Medical Coverage Policy

Effective Date 10/15/2024
Next Review Date 9/15/2025
Coverage Policy Number 0127

Cervical Cancer Screening Visualization Technologies

Table of Contents

Related Coverage Resources

[Preventive Care Services](#)

INSTRUCTIONS FOR USE

The following Coverage Policy applies to health benefit plans administered by Cigna Companies. Certain Cigna Companies and/or lines of business only provide utilization review services to clients and do not make coverage determinations. References to standard benefit plan language and coverage determinations do not apply to those clients. Coverage Policies are intended to provide guidance in interpreting certain standard benefit plans administered by Cigna Companies. Please note, the terms of a customer's particular benefit plan document [Group Service Agreement, Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a customer's benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a customer's benefit plan document always supersedes the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Each coverage request should be reviewed on its own merits. Medical directors are expected to exercise clinical judgment where appropriate and have discretion in making individual coverage determinations. Where coverage for care or services does not depend on specific circumstances, reimbursement will only be provided if a requested service(s) is submitted in accordance with the relevant criteria outlined in the applicable Coverage Policy, including covered diagnosis and/or procedure code(s). Reimbursement is not allowed for services when billed for conditions or diagnoses that are not covered under this Coverage Policy (see "Coding Information" below). When billing, providers

Overview

This Coverage Policy addresses visualization technologies used for cervical cancer detection and identification.

Coverage Policy

The following visualization technologies are considered not medically necessary for any indication including cervical cancer screening:

- cervicography
- spectroscopy/optical detection systems
- speculoscopy

Health Equity Considerations

Health equity is the highest level of health for all people; health inequity is the avoidable difference in health status or distribution of health resources due to the social conditions in which people are born, grow, live, work, and age.

Social determinants of health are the conditions in the environment that affect a wide range of health, functioning, and quality of life outcomes and risks. Examples include safe housing, transportation, and neighborhoods; racism, discrimination and violence; education, job opportunities and income; access to nutritious foods and physical activity opportunities; access to clean air and water; and language and literacy skills.

An estimated 13,820 new cervical cancers and 4,360 cervical cancer deaths will occur in the United States in 2024 (American Cancer Society, 2024). When corrected for the prevalence of hysterectomy, the mortality rate for black women is nearly twice the mortality rate for white women (Beavis, et al., 2017). Also, approximately 1,250,000 women will be diagnosed with precancers annually by cytology using the Papanicolaou (Pap) smear.

General Background

Several technologies have been proposed to enhance the traditional 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.

Colposcopy is a diagnostic procedure in which a colposcope (a dissecting microscope with various magnification lenses) is used to provide an illuminated, magnified view of the cervix, vagina, vulva, or anus. The primary goal of colposcopy is to identify precancerous and cancerous lesions so that they may be treated early. Colposcopy is used as a follow-up test to evaluate abnormal

cervical screening tests (cytology and/or human papillomavirus testing [HPV]) or abnormal findings on gross examination of the cervix, vagina, or vulva (Feltmate and Feldman, 2024). It has not been found to be an effective screening tool for cervical cancer when used alone. Colposcopy along with colposcopically directed biopsies are the primary method for evaluating women with abnormal cervical cytologies. During a colposcopy, the cervix is visualized, excess mucus is gently removed with a dry cotton ball, and the cervix is treated with 3% to 5% acetic acid. Flat condylomata or dysplastic areas will 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 are performed (Damewood, et al., 2008).

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 1997, PapSure® was granted 510(k) approval (K963391) 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 are small and use 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).

Song et al. (2019) conducted a study that compared the screening capacities and cost-effectiveness of the human papillomavirus (HPV) test versus cervicography as an adjunctive test to Papanicolaou (Pap) cytology to detect high-grade cervical neoplasia in Korea, a country with a high prevalence of cervical cancer. The study included 33,531 women who underwent cervicography as a screening test for cervical cancer, with a retrospective analysis of the records of 4117 women who simultaneously or subsequently underwent Pap cytology, an HPV test, cervicography, and colposcopically directed biopsy. At a threshold of cervical intraepithelial neoplasia grade 2 or worse (CIN2+), based on colposcopic biopsy, the diagnostic capacities and cost-effectiveness of these screening tools were compared. The CIN2+ prevalence was 10.8% (446 of 4117 women) and the positive rate of high-risk HPV was 61.0% (2511 of 4117 women). Cervicography as an adjunctive to Pap cytology was a more sensitive test (97.5% vs 93.7%) with a higher odds ratio (15.65 vs 5.86) than the HPV test for detection of CIN2+ (p value = 0.003). The cost of cervicography co-testing was 23% less than that of HPV co-testing. The authors concluded that cervicography and Pap co-testing had superior screening capacity and cost-effectiveness for detection of preinvasive cervical lesions than HPV and Pap co-testing and may be an effective and cost-saving screening strategy in clinical practice in country with a high prevalence of cervical cancer; however, further large, randomized controlled trials comparing the screening capacities of HPV test versus cervicography as an adjunctive test to Pap cytology to detect high-grade cervical neoplasia in general population are needed to obtain more conclusive data. The study was limited by the lack of randomization and retrospective nature of the study.

