



Behavioral Health Conditions and Substance Use in High Risk Pregnancy

OBJECTIVE

The objective of this Clinical Practice Guideline (CPG) is to provide evidence-based practice recommendations for the treatment of behavioral health conditions and substance use disorders (SUDs) in high risk pregnancy. The CPG discusses common behavioral health conditions and SUDs with regard to health risks for the member during pregnancy. In addition, the CPG outlines the organizations that WellCare aligns with regarding the topic and Measureable Health Outcomes.

OVERVIEW

Up to 20% of women suffer from a mood or anxiety disorder during pregnancy. Women who discontinue medications during pregnancy are 5 times as likely to relapse as compared to women who maintained treatment. It is common for patients to discontinue medications during pregnancy as there is incomplete knowledge on the risks of prenatal exposure to psychotropic medications. Women who suffer from psychiatric illnesses during pregnancy are less likely to receive adequate prenatal care and are more likely to use alcohol, tobacco and other substances. Possible complications of maternal depression include low birth weight, fetal growth retardation and an increased risk for pre-eclampsia, C-section and infant admission to NICU. No psychotropic drug has been approved by the FDA for use during pregnancy. The risks of psychotropic drug use include teratogenesis, neonatal toxicity and long-term neurobehavioral sequelae.¹

Women who are pregnant or may soon become pregnant are at increased risk for substance abuse. According to a national survey conducted in 2012, 5.9% of pregnant women use illicit drugs, 8.5% drink alcohol and 15.9% smoke cigarettes. Between 2000 and 2009 the United States also saw a five-fold increase in opiate use during pregnancy. Substance use in pregnancy has been associated with increased risk for miscarriage, stillbirth and infant mortality, congenital abnormalities, low birthweight, reduced gestational age, preterm delivery and small for gestational age, damage to the umbilical cord, ectopic pregnancy, placental abruption and premature abruption of membranes. Opiate use specifically also increases risk for respiratory problems, third trimester bleeding, toxemia, neonatal abstinence syndrome (NAS). NAS can also be caused by methadone and buprenorphine use in utero.²

Hierarchy of Support

GUIDELINE HIERARCHY

CPGs are updated annually or as necessary due to updates made to guidelines or recommendations by the American College of Obstetricians and Gynecologists (ACOG) and the World Health Organization (WHO). When there are differing opinions noted by national organizations, WellCare will default to the member's benefit structure as deemed by state contracts and Medicaid / Medicare regulations. If there is no specific language pertaining to behavioral health conditions and substance use in high risk pregnancy, WellCare will default (in order) to the following:

- National Committee for Quality Assurance (NCQA);
- United States Preventive Services Task Force (USPSTF), National Quality Strategy (NQS), Agency for

Healthcare Research and Quality (AHRQ);

- Specialty associations, colleges, societies, etc. (e.g., American Academy of Family Physicians, American Congress of Obstetricians and Gynecologists, American Cancer Society, etc.).

Links to websites within the CPGs are provided for the convenience of Providers. Listings do not imply endorsement by WellCare of the information contained on these websites. NOTE: All links are current and accessible at the time of MPC approval.

WellCare aligns with ACOG and WHO on the topic of behavioral health conditions and substance use in high risk pregnancy. Highlights from their respective publications are noted below.

AMERICAN COLLEGE OF OBSTETRICIANS AND GYNECOLOGISTS (ACOG)

Behavioral Health Conditions

The American Congress of Obstetricians and Gynecologists offers the following recommendations to assist clinicians with evaluation, and treatment on the following topics:

- [Screening for Perinatal Depression](#)³
 - Screen patients at least once during the perinatal period for depression and anxiety symptoms using a standardized, validated tool.
 - Screen women with current depression or anxiety, a history of perinatal mood disorders, or risk factors for perinatal mood disorders; this may warrant close monitoring, evaluation, and assessment.
 - Screening by itself is insufficient to improve clinical outcomes and must be coupled with appropriate follow-up and treatment when indicated; clinical staff in OBGYN practices should be prepared to initiate medical therapy, refer patients to appropriate behavioral health resources when indicated, or both.
 - Systems should be in place to ensure follow-up for diagnosis and treatment
- [Preventing Fetal Alcohol Syndrome](#)⁴
 - Screen pregnant women and women of childbearing age for alcohol use.
 - Brief interventions such as motivational interviewing may be effective at reducing risk.
 - A woman’s partner, family members and friends can help prevent FASD by sharing information about the importance of not drinking during pregnancy, modeling safe behavior by not drinking themselves, encouraging her to talk about problems in her life that may lead her to drink, and helping her find treatment if she cannot stop drinking
 - Women who need alcohol treatment may not receive it due to lack of money or child care, fear of losing custody of their children, or other barriers.
 - For successful recovery, women often need a continuum of care for an extended period of time, including: comprehensive inpatient or outpatient treatment for alcohol and other drugs, case management, counseling and other mental health treatment, medical and prenatal care, child care, transportation, follow-up pediatric and early intervention services for children, services that respond to women’s needs regarding reproductive health, sexuality, relationships, and victimization.
- [Tobacco and Nicotine Cessation Toolkit](#)¹⁵
 - The toolkit includes screening tools for tobacco and nicotine use and resources to help women stop use through education, medication, counseling, and referral.

