

# Medical Coverage Policy



**Blue Cross  
Blue Shield**  
of Rhode Island

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

Device/Equipment    Drug    Medical    Surgery    Test    Other

<b>Effective Date:</b>	<b>2/15/2011</b>	<b>Policy Last Updated:</b>	<b>3/5/2013</b>
------------------------	------------------	-----------------------------	-----------------

**Prospective review is recommended/required. Please check the member agreement for preauthorization guidelines.**

**Prospective review is not required.**

### Description

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 of any length, may be 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 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 lowgrade dysplasia (LGD) to high-grade dysplasia (HGD) to carcinoma.

The current management of Barrett's esophagus includes treatment of GERD and surveillance endoscopy to detect progression to HGD or adenocarcinoma. The finding of LGD typically warrants only follow-up and surveillance biopsies, whereas the finding of HGD or early-stage adenocarcinoma warrants 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).

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.

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.

The HALO System from BARRX Medical, Inc. (Sunnyvale, Calif.) uses radiofrequency (RF) energy and consists of 2 components: an energy generator and an ablation catheter.

Radiofrequency ablation (RFA) of high-grade dysplasia (HGD) 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. Therefore, RFA may be considered medically necessary for patients with Barrett's esophagus (BE) and HGD.

For patients with low-grade dysplasia (LGD), the benefit of RFA is less certain, as the rate of progression to cancer is variable in the literature. There are no high-quality trials that treat patients with an initial diagnosis of LGD and report improved outcomes. However, based on the available evidence, specialty society guidelines, and the results of clinical vetting, it is possible to define a population with a higher risk of progression by having the initial LGD diagnosis confirmed by an additional pathologist who is an expert in GI pathology. In this subpopulation of patients with LGD, it is likely that the benefit of treatment outweighs the risk. As a result, RFA of LGD may be considered medically necessary when the initial diagnosis of LGD is confirmed by an expert in gastrointestinal (GI) pathology.

For patients with non-dysplastic BE, it cannot be concluded that the benefit of RFA outweighs the risk, and therefore RFA is considered not medically necessary for this population.

Data for the efficacy of cryoablation of BE with or without dysplasia are limited. The studies consist of small numbers of patients with short-term follow-up, and therefore cryoablation of BE is considered not medically necessary.

**Medical Criteria:**

None

**Policy:**

Radiofrequency ablation may be considered **medically necessary** for treatment of Barrett's esophagus with high-grade dysplasia. The diagnosis of high-grade dysplasia should be confirmed by two pathologists prior to radiofrequency ablation.

Radiofrequency ablation may be considered **medically necessary** for treatment of Barrett's esophagus with low-grade dysplasia, when the initial diagnosis of low-grade dysplasia is confirmed by two pathologists, one of whom is an expert in GI Pathology. It is ideal that two experts in GI pathology agree on the diagnosis in order to confirm LGD.

Radiofrequency ablation is considered **not medically necessary** for treatment of Barrett's esophagus in the absence of dysplasia due to lack of peer reviewed literature that supports efficacy.

Cryoablation is considered **not medically necessary** for Barrett's esophagus, with or without dysplasia due to lack of peer reviewed literature that supports efficacy.

**Coverage:**

Benefits may vary between groups/contracts. Please refer to the appropriate member certificate/subscriber agreement for applicable surgery/not medically necessary coverage/benefits

**Coding:**

There is no CPT code specific to radiofrequency or cryoablation of tissue in the esophagus. These procedures would likely be coded using one of the following CPT codes:

**43228, 43258, 43499, 43257**

**Published:**

Provider Update, May 2013

Provider Update, Apr 2012

Provider Update, Jun 2011

**References:**

- I. Bhat S, Coleman HG, Yousef F et al. Risk of malignant progression in Barrett's esophagus patients: results from a large population-based study. J. Natl. Cancer Inst. 2011; 103(13):1049-57.
- II. Semlitsch T, Jeitler K, Schoefl R et al. A systematic review of the evidence for radiofrequency ablation for Barrett's esophagus. Surg. Endosc. 2010; 24(12):2935-43.
- III. NCCN Guidelines. Esophageal cancer (v.2.2011). Available online at: [http://www.nccn.org/professionals/physician\\_gls/PDF/esophageal.pdf](http://www.nccn.org/professionals/physician_gls/PDF/esophageal.pdf). Last accessed November 2011.

**History:**

January 2013 - Annual review

This medical policy is made available to you for informational purposes only. It is not a guarantee of payment or a substitute for your medical judgment in the treatment of your patients. Benefits and eligibility are determined by the member's subscriber agreement or member certificate and/or the employer agreement, and those documents will supersede the provisions of this medical policy. For information on member-specific benefits, call the provider call center. If you provide services to a member which are determined to not be medically necessary (or in some cases medically necessary services which are non-covered benefits), you may not charge the member for the services unless you have informed the member and they have agreed in writing in advance to continue with the treatment at their own expense. Please refer to your participation agreement(s) for the applicable provisions. This policy is current at the time of publication; however, medical practices, technology, and knowledge are constantly changing. BCBSRI reserves the right to review and revise this policy for any reason and at any time, with or without notice.