de Castro Hillmann et al. (2019) conducted a cross sectional study of 212 patients in a colposcopy referral center to evaluate the performance of cervical digital photography (CDP) as an alternative to colposcopy. CDP is also referred to as digital cervicography or digital camera assessment for the detection of cervical intraepithelial neoplasia. Colposcopy and CDP with the cervical digital photographs evaluated through the Internet by three colposcopy experts. The agreement between methods was calculated with kappa and percentages of agreement. Then the sensitivity, specificity, positive predictive value, negative predictive value, and diagnostic accuracy were calculated for colposcopy and cervical digital photography. Histology was used as the gold standard (Canadian Task Force Classification II-2). CDP and colposcopy were in agreement in 89.9% of the cases (κ = 0.588). CDP had higher sensitivity (52.5%) and positive predictive value (60%) than colposcopy (35% and 48.28%, respectively). There were no other significant differences between CDP and colposcopy: specificity was 91.86% and 91.28%, negative predictive value was 89.3% and 85.8%, and diagnostic accuracy was 84.4% and 80.7%, respectively. The authors concluded that CDP is a promising alternative method to colposcopy and additional research could better determine the overall utility of CDP in clinical practice.

Singhakum et al. (2018) conducted a non-inferiority study of new portable device as an alternative method for cervical cancer screening. The performance of device was tested on the assessment of cervical lesions using cervicograph score with the cervical cytology. The study included 325 non-pregnant women. The cervical and vaginal cells from the sample were collected

for cytology, then all of them received the digital cervicography conducted with the new device and scored using cervicograph score. Small pieces of cervical tissues were also collected for histologic examination. Cytology results and cervicograph scores were grouped to two subgroups, two subgroups, ≤ ASC-US and ≥ LSIL, and 0-3 points and 4-6 points, respectively. The data was then correlated with histology results which sub-grouped to ≤ CIN 1 and ≥ CIN 2. The accuracy, sensitivity, specificity, and positive predictive value (PPV) of cervicograph scores 4-6 points to detect CIN 2+ were 92%, 72.41%, 97%, and 84%, respectively which were not inferior to Pap smear. The authors concluded that the digital cervicography device provides similar accuracy to Pap cytology screening and is suitable to use in the area that lacks cytoscreeners, however large-scale use and generalization are required for this new device.

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:
Hermens et al. (2016) reported on the diagnostic value of alternative (digital) colposcopy techniques for detection of cervical intraepithelial neoplasia (CIN) 2 or worse in a colposcopy population. The inclusion criteria included: an alternative (digital) colposcopy technique was used in a colposcopy population; a histologic outcome was reported, classified as CIN, differentiating between mild dysplasia or less (CIN 1 or less), and moderate dysplasia or worse (CIN 2 or greater); the entire cervix was scanned at once or a per-woman analysis was performed; no other topical application than acetic acid and Lugol's solution was used; and at least three eligible studies had to be available within a single technique. Thirteen studies met the inclusion criteria. With six studies on fluorescence and reflectance spectroscopy (2,530 women) with a pooled sensitivity of 93% (95% confidence interval [CI] 89-95%) and specificity of 62% (95% CI 47-76%). Four studies on dynamic spectral imaging were found including 1,173 women with a pooled sensitivity of 69% (95% CI 48-85%) and specificity of 83% (95% CI 76-88%). Previously published conventional colposcopy results showed a sensitivity of 61% (95% CI 58-63%) and a specificity of 85% (95% CI 83-86%). The authors concluded that alternative digital colposcopy techniques may result in increased or similar sensitivity and specificity compared with conventional colposcopy; however, the techniques are still in development, randomized controlled trials comparing alternative techniques with conventional colposcopy are still lacking, and therefore no recommendation for introduction in clinical practice can yet be made.

