



Cigna Medical Coverage Policy

Subject **Cervical Cancer Screening
Visualization Technologies**

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Hyperlink to Related Coverage Policies

[Human Papillomavirus Vaccine
\(Cervarix[®], Gardasil[®]\)](#)

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Coverage Policy

Cigna does not cover the following visualization technologies for any indication including, but not limited to, cervical cancer screening because they are considered experimental, investigational or unproven:

- cervicography
- spectroscopy/optical detection systems
- speculoscopy

General Background

Several technologies have been proposed for the screening or identification of cervical cancer. They are proposed as an adjunct to or a replacement for the standard techniques of Papanicolaou (Pap) smear, human papillomavirus (HPV)-deoxyribonucleic acid (DNA) (HPV-DNA) testing, and colposcopy.

Cervicography

Cervicography is a visual screening method introduced in the 1970s that uses a specially designed 35-mm camera to take photographs of the cervix after the application of a 3–5% acetic acid wash. The film is then sent to a laboratory for processing and evaluation. The theory behind cervicography is that when an expert evaluates the cervical photographs there will be an improvement in identification of cervical lesions and improved ability to discriminate between high grade and more trivial lesions than the mid-level clinicians who perform direct visual inspection (Wright, et al., 2002).

Spectroscopy

A spectroscopy system may be referred to as an optical detection system. Spectroscopy emits light from a probe onto the cervix, allowing the examiner to objectively categorize tissues as either normal or diseased. Spectroscopy is based on the principle that epithelial tissues that are abnormal have different optical properties than normal tissues and that these optical differences can be used to determine whether a tissue is normal or abnormal. Devices that are currently under various stages of research and development for diagnostic purposes use various approaches, including: fluorescence spectroscopy, white light elastic backscatter spectroscopy, infrared spectroscopy, Raman spectroscopy, image analysis of visible images, or combinations of the different methods (Wright, et al., 2002).

One optical detection system is the LUMA[™] Cervical Imaging System (MediSpectra, Inc., Lexington, MA). This device received premarket approval from the FDA in March 2006. The LUMA system uses three different optical measurements to document cervical abnormalities: native evoked fluorescence, diffuse reflectance backscatter, and video imaging. The FDA indicated use is as an adjunct to colposcopy for identification of high-grade disease (cervical intraepithelial neoplasia [CIN] 2, 3+) in women referred for colposcopy with a Pap test result of atypical squamous cells, low-grade squamous intraepithelial lesion, high-grade squamous intraepithelial lesion or cancer.

Speculoscopy

The speculoscopy exam includes the same principle that is used in a colposcopy of applying acetic acid to the cervix, but then utilizes magnified vision and a chemiluminescent light to detect abnormalities. The vaginal vault and cervix are mostly illuminated by light that reflects off of the surface of the cervix, thus producing a nonspecific glare and obscuring the clear-cut definition of any acetowhite lesions that may exist. Lesions that are below the surface of the epithelium may not be detected, thus leading to decreased efficacy of this exam process.

Speculite produces a low-energy, diffuse, blue-white light. Due to chemiluminescence, the light that is emitted is "cold light" and independent of temperature. This light is affixed to the top of the speculum, and through special spectral frequencies it is theorized that early dysplastic lesions that reside on or below the epithelial surface can be discovered. The dysplastic tissue will appear white and have sharp borders between the normal and abnormal epithelium that can be visualized.

In 2002, PapSure[®] was granted 401(k) approval from the FDA. PapSure combines the results of a traditional Pap smear and speculoscopy using Speculite, a disposable, chemiluminescent light for vaginal illumination. Both of these devices are manufactured by Watson Diagnostics, Corona, CA.

Literature Review for Cervicography: The early studies evaluating this technology were very small, used heterogeneous populations and testing protocols. Based on results in large screening studies, cervicography does not appear to have an adequate sensitivity, even when the performance of the test is highly optimized to be used as a primary screening method for cervical cancer screening (Wright, et al., 2002).

