Prenatal Screening (Nongenetic)

Clinical Payment Policy – G2035 – Prenatal Screening (Nongenetic)	Initial Presentation Date: 06/16/2015 Revision History Date: 07/01/2025

I. Policy Description

Prenatal screening encompasses any testing done to determine the health status of the pregnant individual and/or fetus. Biochemical prenatal screening encompasses screening for infectious diseases and conditions that may complicate the pregnancy. Screening refers to testing of asymptomatic or healthy individuals to search for a condition that may affect the pregnancy or individual, whereas diagnostic testing is used to either confirm or refute true abnormalities in an individual.[1,2]

For guidance on thyroid screening in pregnant individuals, please see AHS-G2045-Thyroid Disease Testing. For guidance on screening for Zika virus infection in pregnant individuals, please see AHS-G2158-Testing for Vector-Borne Infections.

II. Related Policies

Policy Number	Policy Title
Clinical Payment Policy-G2036	Hepatitis Testing
Clinical Payment Policy-G2045	Thyroid Disease Testing
Clinical Payment Policy-G2157	Diagnostic Testing of Common Sexually
Clinical Payment Policy-G2158	Testing for Vector-Borne Infections.
Clinical Payment Policy-G2159	β-Hemolytic Streptococcus Testing
Clinical Payment Policy-M2116	Human Immunodeficiency Virus (HIV)
Clinical Payment Policy-M2141	Testing of Homocysteine Metabolism-Related
Clinical Payment Policy-M2179	Prenatal Screening (Genetic)

III. Indications and/or Limitations of Coverage

Application of coverage criteria is dependent upon an individual's benefit coverage at the time of the request. Specifications pertaining to Medicare and Medicaid can be found in the "Applicable State and Federal Regulations" section of this policy document.

1) The following routine prenatal screening **MEETS COVERAGE CRITERIA** for all pregnant individuals:
   a) Antigen/antibody combination assay screening for HIV infection.

b) Screening for *Chlamydia trachomatis* infection.

c) Screening for *Neisseria gonorrhoeae* infection.

d) Triple panel screening (HBsAg, anti-HBs, total anti-HBc) for hepatitis B.

e) Screening for syphilis.

f) Antibody screening for hepatitis C.

g) Screening for type 2 diabetes at the first prenatal visit.

h) Screening for gestational diabetes during gestational weeks 24 – 28 and at the first prenatal visit if risk factors are present.

i) Determination of blood type, Rh(D) status, and antibody status during the first prenatal visit, and repeated Rh (D) antibody testing for all unsensitized Rh (D)-negative individuals at 24 to 28 weeks' gestation, unless the biological father is known to be Rh (D)-negative.

j) Screening for anemia with a CBC or hemoglobin and hematocrit with mean corpuscular volume.

k) Screening for Group B streptococcal disease (once per pregnancy; recommended during gestational weeks 36 to 37).

l) Urinalysis and urine culture.

m) Rubella antibody testing.

n) Testing for varicella immunity.

o) Screening for tuberculosis in pregnant individuals deemed to be at high risk for TB.

2) For individuals who are pregnant with singleton or twin pregnancies and who are presenting in the ambulatory setting with signs or symptoms of preterm labor, a fetal fibronectin (FFN) assay **MEETS COVERAGE CRITERIA**.

3) For individuals with a normal pregnancy without complications, human chorionic gonadotropin (hCG) hormone testing **MEETS COVERAGE CRITERIA**.

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The following does not meet coverage criteria due to a lack of available published scientific literature confirming that the test(s) is/are required and beneficial for the diagnosis and treatment of an individual's illness.

4) As a technique of risk assessment for preterm labor or delivery, serial monitoring of salivary estriol levels **DOES NOT MEET COVERAGE CRITERIA**.

IV. Table of Terminology

Term	Definition
ACMG	American College of Medical Genetics and
ACOG	American College of Obstetricians and
ADA	American Diabetes Association
CDC	Centers for Disease Control and Prevention
EIA	Enzyme immunoassay

ELISA	Enzyme linked immunosorbent assay
FFN	Fetal fibronectin
GBS	Group B streptococcal disease
GDM	Gestational diabetes mellitus
HBsAg	Hepatitis B surface antigen
HBV	Hepatitis B virus
HCV	Hepatitis C virus
HDFN	Hemolytic disease of the fetus and newborn
HIV	Human immunodeficiency virus
HRSA	Health Resources & Services Administration
HSV	Herpes simplex virus
PAH	Phenylalanine hydroxylase
PITC	Provider-initiated HIV testing and counselling
RBC	Red blood cells
RhD	Rh blood group D antigen
STI	Sexually transmitted infection
TB	Tuberculosis
TMRC	Transfusion Medicine Resource Committee
VA/DoD	Veterans Affairs/Department of Defense
WHO	World Health Organization

V. Scientific Background

Prenatal screening is a part of overall prenatal care to promote optimal care of both mother and baby and allows for assessment and monitoring of the fetus for the presence of congenital defects or disease. Various professional medical organizations provide guidelines for prenatal screening. "Screening is an offer on the initiative of the health system or society, rather than a medical intervention in answer to a patient's complaint or health problem. Screening aims at obtaining population health gains through early detection that enables prevention or treatment."[3]

Routine prenatal screening may include several laboratory tests, such as hematocrit or hemoglobin testing to check for anemia and possible thalassemia, pending further diagnostic testing. Blood typing and antibody screening can be performed to prevent possible alloimmunization or hemolytic diseases and glucose testing can screen for possible gestational diabetes mellitus. Screening for asymptomatic bacteriuria and proteinuria is recommended as well as screening for infectious disorders, such as HIV, syphilis, chlamydia, and gonorrhea.[2]

