

Preventive Screening in Adults

Policy Number: AHS – G2009 – Preventive Screening in Adults	Prior Policy Name and Number, as applicable:
Initial Presentation Date: 06/01/2021 Revision Date: N/A	

I. Policy Description

Preventive screening is a healthcare service with the goal of illness prevention and health management. According to the American College of Preventive Medicine (ACPM, 2018), “preventive medicine focuses on the health of individuals, communities, and defined populations. Its goal is to protect, promote, and maintain health and well-being and to prevent disease, disability, and death.”

II. Related Policies

Policy Number	Policy Title
AHS-G2002	Cervical Cancer Screening
AHS-G2005	Vitamin D Testing
AHS-G2006	Hemoglobin A1c
AHS-G2008	Prostate Cancer Screening
AHS-G2035	Prenatal Screening
AHS-G2036	Hepatitis C
AHS-G2042	Pediatric Preventive Screening

AHS-G2050	Cardiovascular Disease Risk Assessment
AHS-G2063	Testing for Diagnosis of Active or Latent Tuberculosis
AHS-G2156	Urine Culture Testing For Bacteria
AHS-G2157	Diagnostic Testing of Sexually Transmitted Infections
AHS-M2003	BRCA
AHS-M2066	Genetic Cancer Susceptibility Using Next Generation Sequencing

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. Medical Policy Statements do not ensure an authorization or payment of services. Please refer to the plan contract (often referred to as the Evidence of Coverage) for the service(s) referenced in the Medical Policy Statement. If there is a conflict between the Medical Policy Statement and the plan contract (i.e., Evidence of Coverage), then the plan contract (i.e., Evidence of Coverage) will be the controlling document used to make the determination.

Application of coverage criteria is dependent upon an individual’s benefit coverage at the time of the request. If there is a conflict between this Policy and any relevant, applicable government policy [e.g. National Coverage Determinations (NCDs) for Medicare] for a particular member, then the government policy will be used to make the determination. For the most up-to-date Medicare policies and coverage, please visit their search website <http://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx?from2=search1.asp&> or [the manual website](#)

The medical necessity criteria below apply to individuals who do not have a pre-existing diagnosis for the disorders listed, and who do not have an increased risk due to other disease diagnoses, other conditions (such as pregnancy), or family history. See individual policies related to the specific disease or condition for further guidance.

1. Please refer to AHS policy G2157 “Diagnostic Testing of Sexually Transmitted Infections” for guidance regarding chlamydia, gonorrhea, and syphilis screening.

2. Please refer to AHS policy G2036 “Hepatitis C” for guidance regarding Hepatitis C screening.
3. Annual screening for Hepatitis B virus infection **MEETS COVERAGE CRITERIA** in asymptomatic individuals at high risk for infections as mentioned below:
 - a. Persons born in geographic regions with HBsAg prevalence of >2 percent
 - b. U.S.-born persons not vaccinated as infants whose parents were born in geographic regions with HBsAg prevalence of >8 percent
 - c. Injection-drug users
 - d. Men who have sex with men
 - e. Persons with elevated ALT/AST of unknown etiology
 - f. Persons with selected medical conditions who require cytotoxic or immunosuppressive therapy
 - g. Pregnant women
 - h. Infants born to HBsAg- positive mothers
 - i. Household contacts and sex partners of HBV-infected persons
 - j. Healthcare and public safety workers exposed to blood or body fluids
 - k. Persons infected with HIV
 - l. Persons with multiple sex partners
 - m. On long-term hemodialysis treatment
4. Screening for HIV infection **MEETS COVERAGE CRITERIA** in adolescents and adults, ages 11 to 65 years, as well as in all pregnant women in the third trimester.
5. Please refer to AHS policy G2050 “Cardiovascular Disease Risk Assessment” for guidance regarding lipid testing.
6. Please refer to AHS policy G2063 “Testing for Diagnosis of Active or Latent Tuberculosis” for guidance regarding latent tuberculosis screening.

