

# MEDICAL POLICY



<b>SUBJECT: CERVICAL CANCER SCREENING and HUMAN PAPILLOMA VIRUS (HPV) TESTING</b>	<b>EFFECTIVE DATE: 11/19/99</b> <b>REVISED DATE: 04/19/01, 07/19/01, 10/25/01, 01/23/03, 02/26/04, 02/24/05, 04/27/06, 04/26/07, 04/24/08, 11/20/08, 05/28/09, 05/27/10, 05/19/11, 05/24/12, 05/23/13, 05/22/14, 05/28/15, 05/25/16, 05/18/17, 03/15/18</b>
<b>POLICY NUMBER: 2.02.04</b> <b>CATEGORY: Technology Assessment</b>	<b>PAGE: 1 OF: 12</b>
<ul style="list-style-type: none"><li>• <i>If a product excludes coverage for a service, it is not covered, and medical policy criteria do not apply.</i></li><li>• <i>If a commercial product (including an Essential Plan product) or a Medicaid product covers a specific service, medical policy criteria apply to the benefit.</i></li><li>• <i>If a Medicare product covers a specific service, and there is no national or local Medicare coverage decision for the service, medical policy criteria apply to the benefit.</i></li></ul>	

## POLICY STATEMENT:

- I. The Health Plan considers routine cervical cancer screening **and HPV testing** with FDA approved techniques (e.g., conventional Pap smear, liquid based cytology, cobas® HPV test) as **medically appropriate**.
- II. Based upon our criteria and review of the peer-reviewed literature, cervical cancer screening with the combined (cotesting) use of cervical cytology testing and an FDA approved test for high-risk subtypes of human papillomavirus (HPV) is considered **medically appropriate** in women 30 years of age and older.
  - A. Retesting with the combined cervical cytology and HPV tests need occur no more frequently than every five years when a women tests negative on both the cervical cytology and HPV test.
  - B. If only one test is negative, screening will be necessary with cervical cytology more frequently than every five years.
- III. Based on our criteria and assessment of the peer-reviewed literature, including the United States Preventative Services Task Force (USPSTF) cervical cancer screening should start at age 21 years. A PAP test no more frequently than every 3 years is considered **medically appropriate** in women who are average risk for cervical cancer.
- IV. Based on our criteria and assessment of the peer-reviewed literature, including the United States Preventative Services Task Force (USPSTF) cervical cancer screening in women younger than 21 years is **not medically necessary**.
- V. Based on our criteria and assessment of the peer-reviewed literature, including the United States Preventative Services Task Force (USPSTF) cervical cancer screening in women older than 65 years who have had adequate prior screening and are not otherwise at high risk for cervical cancer is **not medically necessary**.
- VI. Based on our criteria and assessment of the peer-reviewed literature, including the United States Preventative Services Task Force (USPSTF) cervical cancer screening in women who have had a hysterectomy with removal of the cervix and do not have a history of a high-grade precancerous lesion (ie, cervical intraepithelial neoplasia [CIN] grade 2 or 3) or cervical cancer is **not medically necessary**.
- VII. Based upon our criteria and review of the peer-reviewed literature, human papillomavirus (HPV) testing of high-risk sub-types has been medically proven to be effective and therefore, **medically appropriate** for use in the triage of patients with *atypical squamous cells of undetermined significance (ASCUS)* on cervical screening.
- VIII. Based upon our criteria and review of the peer-reviewed literature, HPV screening is **not medically appropriate** for women under age 30 years since these women frequently test positive for HPV and have an effective immune response that will clear the infection or reduce the viral load to undetectable levels within two years of the initial infection.
- IX. Based upon our criteria and review of the peer-reviewed literature, HPV testing has not been proven to be effective and is therefore, **not medically necessary** in the routine triage of women with *low-grade squamous intraepithelial lesions (LSIL)* found through screening examinations (e.g., cervical cytology).
- X. Based upon our criteria and review of the peer-reviewed literature, Papsure® as an adjunct to cervical cancer screening has not been medically proven to be more effective in improving net health outcomes than standard testing and is, therefore, considered **not medically necessary**.

