MEDICAL POLICY

POLICY TITLE	CERVICOGRAPHY AND SPECULOSCOPY
POLICY NUMBER	MP-2.214

Original Issue Date (Created):	**7/1/2002**
Most Recent Review Date (Revised):	**9/10/2018**
Effective Date:	**11/1/2018**

I. POLICY

TOP

Cervicography:
Cervicography is considered **investigational,** as there is insufficient evidence to support a conclusion concerning the health outcomes or benefits associated with this procedure.

Speculoscopy:
Speculoscopy, with or without direct sampling, is considered **investigational** as an adjunct to a program of cervical cancer screening including initial or repeat Pap smears or DNA testing for human papilloma virus (HPV). There is insufficient evidence to support a conclusion concerning the health outcomes or benefits associated with this procedure.

II. PRODUCT VARIATIONS

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This policy is applicable to all programs and products administered by Capital BlueCross unless otherwise indicated below.

FEP PPO:The FEP program dictates that all drugs, devices or biological products approved by the U.S. Food and Drug Administration (FDA) may not be considered investigational. Therefore, FDA-approved drugs, devices or biological products may be assessed on the basis of medical necessity.

III. DESCRIPTION/BACKGROUND

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Cervicography

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Cervicography refers to the use of a specialized camera to take standardized images of the cervix after application of acetic acid. Proposed uses of cervicography include as a primary technique to screen for cervical cancer, as an adjunct to Pap smear screening, and as a triaging strategy for patients who have low-grade lesions with Pap smear testing.

Cervicography involves the use of a specialized camera that is described as easy to use and not requiring experience in colposcopy. The photographs, referred to as cervigrams™, are static photographic images of the cervix similar to those seen during low-level magnification colposcopy. The images are sent to a central laboratory (National Testing Laboratories, the worldwide exclusive licensee of the product) for interpretation by colposcopists who have received specialized training in interpretation of cervigrams. Cervigrams are interpreted as negative, atypical, positive, or defective.

Cervicography has been investigated in three general settings:

- As an alternative to Pap smear screening as a primary screening technique for cervical cancer. This application has been investigated primarily in "resource poor" areas that do not have cytology expertise to interpret Pap smears.
- As an adjunct to routine Pap smear screening to improve the sensitivity of Pap smear screening for cervical cancer. For example, it is estimated that negative cytology reports are issued on 20% or more of all invasive cervical cancers.
- As a triage technique for colposcopy in patients found to have low-grade lesions on Pap smear specimens.

The management of low-grade lesions, i.e., atypical squamous cells of uncertain significance (ASCUS), has been a subject of investigation. For example, colposcopy is an option for further workup of ASCUS lesions, and yet at colposcopy only 20% of these patients actually have a high-grade lesion. Furthermore, many low-grade lesions that may prompt colposcopy will spontaneously regress. If cervicography can be used to identify which ASCUS cytology results are most likely to harbor higher grade lesions and thus need colposcopy and biopsy, unnecessary colposcopies in patients with innocuous cytologic abnormalities would decrease. Other triaging strategies include repeat Pap smears or evaluation for human papilloma virus (HPV) infection.

U.S. Food and Drug Administration (FDA) Approval or Marketing Clearance of Devices

In June 1982, the Cerviscope Optical System (Fotomedics) was cleared for marketing by the FDA through the 510(k) process. The FDA determined that this device was substantially equivalent to existing devices for viewing tissues of the vagina and cervix.

Speculoscopy

Speculoscopy refers to a visual examination of the cervix that uses specialized blue-white chemiluminescence along with acetic acid and low-power magnification. Proposed uses of speculoscopy include: 1) use of the test as an adjunct to conventional screening smears and 2) as a method of triaging women with positive conventional screening tests smears prior to colposcopy.

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The procedure for conducting a speculoscopy involves several steps. First, the cervix is washed with 3–5% acetic acid. The examining room lights are then dimmed, and the cervix is visually examined using 5X magnifying loupes. The examination takes place using a disposable blue-white chemiluminescent light that is attached to the inner aspect of the upper speculum blade. Epithelial cells with increased keratinization and nuclear cytoplasmic ratios have an increased light reflection and appear white, in clear distinction to the dark blue of the normal epithelium. The presence of white lesions is considered a positive result; these areas may then be sampled for cytologic evaluation.

Speculoscopy must be distinguished from other methods of enhanced visual inspection of the cervix, including cervicography, addressed in policy No. 2.04.04 (archived), and colposcopy. Cervicography involves taking a picture of the cervix with a special macrolens strobe-flash camera after the cervix is swabbed with acetic acid. The photograph is then sent to a central laboratory for interpretation. Colposcopy involves the visual inspection of the cervix using a lighted microscope; unlike cervicography and speculoscopy, colposcopy has not been proposed as a primary screening method.

Two clinical roles of speculoscopy have been proposed, both as an adjunct to conventional cervical cancer screening and as a technique to select women with atypical cytological findings 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., Papanicolaou (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 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. Screening for human papillomavirus (HPV) is increasingly accepted as part of initial cervical cancer screening for women aged 30 years and older. In 2012 guidelines developed jointly by the American Cancer Society (ACS), American Society for Colposcopy and Cervical Pathology (ASCCP), and American Society for Clinical Pathology (ASCP), HPV and cytology “co-testing” every 5 years is the preferred screening strategy recommended for women aged 30-65 years; cytology alone every 3 years is included as an acceptable screening alternative. (1) Similarly, the United States Preventive Services Task Force (USPSTF) 2012 cervical cancer screening guideline recommends screening with a combination of cytology and HPV testing every 5 years for women for women aged 30 to 65 years who want to lengthen their screening interval. (2) Both 2012 guidelines recommend cytology only for women aged 21 to 29 years.

