ANMC OB/GYN Service Medication Assisted Treatment in Pregnancy and Postpartum Initiation and Management Guidelines 12/13/2019 bb/stt

1. Background

Opioid use disorder is a pattern of opioid use characterized by tolerance, craving, inability to control use, and continued use despite adverse consequences. Opioid use disorder is a chronic, treatable disease that can be managed successfully by combining medications with behavioral therapy and recovery support, which enables those with opioid use disorder to regain control of their health and their lives.

Opioid use in pregnancy is associated with increased risk of preterm delivery, intrauterine growth restriction, neonatal abstinence syndrome, and sudden infant death syndrome. Pregnant women with opioid addiction are at increased risk for delayed prenatal care and many fail to disclose their addiction history. Treatment with an opioid-agonist improves pregnancy outcomes for people with Opioid Use Disorder (OUD). The best perinatal and neonatal outcomes are observed when women are enrolled in a comprehensive treatment program. The overarching goals of therapy for opioid dependence during pregnancy are to provide medical support to prevent withdrawal during pregnancy, minimize fetal exposure to illicit substances, and engage the mother as a leader in her recovery. Such engagement provides her the opportunity to receive both medical and ancillary services which will allow her to successfully parent her child. Adequate doses of MAT are encouraged. The risk of serious adverse effects such as an overdose or treatment dropout is greater if a Customer Owner is undertreated with buprenorphine and continues to self-medicate withdrawal symptoms with opioids, alcohol, or other sedative-hypnotics, in particular benzodiazepines.

Office-based therapy during pregnancy favors the Customer Owner that is highly motivated to recovery and parenting. Many women usually agree to substance abuse counseling and the assistance of community resources to aid in the recovery process. Customer Owners unwilling to engage in these services may still be candidates for MAT office-based therapy using a harm reduction model. Inclusion of substance abuse counseling and wrap around services should be strongly encouraged for all Customer Owners, as medication alone may be insufficient for optimal pregnancy and parenting outcomes. Transition planning of MAT care to a primary care provider for post pregnancy should begin at the time of initiation of perinatal MAT care to aid the transition of care when the Customer Owner is greater than eight weeks postpartum.

2. Screening and Diagnosis

2.1. Universal Screening for substance use should be part of comprehensive obstetric care and should be done at the first prenatal or transfer visit in partnership with the pregnant woman. Routine screening should rely on a validated tool, such as 4Ps Plus and SBIRT. Any positive screen should be referred to the OBGYN BHC for further evaluation of motivation to initiate MAT.

2.2. The diagnosis of OUD should be confirmed by DSM-5 criteria (Appendix B), and by urine drug testing. An in-house substance screen is adequate for initiation while advanced toxicology screen is pending. Opioid dependence may also be documented by the presence of opioid withdrawal symptoms, based on the Clinical Opiate Withdrawal Scale, or COWS.

2.3 Diagnosis of pregnancy with a positive HCG in clinic should be obtained prior to initiation of buprenorphine if not previously obtained. Confirmation of viability is not necessary prior to initiation.

2.4 An inventory of past and current substance use and past OUD treatment should be collected.

2.5 A query of the Alaska Prescription Drug Monitoring Program to assess prescription opioid use is recommended.

2.6 Psychiatric co-morbidities (especially depression, anxiety disorders, and PTSD) are common, and need to be evaluated. An assessment of social and environmental factors by the Behavioral Health Consultant should be conducted to identify facilitators and barriers to addiction treatment, and specifically to pharmacotherapy.

2.7 A physical examination should be completed, with attention to potential sequelae of substance use.

2.8 The following laboratory tests may be obtained: Complete Blood Count, Complete Metabolic Profile, Hepatitis A, B, and C, HIV, Syphilis, Gonorrhea, Chlamydia, Trichomonas, Full High Risk Utox from Millenium Lab and PPD placement.

2.9 Anyone with a substance use disorder or living with someone with a substance use disorder should be prescribed naloxone in case of overdose.

3. Management of OUD with Buprenorphine-Naloxone

3.2 Initially, Customer Owners should be seen frequently while induction is being completed, from daily to every 2-3 days. Then weekly visits until they are well stabilized. Once well stabilized, frequency will be determined by the provider and Customer Owner.

