Reimbursement Policy:

Prenatal Screening (Nongenetic) - Lab Benefit Program (LBM)

POLICY NUMBER	EFFECTIVE DATE:	APPROVED BY
AHS-G2035	3/01/2023	RPC (Reimbursement Policy Committee)

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The information provided in our policies is intended to serve only as a general reference resource for services described and is not intended to address every aspect of a reimbursement situation. Other factors affecting reimbursement may supplement, modify or, in some cases, supersede this policy. These factors may include, but are not limited to, legislative mandates, physician or other provider contracts, the member's benefit coverage documents and/or other reimbursement, and medical or drug policies. Finally, this policy may not be implemented the same way on the different electronic claims processing systems in use due to programming or other constraints; however, we strive to minimize these variations.

We follow coding edits that are based on industry sources, including, but not limited to, CPT® guidelines from the American Medical Association, specialty organizations, and CMS including NCCI and MUE. In coding scenarios where there appears to be conflicts between sources, we will apply the edits we determine are appropriate. We use industry-standard claims editing software products when making decisions about appropriate claim editing practices. Upon request, we will provide an explanation of how we handle specific coding issues. If appropriate coding/billing guidelines or current reimbursement policies are not followed, we may deny the claim and/or recoup claim payment.

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 (Grant & Mohide, 1982; Lockwood & Magriples, 2020).

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 State and Federal Regulations section of this policy document.

1) The following routine prenatal screening **MEETS COVERAGE CRITERIA** for all pregnant individuals:

   a) Screening for HIV infection

   b) Screening for *Chlamydia trachomatis* infection

   c) Screening for *Neisseria gonorrhea* infection

   d) Screening for hepatitis B

e) Screening for syphilis

f) Screening for hepatitis C

g) Screening for fetal aneuploidy in accordance with Avalon Policy AHS-G2055-Prenatal Screening for Fetal Aneuploidy

h) Screening for type 2 diabetes at the first prenatal visit

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

j) 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

k) Screening for anemia meets coverage criteria with a CBC or hemoglobin and hematocrit with mean corpuscular volume

l) Screening for Group B strep once, recommended during gestational weeks 36 to 37 by American College of Obstetricians and Gynecologists (ACOG)

m) Urinalysis and urine culture

n) Rubella antibody testing

o) Testing for varicella immunity

p) Screening for tuberculosis in pregnant individuals deemed to be at high risk for TB (i.e., individuals with close contact with individuals with active pulmonary / respiratory tuberculosis or highly contagious active tuberculosis and individuals who are immunocompromised)

2) Third trimester re-screening of *Chlamydia trachomatis*, *Neisseria gonorrhea*, syphilis, and/or HIV infections **MEETS COVERAGE CRITERIA** for pregnant individuals who meet ANY one of the following high-risk criteria:

a) Sexually active young individuals under 25 years

b) New or multiple sexual partners

c) Past history of sexually transmitted diseases (Bacterial Vaginosis, Chancroid, Chlamydia, Gonorrhea, Genital Herpes, Hepatitis B, Hepatitis C, HIV/AIDS, Human Papillomavirus, Lymphogranuloma Venereum, Syphilis, Trichomoniasis)

d) Current sex workers

e) Past or current injection drug use

3) Fetal Fibronectin (FFN) assays **MEET COVERAGE CRITERIA** for pregnant individuals who meet ALL the following criteria:

a) Singleton or twin gestations,

b) Intact membranes,

c) Cervical dilation <3 cm, and

d) Patient experiencing symptoms suggestive of preterm labor between 24 and less than 35 weeks' gestation.

4) Testing pregnant individuals for thyroid dysfunction is covered in accordance with Avalon Policy AHS-G2045-Thyroid Disease Testing.

5) Screening for Zika virus infection is covered in accordance with Avalon Policy AHS-G2133-Zika Virus Testing.

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 a patient's illness.

