
Medical Policy



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***Current Policy Effective Date: 11/1/12**
(See policy history boxes for previous effective dates)

Title: Cervical Cancer Screening Technologies with Pap and HPV

Description/Background

Data suggest that cytologic screening for cervical cancer reduces the incidence of cervical cancer by up to 50 percent. Several technologies have been investigated for their role in detecting cancerous and precancerous cervical lesions.

Background

It is estimated that there will be 12,200 new cases, and 4,210 deaths from cervical cancer in the United States in 2010. The high prevalence and natural history of cervical cancer, as well as the ability to cure patients in pre-invasive stages, create ideal conditions for widespread screening. Cytologic screening, through the sampling of cells of the cervix, has been the gold standard since the introduction of the Papanicolaou (Pap) smear in the 1940s. The Pap smear involves sampling cells of the transformation zone of the cervix, the area most prone to malignant transformation.

False-negative Pap smears are troubling, because a patient with undetected pre-invasive cancer may progress to invasive disease before she undergoes another Pap test, particularly if the patient does not undergo regular Pap smear screening. Pap smear cytology is associated with a false-negative results, ranging from 15 percent to 55 percent. False-negative results may be explained by various factors, including sampling errors, errors in slide preparation, and errors in slide interpretation. Different approaches to reducing the false-negative rate have targeted each step in the process. This policy addresses the technologies that attempt to improve the accurate detection of cervical abnormalities.

Appreciation of the causative effect of human papilloma virus (HPV) infection in most cervical cancers has led to the development of screening techniques for the presence of certain high-risk HPV strains in an attempt to improve the specificity of traditional Pap smears. The Bethesda classification system assigns a degree of atypia to cells seen on Pap smear;

however, a biopsy is necessary to gain information on the tissue structure, or histology, of lesions. The correlation between cytologic grade and histologic grade, and the natural history of cervical cancer, has been an area of rapidly evolving understanding. While HPV infection has been associated with the development of cervical cancer, many infections are cleared spontaneously, and low-grade lesions may regress or disappear, particularly in younger women.

Regulatory Status:

Several liquid-based preparations have received pre-market approval from the U.S. Food and Drug Administration (FDA). For example, in May 1996, “ThinPrep® Pap Test” (Hologic, Bedford, MA) was approved by the FDA through the pre-market approval process for use in collecting and preparing cervical cytology specimens for Pap stain-based screening for cervical cancer.

Several automated screening systems have received pre-market approval through the FDA. For example, in September 1995, “AutoPap® Automatic Pap Screener, now FocalPoint™” (BD Diagnostics, Franklin Lakes, NJ) was approved by the FDA through the pre-market approval process for use in initial screening of cervical cytology slides. This device is intended to be used on both conventionally prepared and prep-stain system cervical cytology slides.

In March 2003, test kit “digene® HPV test” (Qiagen Inc, Valencia, CA) was approved by the FDA through the pre-market approval process for use in diagnostic testing for the qualitative detection of DNA from 13 high-risk human papillomavirus types (16, 18, 31, 33, 35, 39, 45, 51, 52, 56, 58, 59, and 68) in cervical specimens. In March of 2009, the test kit “Cervista® HPV HR” (Hologic, Bedford, MA) was approved by the FDA through the pre-market approval process for use in diagnostic testing for the qualitative detection of DNA from 14 high-risk human papillomavirus types (16, 18, 31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 66, and 68) in cervical specimens.

Medical Policy Statement

The safety and effectiveness of cervical cancer screening technologies with Pap and HPV have been established.

Inclusionary and Exclusionary Guidelines (Clinically based guidelines that may support individual consideration and pre-authorization decisions)

Cervical cytology (conventional or automated) screening with PAP is recommended:

- Every two years for women age 21-29 years of age
- Every three years for women over age 30 who have had three consecutive negative cervical cytology tests
- Women infected with HIV:
 - Twice in the first year after diagnosis
 - Annually thereafter

- Annual screening for women who have been treated for CIN2 and CIN3 or cancer for at least 20 years following treatment
- Every one to two years:
 - In women who are immunosuppressed (eg. renal transplant)
 - Women who were exposed to diethylstilbestrol in utero

Cervical cytology screening can be discontinued:

- Women 70 years of age with three or more consecutive negative cervical cytology tests
- Women who have undergone hysterectomy for benign indications and no prior history of high-grade cervical intraepithelial neoplasia

HPV Testing with PAP is recommended:

- Women over age 30 for cervical abnormalities
- Women over age 30 with prior positive HPV tests
- Women with atypical cells of undetermined significance

Exclusion:

Automated Slide reading systems are not recommended for women who are at high risk (eg. Prior treatment for CIN2, CIN3 or cervical cancer, etc.)

