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Treatment of Substance Use (Including Alcohol and Tobacco) During Pregnancy

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All Recommendations

☑ ALL RECOMMENDATIONS: TREATMENT OF SUBSTANCE USE (INCLUDING ALCOHOL AND TOBACCO) DURING PREGNANCY

Potential Adverse Effects of Opioid Use

- Clinicians should advise pregnant individuals who use opioids to discontinue or minimize use during pregnancy and breast/chestfeeding to prevent harm to themselves and the developing fetus or infant. (A2)
- Clinicians should avoid abruptly discontinuing opioids, including BUP or methadone, in pregnant patients (B2) and should advise patients to avoid abrupt discontinuation (A3), because of the risks posed by withdrawal or return to opioid use.
- Clinicians should provide harm reduction counseling to help minimize the effects of opioids on the patient and the fetus. (A3)

☑ ALL RECOMMENDATIONS: TREATMENT OF SUBSTANCE USE (INCLUDING ALCOHOL AND TOBACCO) DURING PREGNANCY

Buprenorphine or Methadone

- Clinicians should evaluate patients' readiness to engage in treatment and collaborate with them on treatment and harm reduction goals. (A3)
- For pregnant patients with OUD, clinicians should offer medication treatment with BUP or referral for methadone treatment (A1); the treatment choice should be based on patient preference whenever possible. (A3)
  - Switching a pregnant individual who is stable on methadone to BUP is not recommended because of the risk of precipitated opioid withdrawal. (A3)
- For patients who initiate BUP or methadone during pregnancy or who become pregnant while taking BUP or methadone, clinicians should recommend the patient continue treatment through the postpartum period. (A3)
- Clinicians should **not** recommend ER naltrexone initiation, which requires withdrawal from opioids, for pregnant patients who are actively using opioids because of the increased risk of overdose. (A2)
- If a pregnant patient is abstinent from opioids and requests treatment with ER naltrexone or if a patient becomes pregnant while taking ER naltrexone, the clinician should engage in shared decision-making with the patient about the benefits and risks of initiating or continuing the medication. (A3)

Initiating Buprenorphine

- Clinicians experienced in initiating BUP should evaluate individual pregnant patients who are actively using opioids and offer low-dose (with opioid continuation), high-dose, standard, or inpatient BUP initiation as appropriate and increase the dose until a therapeutic dose is reached. (A3)
- Clinicians less experienced in treating pregnant patients with OUD should consult an expert in BUP treatment as feasible in the following situations (A3):
  - Before initiating BUP in a pregnant patient with active OUD, to discuss initiation strategies for avoiding precipitated opioid withdrawal
  - To determine if a higher level of care is required for successful BUP initiation
  - When increasing the dose of BUP >32 mg daily
  - When there is a clear indication (medical reason or strong patient preference) to switch from methadone to BUP, to discuss initiation strategies for avoiding precipitated opioid withdrawal
  - NYSDOH AI Clinical Education Initiative: Clinical Consultation Line (866-637-2342)
  - University of California San Francisco National Clinical Consultation Center
- Clinicians should anticipate that pregnant patients taking BUP may need dose increases as the pregnancy continues and should (A3):
  - Ask the patient at each visit about the level of opioid cravings and any opioid withdrawal symptoms.
  - Advise a split dose (if not already taking a split dose) as needed, increase the dose as appropriate, and reassess at the next visit.
  - Maintain dose increases until postpartum evaluation.

Postpartum: NOWS and Breast/Chestfeeding

- Clinicians should educate patients who take opioids, including BUP or methadone, during pregnancy about the potential risk of NOWS and discuss harm reduction strategies, typical symptoms and duration, and pharmacologic and nonpharmacologic treatment options. (A3)
- Clinicians should inform patients that breast/chestfeeding while taking BUP or methadone is safe and may reduce the risk of NOWS. (A2)

Potential Adverse Effects of Alcohol Use

- Clinicians should advise pregnant individuals who use alcohol to discontinue or minimize use during pregnancy and breast/chestfeeding to prevent harm to themselves and the developing fetus or infant. (A2)
- Clinicians should provide harm reduction counseling to help minimize the effects of alcohol on the patient and the fetus. (A3)

☑ ALL RECOMMENDATIONS: TREATMENT OF SUBSTANCE USE (INCLUDING ALCOHOL AND TOBACCO) DURING PREGNANCY

Alcohol Withdrawal

- Clinicians should recommend inpatient alcohol withdrawal management for pregnant individuals with or at risk of moderate, severe, or complicated alcohol withdrawal (CIWA-Ar score ≥10 or PAWSS ≥4) and should consult with an OB/GYN. (A3)
- Clinicians should weigh the benefits and risks before prescribing a benzodiazepine to treat alcohol withdrawal symptoms in pregnant individuals. (B3)

AUD Treatment Options

- Clinicians should evaluate patients' readiness to engage in treatment and collaborate with them on treatment and harm reduction goals. (A3)
- If a pregnant individual with AUD cannot discontinue or minimize alcohol use, the clinician should discuss pharmacotherapy for AUD and engage the patient in shared decision-making regarding its use. (B3)
- If a patient becomes pregnant while taking medication to treat AUD or requests it during pregnancy, clinicians should inform them of the benefits and birth-parental and fetal risks of taking acamprosate or naltrexone. (A3)
- Clinicians should provide or refer pregnant patients with AUD or unhealthy alcohol use for behavioral treatment, based on availability and patient preference. (A2)

Treatment of Tobacco Use

- For pregnant individuals who use tobacco and other forms of nicotine, clinicians should:
  - Advise patients to discontinue or minimize use during pregnancy and breast/chestfeeding to prevent potential harm to themselves and the developing fetus or infant. (A2)
  - Provide harm reduction counseling to help minimize the effects of tobacco on the patient and the developing fetus or infant, including second-hand exposure for the infant. (A3)
  - Evaluate patients' readiness to engage in treatment and collaborate with them on treatment and harm reduction goals. (A3)
  - Offer NRT with or without bupropion or varenicline after discussing the benefits and risks. (A2)
  - Perform or refer for behavioral treatment and support based on availability and patient preference. (A1)

Cannabis Use

- Clinicians should advise pregnant patients who use cannabis to discontinue or minimize use during pregnancy to reduce or prevent potential harm to themselves and the developing fetus or infant. (A2)
- Clinician should provide harm reduction counseling to pregnant patients to help minimize the potential effects of cannabis on themselves and the developing fetus or infant. (A3)
- Clinicians should discuss the risks and benefits of breast/chestfeeding with pregnant patients who are actively using cannabis. (A3)

Treatment of Methamphetamine and Cocaine Use Disorder

- Clinicians should advise pregnant individuals who use methamphetamines or cocaine to discontinue or minimize use during pregnancy and breast/chestfeeding to reduce or prevent potential harm to themselves and the developing fetus or infant. (A2)
- Clinicians should provide harm reduction counseling, including overdose prevention, to help minimize the potential effects of methamphetamines and cocaine on the patient and the developing fetus or infant. (A3)
- Clinicians should evaluate patients' readiness to engage in treatment and collaborate with them on treatment and harm reduction goals. (A3)
- Clinicians should obtain guidance from a substance use treatment specialist for pharmacologic treatment of methamphetamine or cocaine use disorder and engage the patient in shared decision-making on the benefits and risks. (A3)
  - NYSDOH AI Clinical Education Initiative: Clinical Consultation Line (866-637-2342)
  - University of California San Francisco National Clinical Consultation Center

☑ ALL RECOMMENDATIONS: TREATMENT OF SUBSTANCE USE (INCLUDING ALCOHOL AND TOBACCO) DURING PREGNANCY

- Clinicians should offer or refer pregnant patients to behavioral therapy based on availability and patient preference. (A3)

Abbreviations: AUD, alcohol use disorder; BUP, buprenorphine; CIWA-Ar, Clinical Institute Withdrawal Assessment for Alcohol scale, revised; ER, extended release; NOWS, neonatal opioid withdrawal syndrome; NRT, nicotine replacement therapy; OB/GYN, obstetrician/gynecologist; OUD, opioid use disorder; PAWSS, Prediction of Alcohol Withdrawal Severity Scale.

Purpose of This Guideline

Goals: This guideline on the treatment of substance use disorder (SUD) in pregnant adults (aged ≥18 years) was developed by the New York State Department of Health AIDS Institute (NYSDOH AI) to establish a standard of care in New York State. The goals of this guideline are to:

- Educate clinicians about and promote a harm reduction approach to SUD treatment in pregnant individuals
- Increase clinician awareness of the risks, to the birth parent and the fetus, associated with perinatal substance use
- Provide evidence-based recommendations on pharmacologic and behavioral SUD treatment during pregnancy

Use of this guideline: Many aspects of SUD treatment are the same for pregnant and nonpregnant patients; the recommendations in this guideline are focused on pregnant patients. For recommendations on SUD screening and diagnosis and for additional recommendations on SUD treatment, see the NYSDOH AI guidelines:

- Substance Use Harm Reduction in Medical Care
- Substance Use Screening, Risk Assessment, and Use Disorder Diagnosis in Adults
- Treatment of Opioid Use Disorder
- Treatment of Alcohol Use Disorder
- Clinical Guidance: Stimulant Use

The recommendations presented here address the treatment of SUD in pregnant patients, not the management of pregnancy itself. Communication and coordination among healthcare providers are essential.

Perinatal Harm Reduction

Harm reduction is treatment: A harm reduction approach respects individual autonomy and engages patients in shared decision-making on individualized, practical treatment goals that may reduce the potential negative consequences of substance use. A harm reduction approach can increase patient engagement and improve outcomes. For pregnant patients who use substances or with a substance use disorder (SUD), treatment goals may include:

- Reducing or discontinuing substance use. Most individuals stop or reduce use when they become pregnant but some may be unwilling or unable to do so.
- Preventing or minimizing the adverse effects of substance use for the pregnant individual and fetus.
- Preventing overdose.
- Engaging or staying in prenatal care.
- Reducing potentially high-risk behaviors (e.g., injection drug use, use or reuse of unsterile equipment, and sharing drug use equipment) and related complications, such as infection.
- Improving quality of life and other social conditions, such as employment and housing, and reducing risk of incarceration.
- Providing an opportunity to address and treat other health conditions, such as sexually transmitted infections, HIV, diabetes mellitus, and cardiac issues, which could significantly affect the birth parent and developing fetus/infant.