7. Please refer to AHS policy M2003 “BRCA” for guidance regarding *BRCA* testing.
8. Screening for type 2 diabetes mellitus, with a fasting plasma glucose test, oral glucose tolerance test, or hemoglobin A1c test once every three years, **MEETS COVERAGE CRITERIA** for:
 - a. Asymptomatic individuals aged 40 to 70 years who are overweight or obese (BMI ≥ 25 or >23 in Asian Americans),
 - b. Individuals who have family history of diabetes, gestational diabetes or polycystic ovarian syndrome, or belong to certain ethnic groups (African Americans, American Indians or Alaskan Natives, Asian Americans, Hispanics or Latinos, or Native Hawaiians or Pacific Islanders). Refer to policy G2006 Hemoglobin A1c, for more details on HbA1c testing in individuals with diabetes.
 - c. Women with a history of gestational diabetes mellitus who are not currently pregnant and who have not been previously diagnosed with type 2 diabetes mellitus should be screened for type 2 diabetes mellitus within the first year postpartum and:
 - i. In women with a positive initial postpartum screening result, repeat testing to confirm diagnosis is indicated regardless of the type of test used for initial screening
 - ii. If the initial screening test was hemoglobin A1C, repeat testing is indicated in the first six months postpartum regardless of the result
 - iii. Women with a negative initial postpartum screening result should be rescreened at least every 3 years for a minimum of 10 years after pregnancy
9. Screening for cervical cancer is detailed in Avalon policy G2002: Cervical Cancer Screening.
10. Screening for prostate cancer with the prostate-specific antigen (PSA) is detailed in Avalon policy G2008: Prostate Cancer Screening.
11. Screening for colorectal cancer in asymptomatic individuals, ages 45 to 75 years **MEETS COVERAGE CRITERIA** using the following screening strategies:
 - a. Stool-based test:
 - i. gFOBT every year,
 - ii. FIT every year, or

b. Direct visualization tests:

- i. Colonoscopy every 10 years, or
- ii. CT colonography every 5 years, or
- iii. Flexible sigmoidoscopy every 5 years, or
- iv. Flexible sigmoidoscopy every 10 years with FIT every year

12. Colorectal cancer screening using methylated Septin 9 (ColoVantage) or FIT- DNA (Cologuard) **DOES NOT MEET COVERAGE CRITERIA** for colorectal cancer screening.

13. Screening in the following situations **DOES NOT MEET COVERAGE CRITERIA**:

- a. Colorectal cancer in asymptomatic, average risk individuals over 75 years of age.
- b. Screening of asymptomatic, non-pregnant individuals for thyroid disease.
- c. Screening of asymptomatic, non-pregnant individuals for anemia.
- d. Screening for Herpes Simplex Virus infection in asymptomatic individuals.
- e. The use of culture for detection of Chlamydial infection.

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.

14. Colorectal cancer screening using the following techniques **DOES NOT MEET COVERAGE CRITERIA** due to a lack of evidence such screening improves clinical outcomes:

- a. Screening for anal cytological abnormalities (anal pap smear); OR
- b. Screening for anal HPV infection

IV. Scientific Background

The annual “wellness visit” or checkup visit to a primary care provider has been a common part of routine health care for several decades. Providers typically review an individual’s personal history and family history, perform a physical examination, and run a battery of tests during the annual checkup.

Screening examinations among higher risk populations are less frequent but equally critical for early diagnosis of potential malignancy. The types and number of tests performed can vary widely among providers.

V. Guidelines and Recommendations

The Patient Protection and Affordable Care Act (ACA) established coverage requirements for clinical preventive services for most types of public and private health insurance, with the goal of improving access to a wide range of preventive health services for children and adults (Seiler, Malcarney, Horton, & Dafflito, 2014). Recommendations for screening coverage are derived from the following medical and scientific bodies:

- U.S. Preventive Services Task Force (USPSTF)
- Advisory Committee on Immunization Practices (ACIP)
- Health Resources and Services Administration’s (HRSA’s) Bright Futures Project
- HRSA and the Institute of Medicine (IOM) Committee on Women’s Clinical Preventive Services
- American Cancer Society

The USPSTF provides recommendations regarding clinical preventive services such as screening and counseling. The task force is comprised of an independent panel of experts in primary care and prevention that further specialize in numerous fields. Recommendations are segmented primarily based on factors such as age, gender, and pregnancy status. The USPSTF assigns one of five letter grades to a recommendation (A, B, C, D, or I). Costs are not considered when grading a practice. Furthermore, the recommendations only apply to people who are asymptomatic for a given condition (USPSTF, 2017). The below chart represents screening recommendations from the USPSTF for adults.

USPSTF Recommendations:

Topic	Date	Grade	Recommendation	Do not Recommend (D grade)

<p>Bacteriuria screening (Owens, Davidson, Krist, Barry, Cabana, Caughey, Doubeni, Epling, et al., 2019b; USPSTF, 2008)</p>	<p>September 2019</p>	<p>B</p>	<p>Recommends screening for asymptomatic bacteriuria with urine culture in pregnant women at 12 to 16 weeks' gestation or at the first prenatal visit, if later.</p>	<p>Screening for asymptomatic bacteriuria in men and nonpregnant women.</p>
<p>BRCA risk assessment and genetic counseling/testing (V. A. Moyer, 2014a; Owens, Davidson, Krist, Barry, Cabana,</p>	<p>August 2019</p>	<p>B</p>	<p>Recommends that primary care providers screen women with a personal or family history of breast, ovarian, tubal, or peritoneal cancer, as well as a family history associated with a <i>BRCA1</i> or <i>BRCA2</i> gene mutation with an appropriate screening tool.</p>	<p>Routine genetic counseling or <i>BRCA</i> testing for women whose family history is not associated with an increased risk for potentially harmful mutations in the <i>BRCA1</i> or <i>BRCA2</i> genes.</p>