CPT/HCPCS Level II Codes *(Note: The inclusion of a code in this list is not a guarantee of coverage. Please refer to the medical policy statement to determine the status of a given procedure)*

Established codes:

| | | | | | |
|-------|-------|-------|-------|-------|-------|
| 87620 | 87621 | 87622 | 88141 | 88142 | 88143 |
| 88147 | 88148 | 88150 | 88152 | 88153 | 88154 |
| 88155 | 88164 | 88165 | 88166 | 88167 | 88174 |
| 88175 | | | | | |

Other codes (investigational, not medically necessary, etc.):

N/A

Rationale

Monolayer slide preparation/Liquid-based cytology

Initial literature focused on the goal of improved sensitivity of liquid based cytology when compared to conventional cytology. In 2008, Arbyn and colleagues produced a systematic review and meta-analysis of studies published between 1991 and 2007, comparing conventional and liquid-based cytology in patients who subsequently had histologic biopsy, including one randomized controlled trial (RCT). Of the remaining eight studies, seven were concomitant testing (samples for both methods taken at the same time from the same subject) with blinding of the identities of each sample. For the concomitant studies, sensitivity and specificity could be calculated from pooled data. Data were analyzed from three cutoff points for the decision to proceed to biopsy: high- and low-grade squamous intraepithelial lesions (HSIL, LSIL) and atypical squamous cells of undetermined significance (ASCUS). For the first

two cut-off levels, liquid-based and conventional Pap smears performed similarly. However, when ASCUS was used as the cut-off to further testing (biopsy), liquid-based Pap showed a lower specificity compared to conventional Pap (ratio: 0.91, 95 percent confidence interval [CI]: 0.84-0.98). Specificity at that level was 64.6 percent compared to 71.3 percent for conventional cytology. Lower specificity leads to a larger number of false-positive samples. An accompanying editorial asserts that this increase in false-positives is unlikely to be off-set by any advantage gained in the ability to perform HPV testing on the same sample.

In 2009, Siebers and colleagues published an RCT comparing the effectiveness of liquid-based cytology to conventional Pap smear in the detection of histologic abnormalities. (3) In this Dutch study, 89,784 women were assigned to conventional or liquid-based cytology screening, based on the cluster randomization of 246 participating family physician practices (the unit of randomization). Women with baseline cytologic abnormalities were prospectively followed, and repeat cytology or biopsy was completed within the 18-month study period. The cytology specimens were obtained in the same manner as the initial sample. Cytopathologists and histopathologists who interpreted the follow-up samples were blinded to initial Pap result. The positive predictive values (PPV) of the paired results were analyzed under 3 cut-off scenarios of initial cytopathology: ASCUS or worse, LSIL or worse, and HSIL or worse. The ratios of the positive predictive values (PPVs) of the two methodologies approached unity at all cutoff values. At the ASCUS cutoff and at 95% CI, no significant differences between the 2 methodologies were observed (PPV ratio 0.97, 95% CI: 0.81-1.18).

Automated Slide Reading Systems

This policy is based in part on a 1998 TEC Assessment that focused on monolayer slide preparation and automated slide reading systems. Automated screening of the Papanicolaou (Pap) smear was only evaluated for re-screening in the original TEC Assessment, as there was no FDA approval for initial automated screening at that time. Subsequently, the FocalPoint™ and ThinPrep® systems were approved for automated initial screening. Both monolayer and automated re-screening technologies were found to increase the sensitivity of an individual Pap smear and thus are considered medically necessary based on this limited outcome.

In 1999, and again in 2002, Wilbur and colleagues published performance data of the FocalPoint™ system to traditional manual reading and re-screening. Over 25,000 slides were analyzed in the study. Depending on the cutoff used to determine a positive slide, reading assisted by FocalPoint™ was between four percent and seven percent more sensitive than traditional manual reading. FocalPoint™-assisted reading was also one percent more specific than traditional manual reading in identifying normal slides. Studies of the ThinPrep® imaging system have shown diagnostic performance equivalent or better than manual reading.

