



# CIGNA MEDICAL COVERAGE POLICY

The following Coverage Policy applies to all plans administered by CIGNA Companies including plans administered by Great-West Healthcare, which is now a part of CIGNA.

**Subject Cervical Cancer Screening Technologies**

**Effective Date ..... 9/15/2010**  
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**Coverage Policy Number ..... 0127**

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## Hyperlink to Related Coverage Policies

Hysterectomy  
Quadrivalent Human Papillomavirus (Types 6, 11, 16, 18) Recombinant Vaccine - (Gardasil®)

### INSTRUCTIONS FOR USE

Coverage Policies are intended to provide guidance in interpreting certain **standard** CIGNA HealthCare benefit plans as well as benefit plans formerly administered by Great-West Healthcare. Please note, the terms of a participant's particular benefit plan document [Group Service Agreement (GSA), 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 participant'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 participant's benefit plan document **always supercedes** 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 group 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. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines. Proprietary information of CIGNA. Copyright ©2010 CIGNA

## Coverage Policy

Coverage for cervical cancer screening may be subject to the terms, conditions and limitations of a preventive services benefit as described in the applicable benefit plan's schedule of copayments. Please refer to the applicable benefit plan document and schedules to determine benefit availability and the terms, conditions and limitations of coverage.

If coverage for cervical cancer screening is available, the following conditions apply.

**CIGNA covers primary cervical cancer screening as medically necessary using the following techniques:**

- conventional Papanicolaou (Pap) smear
- liquid-based cytology
- human papillomavirus (HPV)-deoxyribonucleic acid (DNA) used in combination with conventional Pap smear or liquid-based cytology for women age 30 or older, every three years

**CIGNA does not cover primary cervical cancer screening using the following techniques because they are considered experimental, investigational or unproven:**

- cervicography
- spectroscopy/optical detection systems

- speculoscopy
- 

## General Background

There are numerous techniques that can be used for cervical cancer screening. Researchers and data from clinical trials have shown that there is a long preinvasive stage of cervical cancer; a relatively high prevalence of this disease exists in unscreened populations; and the sensitivity of cytologic screening makes cervical carcinoma an ideal target for cancer screening (Eifel, 2008). Some of these are stand-alone tests, and others are used in combination. The efficacy of these techniques varies and may be due to preparation of the cytology sample, insufficient cell sampling, and/or inaccurate interpretation. Several efforts have been taken to improve the efficacy of cervical slide preparation and interpretation, including the development of liquid-based cytology techniques and automated interpretation systems for use within laboratory settings. Medical and oncology textbooks recognize these modifications as potential methods of enhancing the gold standard Pap smear for cervical cancer screening (Abeloff, 2008; Eifel, 2008; Goroll, 2009).

**Pap Smear:** The Pap smear or Pap test was introduced in 1943 and remains 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, 2009). Case-control studies have found that the risk of developing invasive cervical cancer is three to ten times greater in women who have not been screened. In addition it is noted that the risk increases with long duration following the last normal Pap test (NCI-a, 2009). 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.

Thin-layer, liquid-based cytology provides the advantage of placing the cervical tissue sampling directly into a fluid medium, which contains cell-preserving transport fluid. This means of collection permits all of the cellular sampling to be preserved for testing instead of the 20% of cells that are smeared onto a glass slide during preparation of the conventional Pap smear. The greatest impact of these tests would be noticed with a screening interval of three years or longer. Liquid-based cytology permits testing for HPV that would be useful in guiding the management of women whose Pap tests also reveal atypical squamous cells.

To date, several liquid-based preparations have received premarket approval from the U.S. Food and Drug Administration (FDA), including but not limited to:

- ThinPrep<sup>®</sup> Pap Test (Cytec Corp., Boxborough, MA) which received approval in 1996. In 2002 FDA granted approval for including a panel that can detect the presence of chlamydia trachomatis.
- AutoCyte PREP<sup>™</sup> (BD, Franklin Lakes, NJ) was granted approval in 1999.
- Sure-Path<sup>®</sup> system (BD, Franklin Lakes, NJ) received approval in 1999