Evidence-based, individualized care for substance use during pregnancy and parenting improves outcomes for the birth parent and infant [Barber and Terplan 2023]. Even if pharmacologic or behavioral SUD treatment is declined, engaging

pregnant individuals in prenatal care may improve pregnancy outcomes and increase engagement in harm reduction strategies. In a retrospective cohort study, pregnant individuals who used substances and obtained prenatal care delivered infants of greater weight and with larger head circumferences than did those who did not obtain care (P <.05) [Berenson, et al. 1996]. In another retrospective cohort study that stratified results by the level of prenatal care received and current injection drug use status among pregnant individuals, greater engagement in prenatal care improved outcomes [El-Mohandes, et al. 2003]. The risk of prematurity, low birth weight, and small for gestational age decreased in infants born to individuals engaged in prenatal care regardless of injection drug use status. For additional information, see the National Harm Reduction Coalition and American Perinatal Harm Reduction: Pregnancy and Substance Use: A Harm Reduction Toolkit.

Polysubstance use: Many people who use substances use multiple substances simultaneously. When addressing polysubstance use in pregnant individuals, consider which substance has the potential to cause the most harm to the individual and the developing fetus, which substance the individual is most open or adverse to addressing, and whether there are treatment options that might provide relief. Although the use of any substance during pregnancy can be harmful to both the pregnant individual and the developing fetus, alcohol and stimulant use are associated with particularly significant risks. When possible, prioritize treatment and harm reduction efforts for alcohol and stimulant use.

Overdose prevention: In the United States from 2018 through 2023, the leading cause of death among pregnant and postpartum individuals was unintentional drug overdose (1,152/7,901 deaths; 5.2 deaths per 100,000 live births) [Azad, et al. 2026]. As with overall overdose mortality in the United States, pregnancy-associated overdose deaths have been increasingly characterized by synthetic opioid and psychostimulant involvement [Han, et al. 2023; Bruzelius and Martins 2022].

→ KEY POINT

- Naloxone (NLX) should be administered to pregnant individuals in an overdose situation. Untreated opioid overdose will cause death in both the pregnant person and the developing fetus. Overdose reversal with NLX restores oxygenation and circulation both to the pregnant person and developing fetus. Regardless of NLX administration, individuals may still require ventilatory support.

Discussing overdose prevention strategies with pregnant patients who use opioids or stimulants is essential. See Box 1, below.

Box 1: Overdose Prevention [a]

Counsel patients to:

- Assume all drugs obtained without their own prescription may contain fentanyl or other highly potent synthetic opioids; this includes heroin, other opioids, counterfeit pills, stimulants, nonopioid sedatives, and other substances.
- When possible, test substances with fentanyl test strips and consider other drug-checking strategies. Online sources include MATTERS (for New York State residents and programs, no charge), DanceSafe, and BTNX. Some New York State Authorized Syringe Exchange Sites provide fentanyl test strips and other drug checking strategies.
- Avoid using substances alone whenever possible. If using alone, arrange for someone to check in or use phone- and web-based apps (e.g., Never Use Alone at 1-877-696-1996).
- Start with a small amount (low dose) when using any substance.
- Carry naloxone (NLX), learn how to use it to reverse an opioid overdose, and encourage friends and contacts to do the same. The 4 mg NLX nasal spray formulation is available at pharmacies, at NYSDOH-Registered Opioid Overdose Prevention Programs (no charge), and through online resources such as NEXT Distro. NLX is covered by New York State Medicaid and most private insurers.
- Encourage friends and contacts to perform an assessment of and support airway and breathing (e.g., head tilt, chin lift maneuver, rescue breathing) and give NLX in an overdose situation.
  - The New York State 911 Good Samaritan Law protects the person who calls 911 and the person who overdosed from many potential charges associated with substance use.

Note:

a. For more information and resources on overdose prevention in New York State, see the NYSDOH AI guideline Substance Use Harm Reduction in Medical Care.

Barriers to care: Pregnant individuals with SUD may face substantial barriers to healthcare access, including lack of transportation and childcare; internalized, enacted, and anticipated stigma; and fear of legal consequences or involvement with child welfare services. Structural racism and bias in the healthcare, child welfare, and legal systems may further contribute to delays in prenatal care and SUD treatment until late in pregnancy or at the point of delivery, which may lead to negative health consequences for the birth parent and the neonate [Goodman 2024; Hailu, et al. 2024; Schiff, et al. 2024; Schiff, et al. 2022; Schiff, et al. 2020; Jarlenski, et al. 2019; Angelotta, et al. 2016; House, et al. 2016; Stone 2015; Kunins, et al. 2007].

Efforts to increase engagement in care may involve co-locating and coordinating prenatal, substance use, mental health, harm reduction, and trauma and violence services. Integrating the different aspects of care, including social services, helps pregnant individuals attend appointments, address multiple needs, and participate in clinic programming [Rutman, et al. 2020].

Addressing the many biopsychosocial and legal factors that may complicate access to care and treatment for pregnant patients with active substance use can be difficult for individual clinicians and healthcare teams [Wakeman, et al. 2021]. In outpatient nonspecialty settings, clinic staff can:

- **Acknowledge and support the strength and vulnerability required to seek care.** Pregnancy presents an opportunity for positive change, and individuals are often motivated to improve their own health and that of their fetus. Engaging patients with empathy and creativity in evidence-based, family-centered care can help channel this motivation.
- **Prioritize the patient's needs.** Helping patients address their immediate needs and questions related to pregnancy is often an important starting point before discussing risks related to substance use.
- **Be aware of personal bias.** Healthcare providers who have conscious or unconscious bias against pregnant individuals who use substances, including alcohol, cannabis, and tobacco, may be reluctant to provide care or may make erroneous judgments about a patient's fitness as a parent [Schiff, et al. 2022; Terplan, et al. 2015]. For additional information on addressing bias, see How to Identify, Understand, and Unlearn Implicit Bias in Patient Care.
- **Use a trauma-informed care approach.** Individuals who use substances are more likely to have experienced childhood emotional, physical, or sexual abuse [SAMHSA 2026; Karabulut and Genç 2023; Gould, et al. 2021; Karsberg, et al. 2021; Lotzin, et al. 2019; Mills 2015] and to experience mental health diagnoses, such as anxiety, depression, and posttraumatic stress disorder [SAMHSA 2025; Santo, et al. 2022; UNODC 2022; NIDA 2020].
- **In all treatment decisions, consider the benefits and risks to both the patient and the fetus.** Proactively elicit the patient's questions about benefits and risks to both themselves and their fetus. Concern for fetal well-being should not be prioritized over the health of the pregnant patient.
- **Advocate for patients.** Advocacy includes healthcare providers becoming knowledgeable about protections for pregnant individuals who use substances. In New York State, reports to child protective services are not accepted for substance use during pregnancy, only after delivery. Substance use in parenting individuals, in the absence of other indications of abuse or neglect, should not be reported. For more information on New York State and national reporting requirements, see:
  - NYSDOH Office of Addiction Services and Supports: Screening and Testing for Substance Use in Pregnancy
  - New York State CAPTA CARA Information & Resources: CAPTA-CARA requires development of a Plan of Safe Care (POSC) for any pregnant patient who is diagnosed with an SUD, is receiving medication for addiction treatment for an SUD, or is under the care and supervision of a healthcare provider who has prescribed opioids.
  - New York State Office of Children and Family Services: Guidance for Parents Using Substances or in Recovery: The Role of Child Protective Services (CPS) and Tips for Working Together
  - RAND: State Policies Related to Substance Use in Pregnancy

Some pregnant individuals may not be interested in treatment or counseling and will continue using substances throughout their pregnancy. If the clinician focuses solely on treatment and becomes disappointed when a patient does not choose this goal, the patient may disengage from care. Clinicians should avoid shaming patients who continue to use substances and instead engage them in other services, such as prenatal care, supportive counseling, peer support, and harm reduction.

Treatment of Opioid Use Disorder During Pregnancy

Many aspects of opioid use disorder (OUD) treatment for pregnant individuals are similar to those for nonpregnant individuals (see the NYSDOH AI guideline Treatment of Opioid Use Disorder). The recommendations below focus on *differences* in treatment during pregnancy.

