SUMMARY

GOALS
- Patients abstain from illicit drugs.
- Patients with opioid use disorder (OUD) who may benefit from Medication Assisted Treatment (MAT) have early engagement and retention to reduce maternal, fetal, and neonatal risks.
- Providers identify contraindications and drug interactions that would preclude MAT.

ALERTS
- Pregnant women with OUD should be co-managed by an Addiction Medicine Provider and an Obstetrical (OB) Provider (high-risk consult per local operating procedures).
- Patients on buprenorphine or naltrexone in need of acute pain treatment with opioids must be transferred to an emergency department (ED) to overcome partial or full opioid receptor blockade in a monitored setting.

DIAGNOSTIC CRITERIA

DSM-5 OUD is defined as a pattern of opioid use characterized by tolerance, craving, inability to control use, and continued use despite adverse consequences. When the substance being used involves heroin, diverted or misused prescription opioids, or other morphine-like drugs, then OUD is diagnosed.

OUD is manifested by at least two of the criteria listed below occurring within a 12-month period. Severity of illness is determined by the number of criteria present:

- Use of larger amounts/longer period of time than intended
- Repeated attempts to quit/control use
- A great deal of time spent using
- Neglect of work, school, or home in order to use

-Mild: presence of 2-3 criteria
-Moderate: presence of 4-5 criteria
-Severe: presence of 6 or more criteria

EVALUATION

- In addition to a standard history and physical examination, an obstetric and prenatal history should be obtained.
- Assessment should include identifying potential withdrawal symptoms by use of the Clinical Opiate Withdrawal Scale (COWS) and performing urine toxicology surveillance.
- Given the complexities of a potentially high-risk pregnancy, collaborative care with the Primary Care Provider, Nursing, Addiction Medicine Provider, designated Social Worker (SW), Mental Health (MH), Pharmacist, and Correctional Counselors is key.
- MH referral should be considered if the patient presents any signs of peripartum depression and/or underlying mental illness.
- Community High-Risk OB consultation may also be necessary if there is a history of complicated pregnancies in the past, comorbid chronic health conditions, or if unexpected problems develop during the pregnancy.

TREATMENT

- MAT is the use of FDA-approved medications, in combination with counseling and behavioral therapies, to provide a “whole-patient” approach to the treatment of OUD. MAT use in the pregnant woman with OUD is especially useful to stabilize the patient in order to prevent withdrawal and the associated risk of miscarriage, premature delivery, and other serious complications.
- Buprenorphine or methadone are the agents most commonly used for MAT in pregnant women.
- Naltrexone is not typically initiated in pregnant women, but may be continued for those patients already taking this medication.
- Risks and benefits of MAT should be discussed. (See Introduction: OUD in Pregnancy section page 3)
- If a pregnant woman becomes incarcerated and is on MAT at the time of reception, she is to be continued on the same medication and dosing regimen with subsequent adjustment only as needed to promote stabilization.
- Incarcerated women with OUD who become pregnant and are not on MAT may be considered for MAT; order an urgent (within 24 hours) consult to Addiction Services and contact the MAT team upon pregnancy diagnosis via email at MAT@CDCR.CA.GOV.

MONITORING

- While on MAT, patients should be monitored closely with follow-up visits at least every month during pregnancy.
- Frequent maternal follow-up to monitor for OUD relapse or other clinical complications should continue into the first few months postpartum as high risk for relapse exists.
- A urine drug test (UDT) should be performed at baseline and monthly or more frequently based on signs and symptoms of OUD.
- An electrocardiogram (EKG) should also be performed at baseline, within one month of initiating MAT, then annually if continued on treatment.

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Information contained in the Care Guide is not a substitute for a health care professional’s clinical judgment. Evaluation and treatment should be tailored to the individual patient and the clinical circumstances. Furthermore, using this information will not guarantee a specific outcome for each patient. Refer to “Disclaimer Regarding Care Guides” for further clarification. [https://cchcs.ca.gov/clinical-resources/](https://cchcs.ca.gov/clinical-resources/)
Patient arrives at R & R ON MAT with confirmed pregnancy, RN:
- Confirms pregnancy & current MAT dosing
- Obtains documentation of last MAT administration
- Completes COWS (See Attachment A)
- Alerts provider and Addiction Services of admission

- Transfer to TTA or ED for stabilization
- Consult with Addiction Services for MAT dosing

Provider completes H&P including:
- Obstetrical and psychosocial assessment
- PHQ-9 (See Attachment B)
- Labs: CMP, CBC, INR, Lipid Panel, UDT, ECG

Evidence of significant withdrawal?
- Yes
  - (COWS ≥11)

  No
  - (COWS <11)
  
  Dosing of MAT known?
  - Yes

Provider will:
- Order MAT (same medication and dose) for 3 days (See bottom of page 3 for bridging orders)
- Consult with Community High-Risk OB if indicated
- Coordinate with Addiction Services for OUD assessment and ongoing MAT provision
- Consider a MH referral if any signs of peripartum depression and/or underlying mental illness are present

