Close

High-Resolution Anoscopy

Number: 0808

Policy

Aetna considers high-resolution anoscopy (HRA) medically necessary for the diagnosis of a suspicious anal lesion in persons with abnormal anal physical findings (e.g., anogenital warts, hypo-pigmented or hyper-pigmented plaques/lesions, lesions that bleed, or any other lesions of uncertain etiology).

Aetna considers HRA guidance medically necessary for biopsy and ablation of high-grade anal intraepithelial neoplasia.

Aetna considers HRA experimental and investigational for screening of asymptomatic persons for anal dysplasia and anal cancer.

Background

Anal squamous dysplasia refers to a spectrum of diseases that ranges from low-grade squamous intraepithelial lesions (LSIL) to high-grade squamous intraepithelial lesions (HSIL) to invasive anal squamous cell carcinoma (SCC). Recent reports have shown a significant increase in both the incidence and prevalence of both HSIL and anal SCC, especially in immunocompromised individuals and men who have sex with men (MSM). These lesions are associated with chronic infection

Policy History

Last Review 01/08/2016
Effective: 11/19/2010
Next Review: 10/07/2016

Review History

Definitions

Additional Information

Clinical Policy Bulletin Notes

with the human papillomavirus (HPV). There are controversies as to the optimal management of patients with HSIL. There is an ongoing controversy over whether screening of high-risk patients with anal cytology is useful in identifying those who require further evaluation.

Examination of the anorectal region is enhanced with the use of high-resolution anoscopy (HRA), which is analogous to cervical colposcopy. Moreover, HRA can also be used to direct therapy. During HRA, a lubricated anoscope is inserted about 2 inches into the anal canal. A cotton swab wrapped in gauze and soaked in 3 % acetic acid is then inserted through the anoscope, and the anoscope is removed, leaving the gauze in place. The acetic acid reacts with the skin, giving dysplastic epithelium a white appearance. After 2 minutes, the gauze is removed and the anoscope re-inserted. A high-resolution colposcope (magnification of 10x to 40x) is used to view the walls of the anus (Pineda and Welton, 2008; Wilkin, 2010).

Human papillomavirus infections belong to the most common sexually transmitted infections worldwide. In human immunodeficiency virus (HIV)-infected MSM, anal HPV prevalence is more than 90 % and infections with multiple HPV types are common. Consequently, HPV-associated anogenital malignancies occur with high frequency in patients with HIV infection. Anal intraepithelial neoplasia (AIN) is a potential precursor lesion of anal SCC. Similar to cervical intraepithelial neoplasia (CIN), AIN is causally linked to persistent infections with high-risk HPV types such as HPV16 or HPV18. As AIN and CIN share distinct biological similarities, some investigators have suggested AIN screenings analogous to Papanicolaou (Pap) smear programs for CIN in high-risk populations to reduce the incidence of anal carcer. These screenings include cytological analysis followed by HRA in case of anal dysplasia. Treatment guidelines for AIN are not yet available. Treatments can be divided into topical (e.g., imiquimod, photodynamic therapy [PDT], podophyllotoxin, and trichloroacetic acid) and ablative (e.g., electrocautery, infrared coagulation, laser ablation, and surgical excision) measures. However, controlled studies on AIN treatment have not been performed. The impact of HPV

vaccination on AIN development will also need to be assessed. Long-term follow-up of these patients is essential to gain more insight into the natural history of anogenital HPV infection in HIV-positive MSM (Kreuter et al, 2008).