☑ RECOMMENDATIONS

Potential Adverse Effects of Opioid Use

- Clinicians should advise pregnant individuals who use opioids to discontinue or minimize use during pregnancy and breast/chestfeeding to prevent harm to themselves and the developing fetus or infant. (A2)
- Clinicians should avoid abruptly discontinuing opioids, including BUP or methadone, in pregnant patients (B2) and should advise patients to avoid abrupt discontinuation (A3), because of the risks posed by withdrawal or return to opioid use.
- Clinicians should provide harm reduction counseling to help minimize the effects of opioids on the patient and the fetus. (A3)

Buprenorphine or Methadone

- Clinicians should evaluate patients' readiness to engage in treatment and collaborate with them on treatment and harm reduction goals. (A3)
- For pregnant patients with OUD, clinicians should offer medication treatment with BUP or referral for methadone treatment (A1); the treatment choice should be based on patient preference whenever possible. (A3)
  - Switching a pregnant individual who is stable on methadone to BUP is not recommended because of the risk of precipitated opioid withdrawal. (A3)
- For patients who initiate BUP or methadone during pregnancy or who become pregnant while taking BUP or methadone, clinicians should recommend the patient continue treatment through the postpartum period. (A3)
- Clinicians should **not** recommend ER naltrexone initiation, which requires withdrawal from opioids, for pregnant patients who are actively using opioids because of the increased risk of overdose. (A2)
- If a pregnant patient is abstinent from opioids and requests treatment with ER naltrexone or if a patient becomes pregnant while taking ER naltrexone, the clinician should engage in shared decision-making with the patient about the benefits and risks of initiating or continuing the medication. (A3)

Initiating Buprenorphine

- Clinicians experienced in initiating BUP should evaluate individual pregnant patients who are actively using opioids and offer low-dose (with opioid continuation), high-dose, standard, or inpatient BUP initiation as appropriate and increase the dose until a therapeutic dose is reached. (A3)
- Clinicians less experienced in treating pregnant patients with OUD should consult an expert in BUP treatment as feasible in the following situations (A3):
  - Before initiating BUP in a pregnant patient with active OUD, to discuss initiation strategies for avoiding precipitated opioid withdrawal
  - To determine if a higher level of care is required for successful BUP initiation
  - When increasing the dose of BUP >32 mg daily
  - When there is a clear indication (medical reason or strong patient preference) to switch from methadone to BUP, to discuss initiation strategies for avoiding precipitated opioid withdrawal
  - NYSDOH AI Clinical Education Initiative: Clinical Consultation Line (866-637-2342)
  - University of California San Francisco National Clinical Consultation Center
- Clinicians should anticipate that pregnant patients taking BUP may need dose increases as the pregnancy continues and should (A3):
  - Ask the patient at each visit about the level of opioid cravings and any opioid withdrawal symptoms.
  - Advise a split dose (if not already taking a split dose) as needed, increase the dose as appropriate, and reassess at the next visit.
  - Maintain dose increases until postpartum evaluation.

☑ RECOMMENDATIONS

Postpartum: NOWS and Breast/Chestfeeding

- Clinicians should educate patients who take opioids, including BUP or methadone, during pregnancy about the potential risk of NOWS and discuss harm reduction strategies, typical symptoms and duration, and pharmacologic and nonpharmacologic treatment options. (A3)
- Clinicians should inform patients that breast/chestfeeding while taking BUP or methadone is safe and may reduce the risk of NOWS. (A2)

Abbreviations: BUP, buprenorphine; ER, extended release; NOWS, neonatal opioid withdrawal syndrome; OUD, opioid use disorder.

Potential Adverse Effects

Clinicians should advise pregnant individuals who use opioids to discontinue or minimize use during pregnancy and breast/chestfeeding to prevent harm to themselves and the developing fetus or infant and offer treatment, harm reduction counseling, and support. Using opioids during pregnancy has been associated with an increased risk of preterm birth and stillbirth [Bosworth, et al. 2024; Kaltenbach, et al. 2018] and with NOWS [Kocherlakota 2014].

Abruptly discontinuing opioids, including BUP or methadone, should be avoided during pregnancy to prevent or minimize withdrawal symptoms in the pregnant individual and potential effects on the fetus. Sudden changes in opioid levels during pregnancy may precipitate effects on the fetus that can harm placental function and increase the risks of NOWS (see discussion below), stunted growth, preterm labor, fetal convulsions, and fetal death [Hudak and Tan 2012; Kaltenbach, et al. 1998].

Harm reduction: Individuals should be screened appropriately to identify co-occurring conditions and health risks. As part of a harm reduction approach, it is important to provide screening for bloodborne pathogens, sexually transmitted infections, depression, and nutritional deficiencies and educate patients regarding the risks of shared drug equipment, including pipes, stems, straws, and injection equipment. For discussion on harm reduction, see guideline section Perinatal Harm Reduction.

Buprenorphine or Methadone

BUP or methadone is the standard of care: Treatment with BUP or methadone during pregnancy is associated with reductions in use of opioids and opioid overdose. Treatment is further associated with reduced risk of preterm delivery, low infant birth weight, and transmission of HIV to the neonate [Frankeberger, et al. 2023; Suarez, et al. 2022; Minozzi, et al. 2020; ACOG 2017; Binder and Vavrinková 2008]. Although infants exposed to methadone or BUP may develop NOWS, use of these medications improves outcomes for the birth parent and neonate compared with no treatment [Brogly, et al. 2014; Kocherlakota 2014].

→ KEY POINT

- Individual factors such as treatment access, patient preference, treatment response, the likelihood of retention in treatment, available settings, and the clinician's experience affect the choice of OUD treatment.

Table 1, below, lists selected considerations for choosing BUP or methadone for OUD treatment during pregnancy. Methadone is available only through licensed opioid treatment programs (OTPs); see New York State Office of Addiction Services and Supports for OTPs in New York State. BUP can be prescribed in primary care and other outpatient settings; see Initiating Buprenorphine, below.

Patients using fentanyl may experience challenges with BUP initiation due to the lipophilicity of fentanyl and the increased risk of precipitated opioid withdrawal if BUP initiation is timed and/or dosed incorrectly [Sue, et al. 2022; Varshneya, et al. 2022; Silverstein, et al. 2019]. With low-dose initiation strategies, precipitated opioid withdrawal syndrome can be avoided and pregnant individuals may be able to successfully initiate BUP. Additionally, withdrawal from sedative adulterants (e.g., xylazine, medetomidine, synthetic benzodiazepines) in the unregulated opioid drug supply may complicate management. For newly pregnant individuals with untreated OUD, methadone may be easier to initiate and titrate [Nguemeni Tiako, et al. 2024]. If pregnant patients cannot successfully initiate BUP, methadone may be an alternative option.

Table 1: Considerations for Choosing Methadone or Buprenorphine for Opioid Use Disorder Treatment During Pregnancy

Factor	Buprenorphine	Methadone
Setting	BUP is available through office-based care via prescription, at low-threshold harm reduction programs, or at OTPs.	• Methadone is available only through an OTP. See Office of Addiction Services and Supports for OTPs in New York State. • Pregnant individuals receive priority access. • Availability of and access to OTPs may be limited, particularly in rural settings.
Initiation requirement	• Standard BUP initiation requires mild opioid withdrawal symptoms [a]; in the context of highly potent synthetic opioid use, standard initiation may require an inpatient hospital setting with access to OB/GYN and addiction services. • Alternative strategies such as low-dose initiation with opioid continuation or high-dose initiation may mitigate withdrawal symptoms [a].	Withdrawal is not required.
Efficacy in pregnant patients	• BUP and methadone are equally effective in reducing opioid use during pregnancy [Minozzi, et al. 2020]. • Studies suggest methadone treatment may be associated with increased retention in care compared with BUP among nonpregnant adults [Park, et al. 2025; Degenhardt, et al. 2023; Sadek and Saunders 2022; Klimas, et al. 2021; Robin, et al. 2020; SAMHSA 2018].	
Dosing	• Increased dose and dose frequency (split dosing) of both BUP and methadone are likely necessary, particularly during the third trimester of pregnancy. • No association has been found between dose of BUP or methadone and the likelihood of NOWS [Kaltenbach, et al. 1998]. • There is a ceiling effect associated with BUP efficacy. Consult an expert in BUP treatment when increasing the dose >32 mg daily.	
Treatment duration	• For both medications, treatment is continued throughout pregnancy, labor, delivery, and postpartum. • Overdose risk increases in the postpartum period, particularly in the late postpartum period [Bruzelius and Martins 2022].	
Changing from one medication to the other	Switching from BUP to methadone can be considered if needed to control cravings and avoid opioid withdrawal.	Switching from methadone to BUP is not advised because of the potential for precipitated opioid withdrawal symptoms. If a switch is clinically necessary or preferred by the patient, consult a clinician experienced in OUD treatment.
Adverse effects	• There are no clear differences between BUP and methadone in peripartum and neonatal adverse outcomes, including admission to the neonatal intensive care unit; full-term delivery; vaginal delivery; gestational age at delivery; length of neonate hospital stay; and neonate length, birthweight, and head circumference [Ordean and Tubman-Broeren 2023; Link, et al. 2020; Mullins, et al. 2020]. • Some studies indicate increased risk or severity of NOWS in infants exposed to methadone compared with those exposed to BUP [Suarez, et al. 2022; Lappen, et al. 2020; Lund, et al. 2013]. • In children aged ≤5 years with prenatal exposure to methadone or BUP, there were no significant differences in cognitive development scores [Nelson, et al. 2020].	

Table 1: Considerations for Choosing Methadone or Buprenorphine for Opioid Use Disorder Treatment During Pregnancy		
Factor	**Buprenorphine**	**Methadone**
Acute pain management	• Nonopioid and opioid analgesic agents needed for acute pain management during labor, delivery, and postpartum (e.g., after cesarean section) are used *in addition to* the current dose of methadone or BUP [ASAM 2019]. • Adding a short-acting full-agonist opioid can be considered for managing moderate to severe acute pain in patients taking methadone or BUP. When adding a full-agonist opioid analgesic, patients taking BUP or methadone will likely need higher dosing than opioid-naive patients to achieve adequate analgesia.	
Breast/chestfeeding	Both medications are safe for breast/chestfeeding [LactMed 2026g; LactMed 2026b].	
Abbreviations: BUP, buprenorphine; NOWS, neonatal opioid withdrawal syndrome; OB/GYN, obstetrics and gynecology; OTP, opioid treatment program; OUD, opioid use disorder. **Note:** a. See the Clinical Opiate Withdrawal Scale and Subjective Opiate Withdrawal Scale.		

Naltrexone: The NYSDOH AI guideline Treatment of Opioid Use Disorder > Naltrexone recommends naltrexone as an alternative OUD treatment option for nonpregnant individuals who cannot take BUP or methadone or prefer naltrexone. However, if a pregnant individual is currently using opioids, initiating naltrexone is not recommended because it requires acute withdrawal from opioids and the evidence base is limited on naltrexone effects during pregnancy [FDA 2025; Atluru, et al. 2024; Towers, et al. 2020; ACOG 2017; Jones, et al. 2013; Hulse, et al. 2004]. If a patient taking naltrexone becomes pregnant, clinicians should inform them of the benefits and risks of naltrexone, discuss BUP and methadone as preferred options, and engage in shared decision-making. Naltrexone blocks the mu-opioid receptor, decreasing opioid cravings, and with no in utero opioid exposure, poses no risk of NOWS in the neonate. Data are insufficient regarding naltrexone's teratogenicity, effect on milk production, or effects on infants exposed through breast/chestfeeding (see naltrexone prescribing information [FDA 2025]). Additionally, naltrexone reduces opioid tolerance, which could result in overdose if the patient resumes opioid use. If the patient opts to discontinue naltrexone and initiate BUP or methadone, clinicians should educate them about the potential for NOWS.

