Medical Policy

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Title: Endoscopic Radiofrequency Ablation or Cryoablation for Barrett Esophagus

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Populations	Interventions	Comparators	Outcomes
Individuals: • With Barrett esophagus with high-grade dysplasia	Interventions of interest are: • Endoscopic radiofrequency ablation	Comparators of interest are: • Esophagectomy • Endoscopic mucosal resection • Surveillance	Relevant outcomes include: • Change in disease status • Morbid events • Treatment-related mortality • Treatment-related morbidity
Individuals: • With Barrett esophagus with low-grade dysplasia	Interventions of interest are: • Endoscopic radiofrequency ablation	Comparators of interest are: • Surveillance	Relevant outcomes include: • Change in disease status • Morbid events • Treatment-related mortality

Populations	Interventions	Comparators	Outcomes
			• Treatment-related morbidity
Individuals: • With Barrett esophagus without dysplasia	Interventions of interest are: • Endoscopic radiofrequency ablation	Comparators of interest are: • Surveillance	Relevant outcomes include: • Change in disease status • Morbid events • Treatment-related mortality • Treatment-related morbidity
Individuals: • With Barrett esophagus with or without dysplasia	Interventions of interest are: • Endoscopic cryoablation	Comparators of interest are: • Esophagectomy • Endoscopic mucosal resection • Surveillance	Relevant outcomes include: • Change in disease status • Morbid events • Treatment-related mortality • Treatment-related morbidity

DESCRIPTION

In Barrett esophagus (BE), the normal squamous epithelium is replaced by specialized columnar-type epithelium, known as intestinal metaplasia. Intestinal metaplasia is a precursor to adenocarcinoma and may be treated with mucosal ablation techniques such as radiofrequency ablation (RFA) or cryoablation.

OBJECTIVE

The objective of this evidence review is to determine whether the use of endoscopic radiofrequency ablation, with or without endomucosal resection if indicated, or endoscopic cryoablation improves the net health outcome for individuals who have Barrett esophagus.

BACKGROUND

Barrett Esophagus and Risk of Esophageal Carcinoma

The esophagus is normally lined by squamous epithelium. Barrett Esophagus (BE) 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. Occurring in the distal esophagus, BE may be of any length; it may be focal or circumferential and can be seen on endoscopy as being a different color than the background squamous mucosa. Confirmation of BE requires a biopsy of the columnar epithelium and microscopic identification of intestinal metaplasia.

Intestinal metaplasia is a precursor to esophageal adenocarcinoma, which is thought to result from a stepwise accumulation of genetic abnormalities in the specialized epithelium, resulting in the phenotypic expression of histologic features from low grade dysplasia (LGD), to high-grade dysplasia (HGD), to carcinoma. Two large epidemiologic studies published in 2011 reported the

risk of progression to cancer in patients with BE. One reported the rate of progression to cancer in more than 8000 patients with a mean duration of follow-up of 7 years (range, 1 to 20 years).[1,] The de novo progression to cancer from BE at 1 year was 0.13%. The risk of progression was reported as 1.4% per year in patients with LGD and 0.17% per year in patients without dysplasia. This incidence translates into a risk of 10 to 11 times that of the general population. The other study identified more than 11,000 patients with BE and, after a median follow-up of 5.2 years, it reported that the annual risk of esophageal adenocarcinoma was 0.12%.[2,] Detection of LGD on index endoscopy was associated with an incidence rate for adenocarcinoma of 5.1 cases per 1000 person-years, and the incidence rate among patients without dysplasia was 1.0 case per 1000 person-years. Risk estimates for patients with HGD were slightly higher. The reported risk of progression to cancer in BE in older studies was much higher, with an annual incidence of risk of 0.4% to 0.5% per year, with risk estimated at 30 to 40 times that of the general population. Current surveillance recommendations have been based on these higher risk estimates.

There are challenges in diagnostically differentiating between nondysplastic BE and BE with LGD; they are important when considering treatment for LGD.[3,4,] Both sampling bias and interobserver variability have been shown to be problematic. Therefore, analysis of progression to carcinoma in BE with intestinal metaplasia versus LGD is difficult. Initial diagnosis of BE can also be a challenge with respect to histologic grading because inflammation and LGD can share similar histologic characteristics.[5,]

One approach to risk-stratify patients with an initial diagnosis of LGD has been to use multiple pathologists, including experts in gastrointestinal histopathology, to confirm the initial diagnosis of LGD. There is a high degree of interobserver variability among the pathology readings of LGD versus inflammatory changes, and the resultant variability in pathology diagnosis may contribute to the variable rates of progression of LGD reported in the literature.[6,] Kerkhof et al (2007) reported that, in patients with an initial pathologic diagnosis of LGD, review by an expert pathologist would result in the initial diagnosis being downgraded to nondysplasia in up to 50% of cases.[7,] Curvers et al (2010) tested this hypothesis in 147 patients with BE who were given an initial diagnosis of LGD.[8,] All pathology slides were read by 2 expert gastrointestinal pathologists with extensive experience in BE; disagreements among experts in the readings were resolved by consensus. Once this process was completed, 85% of initial diagnoses of LGD were downgraded to nondysplasia, leaving 22 (15%) of 147 patients with a confirmed diagnosis of LGD. All patients were followed for a mean of 5.1 years for progression to HGD or cancer. For patients with confirmed LGD, the rate of progression was 13.4%, compared with 0.5% for patients who had been downgraded to nondysplasia.