Continuation of MAT depends on agent being utilized:
- Methadone: Offsite Specialty Services RN will coordinate care with local community NTP
- Buprenorphine: X-Waivered Provider prescribes buprenorphine which is given daily at the institution

Pre-delivery:
- Follow up with OB provider per usual schedule or more frequently if needed (See page 4)
- UDT done at least 1x every month
- At delivery, records should be sent to outside hospital
- Assess post partum Community Prison Mother Program options to make plan for MAT post-delivery
- Note: MAT medication dose is likely to drop after delivery

Post-delivery MAT continuation:
- Methadone: Patient continues daily transfer to NTP, or, depending on local arrangements, unit dosing may be provided by NTP for onsite daily administration; Addiction Specialist may consider changing to buprenorphine after delivery
- Buprenorphine: Addiction Specialist prescribes buprenorphine and transitions to buprenorphine/naloxone
- Maintain PREGNANCY Medical Classification Chrono (MCC) for 6 weeks

If patient releases on MAT, Addiction Services will:
- Coordinate continuity of care
- Provide discharge MAT RX if indicated
- Ensure Naloxone is provided
- Ensure ROI is completed

HIM will release health records

Acronym Legend:
COWS = Clinical Opiate Withdrawal Scale
H&P = History and Physical Examination
NTP = Narcotic Treatment Program
R&R = Receiving and Release
ROI = Release of Information
PHQ-9 = Patient Health Questionnaire
TTA = Triage and Treatment Area
**INTRODUCTION: OUD in Pregnancy**

OUD in pregnancy has escalated in recent years, paralleling the epidemic observed in the general population. The increased prevalence of opioid use during pregnancy has led to an upsurge in neonatal abstinence syndrome (NAS); however, it is important to remember that NAS is an expected and treatable condition that has not been found to have any significant effect on cognitive development.

MAT improves adherence to prenatal care and addiction treatment programs, and has been shown to reduce the risk of pregnancy complications. It is the recommended course of therapy for pregnant women with OUD.

There may be a select group of women who make an informed decision to discontinue MAT; discontinuation of MAT should be accomplished in a monitored setting under the care of an experienced physician. Regardless of the decision regarding MAT continuation, it is critical that the patient receives long-term follow-up and support to prevent relapse, which can pose grave risks.

Benefits of MAT for pregnant patients with OUD include:
- Stabilizes drug level over the course of the day and prevents opioid withdrawal symptoms
- Reduces the risk of relapse and its associated consequences including risk of infectious diseases
- Improves adherence to prenatal care, addiction treatment programs, and preparation for delivery
- Decreases risk of miscarriage, decreases preterm labor, and improves birthweight
- Reduces maternal mortality and severe morbidity

**Patient Evaluation**

If a patient arrives at R&R and reports they are currently on MAT for OUD, the R&R RN should notify the R&R/On-call provider to order a consult to Addiction Services, order a 3-day bridge (see MAT Continuation below), and notify the MAT team by email: MAT@CDCR.CA.GOV.

- A routine H&P examination should be completed including past, family, and psychosocial history. In addition, an OB/prenatal history should be completed and determination of estimated delivery date.
  - Review current medications, allergies and problem list
  - Labs: CMP, CBC, INR, Lipid Panel, EKG, Urine for Toxicology Screening and pregnancy confirmation
  - PHQ-9 for depression screening should be completed; if >10, refer to MH for assistance with managing peripartum depression. (See Attachment B, Patient Health Questionnaire –9)
  - Aside from a routine H&P, it is important to detect any signs of withdrawal such as achiness, anxiety, increased sensitivity to pain, irritability, restlessness, sweating, pupillary dilation, runny nose, tearing, gastrointestinal upset, tremor, yawning, or gooseflesh skin. (See COWS, Attachment A, Client Opiate Withdrawal Scale)
  - Any signs of withdrawal require immediate attention.
  - For moderate, moderately severe, and severe withdrawal (COWS ≥13), the patient should be treated and monitored in a higher level of care until stabilized. This can often be accomplished in the TTA in coordination with the Addiction Medicine Provider, however if during evenings or weekends, transfer to the ED may be necessary.

**MAT Continuation**

Typically patients enter CDCR from the jail with their pregnancy recognized and already on MAT therapy.

Patients already established on a specific therapy should be continued on that specific therapy. There is no indication to switch medication. Because of the high risk of relapse and possible consequences (i.e., overdose and death), continuation of MAT is highly recommended.

Medications most commonly used to treat OUD include methadone and buprenorphine. Both of these medications prevent opioid withdrawal and reduce opioid cravings, allowing the person to focus on other aspects of recovery.

Comparisons of treatment risks and benefits for both agents is provided on page 6.

Should a patient request to discontinue MAT:
- Ensure the patient is aware of the risks and benefits of doing so
- Arrange hospital transfer for fetal monitoring during the entire withdrawal process

Any prescriber can continue either methadone or buprenorphine for a “bridge” period of 3 days to allow time to arrange longer term therapy continuation.

