of Tennessee

Policy

Reimbursement Policy

Cervical Cancer Screening

I. Policy Description

Cervical cancer screening detects cervical precancerous lesions and cancer through cytology, human papillomavirus (HPV) testing, and if needed, colposcopy (Feldman et al., 2024). The principal screening test to detect cancer in asymptomatic individuals with a cervix is the Papanicolaou (Pap) smear. It involves cells being scraped from the cervix during a pelvic examination and spread onto a slide. The slide is then sent to an accredited laboratory to be stained, observed, and interpreted (Feldman & Crum, 2023).

Human papilloma virus (HPV) has been associated with development of cervical intraepithelial neoplasia, and FDA approved HPV tests detecting the presence of viral DNA from high risk strains have been developed and validated as an adjunct primary cancer screening method (Feldman & Crum, 2023).

For additional information on testing for HPV, please refer to AHS-G2157-Diagnostic Testing of Common Sexually Transmitted Infections.

Terms such as male and female are used when necessary to refer to sex assigned at birth.

II. 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.**

The criteria below are based on recommendations by the U.S. Preventive Services Task Force, The National Cancer Institute, NCCN, The American Society for Colposcopy and Cervical Pathology, The American Cancer Society, The American Society for Clinical Pathology, and the American College of Obstetricians and Gynecologists. Within these coverage criteria, "individual(s)" is specific to individuals with a cervix.

1) For immunocompromised or immunosuppressed individuals, **any one** of the following cervical cancer screening techniques **MEETS COVERAGE CRITERIA**:
   a) Annual cervical cytology testing for individuals of all ages.

b) Co-testing (cervical cytology and high-risk HPV testing) once every 3 years for individuals 30 years of age or older.

2) For individuals 21 to 29 years of age, cervical cancer screening once every 3 years using conventional or liquid-based Papanicolaou (Pap) smears **MEETS COVERAGE CRITERIA**.
3) For individuals 30 to 65 years of age, **any one** of the following cervical cancer screening techniques **MEETS COVERAGE CRITERIA**:
   a) Conventional or liquid-based Pap smear once every 3 years.
   b) Cervical cancer screening using the high-risk HPV test alone once every 5 years.
   c) Co-testing (cytology with concurrent high-risk HPV testing) once every 5 years.
4) For individuals who are over 65 years of age **and** who are considered high-risk (individuals with a high-grade precancerous lesion or cervical cancer, individuals with in utero exposure to diethylstilbestrol (DES)), cervical cancer screening at the frequency described in coverage criterion 3 **MEETS COVERAGE CRITERIA**.
5) For individuals who are HPV positive **and** cytology negative, nucleic acid testing for high-risk strains HPV-16 and HPV-18 **MEETS COVERAGE CRITERIA**.
6) For individuals 65 years of age or younger, annual cervical cancer screening by Pap smear or HPV testing **MEETS COVERAGE CRITERIA** in **any** of the following situations:
   a) For individuals who had a previous cervical cancer screen with an abnormal cytology result and/or who was positive for HPV.
   b) For individuals at high risk for cervical cancer (organ transplant, exposure to the drug DES).
7) For all situations not addressed above, cervical cancer screening (cervical cytology, HPV testing) for individuals less than 21 years of age 0**DOES NOT MEET COVERAGE CRITERIA**.
8) For individuals over 65 years of age who are not considered high-risk **and** who have an adequate screening history, routine cervical cancer screening **DOES NOT MEET COVERAGE CRITERIA**. Adequate screening history is defined as either:
   a) Having three consecutive negative Pap smears.
   b) Having two consecutive negative HPV tests within 10 years before cessation of screening, with the most recent test occurring within 5 years.
9) For individuals who have undergone surgical removal of the uterus and cervix and who have no history of cervical cancer or pre-cancer, cervical cancer screening (at any age) **DOES NOT MEET COVERAGE CRITERIA**.

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.

10) The following **DO NOT MEET COVERAGE CRITERIA**:
   a) Inclusion of low-risk strains of HPV in co-testing.
   b) Other technologies for cervical cancer screening.

III. 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, visit the applicable state Medicaid website.

Food and Drug Administration (FDA)

The FDA has approved the APTIMA HPV 16 18/45 Genotype Assay, a nucleic acid amplification test (NAAT), for the qualitative detection of mRNA for HPV 16, 18, and 45 from Gen-Probe Incorporated on October 12, 2012; however, this test cannot distinguish between 18 and 45. Previously, on October 28, 2011, the FDA approved Gen-Probe Incorporated's APTIMA HPV Assay, an NAAT that tests for 14 high-risk types of HPV but is unable to distinguish between the 14 types.

Hologic, Inc. has two FDA-approved HPV NAAT tests—Cervista HPV 16/18 and Cervista HPV HR and GENFIND DNA Extraction Kit. Both were approved on March 12, 2009. The former is a fluorescent, isothermal-based reaction that detects HPV 16 and 18 whereas the latter screens for DNA from the 14 high-risk HPV strains (FDA, 2023a).

