I. POLICY

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 HPV. There is insufficient evidence to support a conclusion concerning the health outcomes or benefits associated with this procedure.

II. PRODUCT VARIATIONS

[N] = No product variation, policy applies as stated
[Y] = Standard product coverage varies from application of this policy, see below

[N] Capital Cares 4 Kids [Y] Indemnity
[N] PPO [N] SpecialCare
[N] HMO [N] POS
[N] FEP PPO [N] SeniorBlue PPO
[N] SeniorBlue

III. DESCRIPTION/BACKGROUND

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 are as an adjunct to conventional screening with Papanicolaou(Pap) smears and as a method of triaging women with atypical Pap smears prior to colposcopy.
Cervicography

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.

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, and colposcopy. Cervicography involves taking a picture of the cervix with a special macro lens 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 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 cancer screening by enhancing the visual inspection of the cervix.

IV. DEFINITIONS

**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.

V. **Benefit Variations**

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 for benefit information.
VI. DISCLAIMER

Capital’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 considers the information contained in this medical policy to be proprietary and it may only be disseminated as permitted by law.

VII. REFERENCES

Cervical Cancer Screening Technologies with Pap and HPV
Blue Cross and Blue Shield Association Technology Evaluation Center (TEC) Monolayer slide preparation and automated slide reading systems for cervical cancer screening – clinical effectiveness analysis. TEC Assessments 1998; Volume 13, Tab 1
Kaiser Permanente National Cervical Cancer Screening Guideline Development team Cervical Cancer Screening Guideline, National Guideline Clearinghouse, October 2006

Taber’s Cyclopedic Medical Dictionary, 19th edition.


Cervicography


Speculoscopy


VIII. CODING INFORMATION

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.

[Note: Final page is signature page and is kept on file, but not issued with Policy.]
IX. POLICY HISTORY

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<td>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.</td>
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<td>Consensus review.</td>
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<td>CAC 8/28/12</td>
<td>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.</td>
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