



STATE OF MAINE
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OPIOID RESPONSE

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To: Buprenorphine prescriber and pharmacy communities

We want to make you aware of a growing body of evidence regarding the use of combination buprenorphine/naloxone (Suboxone) for the treatment of opioid use disorder during pregnancy. Several studies have demonstrated no adverse obstetric or neonatal effects with the use of the combination product during pregnancy.

The use of buprenorphine monotherapy and avoidance of naloxone containing products during pregnancy was done out of an abundance of caution and was not based on clinical data. Only trace amounts of naloxone are absorbed when the medication is used sublingually, and the use of the combination product makes diversion and misuse less likely. It also removes the need to transition to different buprenorphine formulations during pregnancy and postpartum which many patients find challenging. Finally, it reduces the risk of a pregnant patient going without her medication if a prior authorization for monotherapy is not completed or processed in a timely manner. Use of the combination product in pregnancy has been endorsed by Dartmouth-Hitchcock Medical Center in New Hampshire, the University of Vermont Health Network and other healthcare systems across the US.

Based on our clinical experience and review of the literature (which is provided on the next page), we urge you to use buprenorphine/naloxone as standard practice in the treatment of opioid use disorder during pregnancy. We know that this change might cause concern for patients and staff and we have provided a handout that addresses many of the common questions that may arise. Please join us in this effort to help establish a standard of care in Maine.

Sincerely,
Maine Opioid Response Clinical Advisory Committee

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Maine Opioid Response Clinical Advisory Committee:

Proposed Position on the Use of Buprenorphine-Naloxone in Pregnancy

- A growing body of evidence¹⁻⁸ supports the safety and efficacy of the use of buprenorphine/naloxone combination therapy for treatment of opioid use disorder (OUD) in pregnancy, rather than buprenorphine monotherapy. Studies show similar maternal/fetal outcomes and no increased risk of harm associated with using the combination product during pregnancy.
- The FDA prescribing information does include neonatal opioid withdrawal syndrome as a labelled warning for both buprenorphine/naloxone⁹ and buprenorphine¹⁰ formulations; however, pregnancy is not listed as a contraindication in either label. As the label states, pregnant women on any formulation of buprenorphine should be advised of the risk of withdrawal in the neonate.
- Buprenorphine monotherapy has an average higher street value¹¹ and potential for nonmedical use, placing women at risk of injection drug use (and related potential complications of abscesses/bloodstream infections), diversion, theft, as well as pressure to share/sell the medication from partners and/or others.
- For women receiving medications for OUD, the immediate postpartum period is often challenging due to DHHS involvement and extended infant hospitalization. A change from buprenorphine monotherapy back to buprenorphine/naloxone combination therapy, often causes patient anxiety, pharmacy confusion, insurance issues and new adverse effects, which only adds to these challenges.
- Completing the required MaineCare prior authorizations for buprenorphine monotherapy during pregnancy places women at risk of not having access to their medication if prior authorizations are not completed or approved in a timely manner. When pregnant women cannot access their medication, they are at risk of withdrawal, relapse, and subsequent pregnancy complications.
- Based on our review of the literature as well as our clinical experience, we recommend that all pregnant women be prescribed the buprenorphine/naloxone combination therapy rather than buprenorphine monotherapy during pregnancy, unless otherwise contraindicated.

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Patient Information: Common questions about taking buprenorphine during pregnancy

What are the other names for buprenorphine?

There are a few different medications that have buprenorphine. Suboxone and Subutex are two types that may be prescribed to you. Suboxone also has naloxone in it. These medications make it less likely that you will start using opioids again.

It is important that you take only what your provider prescribes. You may have withdrawal if you don't take your medication as prescribed.

Is it safe to take buprenorphine during pregnancy?

Yes, taking buprenorphine during pregnancy makes it more likely that you will deliver a healthy baby at the right time.

Buprenorphine may cause your baby to have withdrawal after birth. This is called neonatal abstinence syndrome (NAS). Your provider will talk to you about how NAS is safely treated in the hospital after birth.

Is it safe to take Suboxone during pregnancy?

Suboxone contains two medications: buprenorphine and naloxone. Naloxone is added so that this medication doesn't get misused. When taken correctly, the baby will absorb little or no naloxone which is shown to be safe. Taking suboxone during pregnancy means that you do not need to switch to a different medication after your baby is born.

Will the naloxone in Suboxone make my baby's withdrawal worse?

No. Suboxone and Subutex have the same amount of buprenorphine so it affects the withdrawal the same.

Is it safe for me to stop using opioids without any treatment during pregnancy?

No. The safest option for you and your baby is to start treatment so you don't have opioid withdrawal. If you are in withdrawal, your baby is too. Withdrawal can make it more likely that you will have a miscarriage, early birth or other problems. Most people who try to quit without buprenorphine start using opioids again within a month, so it is much safer to take the medicine as prescribed by your provider.

What is the best dose of buprenorphine during pregnancy?

The right dose of buprenorphine is different for every woman. Our goal is to stop your cravings and withdrawal. Your dose does not affect your baby's withdrawal when they're born. Your body may process this medicine differently when you're pregnant so it's important to talk to your provider if you feel like the medicine isn't working or if you are having withdrawal.

Important: Always talk to your provider or care team before you switch or stop taking any medications.