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 intraephithelial 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. (2007) 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 post-menopausal 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, including American Cancer Society (ACS), American College of Obstetricians and Gynecologists (ACOG), and the U.S. Preventive Services Task Force (USPSTF, 2018). In 2021, ACOG joined ASCCP and the Society of Gynecologic Oncology (SGO) in endorsing the U.S. Preventive Services Task Force (USPSTF) cervical cancer screening recommendations. These screening guidelines include criteria for tests that should be used and frequency according to age. The USPSTF guidelines include:
- The USPSTF recommends screening for cervical cancer every 3 years with cervical cytology alone in women aged 21 to 29 years. For women aged 30 to 65 years, the USPSTF recommends screening every 3 years with cervical cytology alone, every 5 years with high-risk human papillomavirus (hrHPV) testing alone, or every 5 years with hrHPV testing in combination with cytology (cotesting).
- The USPSTF recommends against screening for cervical cancer in women younger than 21 years.
- The USPSTF recommends against screening for cervical cancer 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.
- The USPSTF recommends against screening for cervical cancer in women older than 65 years who have had adequate prior screening and are not otherwise at high risk for cervical cancer.

Professional Societies/Organizations
The use of cervicography, speculoscopy or spectroscopy/optical detection systems as a primary screening technique of the cervix for the early detection of cervical cancer, as an alternative or adjunct to pap smear or colposcopy is not included in professional society/organization guidelines for cervical cancer screening.

Medicare Coverage Determinations

	Contractor	Determination Name/Number	Revision Effective Date
NCD	National	No National Coverage Determination found	
LCD		No Local Coverage Determination found	

Note: Please review the current Medicare Policy for the most up-to-date information.
(NCD = National Coverage Determination; LCD = Local Coverage Determination)

Coding Information

Notes:
1. This list of codes may not be all-inclusive since the American Medical Association (AMA) and Centers for Medicare & Medicaid Services (CMS) code updates may occur more frequently than policy updates.
2. Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement.

Considered Not Medically Necessary when used to report cervicography, spectroscopy or speculoscopy:

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

*Current Procedural Terminology (CPT®) ©2023 American Medical Association: Chicago, IL.

References

1. Alvarez RD, Wright TC; Optical Detection Group. Effective cervical neoplasia detection with a novel optical detection system: a randomized trial. Gynecol Oncol. 2007a Feb;104(2):281-9.

2. Alvarez RD, Wright TC Jr; Optical Detection Group. Increased detection of high-grade cervical intraepithelial neoplasia utilizing an optical detection system as an adjunct to colposcopy. Gynecol Oncol. 2007b Jul;106(1):23-8.

3. American Cancer Society: Key Statistics for Cervical Cancer. American Cancer Society, Jun 28, 2024. Accessed Aug 5, 2024. Available at URL address: https://www.cancer.org/cancer/types/cervical-cancer/about/key-statistics.html

4. American Cancer Society (ACS). The American Cancer Society Guidelines for the prevention and early detection of cervical cancer. Last Revised: Last Revised: Apr 22, 2021. Accessed Aug 5, 2024. Available at URL address: https://www.cancer.org/cancer/cervical-cancer/detection-diagnosis-staging/cervical-cancer-screening-guidelines.html

5. American College of Obstetricians and Gynecologists (ACOG). Practice advisory. Cervical cancer screening recommendations. 2021, reaffirmed Apr 2024. Accessed Aug 5, 2024. Available at URL address: https://www.acog.org/clinical/clinical-guidance/practice-advisory/articles/2021/04/updated-cervical-cancer-screening-guidelines

6. Barbieri RL. Cervical cancer screening tests: Visual inspection methods. In: UpToDate, B Goff (Ed), UpToDate, Waltham, MA. Last updated: Jan 25, 2024. Accessed Aug 5, 2024.

7. Beavis AL, Gravitt PE, Rositch AF. Hysterectomy-corrected cervical cancer mortality rates reveal a larger racial disparity in the United States. Cancer. 2017 May 15;123(6):1044-1050. doi: 10.1002/cncr.30507. Epub 2017 Jan 23. PMID: 28112816.

8. Chang VT, Cartwright PS, Bean SM, Palmer GM, Bentley RC, Ramanujam N. Quantitative physiology of the precancerous cervix in vivo through optical spectroscopy. Neoplasia. 2009 Apr;11(4):325-32.