**Title 21, Code of Federal Regulations, Part 1306.07(b):**

Provides a practitioner flexibility in emergency situations where he/she may be confronted with a patient undergoing withdrawal. In such emergencies, it is impractical to require practitioners to obtain a separate registration to treat opioid dependency while arranging for the patient’s referral for treatment under the following conditions:

1. Not more than one day’s medication may be administered or given to a patient at one time;
2. This treatment may not be carried out for more than 72 hours and;
3. This 72-hour period cannot be renewed or extended.
Management of a pregnant patient with OUD on MAT requires a collaborative approach with Nursing, Primary Care Provider, Addiction Medicine Provider, designated SW, MH, Pharmacist, and Correctional Counselors.

<table>
<thead>
<tr>
<th>Role</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>CCHCS OB Provider</td>
<td>Responsible for all medical and prenatal care needs throughout pregnancy and coordinates with other disciplines as needed.</td>
</tr>
<tr>
<td>Community High-Risk OB</td>
<td>Should be consulted for complicated pregnancies (i.e., women with a history of complicated pregnancies in the past, chronic health conditions, and for women who develop unexpected problems during their pregnancy).</td>
</tr>
<tr>
<td>Mental Health</td>
<td>Should be consulted if/when patient presents any signs of peripartum depression and/or underlying mental illness.</td>
</tr>
<tr>
<td>Addiction Medicine Provider</td>
<td>Follows the patient throughout and beyond pregnancy at least monthly to assure uninterrupted MAT provision. In the case of methadone, coordination with a local Narcotic Treatment Program (NTP) will be arranged, whereas buprenorphine will be prescribed and dispensed onsite.</td>
</tr>
<tr>
<td>Designated Social Worker</td>
<td>Reviews placement options for the child, and provides information regarding the Community Prison Mother Program. If the patient is interested, she is referred to their Correctional Counselor I to determine eligibility. The designated SW may also assist with transition planning in cases where the pregnant women is released.</td>
</tr>
</tbody>
</table>

Typical interval for CCHCS OB Provider follow-up visits during pregnancy are as follows:

<table>
<thead>
<tr>
<th>Gestation (weeks)</th>
<th>Minimum Follow-up Frequency</th>
</tr>
</thead>
<tbody>
<tr>
<td>4-28</td>
<td>Monthly</td>
</tr>
<tr>
<td>28-36</td>
<td>Every 2 weeks</td>
</tr>
<tr>
<td>36-40</td>
<td>Weekly</td>
</tr>
</tbody>
</table>

Follow-up frequency may be increased as needed.

In addition to routine prenatal care, it is important to:
- Maintain ongoing assessment for signs or symptoms of acute withdrawal (See COWS, Attachment A),
- Assess for changes in psychosocial needs, and
- Repeat UDT surveillance. UDT should be done at least monthly and more often as indicated.

Any signs of deficient fetal growth may call for antenatal testing. If necessary, such testing should be performed at least 4-6 hours after the last opioid agonist treatment dose in order to reduce false positive rates.

**Labor and Delivery**

Communication is critical when preparing to transfer the patient to the hospital for labor and delivery in order to ensure:
- Uninterrupted continuation of either buprenorphine or methadone at the current dose.
- Appropriate planning for pain management such as utilizing epidural analgesia, as well as oral and injectable acetaminophen and nonsteroidal anti-inflammatory drugs (NSAIDS), and/or short acting opioid medication.
- Appropriate consultations should be made to Community High-Risk OB and Addiction Medicine Providers as needed.

**Postpartum Period**

- Postpartum time frame typically ranges from delivery to six weeks.
- Upon the patients’ return from delivery, the patient will resume care with both the Primary Care Provider and the Addiction Medicine Provider.
- Monitoring for signs and symptoms of intoxication or withdrawal during the postpartum period is important since as fluid shifts and volume of distribution change, medication doses may need to be adjusted.
- Breastfeeding is recommended in women who are stable on their opioid agonist, not using illicit drugs, and have no other contraindication such as HIV infection. Only trace amounts of opioid agonists are found in breast milk.
- Women who wish to discontinue breastfeeding are advised to gradually wean the infant from breast milk to prevent sudden withdrawal in the infant.
- If the patient has access to future conjugal visitations, discuss postpartum contraception options.
- Monitor the patient for postpartum depression.
- Maintain ‘PREGNANCY’ designation in the MCC for at least six weeks post-partum in order to continue bottom bunk assignment and other restrictions.
- MAT is continued by the Addiction Medicine Provider, as clinically appropriate.
**Methadone for OUD can only be provided by a federally licensed NTP.**

At this time, CDCR is not a designated NTP; however, methadone can be ordered and administered for up to three days (see MAT Continuation section page 3).