6) All other applications of the FFN assay **DO NOT MEET COVERAGE CRITERIA**, including, but not limited to the following:

a) As part of routine pregnancy monitoring in asymptomatic individuals with singleton gestation and no risk factors for preterm birth.

b) As part of clinical monitoring of asymptomatic individuals at high risk for preterm birth, including but not limited to those with multiple gestations, history of preterm birth, uterine malformation, cervical incompetence, or history of two or more spontaneous second trimester abortions.

c) As part of clinical monitoring in individuals with triplet or higher-order gestations, intact membranes, cervical dilation <3 cm, and who are experiencing symptoms suggestive of preterm labor.

d) As a test to identify individuals at term being considered for induction who are likely to deliver within 24–48 hours and therefore, do not require induction.

7) Serial monitoring of salivary estriol levels as a technique of risk assessment for preterm labor or delivery **DOES NOT MEET COVERAGE CRITERIA**.

Definitions:

Term	Definition
ACMG	American College of Medical Genetics and Genomics
ACOG	American College of Obstetricians and Gynecologists
ADA	American Diabetes Association
CDC	Centers for Disease Control and Prevention
EIA	Enzyme immunoassay
ELISA	Enzyme linked immunosorbent assay

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Term	Definition
FANCC	Fanconi anemia complementation group C
FFN	Fetal fibronectin
FIA	Fluorescence immunoassay
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
RCOG	Royal College of Obstetricians and Gynaecologists
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

Scientific Background:

Prenatal screening is a part of overall prenatal care to promote optimal care of both mother and baby 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 (de Jong et al., 2015).”

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 (Lockwood & Magriples, 2020).

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 (Calhoun, 2020). 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 (Calhoun, 2020). 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 (Calhoun, 2020). 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) (Calhoun, 2020). 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 (Calhoun, 2020).

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" (Moise Jr, 2022). 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% (Moise Jr, 2022).

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. (Yesilcinar & Guvenc, 2021).

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 2 – 3 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 (Schrag et al., 2002). 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) (Slutsker et al., 2018).

Guidelines and Recommendations:

American College of Obstetricians and Gynecologists (ACOG)

ACOG 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 [reaffirmed in 2021] (ACOG, 2011)."

- **Lead Screening:** Concerning lead screening, they recommend risk assessment at the earliest contact of the patient to lead exposure using blood lead testing if even one single risk factor is identified. This was reaffirmed in 2019 (ACOG, 2012).

- **Subclinical Hypothyroidism:** ACOG Committee Opinion on subclinical hypothyroidism in pregnancy does not recommend routine screening for subclinical hypothyroidism. It states that "thyroid testing in pregnancy should be performed on symptomatic [individuals] and those with a personal history of thyroid disease or other medical conditions associated with thyroid disease (e.g., diabetes mellitus) (ACOG, 2015)."

- **Depression and Anxiety:** "All obstetrician-gynecologists and other obstetric care providers screen patients at least once during the perinatal period for depression and anxiety symptoms using a standardized, validated tool. [They should] complete a full assessment of mood and emotional well-being (including screening for postpartum depression and anxiety with a validated instrument) during the comprehensive postpartum visit for each patient (ACOG, 2018)."

- ***Listeria monocytogenes:*** Concerning testing for *Listeria monocytogenes* (ACOG, 2014), "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." 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. This position was reaffirmed in 2019.

- **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 (eg, 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 (Pollock et al., 2019)."

    - 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 (Pollock et al., 2019)."

- **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 (ACOG, 2017b).

- **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" (ACOG, 2020).

- **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 (ACOG, 2021). ACOG lists the following lab tests to be performed later in pregnancy: glucose screening test and Group B streptococcus (GBS) screening (ACOG, 2021).

- **Zika Virus:** The April 2019 update concerning Zika, ACOG states the following (ACOG, 2019):

    - "Although rates of Zika virus infection have decreased in the United States, obstetrician-gynecologists and other health care providers should continue to assess their patients for potential exposure based on travel or sexual history and test symptomatic patients with possible exposure and pregnant [individuals] with ongoing exposure regardless of symptoms in accordance with the Centers for Disease Control and Prevention recommendations. . . Testing recommendations for pregnant [individuals] with possible Zika virus exposure differ based on the presence or absence of symptoms of Zika virus infection and the circumstances of possible exposure. If obstetrician-gynecologists or other health care providers identify a patient who has possibly been exposed to the Zika virus and may require testing, they should contact their local or state health department for assistance. Consultation with a maternal-fetal medicine specialist or an infectious disease specialist with expertise in the management of infectious diseases in pregnancy may be useful for pregnant [individuals] with possible maternal Zika virus infection or concerning fetal findings. Zika virus identification and follow-up care of infants born to [individuals] with possible exposure to Zika virus during pregnancy are critical and can ensure that appropriate intervention services are available to affected infants"(ACOG, 2019).