In 1996, according to the FDA, Cytec Corporation presented safety and efficacy results from a large-scale, masked, multicenter clinical trial. These results included a comparison of conventional cytology Pap testing to ThinPrep testing and showed sensitivity ratings of 73% versus 94% and specificity of 58% versus 76%. ThinPrep showed an 18% higher detection rate than conventional Pap smear, and AutoCyte PREP (an automated slide preparation system) yielded detection rates that were equivocal to conventional Pap smears. These studies did show sensitivity improved with the use of newer FDA-approved technologies such as liquid-based cytology (i.e., ThinPrep or SurePath) over conventional Pap testing, but the specificity of these tests did not improve results. The use of liquid-based cytology has become a standard of care within the armamentarium of screening protocols for cervical cancer, according to statements from professional and specialty medical organizations, published literature and textbooks (Eifel, 2008; Abeloff, 2008; Smith et al., 2008).

**Automated Screening Systems:** To further increase the sensitivity and specificity of the Pap test, the use of computerized, automated and algorithmic screening systems that can recognize abnormal cells in Pap smears has been developed. Examples of these systems include but are not limited to:

- FOCALPOINT™ System (BD, Franklin Lakes, NJ)
- PrepStain™ System (BD, Franklin Lakes, NJ)
- PAPNET® Testing System (Neuromedical Systems, Suffern, NY).

The users of these systems should be specially trained cyto-pathologists and operate under the direct supervision of a qualified cytology supervisor or laboratory manager/director. As the use of the liquid-based cytology and automated screening systems has been implemented, the sensitivity and specificity of the Pap smear has improved. Research has been conducted and textbooks now refer to the use of these techniques as part of routine screening for cervical cancer as a means to enhance the cytological efficacy of the conventional Pap smear. Screening programs and protocols that include these technologies have been developed in relation to age and risk factors for the early detection of cervical cancer.

**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], 2009f). 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.

In March 2003, the FDA granted premarket approval for expanded commercial use of the Hybrid Capture-II (HC-II) Microtitre assay (HC-II/ QIAGEN Inc., Valencia, CA). This assay uses signal amplification in cervical cellular samples to detect the five most frequent low-risk oncogenic HPV types and the 13 most frequent high-risk oncogenic HPV types. It then combines these findings with the patient's DNA and produces an enzyme-linked immunosorbent assay (ELISA) for each patient. The use of this device is approved for the following:

- To screen patients with atypical squamous cells of undetermined significance (ACUS) Pap smear results to determine the need for referral to colposcopy. The results of this test are not intended to prevent women from proceeding to colposcopy.
- In women 30 years and older, the HC2 High-Risk HPV DNA test to be used in conjunction with Pap test to screen for the presence or absence of high-risk HPV types. This information may be used to guide patient management.

In 2009, the FDA granted premarket approval for Cervista™ HPV HR and Cervista™ HPV 16/18 tests (Hologic, Inc, Madison, WI). Cervista HPV HR tests for the 13 types detected by the Hybrid Capture II HPV DNA test, as well as HPV 66. Cervista HPV 16/18 tests for HPV types 16 and 18, which is known to be associated with approximately 70% of all cervical cancers in the United States (American Society for Colposcopy and Cervical Pathology [ASCCP], 2009). Both tests utilize an isothermal enzymatic DNA amplification process with a fluorescent read out.

The Cervista HPV HR test has been approved for two uses:

- To screen patients with atypical squamous cells of undetermined significance (ASC-US) cervical cytology results to determine the need for referral to colposcopy.
- Used adjunctively with cervical cytology to screen women 30 years and older to assess the presence or absence of high-risk HPV types.

The indications for use of Cervista HPV 16/18 are:

- In women 30 years and older the test can be used adjunctively with the Cervista HPV HR test in combination with cervical cytology to screen to assess the presence or absence of high-risk HPV types 16 and 18
- To be used adjunctively with the Cervista HPV HR test in patients with atypical squamous cells of undetermined significance (ASC-US) cervical cytology results, to assess the presence or absence of high-risk HPV types 16 and 18.

Various strains of the HPV virus have been associated with the development of cervical cancer. Studies conducted to date have shown that the addition of HPV-DNA testing improves the specificity of cytological

detection of cervical changes that warrant additional investigation (Sankaranarayanan, et al., 2009; Cuzick, et al., 2006; Naucler, et al., 2007; Mayrand, et al., 2006; Ronco, et al., 2006; and Denny, et al., 2005).