WORLD HEALTH ORGANIZATION (WHO)

WellCare aligns with the World Health Organization (WHO) on the topic of substance use and substance use disorders during pregnancy and psychosocial management of perinatal depression. For additional information, click [here](#) to access the *Guidelines for Identification and Management of Substance Use and Substance Use Disorders in Pregnancy*.⁵ The WHO provides 18 recommendations to identify and manage substance use and substance use disorders during pregnancy. The WHO outlines research by the Guideline Development Group (GDG).⁵

The guidelines offer five governing principles:

1. Prioritizing prevention
2. Ensuring access to prevention and treatment services
3. Respecting patient autonomy

The guidelines have six focus areas:

1. Screening and brief intervention
2. Psychosocial interventions
3. Detoxification

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|--|---|
| <ul style="list-style-type: none"> 4. Providing comprehensive care 5. Safeguarding against discrimination and stigmatization | <ul style="list-style-type: none"> 4. Dependence management 5. Infant feeding 6. Management of neonatal withdrawal |
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For the list of 18 recommendations, access the guidelines [here](#).

The WHO developed a manual for training community health workers that are non-specialists, such as nurse, on how to support mothers with depression through evidenced based cognitive behavioral techniques that are recommended by the mhGAP program. These include examples of brief, basic psychological interventions. Guidelines include:⁵

- Psychosocial interventions should be the first-line of management of depression during pregnancy and breastfeeding
- Provide social support and psycho-education
- Provide CBT if available
- Provide adjunct treatments such as structured physical activity, relaxation, and problem-solving.
- Reactivate social networks
- Attend to physical as well as psychological health of the mother

Evidence Based Practice

AGENCY FOR HEALTHCARE RESEARCH AND QUALITY (AHRQ)

The Agency for Healthcare Research and Quality (AHRQ) has also published the following evidence based reports:

- [Antidepressant Treatment of Depression During Pregnancy and the Postpartum Period⁶](#) ([click here](#))
The report includes key findings of direct-comparison evidence for antidepressant treatment of depression during pregnancy or postpartum. The AHRQ notes that evidence is lacking regarding the comparative benefits and harms of pharmacological treatment of depression in pregnant and postpartum women.
- [Alcohol Misuse Screening & Behavioral Counseling⁷](#) ([click here](#))
A meta-analysis on behavioral counseling interventions in primary care to reduce risky alcohol use by adults identifies brief multi-contact behavioral interventions as most successful in increasing cessation offs and improving health outcomes. Effective interventions included: advice, feedback, goal setting, and additional contacts for assistance and support.

MEASUREMENT OF COMPLIANCE

WellCare is committed to adhering to the measures and standards published by the Centers for Medicare and Medicaid Services (CMS) and the National Committee for Quality Assurance (NCQA). Please reference WellCare’s Clinical Policy Guiding Document titled *Measures of Compliance*.

NOTE: To access Clinical Policy Guiding Documents visit www.wellcare.com – select the Provider tab, then “Tools” and “Clinical Guidelines”.

Care Management

The goals for Care Management are to support the member’s ability to self-manage their disorder, minimize risk factors and remove barriers preventing the member from achieving goals. Goals of treatment for substance use in pregnancy should also include the achievement of abstinence or reduction in the use and effects of substances during pregnancy, reduction in the frequency and severity of relapse to substance use, and improvement in psychological and social functioning. Goals of treatment for behavioral health conditions in pregnancy should include communication and collaboration between prenatal care provider and behavioral health provider, reducing relapse of behavioral health symptoms requiring hospitalization, and improving the physical and mental health of the mother and fetus. Educate member on Behavioral Health symptoms and Substance Use in High Risk Pregnancy symptoms.

Core functions of Care Managers in this population are:⁸

- Conduct initial and ongoing assessment of patient risk factors and comprehensive medical/psychosocial needs
- Facilitate communication and collaboration between members of the prenatal team and coordinate needed care and services while involving the member in all decisions
- Educate member and members of the ICT about options, community resources, and psychosocial concerns so

timely and informed decisions can be made

- Empower the member to problem-solve by exploring care options to achieve goals. Encourage the appropriate use of healthcare services and work to improve the quality of care while maintaining cost effectiveness.

Behavioral Health Conditions⁹

Psychiatric Medications and Pregnancy

- The first trimester of the pregnancy is considered the highest risk for malformations as this is the period when organ development occurs.
- Although most psychiatric medications are safe during pregnancy, there is an abundance of caution when using them during gestation.
- Before using them, the prescriber should have a thoughtful discussion with the patient to explain potential risks versus benefits of the medication.

Depression During Pregnancy

- Unintended or unwanted pregnancy increases the risk for depression.
- Treatment can include cognitive-behavioral therapy and at times antidepressant medications.
- While depression rates are slightly higher in pregnant women, suicidal behaviors and risks are much lower than depressed women who are not pregnant.
- Women with depression during pregnancy are at higher risk for post-partum depression.

Bipolar Disorder During Pregnancy

- Management of bipolar disorder during pregnancy is very complicated and all pregnant women with bipolar disorder should be considered high risk.
- Discontinuing maintenance medications runs a very high rate of manic relapse.
- Continuing maintenance medications runs a high rate of fetal malformations.
- Psychiatric management throughout the pregnancy is critical.

Psychosis During Pregnancy

- Similar to bipolar disorder, management of psychosis during pregnancy is very complicated and all pregnant women with bipolar disorder should be considered high risk.
- Psychotic women are at risk for poor self-care and prenatal care.
- Discontinuing maintenance medications runs a very high rate of manic relapse.
- Continuing maintenance medications runs a high rate of fetal malformations.
- Psychiatric management throughout the pregnancy is critical.

Anxiety During Pregnancy. Similar to depression, unintended or unwanted pregnancy increases the risk for anxiety or panic attacks. Treatment can include cognitive-behavioral therapy and at times antidepressant medications.