Kim et al. (2013) conducted a study of 261 patients that compared the sensitivities and false-positive rates of cervical cytology (Pap smear), human papilloma virus (HPV) DNA test, cervicography, first double-combined testing (cervical cytology and HPV DNA test), second double-combined testing (cervical cytology and cervicography) and triple-combined testing (cervical cytology, HPV DNA test and cervicography). All women simultaneously underwent cervical cytology, HPV DNA test and cervicography for uterine cervical cancer screening and colposcopy-directed biopsy for diagnostic evaluation. Twenty-eight cases classified as atypical squamous cells of undetermined significance (ASCUS) on cervical cytology were excluded from the statistical analysis due to the ambiguity in classification. The sensitivity of cervical cytology was 87.5%; specificity 93.5%; positive predictive value (PPV) 77.8%; and negative predictive value (NPV) 96.7%. The sensitivity of the HPV DNA test was 72.7%; specificity 91.7%; positive predictive value 70.2%; and negative predictive value 92.7%. The sensitivity of the cervicography was 94.3%; specificity 89.8%, PPV 71.4%; and NPV 98.3%. The sensitivity of this double-combined testing was 92.3%; specificity 86.6%; PPV 65.8%; and NPV 97.6%. Triple-combined testing the sensitivity was 100%; specificity 82.2%; PPV 62.8%; NPV 100%. The authors note that results of this study cannot be applied directly for uterine cervical cancer screening since it was conducted in patients showing a high incidence—further group studies should be carried out using mass screening. In addition, further problems that remain to be resolved include regional biases, objectivity in reading, accuracy in diagnostic

criteria, economic feasibility, excessive treatment due to high sensitivity, and the inconvenient nature of the tests themselves.

The results of a nested study conducted during a large multicenter, randomized, prospective analysis were reported on by Guido[a] et al. (2005). This nested study was designed to address the issue of the topographic distribution of lesions, particularly CIN 3 lesions. The researchers felt that using a population that was already enrolled in the prospective study provided a well-studied and documented source of cervical intraepithelial neoplasia (CIN) of different grades from four diverse clinical centers. During this study, all women were randomized to three treatment arms at the time of their enrollment: 1) immediate colposcopy; 2) HPV triage to colposcopy using Hybrid Capture 2; and 3) conservative management based on repeat cytology with colposcopic referral at an HSIL threshold. All participants had liquid-based cytology sampling for Pap and HPV typing, and cervigrams were taken at enrollment and follow-up visits. Those participants enrolled in the immediate colposcopy arm had both cytology and colposcopic exams conducted on the same day. All participants were followed every six months by cytology and underwent exit colposcopy at two years. Guido and colleagues wanted to study the possible relationship between the outcomes of cervical biopsies, the biopsy's cervical location based on an o'clock position, and the quality of the biopsy based on cervigram acetowhitening. Acetowhite areas were more common on the anterior and posterior lips of the cervix; however, this variance did not correlate to an increase in the number of CIN or HPV positive cytology results. The presence of acetowhitening may have indicated a resolving HPV infection, although acetowhitening appeared when HPV results were negative as well. These findings raised concern that in the absence of disease, the anterior and posterior lips of the cervix still reacted to acetowhitening, causing an increase in the numbers of biopsies taken, but the biopsies did confirm the presence of CIN. The researchers therefore concluded that the use of this technique requires additional research.

Literature Review for Spectroscopy: El-Tawail et al (2008) reported on a comparative study between Pap smear cytology and Fourier transform infrared (FTIR) spectroscopy. Eight hundred cervical scrapings were taken by cytobrush and placed in ThinPrep medium. The samples were dried over infrared transparent matrix. Beams of infrared light were directed at the dried samples at frequency of 4000 to 400 cm⁻¹. The absorption data were produced using a Spectrum BX II FTIR spectrometer. Data was then compared with the reference absorption data of known samples using FTIR spectroscopy software. FTIR spectroscopy was compared with cytology (gold standard). It was noted that FTIR spectroscopy could differentiate normal from abnormal cervical cells in the samples examined—the sensitivity was found to be 85%, specificity 91%, positive predictive value 19.5% and negative predictive value of 99.5%.