Several professional, specialty, medical organizations, including the American College of Obstetricians and Gynecologists (ACOG, 2009); and the American Cancer Society (ACS, 2009f) support the use of HPV-DNA testing in conjunction with a liquid-based Pap smear. When both HPV and Pap results are negative, then it is recommended that rescreening occur every three years for women age 30 or older.

There is insufficient evidence in the published peer-reviewed literature to support the use of HPV-DNA testing alone as a primary screening test for the early detection of cervical cancer. Specific guidelines for its use have not been developed and the role of this testing when used alone as a screening tool has not been established.

### **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 because experts evaluate the cervical photographs they may be better able to identify cervical lesions and discriminate between high grade SIL (CIN 2,3) and more trivial lesions than the mid-level clinicians who perform direct visual inspection (Wright, et al., 2002).

**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).

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.

### **Spectroscopy/Optical Detection Systems**

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).

A spectroscopy system may be referred to as an optical detection system. The LUMA™ Cervical Imaging System (MediSpectra, Inc., Lexington, MA) 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. The approval requires a post approval, multi-center single-arm study (n=950) that is designed to address the relationship of the device performance to patient age, patient HPV status and colposcopist experience.

**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<sup>-1</sup>. 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% vs 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.

## **Speculoscopy**

The speculoscropy exam includes the same principle of applying acetic acid to the cervix and 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<sup>®</sup> was granted 401(k) approval from the FDA. PapSure combines the results of a traditional Pap smear and speculoscropy using Speculite, a disposable, chemiluminescent light for vaginal illumination. Both of these devices are manufactured by Watson Diagnostics, Corona, CA.

**Literature Review for Speculoscropy:** To evaluate the efficacy of Pap smear, speculoscropy, and the combination of Pap smear and speculoscropy (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, speculoscropy, and the first 40 patients each day received simultaneous colposcopic examinations. The remaining patients were referred for colposcopy if their Pap smear or speculoscropy revealed abnormal results. A positive Pap smear was defined as ASUS/AGUS or worse. Positive speculoscropy 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, speculoscropy 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. Speculoscropy 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 speculoscropy 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 speculoscropy exam alone was positive. Of the 800 women Parham screened, 124 had negative Pap smears but positive speculoscropy. 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 speculoscropy-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 speculoscropy readings. Individuals with positive Pap smear results that were read as low-grade SIL or ASCUS were not detected as having cervical neoplasia by speculoscropy alone, but required additional biopsies to confirm the presence of neoplasia. After six months, 29% (13 of 45) positive speculoscropy readings converted from positive to negative; these individuals would not have required a colposcopy.

**Summary of Cervicography, Speculoscopy and Spectroscopy/Optical Detection Systems:** Studies have failed to determine how the use of these techniques as stand-alone primary screening for cervical cancer would improve the detection rates within the general population. Improved detection rates of cervical cancer have also not occurred when these techniques have been used in combination with a Pap smear. Numerous questions remain as to patient selection, appropriate treatment protocols, as well as follow-up intervals or next steps when these tests provide a positive reading. As a result of the lack of evidence regarding improved patient outcomes, the use of these technologies remains unproven as primary cervical cancer screening modalities.

### **Professional Societies/Organizations**

**American Cancer Society (ACS, 2008a):** The ACS guidelines for cervical cancer screening were updated in 2008. These guidelines are still current and include the following recommendations (Smith, et al., 2008):

- Women should begin cervical cancer screening about three years after they begin vaginal intercourse, but no later than when they are 21 years old. Screening should be done every year with the regular Pap test or every two years using the newer liquid-based Pap test.
- Beginning at age 30, women who have had three normal Pap test results in a row may get screening every two to three years. Another reasonable option for women over 30 is to get screening every three years (but not more frequently) with either the conventional or liquid-based Pap test, plus HPV DNA test. Women who have certain risk factors such as diethylstilbestrol (DES) exposure before birth, HIV infection, or a weakened immune system due to organ transplant, chemotherapy, or chronic steroid use should continue to be screened annually.
- Women 70 years of age or older who have had three or more normal Pap tests in a row and no abnormal Pap test results in the last 10 years may choose to stop having cervical cancer screening. Women with a history of cervical cancer, DES exposure before birth, HIV infection or a weakened immune system should continue to have screening as long as they are in good health.
- Women who have had a total hysterectomy (removal of the uterus and cervix) may also choose to stop having cervical cancer screening, unless the surgery was done as a treatment for cervical cancer or precancer. Women who have had a hysterectomy without the removal of the cervix should continue to follow the guidelines above.

