MEDICAL POLICY

SUBJECT: CERVICAL CANCER SCREENING and HUMAN PAPILLOMA VIRUS (HPV) TESTING
POLICY NUMBER: 2.02.04
CATEGORY: Laboratory Test

EFFECTIVE DATE: 10/18/01
REVISED DATE: 10/25/01, 01/23/03, 02/26/04, 02/24/05, 04/27/06, 04/26/07, 04/24/08, 11/20/08, 05/28/09, 05/27/10, 05/19/11, 05/24/12, 05/23/13, 05/22/14, 05/28/15, 07/21/16

PAGE: 1 OF: 12

- If the member's subscriber contract excludes coverage for a specific service it is not covered under that contract. In such cases, medical policy criteria are not applied.
- Medical policies apply to commercial and Safety Net products only when a contract benefit for the specific service exists.

POLICY STATEMENT:

I. The Health Plan considers routine cervical cancer screening with FDA approved techniques (e.g., conventional Pap smear, liquid based cytology, cobas® HPV test) as **medically appropriate**.

II. Based upon our criteria and review of the peer-reviewed literature, cervical cancer screening with the combined use of cervical cytology testing and an FDA approved test for high-risk subtypes of human papillomavirus (HPV) is considered **medically appropriate** in women 30 years of age and older.
   A. Retesting with the combined cervical cytology and HPV tests need occur no more frequently than every three years when a women tests negative on both the cervical cytology and HPV test.
   B. If only one test is negative, screening will be necessary with cervical cytology more frequently than every three years.

III. Based upon our criteria and review of the peer-reviewed literature, human papillomavirus (HPV) testing of high-risk sub-types has been medically proven to be effective and therefore, **medically appropriate** for use in the triage of patients with *atypical squamous cells of undetermined significance* (ASCUS) on cervical screening.

IV. Based upon our criteria and review of the peer-reviewed literature, HPV screening is **not medically appropriate** for women under age 30 years since these women frequently test positive for HPV and have an effective immune response that will clear the infection or reduce the viral load to undetectable levels within two years of the initial infection.

V. Based upon our criteria and review of the peer-reviewed literature, HPV testing has not been proven to be effective and is therefore, **not medically necessary** in the routine triage of women with *low-grade squamous intraepithelial lesions* (LSIL) found through screening examinations (e.g., cervical cytology).

VI. Based upon our criteria and review of the peer-reviewed literature, PapSure® as an adjunct to cervical cancer screening has not been medically proven to be more effective in improving net health outcomes than standard testing and is, therefore, considered **not medically necessary**.

POLICY GUIDELINES:

I. While our review of scientific evidence concludes that use of liquid based monolayer technology at least every three years is sufficient given the sensitivity, specificity, and cost-effectiveness of this technology; coverage will be provided at a frequency determined by the practitioner and member following informed discussions and shared decision-making.

II. Since the utilization of the automated slide reading systems (e.g., FocalPoint™, ThinPrep® Imaging system, MonoPrep LBP processor) have not been proven to have a significantly greater sensitivity than the manual reading of specimens, the benefit for the use of these systems will generally be provided at the same level as that for manual reading of the specimen.
DESCRIPTION:

Cervical cancer is the leading cause of cancer mortality in women worldwide. The Papanicolaou (Pap) smear was introduced in the 1940’s as a method of preventing invasive cervical cancer and has been credited with reducing the incidence of cervical carcinoma by 74% since its introduction.

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

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

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

HPV is a common sexually transmitted disease that has an established causal link in the development of cervical cancer. The relationship between certain types of HPV and the development of cervical cancer is well established. There are more than 100 types of HPV, approximately 30 of which are prevalent in the cervix. Of these, some types (6, 11, 30, 34, 42, 43, 44, 49, 53, 54, 61, 64, and 69) make up the low- or no-oncogenic risk group because they are very unlikely to be associated with cervical cancer. Other types, referred to as high risk HPV sub-types, make up the intermediate and high-risk group (16, 18, 31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 66, 68, and 73) because they are associated with low-grade squamous intrathelial lesions, high-grade intrathelial lesions, and invasive cancers. Of the high-risk types, HPV 16 and 18 are the most carcinogenic and the most prevalent.

