

## Evidence Based Guideline

### Endoscopic Radiofrequency Ablation or Cryoablation for Barrett's Esophagus

**File Name:** endoscopic\_radiofrequency\_ablation\_or\_cryoablation\_for\_barretts\_esophagus  
**Origination:** 4/2009  
**Last CAP Review:** 10/2010  
**Next CAP Review:** 10/2012  
**Last Review:** 10/2011

#### **Description of Procedure or Service**

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##### **Barrett's Esophagus and the Risk of Esophageal Carcinoma**

The esophagus is normally lined by squamous epithelium. Barrett's esophagus is a condition in which the normal squamous epithelium is replaced by specialized columnar-type epithelium known as intestinal metaplasia, in response to irritation and injury caused by gastroesophageal reflux disease (GERD). Barrett's esophagus occurs in the distal esophagus, may be any length, focal or circumferential, and can be visualized by the endoscopist as being a different color than the background squamous mucosa. Confirmation of Barrett's esophagus requires biopsy of the columnar epithelium and microscopic identification of intestinal metaplasia.

Intestinal metaplasia is a precursor to esophageal adenocarcinoma, and patients with Barrett's esophagus are at a 40-fold increased risk for developing this disease compared to the general population. Esophageal adenocarcinoma is thought to result from a stepwise accumulation of genetic abnormalities in the specialized epithelium, which results in the phenotypic expression of histologic features of low-grade dysplasia (LGD) to high-grade dysplasia to carcinoma. Nondysplastic Barrett's esophagus progresses to high-grade dysplasia at a rate of 0.9% per patient, per year, and once high-grade dysplasia is present, the risk of developing adenocarcinoma is 2%-10% per patient, per year.

##### **Management of Barrett's Esophagus**

The current management of Barrett's esophagus includes treatment of GERD, and surveillance endoscopy to detect progression to high-grade dysplasia and adenocarcinoma. The finding of low-grade dysplasia typically warrants only follow-up and surveillance biopsies, whereas the finding of high-grade dysplasia or early-stage adenocarcinoma warrant mucosal ablation or resection (either endoscopic mucosal resection [EMR] or esophagectomy)

EMR, either focal or circumferential, provides a histologic specimen for examination and staging (unlike ablative techniques). A recent study provided long-term results for EMR in 100 consecutive patients with early Barrett's associated adenocarcinoma (limited to the mucosa). The 5-year overall survival (OS) was 98% and metachronous lesions were observed in 11% of patients after a mean of 36.7 months. In a recent review by Pech and colleagues, it is stated that circumferential EMR of the entire segment of Barrett's leads to a stricture rate of 50%, and recurrences occur at a rate of up to 11%.

Mucosal ablation techniques that are available consist of one of several thermal (multipolar electrocoagulation [MPEC], argon plasma coagulation [APC], heater probe, Nd: YAG laser, KTP-YAG laser, diode laser, argon laser, and cryoablation) or nonthermal (5-aminolevulinic acid [5-ALA] and photofrin photodynamic therapy [PDT]) techniques. PDT has been the only therapy shown in a randomized phase III trial to significantly decrease the risk of carcinoma in Barrett's esophagus. Two hundred and eight patients with high-grade dysplasia were randomized to PDT and omeprazole versus omeprazole alone. At 24 months' follow-up, 77% of patients treated with PDT had complete ablation of high-grade dysplasia versus 39% in the control group ( $p < 0.0001$ ) and occurrence of adenocarcinoma

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within a follow-up time of 3.6 years was 13% in the PDT group versus 20% in the control group (p<0.006) (PDT therapy for Barrett's esophagus is discussed in a separate policy) However, the use of PDT for Barrett's esophagus with high-grade dysplasia has decreased dramatically recently, due to the fact that is relatively expensive and associated with a high complication rate, including photosensitivity and esophageal stricture formation in up to 30% of patients treated with this method.

The CryoSpray Ablation™ System (formerly the SprayGenix™ Cryo Ablation System, CSA Medical, Inc.) uses a low-pressure spray for spraying liquid nitrogen through an upper endoscope. Cryotherapy allows for treatment of uneven surfaces, however, disadvantages include the uneven application inherent in spraying the cryogen.

Treating high-grade dysplasia or mucosal cancer solely with ablative techniques risks undertreating the approximately 10% of patients who have undetected submucosal cancer, in whom esophagectomy would have been required.

