

MEDICAL POLICY

MEDICAL POLICY DETAILS	
Medical Policy Title	Cervical Cancer Screening and Human Papilloma Virus (HPV) Testing
Policy Number	2.02.04
Category	Technology Assessment
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Product Disclaimer	<ul style="list-style-type: none"> • <i>If a product excludes coverage for a service, it is not covered, and medical policy criteria do not apply.</i> • <i>If a commercial product (including an Essential Plan or Child Health Plus product), medical policy criteria apply to the benefit.</i> • <i>If a Medicaid product covers a specific service, and there are no New York State Medicaid guidelines (eMedNY) criteria, medical policy criteria apply to the benefit.</i> • <i>If a Medicare product (including Medicare HMO-Dual Special Needs Program (DSNP) 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> • <i>If a Medicare HMO-Dual Special Needs Program (DSNP) product DOES NOT cover a specific service, please refer to the Medicaid Product coverage line.</i>

POLICY STATEMENT

- I. Based upon our criteria and assessment of the peer-reviewed literature, including the United States Preventive Services Task Force (USPSTF) recommendations, cervical cancer and/or human papillomavirus (HPV) screening is considered **medically appropriate** for patients aged 30 to 65 years, using any of the following tests (Please refer to Policy Guideline I):
 - A. combined use (co-testing) of cervical cytology testing and a test approved by the United States Food and Drug Administration (FDA) for high-risk subtypes of HPV (hrHPV) every five years;
 - B. an FDA-approved test for hrHPV alone every five years; or
 - C. cervical cytology alone (e.g., conventional Papanicolaou (Pap) smear or liquid-based cytology) every three years.
- II. Based upon our criteria and assessment of the peer-reviewed literature, including the United States Preventive Services Task Force (USPSTF) recommendations, cervical cancer screening in patients aged 21 to 29 years who are at average risk for cervical cancer is considered **medically appropriate** using cervical cytology alone (e.g., conventional Pap smear or liquid-based cytology) every three years (Please refer to Policy Guideline I).
- III. Based upon our criteria and assessment of the peer-reviewed literature, including the USPSTF recommendations, cervical cancer screening in patients younger than age 21 years is considered **not medically necessary**.
- IV. Based upon our criteria and assessment of the peer-reviewed literature, including the USPSTF recommendations, cervical cancer screening in patients older than age 65 years who have had adequate prior screening and are not otherwise at high risk for cervical cancer is considered **not medically necessary**.
- V. Based upon our criteria and assessment of the peer-reviewed literature, including the USPSTF recommendations, cervical cancer screening in patients who have had a hysterectomy with removal of the cervix and who do not have a history of cervical intraepithelial neoplasia [CIN] grade 2 or 3 or cervical cancer is considered **not medically necessary**.

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- VI. Based upon our criteria and assessment of the peer-reviewed literature, human papillomavirus (HPV) testing of high-risk sub-types has been medically proven to be effective and therefore, is considered **medically appropriate** for use in the triage of patients with atypical squamous cells of undetermined significance (ASCUS) on cervical screening (Please refer to Policy Guideline I).
- VII. Based upon our criteria and assessment of the peer-reviewed literature, HPV screening is considered **not medically necessary** for patients who are under age 30 years, as these patients 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.
- VIII. Based upon our criteria and assessment of the peer reviewed literature, HPV testing in low-grade squamous intraepithelial lesion (LSIL) is considered **medically appropriate** for patients aged 30 years or older as this may determine subsequent management decisions regarding future screening or intervention (Please refer to Policy Guideline I).
- IX. Based upon our criteria and assessment 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, therefore, is considered **not medically necessary**.

POLICY GUIDELINES

- I. This policy applies to all patients with a cervix (assigned female at birth), regardless of their gender identification.
- II. The United States Preventive Services Task Force (USPSTF) recommends that cervical cancer screening should start at age 21 years.
- III. 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.
- IV. Routine cervical cancer screening and HPV testing should be performed using FDA approved techniques (e.g., conventional Pap smear, liquid based cytology, cobas HPV test).
- V. As the utilization of automated slide-reading systems (e.g., FocalPoint, ThinPrep Imaging system, MonoPrep LBP processor) has not been proven to have a significantly greater sensitivity than the manual reading of specimens, the reimbursement for the use of these systems will generally be provided at the same level as that for manual reading of specimens.

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 HPV, can 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 patients should still be screened for cervical cancer.

Despite the dramatic impact of Pap screening, concerns regarding Pap performance remain. Approximately 30% 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

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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 (which 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 cervical examination of a patient 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-risk 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 (without cancer) may regress without treatment, but it is not possible to predict which will regress and when.

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

- 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. ThinPrep Pap test slides screen 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; normal epithelial cells appear blue or purple. The white lesions may then be sampled for cytologic examination. Patients with an abnormal Pap smear, even in the presence of a negative speculoscopy examination, should be referred for additional evaluation.

The Patient Protection and Affordable Care Act (PPACA) also requires coverage of cervical cancer screening in accordance with the recommendations of the USPSTF. As of August 1, 2012, for all non-grandfathered policies, PPACA was expanded to include coverage for certain preventive services, including screening for cervical cancer in patients aged 21 to 65 years with cytology (Pap smear) every three years or, for patients aged 30 to 65 years, screening with a combination of cytology and HPV testing every five years.

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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.excellusbcbcs.com/wps/portal/xl/prv/pc/cpg>.

<https://provider.excellusbcbcs.com/resources/clinical/preventive-health>

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., appropriate 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.