<p>Caughey, Doubeni, Epling, et al., 2019a)</p>			<p>Women with positive screening results should receive genetic counseling and, if indicated after counseling, genetic testing.</p>	
<p>Celiac disease screening (BibbinsDomingo et al., 2017)</p>	<p>March 2017</p>	<p>I</p>	<p>Recommends that current evidence is insufficient to assess the balance of benefits and harms of screening for celiac disease in asymptomatic persons.</p>	<p>n/a</p>

Cervical cancer screening (USPSTF, 2018a)	August 2018	A	Recommends screening for cervical cancer every 3 years with cervical cytology alone in women aged 21 to 29 years. For women aged 30 to 65 years, the USPSTF recommends screening every 3 years with cervical cytology alone, every 5 years with high-risk human papillomavirus (hrHPV) testing alone, or every 5 years with hrHPV testing in combination with cytology (cotesting).	Screening for women older than 65 who have received adequate prior screening and are not high risk patients, screening for any women younger than 21, or screening for women who have had a hysterectomy with removal of the cervix and do not have a history of high-grade precancerous lesions or cervical cancer.
Chlamydia screening: in men (LeFevre, 2014a)	September 2014	I	Current evidence is insufficient to assess the balance of benefits and harms of screening for chlamydia and gonorrhea in men.	n/a
Chlamydia screening: in women (LeFevre, 2014a)	September 2014	B	Recommends screening for chlamydia in sexually active women age 24 years or younger and in older women who are at increased risk for infection.	n/a
Colorectal cancer screening: adults 50-75 years old (USPSTF, 2016a)	June 2016	A	Recommends screening for colorectal cancer starting at age 50 years and continuing until age 75 years.	n/a

Colorectal cancer screening: adults 76-85 years old (USPSTF, 2016a)	June 2016	C	Recommends that the decision to screen in adults aged 76 to 85 should be an individual one, taking into account the patient's overall health and prior screening history.	n/a
Diabetes screening (Siu, 2015)	October 2015	B	Recommends screening for abnormal blood glucose as part of cardiovascular risk assessment in adults aged 40 to 70 years who are overweight or obese. Clinicians should offer or refer patients with abnormal blood glucose to intensive behavioral counseling interventions to promote a healthful diet and physical activity.	n/a
Gestational Diabetes (V. A. Moyer, 2014b)	January 2014	B	Recommends screening for gestational diabetes mellitus in asymptomatic pregnant women after 24 weeks of gestation.	n/a
Gonorrhea screening (LeFevre, 2014a)	September 2014	B	Recommends screening for gonorrhea in sexually active women age 24 years or younger and in older women who are at increased risk for infection.	n/a
Hepatitis B screening (LeFevre, 2014b)	May 2014	B	Recommends screening for hepatitis B virus infection in persons at high risk for infection.	n/a

<p>Hepatitis B screening: pregnant women (Lin & Vickery, 2009; Owens,</p>	<p>July 2019</p>	<p>A</p>	<p>Recommends screening for hepatitis B virus infection in pregnant women at their first prenatal visit.</p>	<p>n/a</p>
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<p>Davidson, Krist, Barry, Cabana, Caughey, Doubeni, Epling, Kemper, et al., 2019)</p>				
<p>Hepatitis C screening (USPSTF, 2020)</p>	<p>March 2020</p>	<p>B</p>	<p>Recommends one-time screening for hepatitis C virus (HCV) infection in “asymptomatic adults aged 18 to 79 years without known liver disease”. The USPSTF still recommends to “periodically screen persons with continued risk for HCV infection”.</p>	<p>n/a</p>

<p>HIV screening: adolescents and adults 15-65 years old (V. A. Moyer & USPSTF, 2013; Owens, Davidson, Krist, Barry, Cabana, Caughey, Curry, et al., 2019b)</p>	<p>June 2019</p>	<p>A</p>	<p>Recommends that clinicians screen for HIV infection in adolescents and adults ages 15 to 65 years. Younger adolescents and older adults who are at increased risk should also be screened.</p>	<p>n/a</p>
<p>HIV screening: pregnant women (V. A. Moyer & USPSTF, 2013; Owens, Davidson, Krist, Barry, Cabana, Caughey, Curry, et al., 2019b)</p>	<p>June 2019</p>	<p>A</p>	<p>Recommends that clinicians screen all pregnant women for HIV, including those who present in labor who are untested and whose HIV status is unknown.</p>	<p>n/a</p>