9. Damewood MD, Keye Jr. WR, Coddington III CC. Gibbs, RS, Karlan BY, Haney AF, Nygaard IE (editors). Chapter 29: Office Gynecology and Surgical Procedures. In: Danforth's Obstetrics and Gynecology 10th edition. Philadelphia: Lippincott Williams & Wilkins; 2008.

10. de Castro Hillmann E, Moreira Bacha O, Roy M, Paris G, Berbiche D, Nizard V, Lopes Ramos JG. Cervical Digital Photography: An Alternative Method to Colposcopy. J Obstet Gynaecol Can. 2019 Aug;41(8):1099-1107.

11. DeSantis T, Chakhtoura N, Twiggs L, Ferris D, Lashgari M, Flowers L, et al. Spectroscopic imaging as a triage test for cervical disease: a prospective multicenter clinical trial. J Low Genit Tract Dis. 2007 Jan;11(1):18-24.

12. Eifel PJ, Berek JS, Markman MA. Chapter 101: Cancer of the Cervix, Vagina, and Vulva. In: DeVita VT, Lawernce TS, Rosenberg SA (editors). Cancer: Principles & Practices of Oncology, 9th ed. Philadelphia: Lippincott Williams & Wilkins; 2011.

13. El-Tawil SG, Adnan R, Muhamed ZN, Othman NH. Comparative study between Pap smear cytology and FTIR spectroscopy: a new tool for screening for cervical cancer. Pathology. 2008 Oct;40(6):600-3.

14. Feltmate CM, Feldman SF. Colposcopy. In: UpToDate, Chakrabarti A. (Ed). Feb 20, 2024. UpToDate, Waltham, MA. Accessed Aug 5, 2024.

15. Guido RS [a], Jeronimo J, Schiffman M, Solomon D. The distribution of neoplasia arising on the cervix: Results from the ALTS trial. Am J Obstet Gynecol. 2005;193:1331-7.

16. Hermens M, Ebisch RM, Galaal K, Bekkers RL. Alternative Colposcopy Techniques: A Systematic Review and Meta-analysis. Obstet Gynecol. 2016 Oct;128(4):795-803.

17. Kim JH, Kim IW, Kim YW, Park DC, Kim YW, Lee KH, et al. Comparison of single-, double- and triple-combined testing, including Pap test, HPV DNA test and cervicography, as screening methods for the detection of uterine cervical cancer. Oncol Rep. 2013 Apr;29(4):1645-51.

18. Lau C, Mirkovic J, Yu CC, O' Donoghue GP, Galindo L, Dasari R, et al. Early detection of high-grade squamous intraepithelial lesions in the cervix with quantitative spectroscopic imaging. J Biomed Opt. 2013 Jul 1;18(7):76013.

19. Marth C, Landoni F, Mahner S, McCormack M, Gonzalez-Martin A, Colombo N; ESMO Guidelines Committee. Cervical cancer: ESMO Clinical Practice Guidelines for diagnosis, treatment and follow-up. Ann Oncol. 2017 Jul 1;28(suppl_4):iv72-iv83.

20. Murali Krishna C, Sockalingum GD, Vidyasagar MS, Manfait M, Fernanades DJ, Vadhiraja BM, et al. An overview on applications of optical spectroscopy in cervical cancers. J Cancer Res Ther. 2008 Jan-Mar;4(1):26-36.

21. Nam K, Kim SN, Sim SH, Han S. The performance of tele-cervicography for detection of preinvasive and invasive disease of the uterine cervix as an adjunctive test to Pap smears. Contemp Oncol (Pozn). 2016;20(5):402-406.

22. National Cancer Institute (NCI[a]). Cervical Cancer Screening (PDQ®): Health Professional Version. Updated: May 23, 2024. Accessed Aug 5, 2024. Available at URL address: http://www.cancer.gov/cancertopics/pdq/screening/cervical/healthprofessional

23. National Cancer Institute (NCI[b]). HPV and Cancer. Updated: Oct 18, 2023. Accessed Aug 5, 2024. Available at URL address: http://www.cancer.gov/cancertopics/factsheet/Risk/HPV

24. National Cancer Institute (NCI[c]). Cervical Cancer Prevention (PDQ®): Health Professional Version. Updated: Mar 6, 2024. Accessed Aug 5, 2024. Available at URL address: https://www.cancer.gov/types/cervical/hp/cervical-prevention-pdq#link/_206

25. National Comprehensive Cancer Network® (NCCN). NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) Cervical Cancer version 3.2024. May 6, 2024. Accessed Aug 5, 2024. Available at URL address: https://www.nccn.org/professionals/physician_gls/pdf/cervical.pdf

26. Novikova T. Optical techniques for cervical neoplasia detection. Beilstein J Nanotechnol. 2017 Sep 6;8:1844-1862.

27. Parham [a] GP, Andrews NR, Lee ML. Comparison of immediate and deferred colposcopy in a cervical screening program. Obstet Gynecol. 2000 Mar;95(3):340-4.