3.3 Consideration for alternatives to Office-Based Inductions for:

3.3.1 Women with acute medical or surgical illness

3.3.2 Complicated obstetric co-morbidities

3.3.3 Customer Owner requests admission

3.3 Considerations for Buprenorphine

3.3.1 Women with polysubstance abuse may be initiated on buprenorphine if the provider believes that the patient has a good likelihood of abstinence from other substances (ie: alcohol, cocaine, methamphetamine) once on opioid replacement therapy. This is often a subjective decision, which can be based on initial interview, past history and substance abuse review and conversations with substance abuse counselor if already engaged.

3.3.2 It is important to discuss the dangers of using benzodiazepines when taking buprenorphine with Customer Owners. Overdose deaths have occurred when buprenorphine and benzodiazepines were concomitantly abused. The customer owner should also be informed of the risk of using alcohol and buprenorphine.

3.3.3 Chronic active hepatitis with laboratory evidence of significant liver damage is not an absolute contraindication, but the provider may need to consider MAT induction using monoproduct (buprenorphine alone/Subutex) and/or maintenance with the monoproduct at lower doses and with closer monitoring.

3.4 Guidelines for MAT Induction of the Pregnant Customer Owner

3.4.1 Instruct Customer Owner to withhold using any opioids prior to induction day in order to precipitate mild to moderate withdrawal symptoms. This period will vary by Customer Owner based on a number of factors. These include the Customer Owner's level of tolerance and the dose of substance that they use. In general, this should take 12-16 hours for short-acting opioids (heroin, hydrocodone. oxycodone-immediate release, morphine), 17-24 hours for intermediate-acting opioids (oxycodone-sustained release, oxycontin), and 30-48 hours, or longer, for long-acting opioids such as methadone. The longer one can hold off on giving the first dose of buprenorphine, the easier the induction will be. Consider giving the Customer Owner a copy of the COWS score.

3.4.2 Review and sign INFORMED CONSENT AND TREATMENT AGREEMENT FORM (Appendix C).

3.4.2.1 DAY ONE

3.4.2.1.1 Instruct Customer Owner on how to take a sublingual tablet or film and review the Customer Owner information about induction.

3.4.2.1.2 Assess for signs of opiate withdrawal and obtain COWS score. This COWS assessment can be performed by the CMA A COWS score >8 will indicate mild withdrawal. (Note: Customer Owners with low opioid dependence may never reach COWS score of 8 or higher).

3.4.2.1.3 Administer Customer Owner's first dose, 2-4 mg of buprenorphine-naloxone sublingual. Withdrawal symptoms may or may not be improved with the first dose, depending on their degree of dependence, and are often not alleviated or improved at all if given 2 mg dose. Significant symptom improvement often does not occur until about 40 minutes following the first dose of the opioid agonist.

3.4.2.1.4 Withdrawal should be assessed every 60 minutes after the first dose with the COWS. If she does not have worsening withdrawal, but still has existing withdrawal symptoms, she should receive an additional 2 or 4 mg SL. Once there are no signs of withdrawal after these doses, then the Customer Owner may leave with an additional 2 or 4 mg dose. Most will respond well with doses of 16 mg or less daily and if symptoms of withdrawal still exist, consider other settings for MAT including residential, Detox, or methadone outpatient.

3.4.2.1.5 Due to increased metabolic rate in pregnancy, twice a day dosing or "split-dosing" can sometimes be more effective than once a day dosing in pregnant Customer Owners. Use caution to avoid the customer owner from getting a positive response instead of the desired elimination of withdrawal symptoms. Customer Owner should be cautioned about taking buprenorphine-naloxone on an as needed basis which reinforces addiction behavior. Prior to initiating split dosing, increase the daily dose to achieve absence of withdrawal symptoms in the 24-hour period.