Page

<p>Prevention of HIV Infection: Preexposure Prophylaxis (PrEP) for Persons at highrisk of HIV acquisition (Owens, Davidson, Krist, Barry, Cabana, Caughey, Curry, et al., 2019a)</p>	<p>June 2019</p>	<p>A</p>	<p>Recommends offering PrEP with effective antiretroviral therapy to persons at high risk of HIV acquisition</p>	<p>n/a</p>
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Rh(D) incompatibility screening: first pregnancy-related care visit (USPSTF, 2005)	February 2004	A	Strongly recommends Rh (D) blood typing and antibody testing for all pregnant women during their first visit for pregnancy-related care.	n/a
Rh(D) incompatibility screening: Unsensitized Rh(D)-negative pregnant women (USPSTF, 2005)	February 2004	B	Recommends repeated Rh (D) antibody testing for all unsensitized Rh (D)negative women at 24 to 28 weeks' gestation, unless the biological father is known to be Rh (D)-negative.	n/a
Syphilis screening: Asymptomatic, nonpregnant adults and adolescents who are at increased risk for syphilis infection (USPSTF, 2016c)	June 2016	A	Recommends screening for syphilis infection in persons who are at increased risk for infection.	n/a
Syphilis screening: pregnant women (USPSTF, 2018b)	September 2018	A	Recommends early screening for syphilis infection in all pregnant women.	n/a

<p>Tuberculosis (TB) screening (BibbinsDomingo et al., 2016; USPSTF, 2016b)</p>	<p>September 2016</p>	<p>B</p>	<p>Recommends screening for latent tuberculosis infection (LTBI) in populations at increased risk.</p>	<p>n/a</p>
<p>Vitamin D Deficiency Screening: communitydwelling, nonpregnant, asymptomatic adults age 18 years and older (USPSTF, 2014)</p>	<p>November 2014</p>	<p>I</p>	<p>Recommends that the current evidence is insufficient to assess the balance of benefits and harms of screening for vitamin D deficiency in asymptomatic adults.</p>	<p>n/a</p>

American Cancer Society (ACS, 2020; Fontham et al., 2020; Wolf et al., 2018)

The ACS has published guidance for the “early detection of cancer”.

For breast cancer, ACS states that women “should have the choice to start annual breast cancer screening with mammograms (x-rays of the breast)...” starting from ages 40-44. Women ages 45-54 should receive annual mammograms, and women 55 and older may have mammograms every 2 years or continue annual mammograms. The ACS notes that screenings should continue “as long as a woman is in good health and is expected to live 10 more years or longer.” (ACS, 2020)

For colorectal cancer (CRC), the ACS recommends screening people at average risk starting at age 45. The ACS notes that a stool test is usable for screening. The ACS states that regular screening should continue at least through age 75. From ages 76-85, the ACS writes that the decision to continue screening should be discussed between patient and provider. From age 85 onward, a patient should no longer receive colorectal cancer screening (ACS, 2020).

The ACS notes the following options for CRC screening using stool: “Fecal immunochemical test every y[ear], High-sensitivity, guaiac-based fecal occult blood test every y[ear] or a Multitarget stool DNA test every 3 y[ears]” For structural examination, the ACS notes the following options: “colonoscopy every 10 y[ears], CT colonography every 5 y[ears], or flexible sigmoidoscopy every 5 y[ears] (Wolf et al., 2018).

For cervical cancer, the ACS recommends starting screening at age 25. From ages 25 to 65, the ACS recommends getting a “primary HPV (human papillomavirus) test* done every 5 years”. A Pap test every 3 years or a “co-test” (HPV test plus Pap test) every 5 years are acceptable alternatives. The ACS notes that patients over 65 “who have had regular cervical cancer testing in the past 10 years with normal results should not be tested for cervical cancer.” Finally, patients whose cervix has been surgically removed do not need cervical cancer screening. (ACS, 2020; Fontham et al., 2020)

For prostate cancer, the ACS recommends that men “make an informed decision with a health care provider about whether to be tested for prostate cancer”. However, they remark that men should have this discussion at different ages; for “African American or have a father or brother who had prostate cancer before age 65”, this discussion should start at age 45; for other men, this discussion should start at 50 (ACS, 2020).

Centers for Disease Control and Prevention (Bloch, 1995; Branson et al., 2006; CDC, 2015; DiNenno et al., 2017; Schillie, Wester, Osborne, Wesolowski, & Ryerson, 2020; Sosa et al., 2019; Weinbaum, Mast, & Ward, 2009)

The CDC provides the below recommendations for **sexually transmitted diseases** (CDC, 2015):

- Annual chlamydia screening of all sexually active women younger than 25 years and all pregnant women under 25 years is recommended, as well as in older women with risk factors such as new or multiple sex partners and for men who have sex with men (MSM). Further, persons who are first screened for HIV should also be tested for chlamydia, and at least annually thereafter.
- Annual gonorrhea screening for all sexually active women younger than 25 years, as well as older women with risk factors such as new or multiple sex partners, and for MSM. Further, persons who are first screened for HIV should also be tested for gonorrhea, and at least annually thereafter.
- Syphilis, HIV, and hepatitis B screening for all pregnant women, and chlamydia and gonorrhea screening for at-risk pregnant women starting early in pregnancy, with repeat testing after treatment as needed.
- MSM at particularly high risk should be screened every 3-to-6 months for chlamydia, gonorrhea and syphilis (CDC, 2015).