Cervical Cytology Screening

The recommendations of the USPSTF (revised August 2018) address cervical cancer screening in patients who have a cervix, regardless of sexual history. The recommendations do not apply to patients who have received a diagnosis of a high-grade precancerous cervical lesion or cervical cancer, patients with in-utero exposure to diethylstilbestrol, or patients who are immunocompromised (such as those who are HIV-positive). The USPSTF recommends the following:

- I. Screening for cervical cancer in patients aged 21 to 29 years with cytology (Pap smear) alone every three years. For patients aged 30 to 65 years, screen every three years with cytology alone, or every five years with high-risk human papillomavirus (hrHPV) testing alone, or every five years with hrHPV testing in combination with cytology (co-testing).-(Recommendation: A*)
- II. Do not screen for cervical cancer in patients younger than age 21 years (Recommendation: D**).
- III. Do not screen for cervical cancer in patients older than age 65 years who have had adequate prior screening and are not otherwise at high-risk for cervical cancer (Recommendation: D**).
- IV. Do not screen for cervical cancer in patients who have had a hysterectomy with removal of the cervix and who do not have a history of cervical intraepithelial neoplasia [CIN] grade 2 or 3 or cervical cancer (Recommendation: D**).

Recommendation Key:

*A: The USPSTF recommends the service. There is high certainty that the net benefit is substantial. Offer or provide this service.

**D: The USPSTF recommends against the service. There is moderate or high certainty that the service has no net benefit or that the harms outweigh the benefits. Discourage the use of this service.

In April 2021, The American College of Obstetricians and Gynecologists (ACOG) released a practice advisory, noting a replacement of their practice bulletin from October 2016, and the full endorsement of the USPSTF cervical cancer screening recommendations. ACOG stated that this adoption expands the options for cervical cancer screening in average-risk individuals who are 30 years and older to include screening every 5 years with primary HPV testing (with a test that is approved by the FDA). Management of abnormal cervical cancer screening results should follow current American Society of Colposcopy and Cervical Pathology (ASCCP) guidelines.

Human Papillomavirus (HPV) Testing

Data from the Atypical Squamous Cells of Undetermined Significance/Low-Grade Squamous Intraepithelial Lesions Triage Study (ALTS) trial showed that 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 ASCCP recommend either repeat Pap smear, immediate colposcopy, or HPV testing for patients who have ASCUS Pap smears.

In March 2003, the FDA approved the Digene Hybrid Capture 2 (HC2) High-Risk HPV DNA test for screening patients over age 30 years for HPV infection when used along with a Pap test; this is in addition to the original approval for testing patients with an abnormal Pap test to determine the need for further evaluation. The approval was based upon several

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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).
- II. The Cervista HPV 16/18 detects the DNA sequences specific for HPV 16 and HPV 18 in cervical cells. In patients aged 30 and older or patients 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 patients who are at low risk for cervical abnormalities. HPV screening is not recommended for patients under age 30 years, 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 patients with LSIL, due to the high prevalence of HPV infection in patients with this diagnosis.

The 2022 guidelines of the American Cancer Society for the early detection of cancer state:

- I. Cervical cancer screening should start at age 25.
- II. Patients aged 25 to 65 years should have a primary HPV test every five years. If primary HPV testing is not available, screening with a Pap test plus an HPV test every five years or a Pap test-alone every three years, may be acceptable.
- III. Patients over age 65 years who have had regular cervical cancer testing in the past 10 years with normal results and no who have no history of CIN2 or more serious diagnosis within the past 25 years should not be tested for cervical cancer. Once testing is stopped, it should not be started again. Patients with a history of a serious cervical pre-cancer should continue to be tested for at least 25 years after that diagnosis, even if testing goes past age 65 years.
- IV. Patients whose uterus and cervix have been removed (a total hysterectomy) for reasons not related to cervical cancer and who have no history of cervical cancer or serious pre-cancer should not be tested.
- V. All patients who have been vaccinated against HPV should still follow the screening recommendations for their age groups.

On April 24, 2014 the FDA approved the cobas HPV Test, which is the first HPV DNA test for patients 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, patients with a cervix who test positive for HPV 16 or HPV 18 should have a colposcopy; those who test 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 stated that 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 and no FDA-approved HPV test for persons assigned male at birth.

Speculoscopy (e.g., PapSure) The Speculite device was approved by the 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.

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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, which focus upon techniques for cervical cancer screening, do not address Papsure or speculscopy.

Other techniques

Even though cervical cancer is regarded as largely preventable through vaccination and screening with appropriate follow-up treatment, participation rates of screening differ among settings with the main determinants being socioeconomic status, ethnic group, health insurance status, education level, and access to services. Given this, there has been investigation into the feasibility and reliability of home-based self-screening. Several variables can exist outside of the controlled office setting, and because of this, the accuracy of home testing has yet to be proven. There are currently no FDA- approved home tests for HPV.

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

CODES

- *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.*
- *Code Key: Experimental/Investigational = (E/I), Not medically necessary/ appropriate = (NMN).*

CPT Codes

Code	Description
87623	Infectious agent detection by nucleic acid (DNA or RNA); Human Papillomavirus (HPV), low-risk types (e.g., 6, 11, 42, 43, 44)
87624	Infectious agent detection by nucleic acid (DNA or RNA); Human Papillomavirus (HPV), high-risk types (e.g., 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

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Code	Description
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
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

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Code	Description
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

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Code	Description
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 (e.g., 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
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

ICD10 Codes

Code	Description
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 uteri (code range)
D39.0	Neoplasm of uncertain behavior of uterus
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- R87.629	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	Low 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

CMS COVERAGE FOR MEDICARE PRODUCT MEMBERS

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=gAAAACA AAAA&>

There is currently a National Coverage Determination (NCD) for Screening for Cervical Cancer with Human Papillomavirus (HPV). Please refer to the following website: <https://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=365&ncdver=1&bc=AAAAGAAAAAA&>