monitoring as well as adjunctive counseling and recovery support. If they return to opioid use, encourage them to return for assessment and reentry into treatment.

Given the high risk of return to illicit opioid use, **offer patients information about opioid overdose prevention and a naloxone prescription they can use in case of overdose.** When patients stop using naltrexone, they will have no tolerance for opioids. Their risk of overdose is very high if they use again.

Provider Quick Texts- XR Naltrexone

New vivitrol

{PATIENT.FIRSTNAME} {PATIENT.LASTNAME} is a {PATIENT.FORMATTEDAGE} year old {PATIENT.SEX} here today to establish care for OUD treatment and ongoing Vivitrol injections.

Current living situation:

Last opioid used (date):

Recent detox and date of completion:

Opioid of choice:

Hx of IDU:

Other drugs of use:

Previous treatment history:

Previous use of buprenorphine/methadone/naltrexone:

Number of previous injections:

Past or current site reaction:

Past or current side effects (Depressed mood, nausea, headache, dizziness, sleepiness, muscle cramps):

New vivitrol visit at James West (transition from Haymarket)

{PATIENT.FIRSTNAME} {PATIENT.LASTNAME} is a {PATIENT.FORMATTEDAGE} year old {PATIENT.SEX} here today to establish care for OUD treatment and ongoing Vivitrol injections.

Current Unit at Haymarket:

How much longer on this unit:

Plan when leaving Haymarket:

Number of previous injections:

Past or current site reaction:

Past or current side effects (Depressed mood, nausea, headache, dizziness, sleepiness, muscle cramps):

Cravings on current dose:

Previous treatment history:

Opioid of choice:

IDU:

.vivplan (vivitrol plan for med provider section of note)

Vivitrol Injection given on XX glut using sterile technique.

PMP reviewed, UTox completed

Patient counselled on medication safety, including risk of overdose and death if a dose of Vivitrol is missed, after stopping opioids, or if attempting to overcome the effects of Vivitrol through using large amounts of opioids.

Pt to return in 4 weeks for next injection.

.vivpi (vivitrol patient information= to go in section of patient education that gets printed)

1. You have received your Vivitrol injection today. It is very important that you return in 4 weeks for your scheduled appointment. If you use opioids after the Vivitrol wears off, you are at high risk of overdose and death. If you do use opioids, use less than you used to use before you got the Vivitrol.

2. If you are not able to make it to your visit, please call or text Megan at 708 298 2502 or Tony at 312 914 0273.

3. Please let us know right away if you develop intense pain at the reaction site.

Vivitrol Follow up Visit Quick Texts

.vivfu (vivitrol follow up- for HPI section)

{PATIENT.FIRSTNAME} {PATIENT.LASTNAME} is a {PATIENT.FORMATTEDAGE} year old
{PATIENT.SEX} here today for follow up on OUD treatment and vivitrol injection.

Living situation:

Cravings:

Drug or Alcohol Use:

Number of days since last Vivitrol injection:

Pain at site/site reaction after last injection:

Changes in mood:

Other side effects:

Support:

Participation in therapy or groups:

Sleep:

Goals:

.vivplan (vivitrol plan for med provider section of note)

Vivitrol Injection given on XX glut using sterile technique.

PMP reviewed, UTox completed

Patient counselled on medication safety, including risk of overdose and death if a dose of Vivitrol is missed, after stopping opioids, or if attempting to overcome the effects of Vivitrol through using large amounts of opioids.

Pt to return in 4 weeks for next injection.

.vivpi (vivitrol patient information= to go in section of patient education that gets printed)

1. You have received your Vivitrol injection today. It is very important that you return in 4 weeks for your scheduled appointment. If you use opioids after the Vivitrol wears off, you are at high risk of overdose and death. If you do use opioids, use less than you used to use before you got the Vivitrol.
2. If you are not able to make it to your visit, please call or text Megan at 708 298 2502 or Tony at 312 914 0273.
3. Please let us know right away if you develop intense pain at the reaction site.

Late Arrival Policy

Late appointment protocols are the same for all STAR clinics and reflect Primary Care appointment policies at Heartland Health Outreach. These policies include the request that participants arrive 15 minutes prior to their appointment time and the tetrising of appointments. All attempts will be made to offer the participant an appointment later during the session if there are open slots with a STAR provider.