Initiating Buprenorphine

Initiating BUP: Ideally, BUP initiation in pregnant patients should be managed in a manner that minimizes the risks of precipitated opioid withdrawal (see the Clinical Opiate Withdrawal Scale and Subjective Opiate Withdrawal Scale) [Wesson and Ling 2003; Handelsman, et al. 1987]. Clinicians less experienced in treating pregnant patients with OUD should consult an expert in BUP treatment before initiating BUP in pregnant patients. Recommendations for BUP initiation in nonpregnant individuals have been revised in response to the increase in fentanyl and other highly potent synthetic opioids in the unregulated drug supply. Reports indicate that standard BUP initiation in patients taking synthetic opioids is associated with a higher risk of precipitated opioid withdrawal [Sue, et al. 2022; Varshneya, et al. 2022; Silverstein, et al. 2019].

→ KEY POINTS

- The benefits of initiating BUP in pregnant patients outweigh any risks of precipitated opioid withdrawal syndrome.
- With low-dose initiation strategies, precipitated opioid withdrawal syndrome may be avoided and pregnant individuals may be able to successfully initiate BUP.

Alternatives such as low-dose BUP initiation with opioid continuation (LDB-OC; previously known as microdosing or microinduction) and high-dose initiation have been explored [Weimer, et al. 2023]. Currently, the NYSDOH AI guideline Treatment of Opioid Use Disorder recommends that clinicians use LDB-OC or a standard initiation approach in nonpregnant adults. With LDB-OC, a small initial dose (e.g., BUP 0.5 mg/naloxone [NLX] 0.125 mg) is followed by incremental increases over 7 days; patients can continue to use other opioids until the therapeutic level of BUP/NLX is reached.

To date, LDB-OC has not been studied in pregnant individuals, but in a systematic review of 7 observational studies, 6 of the 25 patients analyzed experienced minimal, mild, or moderate withdrawal symptoms during LDB-OC initiation, and only 2 experienced precipitated withdrawal [Grenier, et al. 2026; Koenigs, et al. 2024; Patel and Parilla 2024; Galati, et al. 2021;

Irwin, et al. 2021]. The median gestational age in the studies was 26 weeks (9 to 40 weeks), so initiation occurred at different gestational ages. Minimal, mild, or moderate withdrawal was not consistently reported in the studies reviewed. These findings align with those among nonpregnant individuals using LDB-OC initiation.

High-dose BUP initiation (initial BUP dose of >8 mg and rapid up-titration within 1 day) requires onset of opioid withdrawal. Most published experience with high-dose BUP initiation has been with individuals with moderate to severe opioid withdrawal evaluated in the emergency department [D'Onofrio, et al. 2023; Snyder, et al. 2023; Herring, et al. 2019]. However, in a small retrospective case series among 6 pregnant individuals with OUD who initiated high-dose BUP, there were no instances of sedation, respiratory depression, supplemental oxygen use, or death, and all 6 individuals were successfully transitioned to BUP [Berry, et al. 2024]. The individuals received an initial 8 mg sublingual BUP dose and then an additional 8 mg BUP every 30 to 60 minutes as needed based on withdrawal severity (maximum of 32 mg/day). These findings provide support for high-dose BUP initiation in pregnancy, but data from larger studies are needed. A high-dose BUP initiation would be most appropriate in individuals who are already experiencing opioid withdrawal syndrome (e.g., post-NLX administration) and are in a controlled setting.

Initiation of other formulations of BUP (injectable, transdermal patch) and/or full-agonist opioids may have a role for pregnant individuals but has not been well studied. In a randomized controlled trial among pregnant individuals in an outpatient setting, abstinence from opioids was higher among those receiving ER injectable BUP (weekly) than those taking sublingual BUP [Winhusen, et al. 2026].

◊ RESOURCE

- The NYSDOH Buprenorphine Assistance Program (BUPE-AP) covers the cost of BUP for New York State residents who are uninsured or underinsured, who have insurance but with high copayments, or who have insurance through a family member and prefer to keep BUP use private.

Continuing OUD treatment through pregnancy, labor, delivery, and postpartum: Patients with OUD who initiate BUP or methadone during pregnancy or who become pregnant while taking either medication should continue treatment with the same medication throughout the intra- and postpartum periods [Frankeberger, et al. 2023; Meyer, et al. 2015; Lund, et al. 2013; Jones, et al. 2010].

An increased dose or split dosing of BUP or methadone may be required in the second and third trimesters because of increased blood volume and metabolism later in pregnancy [Bastian, et al. 2017; Albright, et al. 2011; Cleary, et al. 2010]. Patients may opt to split their BUP dose during the day if it more effectively controls cravings and withdrawal symptoms. Clinicians should assess withdrawal symptoms and opioid cravings at every visit, and if pregnant patients report opioid withdrawal symptoms or opioid cravings, the BUP dose should be increased, typically in increments of 2 mg to 4 mg per day. Patients may require BUP dose increases up to 32 mg daily. It is essential to ensure the patient understands that increasing the dose of BUP or methadone is not associated with an increased risk of NOWS [Wong, et al. 2018; Cleary, et al. 2010; Jones, et al. 2008].

If treatment goals are not being met with BUP during pregnancy, clinicians should discuss methadone with the patient and offer referral to an OTP for methadone treatment if available [ACOG 2017]. Transitioning from BUP to methadone does not pose a risk of precipitated opioid withdrawal [SAMHSA 2024]. However, during pregnancy, a switch from methadone to BUP is not recommended because the transition could cause precipitated opioid withdrawal symptoms and may require inpatient care and monitoring to decrease the risk of miscarriage or premature delivery. If, despite knowledge of these risks, a pregnant patient requests a change from methadone to BUP, consult with an expert in OUD treatment during pregnancy.

Acute pain management: At minimum, the OUD treatment dose of BUP or methadone is maintained [ASAM 2019]. Nonopioid medications are the first-line option for acute pain management during pregnancy, delivery, and postpartum (e.g., after cesarean section). Adding a short-acting full-agonist opioid can be considered when clinically indicated to manage moderate to severe acute pain. When adding a full-agonist opioid analgesic, patients with OUD will likely need higher dosing than opioid-naive patients to achieve adequate analgesia [ASAM 2019]. Additionally, if the patient is not already splitting their dose of methadone or BUP, split dosing can improve acute pain management.

Telehealth: Telehealth has emerged as a promising modality for increasing access to OUD care, but few outcomes have been reported for pregnant individuals within dedicated telehealth settings. In a nonrandomized controlled trial, pregnant participants receiving virtually integrated OUD care in obstetric practices had outcomes for themselves and their newborns similar to those of pregnant participants receiving in-person care [Guille, et al. 2020]. Outcomes included uninterrupted OUD treatment during pregnancy through 6 to 8 weeks postpartum, urine drug screening results at delivery and 6 to 8 weeks

postpartum, and diagnosis of NOWS. A retrospective cohort study evaluated OUD treatment and pregnancy outcomes among individuals aged ≥18 years taking or initiating BUP or BUP/NLX who were engaged in a low-barrier, dedicated telehealth OUD care program [Coffey, et al. 2024]. Nearly 80% of participants received continuous OUD treatment throughout pregnancy.

Postpartum: Neonatal Opioid Withdrawal Syndrome and Breast/Chestfeeding

NOWS: Clinicians should inform pregnant individuals taking opioids, including BUP or methadone, that in utero exposure may result in NOWS [Kraft, et al. 2016; McQueen and Murphy-Oikonen 2016; Gawronski, et al. 2014; Hall, et al. 2014]. Prenatal treatment with BUP or methadone, compared with ongoing use of opioids, can reduce the severity of NOWS symptoms [Brogly, et al. 2014; Fajemirokun-Odudeyi, et al. 2006]. Advising patients early in the pregnancy that NOWS is an expected and treatable outcome may reduce stress after delivery. Treatment goals for an infant with NOWS are to minimize the severity and duration of withdrawal symptoms, reduce the length of hospital stay, and reduce the need for and duration of adjunctive therapies. See Table 2, below, for NOWS characteristics and treatment.

Box 2: Characteristics and Treatment of Neonatal Opioid Withdrawal Syndrome (NOWS)

Presentation

- Signs of opioid withdrawal generally occur within the first 48 hours of life for neonates exposed to buprenorphine in utero and within 5 days for those exposed to methadone. For neonates exposed to opioids, withdrawal symptoms occur in 6 to 12 hours (short-acting formulations) or 12 to 24 hours (long-acting formulations).
- Symptoms include tremors, hypertonicity, irritability, vomiting, and respiratory distress. The number, severity, and duration of symptoms vary in individual neonates [Zelson, et al. 1973].
- Multiple factors affect the expression of symptoms: neonatal gestational age; sex; genetics; birth-parent substance use factors, such as exposure to medications (e.g., selective serotonin reuptake inhibitors, benzodiazepines, gabapentinoids) and nicotine smoking; and birth-parent metabolism [Kraft, et al. 2016].

Diagnosis

- Diagnosis is based on the birth parent's history and neonatal clinical features, with or without biological testing for opioids [Anbalagan, et al. 2024].
- Scores from tools such as the Finnegan Neonatal Abstinence Scoring System [Finnegan and Kaltenbach 1997] and the MOTHERS score [Jones, et al. 2010] are used to assess severity and guide treatment decisions, including pharmacologic treatment.