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**POLICY GUIDELINES:**

- I. While our review of scientific evidence concludes that use of liquid based monolayer technology at least every three years is sufficient given the sensitivity, specificity, and cost-effectiveness of this technology; coverage will be provided at a frequency determined by the practitioner and member following informed discussions and shared decision-making
- II. Since the utilization of the automated slide reading systems (e.g., FocalPoint™, ThinPrep® Imaging system , MonoPrep LBP processor) have not been proven to have a significantly greater sensitivity than the manual reading of specimens, the benefit for the use of these systems will generally be provided at the same level as that for manual reading of the specimen

**DESCRIPTION:**

The Papanicolaou (Pap) smear was introduced in the 1940's as a method of preventing invasive cervical cancer and has been credited with reducing the incidence of cervical carcinoma by 74% since its introduction. Certain cancers caused by infectious agents, such as human papillomavirus (HPV) could be prevented through treatment of the infection. Screening can help prevent cervical cancers by offering the opportunity to detect cancer early, when treatment is less extensive and more likely to be successful. HPV vaccines cannot protect against established infections, nor do they protect against all types of HPV, which is why vaccinated women should still be screened for cervical cancer.

Despite the dramatic impact of pap screening, concerns regarding Pap performance remain. Approximately 30 percent of cervical cancers result from errors in sampling and interpretation. The effort to reduce the number of undiagnosed cancers because of these errors has acted as a catalyst in the development of new screening technologies. FDA-approved developments in Pap screening technology have been aimed at reducing the rate of false-negative results. Some of the developments are liquid based monolayer slide preparation devices, such as ThinPrep (Cytoc Corporation), SurePath (TriPath Imaging), MonoPrep Pap Test (MonoGen, Inc.), and Liqui-PREP (LGM International).

Liquid based monolayer slide preparations are screening systems that utilize a different type of cell preparation than that used for conventional Pap smear slides. This technology involves dispersing the collected cervical cell sample in a liquid medium, then collecting the cells in a filter and depositing them in a thin layer on the slide. The liquid-based technique contrasts with the conventional method of preparation (that consists of directly swabbing the collected cells onto a glass slide) by removing much of the debris and red blood cells for a clearer slide and reduces artifacts in cellular morphology, thereby decreasing the rate of false negative smears and improving sensitivity.

The specimen obtained for the monolayer Pap test can be utilized to perform reflex testing (from the same liquid base) to test for other conditions, such as Human Papillomavirus (HPV), during the initial office examination of a patient undergoing a cervical examination and eliminates the need for an additional office examination to collect a specimen for HPV testing.

HPV is a common sexually transmitted disease that has an established causal link in the development of cervical cancer. The relationship between certain types of HPV and the development of cervical cancer is well established. There are more than 150 types of HPV, approximately 30 of which are prevalent in the cervix. Of these, some types (6, 11, 30, 34, 42, 43, 44, 49, 53, 54, 61, 64, and 69) make up the low- or no-oncogenic risk group because they are very unlikely to be associated with cervical cancer. Other types, referred to as high risk HPV sub-types, make up the intermediate and high-risk group (16, 18, 31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 66, 68, and 73) because they are associated with low-grade squamous intraepithelial lesions, high-grade intraepithelial lesions, and invasive cancers. Of the high-risk types, HPV 16 and 18 are the most carcinogenic and the most prevalent.

High-risk HPV subtypes have been identified in more than 90% of cervical cancers. All HPV types may regress without treatment (except cancer), but it is not possible to predict which will regress and when.

Three automated slide reading systems have been approved by the FDA:

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- I. The ThinPrep Imaging System®, by Cytoc, is designed to be used with ThinPrep® monolayer slide preparations. The system, according to FDA labeling, is indicated for assisting in primary cervical cancer screening of ThinPrep® Pap test slides for the presence of cervical neoplasia, including its precursor lesions. The ThinPrep® Imaging System highlights areas for focused screening by cytotechnologists.
- II. FocalPoint™ (formerly called AutoPap), by TriPath Imaging, is approved by the FDA for primary screening and rescreening of Pap smears. The system reads each slide and identifies slides without abnormalities that do not require manual reading, slides that should be manually read, and slides that should have a second manual reading. The system is not intended to be used on slides from patients designated as high risk.
- III. The MonoPrep Pap Test (MPPT), by MonoGen, Inc., is used in conjunction with the MonoPrep LBP processor, to collect and prepare cervical-vaginal cytology specimens to screen for cervical cancer, its precursor lesions, and other cytological categories and conditions.