The strategy of having LGD confirmed by expert pathologists is supported by the results of a randomized controlled trial by Phoa et al (2014), which required confirmation of LGD by a central expert panel following initial diagnosis by a local pathologist.[9,] Of 511 patients with an initial diagnosis of LGD, 264 (52%) were excluded because the central expert panel reassigned the classification of LGD, most often from LGD to indefinite or nondysplasia. These findings were further confirmed in a retrospective cohort study by Duits et al (2015), who reported on 293 BE cases with LGD diagnosed over an 11-year period and submitted for expert panel review.[10,] In this sample, 73% of subjects were downstaged.

Management of Barrett Esophagus
The management of BE includes the treatment of gastroesophageal reflux disease and surveillance endoscopy to detect progression to HGD or adenocarcinoma. 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). One 2007 study provided long-term results for EMR in 100 consecutive patients with early Barrett-associated adenocarcinoma (limited to the mucosa).[11,] The 5-year overall survival was 98% and, after a mean of 36.7 months, metachronous lesions were observed in 11% of patients. In a review by Pech and Ell (2009), the authors stated that circumferential EMR of the entire segment of BE leads to a stricture rate of 50%, and recurrences occur at a rate of up to 11%.[12,]

Ablative Techniques
Available mucosal ablation techniques include several thermal (multipolar electrocoagulation [MPEC], argon plasma coagulation [APC], heater probe, neodymium-doped yttrium aluminum garnet [Nd:YAG] laser, potassium titanyl phosphate [KTP]-YAG laser, diode laser, argon laser, cryoablation) or nonthermal (5-aminolevulinic acid, photodynamic therapy) techniques. In a randomized phase 3 trial reported by Overholt et al (2005), photodynamic therapy was shown to decrease significantly the risk of adenocarcinoma in BE.[13]

Radiofrequency ablation affects only the most superficial layer of the esophagus (ie, the mucosa), leaving the underlying tissues unharmed. Measures of efficacy for the procedure are the eradication of intestinal metaplasia and the postablation regrowth of the normal squamous epithelium. (Note: The eradication of intestinal metaplasia does not leave behind microscopic foci). The HALO system uses radiofrequency energy and consists of 2 components: an energy generator and an ablation catheter. Reports of the efficacy of the HALO system in ablating BE have been as high as 70% (comparable with alternative methods of ablation [eg, APC, MPEC]), and even higher in some reports. The incidence of leaving behind microscopic foci of intestinal metaplasia has been reported to be between 20% and 44% with APC and 7% with MPEC; studies using the HALO system have reported 0%.[14,] Another potential advantage of the HALO system is that it is an automated process that eliminates operator-dependent error, which may be seen with APC or MPEC. Cryotherapy allows for the treatment of uneven surfaces and can be administered as either a spray therapy or a balloon catheter..

The risk of treating HGD or mucosal cancer solely with ablative techniques is undertreatment for approximately 10% of patients with undetected submucosal cancer, in whom esophagectomy would have been required.[12,]

REGULATORY STATUS
In 2005, the HALO360 (now Barrx™ 360 RFA Balloon Catheter; Barrx Medical; acquired by Covidien in 2012 [now Medtronic]) was cleared for marketing by the U.S. Food and Drug Administration (FDA) through the 510(k) process and, in 2006, the HALO90 (now Barrx™ 90 RFA Focal Catheter) received clearance.[15,] The FDA labeled indications are for use in coagulation of bleeding and nonbleeding sites in the gastrointestinal tract and include the treatment of BE.

Other focal ablation devices from Barrx include the Barrx™ 60 RFA Focal Catheter, the Barrx™ Ultra Long RFA Focal Catheter, the Barrx™ Channel RFA Endoscopic Catheter.

FDA product code: GEI.

In 2007, the CryoSpray Ablation™ System (formerly the SprayGenix Cryo Ablation system; CSA Medical) was cleared for marketing by the FDA through the 510(k) process for use as a "cryosurgical tool for destruction of unwanted tissue in the field of general surgery, specifically for endoscopic applications."[16,] The CryoBalloon Ablation System has also been cleared by the FDA through the 510(k) process for use as a cryosurgical tool in surgery for endoscopic applications, including ablation of BE with dysplasia.[17,] The next-generation C2 CryoBalloon Ablation System was introduced in 2018.[18,]

FDA product code: GEH.