Typically, subsequent dosing is provided by a nearby NTP with transfers of the patient to the NTP for liquid methadone administration. Depending on local arrangements, a small supply of patient specific daily doses (unit dosing) may be provided to the institution by the NTP for a time period up to one month to reduce the burden of the needing to transport the patient to the NTP as frequently. The methadone is kept securely on-site for daily administration at the institution. While the methadone is being administered at the institution, the Federal license and responsibility of the methadone for MAT remains with the NTP.

Throughout pregnancy, methadone dosing may need to be adjusted due to metabolic and circulatory volume fluctuations. The goal is to maintain the patient on the lowest dose that controls withdrawal symptoms and minimizes the desire to use additional opioids.

**Obtaining a Buprenorphine X-Waiver**

Qualified providers are allowed to apply for waivers to treat opioid dependency with approved buprenorphine products in any setting in which they are qualified to practice, including an office, community hospital, health department, or correctional setting. A qualified provider is limited to treating up to 30 patients in their first year but may petition for increases in subsequent years.

**SOCIAL MEDIA SUPPORT**

**PATIENT EDUCATION/SELF MANAGEMENT**

**Buprenorphine**

In the US, buprenorphine for OUD can be dispensed by an NTP and can be prescribed by providers who have undergone appropriate X-Waiver credentialing.

- Providers with an X-Waiver can continue buprenorphine.
- Providers without an X-Waiver may order buprenorphine to be administered for opiate withdrawal and to prevent withdrawal for up to three days.
- The patient’s buprenorphine dosing should be maintained during intrapartum and postpartum periods.

**Obtaining a Buprenorphine X-Waiver**

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**Additional Information and Resources may be found at:**


**Methadone**

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- Throughout pregnancy, methadone dosing may need to be adjusted due to metabolic and circulatory volume fluctuations. The goal is to maintain the patient on the lowest dose that controls withdrawal symptoms and minimizes the desire to use additional opioids.

**Monitoring**

Close monitoring is important to the health and safety for both the mother and baby.

- The frequency of UDT to monitor adherence to therapy and continued illicit drug use varies by phase of treatment and signs/symptoms of OUD withdrawal. Therefore, UDT frequency is recommended at least monthly and more often as clinically indicated (e.g., during dose adjustments).
- An EKG should be performed at baseline (within the first month of initiating MAT) and annually to monitor for QT Prolongation.
## Treatment (Cont.)
### Comparison of Buprenorphine vs. Methadone in Pregnancy

Programs treating pregnant woman with OUD in the United States use either buprenorphine or methadone for first-line therapy. There are some differences in maternal and fetal/infant effects. Please see the comparison table below.

<table>
<thead>
<tr>
<th>Maternal Considerations</th>
<th>Buprenorphine</th>
<th>Methadone</th>
</tr>
</thead>
<tbody>
<tr>
<td>Treatment retention</td>
<td>No significant difference</td>
<td>No significant difference</td>
</tr>
<tr>
<td>Rate of other opioid use</td>
<td>More</td>
<td>Less</td>
</tr>
<tr>
<td>Starting dose</td>
<td>2 to 4 mg sublingually</td>
<td>20 to 30 mg orally</td>
</tr>
<tr>
<td>Typical dose</td>
<td>16 mg sublingually daily</td>
<td>80 to 120 mg orally daily</td>
</tr>
<tr>
<td>Requires increased dose in pregnancy</td>
<td>Less often</td>
<td>Often (in 2nd and 3rd trimester, methadone dose may need to be increased due to increased metabolism and circulation blood volume)</td>
</tr>
<tr>
<td>Interval at which dose may be increased</td>
<td>Daily, but dose changes should not be made without patient assessment</td>
<td>3 days, but dose changes should not be made without patient assessment</td>
</tr>
<tr>
<td>Risk of sedation</td>
<td>Sedation is possible but typically milder than that with full opioid agonists</td>
<td>Sedation is possible and may be greater than that with partial agonist opioids</td>
</tr>
<tr>
<td>Cardiovascular side effects</td>
<td>Low risk of adverse cardiovascular side effects</td>
<td>Small increase in risk of arrhythmia</td>
</tr>
<tr>
<td>Overdose risk</td>
<td>Lower risk (due to “ceiling effect”)</td>
<td>Higher risk (especially when combined with other central nervous system depressants)</td>
</tr>
</tbody>
</table>