HPV Testing

Regarding HPV testing, data from the ASCUS-LSIL Triage Study (ALTS) showed that triage of smears with atypical squamous cells of unknown significance (ASCUS) using HPV testing for triage to immediate colposcopy was more sensitive and equally specific in identifying cervical intraepithelial neoplasia grade III (CIN 3) as repeat Pap smear using ASCUS as the threshold for colposcopy referral. Based primarily on the results of this trial, 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 smear

results. HPV testing can be performed on the remaining liquid media used as part of the preparation of monolayer slides. Otherwise, if the original Pap smear was prepared conventionally, HPV testing would require an additional office visit to perform an additional Pap smear.

In March 2003, the FDA approved HPV testing, in conjunction with Pap smear screening, for primary screening of women older than age 30. Both the American Cancer Society and the American College of Obstetricians and Gynecologists (ACOG) have endorsed combined screening in women older than age 30, under the condition that, among women who test negative for both tests, screening should not be repeated for three years. It was not clear how women with negative Pap smears and positive HPV tests should be managed. However, the U.S. Preventive Services Task Force (USPSTF), in its 2003 report on screening for cervical cancer, found insufficient evidence to recommend for or against the routine use of HPV testing. As of September 2010, these recommendations are under review by the USPSTF. The basis for the recommendations in support of HPV screening is a consensus of a large body of evidence demonstrating that HPV infection is a strong etiologic factor for cervical abnormalities. However, in women younger than age 30 years, infection is often transient and nonspecific. Thus, screening women in this age group with HPV would be inefficient. However, the absence of HPV infection in conjunction with a normal Pap smear has an extremely high negative predictive value and identifies a group of women at low risk for cervical abnormalities. Screening intervals in these women who are older than age 30 can be safely extended to three years. HPV screening is not recommended for women younger than age 30 because infections are most likely to be transient in this group.

Regarding HPV testing, a later ACOG Practice Bulletin recommended that both tests (HPV and cervical cytology) be repeated at six to 12 months, and a persistently positive HPV test should be followed up with colposcopy regardless of cytology results. Recent practice guidelines reiterate but do not change the recommendations for HPV testing. A consensus document sponsored by the American Society for Colposcopy reiterates the use of HPV to follow-up abnormal Pap smears and the use of HPV in combination with Pap smears to screen women older than age 30; HPV testing for women younger than age 20 was discouraged. This document suggests that follow-up with repeat cytology and HPV testing at 12 months is the best management approach for cytology-negative, HPV-positive women. Women who on repeat testing are persistently HPV-positive should undergo colposcopy, whereas women who are negative on HPV and cytology can be re-screened in three years.

Summary

The evidence regarding the use of liquid-based cytological screening methods for cervical cancer demonstrates similar sensitivity to conventional cytology, possibly at the expense of specificity. The liquid-based system may add to the convenience of subsequent HPV testing, and in some locations, alternatives are not supported by pathology laboratories. Evidence firmly supports the use of HPV testing for both initial screening in women older than age 30 and in triage of ASCUS results for all women. The use of automated slide reading systems is supported by a small body of evidence that the systems may increase sensitivity.

Technology Assessments, Guidelines, and Position Statements

In August 2009, the American College of Obstetricians and Gynecologists published a practice bulletin on cervical cytology screening. A systematic review of the MEDLINE database for the period of June 1985 to July 2009 was described and graded recommendations provided.

However, details of the strength of evidence and quality of included studies were not provided. Level A recommendations (good and consistent evidence) were:

- Cervical cancer screening should begin at 21 years, and avoided prior.
- Cervical cancer screening is recommended every two years for women between the ages of 21 and 29 years.
- Screening interval may be increased to every three years in women 30 years and older who have had three consecutive negative pap smears and no history of Cervical Intraepithelial Neoplasia (CIN) grade II or III, immunosuppression or HIV, and who have not been exposed to diethylstilbestrol in utero.
- Both liquid-based and conventional methods of cervical cytology are acceptable.
- Cervical screening should be discontinued in women after total hysterectomy for benign indications (non-cancerous).

Co-testing cytology with HPV DNA testing is an acceptable strategy in women over 30 years. Patients testing negative for both should not be re-screened for three years.

Government Regulations

National:

National Coverage Determination (NCD) for SCREENING PAP Smears and Pelvic Examinations for Early Detection of Cervical or Vaginal Cancer (210.2), original effective date 6/19/2006.

A screening pap smear and related medically necessary services provided to a woman for the early detection of cervical cancer (including collection of the sample of cells and a physician's interpretation of the test results) and pelvic examination (including clinical breast examination) are covered under Medicare Part B when ordered by a physician (or authorized practitioner) under one of the following conditions:

- She has not had such a test during the preceding two years or is a woman of childbearing age (§1861(nn) of the Act).
- There is evidence (on the basis of her medical history or other findings) that she is at high risk of developing cervical cancer and her physician (or authorized practitioner) recommends that she have the test performed more frequently than every two years.