Anderson and colleagues (2004) stated that some investigators have proposed screening homosexual men for anal cancer and its probable precursor, high-grade AIN. Using widely accepted criteria for the introduction of screening programs, these investigators reviewed the evidence for screening for this condition in this high-risk population and highlighted areas where additional research is needed. While it is accepted that the incidence of anal cancer is at least 20 times higher in homosexual men than the general population, the natural history of anal cancer and its precise relationship with AIN is not clearly understood. Anal intraepithelial neoplasia is a very highly prevalent disease among homosexual men, but little is known about what predicts progression to invasive disease. The screening tests, exfoliate cytology and HRA, have a sensitivity of between 45 % and 70 %. Treatment options for AIN are limited by morbidity and high recurrence rates and there are no randomized controlled trials studying the effectiveness of therapeutic agents or surgery for high-grade AIN, although immunotherapies show very early promise. Theoretically, early detection may lead to better treatment outcomes. Studies of the potential negative consequences of screening programs on the homosexual population are needed. The authors concluded that available data do not support the implementation of a screening program for AIN and anal cancer in homosexual men.

No leading medical professional organizations setting the standard for healthcare maintenance of HIV-infected persons have adopted published recommendations for routine screening of anal dysplasia and anal cancer.

The Centers for Disease Control and Prevention's treatment guidelines on *Special populations: Sexually transmitted diseases (STD)* (2006) stated that "[r]outine laboratory screening for common STDs is indicated for all sexually active MSM". Anoscopy, HRA in particular, for anal dysplasia and anal cancer

was not mentioned. The Ontario Health Technology Advisory Committee (OHTAC, 2007) reviewed the role of anal dysplasia screening in those at high-risk. It did not recommend screening of high-risk individuals based on the low specificity for cytological screening, inadequate evidence of effectiveness for current treatment of pre-cancerous lesions, high recurrence rates, and no evidence that cytological screening reduces the risk of developing anal cancer. High-resolution anosopy was not discussed in the OHTAC report. The Standards Practice Task Force of the American Society of Colon and Rectal Surgeons (Fleshner et al, 2008) noted that based on numerous similarities between AIN and CIN, anal Pap smear cytology has been proposed for both screening of high-risk individuals and surveillance after treatment of AIN. High-resolution anosopy was not mentioned as a tool for screening of anal squamous neoplasms. Furthermore, the National Comprehensive Cancer Network's clinical practice guidelines in oncology on anal carcinoma (2010) does not mention anal cancer screeing.

Berry et al (2009) compared detection of high-grade anal neoplasia by HRA-guided biopsy to that by anal cytology, HPV testing, or the combination. A total of 125 MSM were enrolled in this study: HIV-negative = 85, HIV-positive = 35, and unknown status = 5. A specimen was taken for anal cytology and HPV testing, followed by HRA-guided biopsy of any lesions. A total of 91 % of HIV-positive and 57 % of HIV-negative MSM had anal HPV infection. In HIV-positive men, the sensitivity of abnormal cytology to detect high-grade anal neoplasia was 87 %, and in HIV-negative MSM it was 55 %. Among HIV-negative men, 9 of 20 cases of high-grade anal neoplasia would have been missed because cytology was negative, but the addition of HPV positivity increased sensitivity for the combination to 90 %. The authors concluded that sensitivity and specificity of anal cytology and HPV testing are different in HIV-positive and HIV-negative MSM for detecting high-grade anal neoplasia when patients have HRA-guided biopsy of lesions. The optimum use of HPV testing has yet to be defined. They stated that HRA is an effective tool for diagnosing high-grade anal neoplasia.

Fox (2009) examined whether current evidence and expert

opinion support the routine use of anal cytology and HRA in MSM. Most recently published guidelines do not recommend routine anal cytology, but anal cancer is undoubtedly a serious and growing problem for HIV-positive patients. Two recent cohort studies have provided data that suggested that the precursor lesion, HSIL, might not be more prevalent in patients on highly active anti-retroviral therapy than in historical pre-highly active anti-retroviral therapy cohorts or in HIV-negative MSM. If substantiated by further studies, this would make it easier to focus intervention with HRA on a smaller group of patients. This would be helpful because HRA remains a resource that is both costly and difficult to access in most countries. The sensitivity and specificity of anal cytology is poor and adjuncts to cytology such as p16(ink4a) staining and HPV viral loads might be utilized to further reduce the number of patients requiring HRA. Despite the burden of HSIL in HIV-negative MSM, anal cancer remains uncommon in this group. The author concluded that although routine anal cytology is not advisable for MSM at present, be they HIV-positive or HIV-negative, clinicians should be regularly performing digital rectal examination in those at high-risk of anal cancer.

