



**BlueCross BlueShield
of Alabama**

Name of Policy:
Speculoscopy

Policy #: 095
Category: Medicine/OB Gyn

Latest Review Date: September 2011
Policy Grade: C

Background/Definitions:

As a general rule, benefits are payable under Blue Cross and Blue Shield of Alabama health plans only in cases of medical necessity and only if services or supplies are not investigational, provided the customer group contracts have such coverage.

The following Association Technology Evaluation Criteria must be met for a service/supply to be considered for coverage:

- 1. The technology must have final approval from the appropriate government regulatory bodies;*
- 2. The scientific evidence must permit conclusions concerning the effect of the technology on health outcomes;*
- 3. The technology must improve the net health outcome;*
- 4. The technology must be as beneficial as any established alternatives;*
- 5. The improvement must be attainable outside the investigational setting.*

Medical Necessity means that health care services (e.g., procedures, treatments, supplies, devices, equipment, facilities or drugs) that a physician, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury or disease or its symptoms, and that are:

- 1. In accordance with generally accepted standards of medical practice; and*
- 2. Clinically appropriate in terms of type, frequency, extent, site and duration and considered effective for the patient's illness, injury or disease; and*
- 3. Not primarily for the convenience of the patient, physician or other health care provider; and*
- 4. Not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient's illness, injury or disease.*

Description of Procedure or Service:

Speculoscopy is intended to be an adjunctive procedure to routine pelvic examination and Pap smear in the diagnosis of cervical and vaginal abnormalities. The procedure consists of visualization of acetowhite areas using low power (4-6x) magnification. This procedure is indicated for use in those women who are currently recommended for cervical screening with pelvic examination and Pap smear. Speculoscopy is only to be used as an adjunct to the Pap smear, and only the combination of the two tests affords the clinician-improved sensitivity in identifying women with mucosal abnormalities visualized on colposcopy. The test is performed following a routine Pap smear. The procedure includes activation of the chemiluminescent device and attaching to the inside, upper portion of a speculum with an adhesive strip. The cervix is swabbed with a 3-5% acetic acid solution. After 60 seconds for the solution to take effect, the lights are dimmed. The cervix is examined with a 5x magnification optic that is hand held. The practitioner looks for the presence of distinct white areas with at least one sharply demarcated border, which may indicate potential abnormalities, while normal tissue appears dark blue, or purple. Speculoscopy should never be used without Pap smear. In 1997, the United States Food and Drug Administration (FDA) approved Papsure as an in-office noninvasive visual screening exam for use in conjunction with the Pap smear.

Two clinical roles of speculoscopy have been proposed, both as an adjunct to conventional cervical cancer screening with Pap smears, and as a technique to select women with atypical Pap smears for further evaluation for colposcopy. For example, although cervical cancer screening is considered among the most successful cancer screening programs, it is still considered to be relatively insensitive; i.e., Pap smear cytology is associated with false negative results ranging from 15% to 55%. Speculoscopy is thought to potentially increase the sensitivity of cervical of cervical cancer screening by enhancing the visual inspection of the cervix.

Management of women with atypical Pap smears has evolved over the past several years, with a focus on various strategies to select those women with high-risk lesions who would benefit from further evaluation with colposcopy. For example, further management of those with Pap smears reported as “atypical squamous cells of uncertain clinical significance” (ASCUS) has been particularly controversial, because it is thought that many of these cases represent benign or self-limited lesions. In 2001, the American Society of Colposcopy and Cervical Pathology issued guidelines for the management of women with cervical cytological abnormalities, and these guidelines were updated in 2006. In 2001, for ASCUS cytology, the guidelines recommended that women receive either repeat cytology, human papillomavirus (HPV) testing, or colposcopy. For patients with definitive low-grade squamous intraepithelial lesions (LSIL), colposcopy was recommended as the only diagnostic option, except in special populations. In 2006, the guidelines were changed to state that women under 20 years of age with ASCUS or LSIL were recommended to have repeat cytology after 12 months, with only those found to have high-grade lesions being recommended for a colposcopy referral. Acceptable options for postmenopausal women with LSIL include “reflex” HPV testing, repeat cytology after 6 and 12 months, and colposcopy. Colposcopy is preferred for pregnant women with LSIL, but waiting until at least 6 weeks postpartum is acceptable. For high-grade squamous intraepithelial lesions (HSIL), the 2006 guidelines recommend either colposcopy or an immediate loop electrosurgical excision. Speculoscopy has been suggested as an additional option in those settings in which immediate colposcopy is not the only recommended test.