Alvarez et al. (2007a) conducted multicenter, two-arm, randomized trial to assess whether the use of an optical detection system as an adjunct to colposcopy increases the detection of biopsy confirmed CIN 2, 3. The trial compared colposcopy alone with colposcopy plus a pre-commercial optical detection system that utilized fluorescence, white light tissue reflectance, and cervical video imaging. The patients were recruited from 13 colposcopy clinics in a variety of practice settings. The study involved 2,299 women referred for the evaluation of an abnormal cervical cytology that were randomized with stratification by cytology. The main study outcomes were differences in TP rates (CIN 2, 3 and cancer identified) and FP rates between the study arms. The TP rates were 14.4% versus 11.4% ($p=0.035$, one-sided) for the combined colposcopy and optical detection system arm compared to the colposcopy-only arm, respectively, in women with either an atypical squamous cell (ASC) or low-grade squamous intraepithelial lesion (LSIL) cytology result. The TP rates were similar between the two arms among women referred for the evaluation of high-grade squamous intraepithelial lesion (HSIL) in the combined colposcopy and ODS arm, among women with ASC or LSIL, the PPV of biopsies indicated by optical detection system was 15.0% and the PPV of biopsies indicated by colposcopy was 15.2%.

Alvarez et al. (2007b) conducted a multicenter internally controlled trial to evaluate the impact of using an optical detection system as an adjunct to colposcopy. The trial was designed to evaluate the performance of a pre-commercial optical detection system (LUMA) used as an adjunct to colposcopy among women referred for the evaluation of an abnormal cervical cytology result. The trial included 227 women and was conducted at seven colposcopy clinics in the United States. After exclusions, 193 women remained in the analysis. The main study outcomes were incremental increases in true positives (cervical intraepithelial neoplasia [CIN] 2, 3 and cancer, or CIN 2+) and false positives which were women with additional cervical biopsies not found to be CIN 2+. The Initial colposcopy identified 41 cases of CIN 2+ for a TP rate of 21.2%. Adjunctive use of the optical detection system identified an additional nine cases of CIN 2+ which corresponds to an incremental optical detection system TP rate of 4.7% (95% confidence interval [CI], 2.2% to 8.7%). Adjunctive use of optical detection system

therefore resulted in a 22.0% (95% CI, 6.1% to 37.8%) relative gain in the number of women with CIN 2+ compared to colposcopy alone. The (FP) rate for initial colposcopy was 51.8% (100 of 193 women). An additional 35 subjects had an ODS-directed biopsy that was not diagnosed as CIN 2+, yielding an incremental FP rate of 18.1% (95% CI, 13.0% to 24.3%).

DeSantis et al. (2006) conducted a prospective multicenter study to evaluate the potential safety and effectiveness of tissue spectroscopy for the diagnosis of cervical cancer. The study involved 572 women who were scheduled to undergo colposcopy on the basis of an abnormal Pap test or other risk factor. The spectroscopy measurements were taken over a scan period of four minutes and 30 seconds. The measurements were integrated by a cross-validated pattern recognition model and then compared with biopsy results to yield sensitivity and specificity of cervical spectroscopy. The sensitivity of cervical spectroscopy was 95.1% with a corresponding 55.2% specificity for benign lesions. There were several potential confounding factors (e.g., mucous, blood, patient motion, ambient light) were examined to determine their potential impact on the accuracy of the test. Ambient light appeared to have the greatest effect, but no single factor contributed significantly to the results.

Literature Review for Speculoscopy: To evaluate the efficacy of Pap smear, speculoscopy, and the combination of Pap smear and speculoscopy (PapSure examination) as screening tests in pre- and postmenopausal women, Twu and colleagues conducted a multicenter study in 2006. Based on records within a nationwide government database of Pap smear registration, 1813 women were assessed for possible inclusion in this study and of these, 1701 were eligible (873 premenopausal and 828 postmenopausal). The patients underwent successive Pap smears, speculoscopy, and the first 40 patients each day received simultaneous colposcopic examinations. The remaining patients were referred for colposcopy if their Pap smear or speculoscopy revealed abnormal results. A positive Pap smear was defined as ASUS/AGUS or worse. Positive speculoscopy was defined as a marked acetowhite lesion with sharp margins. Abnormal colposcopic findings were defined as acetowhite lesions with sharp margins, irregular surface, or atypical vessel patterns (coarse punctuations, mosaic, etc.). Punch biopsies and endocervical curettage (ECC) was performed on all patients with unsatisfactory examinations. For premenopausal women, speculoscopy and PapSure had significantly higher sensitivity ($p < 0.005$) and lower specificity ($p < 0.001$) than did the Pap smear. The PapSure examination showed a higher sensitivity than the Pap smear (85.7% versus 57.1%), but the results were not statistically significant. Speculoscopy and PapSure had significantly lower specificity than did Pap smear (96.8%, 96.6% and 99.6%, respectively, [$p < 0.001$]). The authors concluded that based on their data, combining Pap smear with speculoscopy improved sensitivity with minimal reduction in specificity within premenopausal women; however, in postmenopausal women this lower specificity could lead to unnecessary colposcopic examinations or possible conizations. It is unclear if the cytologist was blinded to the findings of other test outcomes as the first 40 individuals were referred on a daily basis for colposcopy examination. Patients were referred for cervical biopsy based on the presence or absence of acetowhite lesions; this referral for additional testing may have led to an increase in false-positive readings that were observed in the premenopausal group versus the postmenopausal women. Although the researchers set the minimum inclusion age at 30, participants younger than this were allowed to be a part of the study, which may have also led to an increase in false-positive outcomes.