Red blood cell antigen discrepancy between a mother and fetus may also occur during pregnancy. This is known as hemolytic disease of the fetus and newborn (HDFN), and causes maternal antibodies to destroy the red blood cells of the neonate or fetus.[4] Alloimmunization is the immune response which occurs in the mother due to foreign antigens after exposure to genetically foreign cells, occurring almost exclusively in mothers with type O blood. However, while ABO blood type incompatibility is identified in almost 15% of pregnancies, HDFN is only identified in approximately 4% of pregnancies.[4] Another important inherited antigen sometimes found on the surface of red blood cells is known as the Rhesus (Rh)D antigen. During pregnancy and delivery, individuals who are RhD negative may be exposed to RhD positive fetal cells, which can lead to

the development of anti-RhD antibodies. This exposure typically happens during delivery and affects subsequent pregnancies; infants with RhD incompatibility tend to experience a more severe form of HDFN than those with ABO incompatibility.[4] The clinical presentation of HDFN may be mild (such as hyperbilirubinemia with mild to moderate anemia) to severe and life-threatening anemia (such as hydrops fetalis).[4] Less severely affected infants may develop hyperbilirubinemia within the first day of life; infants with RhD HDFN may also present with symptomatic anemia requiring a blood transfusion. In more severe cases, infants with severe life-threatening anemia, such as hydrops fetalis, may exhibit shock at delivery requiring an emergent blood transfusion.[4]

The administration of anti-D immune globulin has been able to dramatically reduce, but not eliminate, the number of RhD alloimmunization cases. "Anti-D immune globulin is manufactured from pooled plasma selected for high titers of IgG antibodies to D-positive erythrocytes."[5] Before the development of this anti-D immune globulin, it has been reported that 16% of pregnant RhD-negative individuals with two deliveries of RhD-positive ABO-compatible infants became alloimmunized. However, this rate falls to 1-2% with routine postpartum administration of a single dose of anti-D immune globulin. An additional administration in the third trimester of pregnancy further reduces the incidents of alloimmunization to 0.1-0.3%.[5]

Fetal fibronectin (FFN) is a protein made during pregnancy that is found between the lining of the uterus and the amniotic sac, at the decidual-chorionic interface. FFN is often described as being the glue that holds the amniotic sac to the uterine lining.[6] Disruption of the decidual-chorionic interface releases FFN into cervicovaginal secretions, allowing FFN to be used as a marker for predicting spontaneous preterm birth in individuals with singleton and twin gestations.[7] A meta-analysis of 11 studies found that under 10% of pregnant people with low FFN (<10 ng/mL) delivered before 34 weeks, while 37-67% of pregnant people with high FFN (>200 ng/mL) delivered before 34 weeks.[8] The negative predictive value of FFN in predicting preterm birth is 99.5% within seven days, 99.2% within 14 days, and 84.5% before 37 weeks.[9] FFN is also useful in singleton and twin pregnancies, as multiple pregnancy is a risk factor for preterm birth. For singleton and multiple pregnancies, FFN has a negative predictive value of 100%, sensitivity of 100% for delivery within 10 days, but a positive predictive value of 10% and a specificity of 64%.[10]

Human chorionic gonadotropin (hCG) is a biomarker in the glycoprotein hormone family. Other hormones in this family include luteinizing hormone (LH), follicle-stimulating hormone (FSH), and thyroid stimulating hormone. Human chorionic gonadotropin in pregnancy serves as an important biomarker for the detection of pregnancy-related disorders and hCG is also measured in some prenatal tests for Down syndrome. Low levels of hCG are associated with pregnancy loss and preeclampsia, while high levels can be associated with Down syndrome pregnancies.[11] A qualitative hCG test may be used to screen for pregnancy and gives a simple positive or negative result. A quantitative hCG measurement is used to assess pregnancy viability and screen for disorders. Quantitative hCG tests measures the exact amount of hCG in blood; for example, during 10-12 weeks of gestation, hCG levels are expected to approximately double every 24-48 hours, such that abnormal measurement results for hCG may indicate issues with the pregnancy.[12]

Clinical Utility and Validity

Education and counseling are a key factor in prenatal screening and diagnostic tests. Yesilcinar and Guvenc (2021) found that a proactive intervention approach decreased anxiety and decisional conflict in the pregnant individual and increased attitudes towards the tests, having a positive effect on the pregnant individual's knowledge level and decision satisfaction. This allowed the individual to make more informed decisions, such as opting to have screening and diagnostic testing performed.[13]

Implementation of prenatal screening tests can positively affect pregnancies and pregnancy outcomes. The Centers for Disease Control and Prevention (CDC) reports that implementation of the 1996 guidelines concerning Group B Streptococcus (GBS) had a profound effect. Prior to screening and widespread use of intrapartum antibiotics, invasive neonatal GBS occurred in two to three cases per 1,000 live births; however, after prenatal screening implementation, the rate declined to 0.5 cases per 1,000 live births in 1999.[14] The CDC also reports from a multi-year study that screening for syphilis in all pregnant individuals at the first prenatal visit (and then rescreening in third trimester for individuals at risk) is very important in preventing congenital syphilis, which can cause spontaneous abortion, stillbirth, and early infant death. They show that 88.2% of cases of congenital syphilis was avoided when proper screening was applied; moreover, 30.9% of the cases of congenital syphilis that did occur happened when the mother did not receive proper prenatal care (≥45 days before delivery).[15]

VI. Guidelines and Recommendations

American College of Obstetricians and Gynecologists (ACOG)