Treatment Options

- Treatment approaches vary and protocols are determined by individual hospitals, but current practice encourages nonpharmacologic management and infant-family contact [NIH 2024; Young, et al. 2023; Ryan, et al. 2019; Grossman, et al. 2018]. The Eat, Sleep, Console (ESC) approach has been shown to reduce infant length of stay, reduce costs, and increase family bonding [Young, et al. 2023]. This approach uses nonpharmacologic interventions as first-line treatment and a function-based assessment of withdrawal severity that is focused on an infant's ability to eat, sleep, and be consoled.
- Nonpharmacologic care includes swaddling; keeping rooms quiet and dimly lit; encouraging skin-to-skin contact, breast/chestfeeding, and prone positioning; and keeping an infant with the parent, known as "rooming-in," instead of in a neonatal intensive care unit [Lembeck, et al. 2019; Mangat, et al. 2019; Piccotti, et al. 2019; Ryan, et al. 2019; Holmes, et al. 2016; Saiki, et al. 2010].
- More severe cases of NOWS may require adjunctive medication [Ryan, et al. 2019]. Morphine and, less commonly, methadone are the first-line pharmacologic treatments for NOWS [Sutter, et al. 2022; Kocherlakota 2014; Hudak and Tan 2012; Jansson and Velez 2012; Osborn, et al. 2010b; Osborn, et al. 2010a]. There is evidence that buprenorphine is a safe and effective treatment for NOWS, but its use has not yet been widely adopted [Anbalagan, et al. 2024; Zankl, et al. 2021; Kraft, et al. 2008].

Breast/chestfeeding: Advise individuals to discontinue breast/chestfeeding if actively using opioids that are not prescribed [LactMed 2026f; LactMed 2025; Harris, et al. 2023; ACOG 2017] and discuss harm reduction strategies (see the Washington State Department of Health guide Opioids and Lactation [WADOH 2023]).

Breast/chestfeeding is safe when a patient is taking BUP, methadone, or naltrexone [LactMed 2026i; LactMed 2026g; LactMed 2026b]. Additionally, breast/chestfeeding has been shown to decrease the risk of NOWS and decrease the initiation and duration of pharmacologic treatment and the length of hospital stay when NOWS does occur [Chu, et al. 2022]. This benefit is likely due to the skin-to-skin contact inherent in breast/chestfeeding rather than the minuscule amount of BUP or methadone in human milk. For postpartum individuals who also have HIV and are virally suppressed, breast/chestfeeding is an option if the birth parent chooses [CDC 2025; Pollock and Levison 2023]; see NYSDOH AI NYS Good Practices to Prevent Perinatal HIV Transmission > Infant Feeding. Hepatitis C virus infection is not a contraindication to breast/chestfeeding if the skin of the nipple and areola are intact. Active herpes simplex virus on or around the nipple is a contraindication to breast/chestfeeding.

Ongoing OUD treatment and patient support: In the postpartum period, the birthing parent should continue taking BUP or methadone for as long as a benefit is derived. If the patient's dose of BUP or methadone was increased during pregnancy, the increase should be maintained until the clinician and patient can re-evaluate. Postpartum doses should not be decreased arbitrarily to pre-pregnancy doses.

Following delivery, a patient who is taking OUD treatment will require continued support. The postpartum period can be stressful for new parents, particularly if they lack social support and have comorbidities, such as mental health or chronic medical conditions. One study found that individuals who gave birth to infants with NOWS had a significantly higher incidence of major depression, postpartum depression, and anxiety in the 12 months postpartum than matched controls [Corr, et al. 2020]. During this period, individuals who use opioids are at increased risk for recurrence of use and unintentional overdoses [Frankeberger, et al. 2023; Schiff, et al. 2018]. A population-based study in Massachusetts found that overdose events decreased as pregnancy progressed and were lowest in the third trimester (3.3/100,000 person-days), with the highest risk of overdose at 7 to 12 months after delivery (12.3/100,000 person-days) [Schiff, et al. 2018]. See guideline section Perinatal Harm Reduction > Overdose prevention.

Treatment of Alcohol Use and Alcohol Use Disorder During Pregnancy

This section of the guideline addresses alcohol use and alcohol use disorder (AUD), because the risk of harm to the fetus is greater with any level of alcohol use than with non–physiological-dependent use of other substances.

Some aspects of AUD treatment for pregnant individuals are similar to those for nonpregnant individuals. The recommendations below focus on *differences* in treatment during pregnancy; consult the NYSDOH AI guideline Treatment of Alcohol Use Disorder for additional recommendations.

☑ RECOMMENDATIONS

Potential Adverse Effects of Alcohol Use

- Clinicians should advise pregnant individuals who use alcohol to discontinue or minimize use during pregnancy and breast/chestfeeding to prevent harm to themselves and the developing fetus or infant. (A2)
- Clinicians should provide harm reduction counseling to help minimize the effects of alcohol on the patient and the fetus. (A3)

Alcohol Withdrawal

- Clinicians should recommend inpatient alcohol withdrawal management for pregnant individuals with or at risk of moderate, severe, or complicated alcohol withdrawal (CIWA-Ar score ≥10 or PAWSS ≥4) and should consult with an OB/GYN. (A3)
- Clinicians should weigh the benefits and risks before prescribing a benzodiazepine to treat alcohol withdrawal symptoms in pregnant individuals. (B3)

☑ RECOMMENDATIONS

AUD Treatment Options

- Clinicians should evaluate patients' readiness to engage in treatment and collaborate with them on treatment and harm reduction goals. (A3)
- If a pregnant individual with AUD cannot discontinue or minimize alcohol use, the clinician should discuss pharmacotherapy for AUD and engage the patient in shared decision-making regarding its use. (B3)
- If a patient becomes pregnant while taking medication to treat AUD or requests it during pregnancy, clinicians should inform them of the benefits and birth-parental and fetal risks of taking acamprosate or naltrexone. (A3)
- Clinicians should provide or refer pregnant patients with AUD or unhealthy alcohol use for behavioral treatment, based on availability and patient preference. (A2)

Abbreviations: AUD, alcohol use disorder; CIWA-Ar, Clinical Institute Withdrawal Assessment for Alcohol scale, revised; OB/GYN, obstetrician/gynecologist; PAWSS, Prediction of Alcohol Withdrawal Severity Scale.

Potential Adverse Effects

Healthcare providers should encourage pregnant individuals who use alcohol or have AUD to discontinue or minimize use during pregnancy and breast/chestfeeding. There is no known safe amount of alcohol use during pregnancy, and there is clear evidence that binge drinking and heavy drinking during pregnancy are associated with adverse fetal effects [Carson, et al. 2017; Flak, et al. 2014; O'Leary and Bower 2012]. Because of the potentially serious dose-dependent effect of in utero alcohol exposure on the fetus and neonate, discontinuing or minimizing use is recommended [Chang 2026; May, et al. 2016]. Patients with physiological dependence should not discontinue alcohol use abruptly—cessation for such patients may require expert consultation or inpatient treatment to safely manage alcohol withdrawal.

Alcohol use during pregnancy may increase the risk of miscarriage, stillbirth, and preterm delivery, and the risks may be more pronounced with heavy alcohol use [Bailey and Sokol 2011]. However, it remains unclear how sociodemographic factors that co-occur with alcohol use during pregnancy interact with alcohol use or contribute to outcomes. In a large cohort study from Korea, a diagnosis of AUD preceding delivery was associated with an increased risk of intrauterine growth restriction but not associated with other birth complications [Oh, et al. 2020]. The increased risk was more marked in individuals diagnosed with AUD in the 12 months preceding delivery.

According to the Centers for Disease Control and Prevention, up to 1 in 20 school-aged children in the United States may have fetal alcohol spectrum disorders (FASDs) [CDC 2024; May, et al. 2018]. Subtle manifestations of FASD include mild learning disabilities or physical abnormalities; severe manifestations include central nervous system dysfunction, low IQ, microcephaly, delayed growth, and facial abnormalities [Miller 2018]. A multisite study using active case ascertainment methods estimated an FASD prevalence rate of 1% to 5% among first graders exposed to alcohol in utero [Muggli, et al. 2017]. In a study that compared children aged 9 and 10 years with and without prenatal alcohol exposure, exposure was associated with increased psychopathology, attention deficits, and impulsiveness [Lees, et al. 2020].

Harm reduction: There is substantial evidence that alcohol use during pregnancy can harm the individual, developing fetus, and child. If patients are using alcohol and other substances, alcohol use should be a priority for treatment and harm reduction efforts. Clinicians should discuss and encourage harm reduction strategies for pregnant individuals who use alcohol. Pregnant individuals who cannot or will not discontinue alcohol use may be able to decrease use or address other treatment goals. Harm reduction approaches during pregnancy have been shown to decrease alcohol use, reduce healthcare costs, improve engagement and retention in prenatal services and substance use treatment, and improve health outcomes for parents and their children [Racine, et al. 2009; Poole and Greaves 2007]. See guideline section Perinatal Harm Reduction.

Alcohol Withdrawal

Pregnancy is considered a relative contraindication for ambulatory management of alcohol withdrawal. For pregnant individuals with a score of ≥10 on the CIWA-Ar scale, a score of ≥4 on the PAWSS, or at risk of moderate, severe, or complicated alcohol withdrawal, a referral for inpatient withdrawal management is recommended [ASAM 2020]. Healthcare providers should consult with an OB/GYN during withdrawal management [ASAM 2020].

Symptoms of alcohol withdrawal syndrome include autonomic hyperactivity (sweating, tachycardia); increased hand tremors; insomnia; nausea; vomiting; transient hallucinations or perceptual disturbances of the auditory, visual, or tactile type;

psychomotor agitation; anxiety; and generalized seizures [Kattimani and Bharadwaj 2013]. Physiological and psychological stress during pregnancy can adversely affect the pregnant individual and the fetus and result in preterm birth and low birth weight [DeVido, et al. 2015; Enlow, et al. 2009; Hobel, et al. 2008].