The HALO system from BARRX Medical, Inc. (Sunnyvale, Calif.) uses radiofrequency energy and consists of two components: an energy generator and an ablation catheter. The generator provides rapid (i.e., less than 1 second) delivery of a predetermined amount of radiofrequency energy to catheter. Both the HALO90 and HALO360 are inserted into the esophagus with an endoscope, using standard endoscopic techniques. The HALO90 catheter is plate-based and used for focal ablation of areas of Barrett's esophagus up to 3cm. The HALO360 uses a balloon catheter that is sized to fit the individual esophagus, and is inflated to allow for circumferential ablation.

The ablation with radiofrequency affects only the most superficial layer of the esophagus (the mucosa), leaving the underlying tissues unharmed. Efficacy measures of the procedure include eradication of intestinal metaplasia without leaving behind microscopic (or "buried") foci and post-ablation regrowth of the normal squamous epithelium. Reports of the efficacy of the HALO system in ablating Barrett's esophagus have been as high as 70% (comparable to alternative methods of ablation [e.g., APC and MPEC]), and even higher in some reports. The incidence of leaving behind "buried" foci of intestinal metaplasia has been reported to be 20%-44% with APC and 7% with MPEC; reports using the HALO system have been 0%. Another potential advantage to the HALO system is that because it is automated, it eliminated operator-dependent error that may be seen with APC and MPEC.

## Regulatory Status

The HALO360 received U.S. Food and Drug Administration (FDA) 510(k) clearance for marketing in 2005 and the HALO90 in 2006. The FDA-labeled indications are for use in coagulation of bleeding and nonbleeding sites in the gastrointestinal tract, and include the treatment of Barrett's esophagus. (6) The CryoSpray Ablation™ System received FDA 510(k) marketing clearance in December 2007 for use as a "cryosurgical tool for destruction of unwanted tissue in the field of general surgery, specifically for endoscopic applications."

## Related Policies:

Photodynamic Therapy for Treatment of Specific Cancers

**\*\*\*Note: This Evidence Based Guideline is complex and technical. For questions concerning the technical language and/or specific clinical indications for its use, please consult your physician.**

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Radiofrequency ablation may be appropriate for treatment of Barrett's esophagus with high-grade dysplasia. Radiofrequency ablation for Barrett's esophagus with high-grade dysplasia may be used in combination with endoscopic mucosal resection of nodular/visible lesions. The diagnosis of high-grade dysplasia should be confirmed by two pathologists prior to radiofrequency ablation.

Radiofrequency ablation of high-grade dysplasia in Barrett's esophagus has been shown to be at least as

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effective in eradicating high-grade dysplasia as other ablative techniques with a lower progression rate to cancer, and may be considered as an alternative to esophagectomy.

## **Medical Evidence regarding Endoscopic Radiofrequency Ablation or Cryoablation for Barrett's Esophagus indicates it is not recommended in the following situations:**

Radiofrequency ablation is not recommended for treatment of Barrett's esophagus with low-grade dysplasia or Barrett's esophagus in the absence of dysplasia. More data are required concerning the use of RFA for the eradication of low-grade dysplasia and nondysplastic Barrett's esophagus. Longer follow-up is needed to show that eradication will persist, and that the benefits will outweigh potential complications in these patients who show a lower rate of progression to adenocarcinoma than those with high-grade dysplasia.

Cryoablation is not recommended for Barrett's esophagus, with or without dysplasia. Data for the efficacy of cryoablation of Barrett's esophagus with or without dysplasia are limited. The studies consist of small numbers of patients with short-term follow-up, and therefore this approach is not recommended.

The National Comprehensive Cancer Network clinical practice guidelines for esophageal cancer state that esophageal cancer stage Tis (carcinoma in situ) or T1a (intramucosal invasion) may be treated primarily with endoscopic mucosal resection, esophagectomy, or ablation; radiofrequency ablation is not specifically addressed and the guidelines state that among the methods of mucosal ablation, photodynamic therapy is superior for achieving ablation of metaplastic and dysplastic epithelium as well as for obviating the need for further interventions.

A search (November, 2009) of the U.S. National Institutes of Health Clinical Trials.gov registry identified a phase II/III trial currently recruiting participants with Barrett's esophagus and gastroesophageal reflux disease. The aim of the study is to evaluate the long-term efficacy of evidence-based diagnostic and therapeutic algorithms and techniques (such as radiofrequency). Estimated enrollment is 100 patients, with an estimated study completion date of August 2017 (NCT00513331).