Psychiatric Medications and Breastfeeding. Breast milk confers certain health benefits to the infant and may yield psychological benefits to the mother and infant including emotional bonding. There are other considerations as all psychiatric medications will be present in breast milk of the mother however the concentration of the medications is quite variable. Peak levels in breast milk occur 6-8 hours after dosing. Conversely, lowest drug levels occur right before dosing. This may be the best time to breast feed however infants usually feed every 2-4 hours, making this cycle impractical. Most bipolar medications can be toxic to newborns and alternatives to breast-feeding should be explored. Bipolar mothers who breast-feed are at higher risk for relapse due to sleep disruptions. Women on psychiatric medications should discuss the pros and cons of breast-feeding while on psychiatric medications with their provider.

Postpartum Behavioral Disorders. The “baby blues” are a period of anxiety, sudden weepiness, and trouble sleeping that can impair maternal-child bonding. This common among mothers (50-80%) and is a transient phenomenon. Persistent depression during the weeks after delivery occurs in about 10-15% of women. Those at highest risk for include mothers with a prior history of postpartum depression, bipolar disorder, and/or major depressive disorder

Management of Psychiatric Conditions in Pregnancy. The co-occurrence of a psychiatric condition increases the risks associated with pregnancy and the post-partum period. Psychiatric consultation is important to assess the member’s needs for continued use of prescribed medications while minimizing risks of fetal toxicity. Members with psychotic

disorders or bipolar disorders are at greatest risk for psychiatric relapse during pregnancy and in the post-partum period.

Substance Use

The prevalence of opioid abuse during pregnancy requires that practicing obstetrician–gynecologists be aware of the implications of opioid abuse by pregnant women and of appropriate management strategies. The following are common issues in treating pregnant women with substance use disorders:^{9,10}

- Substance users may not seek prenatal care because of fear, guilt and shame. In addition, there may be concerns about medical and legal intervention.
- Opioid users may not even realize that they are pregnant if they are not planning pregnancy and misinterpret the early signs of pregnancy as opioid withdrawal symptoms (e.g., nausea, vomiting, cramping).
 - Unintended pregnancy is common in these women; in one study, 86 percent of pregnant opioid-using women reported their pregnancy was unintended.
- Opioid withdrawal should not be started before 14 weeks or after 32 weeks gestation.¹⁶
- Medication Assisted Therapy (MAT) is recommended for pregnant women addicted to opioids and preferable to medically supervised withdrawal.¹⁶
 - Methadone and buprenorphine are Pregnancy Category C drugs, therefore a risk/benefit analysis should be done, however there are no known teratogenic effects when medication is taken as directed and relapse is avoided.
 - Methadone and buprenorphine (monotherapy) are the accepted MAT options, but can produce opioid dependence in the newborn.
- Substance use assessment, counseling, and support by a nonjudgmental clinician may motivate some women who use illicit drugs other than opioids to abstain.
- Observational studies suggest that combining treatment of substance abuse with comprehensive prenatal care can reduce the frequency of some maternal and neonatal complications of maternal substance use. Components of this care should be individualized based on patient-specific factors, and may include:
 - Counsel about the risks associated with each drug the mother is using;
 - Encourage the member to moderate and, ideally, discontinue use of illicit drugs (dependent on specific drug and pattern of use);
 - Identify comorbid conditions (e.g., psychiatric disorders and physical/sexual/emotional abuse) frequently found in substance abusers. The interrelationships between these issues and substance use need to be addressed in caring for these patients;
 - Address the needs of poorly nourished, homeless, and/or incarcerated pregnant substance abusers. In addition to education about nutrition and weight gain, some of these women may need referral to food assistance programs and shelters, and provision of transportation vouchers and prenatal multivitamins; and
 - Assemble a multidisciplinary team to comprehensively assess and participate in the care of these women and their offspring – the team may include obstetrical, medical, pediatric, psychiatric, addiction medicine, and social service providers.

The ACOG publication can be view [here](#).¹⁰

MEASURABLE HEALTH OUTCOMES

Targeted Case Management outcomes (**Extended Program Goals**) result from successful self-management (see Case Management Objectives).

- **Symptoms:** EPDS score of <12 completed within 6 weeks after birth
- **Adherence:** Birth of infant born >37 weeks gestation with a birth weight >2,500 grams as evidenced by service authorizations
- **Adherence:** Member achieves recommended weight gain during pregnancy (25 – 35 lbs if average weight) as evidenced by member or provider report
- **Adherence:** Birth of infant born without FAS, cerebral palsy or neural tube defects as evidenced by service authorizations and labs including newborn blood spot screening.
- **Adherence:** Member attended >80% of prenatal appointments and postpartum 6 week check-up as evidenced by medical claims or provider report
- **Adherence:** Reduction or abstinence from alcohol and illicit drug use during pregnancy as evidenced by provider report or CAGE score < 2 within 90 days

- **Adherence:** Continuation of methadone or buprenorphine throughout entire pregnancy (without lapse of medication) as evidenced by pharmacy claims (for members with opiate addictions)
- **Engagement:** Member attends at least one parenting class, support group or self-help group a month within 3 months as evidenced by member or provider report
- **Utilization:** A reduction of ER or inpatient admits related to behavioral health or substance abuse of at least 25% by 8 weeks post-partum as evidenced by service authorizations and medical claims

CASE MANAGEMENT GOALS

Goals should target specific care gaps and/or adherence issues, and measure the member's progress towards self-management and adherence which lead to the targeted health outcomes above.