The following late arrival protocols have been created to ensure that the STAR Team is helping to create an environment that is focused on reducing harm, timely service, delivery of safe care, and participant accountability.

When a participant arrives late to an appointment with their prescribing provider by 15 minutes or more the following workflows are to be utilized:

- PES staff will alert STAR BH team members that the participant has arrived late.
- The participant will be offered an appointment later during the same session if appointments are available. The PES staff will let participant know they may have to wait.
 - If the participant is able to wait, then the visit follows normal workflow.
 - If the participant is not able to wait, or if there is no available appointment, then:
 - STAR BH team member will see the participant, complete a BH assessment note and get a rapid urine drug screen.
 - STAR BH team member will look for the next open STAR follow up visit.
 - STAR BH team member will discuss the rapid UDS, any clinical updates, and the next available appointment with the prescribing provider
 - The prescribing provider will provide a “bridge” prescription until the next available appointment (anywhere from 1 day to 1 week of medication)
- Once the participant returns for their routine appointment with their prescribing provider, the participant will get their prescriptions at the original frequency.
- Participants can receive two “bridge” prescriptions from a STAR team member
- If a participant is late three times to their appointment, an individualized Recovery Plan will be created for them. This may include an increase in frequency of visits to ensure we are able to better understand the participant’s needs. It could also include assistance with transportation benefits through their insurance, changing the day/time of the clinic visits (esp if there are work conflicts), or alternative plans based on the participant’s circumstances. If the Recovery Plan is not successfully followed we will help identify another program that can better meet their needs and support a transfer of care as appropriate.

Lab Process

Uptown Workflow

- AODC/Recovery Coach walks with participant to the bathroom and gives them the rapid urine drug cup. They check temperature to ensure within appropriate range, interpret results, and document in Centricity under UDS form.
- In the event that the AODC/Recovery Coach is not available, the LCSW/LCPC and/or RN can follow the same process.

James West Workflow

- AODC/Recovery Coach walks with participant to the bathroom and gives them the rapid urine drug cup. They check temperature to ensure within appropriate range, interpret results, and document in Centricity under UDS form.
- In the event that the AODC/Recovery Coach is not available, the LCSW/LCPC and/or RN can follow the same process.

Englewood Workflow

- AODC/Recovery Coach walks with participant to the bathroom and gives them the rapid urine drug cup. They check temperature to ensure within appropriate range, interpret results, and document in Centricity under UDS form.
- In the event that the AODC/Recovery Coach is not available, the LCSW/LCPC and/or RN can follow the same process.

Appendix 1: OUD Checklist (this can be used as a reference, but this is now in Centricity as a template)



DSM-5 Criteria for Diagnosis of Opioid Use Disorder

Diagnostic Criteria*

These criteria not considered to be met for those individuals taking opioids solely under appropriate medical supervision.

Check all that apply

	Opioids are often taken in larger amounts or over a longer period of time than intended.
	There is a persistent desire or unsuccessful efforts to cut down or control opioid use.
	A great deal of time is spent in activities necessary to obtain the opioid, use the opioid, or recover from its effects.
	Craving, or a strong desire to use opioids.
	Recurrent opioid use resulting in failure to fulfill major role obligations at work, school or home.
	Continued opioid use despite having persistent or recurrent social or interpersonal problems caused or exacerbated by the effects of opioids.
	Important social, occupational or recreational activities are given up or reduced because of opioid use.
	Recurrent opioid use in situations in which it is physically hazardous
	Continued use despite knowledge of having a persistent or recurrent physical or psychological problem that is likely to have been caused or exacerbated by opioids.
	*Tolerance, as defined by either of the following: (a) a need for markedly increased amounts of opioids to achieve intoxication or desired effect (b) markedly diminished effect with continued use of the same amount of an opioid
	*Withdrawal, as manifested by either of the following: (a) the characteristic opioid withdrawal syndrome (b) the same (or a closely related) substance are taken to relieve or avoid withdrawal symptoms

Total Number Boxes Checked: _____

Severity: **Mild:** 2-3 symptoms. **Moderate:** 4-5 symptoms. **Severe:** 6 or more symptoms

*Criteria from American Psychiatric Association (2013). Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition, Washington, DC, American Psychiatric Association page 541. For use outside of IT MATTTRs Colorado, please contact ITMATTTRColorado@hca.com

Appendix 2- Buprenorphine Agreement (is a document in Centricity that gets printed, signed and scanned back in)

NAME _____ DOB _____ Date: _____

Updated 9/2019

I will get Buprenorphine (Suboxone) only from my provider: _____.