3.4.2.2 DAY TWO or THREE

3.4.2.2.1 Assess Customer Owner's response to first day's dosing.

3.4.2.2.2 Assess vital signs and signs of withdrawal and obtain COWS score.

3.4.2.2.3 If opioid withdrawal symptoms were fully suppressed and Customer Owner is feeling no withdrawal or cravings between doses, then keep dose at first day's total dose. Otherwise increase the dose by 2 or 4 mg on day 2.

3.4.2.3 AFTER INDUCTION

3.4.2.3.1 Once the Customer Owner is stable, continue that dose for 3-7 days until steady-state levels are achieved before increasing the dose further. Doses should be decreased by 2 mg at a time if the Customer Owner experiences intoxication (not withdrawal effects).

3.4.3 Post Induction Surveillance

3.4.3.1 After induction, the Customer Owner should be seen at least weekly by both the provider and the BHC.

3.4.3.2 Assess for any illicit substances by the Customer Owner's report and urine drug testing

3.4.3.3 Assess for use of sedative hypnotic drugs (e.g. benzodiazepines) or heavy alcohol

3.4.3.4 Query of the Prescription Drug Monitoring Program (PDMP) reveals no unexplained, unadmitted, or otherwise concerning findings.

3.4.3.5 Assess whether the Customer Owner is taking buprenorphine as directed, with no requests for early refills, lost/stolen prescriptions, etc. and whether drug craving is under reasonable control.

3.5 Maintenance of Medication-Assisted Treatment during Pregnancy

3.5.1 The goals of maintenance are to prevent the emergence of opioid withdrawal symptoms, suppress the Customer Owner's craving for opioids, and greatly attenuate the effect of self-administered opioids in Customer Owners who continue to episodically use illicit opioids.

3.5.2 Maintenance doses can be determined by 7 days post induction. Most Customer Owners can be stabilized on a dose between 8 mg and 16 mg/24 hours (4 mg or 8 mg SL BID). If the customer owner requires a dose higher than 16 mg daily, consider residential treatment or treatment with outpatient methadone.

3.5.3 The prescribing provider, BHC, and Customer Owner will agree on frequency of visits to monitor MAT. Initially, the Customer Owner should be seen every 2-3 days for the first two weeks and then weekly if indicated.

3.5.4 At each visit, effective dosing should be assessed and monitored.

3.5.5 Doses should be titrated according to regular review of the following clinical signs/symptoms:

3.5.5.1 Intoxication, withdrawal, and cravings over the past 24 hours

3.5.5.2 Additional drug use and the Customer Owner's reason for use of illicit street drugs or prescription opioids

3.5.5.3 Side effects or other adverse events

3.5.5.4 Adherence to dosing regimen

3.5.5.5 Customer Owner's expressed satisfaction

3.5.6 The Community Resource Specialist and the Behavioral Health Consultant will be utilized to see the Customer Owner at each appointment to assess social needs, motivation for recovery, and ongoing support of recovery efforts and plan.

4 Intrapartum and Postpartum Medication-Assisted Treatment

4.1 Methadone, buprenorphine/buprenorphine-naloxone should be continued during antepartum, intrapartum, and postpartum care.

4.2 Be aware of the Customer Owner's usual dose and schedule and try to maintain. (However, withdrawal is unlikely if the Customer Owner is receiving opioids for pain control.)

4.3 Fentanyl may be used for analgesia, but higher and more frequent dosing may be required.

4.4 Epidurals and nitrous oxide are preferred for pain management.

4.5 Stadol (Butorphanol) is to be avoided. It is a partial narcotic antagonist which may precipitate withdrawal.

4.6 Expect decreased FHR variability and fewer accelerations.

4.7 Naloxone (Narcan) may be used as a life-saving measure in the mother. Opioid withdrawal seizures may occur if used during infant resuscitation.

4.8 A urine drug screen should be ordered to confirm the absence of other drugs that may affect management.

4.9 Maximize non-narcotic medications and adjunct comfort measures. Lortab or Percocet may be used while on buprenorphine. Watch the acetaminophen cumulative dose. Providers are encouraged to use the smallest amount of narcotics upon discharge and arrange daily follow up contact either in clinic or by phone.

