

Effective February 26, 2018

Policy Replaced by Article A53408



BlueCross BlueShield
of Alabama

Name of Blue Advantage Policy: **High Resolution Anoscopy**

Policy #: 617
Category: Surgical

Latest Review Date: January 2016
Policy Grade: C

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).*

Description of Procedure or Service:

Anoscopy is a procedure which examines the last two inches of the colon, including the perianal area and the distal rectum. High resolution anoscopy (HRA) is more complex than the standard anoscopy because it involves using an anoscope plus a high resolution colposcope. HRA is also known as colposcopy of the anal canal. During the procedure, acetic acid is applied to the anal canal to identify any suspicious areas. If a suspicious area is found, a biopsy may be taken.

A potentially precancerous condition called anal intraepithelial neoplasia (AIN), also known as anal squamous intraepithelial lesion (SIL), can be categorized into two groups; low grade SIL (LSIL) or high grade SIL (HSIL). LSIL often resolves spontaneously; however, HSIL is unlikely to resolve on its own without treatment. Although HSIL left untreated could eventually become cancerous, most HSIL will probably not. Squamous cell carcinoma (SCC) is the most common type of anal cancer, and appears to be linked to infection by the human papilloma virus (HPV). HPV is associated with a number of benign and malignant lesions in the anogenital tract and is recognized as a cause of cervical dysplasia and cancer.

HRA is currently being investigated for use in high-risk populations for identifying abnormal anal cytology and also as a tool to visualize areas of anal mucosa at risk for dysplasia to direct biopsy.

Policy:

Effective for dates of service on or after February 26, 2018 refer to Article A53408.

Effective for dates of service prior to February 26, 2018:

Blue Advantage will treat high resolution anoscopy for the screening, diagnosing, or management of anal dysplasia or anal cancer as a non-covered benefit and as 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.

Key Points:

A literature review was conducted through January 8, 2015. The following is a summary of the literature to date.

In 2011, Gimenez et al observed for association of risk factors for the development of anal cancer and the presence of anal squamous intraepithelial lesions. Detection of HPV was done via

PCR based method on 128 HIV positive patients for anal canal cytological sampling. HRA was then completed using acetic acid. The prevalences of anal HPV infection and of anal squamous intraepithelial lesions in the studied population were, respectively, 79% and 39.1%. High-resolution anoscopy showed sensibility of 90%, specificity of 19.23%, positive predictive value of 41.67%, negative predictive value of 75%, and a kappa coefficient of 0.076. According to the authors, HRA is demonstrated to be a sensitive, but not specific test for the detection of anal squamous intraepithelial lesions.

In 2014, Berry et al published a retrospective study which included 138 medical records of HIV infected men who developed anal cancer or perianal squamous cancer between 1997 through 2011. According to the authors, only HIV infected men who developed documented anal cancer in the site of previously biopsied HSIL were included. Of the 138 records reviewed, 111 of subjects were excluded from the study. Anal cancer was detected in most men by palpation of a hard mass during a digital anorectal exam (DARE). Only four of the 27 men in the study had anal cancer detected solely by using HRA. The authors concluded by stating, “Carefully controlled studies evaluating efficacy of screening for and treatment of HSIL to prevent anal cancer are needed.”

In 2015, Crawshaw et al conducted a retrospective review of 424 patients comparing HRA with expectant management (standard anoscopy with ablation) for the examination of AIN and the prevention of anal cancer. The patients were to follow up every six months indefinitely. The development of anal squamous cell cancer in each group was the primary endpoint. All patients in the study had biopsy proven anal intraepithelial neoplasia. Three patients (one in HRA group and two in expectant management) developed ASCC while being followed. Two patients were noted to be noncompliant with follow up and HIV treatment, and the third was noncompliant with topical 5-fluorouracil due to an allergy. The study found that AIN rarely progressed to ASCC when patients were compliant with expectant management or HRA. According to the authors, HRA should be further evaluated due to the increased cost, morbidity, and value.

The National Cancer Institute has recently started a multicenter phase III trial to determine if treatment of HSIL in HIV infected individuals can prevent anal cancer from developing. It is stated to be an eight year study with over 5,000 participants.

Summary

Although anal cancer is fairly rare, the incidence of new cases has been rising for several years. Certain risk factors, such as having anal HPV and HIV, seem to increase the risk of developing this disease. However, many people with these risk factors will never develop cancer.

