

Evidence Based Guideline

Endoscopic Radiofrequency Ablation for Barrett's Esophagus

File Name: endoscopic_radiofrequency_ablation_for_barretts_esophagus
Guideline Number: EBG.MED1133
Origination: 4/2009
Last Review: 3/2009
Next Review: 4/2010

Description of Procedure or Service

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 (esophagectomy).

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.

A newly developed ablative method is the HALO System from BARRX Medical, Inc. (Sunnyvale, Calif.).

The HALO system 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

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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.

FDA Clearance

The HALO360 received U.S. Food and Drug Administration (FDA) clearance via 510(k) in 2005 and the HALO90 in 2006. The FA-labeled indications are for the use in coagulation of bleeding and nonbleeding sites in the gastrointestinal tract, and include the treatment of Barrett's esophagus.

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The available evidence does not permit conclusions regarding the effect of Endoscopic Radiofrequency Ablation for Barrett's Esophagus on health outcomes, therefore this procedure is not recommended.

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

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.

No phase III trials have been performed on the use of radiofrequency ablation and the treatment of Barrett's esophagus. To date, studies have been conducted to investigate the safety and efficacy of this technique, and have consisted mainly of small numbers of patients with relatively short follow-up. The long-term effect of this technique in eliminating Barrett's esophagus and its impact on the incidence of esophageal adenocarcinoma are unknown.

According the American College of Gastroenterology for the diagnosis, surveillance, and treatment of Barrett's esophagus, further evaluation of the recent technology of radiofrequency ablation is needed.

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.

A search (November, 2008) 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).

Benefits Application

Please refer to certificate for availability of benefit. This guideline relates only to the services or supplies

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described herein. Benefits may vary according to benefit design; therefore certificate language should be reviewed before applying the terms of the policy.

Billing/Coding/Physician Documentation Information

This policy 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. 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.

Policy Key Words

Key Words: [EBG.MED1133](#).

Medical Term Definitions

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. Last accessed November 2008.

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

Senior Medical Director Review - 3/2009

Policy Implementation/Update Information

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)

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