Benzodiazepines are commonly used to treat alcohol withdrawal in nonpregnant adults, but data on the safety of benzodiazepines during pregnancy are unclear [DeVido, et al. 2015]. In a review of 12 studies, fetal exposure to benzodiazepines in the first trimester was not associated with an increased risk of congenital disabilities [Bellantuono, et al. 2013]. The World Health Organization and the American Society of Addiction Medicine recommend short-term, limited use of benzodiazepines in pregnant individuals who require treatment for alcohol withdrawal, noting the need to balance the risk of fetal adverse events with the potential harm of complications of severe alcohol withdrawal [ASAM 2020; WHO 2014]. Management with benzodiazepines may begin with clonazepam in the first or second trimester and with lorazepam in the third trimester or during postpartum breast/chestfeeding because of the lower associated risk to the infant [Habersham, et al. 2025].

Treatment Options

Pharmacologic treatment: Initiating pharmacologic treatment in pregnant patients with AUD, or continuing treatment in patients who become pregnant, requires a discussion of the benefits and risks and shared decision-making with patients [Kelty, et al. 2019]. With effective treatment, a pregnant individual may be able to reduce or discontinue alcohol use, which may improve birth-parent health and will minimize fetal exposure to alcohol and the risk of associated harms, such as FASD [Reece-Stremtan and Marinelli 2015; WHO 2014]. However, few data are available from well-controlled studies of pharmacologic AUD treatment in pregnant individuals, and the potential carcinogenic, mutagenic, or fertility effects in humans are unknown [Minozzi, et al. 2024].

In nonpregnant individuals, acamprosate and naltrexone are preferred agents for treatment of AUD. Given the potential risks associated with alcohol consumption during pregnancy, the use of acamprosate and naltrexone may be considered for the treatment of pregnant individuals with AUD. Based on the available research of use during pregnancy, acamprosate and naltrexone do not appear to be associated with substantial risks of congenital malformations or other serious consequences [Kelty, et al. 2021]. Gabapentin and disulfiram are alternative agents for the treatment of AUD in nonpregnant adults. Gabapentin does not appear to be associated with substantial risks and may also be considered during pregnancy but should be used with caution during the third trimester, as its use is associated with a higher risk of preterm birth, small for gestational age, and NICU admission [Kelty, et al. 2021; Patorno, et al. 2020]. Disulfiram use may cause serious fetal harm and is not advised during pregnancy [FDA 2020].

Breast/chestfeeding while taking acamprosate is not recommended. It is unknown whether breast/chestfed infants are exposed to acamprosate through human milk [FDA 2012]. Naltrexone use is not contraindicated during breast/chestfeeding; limited data indicate that naltrexone is minimally excreted into human milk [LactMed 2026i].

Behavioral treatment: Clinicians should provide or refer pregnant individuals who use alcohol for counseling or other behavioral treatment. Meta-analyses have found that behavioral interventions effectively increase abstinence during pregnancy and prevent preterm birth [Minozzi, et al. 2024; Popova, et al. 2023; Ujhelyi Gomez, et al. 2021; Minozzi, et al. 2020].

There is wide variability in the efficacy of behavioral interventions, and recommendations and referrals should be tailored to the individual patient's needs and preferences. Cognitive behavioral therapy, motivational interviewing, contingency management, or digital interventions may help a pregnant individual minimize substance use [Oh, et al. 2022; WHO 2014]. Referral options may include intensive outpatient substance use treatment, mental health treatment, peer support groups (e.g., 12-step, SMART Recovery), electronic apps (e.g., SMART Recovery, In the Rooms), public health services, recovery centers, other community-based recovery coaching, and other available psychosocial interventions. Based on the individual patient's needs and preferences, inpatient or residential treatment may also be considered.

Alcohol Use and Breast/Chestfeeding

The effects of alcohol use during lactation are complex, and there is conflicting evidence on the effects of infant exposure to alcohol in human milk [May, et al. 2016; Haastrup, et al. 2014]. Alcohol is excreted into human milk in concentrations similar to those in birth-parental blood, meaning that the amount of alcohol ingested by an infant through human milk is a fraction of the amount consumed by the birth parent. Alcohol can disrupt breast/chestfeeding by decreasing milk production and let down [LactMed 2026a]. However, the effect of occasional alcohol consumption on milk production appears small, temporary,

and clinically insignificant [Haastrup, et al. 2014]. See Box 3, below, for harm reduction strategies and LactMed > Alcohol for a full discussion on the effects of alcohol use during breast/chestfeeding.

Box 3: Harm Reduction Strategies for Alcohol Use While Breast/Chestfeeding

The National Harm Reduction Coalition and the Academy of Perinatal Harm Reduction Pregnancy and Substance Use: A Harm Reduction Toolkit advises that individuals who use alcohol and are breast/chestfeeding:

- After drinking, wait 2 to 4 hours per drink to breast/chestfeed. For example, after 2 drinks, wait at least 4 hours before breast/chestfeeding.
- If they still feel drunk or hungover, even if the recommended time has passed, wait until they feel better before breast/chestfeeding.
- If they have plans that may include alcohol consumption, pump and store enough milk beforehand to cover a couple of feedings or plan to use formula.
- While intoxicated, if breasts become painful or engorged, pump or hand express enough milk to relieve the pressure, then discard it.
- Consider over-the-counter test strips to measure alcohol in breast/chest milk.

Treatment of Tobacco Use Disorder During Pregnancy

☑ RECOMMENDATION

Treatment of Tobacco Use

- For pregnant individuals who use tobacco and other forms of nicotine, clinicians should:
  - Advise patients to discontinue or minimize use during pregnancy and breast/chestfeeding to prevent potential harm to themselves and the developing fetus or infant. (A2)
  - Provide harm reduction counseling to help minimize the effects of tobacco on the patient and the developing fetus or infant, including second-hand exposure for the infant. (A3)
  - Evaluate patients' readiness to engage in treatment and collaborate with them on treatment and harm reduction goals. (A3)
  - Offer NRT with or without bupropion or varenicline after discussing the benefits and risks. (A2)
  - Perform or refer for behavioral treatment and support based on availability and patient preference. (A1)

Abbreviation: NRT, nicotine replacement therapy.

Potential Adverse Effects

Clinicians should advise pregnant patients to discontinue or minimize tobacco use during pregnancy. The perinatal risks associated with tobacco use during pregnancy include orofacial clefts, fetal growth restriction, placenta previa, abruptio placentae, preterm birth, low birth weight, increased perinatal mortality, ectopic pregnancy, and decreased maternal thyroid function [ACOG 2020]. In addition, an estimated 22% of cases of sudden infant death syndrome in the United States can be directly attributed to maternal smoking during pregnancy [Anderson, et al. 2019], and children born to women who smoke during pregnancy are at an increased risk of respiratory infections, asthma, bone fractures, infantile colic, and childhood obesity [ACOG 2020].

Harm reduction: In addition to educating patients about the risks associated with perinatal tobacco/nicotine use, clinicians should offer treatment and provide harm reduction counseling. See guideline section Perinatal Harm Reduction.

Treatment Options

Pharmacologic treatment: Clinicians should provide information about available pharmacologic treatment and, if patient is unable to independently cease smoking, offer NRT, bupropion, varenicline, or a combination of these medications. The choice is guided by patient preference. Treatment considerations specific to pregnancy are outlined in Table 2, below.

Table 2: Pharmacologic Treatment for Tobacco Use Disorder During Pregnancy

Treatment	Considerations
Nicotine replacement therapy (NRT) (i.e., patch, gum, lozenge, nasal spray, or inhaler)	• Limited evidence of efficacy in smoking cessation or reduction; mixed evidence regarding harm [Pesola, et al. 2024; Jackson, et al. 2022; Patnode, et al. 2021; Taylor, et al. 2021; Claire, et al. 2020; Terplan, et al. 2020; Coleman, et al. 2012] • Taken according to instructions for nonpregnant individuals; nicotine metabolizes more quickly in pregnant individuals and dose increases may be warranted [Dempsey, et al. 2002]. • To potentially minimize NRT exposure to the fetus or breast/chestfeeding infant, patients may choose to control dosing with an immediate-release form (e.g., lozenge, gum, inhaler, or nasal spray) [Dempsey, et al. 2002]. • Removing a nicotine patch at night may minimize fetal exposure to nicotine. • An alternative to NRT may be preferred for tobacco cessation treatment for some individuals who are breast/chestfeeding [LactMed 2026j]. Animal data suggest that exposure to nicotine may interfere with lung development or be associated with sudden infant death syndrome, but the risks are not well established for exposure to nicotine in human infants.
Bupropion	• Antidepressant with dopaminergic and noradrenergic activity • Can be prescribed concurrently with NRT for pregnant individuals [Cressman, et al. 2012b] • No clear effect on smoking cessation during pregnancy [Kranzler, et al. 2021; Claire, et al. 2020] • Not associated with an increased risk of pregnancy complications when initiated in the second trimester [Kranzler, et al. 2021] • Rate of congenital heart defects among infants with in utero exposure to bupropion is higher than in the general population but relatively low (2.1/1,000 births) [Byatt, et al. 2013; Alwan, et al. 2010]. • At doses of ≤300 mg daily, produces low levels in human milk that are not expected to cause adverse effects in infants, but data are limited [LactMed 2026c]. There are case reports of seizures in partially breast/chestfed 6-month-old infants, and a risk-benefit discussion with the patient on use during breast/chestfeeding is warranted. See LactMed > Bupropion.
Varenicline	• Partial agonist of α4β2 nicotinic receptors • A population-based cohort study among individuals in the first trimester of pregnancy found a significant reduction in the risk of any adverse perinatal event and no increased risk of major congenital anomalies in infants exposed to varenicline compared with those exposed to NRT [Tran, et al. 2020]. • A follow-up analysis reported no increased risk of major congenital malformations with first-trimester varenicline exposure compared with continued smoking. Some data suggest better outcomes than continued smoking [Tran, et al. 2025]. • No information available on the use of varenicline during breast/chestfeeding; an alternate medication is preferred, especially while breast/chestfeeding a newborn or preterm infant [LactMed 2024]. Although caution is advised because of limited data, given the substantial harms of postpartum return to tobacco use, a risk-benefit discussion using shared decision-making is appropriate. • If an individual chooses to breast/chestfeed while taking varenicline, the infant should be monitored for seizures and excessive vomiting [LactMed 2024; McAllister-Williams, et al. 2017].