The COBAS HPV test by Roche Molecular Systems, Inc. was approved by the FDA on April 19, 2011, as a NAAT for 14 high-risk types of HPV. This test can specifically identify HPV 16 and 18 but cannot distinguish from the other 12 types of HPV. On July 2, 2018, the FDA released an approval order statement (P100020/S025) "for an expansion of the intended use for the FDA-approved cobas HPV Test to include cervical specimens collected in SurePath Preservative Fluid as a specimen type" (FDA, 2023c). This approval allows for the cobas HPV Test to be used as a first-line cervical cancer screening using the SurePath preservative, a medium often used for Pap tests (Rice, 2018). In 2020, the Cobas HPV was FDA approved for use on Cobas 6800/8800 Systems (FDA, 2023b).

On February 12, 2018, the FDA approved the BD Onclarity™ HPV Assay which detects 14 high-risk HPV genotypes including high-risk strains 16 and 18. "The BD Onclarity HPV Assay is a qualitative in vitro test for the detection of Human Papillomavirus in cervical specimens collected by a clinician using an endocervical brush/spatula combination or broom and placed in BD SurePath vial" (FDA, 2018).

For more information regarding HPV, please refer to AHS-G2157 Diagnostic testing of STIs.

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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.

IV. Applicable CPT/HCPCS Procedure Codes

CPT	Code Description
87623	Infectious agent detection by nucleic acid (DNA or RNA); Human Papillomavirus (HPV), low-risk types (eg, 6, 11, 42, 43, 44)
87624	Infectious agent detection by nucleic acid (DNA or RNA); Human Papillomavirus (HPV), high-risk types (eg, 16, 18, 31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 68)
87625	Infectious agent detection by nucleic acid (DNA or RNA); Human Papillomavirus (HPV), types 16 and 18 only, includes type 45, if performed
88141	Cytopathology, cervical or vaginal (any reporting system), requiring interpretation by physician
88142	Cytopathology, cervical or vaginal (any reporting system), collected in preservative fluid, automated thin layer preparation; manual screening under physician supervision
88143	Cytopathology, cervical or vaginal (any reporting system), collected in preservative fluid, automated thin layer preparation; with manual screening and rescreening under physician supervision
88147	Cytopathology smears, cervical or vaginal; screening by automated system under physician supervision
88148	Cytopathology smears, cervical or vaginal; screening by automated system with manual rescreening under physician supervision
88150	Cytopathology, slides, cervical or vaginal; manual screening under physician supervision
88152	Cytopathology, slides, cervical or vaginal; with manual screening and computer-assisted rescreening under physician supervision
88153	Cytopathology, slides, cervical or vaginal; with manual screening and rescreening under physician supervision
88164	Cytopathology, slides, cervical or vaginal (the bethesda system); manual screening under physician supervision
88165	Cytopathology, slides, cervical or vaginal (the bethesda system); with manual screening and rescreening under physician supervision
88166	Cytopathology, slides, cervical or vaginal (the bethesda system); with manual screening and computer-assisted rescreening under physician supervision

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CPT	Code Description
88167	Cytopathology, slides, cervical or vaginal (the bethesda system); with manual screening and computer-assisted rescreening using cell selection and review under physician supervision
88174	Cytopathology, cervical or vaginal (any reporting system), collected in preservative fluid, automated thin layer preparation; screening by automated system, under physician supervision
88175	Cytopathology, cervical or vaginal (any reporting system), collected in preservative fluid, automated thin layer preparation; with screening by automated system and manual rescreening or review, under physician supervision
0500T	Infectious agent detection by nucleic acid (DNA or RNA), Human Papillomavirus (HPV) for five or more separately reported high-risk HPV types (eg, 16, 18, 31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 68) (ie, genotyping)
G0123	Screening cytopathology, cervical or vaginal (any reporting system), collected in preservative fluid, automated thin layer preparation, screening by cytotechnologist under physician supervision
G0124	Screening cytopathology, cervical or vaginal (any reporting system), collected in preservative fluid, automated thin layer preparation, requiring interpretation by physician
G0141	Screening cytopathology smears, cervical or vaginal, performed by automated system, with manual rescreening, requiring interpretation by physician
G0143	Screening cytopathology, cervical or vaginal (any reporting system), collected in preservative fluid, automated thin layer preparation, with manual screening and rescreening by cytotechnologist under physician supervision
G0144	Screening cytopathology, cervical or vaginal (any reporting system), collected in preservative fluid, automated thin layer preparation, with screening by automated system, under physician supervision
G0145	Screening cytopathology, cervical or vaginal (any reporting system), collected in preservative fluid, automated thin layer preparation, with screening by automated system and manual rescreening under physician supervision
G0147	Screening cytopathology smears, cervical or vaginal, performed by automated system under physician supervision
G0148	Screening cytopathology smears, cervical or vaginal, performed by automated system with manual rescreening
G0476	Infectious agent detection by nucleic acid (DNA or RNA); human papillomavirus (HPV), high-risk types (eg, 16, 18, 31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 68) for cervical cancer screening, must be performed in addition to pap test
P3000	Screening Papanicolaou smear, cervical or vaginal, up to three smears, by technician under physician supervision

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CPT	Code Description
P3001	Screening Papanicolaou smear, cervical or vaginal, up to three smears, requiring interpretation by physician
Q0091	Screening Papanicolaou smear; obtaining, preparing and conveyance of cervical or vaginal smear to laboratory

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

V. Evidence-based Scientific References

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