The American College of Obstetricians and Gynecologists has several practice guidelines related to prenatal care as well as both pre-conception and prenatal testing. ACOG recommendations and guidelines include the following:

- **Vitamin D Screening:** Concerning vitamin D screening, "there is insufficient evidence to support a recommendation for screening all pregnant [individuals] for vitamin D deficiency. For pregnant [individuals] thought to be at increased risk of vitamin D deficiency, maternal serum 25-hydroxyvitamin D levels can be considered and should be interpreted in the context of the individual clinical circumstance."[16] This was reaffirmed in 2024.
- **Lead Screening:** Concerning lead screening, ACOG recommends "evaluating risk factors for exposure as part of a comprehensive health risk assessment and perform blood lead testing if a single risk factor is identified. Assessment of lead exposure should take place at the earliest contact with the pregnant patient."[17] This position was reaffirmed in 2023.
- **Depression and Anxiety:** ACOG "recommends screening patients at least once during the perinatal period for depression and anxiety, and, if screening in pregnancy, it should be done again postpartum." Further, ACOG "recommends a full assessment of physical, social, and psychological well-being within a comprehensive postpartum visit that occurs no later than 12 weeks after birth."[18]
- ***Listeria monocytogenes:*** Concerning testing for *Listeria monocytogenes*, "No testing, including blood and stool cultures, or treatment is indicated for an asymptomatic pregnant [individual] who reports consumption of a product that was recalled or implicated during an outbreak of listeria contamination. An asymptomatic patient should be instructed to

return if she develops symptoms of listeriosis within 2 months of eating the recalled or implicated product."[19] If an exposed pregnant individual shows signs and symptoms consistent with infection, then blood culture testing is the standard of care. Stool culture testing is not recommended since it has not been validated as a screening tool.[19] This position was reaffirmed in 2023.

- **HIV:** Concerning HIV, ACOG recommends that all individuals should be tested for HIV with the right to refuse testing. "Human immunodeficiency virus testing using the opt-out approach, which is currently permitted in every jurisdiction in the United States, should be a routine component of care for [individuals] during prepregnancy and as early in pregnancy as possible. Repeat HIV testing in the third trimester, preferably before 36 weeks of gestation, is recommended for pregnant [individuals] with initial negative HIV antibody tests who are known to be at high risk of acquiring HIV infection; who are receiving care in facilities that have an HIV incidence in pregnant [individuals] of at least 1 per 1,000 per year; who are incarcerated; who reside in jurisdictions with elevated HIV incidence; or who have signs and symptoms consistent with acute HIV infection (e.g., fever, lymphadenopathy, skin rash, myalgias, arthralgias, headache, oral ulcers, leukopenia, thrombocytopenia, or transaminase elevation). Rapid screening during labor and delivery or during the immediate postpartum period using the opt-out approach should be done for [individuals] who were not tested earlier in pregnancy or whose HIV status is otherwise unknown. Results should be available 24 hours a day and within 1 hour."[20] This position was reaffirmed in 2024.
    - For pregnant individuals who test positive for HIV, "Additional laboratory work, including $CD4^+$ count; HIV viral load; testing for antiretroviral resistance; hepatitis C virus antibody; hepatitis B surface antigen and viral load; and hepatitis A using antibody testing for immunoglobulin G for [individuals] who have hepatitis B virus infection and who have not already received the hepatitis A virus vaccine series; complete blood count with platelet count; and baseline chemistries with comprehensive metabolic testing, will be useful before prescribing antiretroviral therapy."[20] This opinion was reaffirmed in 2024.
- **Prevention of Rh D Alloimmunization:** Concerning the prevention of Rh D alloimmunization, ACOG has published the guidelines supporting the administration of anti-D immune globulin to individuals in various scenarios. However, these guidelines do not mention the use of cell-free fetal DNA for fetal RHD testing to determine if anti-D immune globulin is needed.[21]
- **Group B Streptococcal (GBS) Disease:** "all pregnant [individuals] should undergo antepartum screening for GBS at 36 0/7–37 6/7 weeks of gestation, unless intrapartum antibiotic prophylaxis for GBS is indicated because of GBS bacteriuria during the pregnancy or because of a history of a previous GBS-infected newborn. This new recommended timing for screening provides a 5-week window for valid culture results that includes births that occur up to a gestational age of at least 41 0/7 weeks."[22] This position was reaffirmed in 2022.
- **Lab Tests:** ACOG lists the following lab tests to be performed early in pregnancy: complete blood count (CBC), blood type and Rh factor, urinalysis, urine culture, rubella, hepatitis B, hepatitis C, HIV, sexually transmitted infection (STI) testing, and tuberculosis.[18] ACOG lists the following lab tests to be performed later in pregnancy: glucose screening test and Group B streptococcus (GBS) screening.[18]

United States Preventive Services Task Force (USPSTF)

The United States Preventive Services Task Force (USPSTF) recommends the following testing for pregnant individuals:

- Screening for gestational diabetes in asymptomatic pregnant individuals at ≥24 weeks of gestation (Grade B).[23]
- Screening for hepatitis B virus (HBV) infection at the first prenatal visit (Grade A).[24]
- Screening for asymptomatic bacteriuria with urine culture is recommended in pregnant persons (Grade B).[25]
- Screening for HIV is recommended in all pregnant persons, including those in labor or whose HIV status is unknown at delivery (Grade A).[26]
- Rh (D) blood typing and antibody testing for all pregnant individuals during their first visit for pregnancy-related care (Grade A).[27]
- Repeated Rh (D) antibody testing for all unsensitized Rh (D)-negative individuals at 24-28 weeks' gestation, unless the biological father is known to be Rh (D)-negative (Grade B).[27]
- Screening early for syphilis infection in all pregnant individuals (Grade A).[28]