High risk factors for cervical and vaginal cancer are:

- Early onset of sexual activity (under 16 years of age).
- Multiple sexual partners (five or more in a lifetime).
- History of sexually transmitted disease (including HIV infection).
- Fewer than three negative or any pap smears within the previous 7 years.; and
- DES (diethylstilbestrol) - exposed daughters of women who took DES during pregnancy.

National Coverage Determination (NCD) for DIAGNOSTIC PAP Smears (190.2), original effective date 6/19/2006.

A diagnostic pap smear and related medically necessary services are covered under Medicare Part B when ordered by a physician under one of the following conditions:

- Previous cancer of the cervix, uterus, or vagina that has been or is presently being treated;
- Previous abnormal pap smear;
- Any abnormal findings of the vagina, cervix, uterus, ovaries, or adnexa;
- Any significant complaint by the patient referable to the female reproductive system; or
- Any signs or symptoms that might in the physician's judgment reasonably be related to a gynecologic disorder.

Local:

WPS LCD - L31080 - Diagnostic Pap Tests, Original effective date 11/15/2010, Revision date 02/21/2011.

Indications and Limitations of Coverage and/or Medical Necessity:

The Pap test (sometimes called a Pap smear but more correctly called cervicovaginal cytology) is a way to examine cells collected from the cervix and vagina. This test can show the presence of infection, inflammation, abnormal cells, or cancer.

Indications:

A diagnostic Pap test and related medically necessary services are covered under Medicare Part B when ordered by a physician under one of the following conditions:

- Previous cancer of the cervix, uterus, or vagina that has been or is presently being treated
- Previous abnormal pap test
- Any abnormal physical findings of the vagina, cervix, uterus, ovaries, or adnexa; Any significant complaint by the patient referable to the female reproductive system
- Any signs or symptoms that might in the physician's judgment reasonably be related to a gynecologic disorder
- Previous cervical biopsies performed for abnormality, suspected precancerous or cancerous condition
- Previous hysterectomy for cervical abnormality
- Previous HPV positive screening test in the last year

Limitations:

Cervical and vaginal cytology do not require interpretation by a physician (usually a pathologist) unless the results are, or appear to be, abnormal. In such cases, a physician personally conducts a separate microscopic evaluation to determine the nature of an abnormality. Separate payment is allowed under the physician fee schedule for patients in any setting if the laboratory's screening personnel suspect an abnormality and the physician reviews and interprets the Pap smear. This physician service should be reported using code 88141.

Cyto-hormonal study (88155) is not intended for use as a routine service. Cyto-hormonal study (88155) is not recommended although it has been cited as helpful in the evaluation of certain kinds of endocrine abnormalities (e.g., infertility, failure to ovulate, possible abnormal sexual development.) The specimen is performed on the lateral vaginal wall and NOT as a cervico-vaginal sample. Only claims submitted for conditions such as this should be coded as 88155.

Types of Technology:

Conventional Pap smear (88150, 88153, 88164 or 88165). This is the traditional method where the care provider obtains a specimen from the cervix and/or vagina, smears it directly on a slide and then immediately fixes the specimen (spray or immersion) immediately in the office. The slide(s) is sent to the cytology laboratory, where it is processed and stained and subsequently screened by a cytotechnologist. If necessary, it is then interpreted by a pathologist (88141). The laboratory reporting format is either The Bethesda System (88164 or 88165) or any other descriptive system (88150 or 88153).

Liquid-based cervicovaginal cytology (thin layer preparation) (88142 or 88143). This is an alternative to the conventional Pap smear. The care provider obtains a specimen from the cervix and/or vagina, then immediately transfers it to a container of proprietary fixative. The container is sent to the cytology laboratory, where an instrument is used to produce a concentrated thin layer cell preparation. The preparation is then stained and subsequently screened by a cytotechnologist. If necessary, it is then interpreted by a pathologist (88141). The preferred reporting format is The Bethesda System, but any descriptive reporting system may be used (88141 or 88143). The diagnostic advantages are that some obscuring factors (blood, mucus, inflammatory cells) are removed and cells of interest are evenly dispersed in an easier to view circumscribed monolayer.

