

MEDICAL POLICY

SUBJECT: HIGH RESOLUTION ANOSCOPY

EFFECTIVE DATE: 12/20/12

**REVISED DATE: 11/21/13, 10/16/14, 09/17/15,
9/15/16**

ARCHIVED DATE: 09/21/17

EDITED DATE: 09/20/18

POLICY NUMBER: 2.01.49

CATEGORY: Technology Assessment

PAGE: 1 OF 5

- *If a product excludes coverage for a service, it is not covered, and medical policy criteria do not apply.*
- *If a commercial product (including an Essential Plan product) or a Medicaid product covers a specific service, medical policy criteria apply to the benefit.*
- *If a Medicare product covers a specific service, and there is no national or local Medicare coverage decision for the service, medical policy criteria apply to the benefit.*

POLICY STATEMENT:

- I. Based upon our review and assessment of the literature, use of high resolution anoscopy has been medically proven to be effective and is **medically appropriate** to assist in the diagnosis of suspicious anal lesions in the following circumstances:
 - A. When there are abnormal anal findings on physical exam (e.g., anogenital warts, hypo- or hyperpigmented perianal lesions); or
 - B. When there is an abnormal anal pap smear.
- II. Based upon our review and assessment of the literature, use of high resolution anoscopy is considered **medically appropriate** as a screening tool for anal dysplasia in human immunodeficiency virus (HIV) infected men and women.
- III. Based upon our criteria and assessment of peer-reviewed literature, use of high resolution anoscopy has not been medically proven to be effective and is therefore considered **investigational** as a screening tool for all other asymptomatic persons, even though they may be considered at high risk (e.g., homosexual or bisexual men).

POLICY GUIDELINES:

The Federal Employee Health Benefit Program (FEHBP/FEP) requires that procedures, devices or laboratory tests approved by the U.S. Food and Drug Administration (FDA) may not be considered investigational and thus these procedures, devices or laboratory tests may be assessed only on the basis of their medical necessity.

DESCRIPTION:

High resolution anoscopy (HRA), also known as colposcopy of the anal canal, involves careful examination of the anal canal using an anoscope and a high-resolution colposcope. During the procedure, an anoscope is inserted approximately two inches into the anal canal. Then, a standard gynecologic colposcope is utilized to magnify the area in order to identify any suspicious lesions. Dysplastic changes in the mucosa or suspicious lesions are identified by topically applying a 3% acetic acid solution. Lugol's solution may also be applied to identify normal mucosa. If suspicious lesions are found, biopsies are taken and sent for microscopic examination and/or are ablated.

High resolution anoscopy has been investigated as a method to identify abnormal anal cytology in high-risk populations and as an adjunct tool in anal cytology screening. Moreover, HRA can also be used to direct therapy. Due to the similarities between anal intraepithelial neoplasia (AIN) and cervical intraepithelial neoplasia (CIN), anal Papanicolaou (Pap) smear has been proposed for both screening high-risk individuals and for surveillance after treatment of AIN.

According to the AIDS Education and Training Centers National Resource Center (AETC), anal cancer is a squamous cell cancer associated with human papillomavirus (HPV), with a range of pre-invasive changes and is classified as anal epithelial neoplasia (AIN) I, II, III, and carcinoma-in-situ. It is the same virus that is associated with cervical cancer. The incidence of anal cancer is significantly higher in HIV-infected women and men than in the general population. Rates are also higher in men who have sex with men (MSM), whether HIV infected or uninfected.

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RATIONALE:

Although there have not been randomized or cohort studies to demonstrate improved survival or clinical outcome with the use of HRA, it would appear logical that the population most in need of these services would benefit from early identification and treatment of the abnormal cytology. The incidence of anal cancer has increased in the past decade, particularly among certain high-risk populations which include HIV-infected men with a history of sex with other men, HIV-infected women with a history of cervical or vulvar dysplasia and/or anyone with a history of anogenital condyloma (a wartlike growth around the anus, vulva or glans penis). Treatment for anal dysplasia can prevent the progression of the dysplasia to squamous cell carcinoma (cancer) of the anus.

Pineda, et al. (2007) reviewed the records of 42 patients who underwent HRA-targeted surgical therapy of anal dysplasia. The records spanned a 10-year period. High-risk patients who tested positive on initial testing were followed with physical examination, cytology, HRA and biopsy if indicated. Patients with disease that were determined to be amenable to local therapy were treated with office-based HRA-directed therapies. Thirty men ranging from ages 21 to 63 (with a mean age of 39 years) and 12 women (mean age of 50 years, range of 31 to 71 years) were included in the study. High-grade squamous intraepithelial lesions were present in 33 patients. Four of the patients underwent planned staged treatment due to circumferential disease. These lesions recurred in 45 percent of the patients, who were successfully retreated by another office procedure. Progression to HSIL was seen in one patient with LSIL and to squamous SCC in one patient with HSIL despite therapy. Zero patients with LSIL had dysplasia at last follow-up. Minor complications occurred in three patients. Surgical therapy under HRA guidance coupled with surveillance and retreatment with office-based therapies was effective in controlling anal dysplasia in these immunocompromised patients. Morbidity was minimal, and the progression to cancer rate was 2.4 percent.