Additional recommendations from the USPSTF that may be relevant during pregnancy include:

- The USPSTF recommends screening for chlamydia in all sexually active [individuals] 24 years or younger and in [individuals] 25 years or older who are at increased risk for infection (Grade B).[29]
- The USPSTF recommends screening for gonorrhea in all sexually active [individuals] 24 years or younger and in [individuals] 25 years or older who are at increased risk for infection (Grade B).[29]
- The USPSTF recommends that clinicians provide or refer pregnant and postpartum persons who are at increased risk of perinatal depression to counseling interventions (Grade B).[30]

Screening for hepatitis C virus (HCV) infection is recommended in all adults aged 18 to 79 years (Grade B).[31]

Concerning screening adults for drug use, Krist, et al. (2020) state that "the USPSTF recommends screening by asking questions about unhealthy drug use in adults ages 18 years or older. Screening should be implemented when services for accurate diagnosis, effective treatment, and appropriate care can be offered or referred. (Screening refers to asking questions about unhealthy drug use, not testing biological specimens.)" The USPSTF also states that "this new evidence supports the current recommendation that primary care clinicians offer screening to adults 18 years or older, including those who are pregnant or postpartum, when services for accurate diagnosis, effective treatment, and appropriate care can be offered or referred."[32]

However, the USPSTF recommends against the following tests during pregnancy:

- Screening for bacterial vaginosis in pregnant individuals who are not at risk for preterm delivery (grade D); further, current evidence is insufficient for screening pregnant persons who are at increased risk for preterm delivery.[33]
- Serological screening for herpes simplex virus (HSV) in asymptomatic pregnant individuals.[34]

- Screening for elevated blood lead levels in asymptomatic pregnant individuals has been given an I recommendation as current evidence is insufficient to determine if this testing is beneficial or not.[35]
- "The USPSTF concludes that the current evidence is insufficient to assess the balance of benefits and harms of screening for iron deficiency anemia in pregnant [individuals] to prevent adverse maternal health and birth outcomes."[36]

American Diabetes Association (ADA)

The American Diabetes Association in the 2023 *Standards of Medical Care in Diabetes* make the following recommendations:[37]

- "Starting at puberty and continuing in all [individuals] with diabetes and reproductive potential, preconception counseling should be incorporated into routine diabetes care. [Grade] **A**
- Preconception counseling should address the importance of achieving glucose levels as close to normal as is safely possible, ideally A1C <6.5% (48 mmol/mol), to reduce the risk of congenital anomalies, preeclampsia, macrosomia, preterm birth, and other complications. [Grade] **A**
- Individuals with preexisting diabetes who are planning a pregnancy should ideally begin receiving care in preconception at a multidisciplinary clinic in including an endocrinologist, maternal-fetal medicine specialist, registered dietitian nutritionist, and diabetes care and education specialist, when available. [Grade] **B**
- In addition to focused attention on achieving glycemic targets, standard preconception care should be augmented with extra focus on nutrition, diabetes education, and screening for diabetes comorbidities and complications. [Grade] B
- Individuals with preexisting type 1 or type 2 diabetes who are planning pregnancy or who have become pregnant should be counseled on the risk of development and/or progression of diabetic retinopathy. Dilated eye examinations should occur ideally before pregnancy or in the first trimester, and then patients should be monitored every trimester and for 1 year postpartum as indicated by the degree of retinopathy and as recommended by the eye care provider. [Grade] **B**
- Screen individuals with a recent history of gestational diabetes mellitus at 4–12 weeks postpartum, using the 75-g oral glucose tolerance test and clinically appropriate nonpregnancy diagnostic criteria. [Grade] **B**
- Individuals with a history of gestational diabetes mellitus should have lifelong screening for the development of type 2 diabetes or prediabetes every 1–3 years. [Grade] **B**
- Individuals with a history of gestational diabetes mellitus found to have prediabetes should receive intensive lifestyle interventions and/or metformin to prevent diabetes. [Grade] **A**
- Individuals with a history of gestational diabetes mellitus should seek preconception screening for diabetes and preconception care to identify and treat hyperglycemia and prevent congenital malformations. [Grade] **E**"

Centers for Disease Control and Prevention (CDC)

The Centers for Disease Control and Prevention (CDC) recommends:[38]

Disease	Recommendations for Pregnant Individuals

Chlamydia	All pregnant individuals under 25 years of age Pregnant individuals 25 years of age and older if at increased risk* Retest during the 3rd trimester for individuals under 25 years of age or at risk Pregnant individuals with chlamydial infection should have a test of cure 4 weeks after treatment and be retested within 3 months
Gonorrhea	All pregnant individuals under 25 years of age, and those 25 and older if at increased risk* Retest during the 3rd trimester for individuals under 25 years of age or at risk Pregnant individuals with gonorrhea should be retested within 3 months
Syphilis	All pregnant individuals at the first prenatal visit Retest at 28 weeks gestation and at delivery if at increased risk due to geography or personal risk (substance use, STIs during pregnancy, multiple partners, a new partner, partner with STIs
Herpes†	Routine HSV-2 serologic screening among asymptomatic pregnant individuals is not recommended. However, type-specific serologic tests might be useful for identifying pregnant individuals at risk for HSV infection and guiding counseling regarding the risk for acquiring genital herpes during pregnancy.
HIV	All pregnant individuals should be screened at first prenatal visit (opt-out) Retest in the 3rd trimester if at increased risk (people who use drugs, have STIs during pregnancy, have multiple sex partners during pregnancy, have a new sex partner during pregnancy, live in areas with high HIV prevalence, or have partners with HIV) Rapid testing should be performed at delivery if not previously screened during pregnancy
HPV, Cervical Cancer	Pregnant individuals should be screened at same intervals as nonpregnant individuals
Hepatitis B Screening	Test for HBsAg at first prenatal visit of each pregnancy regardless of prior testing; retest at delivery if at increased risk
Hepatitis C Screening	Pregnant individuals should be screened for hepatitis C except in settings where the hepatitis C infection (HCV) positivity is < 0.1%