4.10 Breastfeeding should be encouraged in women who are stable on their opioid agonists, without using illicit drugs for at least 90 days. If they are stable with their treatment without relapse for

30-90 days the recommendation for breastfeeding should be made on a case by case basis factoring in their likelihood for relapse into illicit drug use. The amount of buprenorphine in human milk is small and unlikely to have short-term negative effects on the developing infant. Breastfed infants have less severe NAS and are less likely to require pharmacological intervention than the formula-fed infants. Women should be counseled about the need to suspend breastfeeding in the event of a relapse.

4.11 The neonate will need to stay at least 72 hours. During the time from the mother's discharge to the baby's discharge, the Customer Owner should have their own buprenorphine or methadone to take. Rooming in with newborn is encouraged.

4.12 Access to adequate postpartum psychosocial support services, including substance use disorder treatment and relapse prevention programs, should be made available.

4.13 Contraceptive counseling and access to contraceptive services should be a routine part of substance use disorder treatment among women of reproductive age to minimize the risk of unplanned pregnancy.

References:

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Vermont Guidelines for Medication Assisted Treatment (MAT) for Pregnant Women. http://contentmanager.med.uvm.edu/docs/default-source/vchip-documents/vchip_4mat_guidelines.pdf?sfvrsn=2

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Dosing Guide For Optimal Management of Opioid Dependence. http://www.naabt.org/documents/Suboxone_Dosing_guide.pdf

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APPENDIX A
Clinical Opiate Withdrawal Scale

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

Customer Owner's Name:_____ Date and Time ____/_____/____:_____ **Reason for this assessment**:_____	
Resting Pulse Rate: _____beats/minute *Measured after Customer Owner is sitting or lying for one minute* 0 pulse rate 80 or below 1 pulse rate 81-100 2 pulse rate 101-120 4 pulse rate greater than 120	**GI Upset**: *over last ½ hour* 0 no GI symptoms 1 stomach cramps 2 nausea or loose stool 3 vomiting or diarrhea 5 Multiple episodes of diarrhea or vomiting
Sweating: *over past ½ hour not accounted for by room temperature or Customer Owner activity.* 0 no report of chills or flushing 1 subjective report of chills or flushing 2 flushed or observable moistness on face 3 beads of sweat on brow or face 4 sweat streaming off face	**Tremor** *observation of outstretched hands* 0 No tremor 1 tremor can be felt, but not observed 2 slight tremor observable 4 gross tremor or muscle twitching
Restlessness *Observation during assessmen*t 0 able to sit still 1 reports difficulty sitting still, but is able to do so 3 frequent shifting or extraneous movements of legs/arms 5 Unable to sit still for more than a few seconds	**Yawning** *Observation during assessment* 0 no yawning 1 yawning once or twice during assessment 2 yawning three or more times during assessment 4 yawning several times/minute
Pupil size 0 pupils pinned or normal size for room light 1 pupils possibly larger than normal for room light 2 pupils moderately dilated 5 pupils so dilated that only the rim of the iris is visible	**Anxiety or Irritability** 0 none 1 Customer Owner reports increasing irritability or anxiousness 2 Customer Owner obviously irritable anxious 4 Customer Owner so irritable or anxious that participation in the assessment is difficult
Bone or Joint aches *If Customer Owner was having pain previously, only the additional component attributed to opiates withdrawal is scored* 0 not present 1 mild diffuse discomfort 2 Customer Owner reports severe diffuse aching of joints/ muscles 4 Customer Owner is rubbing joints or muscles and is unable to sit still because of discomfort	**Gooseflesh skin** 0 skin is smooth 3 piloerrection of skin can be felt or hairs standing up on arms 5 prominent piloerrection
Runny nose or tearing *Not accounted for by cold symptoms or allergies* 0 not present 1 nasal stuffiness or unusually moist eyes 2 nose running or tearing 4 nose constantly running or tears streaming down cheeks	Total Score _____ The total score is the sum of all 11 items Initials of person completing Assessment: _____

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

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APPENDIX B

DSM-V OPIOID USE DISORDER CRITERIA

Diagnostic and Statistical Manual of Mental Disorders, 5th edition (DSM-5)

Opioid use disorder is defined as **two or more** of the following within a 12-month period:

- Using larger amounts of opioids or over a longer period than was intended
- Persistent desire to cut down or unsuccessful efforts to control use
- Great deal of time spent obtaining, using, or recovering from use
- Craving, or a strong desire or urge to use substance
- Failure to fulfill major role obligations at work, school, or home due to recurrent opioid use
- Continued use despite recurrent or persistent social or interpersonal problems caused or exacerbated by opioid use
- Giving up or reducing social, occupational, or recreational activities due to opioid use
- Recurrent opioid use in physically hazardous situations
- Continued opioid use despite physical or psychological problems caused or exacerbated by its use
- Tolerance (marked increase in amount; marked decrease in effect)
- Withdrawal syndrome as manifested by cessation of opioids or use of opioids (or a closely related substance) to relieve or avoid withdrawal symptoms.
- Tolerance and withdrawal criteria are not considered to be met for those taking opioids solely under appropriate medical supervision.
- Severity of opioid use disorder is categorized as mild (presence of 2-3 symptoms), moderate (4-5 symptoms), or severe (6 or more symptoms).
- Remission of opioid use disorder is categorized as:
- In early remission: where none of the criteria for opioid use disorder have been met for at least 3 months but for less than 12 months (with the exception of craving, or a strong desire or urge to use opioids), but full criteria for opioid use disorder were previously met.
- In sustained remission: where none of the criteria for opioid use disorder have been met at any time during a period of 12 months or longer (with the exception of craving, or a strong desire or urge to use opioids), but full criteria for opioid use disorder were previously met.

APPENDIX C

Suboxone or Subutex Treatment Agreement

I, (name of patient) _____, DOB: _____, have been advised of the risks and benefits of the use of Suboxone or Subutex in the treatment of opioid abuse and dependence. I freely and voluntarily agree to accept this treatment agreement as follows:

1) I agree to keep, and be on time to, all my scheduled appointments with the physician and/or treatment team. I agree to call the OB provider team if I am running late for any reason.

2) I agree to conduct myself in a courteous manner in the treatment setting.

3) I agree not to arrive at the office intoxicated or under the significant influence of drugs or alcohol. If I do, I will not be given a prescription.

4) I agree not to sell, share, give, or steal any medication from another individual. I understand that such mishandling of my medication is a serious violation of this agreement.

5) I agree that my medications (or prescriptions) can be given to me only at my regularly scheduled appointments. Any missed appointments may result in my not being able to receive medications until my next scheduled appointment.

6) I agree that the medication I receive is my responsibility and that I will keep it in a safe, secure place, especially away from children. I agree that lost or stolen medication will not be replaced regardless of the reasons for such loss.

7) I agree not to obtain any controlled substances from any physician, pharmacy, or other source without informing my OB provider team. I understand that mixing Suboxone or Subutex with other medications, especially benzodiazepines such as diazepam/Valium, lorazepam/Ativan, alprazolam/Xanax, and other drugs of abuse can be lethal. I also understand that a number of deaths have been reported among individuals mixing Suboxone or Subutex with alcohol.

8) I agree to take my medication as the OB provider has instructed and not to alter the way I take my medications without first consulting with my provider.

9) I understand that medication alone is not sufficient treatment for opioid dependence, and I agree to participate in the treatment plan as agreed upon with the treatment team.

10) I agree to abstain from alcohol, opioids, benzodiazepines, marijuana, stimulants such methamphetamine and cocaine, and other addictive substances (with the exception of nicotine and caffeine only).

11) I agree to return all phone calls as soon as possible, no later than 24 hours from the time that I am called.

12) I agree to complete random urine drug/alcohol screens as requested by the treatment team and within 24 hours of being called.

13) I agree to complete random pill or strip counts as requested by the treatment team and within 24 hours of being called.

14) I understand that if I am unable to consistently work together with the OB provider team to meet the above components of this Treatment Agreement, then I may require increased support such as: more frequent visits or increased peer-support meeting attendance, referral to a higher level of care such as outpatient, intensive outpatient, or residential treatment, referral to a more regimented suboxone program, referral to a methadone program, or other changes in my treatment plan.

Patient signature: _____ Date: _____