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) (Pillay et al., 2021; USPSTF, 2021)

- Screening for hepatitis B virus (HBV) infection at the first prenatal visit (Grade A) (Owens, Davidson, Krist, Barry, Cabana, Caughey, Doubeni, Epling, Kemper, et al., 2019; USPSTF, 2009, 2019)

- Screening for asymptomatic bacteriuria with urine culture is recommended in pregnant persons (Grade B) (Owens, Davidson, Krist, Barry, Cabana, Caughey, Doubeni, Epling, Kubik, et al., 2019; USPSTF, 2008a)

- Screening for HIV is recommended in all pregnant persons, including those in labor or whose HIV status is unknown at delivery (Grade A) (Moyer & USPSTF, 2013b; Owens, Davidson, Krist, Barry, Cabana, Caughey, Curry, et al., 2019)

- Rh (D) blood typing and antibody testing during the first prenatal visit (Grade A) (USPSTF, 2005)
- 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) (USPSTF, 2005)
- Screening early for syphilis infection in all pregnant individuals (Grade A) (USPSTF, 2018)

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

- Screening for chlamydia in sexually active individuals aged 24 years or younger and in older individuals who are at increased risk for infection (Grade B) (LeFevre & USPSTF, 2014)
- Screening for gonorrhea in sexually active individuals aged 24 years or younger and in older individuals who are at increased risk for infection (Grade B) (LeFevre & USPSTF, 2014)
- Screening for depression in general population, including pregnant and post-partum individuals (Grade B) (Siu & USPSTF, 2016)

Screening for hepatitis C virus (HCV) infection is recommended in all adults aged 18 to 79 years (Grade B) (Chou et al., 2020; Moyer & USPSTF, 2013a)

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 age 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."

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 (Owens et al., 2020; USPSTF, 2008b)
- Serological screening for herpes simplex virus (HSV) in asymptomatic pregnant individuals (USPSTF, 2016)
- 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 (Curry et al., 2019; USPSTF, 2006)
- "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 (Siu, 2015)."

American Diabetes Association (ADA)

The American Diabetes Association in the 2021 *Standards of Medical Care in Diabetes* make the following recommendations (American Diabetes, 2021a, 2021b):

- "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] **B**

- [individuals] with preexisting diabetes who are planning a pregnancy should ideally be managed beginning in preconception in a multidisciplinary clinic including an endocrinologist, maternal-fetal medicine specialist, registered dietitian nutritionist, and diabetes care and education specialist, when available. [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**

- Test for undiagnosed prediabetes at the first prenatal visit in those with risk factors, using standard diagnostic criteria. [Grade] **B**

- Test for gestational diabetes mellitus at 24–28 weeks of gestation in pregnant [individuals] not previously found to have diabetes. [Grade] **A**

- 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:

Disease	First Prenatal Visit	Third Trimester	At Delivery
Syphilis	All pregnant individuals	Certain groups of pregnant individuals[5] at 28-32 weeks	Certain groups of pregnant individuals[5] at delivery
HIV	All pregnant individuals[1]	Rescreen individuals at high risk for acquiring HIV infection	Pregnant individuals not screened during pregnancy
Hepatitis B (HBV)	All pregnant individuals[2]	Test those not screened prenatally and whose	Pregnant individuals not screened during pregnancy[6],

Disease	First Prenatal Visit	Third Trimester	At Delivery
		who engage in behaviors that put them at a high risk[7] for infection	who are at high risk[7], or with signs or symptoms of hepatitis
Chlamydia	All pregnant individuals <25 years of age and older pregnant individuals at increased risk[3]	Pregnant individuals <25 years of age or continued high risk[3]	N/A
Gonorrhea	All pregnant individuals <25 years of age and older pregnant individuals at increased risk[4]	Pregnant individuals at continued high risk[4]	N/A
Hepatitis C (HCV)	All[8] pregnant individuals during each pregnancy	N/A	N/A