- **Symptoms:** Within 60 days, member will list at least 3 coping skills or relaxation techniques to improve sleep & reduce stress; will obtain mood journal to track sleep patterns, general mood and anxiety, coping skills used
- **Adherence:** Member will fill prescribed medications on time and list at least one reason for the importance of taking each medication within 30 days
- **Adherence:** Member will list at least 3 foods that should not be eaten during pregnancy and at least 3 foods that are healthy for pregnant mothers within 30 days
- **Engagement:** Member will be connected to at least one parent education class or parent support group within 60 days
- **Engagement:** Member will be connected to at least one agency providing child care, family planning, employment resources and/or baby supplies within 60 days
- **Engagement:** Member will be connected to at least one community resources to assist with food, housing and/or domestic violence assistance within 60 days
- **Utilization:** Member will schedule prenatal appointments once a month for the first two trimesters, twice a month until week 36 and once week after that, and verbalize at least 2 reasons for the importance of following treatment

Case Management goals specific to behavioral health conditions in pregnancy

- **Adherence:** Member will schedule therapy sessions and/or sign up for Cobalt within 30 days
- **Symptoms:** Within 2 weeks, member will list at least 3 people she can call if thoughts of self-harm occur
- **Adherence:** Member will schedule psychiatry appointments and psychiatrist will collaborate with prenatal care provider within 30 days

Case Management goals specific to substance use conditions in pregnancy

- **Adherence:** Within 30 days, member will be set up with 12-step meetings and/or an inpatient or outpatient substance abuse program and verbalize 3 reasons why a reduction of consumption of alcohol or illicit substances is important during pregnancy
- **Engagement:** Member will be connected to a peer support such as a mentor, coach or sponsor to assist with substance use reduction within 30 days
- **Engagement:** Member will be connected with a sober living home for pregnant women within 30 days

CASE MANAGEMENT OBJECTIVES

- Assess for suicidality; including, past attempts, thoughts, plans, intent and availability of means
- Assess for psychosocial concerns and threats to safety including domestic violence or emotional abuse, homelessness or threat of homelessness, lack of support system, financial difficulties, lack of adequate food, and other sources of extreme stress or trauma
- Screen for common co-morbid health conditions such as gestational diabetes, obesity, tobacco use and hypertension
- Educate on the importance of regular prenatal appointments and assist with appointment set up and transportation as needed and address any other barriers to keeping appointments
- Refer to WIC, parenting classes and pregnancy support groups and programs and empower members to utilize resources themselves.
- Refer to home intervention programs in the area if available such as Healthy Start and Healthy Families
- Educate the patient about the importance of avoiding tobacco, alcohol and drug use, eating a healthy diet,

taking a prenatal vitamin, and getting regular prenatal checks

- Ensure that member is able to obtain prescribed medications and understands how to take them
- Review warning signs of preterm labor and how to seek appropriate medical care
- Refer to Cobalt if appropriate
- Screen for high risk behavior such as unprotected sex and educate on safe sex practices
- Educate on sleep hygiene and relaxation techniques to improve sleep and reduce stress
- For adolescent members; link to services available at gateway agencies such as schools, churches and juvenile justice agencies or programs such as Young Parenthood Program and Strong Foundations if available.

General objectives specific to managing behavioral health conditions in pregnancy include:

- Encourage member to discuss behavioral health concerns with prenatal care provider
- Refer to therapist and/or psychiatrist specializing in managing behavioral health disorders in pregnant members and ensure collaboration with behavioral health providers and prenatal care provider
- Educate on recognizing psychotic symptoms such as hallucinations and delusions and reporting them to prenatal care provider and behavioral health provider

General objectives specific to managing substance use disorders in pregnancy include:¹

- Utilize motivational interviewing and provide information when the member is ready, to assist them in understanding the consequences of continued substance use during the pregnancy.
- Use medication assisted therapy for opioid addiction, in addition to behavioral therapies.
- Refer to inpatient or outpatient substance abuse programs as appropriate
- Refer member to 12 step meetings and other community resources to support recovery
- Utilize family and friends to assist with support and recovery
- SUD treatment services should include childcare, transportation, reproductive health, nutrition and parenting.
- Women on methadone or buprenorphine should have medication maintained and not discontinued during pregnancy. Detoxification is not recommended.

MEDICAL BEHAVIORAL INTEGRATION

Substance abuse during pregnancy is common. Nationally, up to 25 percent of expectant mothers use illicit drugs. When a pregnant woman is addicted to drugs or alcohol, her baby is also addicted. Various pilot programs exist to medically stabilize the expectant mother and her baby. Replacement therapy and/or complete detoxification may be recommended depending on the clinical situation and staff at the pilot programs may assist with making that determination. Women with behavioral health conditions have a higher rate of co-morbid health conditions such as diabetes and hypertension and also have an increased likelihood of poorer nutrition and self-care.

MEMBER EDUCATIONAL RESOURCES

WellCare contracts with Krames/StayWell for Member educational materials utilized by Case Managers. Items are available to review with Members to address knowledge gaps. Case Managers verbally educate Members on the topics below related to behavioral health conditions and substance use disorder.

- Recognizing the Signs of Substance Abuse in Teens
- When you Suspect Your Child is Using Alcohol or Drugs
- For Teens: Understand the Cycle of Addiction
- Signs of Addiction: Social Use
- Understanding the Disease of Addiction
- Understanding Inhalant Abuse
- Understanding Methamphetamine Abuse and Addiction
- Understanding Marijuana Abuse
- Understanding Heroin Abuse and Addiction
- Addiction: Ask Yourself These Questions
- Addiction: Getting Help
- Cocaine: Getting Help
- Alcoholism: Getting Help
- Alcoholism: Resources for Family and Friends
- Treating Heroin Addiction
- Treating Drug Abuse and Addiction
- Treating Inhalant Abuse
- Life After Combat: Coping with Alcohol Abuse
- Recovering from Addiction: Continuing with Counseling
- Recovering from Addiction: Coping with Relapse
- Recovering from Addiction

Providers may wish to research the titles above related to pneumonia that Case Managers utilize with Members.