I will tell all other health providers (including dentists) that I am taking buprenorphine and can only get it from the provider listed above.

I agree not to get medications on the "Meds to Avoid" list without talking to my provider first.

I understand that people have died by mixing buprenorphine with alcohol and other drugs like benzodiazepines (Valium, Klonopin, and Xanax). I understand that buprenorphine will interact with opioid pain medicines like Norco, Vicodin, and Tylenol #3 and will not get any prescriptions for any of these medications at outside facilities without talking to my provider first.

I will take my medicine only as prescribed and will not take someone else's medicine.

I will tell the provider listed above about all other medicines I am taking.

I will not share, sell, or trade buprenorphine or any other medication with anyone. I understand that doing so is illegal and would lead to immediate termination from the program.

I will tell the provider listed above about all my health problems.

I will not request early refills for my buprenorphine for any reason, including lost or stolen, and I understand that my provider cannot give early refills.

I will keep all my appointments with the provider listed above and other members of the health care team. If I cannot make it to an appointment, I will call to discuss with the STAR team to develop an alternative plan.

I understand that missing an appointment usually means I will run out of medication early, which will cause symptoms of withdrawal.

I will meet with the STAR team at least weekly initially, and visits will be spaced out I become more stable in my recovery. How often I meet with the STAR team will be based on how stable I am in my recovery.

I understand that buprenorphine is only part of the treatment, the other part is therapy. I will work with the STAR team on a treatment plan.

I will keep my medicine in a safe place and away from children. I understand that if a child takes this medicine, he/she could die.

I will talk to the STAR team about any alcohol or drug use.

I understand that I am required to give urine for drug testing so the provider listed above can make sure that I am taking the buprenorphine as prescribed and there are no substances that might interact with buprenorphine.

I understand that the provider listed above will check the Illinois Prescription Monitoring Program to make sure I am not getting prescriptions for medications that might interact with the buprenorphine.

I understand that violence, threatening language or behavior, or participation in any illegal activity at the office will not be tolerated and can lead to termination from treatment services.

I agree that I will not deal, steal, or conduct any other illegal or disruptive activities in the health center.

I understand that there is no fixed time for being on buprenorphine and that the goal of treatment is for me to stop or reduce drug use and become successful in all aspects of my life.

I understand that I may experience opioid withdrawal symptoms when I stop taking buprenorphine.

I have been provided education about the other two FDA-approved medications used for opioid use disorder treatment- methadone and naltrexone.

I have been provided education about the increased chance of pregnancy when stopping illicit opioid use and starting buprenorphine treatment and been informed about methods for preventing pregnancy.

I understand that my treatment plan is individualized. The STAR team will work with me to develop a plan with me that works for me and my life. There may be times when the STAR team will recommend that I should get more services- sometimes called in a higher level of care, like going to a residential or intensive outpatient program for example. If this happens, the STAR team will work with me to find a program and make sure that I can get services there.

I understand that if I am late for an appointment (15 minutes past scheduled time), my provider may not be able to see me. This means that I may not get medication that day. If I do not get medication, I will have withdrawal symptoms. If I know I am going to be late, I should contact the STAR team to let them know and they will work with me to develop a plan.

I understand that if I miss an appointment I will run out of medication and will have withdrawal symptoms. If I know I am going to miss an appointment, I should contact the STAR team to let them know and they will work with me to develop a plan. In most cases, the plan will be scheduling an appointment at the next available STAR visit.

I have read and understand this agreement. A copy of this agreement has been given to me. A copy will remain in my medical record.