The CDC recommends the following screening guidelines for **hepatitis C (HCV)** (Schillie et al., 2020)

- Adults born from 1945 through 1965 should be tested once (without prior ascertainment of HCV risk factors)
- HCV testing is recommended for those who:
 - Currently injecting drugs
 - Ever injected drugs and shared needles, syringes, or other drug preparation equipment, including those who injected once or a few times many years ago
 - Have certain medical conditions, including persons:
 - Who were ever on maintenance hemodialysis
 - With persistently abnormal alanine aminotransferase (ALT) levels
 - Who have HIV infection
 - Were prior recipients of transfusions or organ transplants, including persons who:

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- Who received clotting factor concentrates produced before 1987
Were notified that they received blood from a donor who later tested positive for HCV infection
- Received a transfusion of blood, blood components, or an organ transplant before July 1992
 - HCV- testing based on a recognized exposure is recommended for:
- Healthcare, emergency medical, and public safety workers after needle sticks, sharps, or mucosal exposures to HCV-positive blood
- Children born to HCV-positive women

The CDC recommends the following populations for **chronic hepatitis B screening** (CDC, 2015; Weinbaum et al., 2009):

- Persons born in regions with HBV prevalence of $\geq 2\%$
- US-born persons not vaccinated as infants whose parents were born in geographic regions with high rates of HBV ($\geq 8\%$)
- Injection-drug users
- Men who have sex with men (MSM) should be tested for HBsAg
- Persons with liver disease of unknown etiology or with elevated ALT or AST levels of unknown etiology
- Persons with certain medical conditions who require immunosuppressive or cytotoxic therapy
- Pregnant women (antiviral therapy may be considered if a positive test occurs)
 - Test at first prenatal visit of each pregnancy regardless of prior testing and retest at delivery if high-risk
- Infants born to HBsAg-positive mothers (HBsAg is the distinctive surface antigen of a hepatitis B infection)
- Household contacts and sex partners of HBV-infected persons
- Persons who are the source of blood or body fluid exposures that might warrant postexposure prophylaxis (such as needlestick injury to a health care worker)
- Persons infected with HIV should be tested for HBsAg and anti-HBc and/or anti-HBs (Weinbaum et al., 2009).

The CDC recommends the following guidelines for **HIV** (Branson et al., 2006; CDC, 2015):

- All persons aged 13–64 years should be screened for HIV at least once.
- Patients initiating treatment for TB should be screened routinely for HIV infection.

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- Patients seeking treatment for STIs (including any patient attending an STI clinic) should be screened routinely for HIV during each visit for a new complaint.
High risk populations (such as injection drug users, MSM, or partners of HIV-infected persons) should be screened at least annually. Repeated screening of persons not likely to be at high risk should be done based on clinical judgment.
- All pregnant women should be screened for HIV as early as possible in the pregnancy (Branson et al., 2006) and should be retested in the third trimester if they are considered high risk (CDC, 2015)

A 2017 CDC review of HIV screening guidelines for the high-risk population MSM found insufficient evidence to change the current recommendation of annual screening to a more frequent schedule; however, individual clinicians may consider the potential benefits of a more frequent screening schedule (DiNenno et al., 2017).

The CDC recommends the following guidelines for **tuberculosis (TB) and latent TB infection (LTBI)** screening and testing of health care professionals (HCP) (Bloch, 1995; Sosa et al., 2019):

- Screening high risk populations such as patients with HIV, is of the highest priority. The high-risk populations include, but are not limited to:
 - People who have spent time with someone (“close contact”) who has TB
 - People from a country where TB is more prevalent (most countries in Latin America, Africa, Asia)
 - People who live or work in high-risk settings such as correctional facilities or longterm care facilities (Bloch, 1995)
- “All U.S. health care personnel should have baseline TB screening, including an individual risk assessment
- After known exposure to a person with potentially infectious TB disease without use of adequate personal protection, health care personnel should have a timely symptom evaluation and additional testing, if indicated. Those without documented evidence of prior LTBI or TB disease should have an IGRA or a TST performed. Those with an initial negative test should be retested 8–10 weeks after the last exposure, preferably by using the same test type as was used for the prior negative test.
- In the absence of known exposure or evidence of ongoing TB transmission, U.S. health care personnel (as identified in the 2005 guidelines) without LTBI should not undergo routine serial TB screening or testing at any interval after baseline (e.g., annually). Health care facilities might consider using serial TB screening of certain groups who might be at increased occupational risk for TB exposure (e.g., pulmonologists or respiratory therapists)

- or in certain settings if transmission has occurred in the past (e.g., emergency departments)
- Health care personnel with a newly positive test result (with confirmation for those persons at low risk as described previously) should undergo a symptom evaluation and chest radiograph to assess for TB disease” (Sosa et al., 2019)
- Screening low-risk populations (including young children) is typically not recommended, as the false positive rate is high. This is usually due to the tuberculin reacting with a noninfectious species of bacteria (Bloch, 1995).