### Fetal/Infant Considerations

<table>
<thead>
<tr>
<th>Considerations</th>
<th>Buprenorphine</th>
<th>Methadone</th>
</tr>
</thead>
<tbody>
<tr>
<td>Spontaneous fetal death</td>
<td>No difference</td>
<td>No difference</td>
</tr>
<tr>
<td>Congenital anomalies</td>
<td>No difference</td>
<td>No difference</td>
</tr>
<tr>
<td>Preterm birth</td>
<td>Lower risk</td>
<td>Higher risk</td>
</tr>
<tr>
<td>Birth weight</td>
<td>Higher</td>
<td>Lower</td>
</tr>
<tr>
<td>Head circumference</td>
<td>Larger</td>
<td>Smaller</td>
</tr>
<tr>
<td>Sudden infant death</td>
<td>No significant difference</td>
<td>No significant difference</td>
</tr>
<tr>
<td>Birth defects</td>
<td>Rare. Incidence similar to what would be in the general population</td>
<td>Rare. Incidence similar to what would be in the general population</td>
</tr>
<tr>
<td>Risk of NAS</td>
<td>Approximately 50% of exposed neonates are treated for NAS; NAS may be milder with buprenorphine</td>
<td>Approximately 50% of exposed neonates are treated for NAS</td>
</tr>
<tr>
<td>Onset of NAS</td>
<td>12-48 hours</td>
<td>48-72 hours (up to 1 month)</td>
</tr>
<tr>
<td>Duration of NAS</td>
<td>Shorter</td>
<td>Longer</td>
</tr>
<tr>
<td>Breastfeeding</td>
<td>Low amounts excreted in breast milk. Encouraged in women who are stable on opioid agonists, not using illicit drugs and no other contraindications</td>
<td>Low amounts excreted in breast milk. Encouraged in women who are stable on opioid agonists, not using illicit drugs and no other contraindications</td>
</tr>
<tr>
<td>Neurodevelopmental outcomes</td>
<td>Most studies show no difference between prenatal buprenorphine exposure when compared to other opioids or controls up to five years. Research base is limited</td>
<td>Most studies show no difference between prenatal methadone exposure when compared to other opioids or controls up to five years. Research base is limited</td>
</tr>
</tbody>
</table>
# CCHCS Care Guide: MAT for Opioid Use Disorder in Pregnancy

October 2019

## Medications

<table>
<thead>
<tr>
<th>Medication</th>
<th>Dosing</th>
<th>Adverse Effects/Interactions*</th>
<th>Contraindications/Comments*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Buprenorphine (generic)</td>
<td>SL Tabs: 2mg – 8mg $$ - $$$</td>
<td>Adverse effects: Major: Addiction, abuse, misuse, lethargy, respiratory and CNS depression; avoid combining with other depressants, hypersensitivity reactions, elevation of cerebrospinal fluid pressure (caution in patients with head injury); elevation of intracholedochal pressure (caution in patients with biliary tract dysfunction); adrenal insufficiency. Common: Headache, dizziness, nausea, constipation, opioid withdrawal. Other: Neonatal Opioid Withdrawal Syndrome, hepatic events, orthostatic hypotension. May impair ability to drive or operate machinery. May obscure diagnosis and clinical course of an acute abdominal condition. Drug Interactions: CNS depressants- to include Benzodiazepine and muscle relaxants, and other opioids. Inhibitors of CYP3A4- can increase plasma concentrations of buprenorphine. Inducers of CYP3A4- can decrease plasma concentrations of buprenorphine. Serotonergic Drugs- serotonin syndrome. MAOIs- may cause serotonin syndrome, recommend to be off MAOIs x 14 day prior to initiation. Diuretics- opioids may reduce efficacy of diuretics. Anticholinergic Drugs- increases risk of urinary retention and constipation. Antiretrovirals. NNRTIs- may act as CYP3A4 inducer. Pls- may act as CYP3A4 inhibitor.</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Contraindications: Hypersensitivity to buprenorphine or any component of the product or delivery system. Avoid abrupt withdrawal.</td>
<td></td>
</tr>
</tbody>
</table>

**Bold = On Formulary for those participating in MAT**

*See prescribing information for complete description of dosing, adverse effects, contraindications, precautions and drug interactions.

The cost scale $-$$\$\$\$\$ represents the relative cost of acquisition of medication only. Frequency and complexity of medication administration (institution workload, effect on adherence) should be considered when determining overall cost-effectiveness of treatment.
### Methadone

For OUD can only be given in a federally licensed NTP beyond a 3-day bridge order and must be given as a.

**Soln:** 10mg/ml

At this time CDCR does not have a license to dispense methadone for OUD; please send patient to local NTP.

$3

### Dosing

Dosing information is for background only. Typically, dosing will already be established by an NTP provider. CCHCS will maintain the NTP’s dosing for 3-day bridge orders when needed.

- **Starting dose:** 20-30mg orally daily
- **Typical dose:** 80-120mg orally daily for maintenance
- **Max effect:** 7-10 days

- Severe renal (CrCl <10 mL/min) and severe hepatic (Child Pugh Class C) impairment:
- Dose adjustments recommended; monitor for signs of respiratory and CNS depression

### Adverse effects

- **Major:** Addiction, abuse, misuse, QT prolongation, sudden death, respiratory depression, hypotension
- **Common:** Nausea, vomiting, constipation, dizziness, sedation, sweating, weight gain
- **Other:** Neonatal Opioid Withdrawal Syndrome, seizures, increased cholesterol/triglycerides
- May impair ability to drive or operate machinery
- May obscure diagnosis and clinical course of an acute abdominal condition

