



Medical Policy

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Title: Speculoscopy

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Public Statement:

Speculoscopy refers to an endoscopic visual examination of the cervix that uses specialized "blue-white" chemiluminescence along with acetic acid and low-power magnification. Speculoscopy must be distinguished from other methods of enhanced visual inspection of the cervix, including cervicography and colposcopy.

Medical Policy Statement:

Speculoscopy with or without directed sampling as an adjunct to a program of cervical cancer screening including initial or repeat Pap smears or DNA testing for HPV is considered investigational and is not a covered procedure.

Background:

Speculoscopy has been proposed as an adjunctive cervical cancer screening method. Therefore, to determine its clinical performance compared to conventional Pap smear screening alone, speculoscopy must be evaluated in prospective studies of patients undergoing routine screening. To determine the sensitivity of speculoscopy compared to Pap smears, ideally, all patients would be referred to colposcopy, which is currently considered the gold standard. However, this type of testing is not feasible on a large scale, and thus it is likely that only patients with positive results on Pap smears or speculoscopy would then be referred to colposcopy.

The ASCCP guidelines do not address any potential role of speculoscopy, but presumably the technique could be offered as a management option (in addition to either repeat cytology or HPV testing) to either identify those women who would most benefit from colposcopy (i.e., positive predictive value) or those who could safely forego colposcopy (negative predictive value). Given these guidelines, evaluation of this role of speculoscopy would require a prospective, controlled trial comparing the diagnostic

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performance of speculoscopy to either repeat cytology or HPV testing in the above groups of patients. The results of 2 multicenter trials have been published, both prior to the now-accepted strategy of using HPV testing as a triage strategy for colposcopy. However, both are reviewed below.

Massad and colleagues reported on a multicenter study of 137 with atypical Pap smears who underwent colposcopy. (Massad et al. 1993) Patients underwent Pap smear, followed by speculoscopy, and then colposcopy. Any aceto-white areas noted on the speculoscopy exam were considered positive. Of the 94 women who had positive colposcopy results, 73% and 27% had positive and negative speculoscopies, respectively. Using colposcopy as the gold standard, the sensitivity, specificity, and positive and negative predictive values for speculoscopy were 73%, 93%, 96%, and 62%, respectively. It is unclear how, based on this diagnostic performance, speculoscopy would be integrated into a program of cervical cancer screening. It is likely that a negative predictive value of 62% would be considered adequate to consider foregoing a colposcopy, and it is unclear how the positive predictive value of 96% would affect the decision to undergo colposcopy. The results are not compared with the alternative options of repeat cytology or HPV testing.

In a second study from the same group of investigators, 395 patients referred for colposcopy underwent a repeat cervical smear followed immediately by a colposcopy, performed by the same physician (Lonky et al. 1995). Histologic diagnoses were compared with cytology, speculoscopy, and colposcopy results. An antecedent aceto-white abnormality detected during speculoscopy was highly predictive (97% positive predictive value) of a subsequent abnormal colposcopy. This study suffers from the same limitations as the earlier study.

Speculoscopy is not specifically addressed as a screening method by the U.S. Preventive Services Taskforce. In 2002, the American Cancer Society published guidelines for cervical cancer screening; speculoscopy was not discussed. Also in 2002, the American College of Obstetrics and Gynecology issued a technology assessment focusing on techniques for cervical cancer screening. Speculoscopy was not included in this discussion.

Two studies from Asia 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 (Twu et al. 2007). 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.

There is limited literature on the sensitivity/specificity of this procedure compared with current technologies in the United States and little evidence that this procedure leads to improved health outcomes.

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Application to Products

This policy applies to ARBenefits. Consult ARBenefits Summary Plan Description (SPD) for additional information.

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