Papsure® is a method of cervical cancer screening in which a conventional Pap smear is combined with speculoscopy, an endoscopic visualization of the cervix. Papsure® is utilized as an adjunct to the Pap smear and as a technique in selecting women with atypical Pap smears for further evaluation for colposcopy. It is thought that Papsure® will increase the sensitivity of cervical cancer screening by enhancing the visual inspection of the cervix. Following a cervical examination the cervix is washed with acetic acid (vinegar). A chemiluminescent disposable light, known as a Speculite®, is attached to the speculum. The cervix is visualized using a magnification loupe. Abnormal epithelial cells, those with increased keratinization and nuclear cytoplasmic ratios, show an increased reflection of light and appear white; while normal epithelial cells appear blue or purple. The white lesions may then be sampled for cytologic examination. Women with an abnormal Pap smear, even in the presence of a negative speculoscopy examination, should be referred for additional evaluation.

According to New York State Law, every policy that provides hospital, surgical or medical care coverage or provides reimbursement for laboratory tests or diagnostic x-rays shall provide annual cervical cytology screening for cervical cancer and its precursor states for women aged 18 and older. Cervical cytology screening includes an annual pelvic examination, collection and preparation of a Pap smear, and laboratory and diagnostic services provided in connection with examining and evaluating the Pap smear. In addition, policies shall provide coverage for evidence-based items or services for cervical cytology that have in effect a rating of ‘A’ or ‘B’ in the current recommendations of the United States preventive services task force (USPSTF).

The Patient Protection and Affordable Care Act (PPACA) also requires coverage of cervical cancer screening in accordance with the recommendations of the U.S. Preventive Services Task Force (USPSTF). As of August 1, 2012, for all non-grandfathered policies, PPACA was expanded to include coverage for certain preventive services for women; including screening for cervical cancer in women age 21 to 65 with cytology (Pap smear) every 3 years or, for women age 30 to 65 years who want to lengthen the screening interval, screening with a combination of cytology and HPV testing every 5 years.

Cervical cancer screening is an important part of preventive health care and is supported by the Health Plan. Refer to our Preventive Health Guidelines for specific recommendations. Guidelines are located on our website at:

<https://www.excellusbcs.com/wps/portal/xl/prv/pc/cpg>.

**RATIONALE:**

Several studies have been published that compare the efficacy of HPV based screening with cytology screening. Some study results favor HPV based screening although limitations need to be addressed and several questions remain that need to be answered (e.g., age to begin HPV based screening, length of screening intervals) before consideration can be given to recommending changes in screening protocols. No specialty societies have published statements recommending primary HPV based screening over cytology screening.

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### Cervical Cytology Screening

The March 2012 (current Feb 2018) recommendations of the U.S. Preventive Services Task Force (USPSTF) address cervical cancer screening in women who have a cervix, regardless of sexual history. The recommendations do not apply to women who have received a diagnosis of a high-grade precancerous cervical lesion or cervical cancer, women with in utero exposure to diethylstilbestrol, or women who are immunocompromised (such as those who are HIV positive). The USPSTF recommends:

- I. Screening for cervical cancer in women age 21 to 65 years with cytology (Pap smear) every 3 years or, for women age 30 to 65 years who want to lengthen the screening interval, screening with a combination of cytology and human papillomavirus (HPV) testing every 5 years. (A rating recommendation)
- II. Against screening for cervical cancer in women younger than age 21 years.
- III. Against screening for cervical cancer in women older than age 65 years who have had adequate prior screening and are not otherwise at high risk for cervical cancer.
- IV. Against screening for cervical cancer in women who have had a hysterectomy with removal of the cervix and who do not have a history of a high-grade precancerous lesion (CIN grade 2 or 3) or cervical cancer.
- V. Against screening for cervical cancer with HPV testing, alone or in combination with cytology, in women younger than age 30 years.

The January 2016 practice bulletin of the American College of Obstetricians and Gynecologists (ACOG) addressing cervical cancer screening and prevention states:

- I. The following recommendations are based on good and consistent scientific evidence (Level A):
  - A. Cervical cancer screening should begin at age 21 years. With the exception of women who are infected with HIV, women younger than age 21 years should not be screened regardless of the age of sexual initiation or the presence of other behavior-related risk factors.
  - B. Women aged 21–29 years should be tested with cervical cytology alone, and screening should be performed every 3 years. Co-testing should not be performed in women younger than 30 years. Annual screening should not be performed.
  - C. For women aged 30–65 years, co-testing with cytology and HPV testing every 5 years is preferred.
  - D. In women aged 30–65 years, screening with cytology alone every 3 years is acceptable. Annual screening should not be performed.
  - E. Liquid-based and conventional methods of cervical cytology collection are acceptable for screening.
  - F. Screening by any modality should be discontinued after age 65 years in women with evidence of adequate negative prior screening results and no history of CIN 2 or higher. Adequate negative prior screening results are defined as three consecutive negative cytology results or two consecutive negative co-test results within the previous 10 years, with the most recent test performed within the past 5 years.
  - G. In women who have had a hysterectomy with removal of the cervix (total hysterectomy) and have never had CIN 2 or higher, routine cytology screening and HPV testing should be discontinued and not restarted for any reason.
  - H. Women with any of the following risk factors may require more frequent cervical cancer screening than recommended in the routine screening guidelines, which were intended for average-risk women: women who are infected with HIV, women who are immunocompromised, women who were exposed to diethylstilbestrol in utero, women previously treated forcing 2, CIN 3, or cancer.
- II. The following recommendations are based on limited and inconsistent scientific evidence (Level B):
  - A. Women with a history of CIN 2, CIN 3, or adenocarcinoma in situ should continue screening for a total of 20 years after spontaneous regression or appropriate management of CIN 2, CIN 3, or adenocarcinoma in situ, even if it requires that screening continue past age 65 years.
  - B. Women should continue to be screened if they have had a total hysterectomy and have a history of CIN 2 or higher in the past 20 years or cervical cancer ~~ever~~ at any point. Screening with cytology alone every 3 years for 20 years after the initial post-treatment surveillance period seems to be reasonable for these women.
  - C. In women 25 years and older, the FDA-approved primary HPV screening test can be considered as an alternative to current cytology-based cervical cancer screening methods. Cytology alone and cotesting remain the options specifically recommended in current major society guidelines. If screening with primary HPV testing is used, it should be performed as per the ASCCP and SGO interim guidance.

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- D. Women with ASC-US cytology and negative HPV test results, whether from reflex HPV testing or co-testing, have a low risk of CIN 3, but it is slightly higher than the risk in women with a negative cotest result, and it is recommended that they have contesting in 3 years.
- E. Cytology-negative, HPV-positive co-test results in women who are 30 years and older should be managed in one of two ways:
  1. Repeat co-testing in 12 months. If the repeat cervical cytology test result is ASC-US or higher or the HPV test result is still positive, the patient should be referred for colposcopy. Otherwise, the patient should have co-testing in 3 years.
  2. Immediate HPV genotype-specific testing for HPV-16 or HPV 18 can be performed. Women with positive test results for either HPV genotype should be referred directly for colposcopy. Women with negative results for both HPV genotypes should be contested in 12 months, with management of results as described in the 2012 ASCCP revised guidelines for the management of abnormal cervical cancer screening test results.
- III. The following recommendations are based primarily on consensus and expert opinion (Level C): Women who have received the HPV vaccine should be screened according to the same guidelines as women who have not been vaccinated

A guideline addressing cervical cancer screening that was published by the American Cancer Society (ACS), the American Society for Colposcopy and Cervical Pathology (ASCCP), and the American Society for Clinical Pathology (ASCP) in 2012 is similar to the ACOG recommendations. The National Comprehensive Cancer Network (NCCN) Guidelines Panel for Cervical Cancer Screening endorses this guideline and discontinued their guideline in July 2013 in order to avoid duplication of effort (2014).

In March 2013, the National Guideline Clearinghouse published a guideline synthesis of the recommendations published by ACOG, the ACS/ASCCP/ASCP, and the USPSTF addressing cervical cancer screening for women at average risk and found no significant areas of difference between the recommendations. In January 2016, the synthesis was revised to remove the ACOG recommendations.

Published studies comparing the FocalPoint™ and ThinPrep® Imaging automated slide reading systems to traditional manual reading and rescreening identified the: 1) FocalPoint™ system to be between 4 to 7% more sensitive in determining a positive slide, depending on the cutoff, than traditional manual reading and approximately 1% more specific in identifying normal slides; and 2) the ThinPrep® Imaging system to be equivalent to manual review by a cytotechnologist.

#### Human Papillomavirus (HPV) Testing

Data from the Atypical Squamous Cells of Undetermined Significance/Low-Grade Squamous Intraepithelial Lesions Triage Study (ALTS) trial showed the triage of ASCUS smears using HPV testing for triage to immediate colposcopy was more sensitive and equally specific in identifying cervical intraepithelial neoplasia grade 3 (CIN 3) as repeat Pap smear using ASCUS as the threshold for colposcopy referral. Based primarily on the results of this trial, recent guidelines issued by the American Society for Colposcopy and Cervical Pathology recommend either repeat Pap smear, immediate colposcopy, or HPV testing for women who have ASCUS Pap smears.