### Drug Interactions

- Azole antifungals
- Antiarrhythmics
- Benzodiazepines
- Antipsychotics
- Cimetidine
- Cyclobenzaprine
- Macrolides
- Fluoroquinolones
- SSRIs
- TCAs
- Pentamidine
- Some HIV Meds
- Rifampin
- Carbamazepine
- Risperidone
- Phenobarbital
- Phenytoin

### Contraindications

- **Statements from the FDA regarding methadone:** Prescribers of methadone should be familiar with methadone’s toxicities and unique pharmacokinetic properties. Methadone dose should be slowly titrated. Physicians should closely monitor patients when changing the methadone dose, and thoroughly instruct patients how to take methadone.
- **Boxed warnings:** Life-threatening respiratory depression—monitor for respiratory depression especially during initiation or following dose increases.
- **Life-threatening QT prolongation—closely monitor patients for changes in cardiac rhythm during initiation and titration.

### Methadone use is associated with more frequent deaths than other opioids.

### Contraindications

- Hypersensitivity to methadone or any component of the product
- Significant respiratory disorder, acute or severe bronchial asthma in an unmonitored setting or in the absence of resuscitative equipment, paralytic ileus, hypercarbia

### Precautions

- Use caution in patients with chronic pulmonary disease, cardiac disease, urethral stricture, concurrent use with CNS depressants, pregnancy, hepatic or renal insufficiency, elderly
- Obtain ECG at baseline, 1 month & annually due to QT prolongation. (Increase ECG monitoring if patient receiving >100 mg/day or if unexplained syncope or seizure occurs while on methadone):
  - If QTc is >450 ms but <500 ms; consider risk vs. benefit- monitor more frequently
  - If QTc is >500 ms consider alternative therapy (buprenorphine or naltrexone), dose reduction, or elimination of contributing factors (e.g., other medications)

### Methadone’s elimination half-life (8-59 hours) is longer than its duration of analgesic action (4-8 hours).

Methadone’s peak respiratory depressant effects typically occur later, and persist longer than its peak analgesic effects. During treatment initiation, methadone’s full analgesic effect is usually not attained until 3-5 days of dosing. Initiation and titration to analgesic effect and dose adjustments should be done cautiously. In chronic use, methadone may be retained in the liver and then slowly released, prolonging the duration of action despite low plasma concentrations.

Incomplete cross-tolerance between methadone and other opioids makes the conversion of patients on other opioids to methadone complex and does not eliminate the possibility of methadone overdose, even in patients tolerant to other opioids. Deaths have been reported during conversion from chronic, high-dose treatment with other opioid agonists to methadone.

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**Bold = On Formulary for those participating in MAT**

*See prescribing information for complete description of dosing, adverse effects, contraindications, precautions and drug interactions.*

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The cost scale S-SSSSS represents the relative cost of acquisition of medication only. Frequency and complexity of medication administration (institution workload, effect on adherence) should be considered when determining overall cost-effectiveness of treatment.
# CCHCS Care Guide: MAT for Opioid Use Disorder in Pregnancy

## October 2019

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<tr>
<th>SUMMARY</th>
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<th>PATIENT EDUCATION/SELF MANAGEMENT</th>
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**WHAT IS OPIOID USE DISORDER?**

Opioid use disorder (OUD) is a treatable disease that can be caused by frequent opioid use. It is also known as opioid addiction.

- Addiction is a chronic disease. No one knows exactly why some people get addicted and some people do not. Your genes are a part of it. Often addiction runs in families.
- Lifestyle and your surroundings can put someone at higher risk of becoming addicted.
- Addiction cannot be cured, however it can be managed with counseling, medication, and support from family and friends.
- Recovery takes a lifetime of commitment, one day at a time.

Symptoms include:
- Strong cravings for drugs
- Feeling unable to stop or reduce opioid use
- Having work, school, legal, or family problems caused by your opioid use
- Needing more opioids to get the same effect
- Feeling sick after stopping or lowering use

**WHAT ARE THE RISKS OF OUD DURING PREGNANCY?**

OUD in pregnancy has a high risk of serious complications to you and your baby including:

- Fetal growth problems
- Preterm birth
- Stillbirth/death
- Increased risk for infection for the mother

You are also at risk of overdose. If you take too much of the drug you can pass out, your breathing can slow down or stop and you can die.

**HOW DOES OPIOID USE DURING PREGNANCY AFFECT A NEWBORN?**

When a baby is born to a woman who used opioids during pregnancy, they may have withdrawal symptoms. This is called neonatal abstinence syndrome (also known as NAS) and can last for days to weeks or months.

Symptoms of NAS include:
- Shaking and tremors
- Poor feeding or sucking
- Inconsolable crying
- Fever
- Diarrhea
- Vomiting
- Sleep problems

The use of other substances can make NAS syndrome worse in your baby. You should avoid smoking, alcohol use, and any other illicit drugs.
October 2019  CCHCS Care Guide: MAT for Opioid Use Disorder in Pregnancy

HOW IS OUD TREATED DURING PREGNANCY?