Policy:

Speculoscopy does not meet Blue Cross and Blue Shield of Alabama's medical criteria for coverage and is considered **investigational**.

Blue Cross and Blue Shield of Alabama does not approve or deny procedures, services, testing, or equipment for our members. Our decisions concern coverage only. The decision of whether or not to have a certain test, treatment or procedure is one made between the physician and his/her patient. Blue Cross and Blue Shield of Alabama administers benefits based on the members' contract and corporate medical policies. Physicians should always exercise their best medical judgment in providing the care they feel is most appropriate for their patients. Needed care should not be delayed or refused because of a coverage determination.

Key Points:

According to the National Cancer Institute, during 2002, about 4,100 women in the United States died from cervical cancer, the second leading cause of cancer death worldwide. This reflects a 70% decline from the mid-20th century, when the Papanicolaou (Pap) test was first introduced as a screening tool. Cervical cancer screening is important to detect significant abnormal cell changes that may arise before cancer develops. Early detection permits treatment at an earlier stage.

In review of earlier research literature, Lonky and Edwards compared speculoscopy against low-power magnification with incandescent light. Of 37 patients, 35 (95%) demonstrated acetowhitening with speculoscopy and 11 (30%) had acetowhitening with magnified incandescent light. In addition, their multivariate analysis indicated that compared with speculoscopy alone and pap smear alone the combination of the pap smear and speculoscopy did not increase the detection of low-grade or high-grade lesions significantly. Mann and colleagues had 189 women with normal Paps and colposcopy, 10 had abnormal speculoscopy. In this study the sensitivity of Pap plus speculoscopy (83%) exceeded that of Pap alone (31%), but the specificity of the Pap alone (99%) exceeded that of speculoscopy alone (87%). Massad et al with a group of 137 women with atypia on Pap using colposcopy and speculoscopy detected 73% of abnormalities seen on colposcopy and specificity was 93%. Wertlake presented speculoscopy results on 7000 women as performed by community-based providers. The false negative rate for Pap alone was 10.3%; for speculoscopy alone, 4.5%, and for both tests 3.5%. Most of the cancers detected by speculoscopy and by Pap were low-grade lesions, but 35 % of the high-grade squamous lesions were found on speculoscopy alone.

In a response by Spitzer regarding comparison of speculoscopy with colposcopy and cervicography, there remains insufficient evidence in the literature to support the ability of speculoscopy to detect cervical cancer. Spitzer even cited Massad, stating that using speculoscopy as a routine adjunct to cytologic screening for women with a history of normal smears cannot be recommended until a larger trial that has included cost analysis.

Wright, et al, published the 2001 Consensus Guidelines for the Management of Women with Cervical Cytological Abnormalities in JAMA in 2002 stated that women with atypical squamous cells undetermined significance (ASC-US) should be managed with two repeat cytology tests, immediate colposcopy or DNA testing for high-risk types of human papillomavirus (HPV). Most women with atypical squamous cells, low-grade squamous intraepithelial lesion and other atypical glandular cells should be referred for immediate colposcopic evaluation.

In November 2002, the American Cancer Society issued new guidelines for when and how often women should get early detection tests for cervical cancer and pre-cancer. In summary, screenings should begin about three years after a woman begins having vaginal intercourse, but no later than age 21. Screening should be done every year with regular pap tests or every two years using liquid-based pap tests. At age 30, women with three normal test results in a row may get screened every two to three years, unless certain risk factors are present. Women age 70 or older with three or more normal pap tests and no abnormal results in the last 10 years may choose to stop cervical cancer screening. Screening after a total hysterectomy (with removal of cervix) is not necessary if the surgery was performed for cervical cancer or pre-cancer. Some other conditions may require continued screening. If a hysterectomy has been performed without removal of the cervix, screening should continue until at least age 70.