Kreuter et al (2010) stated that anal dysplasia is common in HIV patients, especially in HIV-positive MSM. High-grade anal dysplasia can progress to invasive anal cancer. As in cervical carcinoma, there is a cause-and-effect relationship between anal cancer and HPV infection, especially with high-risk types such as HPV16. Several experts have recommended screening programs for anal cancer, including anal cytology along the lines of the Pap smear in women. Such screenings should only be performed if pathological findings result in further diagnostic steps and, if necessary, appropriate treatment. Clinical inspection, lesion biopsy, and treatment of anal dysplasia are performed under HRA.

Park and Palefsky (2010) stated that the incidence of HPV-associated anal cancer in MSM is striking and has not been mitigated by the use of highly active anti-retroviral therapy. Detection and treatment of high-grade AIN may reduce the incidence of anal cancer. Anal cytology is a useful tool to detect

high-grade AIN; annual screening of HIV-positive MSM and biennial screening of HIV-negative MSM appears to be cost-effective. Men who have sex with men and who exhibit abnormal cytology should be referred for HRA and biopsy. Individuals with high-grade AIN should receive treatment; treatment modalities for high-grade AIN show moderate effectiveness and are usually well-tolerated, but greater study is needed to ascertain which treatment is optimal. The authors also noted that large prospective studies are needed to document the effectiveness of screening and treatment of high-grade AIN on the incidence of anal cancer.

Santoso and colleagues (2010) estimated the prevalence of AIN in heterosexual women with genital intraepithelial neoplasia, and compared anal cytology with colposcopy for their effectiveness in AIN screening. Women with confirmed intraepithelial neoplasia on the cervix, vagina, or vulva were referred for gynecological oncology care. Subjects underwent anal cytology and HRA. Any lesion detected on HRA was biopsied. Wilson score method was used to estimate 95 % confidence interval for prevalence. McNemar's test compared the 2 screening methods. Women with average age of 39.6 years (range of 14 to 83 years) underwent anal cytology and anoscopy (n = 205). Of the 205 patients with genital intraepithelial neoplasia, 25 patients (12.2 %) had biopsy-proven AIN. Twelve patients (5.9 %) had abnormal anal cytology (9 with atypical squamous cells of undetermined significance [ASC-US], 3 with LSIL). None of the 9 patients with anal ASC-US had biopsy-proven AIN. Of the 3 patients with anal LSIL, 2 had AIN II and 1 had condyloma on biopsy. However, 78 patients (38 %) had abnormal anoscopic findings that resulted in 25 biopsy-proven AIN (8 AIN I, 5 AIN II, 12 AIN III), condylomas (n = 11), and hyper-keratosis (n = 8). Anoscopy identified 32 % (n = 25) with AIN out of 78 abnormal anoscopic examinations. In diagnosing AIN, anoscopy has 100 % sensitivity and 71 % specificity; anal cytology has 8 % sensitivity and 94 % specificity. The authors concluded that patients with cervical, vulvar, and vaginal intraepithelial neoplasia have 12.2 % prevalence of AIN and should be screened with HRA. In AIN screening, anoscopy is more sensitive, but less specific than anal cytology.

The authors noted that this study has several drawbacks. One of them was that the study population and screening procedures were carried out by 1 gynecological oncologist, which may limit the application of the results to other populations and practices. Another limitation was that the high rate of AIN in this study may not be a good representation of the general population of patients because the authors' facility is a referral center for genital intraepithelial neoplasia. Also, the total number of 26 patients with the diagnosis of AIN is still inadequate to assess the role of HIV, sexual practice, number of sexual partners, smoking, and other factors that may contribute to the development of AIN and anal cancer. These investigators stated that further studies are needed to clarify factors that may contribute to the development of AIN and confirm a better screening method for AIN.