OUD can be treated during pregnancy with Medication Assisted Therapy (MAT). MAT has two parts:

1. **Counseling**: the opportunity to talk with a health care provider one-on-one or in a group
2. **Medication**: Opioid replacement medication

The use of MAT will help:
- Stabilize chemicals in your brain.
- Decrease withdrawal symptoms and cravings for opioids.
- Allow you to focus on therapy and not your next fix.

Through counseling, you can learn to:
- Move away from doing things that are bad for you.
- Change addictive thinking into non-addictive thinking.
- Make healthy decisions.
- Handle setbacks and stress.
- Move forward with your life.
- Move into a way of living referred to as recovery.
- Deal with feelings such as low self-worth.

WHAT IS THE GOAL OF MEDICATION ASSISTED THERAPY (MAT)?

- The goal of MAT is to help you avoid using the drug that you are addicted to.
- The risks of not taking MAT are much higher for you and the baby.

OPIOID REPLACEMENT MEDICATION

- Standard treatment for pregnant women with OUD is opioid replacement medication.
- The medications given are long-acting opioids, and they stay active in your body for a long time.
- These medications help reduce cravings for opioids, but do not cause the good feeling “high” that other opioids cause.
- Your health care provider will monitor you throughout your treatment to change doses if needed, and address any concerns you have.
- It is important to take the exact amount you have been prescribed.
- Treatment with the selected medication makes it more likely that your baby will grow normally and not be born too early.
- Based on many years of research, opioid replacement medication has NOT been found to cause birth defects.

WHEN DO I NEED TO REACH OUT TO MY HEALTH CARE PROVIDER?

You should NOT stop using opioids without medical supervision. Quitting without your provider’s help often leads to return to drug use which can be harmful for you AND your baby.

If you have any feelings of withdrawal, or immediate concerns, reach out to your health care provider.
EL TRASTORNO POR USO DE OPIOIDES Y EL EMBARAZO

¿QUÉ ES EL TRASTORNO DE USO DE OPIOIDES?

- El trastorno por uso de opioides (OUD) es una enfermedad tratable que puede ser causada por el uso frecuente de opioides. También se conoce como adicción a los opioides.
- La adicción es una enfermedad crónica. Nadie sabe exactamente por qué algunas personas se vuelven adictas y otras no. Sus genes juegan un papel en la adicción. A menudo la adicción ocurre en las familias.
- El estilo de vida y su entorno pueden aumentar el riesgo de que una persona se vuelva adicta.
- La adicción no se puede curar, sin embargo, se puede manejar con asesoramiento, medicamentos y apoyo de familiares y amigos.
- La recuperación requiere una vida de compromiso, un día a la vez.

Los síntomas incluyen:
- Antojos fuertes de drogas
- Sentirse incapaz de detener o reducir el uso de opioides
- Tener problemas laborales, escolares, legales o familiares causados por su uso de opioides
- Necesitando más opioides para obtener el mismo efecto
- Sentirse enfermo después de parar o bajar el uso de opioides

¿CUÁLES SON LOS RIESGOS DE OUD DURANTE EL EMBARAZO?

La OUD en el embarazo tiene un alto riesgo de complicaciones graves para usted y su bebé, que incluyen:
- Problemas de crecimiento fetal
- Parto prematuro
- Muerte fetal/muerte
- Mayor riesgo de infección para la madre

Usted también está en riesgo de sobredosis. Si toma demasiado de la droga puede desmayarse, su respiración puede disminuir o detenerse y puede morir.

¿CÓMO AFECTA EL USO DE OPIOIDES DURANTE EL EMBARAZO A UN RECIÉN NACIDO?

Cuando un bebé nace de una mujer que consumió opioides durante el embarazo, puede tener síntomas de abstinencia. Esto se llama síndrome de abstinencia neonatal (también conocido como NAS) y puede durar de días a semanas o meses.

Los síntomas de NAS incluyen:
- Temblores y estremecimiento
- Mala alimentación o succión
- Llanto inconsolable
- Fiebre
- Diarrea
- Vómito
- Problemas para dormir

El uso de otras sustancias puede empeorar el síndrome NAS en su bebé. Debe evitar fumar, el consumo de alcohol y cualquier otra droga ilícita.
¿Cómo se trata la OUD durante el embarazo?

La OUD se puede tratar durante el embarazo con la terapia asistida por medicamentos (MAT). MAT tiene dos partes:

1. **Asesoramiento**: la oportunidad de hablar con un proveedor de atención médica individualmente o en grupo
2. **Medicamentos**: medicamentos de reemplazo de opioides

El uso de MAT ayudará a:

- Estabilizar los químicos en su cerebro.
- Disminuir los síntomas de abstinencia y los antojos de opioides.
- Enfocarse en la terapia y no en su próxima dosis de droga.

A través del asesoramiento, puede aprender a:

- Alejarse de hacer cosas que son malas para ud.
- Cambiar el pensamiento adictivo en el pensamiento no adictivo.
- Tomar decisiones saludables.
- Manejar los contratiempos y el estrés.
- Avanzar con su vida.
- Entrar en una forma de vida llamada recuperación.
- Manejar sentimientos como la baja autoestima.