ELEMENTS OF TREATMENT

The goals of treatment include the achievement of abstinence or reduction in the use and effects of substances during pregnancy, reduction in the frequency and severity of relapse to substance use, and improvement in psychological and social functioning. To accomplish these goals, Providers should include the following elements below.

FETAL ALCOHOL SPECTRUM DISORDER (FASD) ^{9,11}

Fetal Alcohol Syndrome Disorder (FASD) is an umbrella term that encompasses the range of physical, mental, behavioral, and/or learning disabilities with lifelong implications. All women are at risk of having a child with an FASD if they drink alcohol at any time during pregnancy. Conditions associated with prenatal exposure include:

- Fetal alcohol syndrome (FAS)
- Partial fetal alcohol syndrome (pFAS)
- Neurobehavioral disorder associated with prenatal alcohol exposure (ND-PAE)
- Alcohol Related Neurodevelopmental Disorder (ARND)

Early identification of FASD is key to receiving appropriate educational and mental support. Many symptoms of FASD cannot be determined at birth. Symptoms that can lead to assessment of FASD at a later time include:

- | | |
|----------------------|----------------------|
| • Small head | • Short nose |
| • Epicanthal folds | • Smooth philtrum |
| • Low nasal bridge | • Thin upper lip |
| • Small eye openings | • Underdeveloped jaw |
| • Flat midface | |

Drinking alcohol during pregnancy can cause miscarriage, still birth and a range of lifelong physical, behavioral and intellectual disabilities.

- | | |
|-------------------------------|--|
| • Small head | • Difficulty in school |
| • Abnormal facial features | • Learning disabilities |
| • Small head size | • Speech and language delays |
| • Shorter-than-average height | • Intellectual disability or low IQ |
| • Low body weight | • Poor reasoning and judgement skills |
| • Poor coordination | • Sleep and sucking problems as a baby |
| • Hyperactive behavior | • Vision or hearing problems |
| • Difficulty with attention | • Problems with heart, kidney or bones |
| • Poor memory | |

Prenatal exposure to alcohol can also affect executive functions, which are controlled by the frontal lobe:

- Planning – Inability to apply consequences from past actions.
- Time Perception – Difficulty with abstract concepts of time and money.
- Internal ordering – Difficulty with sequencing, difficulty processing information.
- Working memory – Difficulty storing and/or retrieving information
- Self-Monitoring – Requires frequent cues, assistance from others with monitoring behavior.
- Verbal Self-Regulation – Needs self-talk, verbal self-feedback.
- Motor Control – Fine motor skills more affected than gross motor skills.
- Regulation of emotion – Difficulty in maintaining stable emotional state, swings from emotional highs to lows; unable to regain composure without assistance.
- Motivation – Requires external motivators, may demonstrate lack of remorse.

Clinical Features of FASD. The characteristic clinical features of FASD include three facial dysmorphisms (short palpebral fissures, thin vermilion border, and smooth philtrum), growth retardation, and central nervous system (CNS) abnormalities. The predominant clinical features may vary with age. Facial dysmorphisms may be apparent at birth (though may not be recognized). Growth retardation may occur prenatally or post-natally. CNS impairment may not be apparent until the child is in school. Most individuals with FASD are diagnosed during childhood.

Effects of Alcohol in Pregnancy. Despite the risk factors listed below, all women are at risk of giving birth to a child with FASD if they consume alcohol:

- Low educational attainment
- Higher maternal age
- Higher gravidity and parity
- History of miscarriages and stillbirths
- Poor maternal nutrition during pregnancy
- History of FASD in previous children
- Substance use, including tobacco
- Mental health problems including depression
- History of physical or sexual abuse
- Social isolation including living in a rural area during pregnancy
- Intimate partner violence
- Paternal alcohol and drug use at the time of pregnancy
- Other maternal family members with substance use at the time of pregnancy
- Poverty

Additional key points about the effects of alcohol include:

- Is teratogenic (interferes with normal development) and may cause irreversible central nervous system effects.
- Abnormalities include reduced brain volume with specific reductions in the frontal lobe, striatum and caudate nucleus, thalamus, and cerebellum; thinning of the corpus callosum; and abnormal functioning of the amygdala. These areas influence impulse control and judgment, transfer of information between the hemispheres, memory and learning, motor coordination, ability work toward goals, and perception of time.
- A “safe” threshold or pattern of alcohol consumption has not been identified. A fetus is particularly vulnerable to maternal alcohol consumption due to inefficient elimination and prolonged exposure. Alcohol is eliminated from the fetal compartment at a rate of only 3 to 4 percent of the maternal rate. In addition, much of the alcohol excreted by the fetus into the amniotic fluid is “recycled” through fetal swallowing of amniotic fluid and intramembranous absorption.
- Alcohol has the potential to cause deleterious effects at all stages of gestation.
 - Significant alcohol exposure during the first trimester is associated with facial anomalies and major structural anomalies, including brain anomalies.
 - Exposure in the second trimester increases the risk of spontaneous abortion.
 - Exposure in the third trimester predominantly affects weight, length, and brain growth. However, neurobehavioral effects may occur with a range of exposures throughout gestation, even in the absence of facial or structural brain anomalies.
- Teratogenic effects vary depending upon the quantity and pattern (e.g., binge drinking, daily drinking) of alcohol consumption, maternal and fetal genetics, maternal age, maternal nutrition, and smoking, among other factors.