In an editorial that accompanied the afore-mentioned paper, Eckert (2010) stated that "[t]he 8.3 % prevalence of anal intraepithelial neoplasm 2-3 found in this study is higher and raises concern. However, before recommending routine anal screening in women with HPV disease, we need better understanding of both disease burden and the natural history of this disease. Currently, neither the U.S. Preventive Task Force, nor the American College of Obstetricians and Gynecologists has screening recommendations for anal intraepithelial neoplasia. In my opinion, we are not ready for a recommendation that all women with genital intraepithelial neoplasm undergo anal screening. Nor are we ready to state definitively how to screen and whom to treat. In HIV-seronegative women, a provider should use clinical judgment with the understanding that HPV disease is multifocal and that a woman with high-grade cervical, vulvar, or vaginal intraepithelial neoplasm is at risk for anal disease ... We can prevent the need for future evaluation of genital intraepithelial lesions in a significant portion of women by increasing HPV vaccine coverage. Let us seize our current prevention opportunity, even as we continue to gather needed data regarding anal HPV disease".

Guidelines on *Human papillomavirus* (2007) and *Preventive medicine: Gynecologic care* (2009) from the New York State

Department of Health recommended that clinicians should refer women with cervical HSIL and individuals with abnormal anal physical findings (e.g., anogenital warts, hypo-pigmented or hyper-pigmented plaques/lesions, lesions that bleed, or any other lesions of uncertain etiology) for HRA and/or examination with biopsy of abnormal tissue.

The Centers for Disease Control and Prevention, the National Institutes of Health, and the HIV Medicine Association of the Infectious Diseases Society of America's guidelines on *Prevention and treatment of opportunistic infections in HIV-infected adults and adolescents* (Kaplan et al, 2009) noted that no national recommendations exist for routine screening for anal cancer. Until such time, certain specialists recommend an annual digital rectal examination as an important procedure to detect masses on palpation that might be anal cancer (BIII). In addition, certain specialists recommend anal cytologic screening for HIV-sero-positive men and women (CIII). If anal cytology is performed and indicates atypical squamous cell of undetermined significance or atypical squamous cells suggestive of high-grade, LSIL, or HSIL (BIII), then it should be followed by HRA. Visible lesions should be biopsied to determine the level of histological changes and to rule out invasive cancer (BIII).

- Strength of the recommendation "B" refers to moderate evidence for efficacy -- or strong evidence for efficacy but only limited clinical benefit -- supports recommendation for use. Should generally be offered.
- Strength of the recommendation "C" refers to evidence for efficacy is insufficient to support a recommendation for or against use. Or evidence for efficacy might not outweigh adverse consequences (e.g., drug toxicity, drug interactions) or cost of the treatment or alternative approaches. Optional.
- Quality of evidence supporting the recommendation "III" denotes evidence from opinions of respected authorities based on clinical experience, descriptive studies, or reports of expert committees.

Treatments for anal squamous dysplasia vary in terms of morbidity and success rates. Wide local excision is associated

with significant morbidity. Newer therapies such as topical immuno-modulation, PDT, and therapeutic vaccines have been proposed, but long-term follow-up is unavailable. Compared with the use of wide local excision, the use of a comprehensive approach of cytology and office-based and/or operating room procedures directed with HRA has been reported to result in less morbidity, clearance of HSIL in up to 80 % of patients, and malignant progression in 1 % (Pineda and Welton, 2008).