American Association of Clinical Endocrinologists (AACE) (AACE, 2015; Handelsman et al., 2015)

The AACE provides the following inclusion criteria for individuals who should be screened for prediabetes or type 2 diabetes:

- Age ≥ 45 years without other risk factors
- CVD or family history of T2D
- Overweight or obese
- Sedentary lifestyle
- Member of an at-risk racial or ethnic group:
 - Asian
 - African American
 - Hispanic
 - Native American (Alaska Natives and American Indians)
 - Pacific Islander
- High-density lipoprotein cholesterol (HDL-C) < 35 mg/dL (0.90 mmol/L) and/or a triglyceride level > 250 mg/dL (2.82 mmol/L)
- Impaired glucose tolerance (IGT), impaired fasting glucose (IFG), and/or metabolic syndrome
- Polycystic ovary syndrome (PCOS), acanthosis nigricans, or nonalcoholic fatty liver disease (NAFLD)
- Hypertension (blood pressure $> 140/90$ mm Hg or on antihypertensive therapy)
- History of gestational diabetes or delivery of a baby weighing more than 4 kg (9 lb)
- Antipsychotic therapy for schizophrenia and/or severe bipolar disease
- Chronic glucocorticoid exposure

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- Sleep disorders in the presence of glucose intolerance (A1C >5.7%, IGT, or IFG on previous testing), including obstructive sleep apnea (OSA), chronic sleep deprivation, and nightshift occupation (AACE, 2015; Handelsman et al., 2015)

The AACE recommends repeat testing at least every 3 years for individuals with normal results.

Consider annual screening for patients with 2 or more risk factors (AACE, 2015; Handelsman et al., 2015)

Women's Preventive Services Initiative (WPSI) Health Resources and Services Administration (WPSI, 2019)

2017 Health Resources and Services Administration (HRSA), Department of Health and Human Services (HHS). Women's Preventive Services Guidelines:

HRSA added two additional services to the nine existing preventive services including screening for diabetes mellitus after pregnancy recommendations on December 29, 2017. This recommendation includes screening for diabetes mellitus after pregnancy in women, as long as for 10 years postpartum depending on the results of initial postpartum screening. The list of research recommendations of the Women's Preventive Services Initiative (WPSI) in association with ACOG are as follows (WPSI, 2018):

- "1. Determine the optimal timing of diabetes mellitus testing after pregnancy
- 2. Establish when hemoglobin A1c becomes a reliable screening test after pregnancy
- 3. Develop methods for improving compliance with postpartum testing for both patients and providers
- 4. Measure the impact of weight changes, anemia correction, and lactation on screening test results
- 5. Identify tests or protocols that improve accuracy for detecting diabetes mellitus in the immediate postpartum period
- 6. Establish time frame for continuing screening women with initial negative screening test results
- 7. Identify appropriate counseling strategies for women with negative screening test results
- 8. Determine what predictors lead to the development of diabetes mellitus in women with initial negative screening test results
- 9. Develop GDM prevention strategies and programs"

The WPSI has published the following relevant recommendations with the support of the HRSA:

Regarding screening for cervical cancer, WPSI recommends "cervical cancer screening for average-risk women aged 21 to 65 years. For women aged 21 to 29 years, the Women's Preventive Services Initiative recommends cervical cancer screening using cervical cytology (Pap test) every 3 years. Cotesting with cytology and human papillomavirus testing is not recommended for women younger than 30 years. Women aged 30 to 65 years should be screened with cytology and human papillomavirus testing every 5 years or cytology alone every 3 years. Women who are at average risk should not be screened more than once every 3 years."

Regarding screening for gestational diabetes mellitus, WPSI recommends "screening pregnant women for gestational diabetes mellitus after 24 weeks of gestation (preferably between 24 and 28 weeks of gestation) in order to prevent adverse birth outcomes. Screening with a 50-g oral glucose challenge test (followed by a 3-hour 100-g oral glucose tolerance test if results on the initial oral glucose challenge test are abnormal) is preferred because of its high sensitivity and specificity", further "suggest[ing] that women with risk factors for diabetes mellitus be screened for preexisting diabetes before 24 weeks of gestation—ideally at the first prenatal visit, based on current clinical best practices".