Parham [a] et al. (2000) reviewed the outcomes of using immediate (i.e., within four weeks) colposcopy on women who had a positive Pap smear versus delaying colposcopy for six months if the speculoscopy exam alone was positive. Of the 800 women Parham screened, 124 had negative Pap smears but positive speculoscopy. Of the 124 women, 57 were offered immediate colposcopy and 67 were offered colposcopy in six months. More than 80% of the women in the immediate group had positive colposcopy results, with 64.9% histologically-proven neoplasms. Thirteen (29%) lesions in the deferred group showed speculoscopy-negative results on repeat testing. Of the lesions that remained positive at the six-month mark, 90.6% were confirmed neoplasms on biopsy; this provided a sensitivity yield of 65–90%. The researchers concluded that this sensitivity yield was due to the combination of the Pap smear, colposcopy and additional biopsy of tissues. The population set that was studied by delayed colposcopy was small in size (14 of 67 lost to follow-up). Individuals were subjected to additional diagnostic tests due to false-positive speculoscopy readings. Individuals with positive Pap smear results that were read as low-grade SIL or ASCUS were not detected as having cervical neoplasia by speculoscopy alone, but required additional biopsies to confirm the presence of neoplasia. After six months, 29% (13 of 45) positive speculoscopy readings converted from positive to negative; these individuals would not have required a colposcopy.

Cervical Cancer Screening

Several professional organizations have published guidelines for cervical cancer screening. These screening guidelines include criteria for tests that should be used and frequency according to age. The guidelines include the following standard techniques used in cervical cancer screening include:

- **Pap smear:** The Pap smear or Pap test is the gold standard of cervical cancer screening tests. While the clinical utility of this test has never been examined in a randomized controlled trial, there is a large body of consistent observational data that supports its effectiveness in reducing mortality from cervical cancer (NCI-a, 2013). The Pap smear remains the standard of screening for cervical cancer, being recognized by numerous guidelines from professional organizations and medical/specialty associations and included in medical textbooks.
- **Liquid-Based Cytology:** In an attempt to improve the Pap smear's sensitivity and specificity, researchers have developed, studied and implemented the use of liquid-based cytology collection systems and automated screening computerized programs. The use of liquid-based cytology has become a standard of care in screening protocols for cervical cancer, according to statements from professional and specialty medical organizations, published literature and textbooks (Eifel, et al., 2011; Niederhuber, et al., 2013; Smith, et al., 2008).
- **Human Papillomavirus Deoxyribonucleic Acid (HPV-DNA) Testing:** The major risk factor for cervical cancer is infection by the human papilloma virus (HPV). HPV is a group of more than 100 related viruses. There are certain types of HPV that are considered high-risk or carcinogenic since they often lead to cancer of the cervix. These types include HPV 16, HPV 18, HPV 31, HPV 33, HPV 45—approximately 70% of all cervical cancers are caused by HPV 16 and 18 (American Cancer Society [ACS], 2014a). HPV-DNA testing allows for the detection of primary etiologic infectious carcinogenic carriers. The HPV-DNA test, like the Pap test, is performed by collecting cells from the cervix and then sending them to a laboratory for analysis. The test detects high-risk types of HPV in cell DNA even before there are any conclusive visible changes to the cervical cells.
- **Colposcopy:** colposcopy along with colposcopically directed biopsies is the primary method for evaluating women with abnormal cervical cytologies. During a colposcopy, the cervix is visualized and excess mucus is gently removed with a dry cotton ball, the cervix is treated with 3% to 5% acetic acid. Flat condylomata or dysplastic areas turn white or develop a vascular pattern with a mosaic appearance or punctuation. The squamocolumnar junction and transformation zone are then inspected thoroughly, and biopsy of suspicious areas is performed (Damewood, et al., 2008).