Pineda et al (2007) reviewed 42 patients who underwent HRA-targeted surgical therapy of anal dysplasia in the past 10 years. Patients were followed-up with physical examination, cytology, HRA, and biopsy if indicated. Patients with disease amenable to local therapy were treated with office-based HRA-directed therapies. A total of 30 men (mean age of 39 years, range of 21 to 63 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, with 4 undergoing planned staged treatment due to circumferential disease. These lesions recurred in 45 %, and most were re-treated successfully in-office. Progression to HSIL was seen in 1 patient with LSIL and to squamous SCC in 1 patient with HSIL despite therapy. No patients with LSIL had dysplasia at last follow-up. Minor complications occurred in 3 patients. Surgical therapy under HRA guidance coupled with surveillance and re-treatment with office-based therapies offered an effective method in controlling anal dysplasia in immuno-competent patients. Morbidity is minimal, and the progression to cancer rate is low (2.4 %).

Anal intraepithelial neoplasia III (AIN III) is a risk factor for anal cancer with poor curative results and high morbidity. High-resolution anoscopy is a minimally invasive means of identifying and treating AIN III early. Chung and Rosenfeld (2007) retrospectively reviewed HRA in the treatment of AIN III in a community setting. From January 2002 through November 2005, a total of 76 patients with AIN III diagnosed by anal Pap smear, colposcopy, or biopsy underwent HRA for diagnosis and treatment; 21 patients with AIN III on initial HRA underwent follow-up HRA for re-assessment and treatment at 6 months.

Recurrence/persistence of disease was recorded and compared with patient characteristics. Of the 21 patients with repeat HRA, 4 were HIV-negative and 17 were HIV-positive; 12 of 21 (57 %) had intra-anal recurrence/persistence; 9 of 21 (43 %) had no AIN III. Eleven (92 %) with recurrence were HIV-positive; 1 (8 %) was HIV-negative. Three (75 %) HIV-negative patients had no recurrence/persistence; 1 of 4 (25 %) had recurrence; and 11 of 17 (65 %) HIV-positive patients had persistence of disease. The authors concluded that HRA is an alternative tool to treat AIN III and can be performed in a community setting yielding results comparable to the university setting.

Pineda et al (2008) examined if HRA-directed surgical destruction of anal HSIL is effective in controlling these lesions while preserving normal tissues. A retrospective review of 246 patients with HSIL treated with HRA-targeted surgical destruction from 1996 to 2006 was performed, with at least 1 follow-up at a minimum 2 months with physical examination, HRA, cytology, and biopsy when indicated. Lesions were extensive in 197 patients (81 %); 207 (84 %) were men, and 194 (79 %) were immuno-compromised (HIV or other). Persistent disease occurred in 46 patients (18.7 %), requiring planned staged therapy; 10 required surgery. Recurrent HSIL occurred in 114 patients (57 %) at an average 19 (range of 3 to 92) months; 26 of these required surgery. All other patients were re-treated in-office with HRA-directed therapies. Complications were seen in 9 patients (4 %). Despite treatment, 3 patients progressed to invasive cancer (1.2 %). At their last visit, 192 patients (78 %) had no evidence of HSIL. The authors concluded that HRA-targeted destruction combined with office-based surveillance and therapy is effective in controlling HSIL and is superior to expectant management or traditional mapping procedures.

The Standards Practice Task Force of the American Society of Colon and Rectal Surgeons (Fleshner et al, 2008) stated that targeted destruction guided by HRA is effective to identify, biopsy, and destroy high-grade AIN without the morbidity associated with wide local excision; however there is a high risk for persistent or recurrent disease among HIV-positive patients.