"* Per USPSTF, sexually active [individuals] 25 years or older are at increased risk for chlamydial and gonococcal infections if they have a new partner, more than one sex partner, a sex partner with concurrent partners, or a sex partner who has an STI; practice inconsistent condom use when not in a mutually monogamous relationship; have a previous or coexisting STI; have a history of exchanging sex for money or drugs; or have a history of incarceration.

† Type-specific HSV-2 serologic assays for diagnosing HSV-2 are useful in the following scenarios: recurrent or atypical genital symptoms or lesions with a negative HSV PCR or culture result, clinical diagnosis of genital herpes without laboratory confirmation, and a patient's partner has genital herpes. HSV-2 serologic screening among the general population is not recommended. Patients who are at higher risk for infection (e.g., those presenting for an STI evaluation, especially for persons with ≥10 lifetime sex partners, and persons with HIV infection) might need to be assessed for a history of genital herpes symptoms, followed by type-specific HSV serologic assays to diagnose genital herpes for those with genital symptoms."[38]

- "Everyone who is pregnant should be tested for syphilis, HIV, hepatitis B, and hepatitis C starting early in pregnancy. Repeat testing may be needed."[39]
- Pregnant people at risk should also be tested for chlamydia and gonorrhea starting early in pregnancy. Repeat testing may be needed in some cases."[39]
- "A second test during the third trimester, preferably at <36 weeks' gestation, should be considered and is recommended for [individuals] who are at high risk for acquiring HIV infection, [individuals] who receive health care in jurisdictions with high rates of HIV, and [individuals] examined in clinical settings in which HIV incidence is ≥1 per 1,000 [individuals] screened per year."[40]
- "Providers should use a laboratory-based antigen/antibody (Ag/Ab) combination assay as the first test for HIV, unless persons are unlikely to follow up with a provider to receive their HIV test results; in those cases screening with a rapid POC test can be useful."[40]
- "Regardless of whether they have been previously tested or vaccinated, all pregnant [individuals] should be tested for HBsAg at the first prenatal visit and again at delivery if at high risk for HBV infection (see STI Detection Among Special Populations). Pregnant [individuals] at risk for HBV infection and without documentation of a complete hepatitis B vaccine series should receive hepatitis B vaccination."[41]
- Recommendation for HBV screening in "All pregnant persons during each pregnancy, preferably in the first trimester, regardless of vaccination status or history of testing."[42]
- "Pregnant persons with a history of appropriately timed triple panel screening and without subsequent risk for exposure to HBV (i.e., no new HBV exposures since triple panel screening) only need HBsAg screening. Testing pregnant persons known to be chronically infected or immune enables documentation of the HBsAg test result during that pregnancy to ensure timely prophylaxis for exposed infants."[42]
- "Using the triple panel (HBsAg, anti-HBs, and total anti-HBc) is recommended for initial screening because it can help identify persons who have an active HBV infection and could be linked to care, have resolved infection and might be susceptible to reactivation (e.g., immunosuppressed persons), are susceptible and need vaccination, or are vaccinated. When someone receives triple panel screening, any future periodic testing can use tests as appropriate (e.g., only HBsAg and anti-HBc if the patient is unvaccinated)."[42]
- "[individuals] aged <25 years and those at increased risk for chlamydia (i.e., those who have a new sex partner, more than one sex partner, a sex partner with concurrent partners, or a sex partner who has an STI) should be screened at the first prenatal visit and rescreened during the third trimester to prevent maternal postnatal complications and chlamydial infection in the infant."[43]
- "Annual screening for *N. gonorrhoeae* infection is recommended for all sexually active [individuals] aged <25 years and for older [individuals] at increased risk for infection (e.g., those aged ≥25 years who have a new sex partner, more than one sex partner, a sex partner with concurrent partners, or a sex partner who has an STI . . . [All individuals] who have been treated for gonorrhea should be retested 3 months after treatment regardless of whether they believe their sex partners were treated."[44]
- "CDC recommends hepatitis C screening . . . all [individuals] during each pregnancy, except in settings where the prevalence of HCV infection is <0.1%."[45]
- Zika virus recommendations for asymptomatic pregnant patients:

- "Lived in or traveled to the United States and its territories during pregnancy: Since no confirmed cases of Zika virus disease have been detected in the United States and its territories since 2018, routine Zika virus testing is not recommended."
- "Traveled to an area with an active CDC Zika Travel Health Notice during pregnancy: NAAT testing may be considered up to 12 weeks after travel."
- "Traveled to an area with current or past Zika virus transmission outside the US and its territories during pregnancy: Routine testing is not recommended. If the decision is made to test, NAAT testing can be done up to 12 weeks after travel."[46]