High resolution anoscopy has been investigated for the screening, diagnosing, and/or managing anal dysplasia and anal cancer. Currently, the available evidence is insufficient to determine with certainty the effect of this technology on net health outcomes. According to one study, the digital exam is the most common way anal cancer was detected. Another study showed that if patients are compliant with their treatment regimen, the rate of developing anal cancer is low with or without HRA. Randomized controlled trials with long term follow up data are needed to prove that HRA is the most beneficial way to treat patients with this condition.

Practice Guidelines and Position Statements

National Comprehensive Cancer Network (NCCN)

The National Comprehensive Cancer Network (NCCN) includes high resolution anoscopy as a diagnostic tool in the work-up of individuals who present with anal margin lesions and anal canal cancer. With regard to the benefits and limitations of high resolution anoscopy, the NCCN states the following:

“High-grade anal intraepithelial neoplasia (AIN) can be a precursor to anal cancer, and treatment of high-grade AIN may prevent the development of anal cancer. AIN can be identified by cytology, HPV testing, digital rectal examination (DRE), high-resolution anoscopy, and/or biopsy. Estimates from a recent systematic review and meta-analysis of studies in men who have sex with men, however, suggest that the progression rates of AIN to cancer might be quite low, although prospective data are lacking. In addition, the spontaneous regression rate of high-grade AIN is not known.

Routine screening for AIN in high-risk individuals such as HIV-positive patients or men who have sex with men, is controversial because randomized controlled trials showing that such screening programs are efficacious at reducing anal cancer incidence and mortality are lacking while the potential benefits are quite large.”

American Society of Colon and Rectal Surgeons

In 2012, the American Society of Colon and Rectal Surgeons recommended for anal pap smear cytological examination in detection and follow up of LSIL/HSIL as Grade 1C (strong recommendation, low or very low quality evidence).

U.S. Preventative Services Task Force Recommendations

The U.S. Preventative Services Task Force Recommendation has not addressed the treatment of high resolution anoscopy.

Key Words:

Anal cancer, high grade, anal intraepithelial neoplasia, AIN, anal squamous intraepithelial lesion, SIL, high grade SIL, HSIL, HRA, anoscopy, ASCC

Approved by Governing Bodies:

Not applicable

Benefit Application:

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

Current Coding:

CPT Codes:

- 46601** Anoscopy; diagnostic with high-resolution magnification (HRA) (e.g. colposcope, operating microscope) and chemical agent enhancement, including collection of specimen(s) by brushing or washing, when performed. **(Effective 1/1/15)**
- 46607** Anoscopy; with high-resolution magnification (HRA) (e.g. colposcope, operating microscope) and chemical agent enhancement, with biopsy, single or multiple. **(Effective 1/1/15)**

Previous Coding:

- G6027** Anoscopy, high resolution (HRA) (with magnification and chemical agent enhancement); diagnostic, including collection of specimen(s) by brushing or washing when performed **(Deleted 12/31/15)**
- G6028** Anoscopy, high resolution (HRA) (with magnification and chemical agent enhancement); with biopsy(ies) **(Deleted 12/31/15)**

References:

1. American Cancer Society. What is anal cancer? [//www.cancer.org/cancer/analcancer/detailedguide/anal-cancer-what-is-anal-cancer](http://www.cancer.org/cancer/analcancer/detailedguide/anal-cancer-what-is-anal-cancer).
2. American Society of Colon and Rectal Surgeons. Clinical practice guidelines for anal squamous neoplasms. 2012. <https://www.fascrs.org/physicians/clinical-practice-guidelines>.
3. Berry JM, Jay N, Cranston RD et al. Progression of anal high-grade squamous intraepithelial lesions to invasive anal cancer among HIV-infected men who have sex with men. *Int. J. Cancer*: 134, 1147-1155.
4. Crawshaw BP, Russ AJ, Stein SL et al. High-resolution or expectant management for anal intraepithelial neoplasia for the prevention of anal cancer: is there really a difference? *Dis Colon rectum* 2015; 58:53-59.
5. Gimenez F, Costa-e-Silva IT, Jd a, et al. The value of high-resolution anoscopy in the diagnosis of anal cancer precursor lesions in HIV-positive patients. *Arq Gastroenterol*. 2011; 48(2): 136-45.
6. National Cancer Institute. Multi-center anal pre-cancer treatment and cancer prevention study launched in HIV infected persons. [//www.cancer.gov/news-events/press-releases/2015/anchor-trial-launch](http://www.cancer.gov/news-events/press-releases/2015/anchor-trial-launch).
7. National Comprehensive Cancer Network. NCCN clinical practice guidelines in oncology. Anal carcinoma. V1.2016.

Policy History:

Adopted for Blue Advantage, December 2015

Available for comment January 14 through February 28, 2016

Medical Policy Group, February 2018

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.