Endnotes:

1. To promote informed and timely therapeutic decisions, health care providers should test individuals for HIV as early as possible during each pregnancy.
2. All pregnant individuals should be tested for hepatitis B surface antigen (HbsAg) during an early prenatal visit (e.g., first trimester) in each pregnancy, even if they have been vaccinated or tested previously.
3. “Increased risk” means new or multiple sex partners, sex partner with concurrent partners, sex partners who have a sexually transmitted infection (STI).
4. “At increased risk” means living in a high-morbidity area, having a previous or coexisting STI, new or multiple sex partners, inconsistent condom use among persons not in mutually monogamous relationships, exchanging sex for money or drugs.
5. “Certain groups” includes individuals who are at high risk for syphilis during pregnancy, who live in areas with high numbers or syphilis cases, and/or who were not previously tested or had a positive test in the first trimester.
6. Individuals admitted for delivery at a health care facility without documentation of HbsAg test results should have blood drawn and tested as soon as possible after admission.
7. Having had more than one sex partner during the previous 6 months, an HbsAg-positive sex partner, evaluation or treatment for a STD, or injection-drug use (IDU).
8. All pregnant individuals except in a setting where the prevalence of HCV infection is (HCV RNA-positivity) <0.1%.” (CDC, 2021a)

- "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" (CDC, 2021f).

- "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" (CDC, 2021d).

- "[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" (CDC, 2021b).

- "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" (CDC, 2021c).

- "CDC recommends hepatitis C screening . . . all [individuals] during each pregnancy, except in settings where the prevalence of HCV infection is <0.1%" (CDC, 2021e).

- Zika virus testing for asymptomatic individuals is not currently recommended. For symptomatic pregnant individuals:

    - "For symptomatic pregnant [individuals] who had recent travel to areas with active dengue transmission and a risk of Zika, specimens should be collected as soon as possible after the onset of symptoms up to 12 weeks after symptom onset.

        - The following diagnostic testing should be performed at the same time:

            - Dengue and Zika virus NAAT testing on a serum specimen, and Zika virus NAAT on a urine specimen, and

            - IgM testing for dengue only.

        - Zika virus IgM testing is NOT recommended for symptomatic pregnant [individuals].

            - Zika IgM antibodies can persist for months to years following infection. Therefore, detecting Zika IgM antibodies might not indicate a recent infection.

            - There is notable cross-reactivity between dengue IgM and Zika IgM antibodies in serologic tests. Antibodies generated by a recent dengue virus infection can cause the Zika IgM to be falsely positive.

        - If the Zika NAAT is positive on a single specimen, the Zika NAAT should be repeated on newly extracted RNA from the same specimen to rule out false-positive NAAT results. If the dengue

NAAT is positive, this provides adequate evidence of a dengue infection and no further testing is indicated.

- If the IgM antibody test for dengue is positive, this is adequate evidence of a dengue infection and no further testing is indicated (CDC, 2019)."

- "Evidence does not support routine HSV-2 serologic testing among asymptomatic pregnant [individuals]" (CDC, 2021a).

- "Evidence does not support routine screening for BV in asymptomatic pregnant [individuals] at high or low risk for preterm delivery" (CDC, 2021a).

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 (Vockley et al., 2014)."

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 (WHO, 2016):

- 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 (WHO, 2016)."

To help circumvent prenatal transmission, the CDC also "recommends that all pregnant [individuals] get tested for HIV, hepatitis B virus (HBV), hepatitis C virus (HCV), and syphilis during each pregnancy" as "screening is necessary to access medical services for HCV and treatment to prevent transmission of HIV, HBV, and syphilis to the infant" (CDC, 2020).