**American College of Obstetrics and Gynecologists (ACOG, 2009):** In 2009, ACOG published revised guidelines for cervical cytology screening. The guidelines include the following recommendations:

- Cervical cancer screening should begin at age 21.
- Cervical cytology screening is recommended every two years for women aged 21–29 years.
- Both conventional methods and liquid-based methods of cervical cytology are acceptable for screening.
- Women age 30 and older who have had three consecutive cervical cytology tests that are negative for intraepithelial lesions and malignancy may be screened every three years.
- Women with specific risk factors may require more frequent cervical cytology screening. These factors include:
  - infection with human immunodeficiency virus (HIV)
  - immunosuppressed (e.g., renal transplants)
  - exposed to diethylstilbestrol in utero
  - previously treated for cervical intraepithelial neoplasia (CIN) 2, CIN 3, or cancer
- In women who have had a total hysterectomy for benign indication and have no history of high-grade CIN, routine cytology should be discontinued.
- HPV testing may be used as an adjunct to cytology for primary screening in women older than 30 years.

**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.

**Cytopathology Education and Technology Consortium (CETC):** CETC published a statement regarding HPV DNA test utilization based in part on the decision aid developed by the American Society for Colposcopy and Cervical Pathology (ASCCP) and endorsed by several groups including American Cancer Society (ACS), American Society of Clinical Pathology, ASCP and College of American Pathologists (CAP) (Solomon, et al., 2009). The guidelines include the following recommendations for screening:

- High-risk HPV DNA testing is appropriate for routine cervical cancer screening in conjunction with cervical cytology (dual testing or cotesting) for women 30 years or older:
  - For women who are cytology negative but HPV-positive, repeat both tests in 12 months(HPV-16 positive and/or HPV-18 positive women 30 years or older are referred directly to colposcopy)
  - For women who are both cytology and HPV negative, repeat both tests only after a three-year interval.
- High-risk (oncogenic) HPV DNA testing is generally not appropriate in the following situations:
  - Routine cervical cancer screening in women younger than 30 years
  - Routine screening with HPV testing and cervical cytology more often than every three years for women 30 years or older whose tests were negative at the last screening.

**National Comprehensive Cancer Network (NCCN):** the NCCN have published guidelines (National Comprehensive Cancer Network Guidelines™ [NCCN Guidelines™]) including guidelines for cervical cancer screening. The NCCN panel adopted the recommendations of the ACS regarding the initiation and frequency of cervical cancer screening (NCCN, 2010).

**U.S. Preventive Services Task Force (USPSTF, 2003):** In 2003, the USPSTF published the following recommendations on screening for cervical cancer, based on the scientific evidence:

- Strongly recommends screening for cervical cancer in women who have been sexually active and have a cervix. Indirect evidence suggests most of the benefit can be obtained by beginning screening within three years of onset of sexual activity or age 21 (whichever comes first) and screening at least every three years. Direct evidence is limited to conclude an exact starting or stopping age or screening interval.
- Recommends against routinely screening women older than age 65 for cervical cancer if they have had adequate recent screening with normal Pap smears and are not otherwise at high risk for cervical cancer.
- Recommend against routine Pap smear screening in women who have had a total hysterectomy for benign disease.
- Evidence is insufficient to recommend for or against the routine use of new technologies to screen for cervical cancer.
- Evidence is insufficient to recommend for or against the routine use of human papillomavirus (HPV) testing as a primary screening test for cervical cancer.

### Summary

The clinical utility of early detection and the prevention of invasive cervical cancer have been demonstrated. The use of screening protocols; patient, public and provider education, as well as ongoing strategies to improve the efficiency of cervical cancer screening technologies, and primary prevention needs to continue. Sufficient evidence exists in the published, peer-reviewed scientific literature and medical textbooks to support cervical cancer screening using the following techniques: conventional Pap smear, liquid-based cytology and Human Papillomavirus Deoxyribonucleic Acid (HPV-DNA) in combination with cytology screening.