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

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

I. The ThinPrep Imaging System®, by Cytyc, is designed to be used with ThinPrep® monolayer slide preparations. The system, according to FDA labeling, is indicated for assisting in primary cervical cancer screening of ThinPrep® Pap test slides for the presence of cervical neoplasia, including its precursor lesions. The ThinPrep® Imaging System highlights areas for focused screening by cytotechnologists.

II. FocalPoint™ (formerly called AutoPap), by TriPath Imaging, is approved by the FDA for primary screening and rescreening of Pap smears. The system reads each slide and identifies slides without abnormalities that do not require manual reading, slides that should be manually read, and slides that should have a second manual reading. The system is not intended to be used on slides from patients designated as high risk.

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

According to New York State Law, every policy that provides hospital, surgical or medical care coverage or provides reimbursement for laboratory tests or diagnostic x-rays shall provide annual cervical cytology screening for cervical cancer and its precursor states for women aged 18 and older. Cervical cytology screening includes an annual pelvic examination, collection and preparation of a Pap smear, and laboratory and diagnostic services provided in connection with examining and evaluating the Pap smear.

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

Cervical cancer screening is an important part of preventive health care and is supported by the Health Plan. Refer to our Preventive Health Guidelines for specific recommendations. Guidelines are located on our website at: https://www.univerahealthcare.com/wps/portal/uv/prv/pc/hpp/guidelines.

**RATIONAL:**

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

**Cervical Cytology Screening**

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

I. screening for cervical cancer in women age 21 to 65 years with cytology (Pap smear) every 3 years or, for women age 30 to 65 years who want to lengthen the screening interval, screening with a combination of cytology and human papillomavirus (HPV) testing every 5 years.

II. against screening for cervical cancer in women younger than age 21 years.

III. against screening for cervical cancer in women older than age 65 years who have had adequate prior screening and are not otherwise at high risk for cervical cancer.

IV. against screening for cervical cancer in women who have had a hysterectomy with removal of the cervix and who do not have a history of a high-grade precancerous lesion (CIN grade 2 or 3) or cervical cancer.

V. against screening for cervical cancer with HPV testing, alone or in combination with cytology, in women younger than age 30 years.
The updated November 2012 practice bulletin of the American College of Obstetricians and Gynecologists (ACOG) addressing cervical cytology screening states:

I. The following recommendations are based on good and consistent scientific evidence (Level A):
   A. Cervical cancer screening should begin at age 21 years regardless of the age of sexual initiation or the presence of other behavior-related risk factors. Women younger than age 21 years should not be screened regardless of the age of sexual initiation or the presence of other behavior-related risk factors.
   B. Women aged 21–29 years should be tested with cervical cytology alone, and screening should be performed every 3 years. Co-testing should not be performed in women younger than 30 years.
   C. For women aged 30–65 years, co-testing with cytology and HPV testing every 5 years is preferred.
   D. In women aged 30–65 years, screening with cytology alone every 3 years is acceptable. Annual screening should not be performed.
   E. 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.
   F. Both liquid-based and conventional methods of cervical cytology collection are acceptable for screening.
   G. In women who have had a hysterectomy with removal of the cervix (total hysterectomy) and have never had CIN 2 or higher, routine cytology screening and HPV testing should be discontinued and not restarted for any reason.
   H. Screening by any modality should be discontinued after age 65 years in women with evidence of adequate negative prior screening results and no history of CIN 2 or higher. Adequate negative prior screening results are defined as three consecutive negative cytology results or two consecutive negative co-test results within the previous 10 years, with the most recent test performed within the past 5 years.

II. The following recommendations are based on limited and inconsistent scientific evidence (Level B):
   A. Women with ASCUS 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.
   B. 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.
   C. 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 3 years for 20 years after the initial post-treatment surveillance period seems reasonable for women with a hysterectomy.
   D. 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:
      1. Repeat co-testing in 12 months. If the repeat cervical cytology test result is 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.
      2. 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 contested in 12 months, with management of results as described.

III. The following recommendations are based primarily on consensus and expert opinion (Level C):
   A. Women who have received the HPV vaccine should be screened according to the same guidelines as women who have not been vaccinated.