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## **Benefits Application**

This medical policy relates only to the services or supplies described herein. Please refer to the Member's Benefit Booklet for availability of benefits. Member's benefits may vary according to benefit design; therefore member benefit language should be reviewed before applying the terms of this medical policy.

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## **Billing/Coding/Physician Documentation Information**

This guideline may apply to the following codes. Inclusion of a code in this section does not guarantee that it will be reimbursed. For further information on reimbursement guidelines, please see Administrative Policies on the Blue Cross Blue Shield of North Carolina web site at [www.bcbsnc.com](http://www.bcbsnc.com). They are listed in the Category Search on the Medical Policy search page.

*Applicable codes: There are no specific CPT or HCPCS codes for this service.*

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## **Scientific Background and Reference Sources**

Wang KK, Sampliner RE; Practice Parameters Committee of the American College of Gastroenterology. Updated guidelines 2008 for the diagnosis, surveillance and therapy of Barrett's esophagus. *Am J Gastroenterol* 2008; 103(3):788-797. Available at: <http://www.acg.gi.org/physicians/guidelines/BarrettsEsophagus08.pdf> Last accessed November 2008.

Esophageal Cancer. National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology, v.1.2009; [http://www.nccn.org/professionals/physician\\_gls/PDF/esophageal.pdf](http://www.nccn.org/professionals/physician_gls/PDF/esophageal.pdf). Last accessed November 2008.

BCBSA Medical Policy Reference Manual [Electronic Version]. 2.01.80, 12/11/2008

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Senior Medical Director Review - 3/2009

BCBSA Medical Policy Reference Manual [Electronic Version]. 2.01.80, 12/10/2009

Shaheen NJ, Sharma P, Overholt BF et al. Radiofrequency ablation in Barrett's esophagus with dysplasia. *N Engl J Med* 2009; 360(22):2277-88.

Senior Medical Director Review 3/2010

BCBSA Medical Policy Reference Manual [Electronic Version]. 2.01.80, 12/09/2010

Medical Director review – 10/2011

## Policy Implementation/Update Information

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| 4/13/09  | Evidence based guideline adopted from the BCBS Association. Reviewed with Senior Medical Director 3/16/2009. Endoscopic Radiofrequency Ablation for Barrett's Esophagus is not recommended as a treatment of Barrett's esophagus with or without associated dysplasia or early-stage adenocarcinoma. (btw)  |
| 4/27/10  | Policy name changed to include Cryoablation. "Guideline Number" removed. Updated "Description" section. Added "Radiofrequency ablation may be appropriate for treatment of Barrett's esophagus with high-grade dysplasia. Radiofrequency ablation for Barrett's esophagus with high-grade dysplasia may be used in combination with endoscopic mucosal resection of nodular/visible lesions. The diagnosis of high-grade dysplasia should be confirmed by two pathologists prior to radiofrequency ablation. Radiofrequency ablation of high-grade dysplasia in Barrett's esophagus has been shown to be at least as effective in eradicating high-grade dysplasia as other ablative techniques with a lower progression rate to cancer, and may be considered as an alternative to esophagectomy." "Radiofrequency ablation is not recommended for treatment of Barrett's esophagus with low-grade dysplasia or Barrett's esophagus in the absence of dysplasia. More data are required concerning the use of RFA for the eradication of low-grade dysplasia and nondysplastic Barrett's esophagus. Longer follow-up is needed to show that eradication will persist, and that the benefits will outweigh potential complications in these patients who show a lower rate of progression to adenocarcinoma than those with high-grade dysplasia. Cryoablation is not recommended for Barrett's esophagus, with or without dysplasia. Data for the efficacy of cryoablation of Barrett's esophagus with or without dysplasia are limited. The studies consist of small numbers of patients with short-term follow-up, and therefore this approach is considered investigational." Added to the "When not recommended" section. Reviewed with the Senior Medical Director 3/28/2010. References added. (btw) |
| 11/23/10 | Specialty Matched Consultant Advisory Panel review 10/28/10. Evidence Based Guideline accepted as written. (adn)  |
| 11/8/11  | Routine annual review. No change to guideline. (adn)  |

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