E-cigarettes: Limited data are available on the effectiveness and safety of e-cigarettes for smoking cessation among adults [Patnode, et al. 2021]. In randomized studies, regular use of e-cigarettes was not associated with adverse pregnancy outcomes [Pesola, et al. 2024; Przulj, et al. 2023].

Behavioral treatment: For pregnant individuals who use tobacco, clinicians should perform or refer for smoking cessation counseling or other behavioral treatment. In a systematic review, pharmacotherapy, behavioral interventions, and e-cigarettes for tobacco cessation were examined, and behavioral interventions (compared with no intervention) were associated with greater smoking cessation during late pregnancy [Patnode, et al. 2021]. An earlier meta-analysis found that counseling, feedback, and incentive-based programs (contingency management [CM]) increased the proportion of individuals who stopped smoking in late pregnancy and were associated with a 17% reduction in low birthweight, a significantly higher mean birthweight, and a 22% reduction in neonatal intensive care unit admissions infants [Chamberlain, et al. 2017]. In 2 CM studies, financial incentives were associated with an increased smoking abstinence rate in pregnant smokers in France [Berlin, et al. 2021] and were highly effective as an addition to routine stop smoking services in the United Kingdom (although most participants who stopped smoking returned to use after delivery) [Tappin, et al. 2022]. Evidence is accumulating on the efficacy of CM as a component of treatment, but CM is not readily available in the clinical setting.

The efficacy of behavioral interventions varies widely, and recommendations and referrals should be tailored to the individual patient's needs and preferences.

◊ RESOURCES

Providers

- U.S. Preventive Services Task Force: Tobacco Smoking Cessation in Adults, Including Pregnant Persons: Interventions
- Centers for Disease Control and Prevention: Clinical Interventions to Treat Tobacco Use and Dependence Among Adults > For Pregnant Patients

Patients

- Centers for Disease Control and Prevention: Pregnant or Planning to Have a Baby
- Smokefree.gov:
  - Quitting Smoking While Pregnant
  - Smokefree Text Messaging Programs > SmokefreeMOM
- NYS Quitline: Help to Quit Tobacco

Breast/Chestfeeding

Clinicians should advise patients to discontinue or minimize tobacco use while breast/chestfeeding and engage patients in harm reduction counseling. Smoking tobacco decreases milk supply and often causes individuals to stop breast/chestfeeding early [LactMed 2026j; Hopkinson, et al. 1992; Vio, et al. 1991]. See Table 3, above, for potential risks associated with breast/chestfeeding while taking medications used for tobacco use disorder treatment and LactMed > Nicotine for a full discussion on the effects of nicotine use during breast/chestfeeding.

→ KEY POINT

- Provide continual support for tobacco use cessation, and in the postpartum period, address psychosocial stressors that may contribute to tobacco use [ACOG 2020].

Cannabis Use During Pregnancy

☑ RECOMMENDATIONS

Cannabis Use

- Clinicians should advise pregnant patients who use cannabis to discontinue or minimize use during pregnancy to reduce or prevent potential harm to themselves and the developing fetus or infant. (A2)
- Clinician should provide harm reduction counseling to pregnant patients to help minimize the potential effects of cannabis on themselves and the developing fetus or infant. (A3)
- Clinicians should discuss the risks and benefits of breast/chestfeeding with pregnant patients who are actively using cannabis. (A3)

Potential adverse effects: Clinicians should discuss the potential risks, to the patient and their fetus or infant, associated with prenatal cannabis use and encourage patients to discontinue or minimize use during pregnancy. Prenatal cannabis use has been associated with an increased risk of low birth weight, small for gestational age, and preterm birth among other potential effects [Young-Wolff, et al. 2024b; Avalos, et al. 2024; Baía and Domingues 2024; Lo, et al. 2024; Duko, et al. 2023; Marchand, et al. 2022]. Some studies suggest a dose-dependent effect, with higher odds of negative outcomes among pregnant individuals who reported heavy use and with continued use during the second and third trimesters [Baía and Domingues 2024]. More evidence from controlled studies is needed on the effects of the timing and frequency of use, the route of administration, tetrahydrocannabinol level and potency of the cannabis, and polysubstance use, particularly tobacco use. Many studies related to prenatal cannabis use have mixed or inconclusive outcomes and are not well controlled for other confounders, such as tobacco use, socioeconomic status, and use of other substances [Ainiti, et al. 2023; Delker, et al. 2023; Sujan, et al. 2023; Thompson, et al. 2023].

Harm reduction: Explore with patients the reasons why they are using cannabis. Many individuals use cannabis during pregnancy to counteract negative effects of pregnancy, such as nausea and vomiting, anxiety, sleep disturbances, and pain, and clinicians can discuss alternative treatment options with patients [Young-Wolff, et al. 2024a; Chang, et al. 2019; Wang 2017; Young-Wolff, et al. 2017]. Clinicians should help pregnant patients who use cannabis identify strategies for harm reduction, including reduced use and ongoing engagement in prenatal care [Vanstone, et al. 2022] (see guideline section Perinatal Harm Reduction). There is no evidence to support use of medical cannabis to manage pregnancy-associated nausea and vomiting [ACOG 2025]. For pregnant patients who use unregulated cannabis to treat specific symptoms, such as those associated with posttraumatic stress disorder, medical cannabis may be the safer choice if they plan to continue using. See NYSDOH AI guideline Therapeutic Use of Medical Cannabis in New York State for more information.

Treatment: No pharmacologic treatments for cannabis use disorder (CUD) are approved by the U.S. Food and Drug Administration. For behavioral CUD treatment, a systematic review of interventions including brief counseling, cognitive behavioral therapy, motivational interviewing, motivational enhancement therapy with cognitive behavioral therapy, computer-delivered psychotherapy, and psychoeducation concluded that interventions involving cognitive behavioral therapy and motivational interviewing may help decrease cannabis use during pregnancy [Groff, et al. 2023].

Breast/chestfeeding: Few data are available on the risks of active cannabis use in any form while breast/chestfeeding, and no clear guidance is available on the length of time to wait after cannabis use before breast/chestfeeding. When counseling patients with CUD who are breast/chestfeeding their infant, it is important to discuss potential risks, reasons for cannabis use, and possible alternatives to use [LactMed 2026d; ACOG 2025; Metz and Borgelt 2018]. Extrapolating from the association between tobacco smoking and sudden infant death syndrome, patients should be advised to avoid smoking cannabis around infants [Anderson, et al. 2019].

◊ RESOURCES

- American Academy of Pediatrics: Marijuana Use During Pregnancy and Breastfeeding: Implications for Neonatal and Childhood Outcomes
- American College of Obstetricians and Gynecologists: Cannabis Use During Pregnancy and Lactation

Treatment of Methamphetamine and Cocaine Use Disorder During Pregnancy

The recommendations and text below focus on use of methamphetamine and cocaine. For full recommendations and evidence review, see the American Society of Addiction Medicine/American Academy of Addiction Psychiatry (ASAM/AAAP) stimulant use disorder guideline.

☑ RECOMMENDATIONS

Treatment of Methamphetamine and Cocaine Use Disorder

- Clinicians should advise pregnant individuals who use methamphetamines or cocaine to discontinue or minimize use during pregnancy and breast/chestfeeding to reduce or prevent potential harm to themselves and the developing fetus or infant. (A2)
- Clinicians should provide harm reduction counseling, including overdose prevention, to help minimize the potential effects of methamphetamines and cocaine on the patient and the developing fetus or infant. (A3)
- Clinicians should evaluate patients' readiness to engage in treatment and collaborate with them on treatment and harm reduction goals. (A3)
- Clinicians should obtain guidance from a substance use treatment specialist for pharmacologic treatment of methamphetamine or cocaine use disorder and engage the patient in shared decision-making on the benefits and risks. (A3)
  - NYSDOH AI Clinical Education Initiative: Clinical Consultation Line (866-637-2342)
  - University of California San Francisco National Clinical Consultation Center
- Clinicians should offer or refer pregnant patients to behavioral therapy based on availability and patient preference. (A3)

Potential adverse effects: Clinicians should discuss the risks, to the patient and the fetus or infant, associated with prenatal methamphetamine or cocaine use and encourage patients to discontinue or minimize use during pregnancy.

Prenatal stimulant use has been associated with lower birth weight, preterm delivery, and other complications [Perez, et al. 2022; Graves, et al. 2021; Oni-Orisan, et al. 2021; Dos Santos, et al. 2018; Kalaitzopoulos, et al. 2018; Gouin, et al. 2011]. Results from studies examining the effects of prenatal methamphetamine exposure on early childhood outcomes (up to 7.5 years) are mixed but point to the influence of other factors (e.g., quality of home, caregiver psychological symptoms) on child behavior in this population [Chu, et al. 2020; Eze, et al. 2016]. The association between the amount and duration of cocaine use and long-term effects on infants exposed in utero is unclear [Cestonaro, et al. 2022]. Many studies related to prenatal stimulant use have mixed or inconclusive outcomes and are not well controlled for other confounders, such as tobacco use, socioeconomic status, and use of other substances [Suarez, et al. 2024b; Kunkler, et al. 2022; Pham, et al. 2020].

Educate pregnant patients who use stimulants that newborns exposed in utero may exhibit symptoms, such as irritability, hypertonia, tremors, high-pitched crying, and poor sleep regulation, which generally peak 2 to 3 days after birth. These symptoms reflect neurotoxicity or direct substance effects rather than neonatal withdrawal syndrome as observed with opioid exposure [Shah, et al. 2025]. Preferred treatment strategies for the newborn include low-stimulation environments (quiet with low lighting), on-demand feeding, parental presence, swaddling, calming, and cuddling [Yazı, et al. 2025]. Consider involving a neonatologist as needed for infant symptoms. Advising patients of the potential for these symptoms and the treatment approach early in the pregnancy may reduce stress after delivery.