Participant signature_____ Date_____

Staff signature_____ Date_____

Appendix 3- Buprenorphine Intake Checklist

Updated September 2019

Buprenorphine Intake Check List

- Substance use and treatment history documented (“MAT Initial Assessment” in Centricity)
- TNQ completed (“Treatment Needs Questionnaire” in Centricity)
- Rapid Urine Drug screen completed & documented (“Urine Drug Screen” in Centricity)
 - Morphine, Oxycodone, or “Opiates” present
 - If methadone was present, collected circumstances around methadone use and discussed with provider (refer to Methadone to Buprenorphine Transition document)
 - If opiates were not present, circumstances documented, and send out for fentanyl obtained
- Moderate to Severe Opioid Use Disorder diagnosis confirmed with DSM 5 (documented in Centricity)
- Prescription Monitoring Program record reviewed in Centricity
 - Any concerns (recent opioid or benzodiazepine prescriptions) were discussed with participant and ROI completed as appropriate
- Treatment Agreement reviewed and signed by participant
- Electronic Communication Agreement signed by participant
- Overdose education offered and naloxone handout given
- As applicable, housing resources given
- Release of Information completed for any outside providers or treatment programs

Staff Completing Assessment

Date

Appendix 4- Injectable XR Naltrexone (Vivitrol) Agreement

Goal of Treatment: Treatment of Opioid Use Disorder or Alcohol Use Disorder.

___ I understand that there are 3 FDA-approved medicines for opioid use disorder: methadone, buprenorphine (Suboxone), and Vivitrol. They all work in slightly different ways and the available medical evidence suggests that there are better outcomes associated with methadone and buprenorphine.

___ I have been given the Vivitrol safety handout and have read it and all questions have been answered.

___ I confirm that I have not used any opioids in more than 10 days. I have not used buprenorphine or methadone in more than 2 weeks. I understand that Vivitrol works by binding to the same centers in the brain as opioids (heroin, methadone, other opioid pain medications) and lasts for 28 days. If I have used any opioids in the past 7-10 days, getting this injection will make me sick (precipitated withdrawal). Longer-acting opioids like methadone and buprenorphine often take two weeks to clear from the body. I understand that sometimes the withdrawal caused by Vivitrol can be so severe it can require hospitalization (it is much more severe withdrawal than what occurs naturally)

___ I understand that if I use small doses of opioids for any reason during the 28 days that Vivitrol is active, they will not have any effect. If I take a high dose of opioids (heroin or other opioid pain medications) to try to bypass the Vivitrol, it may lead to coma or death.

___ I understand that it is important for me to let any doctors or dentists know I am receiving this medication so they can give me non-opioid pain medications. Opioid pain medications will not be effective during the 28 days after my injection. Opioid-containing medications for cough or diarrhea will also not be effective during this period.

___ I understand that my tolerance for opioids goes down significantly after a period of no opioids in my body. If I do use opioids at the end of the 28 day period, I need to use a significantly smaller amount to reduce risk of overdose. I understand that I am also receiving a prescription for naloxone today. This is a medication that is used to reverse an opioid overdose. I will let friends and family members know I have this medication and will share the handout I am receiving today on how to give it.

___ I understand that while on Vivitrol, I am still able to overdose on other drugs, including but not limited to benzodiazepines, alcohol, cocaine.

___ I understand that Vivitrol is only half the treatment, the other half being therapy. I agree that I will work on a treatment plan with the HHO team and will participate in some type of additional behavioral therapy.

___ I understand that there is a risk for a reaction at the site of the Vivitrol injection. Reactions can include pain, tenderness, induration, swelling, redness, bruising or itching. More serious site reactions can include skin and tissue necrosis. There are reports of site reactions requiring surgery. If I have any site reaction, I will be sure to let a medical professional know right away to avoid any long-term complications and so I can receive any necessary treatment immediately.

___ I understand that Vivitrol can cause liver injury. My provider will check my liver function (blood test) before starting therapy and every 3-6 months thereafter. I will let my provider know if I develop any signs of liver injury: yellow skin, itchy skin, very dark urine

_____ I understand that some people on Vivitrol experience depression while taking this medication. I understand that I need to let friends and family know that I'm taking this medication and tell them to call a medical provider right away if I become depressed or experience symptoms of depression.

_____ I understand that Vivitrol can cause an allergic pneumonia (lung infection). I will immediately notify my provider if I develop signs or symptoms of pneumonia, including difficulty breathing, coughing or wheezing.

_____ I understand I should not take Vivitrol if I've been told I'm allergic to Vivitrol.

_____ I understand I may feel nausea after the Vivitrol injection. This is usually mild and will go away within a few days of the injection. The nausea is less likely after future injections. I may also experience tiredness, headache, vomiting, decreased appetite, painful joints and muscle cramps.

_____ I understand that because Vivitrol is an injection, once it is injected, it is not possible to remove it from the body.

_____ I understand that Vivitrol makes some people feel dizzy. I will not drive or operate heavy machinery until I understand how Vivitrol affects me.