WPSI also recommends testing all women for HIV at least once in their lifetime and recommends screening for HIV “for all pregnant women upon initiation of prenatal care with retesting during pregnancy based on risk factors. Rapid HIV testing is recommended for pregnant women who present in active labor with an undocumented HIV status”.

The WPSI “recommends women with a history of gestational diabetes mellitus (GDM) who are not currently pregnant and who have not previously been diagnosed with type 2 diabetes mellitus should be screened for diabetes mellitus. Initial testing should ideally occur within the first year postpartum and can be conducted as early as 4-6 weeks postpartum. Women with a negative initial postpartum screening test result should be rescreened at least every 3 years for a minimum of 10 years after pregnancy. For women with a positive postpartum screening test result, testing to confirm the diagnosis of diabetes is indicated regardless of the initial test (eg, oral glucose tolerance test, fasting plasma glucose, or hemoglobin A1c). Repeat testing is indicated in women who were screened with hemoglobin A1c in the first 6 months postpartum regardless of the result” (WPSI, 2019).

Preventive Services Under the Affordable Care Act (Seiler et al., 2014)

Preventive services codified at §2713 of the Public Health Service Act, referred to as “§2713 services,” are listed in the table below (taken from (Seiler et al., 2014)):

Demographic	Preventive services provided
Adults	<ul style="list-style-type: none"> • Abdominal aortic aneurysm one-time screening for men of specified ages who have ever smoked • Alcohol misuse screening and counseling • Aspirin use to prevent cardiovascular disease for men and women of certain ages • Blood pressure screening for all adults • Cholesterol screening for adults of certain ages or at higher risk • Colorectal cancer screening for adults >50 years of age • Depression screening for adults • Diabetes (Type 2) screening for adults with high blood pressure • Diet counseling for adults at higher risk for chronic disease • HIV screening for those aged 15–65 years and other ages at increased risk • Immunization vaccines for adults: doses, recommended ages, and recommended populations vary • Obesity screening and counseling for all adults • STI prevention counseling for adults at higher risk • Syphilis screening for all adults at higher risk • Tobacco use screening for all adults and cessation interventions for tobacco users
Women	<ul style="list-style-type: none"> • Anemia screening on a routine basis for pregnant women • Breast cancer genetic test counseling for women at higher risk for breast cancer • Breast cancer mammography screenings every 1–2 years for women >40 years of age • Breast cancer chemoprevention counseling for women at higher risk • Breastfeeding comprehensive support and counseling and access to breastfeeding supplies • Cervical cancer screening for sexually active women • Chlamydia infection screening for younger women and other women at higher risk • Contraception: Food and Drug Administration-approved contraceptive methods, sterilization, and counseling • Domestic and interpersonal violence screening and counseling for all women • Folic acid supplements for women who may become pregnant • Gestational diabetes screening for women who are 24–28 weeks pregnant and those at high risk • Gonorrhea screening for all women at higher risk • Hepatitis B screening for pregnant women at their first prenatal visit • HIV screening and counseling for sexually active women • Human papillomavirus DNA test every three years for women ≥30 years of age with normal cytology • Osteoporosis screening for women >60 years of age depending on risk factors • Rh incompatibility screening for all pregnant women and follow-up testing for women at higher risk • STI counseling for sexually active women • Syphilis screening for all pregnant women or other women at increased risk • Tobacco use screening and interventions for all women and expanded counseling for pregnant women • Urinary tract or other infection screening for pregnant women • Well-woman visits to get recommended services for women <65 years of age
Children	<ul style="list-style-type: none"> • Autism screening • Behavioral assessments • Blood pressure screening • Cervical dysplasia screening • Depression screening • Developmental screening • Dyslipidemia screening • Fluoride chemoprevention supplements • Gonorrhea preventive medication • Hearing screening • Height, weight, and body mass index measurements • Hematocrit or hemoglobin screening • Hemoglobinopathies or sickle cell screening • HIV screening • Hypothyroidism screening • Immunization vaccines • Iron supplements • Lead screening • Medical history • Obesity screening and counseling • Oral health risk assessment • Phenylketonuria screening • STI prevention counseling and screening • Tuberculin testing • Vision screening

VI. State and Federal Regulations, as applicable

The FDA approved the Epi proColon by Epigenomics AG on 04/12/2016.