Harm reduction: Clinicians should provide harm reduction counseling, including overdose prevention, and referrals for pregnant individuals who use methamphetamines. Persons using stimulants may be either accidentally or intentionally exposed to opioids, so should be educated regarding and provided with naloxone and fentanyl test strips. Evidence suggests that individuals using methamphetamines are more vulnerable, marginalized, and low-income and experience more sexually transmitted infections, sexual and domestic violence, unintended pregnancies, and mental health conditions than pregnant individuals who use other substances [Perez, et al. 2022; Graves, et al. 2021; Wakeman, et al. 2021]. Individuals should be screened appropriately to identify risks. As part of a harm reduction approach, it is important to provide screening for bloodborne pathogens, sexually transmitted infections, depression, and nutritional deficiencies and to educate patients regarding the risks of shared drug equipment, including pipes, stems, straws, and injection equipment.

There is substantial evidence that stimulant use during pregnancy can harm the individual, developing fetus, and infant. If patients are using stimulants and other substances, stimulant use may be a priority for treatment and harm reduction efforts.

Treatment for intoxication and withdrawal: Stimulant intoxication and withdrawal can result in acute issues and complications that require urgent medical management. Overamping is the term for a stimulant "overdose" and can involve both physical and psychological symptoms, such as agitation, psychosis, and risk of harm to self or others. A basic assessment of vital signs and focused mental status evaluation can determine the need for urgent or emergent treatment or referral for further medical evaluation [ASAM/AAAP 2024].

Mild stimulant intoxication can typically be managed with behavioral and environmental interventions meant to help the patient feel calm and safe, including isolation in a non-stimulating environment (quiet with low lighting); supportive care such as vitamins, fluids, electrolytes, and nutrition; and reassuring communication with the patient [ASAM/AAAP 2024].

For recommendations and a full discussion on managing intoxication and withdrawal, see ASAM/AAAP Clinical Practice Guideline on the Management of Stimulant Use Disorder.

Pharmacologic treatment for stimulant use disorder (StUD): No medications are approved by the U.S. Food and Drug Administration to treat StUD in pregnant or nonpregnant patients. However, several treatment regimens have been associated with reductions in stimulant use in some nonpregnant individuals with cocaine or methamphetamine use disorder. See NYSDOH AI Clinical Guidance: Stimulant Use > Treatment. There is minimal direct evidence on the efficacy and safety of medications for treatment of StUD in pregnant patients. Clinicians should seek guidance from substance use treatment specialists on treatment options and engage in shared decision-making with patients on the benefits and risks, including the risk of ongoing use of stimulants. Risk level may vary based on trimester. Concern for fetal well-being should not be prioritized over the health of the pregnant patient [ASAM/AAAP 2024]. Bupropion with or without naltrexone and mirtazapine are reasonable StUD treatment options during pregnancy [Chavan, et al. 2025]. Patients should be referred to substance use treatment specialists if psychostimulant treatment for StUD is being considered. Topiramate, valproic acid, modafinil, and amphetamine/dextroamphetamine are generally contraindicated during pregnancy.

Behavioral treatment: In agreement with the current ASAM/AAAP guidelines, this committee recommends that clinicians offer or refer pregnant patients who use stimulants for behavioral treatment, including parent-focused and family-based treatment to address other needs. When available, evidence-based contingency management (CM) programs should be used to incentivize attendance at prenatal appointments [ASAM/AAAP 2024; Washio, et al. 2021; Ronsley, et al. 2020]. In nonpregnant adults, evidence indicates that CM is more effective than other behavioral or pharmacologic treatments for stimulant use disorder [ASAM/AAAP 2024; Bentzley, et al. 2021; De Crescenzo, et al. 2018], but studies are limited among pregnant adults [Hand, et al. 2017]. Evidence supports the efficacy of CM as a component of treatment, but CM is not readily available in many clinical settings.

Telemedicine and digital therapeutics or web-based platforms to deliver behavioral interventions may help individuals with challenges accessing care [ASAM/AAAP 2024]. Based on the individual patient's needs and preferences, inpatient or residential treatment may also be considered.

For discussion of behavioral treatment for StUD, see ASAM/AAAP Clinical Practice Guideline on the Management of Stimulant Use Disorder > Population-Specific Considerations > Pregnant and Postpartum Patients.

Breast/chestfeeding: Breast/chestfeeding is not recommended for individuals actively using cocaine or methamphetamines. Both substances are excreted in human milk [LactMed 2026h; LactMed 2026e; Graves, et al. 2021]. Based on very limited data, waiting 48 to 100 hours after methamphetamine use [LactMed 2026h; Chomchai, et al. 2016; Bartu, et al. 2009] and 24 hours after cocaine use [LactMed 2026e; Cressman, et al. 2012a] to breast/chestfeed have been suggested to allow for drug elimination.

Ongoing support: Provide additional treatment support around the time of birth, as the postpartum period may be a time of increased stress and risk of return to stimulant use [ASAM/AAAP 2024].

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Supplement: Guideline Development and Recommendation Ratings

Table S1: Guideline Development: New York State Department of Health AIDS Institute Clinical Guidelines Program	
Developer	New York State Department of Health AIDS Institute (NYSDOH AI) Clinical Guidelines Program
Funding source	NYSDOH AI
Program manager	Clinical Guidelines Program, Johns Hopkins University School of Medicine, Division of Infectious Diseases. See Program Leadership and Staff.
Mission	To produce and disseminate evidence-based, state-of-the-art clinical practice guidelines that establish uniform standards of care for practitioners who provide prevention or treatment of HIV, viral hepatitis, other sexually transmitted infections, and substance use disorders for adults throughout New York State in the wide array of settings in which those services are delivered.
Expert committees	The NYSDOH AI Medical Director invites and appoints committees of clinical and public health experts from throughout New York State to ensure that the guidelines are practical, immediately applicable, and meet the needs of care providers and stakeholders in all major regions of New York State, all relevant clinical practice settings, key New York State agencies, and community service organizations.
Committee structure	• Leadership: AI-appointed chair, vice chair(s), chair emeritus, clinical specialist(s), JHU Guidelines Program Director, AI Medical Director, AI Clinical Consultant, AVAC community advisor • Contributing members • Guideline writing groups: Lead author, coauthors if applicable, and all committee leaders
Disclosure and management of conflicts of interest	• Annual disclosure of financial relationships with commercial entities for the 12 months prior and upcoming is required of all individuals who work with the guidelines program, and includes disclosure for partners or spouses and primary professional affiliation. • The NYSDOH AI assesses all reported financial relationships to determine the potential for undue influence on guideline recommendations and, when indicated, denies participation in the program or formulates a plan to manage potential conflicts. Disclosures are listed for each committee member.
Evidence collection and review	• Literature search and review strategy is defined by the guideline lead author based on the defined scope of a new guideline or update. • A comprehensive literature search and review is conducted for a new guideline or an extensive update using PubMed, other pertinent databases of peer-reviewed literature, and relevant conference abstracts to establish the evidence base for guideline recommendations. • A targeted search and review to identify recently published evidence is conducted for guidelines published within the previous 3 years. • Title, abstract, and article reviews are performed by the lead author. The JHU editorial team collates evidence and creates and maintains an evidence table for each guideline.
Recommendation development	• The lead author drafts recommendations to address the defined scope of the guideline based on available published data. • Writing group members review the draft recommendations and evidence and deliberate to revise, refine, and reach consensus on all recommendations. • When published data are not available, support for a recommendation may be based on the committee's expert opinion. • The writing group assigns a 2-part rating to each recommendation to indicate the strength of the recommendation and quality of the supporting evidence. The group reviews the evidence, deliberates, and may revise recommendations when required to reach consensus.

Table S1: Guideline Development: New York State Department of Health AIDS Institute Clinical Guidelines Program	
Review and approval process	• Following writing group approval, draft guidelines are reviewed by all contributors, program liaisons, and a volunteer reviewer from the AI Community Advisory Committee. • Recommendations must be approved by two-thirds of the full committee. If necessary to achieve consensus, the full committee is invited to deliberate, review the evidence, and revise recommendations. • Final approval by the committee chair and the NYSDOH AI Medical Director is required for publication.
External reviews	• External review of each guideline is invited at the developer's discretion. • External reviewers recognized for their experience and expertise review guidelines for accuracy, balance, clarity, and practicality and provide feedback.
Update process	• JHU editorial staff ensure that each guideline is reviewed and determined to be current upon the 3-year anniversary of publication; guidelines that provide clinical recommendations in rapidly changing areas of practice may be reviewed annually. Published literature is surveilled to identify new evidence that may prompt changes to existing recommendations or development of new recommendations. • If changes in the standard of care, newly published studies, new drug approval, new drug-related warning, or a public health emergency indicate the need for immediate change to published guidelines, committee leadership will make recommendations and immediate updates and will invite full committee review as indicated.

Table S2: Recommendation Ratings and Definitions		
Strength	**Quality of Evidence**	
A: Strong B: Moderate C: Optional	1	Based on published results of at least 1 randomized clinical trial with clinical outcomes or validated laboratory endpoints.
	*	Based on either a self-evident conclusion; conclusive, published, in vitro data; or well-established practice that cannot be tested because ethics would preclude a clinical trial.
	2	Based on published results of at least 1 well-designed, nonrandomized clinical trial or observational cohort study with long-term clinical outcomes.
	2†	Extrapolated from published results of well-designed studies (including nonrandomized clinical trials) conducted in populations other than those specifically addressed by a recommendation. The source(s) of the extrapolated evidence and the rationale for the extrapolation are provided in the guideline text. One example would be results of studies conducted predominantly in a subpopulation (e.g., one gender) that the committee determines to be generalizable to the population under consideration in the guideline.
	3	Based on committee expert opinion, with rationale provided in the guideline text.