¿Cuál es el objetivo de la terapia asistida con medicamentos (MAT)?

- El objetivo de MAT es ayudarle a evitar el uso de la droga a la que es adicto.
- Los riesgos de no tomar MAT son mucho mayores para usted y para el bebé.

**Medicamento de reemplazo de opioides**

- El tratamiento estándar para mujeres embarazadas con OUD es un medicamento de reemplazo de opioides.
- Los medicamentos que se administran son opioides de acción prolongada y permanecen activos en su cuerpo durante mucho tiempo.
- Estos medicamentos ayudan a reducir los antojos de opioides, pero no causan la buena sensación de "estar drogado" que otros opioides causan.
- Su proveedor de atención médica lo controlará durante todo el tratamiento para cambiar las dosis si es necesario, y tratará cualquier inquietud que tenga.
- Es importante que tome la cantidad exacta que le recetaron.
- El tratamiento con el medicamento seleccionado aumenta la probabilidad de que su bebé crezca normalmente y no nazca demasiado pronto.
- Basándose en muchos años de investigación, no se ha encontrado que la medicación de reemplazo de opioides cause defectos de nacimiento.

¿Cuándo necesito contactar a mi proveedor de cuidado de la salud?

NO debe dejar de usar opioides sin supervisión médica. Dejar de usar opioides sin la ayuda de su proveedor a menudo lleva a volver al uso de drogas que pueden ser perjudiciales para usted y su bebé.

Si tiene sentimientos de abstinencia o inquietudes inmediatas, comuníquese con su proveedor de atención médica.
**Clinical Opiate Withdrawal Scale (COWS)**
*(Provider Completes)*

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

<table>
<thead>
<tr>
<th>Patient’s Name:_________________________</th>
<th>Date and Time:________________</th>
</tr>
</thead>
</table>

**Reason for this assessment:**
________________________________________

**Resting Pulse Rate:** _____beats/min

*Measured after the patient is sitting or lying for 1 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 patient activity

0 - no report of chills or flushing
1 - subjective report of chills or flushing
2 - flushed or observable moistness on face
3 - beads of sweat on brow or face
4 - sweat streaming off face

**Tremor:** Observation of outstretched hands

0 - no tremor
1 - tremor can be felt, but not observed
2 - slight tremor observable
4 - gross tremor or muscle twitching

**Restlessness:** Observation during assessment

0 - able to sit still
1 - reports difficulty sitting still, but is able to do so
3 - frequent shifting or extraneous movements of legs/arms
5 - unable to sit still for more than a few seconds

**Yawning:** Observation during assessment

0 - no yawning
1 - yawning once or twice during assessment
2 - yawning three or more times during assessment
4 - yawning several times/minute

**Pupil Size**

0 - pupils pinned or normal size for room light
1 - pupils possibly larger than normal for room light
2 - pupils moderately dilated
5 - pupils so dilated that only the rim of the iris is visible

**Anxiety or Irritability**

0 - none
1 - patient reports increasing irritability or anxiousness
2 - patient obviously irritable or anxious
4 - patient so irritable or anxious that participation in the assessment is difficult

**Bone or Joint Aches:** *If the patient was having pain previously, only the additional component attributed to opiate withdrawal is scored*

0 - not present
1 - mild diffuse discomfort
2 - patient reports severe diffuse aching of joints/muscles
4 - patient is rubbing joints or muscles and is unable to sit still because of discomfort

**Gooseflesh Skin**

0 - skin is smooth
3 - piloerection of skin can be felt or hairs standing up on arms
5 - prominent piloerection

**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

---

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

**Patient Health Questionnaire-9 (PHQ-9)**

*(Patient Completes)*

Over the last 2 weeks, how often have you been bothered by any of the following problems? *(Circle the number to indicate your answer)*

<table>
<thead>
<tr>
<th></th>
<th>Not at all</th>
<th>Several days</th>
<th>More than half the days</th>
<th>Nearly every day</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Little interest or pleasure in doing things</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>2. Feeling down, depressed, or hopeless</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>3. Trouble falling or staying asleep, or sleeping too much</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>4. Feeling tired or having little energy</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>5. Poor appetite or overeating</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>6. Feeling bad about yourself — or that you are a failure or have let yourself or your family down</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>7. Trouble concentrating on things, such as reading the newspaper or watching television</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>8. Moving or speaking so slowly that other people could have noticed? Or the opposite — being so fidgety or restless that you have been moving around a lot more than usual</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>9. Thoughts that you would be better off dead or of hurting yourself in some way</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
</tbody>
</table>

Add columns: _____ + _____ + _____ + _____

= Total Score: _____

*Modified from: Kroenke K, Spitzer R L, Williams J B (2001). The PHQ-9: validity of a brief depression severity measure. Journal of General Internal Medicine, 16(9): 606-613*