KA Swedish and colleagues (2011) conducted a retrospective chart review on the anal cytology results of 1,1189 men who have sex with men who were screened in a 1-year period with subsequent high resolution anoscopy and biopsy if needed. There were 315 (37.2%) biopsy-verified instances of high-grade anal intraepithelial neoplasia. Regression analysis determined that age, HIV status, infection by high-risk human papillomavirus, and abnormal cytology results were significant predictors of high-grade anal intraepithelial neoplasia. In a 1-year period, the number of men who have sex with men screened was nearly 7 times greater than in the 2-year period studied 10 years earlier. The authors concluded that the severity of cytology and infection with high-risk human papillomavirus are the most significant predictors of high-grade anal intraepithelial neoplasia, underscoring the importance of anal dysplasia screening. Their ability to identify high-grade anal intraepithelial neoplasia has improved with 10 years of experience performing high-resolution anoscopy.

Chung and colleagues (2007) retrospectively reviewed HRA in the treatment of AIN III in a community setting. From January 2002 through November 2005, 76 patients with AIN III diagnosed by anal Pap smear, colposcopy or biopsy underwent HRA for diagnosis and treatment. Twenty-one patients with AIN III on initial HRA underwent follow-up HRA for reassessment and treatment at six months. Recurrence/persistence of disease was recorded and compared with patient characteristics. Of 21 patients with repeat HRA, four were HIV-negative and 17 were HIV positive. Twelve of 21 (57 percent) had intraanal recurrence/persistence; nine of 21 (43 percent) had no AIN III. Eleven (92 percent) with recurrence were HIV-positive; one (8 percent) was HIV-negative. Three (75 percent) HIV-negative patients had no recurrence/persistence; one of four (25 percent) had recurrence; and 11 of 17 (65 percent) HIV-positive patients had persistence of disease.

Unlike cervical cancer, there are no universally accepted guidelines or standards of care for anal pre cancer lesions. The New York State Department of Health AIDS Institute released recommendations in 2007 for the routine use of anal Pap testing in high risk groups. Recommendations state that primary care providers should perform a yearly anal pap in MSM, women with a history of cervical cancer, and in persons with a history of anogenital warts. Recent updates to the recommendations state that HRA has been found to be cost-effective in screening for anal dysplasia among HIV-infected men, and may be considered as an initial screening modality if the resources are available.

The Centers for Disease Control and Prevention (CDC), in its 2009 Treatment Guidelines in HIV Infected Adults and Adolescents (Kaplan, et al.), reports that no national recommendations exist for the routine screening for anal cancer and

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that the evidence of the efficacy of screening high risk individuals with anal cytology is insufficient to support a recommendation for or against its use at this time. The CDC concluded that evidence is limited to the opinions of clinicians based on their personal experience, descriptive studies or reports of expert committees and that studies of screening and treatment programs for anal dysplasia need to be implemented before definitive recommendations for anal cytology screening are made.

A practice guideline published by the HIV Medicine Association of the Infectious Diseases Society of America (Aberg, et al. 2009) recommends that high-resolution anoscopy with biopsy be performed in HIV infected women and HIV infected men having sex with men (MSM) who have abnormal anal cytology; the guideline also indicates that anal cytology screening warrants further study and is not considered to be standard of care at this time.

The Standards Committee of the American Society of Colon and Rectal Surgeons practice guideline for anal squamous neoplasm concluded that the evidence to support anal cytology screening for high risk individuals was Level III (evidence from well designed, quasi-experimental studies such as non-randomized, controlled, single group comparison or matched case-control series) and offered a "C" (inconsistent findings) recommendation for its use (Fleshner, et al. 2008).

CODES: Number Description

Eligibility for reimbursement is based upon the benefits set forth in the member's subscriber contract.

CODES MAY NOT BE COVERED UNDER ALL CIRCUMSTANCES. PLEASE READ THE POLICY AND GUIDELINES STATEMENTS CAREFULLY.

Codes may not be all inclusive as the AMA and CMS code updates may occur more frequently than policy updates.

Code Key: Experimental/Investigational = (E/I), Not medically necessary/ appropriate = (NMN).

<u>CPT:</u>	46601	Anoscopy; diagnostic, with high-resolution magnification (hra) (eg, colposcope, operating microscope) and chemical agent enhancement, including collection of specimen(s) by brushing or washing, when performed
	46607	Anoscopy; with high-resolution magnification (hra) (eg, colposcope, operating microscope) and chemical agent enhancement, with biopsy, single or multiple

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HCPCS: No code

<u>ICD10:</u>	B20	Human immunodeficiency virus (HIV) disease
	B97.7	Papillomavirus as cause of diseases classified elsewhere
	Z12.12	Encounter for screening for malignant neoplasm of rectum
	Z12.89	Encounter for screening for malignant neoplasm of other sites

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* key article

KEY WORDS:

Anal colposcopy, anoscopy, high-resolution

CMS COVERAGE FOR MEDICARE PRODUCT MEMBERS

Based on our review, high resolution anoscopy is not addressed in National or Regional Medicare coverage determinations or policies.