Professional Societies/Organizations

The American Cancer Society (ACS), the American College of Obstetricians and Gynecologists (ACOG), National Comprehensive Cancer Network® (NCCN®) and the U.S. Preventive Services Task Force (USPSTF): These professional societies/organizations do not recognize cervicography, speculoscopy or spectroscopy/optical detection systems as primary screening techniques of the cervix for the early detection of cervical cancer.

American Cancer Society: The ACS guidelines for cervical cancer screening are joint guidelines with the American Society for Colposcopy and Cervical Pathology (ASCCP) and the American Society for Clinical Pathology (ASCP). They include the following recommendations (ACS, 2014a; Saslow, et al., 2012):

- Cervical cancer screening (testing) should begin at age 21. Women under age 21 should not be tested.
- Women between ages 21 and 29 should have a Pap test every three years. HPV testing should not be used in this age group unless it is needed after an abnormal Pap test result.
- Women between the ages of 30 and 65 should have a Pap test plus an HPV test every five years. This is the preferred approach, but it is also acceptable to have a Pap test alone every three years.
- Women over age 65 who have had regular cervical cancer testing 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 continues past age 65.
- A woman who has had her uterus removed (and also her cervix) for reasons not related to cervical cancer and who has no history of cervical cancer or serious pre-cancer should not be tested.
- A woman who has been vaccinated against HPV should still follow the screening recommendations for her age group.

American College of Obstetrics and Gynecologists (ACOG, 2012): In 2012, ACOG published revised guidelines for cervical cytology screening. The guidelines include the following recommendations:

These recommendations are based on good and consistent scientific evidence (Level A):

- Cervical cancer screening should begin at age 21 years. 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.
- Women aged 21–29 years should be tested with cervical cytology alone, and screening should be performed every three years. Co-testing should not be performed in women younger than 30 years.
- For women aged 30–65 years, co-testing with cytology and HPV testing every five years is preferred.
- In women aged 30–65 years, screening with cytology alone every three years is acceptable. Annual screening should not be performed.
- Women who have a history of cervical cancer, have HIV infection, are immunocompromised, or were exposed to diethylstilbestrol in utero should not follow routine screening guidelines.
- Both liquid-based and conventional methods of cervical cytology collection are acceptable for screening.
- In women who have had a hysterectomy with removal of the cervix (total hysterectomy) and have never had cervical intraepithelial neoplasia (CIN) 2 or higher, routine cytology screening and HPV testing should be discontinued and not restarted for any reason.
- 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 five years.

These recommendations are based on limited and inconsistent scientific evidence (Level B):

- Women with ASC-US cytology and negative HPV co-testing results have a very low risk of CIN 3 and should continue with routine screening as indicated for their age.
- Women with a history of CIN 2, CIN 3, or adenocarcinoma in situ should continue to undergo routine age-based screening for 20 years after the initial post-treatment surveillance period, even if it requires that screening continue past age 65 years.
- 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. Continued screening for 20 years is recommended in women who still have a cervix and a history of CIN 2 or higher. Therefore, screening with cytology alone every three years for 20 years after the initial post-treatment surveillance period seems reasonable for women with a hysterectomy.
- Women with negative cytology and positive HPV co-testing results who are aged 30 years and older should be managed in one of two ways:
 - Repeat co-testing in 12 months. If the repeat cervical cytology test result is low-grade squamous intraepithelial lesion (LSIL) or higher or the HPV test result is still positive, the patient should be referred for colposcopy. Otherwise, the patient should return to routine screening.
 - Immediate HPV genotype-specific testing for HPV-16 alone or HPV-16/18 should be performed.
- Women with positive results from tests for HPV-16 alone or HPV-16/18 should be referred directly for colposcopy. Women with negative results from tests for HPV-16 or HPV-16/18 should be co-tested in 12 months, with management of results as described.