A guideline addressing cervical cancer screening that was published by the American Cancer Society (ACS), the American Society for Colposcopy and Cervical Pathology (ASCCP), and the American Society for Clinical Pathology (ASCP) in 2012 is similar to the ACOG recommendations. The National Comprehensive Cancer Network (NCCN) Guidelines Panel for Cervical Cancer Screening endorses this guideline and discontinued their guideline in July 2013 in order to avoid duplication of effort (2014).
In March 2013, the National Guideline Clearinghouse published a guideline synthesis of the recommendations published by ACOG, the ACS/ASCCP/ASCP, and the USPSTF addressing cervical cancer screening for women at average risk and found no significant areas of difference between the recommendations.

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

Human Papillomavirus (HPV) Testing

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

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

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

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

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

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

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

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

The 2012 National Comprehensive Cancer Network’s guideline addressing cervical cancer screening states HPV DNA testing is not recommended as routine screening in women younger than 30 years and for women 30-65 years of age screening by HPV testing alone is not recommended in most clinical settings.

The 2014 guidelines of the American Cancer Society for the early detection of cancer state women between the ages of 30 and 65 should have a Pap test plus an HPV test every 5 years, however a Pap test may be performed alone every 3 years, and HPV testing should not be used in those women ages 21 through 29 years unless it is needed after an abnormal Pap test result.
On April 24, 2014 the FDA approved the first HPV DNA test for women age 25 years and older that can be used alone to help a health care professional assess the need for a woman to undergo additional diagnostic testing for cervical cancer. Using a sample of cervical cells, the cobas® HPV Test detects DNA from 14 high-risk HPV types. The test specifically identifies HPV 16 and HPV 18, while concurrently detecting 12 other types of high-risk HPVs (31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 66 and 68). Based on results of the cobas® HPV test, women who test positive for HPV 16 or HPV 18 should have a colposcopy and women testing positive for one or more of the 12 other high-risk HPV types should have a Pap test to determine the need for a colposcopy. The FDA states health care professionals should use the cobas® HPV Test results together with other information, such as the patient screening history and risk factors, and current professional guidelines. The approval of the cobas® HPV DNA test did not change the recommendations of any current practice guidelines for cervical cancer screening.

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

Speculoscopy (e.g., PapSure®)

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

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

Other techniques

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

CODES: Number Description

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

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

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

CPT: 87623 Infectious agent detection by nucleic acid (DNA or RNA); Human Papillomavirus (HPV), low-risk types (eg, 6, 11, 42, 43, 44)

87624 Infectious agent detection by nucleic acid (DNA or RNA); Human Papillomavirus (HPV), high-risk types (eg, 16, 18, 31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 68)

87625 Infectious agent detection by nucleic acid (DNA or RNA); Human Papillomavirus (HPV), types 16 and 18 only, includes type 45, if performed

88141 Cytopathology, cervical or vaginal (any reporting system); requiring interpretation by physician

88142 Cytopathology, cervical or vaginal, (any reporting system), collected in preservative fluid, automated thin layer preparation; manual screening under physician supervision

88143 with manual screening and rescreening under physician supervision

88147 Cytopathology smears, cervical or vaginal; screening by automated system under physician supervision
<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>88148</td>
<td>Screening by automated system with manual rescreening under physician supervision</td>
</tr>
<tr>
<td>88150</td>
<td>Cytopathology, slides, cervical or vaginal; manual screening under physician supervision</td>
</tr>
<tr>
<td>88152</td>
<td>with manual screening and computer-assisted rescreening under physician supervision</td>
</tr>
<tr>
<td>88153</td>
<td>with manual screening and rescreening under physician supervision</td>
</tr>
<tr>
<td>88154</td>
<td>with manual screening and computer-assisted rescreening using cell selection and review under physician supervision</td>
</tr>
<tr>
<td>88164</td>
<td>Cytopathology, slides, cervical or vaginal (the Bethesda system); manual screening under physician supervision;</td>
</tr>
<tr>
<td>88165</td>
<td>with manual screening and rescreening under physician supervision</td>
</tr>
<tr>
<td>88166</td>
<td>with manual screening and computer-assisted rescreening under physician supervision</td>
</tr>
<tr>
<td>88167</td>
<td>with manual screening and computer-assisted rescreening using cell selection and review under physician supervision</td>
</tr>
<tr>
<td>88174</td>
<td>Cytopathology, cervical or vaginal (any reporting system), collected in preservative fluid, automated thin layer preparation; screening by automated system, under physician supervision</td>
</tr>
<tr>
<td>88175</td>
<td>with screening by automated system and manual rescreening or review, under physician supervision</td>
</tr>
</tbody>
</table>