March 2007 Update

No new published peer-reviewed literature was located that would alter the coverage statement on the policy.

March 2008 Update

There continues to be a lack of well-designed, randomized controlled trials in the published peer-reviewed literature for speculoscopy. Therefore, the policy statement remains unchanged.

March 2009 Update

No changes in guidelines were found in a recent literature search. The search identified 2 studies from Asia that assessed the combined use of speculoscopy and Pap smear (PapSure) for cervical cancer screening. One of these was a multicenter study that enrolled 1,813 pre- and postmenopausal women who had not received a Pap smear in the previous 3 years; 112 did not meet the study criteria or were lost to follow-up, leaving results of 873 premenopausal and 828 postmenopausal (94%) women for analysis. Colposcopy was conducted in 870 randomly selected women with negative screenings and 214 women who had positive screening test results. Nineteen women were diagnosed with high-grade squamous intraepithelial lesions (HGSIL) on biopsy, resulting in a rate of 1.1% for the population of 1,701 women. Sensitivity of Pap smear alone was 53%, speculoscopy alone was 63%, and the combined sensitivity was 90%, identifying 17 of 19 cases of HGSIL. Combined testing decreased specificity from nearly 100% with Pap smear alone to 90%. The positive predictive value of combined testing was 8.8% and the negative predictive value was 99.9%. Speculoscopy identified 7 additional positive cases of HGSIL of a total of 19 (equating to 0.4% out of the 1,701 women included in the study and 37% of the population with cervical cancer). When evaluated by menopausal status, results were significant for premenopausal women but not for postmenopausal women; however, this result is limited by the low number of positive cases (n=7) in the postmenopausal group. These results are consistent with the studies reviewed above, with a 0.4% increase in detection rate and a larger

increase in the number of women being referred for colposcopy. Due to the limited literature on the sensitivity/specificity of this procedure compared with current technologies (thin layer or liquid Pap) in the United States, speculoscopy is considered investigational.

March 2010 Update

A literature search for this update did not identify any published studies on this topic. No updated guidelines on cervical cancer screening from the American cancer Society or the American Society for Colposcopy and Cervical Pathology were identified. The policy statement remains unchanged.

September 2010 Update

Due to the limited literature on the difference in diagnostic accuracy of speculoscopy added to Pap smears alone, speculoscopy is considered investigational as an adjunct to routine cervical cancer screening. Due to a lack of literature comparing speculoscopy for triaging women with a positive Pap smear to other approaches such as repeat cytology or HPV testing, speculoscopy is considered investigational as a technique to triage women for colposcopy.

September 2011 Update

No new published peer-reviewed literature was located that would alter the coverage statement on the policy.

Technology Assessments, Guidelines and Position Statements

American Society for Colposcopy and Cervical Pathology

Their 2006 guidelines state:

Women under 20 years of age with ASCUS or LSIL are recommended to have repeat cytology after 12 months, with only those found to have high-grade lesions being recommended for a colposcopy referral. Acceptable options for postmenopausal women with LSIL include “reflex” HPV testing, repeat cytology after 6 and 12 months, and colposcopy. Colposcopy is preferred for pregnant women with LSIL, but waiting until at least 6 weeks postpartum is acceptable. For high-grade squamous intraepithelial lesions (HSIL), the 2006 guidelines recommend either colposcopy or an immediate loop electrosurgical excision. Speculoscopy has been suggested as an additional option in those settings in which immediate colposcopy is not the only recommended test.

American College of Obstetrics and Gynecology (ACOG)

In 2009, ACOG issued an updated practice on cervical cancer screening. Speculoscopy was not included in the bulletin.

American Cancer Society

They published guidelines for cervical cancer screening in 2002; speculoscopy was not discussed.

U.S. Preventive Services Task Force

Speculoscopy for cervical cancer screening is not specifically discussed.

Key Words:

Speculoscopy, Pap smear, Papsure, colposcopy, cervicography, cervical cancer

Approved by Governing Bodies:

The U.S. Food and Drug Administration approved Papsure in 1997.