The following recommendation is 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.

National Comprehensive Cancer Network (NCCN): NCCN has published guidelines (National Comprehensive Cancer Network Guidelines™ [NCCN Guidelines™]) for cervical cancer screening. The NCCN panel has adopted the joint guidelines from the American Cancer Society (ACS)/American Society for Colposcopy and Cervical Pathology (ASCCP)/American Society for Clinical Pathology (ASCP) (NCCN, 2014).

U.S. Preventive Services Task Force (USPSTF, 2012): In 2012, the USPSTF published updated guidelines for cervical cancer screening. This recommendation statement applies to women who have a cervix, regardless of sexual history. This recommendation statement does 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 (e.g., HIV positive). The guidelines include the following recommendations:

- Recommends screening for cervical cancer in women age 21 to 65 years with cytology (Pap smear) every three 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 five years. (A recommendation*)
- Recommends against screening for cervical cancer in women younger than age 21 years (D recommendation*).
- Recommends 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. (D recommendation*).
- Recommends 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 (cervical intraepithelial neoplasia [CIN] grade 2 or 3) or cervical cancer (D recommendation*).
- Recommends against screening for cervical cancer with HPV testing, alone or in combination with cytology, in women younger than age 30 years (D recommendation*).

* Recommendations:

Grade A: The USPSTF recommends the service. There is high certainty that the net benefit is substantial.

Grade 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.

Use Outside of the US

NHS Cervical Screening Programme (United Kingdom): the NHS includes the following recommendations (NHS, 2013):

- Women age less than 24: not invited to screen
- Women age 25-49: every three years with cytology
- Women age 50-64 years: every 5 years with cytology
- Women aged ≥ 65 years: to undergo screening only if they have not had screening since age 50, or they have had recent abnormal test results
- HPV testing: additional (triage) HPV testing is recommended for women ≥ 25 years with abnormal test results in some circumstances

Singapore Ministry of Health: The Singapore Ministry of Health published guidelines for cancer screening. Regarding cervical cancer screening, the guidelines include (2010):

- All women who have ever had sexual intercourse should undergo screening for cervical cancer from the age of 25 years. Grade C, Level 2⁺
- Pap smear screening should be performed at least once every 3 years. Grade B, Level 2⁺⁺
- Screening should be performed using the Papanicolaou (Pap) smear. Grade B, Level 2⁺⁺

1⁺⁺: High quality meta-analyses, systematic reviews of randomized controlled trials (RCTs), or RCTs with a very low risk of bias

1⁺: Well conducted meta-analyses, systematic reviews of RCTs, or RCTs with a low risk of bias.

2⁺⁺: High quality systematic reviews of case control or cohort studies. High quality case control or cohort studies with a very low risk of confounding or bias and a high probability that the relationship is causal

2⁺: Well conducted case control or cohort studies with a low risk of confounding or bias and a moderate probability that the relationship is causal

Grade B: A body of evidence including studies rated as 2⁺⁺, directly applicable to the target population, and demonstrating overall consistency of results; or extrapolated evidence from studies rated as 1⁺⁺ or 1⁺

Grade C: A body of evidence including studies rated as 2⁺, directly applicable to the target population and demonstrating overall consistency of results; or extrapolated evidence from studies rated as 2⁺⁺

Summary

Due to the lack of well-designed, randomized controlled trials within the published peer-reviewed literature, there is insufficient evidence to support the use of cervicography, speculoscopy, or spectroscopy/optical detection systems as primary standalone or as an adjunct to standard screening techniques for the detection of cervical cancer. Studies have also failed to show that the use of these techniques in conjunction with the conventional Pap smear or liquid-based cytology would improve the early detection of cervical cancer. The diagnostic utility of these technologies has not yet been established.

Coding/Billing Information

Note: 1) This list of codes may not be all-inclusive.

2) Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement

Experimental/Investigational/Unproven/Not Covered when used to report cervicography, spectroscopy or speculoscopy:

CPT* Codes	Description
58999	Unlisted procedure, female genital system (nonobstetrical)

***Current Procedural Terminology (CPT®) © 2013 American Medical Association: Chicago, IL.**

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