**HCPCS:**

- **G0101** Cervical or vaginal cancer screening; pelvic and clinical breast examination
- **G0123** Screening cytopathology, cervical or vaginal (any reporting system), collected in preservative fluid, automated thin layer preparation, screening by cytotechnologist under physician supervision
- **G0124** Screening cytopathology, cervical or vaginal (any reporting system) collected in preservative fluid, automated thin layer preparation, requiring interpretation by physician
- **G0141** Screening cytopathology smears, cervical or vaginal, performed by automated system, with manual rescreening, requiring interpretation by physician
- **G0143** Screening cytopathology, cervical or vaginal (any reporting system), collected in preservative fluid, automated thin layer preparation; with manual screening and rescreening by cytotechnologist under physician supervision
- **G0144** Screening cytopathology, cervical or vaginal (any reporting system), collected in preservative fluid, automated thin layer preparation; with screening by automated system, under physician supervision
- **G0145** Screening cytopathology, cervical or vaginal (any reporting system), collected in preservative fluid, automated thin layer preparation; with screening by automated system and manual rescreening under physician supervision
- **G0147** Screening cytopathology smears, cervical or vaginal; performed by automated system
under physician supervision

G0148 Screening cytopathology smears, cervical or vaginal; performed by automated system with manual rescreening

P3000 Screening Papanicolaou smear, cervical or vaginal, up to three smears, by technician under physician supervision

P3001 Screening Papanicolaou smear, cervical or vaginal, up to three smears, requiring interpretation by physician

Q0091 Screening Papanicolaou smear; obtaining preparing and conveyance of cervical or vaginal smear to laboratory

ICD9:
079.4 Human papillomavirus
180.0-180.9 Malignant neoplasm of cervix uteri (code range)
198.82 Secondary malignant neoplasm of genital organs
233.1 Severe dysplasia of cervix (CIN III)
236.0 Neoplasm of uncertain behavior of uterus
239.5 Neoplasms of unspecified nature of other genitourinary organs
622.10-622.12 Dysplasia of cervix (uteri) (code range)
795.0-795.09 Abnormal Papanicolaou smear of cervix and cervical HPV (code range)
795.1-795.19 Abnormal Papanicolaou smear of vagina and vaginal HPV (code range)

ICD10:
B97.7 Papillomavirus as the cause of diseases classified elsewhere
C53.0-C53.9 Malignant neoplasm of cervix uteri (code range)
C79.82 Secondary malignant neoplasm of genital organs
D06.0-D06.9 Carcinoma in situ of cervix (code range)
D39.0 Neoplasm of uncertain behavior of uterus
D49.5 Neoplasm of unspecified behavior of other genitourinary organs
N87.0-N87.9 Dysplasia of cervix uteri (code range)
R87.610-R87.619 Abnormal cytological findings in specimens from cervix uteri (code range)
R87.620-R87.628 Abnormal cytological findings on specimens from vagina (code range)
R87.810-R87.811 High risk human papillomavirus [HPV] DNA test positive from female genital organs (code range)
R87.820-R87.821 High risk human papillomavirus [HPV] DNA test positive from female genital organs (code range)

REFERENCES:


Proprietary Information of YourCare Health Plan
<table>
<thead>
<tr>
<th>SUBJECT: CERVICAL CANCER SCREENING and HUMAN PAPILLOMA VIRUS (HPV) TESTING</th>
<th>EFFECTIVE DATE: 10/18/01</th>
</tr>
</thead>
<tbody>
<tr>
<td>POLICY NUMBER: 2.02.04</td>
<td>REVISED DATE: 10/25/01, 01/23/03, 02/26/04, 02/24/05, 04/27/06, 04/26/07, 04/24/08, 11/20/08, 05/28/09, 05/27/10, 05/19/11, 05/24/12, 05/23/13, 05/22/14, 05/28/15, 07/21/16</td>
</tr>
<tr>
<td>CATEGORY: Laboratory Test</td>
<td></td>
</tr>
</tbody>
</table>


Malila N, et al. The HPV test has similar sensitivity but more overdiagnosis than the Pap test--a randomised health services study on cervical cancer screening in Finland. *Int J Cancer* 2013 May 1;132(9):2141-7.


New York State Consolidated Laws § 3216 (15) (A) and (B).


**KEY WORDS:**

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