Reimbursement Policy:

Prenatal Screening (Nongenetic) - Lab Benefit Program (LBM)

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

In the 3rd edition of the VA/DoD *Clinical Practice Guideline for the Management of Pregnancy (VA & DOD, 2018)*, they list the following lab tests as routine for all pregnancies in the first prenatal visit: HIV, CBC, ABO Rh blood typing, Antibody screen, anemia/hemoglobinopathies screen, rapid plasma 13egain, gonorrhea, chlamydia, hepatitis B surface antigen test, rubella IgG, Urinalysis and culture, and varicella IgG (if status is unknown). They also list the following among their recommendations (VA & DOD, 2018):

- "We recommend screening for use of tobacco, alcohol, illicit drugs, and unauthorized use of prescription medication because their use is common and can result in adverse outcomes. For [individuals] who screen positive, we recommend additional evaluation and treatment." [Strong]
- "We recommend screening for depression 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 suggest making prenatal diagnostic testing for aneuploidy available to all pregnant [individuals]." [Weak]
- "We recommend offering prenatal screening for aneuploidy and the most common clinically significant genetic disorders to all pregnant [individuals]. When aneuploidy screening is desired, cellfree fetal DNA screening should be considered; however, screening test selection should be individualized and take into account the patient's age, baseline aneuploidy risk, and test performance for a given condition." [Strong]
- "We suggest the two-step process (one-hour oral glucose challenge test followed by three-hour oral glucose tolerance test) to screen for gestational diabetes mellitus at 24-28 weeks gestation for all pregnant [individuals]." [Weak]
- "We suggest that pregnant [individuals] with an unexplained elevation of maternal serum alpha-fetoprotein be evaluated and counseled by a qualified obstetric provider due to increased risk for adverse perinatal outcomes." [Weak]
- "We recommend **against** routine screening for preterm delivery using the fetal fibronectin test in asymptomatic [individuals]." [Strong, against]
- "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 that [individuals] who have undergone bariatric surgery should 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-supported Women's Preventive Services Initiative (HRSA, 2017) 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

Reimbursement Policy:

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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 http://www.cms.gov/medicare-coverage-database/overview-and-quick-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.

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 (eg, 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 (eg, VDRL, RPR, ART) (86592) Antibody screen, RBC, each serum technique (86850) Blood typing, ABO (86900) AND Blood typing, Rh (D) (86901)
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

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CPT	Code Description
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
83020	Hemoglobin fractionation and quantitation; electrophoresis (eg, A2, S, C, and/or F)
83021	Hemoglobin fractionation and quantitation; chromatography (eg, A2, S, C, and/or F)
83036	Hemoglobin; glycosylated (A1C)
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
85048	Blood count; leukocyte (WBC), automated
86480	Tuberculosis test, cell mediated immunity antigen response measurement; gamma interferon
86580	Skin test; tuberculosis, intradermal
86592	Syphilis test, non-treponemal antibody; qualitative (eg, VDRL, RPR, ART)
86593	Syphilis test, non-treponemal antibody; quantitative
86631	Antibody; Chlamydia
86632	Antibody; Chlamydia, IgM
86701	Antibody; HIV-1
86702	Antibody; HIV-2
86703	Antibody; HIV-1 and HIV-2, single result

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CPT	Code Description
86704	Hepatitis B core antibody (HBcAb); total
86706	Hepatitis B surface antibody (HBsAb)
86762	Antibody; rubella
86780	Antibody; Treponema pallidum
86787	Antibody; varicella-zoster
86803	Hepatitis C antibody
86804	Hepatitis C antibody; confirmatory test (eg, 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, (eg, 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, (eg, 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, (eg, enzyme immunoassay [EIA], enzyme-linked immunosorbent assay [ELISA], immunochemiluminometric assay [IMCA]) qualitative or semiquantitative, multiple-step method; hepatitis B surface antigen (HBsAg) neutralization
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

Reimbursement Policy:

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CPT	Code Description
87591	Infectious agent detection by nucleic acid (DNA or RNA); Neisseria gonorrhoeae, amplified probe technique
87592	Infectious agent detection by nucleic acid (DNA or RNA); Neisseria gonorrhoeae, quantification
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
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)
G0432	Infectious agent antibody detection by enzyme immunoassay (EIA) technique, HIV-1 and/or HIV-2, screening
G0433	Infectious agent antibody detection by enzyme-linked immunosorbent assay (ELISA) technique, HIV-1 and/or HIV-2, screening
G0435	Infectious agent antibody detection by rapid antibody test, HIV-1 and/or HIV-2, screening
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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Revision History

Company(ies)	DATE	REVISION
EmblemHealth ConnectiCare	11/2022	• Reformatted and reorganized policy, transferred content to new template with new Reimbursement Policy Number