- Zika virus recommendations for symptomatic pregnant patients:
  - "Lived in or traveled to an area with an active CDC Zika Travel Health Notice during pregnancy OR had sex during pregnancy with someone living in or with recent travel to an area with an active CDC Zika Travel Health Notice:
    - Specimens should be collected as soon as possible after onset of symptoms up to 12 weeks after symptom onset.
    - Perform dengue and Zika virus NAAT and IgM testing on a serum specimen and Zika virus NAAT on a urine specimen.
    - If Zika NAAT is positive and the Zika IgM is negative, repeat NAAT test on newly extracted RNA from same specimen to rule out false-positive results.
    - If both dengue and Zika virus NAATs are negative but either IgM antibody test is positive, confirmatory PRNTs should be performed against dengue, Zika, and other flaviviruses endemic to the region where exposure occurred.
  - Lived in or traveled to an area with current or past Zika virus transmission during pregnancy:
    - Specimens should be collected as soon as possible after onset of symptoms up to 12 weeks after symptom onset.
    - Perform dengue and Zika virus NAAT testing on a serum specimen and Zika virus NAAT on a urine specimen.
    - If Zika NAAT is positive, repeat test on newly extracted RNA from same specimen to rule out false-positive results.
    - Perform IgM testing for dengue only.
    - If dengue NAAT or IgM test is positive, this provides adequate evidence of dengue infection, and no further testing is indicated.
  - Had sex during pregnancy with someone living in or with recent travel to an area with current or past Zika virus transmission:
    - Specimens should be collected as soon as possible after onset of symptoms up to 12 weeks after symptom onset.
    - Only Zika NAAT should be performed.
    - If Zika NAAT is positive, repeat test on newly extracted RNA from same specimen to rule out false-positive results."[46]
- Zika virus recommendations for pregnant patients having a fetus with prenatal ultrasound findings consistent with congenital Zika virus infection:
  - "Lived in or traveled during pregnancy to an area with an active CDC Zika Travel Health Notice or current or past Zika virus transmission OR had sex during pregnancy with someone living in or with recent travel to an area with an active CDC Zika Travel Health Notice or current or past Zika virus transmission:

- Zika virus NAAT and IgM testing should be performed on pregnant person's serum and NAAT on pregnant person's urine.
- If the Zika virus NAATs are negative and the IgM is positive, confirmatory PRNTs should be performed against Zika and dengue.
- If amniocentesis is being performed as part of clinical care, Zika virus NAAT testing of amniocentesis specimens should also be performed and results interpreted within the context of the limitations of amniotic fluid testing.
- Testing of placental and fetal tissues may also be considered."[46]

- "Evidence does not support routine screening for BV among asymptomatic pregnant [individuals]

at high risk for preterm delivery (159). Symptomatic [individuals] should be evaluated and treated (see Bacterial Vaginosis). Evidence does not support routine screening for Trichomonas vaginalis among asymptomatic pregnant [individuals]. [Individuals] who report symptoms should be evaluated and treated (see Trichomoniasis). In addition, evidence does not support routine HSV-2 serologic screening among asymptomatic pregnant [individuals]. However, type-specific serologic tests might be useful for identifying pregnant [individuals] at risk for HSV-2 infection and for guiding counseling regarding the risk for acquiring genital herpes during pregnancy. Routine serial cultures for HSV are not indicated for [individuals] in the third trimester who have a history of recurrent genital herpes."[47]

- "Prenatal screening for some infections (HIV, syphilis, hepatitis B virus, and hepatitis C virus) is recommended for all pregnant [individuals]. Screening for other infections (chlamydia, gonorrhea, and TB) is recommended for some [individuals] at risk for infection."[48]

American College of Medical Genetics and Genomics (ACMG)

In 2014, the ACMG released guidelines concerning the diagnosis and management of phenylalanine hydroxylase (PAH) deficiency. They recommend PAH testing be part of newborn screening and that "quantitative blood amino acids testing should be performed for diagnostic testing following a positive newborn screen of PAH deficiency. Additional testing is needed to define the cause of elevated PHE and should include analysis of pterin metabolism; PAH genotypic is indicated for improved therapy planning."[49]

World Health Organization (WHO)

In 2016, the WHO released their publication titled, *WHO recommendations on antenatal care for a positive pregnancy experience*, which had the following recommendations:[50]

- Anemia (Context-specific recommendation)—"Full blood count testing is the recommended method for diagnosing anaemia in pregnancy."
- Asymptomatic bacteriuria (Context-specific recommendation)—"Midstream urine culture is the recommended method for diagnosing asymptomatic bacteriuria (ASB) in pregnancy. In settings where urine culture is not available, on-site midstream urine Gram-staining is recommended over the use of dipstick tests as the method for diagnosing ASB in pregnancy."

- Gestational diabetes mellitus (Recommended)—"Hyperglycaemia first detected at any time during pregnancy should be classified as either gestational diabetes mellitus (GDM) or diabetes mellitus in pregnancy, according to WHO criteria."
- HIV and syphilis (Recommended)—"In high-prevalence settings, provider-initiated HIV testing and counselling (PITC) for HIV should be considered a routine component of the package of care for pregnant [individuals] in all antenatal care settings. In low-prevalence settings, PITC can be considered for pregnant [individuals] in antenatal care settings as a key component of the effort to eliminate mother-to-child transmission of HIV, and to integrate HIV testing with syphilis, viral or other key tests, as relevant to the setting, and to strengthen the underlying maternal and child health systems."
- Tuberculosis (Context-specific recommendation)—"In settings where the tuberculosis (TB) prevalence in the general population is 100/100 000 population or higher, systematic screening for active TB should be considered for pregnant [individuals] as part of antenatal care."[50]

Department of Veterans Affairs/Department of Defense (VA/DoD)