SMOKING USE IN PREGNANCY^{9,12}

Cigarette smoking during pregnancy is the most important modifiable risk factor associated with adverse pregnancy outcomes. In 2002 in the United States, 5 to 8 percent of preterm deliveries, 13 to 19 percent of full-term infants with growth restriction, 5 to 7 percent of preterm-related deaths, and 23 to 34 percent of sudden infant death syndrome (SIDS) deaths were attributable to prenatal smoking. In addition, smoking and secondhand smoke exposure increase the risk of infertility, placental abruption, preterm premature rupture of membranes (PPROM), and placenta previa.

Despite the known harmful effects of smoking, 23 percent of American women report smoking cigarettes in the three months before pregnancy. The Pregnancy Risk Assessment Monitoring System (PRAMS) survey reported a prevalence of 11 percent during the last three months of pregnancy in 2010. Smoking prevalence was highest in women aged 20 to 24 years (17.6 percent), were American Indians/Alaska Natives (26.0 percent), had <12 years of education (17.4 percent), and had Medicaid coverage during pregnancy or at delivery (17.6 percent). The use of biochemical markers, including exhaled carbon monoxide and urinary cotinine, has shown that pregnant women underreport both smoking status and the extent of smoking.

Effects of Smoking in Pregnancy

- Impaired fetal oxygen delivery is the best-studied cause of adverse outcome in pregnant women who smoke. Pathologic evaluations of the placentas of smokers have shown structural changes, including a reduction in the fraction of capillary volume and increased thickness of the villous membrane when compared to nonsmokers.
- Another problem is that carbon monoxide exposure from smoking causes the formation of carboxyhemoglobin, which also impairs fetal oxygen delivery.
- Smoking may also result in direct damage to fetal genetic material.

- Other possible mechanisms responsible for adverse fetal outcomes in mothers who smoke include direct toxicity of the more than 2500 substances found in cigarettes, such as ammonia, polycyclic aromatic hydrocarbons, hydrogen cyanide, vinyl chloride, nitrogen oxide, and carbon monoxide.
- Finally, exposure to nicotine results in sympathetic activation leading to acceleration of fetal heart rate and a reduction in fetal breathing movement.

Adverse Outcomes in Pregnant Smokers

- **Reduction in birth weight.** The birth weight deficit associated with smoking is 100-300 grams, depending on the number of cigarettes smoked. Smoking in the third trimester appears to have the greatest impact. Women who smoke are 1.5 to 3.5 times more likely to have a LBW infant; risk increases cigarette consumption.
- **Stillbirth.** Studies have shown a relative risk ranging from 1.2 to 1.4 in smokers. A dose response curve has been reported, with heavy smokers having the greatest risk.
- **Preterm premature rupture of membranes (PPROM).** There is a consistent increase in risk of PPRM among smokers, with relative risks ranging from 1.9 to 4.2.
- **Placental abruption/placenta previa.** Cigarette smoking increases the risk of placental abruption, with reported adjusted relative risks of 1.4 to 2.5. Dose-response curve analysis has consistently revealed that the risk of abruption is greatest among heavy smokers. Cigarette smoking has also been consistently associated with placenta previa, with reported relative risks ranging from 1.4 to 4.4. A dose-response curve for this complication has not been consistently replicated

ACOG Tobacco and Nicotine Cessation Tool Kit

The American Congress of Obstetricians and Gynecologists (ACOG) published guidance for Providers. Topics include the physiology and complications of smoking; treatment and cessation; electronic nicotine delivery systems; unique populations; office practice and coding; and advocacy. The Tool Kit is available [here](#).¹⁶

COCAINE USE IN PREGNANCY⁹

Public and professional interest in prenatal cocaine use is high, although many more pregnant women smoke cigarettes, drink alcohol, or smoke marijuana than use cocaine. Female crack/cocaine users in their thirties constitute a fast growing group of new users who do not use other substances. Cocaine readily crosses the placenta and fetal blood-brain barrier; vasoconstriction is the major purported mechanism for fetal and placental damage. The few adequately controlled reports suggest that cocaine's effects are related to dose and stage of pregnancy. Studies that evaluated the relationship between maternal exposure to cocaine during pregnancy significantly increased the risks of: preterm birth, low birth weight, small for gestational age infant, shorter gestational age at delivery, and reduced birth weight. Others have reported increased risks of miscarriage, placental abruption and decreased length and head circumference at birth. In addition, the use of cocaine and amphetamine use in pregnancy can cause the following:

- Cardiovascular cocaine toxicity is increased in pregnant women.
- Cocaine toxicity usually causes hypertension, which may mimic preeclampsia.
- Amphetamines including methamphetamine — a diagnosis of amphetamine abuse is becoming more common among women of reproductive age, including hospitalized pregnant women.
- Methamphetamine, commonly known as speed, meth, and chalk, or as ice, crystal, and glass when smoked, is a powerfully addictive stimulant. It is a known neurotoxic agent, which damages the endings of brain cells containing dopamine.
- Amphetamines and their byproducts cross the placenta.
- Methamphetamine exposure during pregnancy has been associated with maternal and neonatal morbidity and mortality. In studies that controlled for confounders, methamphetamine exposure was associated with a two- to fourfold increase in risk of fetal growth restriction, gestational hypertension, preeclampsia, abruption, preterm birth, intrauterine fetal demise, neonatal death, and infant death.

MARIJUANA USE IN PREGNANCY^{9,13}

Marijuana is the most common illicit substance used during pregnancy. The drug is transferred across the placenta and into breast milk. The impact of prenatal marijuana use on pregnancy outcome is not clear. Adverse effects have not been consistently reported and there is no strong evidence of an increase in congenital anomalies or growth restriction. Observational studies have not reported an association between marijuana use and preterm birth.