Goon et al (2015) noted that anal cancer is uncommon, with an incidence rate of 0.5 to 1.0 per 100000 of the population but incidence rates have been steadily increasing over the last 3 decades. Biological and epidemiological evidence have been mounting and demonstrated that anal cancer has many similarities to cervical cancer, especially in regard to its etiology. High-resolution anoscopy of the anal region, analogous to colposcopy of the cervix, is a technique that is not well-known in the medical and surgical fraternity. Evidence to support the use of HRA for detection and treatment in the surveillance of AIN exists and strongly suggests that it is beneficial, resulting in reduced rates of cancer progression. Pilot data from these researchers' study showed a local disease failure rate of 1.73 per 1,000 patient-months compared with a published rate of 9.89 per 1,000 patient-months. This demonstrated a 5.72-fold reduction in local disease failure rates of patients with T1-T3 tumors; these data therefore suggested that use of HRA for detection and treatment in surveillance of anal cancer patients will help prevent local regional relapse at the anal site. The authors concluded that there is an urgent need for a large, randomized controlled clinical trial (RCT) to definitively test this hypothesis.

Dalla Pria and colleagues (2014) stated that the ability to detect and treat pre-malignant anal lesions suggests screening may prevent anal cancer. The incidence of anal cancer in men who have sex with men (MSM) living with HIV exceeds that of cervical cancer before screening was introduced. These researchers reported the longitudinal results from a pilot study of HRA screening of HIV-positive MSM. High-resolution anoscopy with intervention for HSILs was offered to asymptomatic HIV-positive MSM. Patients with HSILs were treated and follow-up HRA performed after 6 months, while patients with LSILs had a repeat HRA after 12 months. A total of 368 asymptomatic MSM had a total of 1,497 HRAs during a median follow-up of 4.2 years (maximum of 13 years). At first HRA, 36 % had normal appearances, 16 % had no dysplasia, 15 % AIN-1, 19 % AIN-2 and 13 % AIN-3. During follow-up, 5 patients (1.4 %) developed invasive anal cancer (incidence 2.7 per 1,000 person-years). The 5-year cancer rate for the 368 patients was 0.3 % (95 %

confidence interval [CI]: 0 to 0.6 %). Progression to cancer was associated with higher age (p = 0.049) and AIN-3 (p = 0.024); 90 patients had AIN-3 present at least at one HRA. The cumulative risk of cancer from first AIN-3 diagnosis was 3.2 % (95 % CI: 0 to 7.8 %) at 5 years; 171 patients had HSILs (AIN-2 or 3) present at least once. The cumulative risk of cancer from first HSIL diagnosis was 0.6 % (95 % CI: 0 to 1.8 %) at 5 years. The authors concluded that AIN-3 is a significant risk factor for subsequent anal cancer, although the tumors detected in screened patients were small localized, and generally the outcomes were favorable.

CPT Codes / HCPCS Codes / ICD-10 Codes	
Information in the [brackets] below has been added for clarification purposes. Codes requiring a 7th character are represented by "+":	
ICD-10 codes will become effective as of October 1, 2015:	
CPT codes covered for indications listed in the CPB:	
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
HCPCS codes covered if selection criteria are met:	
G6027 - G6028	Anoscopy, high resolution (HRA) (with magnification and chemical agent enhancement)
ICD-10 codes covered if selection criteria are met:	
A63.0	Anogenital (venereal) warts
C21.0 - C21.1	Malignant neoplasm of anal canal and anus, unspecified
C78.5	Secondary malignant neoplasm of large intestine and rectum
D01.3	Carcinoma in situ of anus and anal canal
D12.7 - D12.9	Benign neoplasm of rectum and anal canal

K62.0 - K62.1	Anal and rectal polyp
K62.5 - K62.89	Other diseases of anus and rectum
R85.610 - R85.619	Abnormal cytological findings in specimens from anus
R85.81	Anal high risk human papillomavirus (HPV) DNA test positive
R85.82	Anal low risk human papillomavirus (HPV) DNA test positive
ICD-10 codes not covered for indications listed in the CPB (not all-inclusive):	
Z12.10 - Z12.13	Encounter for screening for malignant neoplasm of intestinal tract
Z12.89	Encounter for screening for malignant neoplasm of other sites
Z12.9	Encounter for screening for malignant neoplasm, site unspecified

The above policy is based on the following references:

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