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 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 or their enhanced images using digital or video filming has not yet been established.

### Coding/Billing Information

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

**Covered when medically necessary:**

87620	Infectious agent detection by nucleic acid (DNA or RNA); papillomavirus, human, direct probe technique
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87621	Infectious agent detection by nucleic acid (DNA or RNA); papillomavirus, human, amplified probe technique
87622	Infectious agent detection by nucleic acid (DNA or RNA); papillomavirus, human, quantification
88141	Cytopathology, cervical or vaginal (any reporting system); requiring interpretation by physician
88142	Cytopathology, cervical or vaginal (any reporting system), collected in preservative fluid, automated thin layer preparation; manual screening under physician supervision
88143	Cytopathology, cervical or vaginal (any reporting system), collected in preservative fluid, automated thin layer preparation; with manual screening and rescreening under physician supervision
88147	Cytopathology smears, cervical or vaginal; screening by automated system under physician supervision
88148	Cytopathology smears, cervical or vaginal; screening by automated system with manual rescreening under physician supervision
88150	Cytopathology, slides, cervical or vaginal; manual screening under physician supervision
88152	Cytopathology, slides, cervical or vaginal; with manual screening and computer-assisted rescreening under physician supervision
88153	Cytopathology, slides, cervical or vaginal; with manual screening and rescreening under physician supervision
88154	Cytopathology, slides, cervical or vaginal; with manual screening and computer-assisted rescreening using cell selection and review under physician supervision
88164	Cytopathology, slides, cervical or vaginal (the Bethesda System); manual screening under physician supervision
88165	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, under physician supervision

<b>HCPCS Codes</b>	<b>Description</b>
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, cervical smears, cervical or vaginal, performed by automated system, with manual rescreening, requiring interpretation by physician
G0143	Screening cytopathology, cervical or vaginal (any reporting system), collected in preservative fluid, automated thin layer preparation; with manual screening and rescreening by cytotechnologist under physician supervision
G0144	Screening cytopathology, cervical or vaginal (any reporting system), collected in preservative fluid, automated thin layer preparation; with screening by automated system, under physician supervision

G0145	Screening cytopathology, cervical or vaginal (any reporting system), collected in preservative fluid, automated thin layer preparation; with screening by automated system and manual rescreening under physician supervision
G0147	Screening cytopathology smears, cervical or vaginal; performed by automated system under physician supervision
G0148	Screening cytopathology smears, cervical or vaginal; performed by automated system with manual rescreening
P3000	Screening Papanicolaou smear, cervical or vaginal, up to three smears; by technician under physical 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

ICD-9-CM Diagnosis Codes	Description
V73.81	Special screening examination for other specified viral and chlamydial diseases; Human papillomavirus (HPV)
V76.2	Special screening for malignant neoplasm; cervix

**Experimental/Investigational/Unproven/Not Covered:**

CPT* Codes	Description
58999 <sup>†</sup>	Unlisted procedure, female genital system (nonobstetrical)

<sup>†</sup>**Note:** Experimental/Investigational/Unproven/Not Covered when used to report cervicography, spectroscopy or speculscopy.

ICD-9-CM Diagnosis Codes	Description
	All codes

\*Current Procedural Terminology (CPT®) © 2010 American Medical Association: Chicago, IL.

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## Policy History

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<u>Pre-Merger Organizations</u>	<u>Last Review Date</u>	<u>Policy Number</u>	<u>Title</u>
CIGNA HealthCare	9/15/2008	0127	Cervical Cancer Screening Technologies
Great-West Healthcare	11/30/2007	98.250.05	Cervical Cancer Screening

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Connecticut General Life Insurance Company has acquired the business of Great-West Healthcare from Great-West Life & Annuity Insurance Company (GWLA). Certain products continue to be provided by GWLA (Life, Accident and Disability, and Excess Loss). GWLA is not licensed to do business in New York. In New York, these products are sold by GWLA’s subsidiary, First Great-West Life & Annuity Insurance Company, White Plains, N.Y.