_____ If applicable, I will alert my provider immediately if I become pregnant or intend to become pregnant while on treatment with Vivitrol, am breastfeeding, experience any breathing symptoms while taking Vivitrol, experience any allergic reactions while taking Vivitrol, experience any other unusual side effects while taking Vivitrol.

_____ I understand I can receive a wallet card or medical alert bracelet from: 1-800-848-4876, Option #1.

_____ It is my responsibility to make and keep my appointments with my medical provider. I understand not doing so may cause there to be a delay in me being able to get my next injection.

_____ It is my responsibility to make sure I keep my insurance active.

I have read and understand this agreement. A copy of this agreement has been given to me. A copy will remain in my medical record.

Participant signature _____ Date: [DATE]

Staff signature _____ Date: [DATE]

Appendix 5- Injectable XR Naltrexone Check list

Injectable XR Naltrexone (Vivitrol) Intake Check List

- Substance use and treatment history documented (“MAT Initial Assessment” in Centricity)
- TNQ completed (“Treatment Needs Questionnaire” in Centricity)
- Participant confirms not opioid use in at least 10 days
- Rapid Urine Drug screen completed & documented (“Urine Drug Screen” in Centricity)
 - Morphine, Oxycodone, or “Opiates” should be negative
 - Methadone should be negative
 - If opiates were present, circumstances documented, and discussion about the fact Vivitrol can’t be given because it’s unsafe if opioids in system; discussion about treatment options
- Opioid Use Disorder diagnosis confirmed with DSM 5 (in Centricity)
- Prescription Monitoring Program record reviewed in Centricity
 - Any concerns (recent opioid prescriptions) were discussed with participant and ROI completed as appropriate
- Vivitrol Treatment Agreement reviewed and signed by participant
- Electronic Communication Agreement signed by participant
- Overdose education offered and naloxone handout given
- As applicable, housing resources given
- Release of Information completed for any outside providers or treatment programs

Staff Completing Assessment

Date

Appendix 6- Patient Counseling Tool for Vivitrol

Patient Counseling Tool
VIVITROL® (naltrexone for extended-release injectable suspension)

Risk of sudden opioid withdrawal during initiation and re-initiation of VIVITROL

Using any type of opioid including street drugs, prescription pain medicines, cough, cold or diarrhea medicines that contain opioids, or opioid dependence treatments buprenorphine or methadone, in the 7 to 14 days before starting VIVITROL may cause severe and potentially dangerous sudden opioid withdrawal.

Risk of opioid overdose

Patients may be more sensitive to the effects of lower amounts of opioids:

- After stopping opioids (detoxification)
- When the next VIVITROL dose is due
- If a dose of VIVITROL is missed
- After VIVITROL treatment stops

Patients should tell their family and people close to them about the increased sensitivity to opioids and the risk of overdose even when using lower doses of opioids or amounts that they used before treatment. Using large amounts of opioids, such as prescription pain pills or heroin, to overcome effects of VIVITROL can lead to serious injury, coma, and death.

Risk of severe reactions at the injection site

Remind patients of these **possible** symptoms at the **injection site**:

- Intense pain
- The area feels hard
- Large areas of swelling
- Lumps
- Blisters
- Open wound
- Dark scab

Some of these injection site reactions have required surgery. Tell your patients to contact a healthcare provider if they have any reactions at the injection site.

Risk of liver injury, including liver damage or hepatitis

Remind patients of the **possible symptoms of liver damage or hepatitis**.

- Stomach area pain lasting more than a few days
- Dark urine
- Yellowing of the whites of eyes
- Tiredness

Patients may not feel the therapeutic effects of opioid-containing medicines for pain, cough or cold, or diarrhea while taking VIVITROL.

Patients should carry written information with them at all times to alert healthcare providers that they are taking VIVITROL, so they can be treated properly in an emergency.

A Patient Wallet Card or Medical Alert Bracelet can be ordered from: 1-800-848-4876, Option #1.

PLEASE SEE PRESCRIBING INFORMATION AND MEDICATION GUIDE.



Alkermes® and VIVITROL® are registered trademarks of Alkermes, Inc.
©2013 Alkermes, Inc.
All rights reserved VIV-001317 Printed in U.S.A
www.vivitrol.com

Vivitrol®
(naltrexone for extended-release injectable suspension)