In the 4th edition of the VA/DoD *Clinical Practice Guideline for the Management of Pregnancy,*[51] they list the following lab tests as routine for all pregnancies in the first prenatal visit: HIV, CBC, ABO Rh blood typing, Antibody screen, gonorrhea, chlamydia, hepatitis C antibody, syphilis screen, hepatitis B surface antigen test, rubella IgG, urinalysis and culture, and varicella IgG (if status is unknown). The following tests are offered to all patients: hemoglobin electrophoresis, aneuploidy screening, cystic fibrosis carrier screening, spinal muscle atrophy carrier screening, maternal serum alpha fetoprotein (15-22 weeks). They also list the following among their recommendations:[51]

- "We recommend screening for use of tobacco and nicotine products, alcohol, cannabis, illicit drugs, and inappropriate use of prescription medication." [Strong]
- "We recommend screening for depression periodically using a standardized tool such as the Edinburgh Postnatal Depression Scale or the 9- item Patient Health Questionnaire periodically during pregnancy and postpartum." [Strong]
- "We recommend offering non-invasive prenatal testing as the prenatal screening test of choice for all patients with singleton pregnancies who choose aneuploidy screening." [Weak]
- "We suggest non-invasive prenatal testing for patients with twin pregnancies who choose aneuploidy screening." [Weak]
- "We recommend considering the use of fetal fibronectin testing as a part of the evaluation strategy in [individuals] between 24 and 34 6/7 weeks gestation with signs and symptoms of preterm labor, particularly in facilities where the result might affect management of delivery." [Strong]
- "We suggest patients who have undergone bariatric surgery be evaluated for nutritional deficiencies and need for nutritional supplementation where indicated (e.g., vitamin B12, folate, iron, calcium)." [Weak]

Health Resources & Services Administration (HRSA)

The HRSA recommends the following:

- "Screening pregnant individuals for gestational diabetes mellitus after 24 weeks of gestation (preferably between 24 and 28 weeks of gestation)
- Individuals with risk factors for diabetes mellitus be screened for preexisting diabetes before 24 weeks of gestation—ideally at the first prenatal visit.
- Screening for HIV is recommended for all pregnant [individuals] upon initiation of prenatal care with retesting during pregnancy based on risk factors.
- Rapid HIV testing is recommended for pregnant [individuals] who present in active labor with an undocumented HIV status."[52]

VII. Applicable State and Federal Regulations

DISCLAIMER: If there is a conflict between this Policy and any relevant, applicable government policy for a particular member [e.g., Local Coverage Determinations (LCDs) or National Coverage Determinations (NCDs) for Medicare and/or state coverage for Medicaid], then the government policy will be used to make the determination. For the most up-to-date Medicare policies and coverage, please visit the Medicare search website: https://www.cms.gov/medicare-coverage-database/search.aspx. For the most up-to-date Medicaid policies and coverage, please visit the applicable state Medicaid website.

Food and Drug Administration (FDA)

The FDA has approved many tests for conditions that can be included in a prenatal screening, such as HSV, chlamydia, gonorrhea, syphilis, and diabetes. Additionally, many labs have developed specific tests that they must validate and perform in house. These laboratory-developed tests (LDTs) are regulated by the Centers for Medicare and Medicaid (CMS) as high-complexity tests under the Clinical Laboratory Improvement Amendments of 1988 (CLIA '88). LDTs are not approved or cleared by the U. S. Food and Drug Administration; however, FDA clearance or approval is not currently required for clinical use.

VIII. Applicable CPT/HCPCS Procedure Codes

CPT	Code Description
80055	Obstetric panel This panel must include the following: Blood count, complete (CBC), automated and automated differential WBC count (85025 or 85027 and 85004) OR Blood count, complete (CBC), automated (85027) and appropriate manual differential WBC count (85007 or 85009) Hepatitis B surface antigen (HBsAg) (87340) Antibody, rubella (86762) Syphilis test, non-treponemal antibody; qualitative (e.g., VDRL, RPR, ART) (86592) Antibody screen, RBC, each serum technique (86850) Blood typing, ABO (86900) AND Blood typing, Rh (D) (86901)
80081	Obstetric panel (includes HIV testing) This panel must include the following: Blood count, complete (CBC), and automated differential WBC count (85025 or 85027 and 85004) OR Blood count, complete (CBC), automated (85027) and appropriate manual differential WBC count (85007 or 85009) Hepatitis B surface antigen (HBsAg) (87340) HIV-1 antigen(s), with HIV-1 and HIV-2 antibodies, single result (87389) Antibody, rubella (86762) Syphilis test, non-treponemal antibody; qualitative (e.g., VDRL, RPR, ART) (86592) Antibody screen, RBC, each serum technique (86850) Blood typing, ABO (86900) AND Blood typing, Rh (D) (86901)