In March 2003, the U.S. Food and Drug Administration (FDA) approved the Digene Hybrid Capture 2 (HC2) High-Risk HPV DNA test for screening women over 30 years of age for HPV infection when used along with a Pap test; in addition to the original approval for testing women with an abnormal Pap test to determine need for further evaluation. The approval was based upon several large clinical studies demonstrating HPV infection as a strong etiologic factor for cervical abnormalities, but often transient and nonspecific. The HC2 test can identify 13 strains of high-risk HPV DNA but cannot determine the specific HPV strain(s) in the specimen and reports only the presence or absence of high-risk HPV DNA.

On March 12, 2009, the FDA approved two DNA tests that identify HPV types:

- I. The Cervista™ HPV HR test, detects 14 high-risk HPV types in cervical cell samples; including the 13 types detected by the HC2 test plus one other (HPV 66).

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II. The Cervista™ HPV 16/18, detects the DNA sequences specific for HPV type 16 and HPV type 18 in cervical cells. In women age 30 and older or women with borderline cytology (e.g., ASCUS) the Cervista™ HPV 16/18 test can be used together with cytology and the Cervista™ HPV HR test to assess risk of cervical disease.

Both tests utilize an isothermal enzymatic DNA amplification process with a fluorescent read out and both are approved for use with ThinPrep® samples. The Cervista™ HPV tests (formerly known as Invader HPV) were developed by Third Wave Technologies which was acquired in 2008 by Hologic Inc., the manufacturer of the ThinPrep® Pap test.

The absence of HPV infection in conjunction with a normal Pap smear has a high negative predictive value and identifies a group of women at low risk for cervical abnormalities. HPV screening is not recommended for women under 30 years of age as HPV infections are most likely to be transient in this group.

Published clinical trials have provided evidence that HPV testing for high-risk sub-groups has utility in triaging patients with ASCUS results to avoid unnecessary invasive work-up but does not support the use of HPV testing in women with LSIL due to the high prevalence of HPV infection in women with this diagnosis.

The 2015 guidelines of the American Cancer Society for the early detection of cancer state:

- I. Cervical cancer screening should start at age 21,
- II. Women between the ages of 21 and 29 should have a Pap test every 3 years and HPV testing should not be used in this age group unless it's needed after and abnormal test result,
- III. Women between the ages of 30 and 65 should have a Pap test plus an HPV test every 5 years, however a Pap test may be performed alone every 3 years,
- IV. Women over age 65 who have had regular cervical cancer testing in the past 10 years with normal results should not be tested for cervical cancer. Once testing is stopped, it should not be started again. Women with a history of a serious cervical pre-cancer should continue to be tested for at least 20 years after that diagnosis, even if testing goes past age 65.
- V. A woman who has had her uterus and cervix removed (a total hysterectomy) for reasons not related to cervical cancer and who has no history of cervical cancer or serious pre-cancer should not be tested.
- VI. All women who have been vaccinated against HPV should still follow the screening recommendations for their age groups.

On April 24, 2014 the FDA approved the first HPV DNA test for women age 25 years and older that can be used alone to help a health care professional assess the need for a woman to undergo additional diagnostic testing for cervical cancer. Using a sample of cervical cells, the cobas® HPV Test detects DNA from 14 high-risk HPV types. The test specifically identifies HPV 16 and HPV 18, while concurrently detecting 12 other types of high-risk HPVs (31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 66 and 68). Based on results of the cobas® HPV test, women who test positive for HPV 16 or HPV 18 should have a colposcopy and women testing positive for one or more of the 12 other high-risk HPV types should have a Pap test to determine the need for a colposcopy. The FDA states health care professionals should use the cobas® HPV Test results together with other information, such as the patient screening history and risk factors, and current professional guidelines. The approval of the cobas® HPV DNA test did not change the recommendations of any current practice guidelines for cervical cancer screening.

According to the Centers for Disease Control and Prevention there are currently no guidelines for HPV testing in men nor is there a HPV test for men that has been approved by the FDA.

Speculoscopy (e.g., PapSure®) The Speculite® device was approved by the U.S. Food and Drug Administration (FDA) in December 2000 for vaginal illumination during the PapSure® procedure when used as an adjunct to conventional Pap smears. It is not intended to be used to grade lesions identified during the procedure.