The self-reported prevalence of marijuana use during pregnancy ranges from 2% to 5% in most studies. A growing number of states are legalizing marijuana for medicinal or recreational purposes, and its use by pregnant women could increase even further as a result. Because of concerns regarding impaired neurodevelopment, as well as maternal and fetal exposure to the adverse effects of smoking, women who are pregnant or contemplating pregnancy should be encouraged to discontinue marijuana use. Obstetrician–gynecologists should be discouraged from prescribing or suggesting the use of marijuana for medicinal purposes during preconception, pregnancy, and lactation. There are insufficient data to evaluate the effects of marijuana use on infants during lactation and breastfeeding, and in the absence of such data, marijuana use is discouraged. In addition, ACOG recommends the following:⁷

- Before pregnancy and in early pregnancy, all women should be asked about their use of tobacco, alcohol, and other drugs, including marijuana and other medications used for nonmedical reasons.
- Women reporting marijuana use should be counseled about concerns regarding potential adverse health consequences of continued use during pregnancy.
- Women who are pregnant or contemplating pregnancy should be encouraged to discontinue marijuana use.
- Pregnant women or women contemplating pregnancy should be encouraged to discontinue use of marijuana for medicinal purposes in favor of an alternative therapy for which better pregnancy-specific safety data exists.

OPIATE USE IN PREGNANCY

Opioid abuse in pregnancy includes the use of heroin and the misuse of prescription opioid analgesic medications. Opioid use in pregnancy is not uncommon, and the use of illicit opioids during pregnancy is associated with an increased risk of adverse outcomes. The current standard of care for pregnant women with opioid dependence is referral for opioid-assisted therapy with methadone, but emerging evidence suggests that buprenorphine also should be considered. Medically supervised tapered doses of opioids during pregnancy often result in relapse to former use. Abrupt discontinuation of opioids in an opioid-dependent pregnant woman can result in preterm labor, fetal distress, or fetal demise. During the intrapartum and postpartum period, special considerations are needed for women who are opioid dependent to ensure appropriate pain management, to prevent postpartum relapse and a risk of overdose, and to ensure adequate contraception to prevent unintended pregnancies. Patient stabilization with opioid-assisted therapy is compatible with breastfeeding. Neonatal abstinence syndrome is an expected and treatable condition that follows prenatal exposure to opioid agonists.¹⁰

Many of the medical risks associated with heroin addiction are the same for both pregnant and non-pregnant women, and similar for addiction to other opiates. Opiate users typically have financial, social, and psychological problems that cause psychosocial stress, expose them to violence, and affect their options and treatment. Multiple obstetrical complications have been associated with opiate-dependence in pregnancy including:⁹

- Placental abruption
- Intra-amniotic infection
- Preeclampsia
- Premature rupture of membranes
- Miscarriage
- Fetal death
- Fetal growth restriction
- Premature labor and delivery
- Placental insufficiency
- Postpartum hemorrhage

Opioid Maintenance Assisted Therapy in Pregnancy⁹

- For opioid-dependent women, medication assisted therapy with methadone or buprenorphine offers overwhelming advantages compared to continued use of heroin (e.g., oral administration, known dose and purity, safe and steady availability, improved maternal/fetal/neonatal outcomes).
- Therapy offers a unique opportunity to bring women into medical and obstetrical care systems.
- Maintenance therapy is preferable to medication-assisted withdrawal (detoxification) because it is safe and associated with a lower rate of resumption of heroin use.
- After delivery, Neonatal Abstinence Syndrome (NAS) is likely to occur.

Medication assisted therapy can ensure the safety of pregnant women and their infants. Objectives include a reduction in adverse birth and pregnancy outcomes. It is important to note that infant withdrawal is treatable and shows no long-term adverse neurobehavioral consequences with *in utero* exposure.

Pharmacology and Physiology of Opioid Addiction¹⁰

Opioid addiction may develop with repetitive use of either prescription opioid analgesics or heroin. Heroin is the most

rapidly acting of the opioids and is highly addictive. Prescribed opioids that may be abused include codeine, fentanyl, morphine, opium, methadone, oxycodone, meperidine, hydromorphone, hydrocodone, propoxyphene, and buprenorphine (the partial agonist). The onset and intensity of euphoria will vary based on how the drug was taken and the formulation; however, all have the potential for overdose, physical dependence, abuse, and addiction. Injection of opioids also carries the risk of cellulitis and abscess formation at the injection site, sepsis, endocarditis, osteomyelitis, hepatitis B, hepatitis C, and human immunodeficiency virus (HIV) infection.

During pregnancy, chronic untreated heroin use is associated with an increased risk of fetal growth restriction, placental abruption, fetal death, preterm labor, and intrauterine passage of meconium. These effects may be related to the repeated exposure of the fetus to opioid withdrawal as well as the effects of withdrawal on placental function. Additionally, the lifestyle issues associated with illicit drug use put the pregnant woman at risk of engaging in activities, such as prostitution, theft, and violence, to support herself or her addiction. Such activities expose women to sexually transmitted infections, becoming victims of violence, and legal consequences, including loss of child custody, criminal proceedings, or incarceration.