CPT	Code Description
81001	Urinalysis, by dip stick or tablet reagent for bilirubin, glucose, hemoglobin, ketones, leukocytes, nitrite, pH, protein, specific gravity, urobilinogen, any number of these constituents; automated, with microscopy
81002	Urinalysis, by dip stick or tablet reagent for bilirubin, glucose, hemoglobin, ketones, leukocytes, nitrite, pH, protein, specific gravity, urobilinogen, any number of these constituents; non-automated, without microscopy
81003	Urinalysis, by dip stick or tablet reagent for bilirubin, glucose, hemoglobin, ketones, leukocytes, nitrite, pH, protein, specific gravity, urobilinogen, any number of these constituents; automated, without microscopy
81007	Urinalysis; bacteriuria screen, except by culture or dipstick
81015	Urinalysis; microscopic only
82677	Estriol
82731	Fetal fibronectin, cervicovaginal secretions, semi-quantitative
82947	Glucose; quantitative, blood (except reagent strip)
82950	Glucose; post glucose dose (includes glucose)
82951	Glucose; tolerance test (GTT), 3 specimens (includes glucose)
82962	Glucose, blood by glucose monitoring device(s) cleared by the FDA specifically for home use
83036	Hemoglobin; glycosylated (A1C)
84702	Gonadotropin, chorionic (hCG); quantitative
84703	Gonadotropin, chorionic (hCG); qualitative
84704	Gonadotropin, chorionic (hCG); free beta chain
85004	Blood count; automated differential WBC count
85007	Blood count; blood smear, microscopic examination with manual differential WBC count
85009	Blood count; manual differential WBC count, buffy coat
85014	Blood count; hematocrit (Hct)
85018	Blood count; hemoglobin (Hgb)
85025	Blood count; complete (CBC), automated (Hgb, Hct, RBC, WBC and platelet count) and automated differential WBC count
85027	Blood count; complete (CBC), automated (Hgb, Hct, RBC, WBC and platelet count)
85032	Blood count; manual cell count (erythrocyte, leukocyte, or platelet) each
85041	Blood count; red blood cell (RBC), automated
86480	Tuberculosis test, cell mediated immunity antigen response measurement; gamma interferon
86580	Skin test; tuberculosis, intradermal
86592	Syphilis test, non-treponemal antibody; qualitative (e.g., VDRL, RPR, ART)
86593	Syphilis test, non-treponemal antibody; quantitative
86631	Antibody; Chlamydia
86632	Antibody; Chlamydia, IgM
86704	Hepatitis B core antibody (HBcAb); total
86706	Hepatitis B surface antibody (HBsAb)
86762	Antibody; rubella
86780	Antibody; Treponema pallidum

CPT	Code Description
86787	Antibody; varicella-zoster
86803	Hepatitis C antibody
86804	Hepatitis C antibody; confirmatory test (e.g., immunoblot)
86850	Antibody screen, RBC, each serum technique
86900	Blood typing, serologic; ABO
86901	Blood typing, serologic; Rh (D)
87077	Culture, bacterial; aerobic isolate, additional methods required for definitive identification, each isolate
87081	Culture, presumptive, pathogenic organisms, screening only;
87086	Culture, bacterial; quantitative colony count, urine
87088	Culture, bacterial; with isolation and presumptive identification of each isolate, urine
87110	Culture, chlamydia, any source
87270	Infectious agent antigen detection by immunofluorescent technique; Chlamydia trachomatis
87320	Infectious agent antigen detection by immunoassay technique, (e.g., enzyme immunoassay [EIA], enzyme-linked immunosorbent assay [ELISA], immunochemiluminometric assay [IMCA]) qualitative or semiquantitative, multiple-step method; Chlamydia trachomatis
87340	Infectious agent antigen detection by immunoassay technique, (e.g., enzyme immunoassay [EIA], enzyme-linked immunosorbent assay [ELISA], immunochemiluminometric assay [IMCA]) qualitative or semiquantitative, multiple-step method; hepatitis B surface antigen (HBsAg)
87341	Infectious agent antigen detection by immunoassay technique, (e.g., enzyme immunoassay [EIA], enzyme-linked immunosorbent assay [ELISA], immunochemiluminometric assay [IMCA]) qualitative or semiquantitative, multiple-step method; hepatitis B surface antigen (HBsAg) neutralization
87389	Infectious agent antigen detection by immunoassay technique, (e.g., enzyme immunoassay [EIA], enzyme-linked immunosorbent assay [ELISA], fluorescence immunoassay [FIA], immunochemiluminometric assay [IMCA]) qualitative or semiquantitative; HIV-1 antigen(s), with HIV-1 and HIV-2 antibodies, single result
87490	Infectious agent detection by nucleic acid (DNA or RNA); Chlamydia trachomatis, direct probe technique
87491	Infectious agent detection by nucleic acid (DNA or RNA); Chlamydia trachomatis, amplified probe technique
87590	Infectious agent detection by nucleic acid (DNA or RNA); Neisseria gonorrhoeae, direct probe technique
87591	Infectious agent detection by nucleic acid (DNA or RNA); Neisseria gonorrhoeae, amplified probe technique
87653	Infectious agent detection by nucleic acid (DNA or RNA); Streptococcus, group B, amplified probe technique
87800	Infectious agent detection by nucleic acid (DNA or RNA), multiple organisms; direct probe(s) technique
87802	Infectious agent antigen detection by immunoassay with direct optical observation; Streptococcus, group B

CPT	Code Description
87810	Infectious agent antigen detection by immunoassay with direct optical observation; Chlamydia trachomatis
87850	Infectious agent antigen detection by immunoassay with direct optical observation; Neisseria gonorrhoeae
G0306	Complete CBC, automated (HgB, HCT, RBC, WBC, without platelet count) and automated WBC differential count
G0307	Complete (CBC), automated (HgB, HCT, RBC, WBC; without platelet count)
G0472	Hepatitis C antibody screening, for individual at high risk and other covered indication(s)
S3652	Saliva test, hormone level; to assess preterm labor risk

Procedure codes appearing in Medical Policy documents are included only as a general reference tool for each policy. They may not be all-inclusive.

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X. Revision History

Revision Date	Summary of Changes
07/01/2025	Off-cycle coding modification: Removed CPT code 87592 (screening addressed in policy is performed by qualitative measures; code represents quantitative testing and is not appropriate for policy).
12/04/2024	Off-cycle coding modification: Revised code description for CPT code 80081 (effective date 1/1/2025)