Published, peer-reviewed literature has not demonstrated improvements in the net health outcome with the utilization of Papsure®. Society guidelines/statements issued by the US Preventive Services Taskforce, the American Cancer Society, and the American College of Obstetricians and Gynecologists, that focus upon techniques for cervical cancer screening, do not address Papsure® or speculoscopy.

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Other techniques

Other methods of cervical cancer screening and/or HPV testing currently under investigation include testing of self-collected specimens, urine testing, and an ELISA based test of the biomarker p16(INK4A) for protein expression.

**CODES:**    Number            Description

*Eligibility for reimbursement is based upon the benefits set forth in the member's subscriber contract.*

**CODES MAY NOT BE COVERED UNDER ALL CIRCUMSTANCES. PLEASE READ THE POLICY AND GUIDELINES STATEMENTS CAREFULLY.**

Codes may not be all inclusive as the AMA and CMS code updates may occur more frequently than policy updates.

<b><u>CPT:</u></b>	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	with manual screening and rescreening under physician supervision
	88147	Cytopathology smears, cervical or vaginal; screening by automated system under physician supervision
	88148	screening by automated system with manual rescreening under physician supervision
	88150	Cytopathology, slides, cervical or vaginal; manual screening under physician supervision
	88152	with manual screening and computer-assisted rescreening under physician supervision
	88153	with manual screening and rescreening under physician supervision
	88154	with manual screening and computer-assisted rescreening using cell selection and review under physician supervision
	88164	Cytopathology, slides, cervical or vaginal (the Bethesda system); manual screening under physician supervision;
	88165	with manual screening and rescreening under physician supervision
	88166	with manual screening and computer-assisted rescreening under physician supervision
	88167	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

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supervision

88175 with screening by automated system and manual rescreening or review, under physician supervision

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<b><u>HCPCS:</u></b>	G0101	Cervical or vaginal cancer screening; pelvic and clinical breast examination
	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, 58, 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
	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
<b><u>ICD10:</u></b>	B97.7	Papillomavirus as the cause of diseases classified elsewhere
	C53.0-C53.9	Malignant neoplasm of cervix uteri (code range)
	C79.82	Secondary malignant neoplasm of genital organs
	D06.0-D06.9	Carcinoma in situ of cervix (code range)

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D39.0	Neoplasm of uncertain behavior of uterus
D49.5	Neoplasm of unspecified behavior of other genitourinary organs
N87.0-N87.9	Dysplasia of cervix uteri (code range)
R87.610- R87.619	Abnormal cytological findings in specimens from cervix uteri (code range)
R87.620- R87.628	Abnormal cytological findings on specimens from vagina (code range)
R87.810- R87.811	High risk human papillomavirus [HPV] DNA test positive from female genital organs (code range)
R87.820- R87.821	High risk human papillomavirus [HPV] DNA test positive from female genital organs (code range)

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\* key article

**KEY WORDS:**

Cervista™, cobas® HPV test, DNA with PAP, HPV, HPV DNA testing, Human Papillomavirus, HC 2, Hybrid Capture 2, Liqui-PREP®, Pap/ Papanicolaou smear: Direct visualization, Monolayer, Optical; FocalPoint™, MonoPrep Pap Test (MPPT), PapSure®, Speculite®, Speculoscopy, SurePath, ThinPrep®

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## CMS COVERAGE FOR MEDICARE PRODUCT MEMBERS

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There is currently a National Coverage Determination (NCD) for Screening Pap Smears and Pelvic Examinations for Early Detection of Cervical or Vaginal Cancer. Please refer to the following websites for Medicare Members:

<http://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=185&ncdver=3&CoverageSelection=Both&ArticleType=All&PolicyType=Final&s=New+York+-+Upstate&Keyword=cervical+cancer+screening&KeywordLookUp=Title&KeywordSearchType=And&bc=gAAAACAAAA&>

CMS published a Decision Memo addressing Screening for Cervical Cancer with Human Papillomavirus (HPV) Testing in July 2015. Please refer to the following website: <https://www.cms.gov/medicare-coverage-database/details/nca-decision-memo.aspx?NCAId=278&CoverageSelection=Both&ArticleType=All&PolicyType=Final&s=New+York+-+Entire+State&Keyword=human+papillomavirus&KeywordLookUp=Title&KeywordSearchType=And&bc=gAAAABAAAgEAAA%3d%3d&>