28. Parham [b] GP. Comparison of cell collection and direct visualization cervical cancer screening adjuncts. Am J Obstet Gynecol. 2003 Mar;188(3 Suppl):S13-20.

29. Perkins RB, Guido RS, Castle PE, Chelmow D, Einstein MH, Garcia F, et al.; 2019 ASCCP Risk-Based Management Consensus Guidelines Committee. 2019 ASCCP Risk-Based Management Consensus Guidelines for Abnormal Cervical Cancer Screening Tests and Cancer Precursors. J Low Genit Tract Dis. 2020 Apr;24(2):102-131.

30. Ramos IR, Malkin A, Lyng FM. Current Advances in the Application of Raman Spectroscopy for Molecular Diagnosis of Cervical Cancer. Biomed Res Int. 2015;2015:561242.

31. Singhakum N, Laiwejpithaya S, Chaopotong P. Digital Cervicography by Simply Portable Device as an Alternative Test for Cervical Cancer Screening in Rural Area of Thailand. Asian Pac J Cancer Prev. 2018;19(4):1145-1149.

32. Smith RA, Cokkinides V, Brawley OW. Cancer screening in the United States, 2008: a review of current American Cancer Society guidelines and cancer screening issues. CA Cancer J Clin. 2008 May-Jun;58(3):161-79.

33. Song T, Seong SJ, Lee SK, et al. Screening capacity and cost-effectiveness of the human papillomavirus test versus cervicography as an adjunctive test to Pap cytology to detect high-grade cervical dysplasia. Eur J Obstet Gynecol Reprod Biol. 2019;234:112-116.

34. Twu N-F, Chen Y-J, Wang P-H, Yu BK-J, Lai C-R, Chao K-C, et al. Improved cervical cancer screening in premenopausal women by combination of Pap smear and speculoscopy. Eur J Obstet Gynecol Reprod Biol. 2007 Jul;133(1):114-8.

35. U.S. Food nd Drug Administration (FDA). 510(k) Premarket Notification: Speculite (K963391). December 1997. Accessed Aug 5, 2024. Available at URL address: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm?ID=k963391

36. U.S. Food and Drug Administration (FDA). Premarket approval LUMA™ Cervical Imaging System. March 2006. Accessed Aug 5, 2024. Available at URL address: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P040028

37. U.S. Preventive Services Task Force (USPSTF). Cervical Cancer: Screening. August 2018. Accessed Aug 5, 2024. Available at URL address: https://www.uspreventiveservicestaskforce.org/uspstf/recommendation/cervical-cancer-screening

38. Wang W, Zhao J, Short M, Zeng H. Real-time in vivo cancer diagnosis using raman spectroscopy. J Biophotonics. 2015 Jul;8(7):527-45.

39. Wertlake PT, Francus K, Newkirk GR, Parham GP. Effectiveness of the Papanicolaou smear and speculoscopy as compared with the Papanicolaou smear alone: a community-based clinical trial. Obstet Gynecol. 1997 Sep;90(3):421-7.

40. Wright TC Jr, Massad LS, Dunton CJ, Spitzer M, Wilkinson EJ, Solomon D; 2006 American Society for Colposcopy and Cervical Pathology-sponsored Consensus Conference. 2006 consensus guidelines for the management of women with abnormal cervical cancer screening tests. Am J Obstet Gynecol. 2007 Oct;197(4):346-55.

41. Wright TC, Denny L, Kuhn L, Goldie S. Use of visual screening methods for cervical cancer screening. Obstetrics and Gynecology Clinics. Dec 2002; Vol. 29(4).

42. Wright TC Jr. Chapter 10: Cervical cancer screening using visualization techniques. J Natl Cancer Inst Monogr. 2003;(31):66-71.

43. Yu BK, Kuo BI, Yen MS, Twu NF, Lai CR, Chen PJ, Chien PS, Chao KC, Yuan CC. Improved early detection of cervical intraepithelial lesions by combination of conventional Pap smear and speculoscopy. Eur J Gynaecol Oncol. 2003;24(6):495-9.

Revision Details

Type of Revision	Summary of Changes	Date
Annual review	• No clinical policy statement changes	9/15/2024