“The Epi proColon test is a qualitative in vitro diagnostic test for the detection of methylated Septin 9 DNA in EDTA plasma derived from patient whole blood specimens. Methylation of the target DNA sequence in the promoter region of the SEPT9_v2 transcript has been associated with the occurrence of colorectal cancer (CRC). The test uses a real-time polymerase chain reaction (PCR) with a fluorescent hydrolysis probe for the methylation specific detection of the Septin 9 DNA target. The

Epi proColon test is indicated to screen adults of either sex, 50 years or older, defined as average risk for CRC, who have been offered and have a history of not completing CRC screening. Tests that are available and recommended in the USPSTF 2008 CRC screening guidelines should be offered and declined prior to offering the Epi proColon test. Patients with a positive Epi proColon test result should be referred for diagnostic colonoscopy. The Epi proColon test results should be used in combination with physician's assessment and individual risk factors in guiding patient management" (FDA, 2016). The FDA has also approved Cologuard™ by Exact Sciences Corporation on 08/11/2014.

"Cologuard is intended for the qualitative detection of colorectal neoplasia associated DNA markers and for the presence of occult hemoglobin in human stool. A positive result may indicate the presence of colorectal cancer (CRC) or advanced adenoma (AA) and should be followed by diagnostic colonoscopy. Cologuard is indicated to screen adults of either sex, 50 years or older, who are at typical average-risk for CRC. Cologuard is not a replacement for diagnostic colonoscopy or surveillance colonoscopy in high risk individuals (FDA, 2014)."

The FDA also lists contraindications for Cologuard, noting that certain populations were not clinically evaluated for Cologuard use. These populations include:

- "Patients with a history of colorectal cancer, adenomas, or other related cancers.
- Patients who have had a positive result from another colorectal cancer screening method within the last 6 months.
- Patients who have been diagnosed with a condition that is associated with high risk for colorectal cancer. These include but are not limited to:
 - Inflammatory Bowel Disease (IBD)
 - Chronic ulcerative colitis (CUC)
 - Crohn's disease
 - Familial adenomatous polyposis (FAP)
 - Family history of colorectal cancer
- Patients who have been diagnosed with a relevant familial (hereditary) cancer syndrome, such as Hereditary non-polyposis colorectal cancer syndrome (HNPCCC or Lynch Syndrome), PeutzJeghers Syndrome, MYH-Associated Polyposis (MAP), Gardner's syndrome, Turcot's (or Crail's) syndrome, Cowden's syndrome, Juvenile Polyposis, Cronkhite-Canada syndrome, Neurofibromatosis, or Familial Hyperplastic Polyposis." (FDA, 2014)

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). As an LDT, the U. S. Food and Drug Administration has not approved or cleared this test; however, FDA clearance or approval is not currently required for clinical use.

VII. Applicable CPT/HCPCS Procedure Codes

	Code Description
81327	SEPT9 (Septin9) (eg, colorectal cancer) promoter methylation analysis
81528	Oncology (colorectal) screening, quantitative real-time target and signal amplification of 10 DNA markers (KRAS mutations, promoter methylation of NDRG4 and BMP3) and fecal hemoglobin, utilizing stool, algorithm reported as a positive or negative result
82270	Blood, occult, by peroxidase activity (eg, guaiac), qualitative; feces, consecutive collected specimens with single determination, for colorectal neoplasm screening (ie, patient was provided 3 cards or single triple card for consecutive collection)
82274	Blood, occult, by fecal hemoglobin determination by immunoassay, qualitative, feces, 1-3 simultaneous determinations
82947	Glucose; quantitative, blood (except reagent strip)
82950	Glucose; post glucose dose (includes glucose)
82951	Glucose; tolerance test (GTT), 3 specimens (includes glucose)

82952	Glucose; tolerance test, each additional beyond 3 specimens (List separately in addition to code for primary procedure)
83540	Iron

84443	Thyroid stimulating hormone (TSH)
86689	Antibody; HTLV or HIV antibody, confirmatory test (eg, Western Blot)
86701	Antibody; HIV -1
86702	Antibody; HIV -2
86703	Antibody; HIV -1 and HIV -2, single result
86704	Hepatitis B core antibody (hbcAb); total
86705	Hepatitis B core antibody (HBcab); igm antibody
86706	Hepatitis B surface antibody (HBsAb)
86707	Hepatitis Be antibody (HbeAb)

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
87389	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; HIV-1 antigen(s), with HIV-1 and HIV-2 antibodies, single result
87390	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; HIV-1

87391	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; HIV-2
87806	Infectious agent antigen detection by immunoassay with direct optical observation; HIV-1 antigen(s), with HIV-1 and HIV-2 antibodies
G0328	Colorectal cancer screening; fecal occult blood test, immunoassay, 1-3 simultaneous
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 HIV2, screening
G0499	Hepatitis B screening in nonpregnant, high risk individual includes hepatitis B surface antigen (HBSAG) followed by a neutralizing

	confirmatory test for initially reactive results, and antibodies to HBSAG (anti-HBS) and hepatitis B core antigen (anti-HBC)
G0475	HIV antigen/antibody, combination assay, screening
S3645	HIV -1 antibody testing of oral mucosal transudate

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IX. Revision History

Revision Date	Summary of Changes
06/01/2021	Initial presentation