Computer-assisted screening or re-screening: (88147, 88148, 88152, 88154, 88166, 88167, 88174 or 88175). These procedures are performed in the cytology laboratory using either type of specimen above. Stained slides are read on a special microscope linked to a computer with image analysis software. Various systems are in use either for initial screening of slides (88147, 88148, 88174 or 88175) or for re-screening of cases negative for intraepithelial lesion or malignancy on initial review (88152, 88154, 88166, 88167).

Michigan Department of Community Health:

Medicaid follows the Medicare guidelines.

(The above Medicare information is current as of the review date for this policy. However, the coverage issues and policies maintained by the Centers for Medicare & Medicare Services [CMS, formerly HCFA] are updated and/or revised periodically. Therefore, the most current CMS information may not be contained in this document. For the most current information, the reader should contact an official Medicare source.)

Related Policies

Human Papillomavirus (HPV) Vaccine for Males

References

- ACOG Practice Bulletin No.109, "Cervical cytology screening," *Obstetrics and Gynecology*, 2009, Vol. 114, No. 6, pp. 1409-1420.
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- *National Government Services*, "Human Papillomavirus (HPV) Testing," *National Government Services Local Coverage Determination*, L29508, Michigan effective date 07/01/2009, most recent Michigan revision date 04/01/2011, <[http://www.cms.gov/medicare-coverage-database/details/lcd-details.aspx?LCDId=29508&ContrId=64&ver=16&ContrVer=1&CoverageSelection=Both&ArticleType=All&PolicyType=Final&s=All&KeyWord=Human+Papillomavirus+\(HPV\)+Testing&KeyWordLookUp=Title&KeyWordSearchType=And&bc=gAAAABAAAA&](http://www.cms.gov/medicare-coverage-database/details/lcd-details.aspx?LCDId=29508&ContrId=64&ver=16&ContrVer=1&CoverageSelection=Both&ArticleType=All&PolicyType=Final&s=All&KeyWord=Human+Papillomavirus+(HPV)+Testing&KeyWordLookUp=Title&KeyWordSearchType=And&bc=gAAAABAAAA&)> (5/3/11)
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The articles reviewed in this research include those obtained in an Internet based literature search for relevant medical references through 7/18/12, the date the research was completed.

Joint BCBSM/BCN Medical Policy History

| Policy Effective Date | BCBSM Signature Date | BCN Signature Date | Comments |
|-----------------------|----------------------|--------------------|--|
| 7/1/02 | 7/1/02 | 7/1/02 | Joint policy established |
| 12/5/03 | 12/5/03 | 1/16/04 | Policy update (title change, HPV “surveillance ” guideline added, verbiage in policy statement, rationale, etc. now includes reference to surveillance) |
| 7/1/06 | 5/2/06 | 4/27/06 | Routine maintenance |
| 1/1/09 | 12/9/08 | 12/21/08 | Routine maintenance |
| 9/1/11 | 6/21/11 | 6/21/11 | Routine maintenance; additional CPT codes 87622, 88141, 88142, 88143, 88147, 88148, 88150, 88152, 88153, 88154, 88155, 88164, 88165, 88166, 88167, 88174 and 88175 added to the policy for pap testing; policy criteria updated. Policy title changed from “HPV (Human Papilloma Virus) Surveillance with Pap Test” to “Cervical Cancer Screening Technologies with Pap and HPV”. |
| 11/1/12 | 8/21/12 | 8/21/12 | Routine maintenance, policy retired, refer to current USPSTF practice guidelines |

Next Review Date: Review no longer required, policy retired.

BLUE CARE NETWORK BENEFIT COVERAGE
POLICY: CERVICAL CANCER SCREENING TECHNOLOGIES WITH PAP AND HPV

I. Coverage Determination:

| | |
|--|---|
| Commercial HMO (includes Self-Funded groups unless otherwise specified) | Covered. |
| BCNA (Medicare Advantage) | Covered. |
| BCN65 (Medicare Complementary) | Coinsurance covered if primary Medicare covers the service. |
| Blue Cross Complete of Michigan | Covered. |

II. Administrative Guidelines:

- The member's contract must be active at the time the service is rendered.
- The service must be authorized by the member's PCP except for Self-Referral Option (SRO) members seeking Tier 2 coverage.
- Services must be performed by a BCN-contracted provider, if available, except for Self-Referral Option (SRO) members seeking Tier 2 coverage.
- Payment is based on BCN payment rules, individual certificate and certificate riders.
- Appropriate copayments will apply. Refer to certificate and applicable riders for detailed information.
- CPT - HCPCS codes are used for descriptive purposes only and are not a guarantee of coverage.