



BlueCross BlueShield
of Alabama

Name of Blue Advantage Policy:
Speculoscopy

Policy #: 095
Category: Medicine/OB Gyn

Latest Review Date: November 2020
Policy Grade: **Active Policy but no longer scheduled for regular literature reviews and updates effective October 22, 2012.**

BACKGROUND:

Blue Advantage medical policy does not conflict with Local Coverage Determinations (LCDs), Local Medical Review Policies (LMRPs) or National Coverage Determinations (NCDs) or with coverage provisions in Medicare manuals, instructions or operational policy letters. In order to be covered by Blue Advantage the service shall be reasonable and necessary under Title XVIII of the Social Security Act, Section 1862(a)(1)(A). The service is considered reasonable and necessary if it is determined that the service is:

1. *Safe and effective;*
2. *Not experimental or investigational*;*
3. *Appropriate, including duration and frequency that is considered appropriate for the service, in terms of whether it is:*
 - *Furnished in accordance with accepted standards of medical practice for the diagnosis or treatment of the patient's condition or to improve the function of a malformed body member;*
 - *Furnished in a setting appropriate to the patient's medical needs and condition;*
 - *Ordered and furnished by qualified personnel;*
 - *One that meets, but does not exceed, the patient's medical need; and*
 - *At least as beneficial as an existing and available medically appropriate alternative.*

Routine costs of qualifying clinical trial services with dates of service on or after September 19, 2000 which meet the requirements of the Clinical Trials NCD are considered reasonable and necessary by Medicare. Providers should bill **Original Medicare for covered services that are related to **clinical trials** that meet Medicare requirements (Refer to Medicare National Coverage Determinations Manual, Chapter 1, Section 310 and Medicare Claims Processing Manual Chapter 32, Sections 69.0-69.11).*

POLICY:

Blue Advantage will treat **speculoscopy** as a **non-covered** benefit and is considered **investigational**.

Blue Advantage 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 Advantage administers benefits based on the members' contract and 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.

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.

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. Speculoscopy is thought to potentially increase the sensitivity of cervical of cervical cancer screening by enhancing the visual inspection of the cervix.

KEY POINTS:

A literature search was conducted through November 18, 2020.

Summary of Evidence

Due to the limited literature on the sensitivity/specificity of this procedure compared with current technologies (thin layer or liquid Pap), the evidence is insufficient to determine the effects of net health outcome.

Practice Guidelines and Position Statements

American Society for Colposcopy and Cervical Pathology

In 2014, the ASCCP updated their guidelines for Managing Abnormal Cervical Cancer Screening Tests and Cancer Precursors. Speculoscopy is not mentioned.

National Comprehensive Cancer Network

In 2019, NCCN issued guidelines for cervical cancer. Speculoscopy was not mentioned.

American Cancer Society

The ACS published guidelines for cervical cancer screening in 2016; 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, LUMA

APPROVED BY GOVERNING BODIES:

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

BENEFIT APPLICATION:

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

CURRENT CODING:

CPT codes:

88199	Unlisted cytopathology procedure
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REFERENCES:

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4. American College of Obstetricians and Gynecologists (ACOG). Cervical Cytology Screening. ACOG Practice Bulletin, Clinical Management Guidelines for Obstetrician—Gynecologists, December 2009, No. 109.
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16. 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:

Adopted for Blue Advantage, March 2005

Available for comment May 1-June 14, 2005

Medical Policy Group, March 2006

Medical Policy Group, March 2007

Medical Policy Group, March 2008

Medical Policy Group, March 2009

Medical Policy Group, March 2010

Medical Policy Group, September 2010

Medical Policy Group, September 2011

Medical Policy Group, October 2012

Medical Policy Group, August 2019

Medical Policy Group, November 2020

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.