Regulatory Status

In 1995, speculoscopy using the Speculite® (Trylon Corp.; Monarch Beach, CA), a chemiluminescent light source, was cleared for marketing by the U.S. Food and Drug Administration (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.

IV. RATIONALE

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Summary

Cervicography alone has an inferior sensitivity compared to cytology, and therefore is not recommended in settings where adequate cytology services are available. As an adjunct to Pap smear screening, cervicography may increase the sensitivity for detecting cervical abnormalities, but will decrease the specificity, potentially resulting in increased referrals for colposcopy. As a triaging strategy for patients with mildly abnormal cytology results, cervicography is a promising technique that appears to be similar in terms of positive and negative predictive values compared to other options, including repeat cytology or HPV testing. However, if the original Pap smear was collected in a liquid medium, subsequent HPV testing in patients whose cytology was mildly abnormal could be done on the same sample. Therefore, these patients do not need to return for a repeat office visit. Both repeat Pap smear and cervicography would require an additional office visit. At present, no clinical guidelines are available from the American College of Obstetricians and Gynecologists, U.S. Preventive Services Task Force, or related organizations that recommend the use of cervicography in any of the above clinical situations.

2011-2018 Update

Literature review completed does not reveal any evidence to initiate changes to the policy statements.

Speculoscopy

Summary

There is insufficient evidence on the diagnostic accuracy of speculoscopy added to Pap smears compared to Pap smears alone. In addition, there is insufficient evidence on the diagnostic accuracy of speculoscopy for triaging women with a positive Pap smear to additional follow-up such as repeat cytology or HPV testing. Thus, speculoscopy is considered investigational.

2018

Literature review completed does not reveal any evidence to initiate changes to the policy statement.

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V. DEFINITIONS

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BIOPSY is the obtaining of a representative tissue sample for microscopic examination, usually to establish a diagnosis.

CERVIX refers to the neck of the uterus; the lower part of the uterus from the internal os outward to the external os. It is round and conical, and a portion protrudes into the vagina.

COLPOSCOPY refers to the examination of vaginal and cervical tissues by means of a colposcope. Colposcopy is used to select sites of abnormal epithelium for biopsy in patients with abnormal Pap smears.

PAPANICOLAOU TEST is a cytological study used to detect cancer in cells that an organ has shed. The Pap test has been used most often in the diagnosis and prevention of cervical cancers**.**

THE PAP SMEARS AND GYNECOLOGICAL EXAMS ACT (ACT 20 OF 1994) -refers to a Pennsylvania state mandate that addresses coverage for annual gynecological exams, including pelvic exams, clinical breast exams, and routine pap smears.

VI. BENEFIT VARIATIONS

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The existence of this medical policy does not mean that this service is a covered benefit under the member's contract. Benefit determinations should be based in all cases on the applicable contract language. Medical policies do not constitute a description of benefits. A member's individual or group customer benefits govern which services are covered, which are excluded, and which are subject to benefit limits and which require preauthorization. Members and providers should consult the member's benefit information or contact Capital BlueCross for benefit information.

VII. DISCLAIMER

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Capital BlueCross's medical policies are developed to assist in administering a member's benefits, do not constitute medical advice and are subject to change. Treating providers are solely responsible for medical advice and treatment of members. Members should discuss any medical policy related to their coverage or condition with their provider and consult their benefit information to determine if the service is covered. If there is a discrepancy between this medical policy and a member's benefit information, the benefit information will govern. Capital BlueCross considers the information contained in this medical policy to be proprietary and it may only be disseminated as permitted by law.

VIII. CODING INFORMATION

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Note: This list of codes may not be all-inclusive, and codes are subject to change at any time. The identification of a code in this section does not denote coverage as coverage is determined by the terms of member benefit information. In addition, not all covered services are eligible for separate reimbursement.

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Investigational; therefore not covered: when used to report Cervicography or Speculoscopy

CPT Codes®								
58999								

IX. REFERENCES

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Other sources:

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X. POLICY HISTORY

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MP 2.214	**CAC 4/27/04**
	CAC 6/28/05
	CAC 7/25/06
	CAC 9/26/06
	CAC 9/25/07
	CAC 11/25/08
	CAC 1/26/10 Minor revision. Speculoscopy information added to the policy, considered investigational. Policy statements for HPV testing were clarified regarding screening and follow-up testing in women over the age of 30.
	CAC 4/26/11 Consensus review.
	CAC 8/28/12 Criteria and information related to PAP smears removed from the policy. Title revised to "Cervicography and Speculoscopy". Medical Policy Committee instructed on 4/4/12 to remove information related to PAP smears due to Health Care Reform.
	Codes reviewed 8/13/12
	CAC 9/30/14 Consensus. No change to policy statements. Rationale section added. References reviewed. Coding reviewed.
	CAC 9/29/15 Consensus review. No change to policy statements. Rationale and references reviewed. Coding reviewed.
	CAC 11/29/16 Consensus review. No change to policy statements. Rationale and references reviewed. Coding reviewed. Variation reformatting.
	CAC 12/19/17 Consensus review. Policy statements unchanged. Rationale and Reference sections updated. Admin coding review 2/28/18: No changes.
	9/10/18 Consensus review. No changes to the policy statements. References reviewed. Rationale revised**.**

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