Screening for Opioid Use, Abuse, and Addiction

Screening for substance abuse is a part of complete obstetric care and should be done in partnership with the pregnant woman. Both before pregnancy and in early pregnancy, all women should be routinely asked about their use of alcohol and drugs, including prescription opioids and other medications used for nonmedical reasons. Routine screening should rely on validated screening tools, such as questionnaires including 4P's and CRAFFT (for women aged 26 years or younger) (below).¹⁴

<p>4 P's⁴</p> <p><u>Parents:</u> Did any of your parents have a problem with alcohol or other drug use?</p> <p><u>Partner:</u> Does your partner have a problem with alcohol or drug use?</p> <p><u>Past:</u> In the past, have you had difficulties in your life because of alcohol or other drugs, including prescription medications?</p> <p><u>Present:</u> In the past month have you drunk any alcohol or used other drugs?</p> <p><i>Scoring: Any "yes" should trigger further questions.</i></p>	<p>CRAFFT—Substance Abuse Screen for Adolescents and Young Adults^{6,8}</p> <p>C Have you ever ridden in a CAR driven by someone (including yourself) who was high or had been using alcohol or drugs?</p> <p>R Do you ever use alcohol or drugs to RELAX, feel better about yourself, or fit in?</p> <p>A Do you ever use alcohol or drugs while you are by yourself or ALONE?</p> <p>F Do you ever FORGET things you did while using alcohol or drugs?</p> <p>F Do your FAMILY or friends ever tell you that you should cut down on your drinking or drug use?</p> <p>T Have you ever gotten in TROUBLE while you were using alcohol or drugs?</p> <p><i>Scoring: Two or more positive items indicate the need for further assessment.</i></p>
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Pregnant women with opioid addiction often seek prenatal care late in pregnancy; exhibit poor adherence to their appointments; experience poor weight gain; or exhibit sedation, intoxication, withdrawal, or erratic behavior. On physical examination, some signs of drug use may be present, such as track marks from intravenous injection, lesions from interdermal injections or "skin popping," abscesses, or cellulitis. Positive results of serologic tests for HIV, hepatitis B, or hepatitis C also may indicate substance abuse. Urine drug testing is an adjunct to detect or confirm suspected substance use, but should be performed only with the patient's consent and in compliance with state laws. Pregnant women must be informed of the potential ramifications of a positive test result, including any mandatory reporting requirements. Laboratory testing for HIV, hepatitis B, and hepatitis C should be repeated in the third trimester, if indicated. The use of an antagonist, such as naloxone, to diagnose opioid dependence in pregnant women is contraindicated because induced withdrawal may precipitate preterm labor or fetal distress. Naloxone should be used only in the case of maternal overdose to save the woman's life.¹⁴

Intrapartum and Postpartum Management. Women receiving opioid-assisted therapy who are undergoing labor should receive pain relief as if they were not taking opioids because the maintenance dosage does not provide adequate analgesia for labor. Epidural or spinal anesthesia should be offered where appropriate for management of pain in labor or for delivery. Narcotic agonist-antagonist drugs, such as butorphanol, nalbuphine, and pentazocine, should be avoided because they may precipitate acute withdrawal. Buprenorphine should not be administered to a patient who takes methadone. Pediatric staff should be notified of all narcotic-exposed infants. In general, patients undergoing opioid maintenance treatment will require higher doses of opioids to achieve analgesia than other patients.

Women should be counseled that minimal levels of methadone and buprenorphine are found in breast milk regardless of the maternal dose. Breastfeeding should be encouraged in patients without HIV who are not using additional drugs and who have no other contraindications. The current buprenorphine package insert advises against breastfeeding; however, a consensus panel stated that the effects on the breastfed infant are likely to be minimal and that breastfeeding is not contraindicated. Swaddling associated with breastfeeding may reduce neonatal abstinence syndrome symptoms, and breastfeeding contributes to bonding between mother and infant as well as providing immunity to the infant.⁹

Neonatal Abstinence Syndrome. Although maternal methadone or buprenorphine therapy improves pregnancy outcomes and reduces risky behavior, its use puts the neonate at risk of neonatal abstinence syndrome, which is characterized by hyperactivity of the central and autonomic nervous systems. Infants with neonatal abstinence syndrome may have uncoordinated sucking reflexes leading to poor feeding, become irritable, and produce a high-pitched cry. In infants exposed to methadone, symptoms of withdrawal may begin at any time in the first 2 weeks of life, but usually appear within 72 hours of birth and may last several days to weeks. Infants exposed to buprenorphine who develop neonatal abstinence syndrome generally develop symptoms within 12–48 hours of birth that peak at 72–96 hours and resolve by 7 days. Close communication between the obstetrician and pediatrician is necessary for optimal management of the neonate. All infants born to women who use opioids during pregnancy should be monitored for neonatal abstinence syndrome and treated if indicated. Treatment is adequate if the infant has rhythmic feeding and sleep cycles and optimal weight gain.

Long-Term Infant Outcome. Recent data on long-term outcomes of infants with in utero opioid exposure are limited. For the most part, earlier studies have not found significant differences in cognitive development between children up to 5 years of age exposed to methadone in utero and control groups matched for age, race, and socioeconomic status, although scores were often lower in both groups compared with population data. Preventive interventions that focus on enriching the early experiences of such children and improving the quality of the home environment are beneficial.

Related WellCare Guidelines

In addition to the information contained in this document, please reference the following CPGs: *Preconception and Interpregnancy: HS-1028* and *Pregnancy and Post-Partum Care: HS-1029*

NOTE: Clinical Policies can be accessed by going to www.wellcare.com – select the Provider tab, then “Tools” and “Clinical Guidelines”.

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*Easy Choice Health Plan ~ Harmony Health Plan of Illinois ~ Missouri Care ~ ‘Ohana Health Plan, a plan offered by WellCare Health Insurance of Arizona
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Medical Policy Committee Approval History

Date	History and Revisions by the Medical Policy Committee
4/5/2018	<ul style="list-style-type: none"> • Approved by MPC. Included updates re: opioid withdrawal and Medication Assisted Therapy (MAT).
6/28/2017	<ul style="list-style-type: none"> • Approved by MPC. Enhanced Care Management and Measures of Compliance sections. Revised with CM, DM, QI, UM, BH and the Chief Medical Directors. Merged with Substance Use Disorders in High Risk Pregnancy: HS-1041.
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