In 1995, speculoscopy using the Speculite® (Trylon Corp.; Monarch Beach, CA), a chemiluminescent light source, was cleared for marketing by the FDA through the 510(k) process. Later in 1995, the Pap Plus Speculoscopy (Trylon Corp.) was also cleared for marketing by the FDA, and was later renamed PapSure®. It combined the Speculite device with a vaginal speculum which is used for obtaining a Pap smear. In 2002, Watson Diagnostics, Inc. acquired the rights to PapSure and Speculite from Trylon Corporation, and they continue to market the combination device as PapSure. Speculite is intended for use only in conjunction with the Pap smear and is indicated for use in women currently recommended to undergo cervical screening with Pap smears.

Benefit Application:

Coverage is subject to member's specific benefits. Group specific policy will supersede this policy when applicable.

ITS: Covered if covered by the Participating Home Plan

BellSouth/AT&T contracts: Considers investigational

FEP contracts: FEP does not consider investigational if FDA approved. Will be reviewed for medical necessity.

Wal-Mart: Special benefit consideration may apply. Refer to member's benefit plan.

Pre-certification/Pre-determination requirements: Not required

Coding:

CPT codes:

~~0031T~~ Speculoscopy (**Code deleted effective January 1, 2009**)

~~0032T~~ Speculoscopy; with directed sampling (**Code deleted effective January 1, 2009**)

88199 Unlisted cytopathology procedure

References:

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2. American College of Obstetricians and Gynecologists (ACOG). *Cervical Cytology Screening*. ACOG Practice Bulletin, Clinical Management Guidelines for Obstetrician—Gynecologists, December 2009, No. 109.
3. Blue Cross Blue Shield Association. *Speculoscopy*. Medical Policy Reference Manual, September 2010.

4. Lonky Stewart A. *Letters to the Editors: Speculoscopy*. American Journal of Obstetrics and Gynecology, March 1999, Vol. 180, No. 3.
5. Medscape Women's Health eJournal. *Innovation: Speculoscopy*, http://www.medscape.com/viewarticle/408820_4.
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7. Spitzer Mark. *Letters to the Editors: Reply* (Stewart A. Lonky article). American Journal of Obstetrics and Gynecology, March 1999, Vol. 180, No. 3.
8. Twu NF, Chen YJ, et al. *Improved cervical cancer screening in premenopausal women by combination of Pap smear and speculoscopy*. Eur J Obstet Gynecol Reprod Biol, July 2007; 133(1): 114-118.
9. Wright Jr Thomas C, Denny Lynette, et al. *Use of visual screening methods for cervical cancer screening*. Obstetrics and Gynecology Clinics, December 2002, Vol. 29, No. 4.
10. Wright Jr Thomas C, Cox J Thomas, et al. *2001 Consensus guidelines for the management of women with cervical cytological abnormalities*. JAMA, April 2002, Vol. 287, No. 16.
11. Wright Jr TC, Massad LS, et al. *2006 consensus guidelines for the management of women with abnormal cervical screening tests*. J Low Genit Tract Disease, July 2008; 12(3): 255

Policy History:

Medical Policy Group, February 2003 **(3)**

Medical Policy Administration Committee, February 2003

Available for comment February 19-April 7, 2003

Medical Policy Group, March 2004

Medical Policy Group, March 2005 **(1)**

Medical Policy Group, March 2006 **(1)**

Medical Policy Group, March 2007 **(1)**

Medical Policy Group, March 2008 **(1)**

Medical Policy Group, March 2009 **(1)**

Medical Policy Group, March 2010 **(1)** Description and Key Points updated, reference added

Medical Policy Group, September 2011 **(1)** Update to Key Points, no references added

This medical policy is not an authorization, certification, explanation of benefits, or a contract. Eligibility and benefits are determined on a case by case basis according to the terms of the member's plan in effect as of the date services are rendered. All medical policies are based on (i) research of current medical literature and (ii) review of common medical practices in the treatment and diagnosis of disease as of the date hereof. Physicians and other providers are solely responsible for all aspects of medical care and treatment, including the type, quality, and levels of care and treatment.

This policy is intended to be used for adjudication of claims (including pre-admission certification, pre-determinations, and pre-procedure review) in Blue Cross and Blue Shield's administration of plan contracts.