In 2002, the Polar Wand® device (Chek-Med Systems), a cryosurgical device that uses compressed carbon dioxide, was cleared for marketing by the FDA through the 510(k) process. Indications for use are "ablation of unwanted tissue in the fields of dermatology, gynecology, general surgery, urology, and gastroenterology."[19,]

POLICY

A. Radiofrequency ablation may be considered **medically necessary** for the treatment of Barrett esophagus with high-grade dysplasia (see Policy Guidelines).

B. Radiofrequency ablation may be considered **medically necessary** for the treatment of Barrett esophagus with low-grade dysplasia, when the initial diagnosis of low-grade dysplasia is confirmed by 2 pathologists. (see Policy Guidelines).

C. Radiofrequency ablation is considered **experimental / investigational** for the treatment of Barrett esophagus when the above criteria are not met, including but not limited to Barrett esophagus in the absence of dysplasia.

D. Cryoablation is considered **experimental / investigational** for the treatment of Barrett esophagus, with or without dysplasia.

POLICY GUIDELINES

A. Radiofrequency ablation for Barrett esophagus with high-grade dysplasia (HGD) may be used in combination with endoscopic mucosal resection (EMR) of nodular or visible lesions. The diagnosis of HGD should be confirmed by 2 pathologists before initiating radiofrequency ablation. The American Society for Gastrointestinal Endoscopy and the American Gastroenterological Association both recommend that a reading of HGD should be confirmed by an experienced gastrointestinal pathologist [Wani et al 2018, PMID 29397943; Rubenstein et al 2024, PMID 38763697]. Two cohort studies found that reevaluation of HGD after an initial evaluation resulted in 40% to 53% of individuals receiving a lower-grade evaluation on repeat endoscopy, highlighting the need for confirmation by an expert center [Sangle et al 2015, PMID 25676554; Verbeek et al 2014; PMID 24388501]. Additionally, for HGD, it is important to rule out adenocarcinoma; referral to an expert center that can conduct high-definition white-light endoscopy and other diagnostic techniques has been found to increase the rate of adenocarcinoma detection and proper referral for EMR [Cameron et al 2014; PMID 24929493].

B. There is considerable interobserver variability in the diagnosis of low-grade dysplasia (LGD), and the potential exists for overdiagnosis of LGD by nonexpert pathologists (overdiagnosis is due primarily to the difficulty in distinguishing inflammatory changes from LGD). There is evidence in the literature that expert gastrointestinal (GI) pathologists will downgrade a substantial portion of biopsies that are initially read as LGD by nonexperts (Curvers et al [2010]; Kerkhof et al [2007]). As a result, it is ideal that 2 experts in gastrointestinal pathology agree on the diagnosis in order to confirm LGD; this may result in greater than 75% of initial diagnoses of LGD being downgraded to nondysplasia (Curvers et al [2010]). A review by a single expert gastrointestinal pathologist will also result in a large number of LGD diagnoses being downgraded, although probably not as many as achieved using 2 expert pathologists (Kerkhof et al, 2007).

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RATIONALE

This evidence review was created using searches of the PubMed database. The most recent literature update was performed through September 11, 2025.

Evidence reviews assess the clinical evidence to determine whether the use of technology improves the net health outcome. Broadly defined, health outcomes are the length of life, quality of life, and ability to function-including benefits and harms. Every clinical condition has specific outcomes that are important to patients and managing the course of that condition. Validated outcome measures are necessary to ascertain whether a condition improves or worsens; and whether the magnitude of that change is clinically significant. The net health outcome is a balance of benefits and harms.

To assess whether the evidence is sufficient to draw conclusions about the net health outcome of technology, 2 domains are examined: the relevance, and quality and credibility. To be relevant, studies must represent one or more intended clinical use of the technology in the intended population and compare an effective and appropriate alternative at a comparable intensity. For some conditions, the alternative will be supportive care or surveillance. The quality and credibility of the evidence depend on study design and conduct, minimizing bias and confounding that can generate incorrect findings. The randomized controlled trial (RCT) is preferred to assess efficacy; however, in some circumstances, nonrandomized studies may be adequate. RCTs are rarely large enough or long enough to capture less common adverse events and long-term effects. Other types of studies can be used for these purposes and to assess generalizability to broader clinical populations and settings of clinical practice.

RADIOFREQUENCY ABLATION FOR BARRETT ESOPHAGUS WITH HIGH-GRADE DYSPLASIA

Clinical Context and Therapy Purpose

In patients diagnosed with Barrett Esophagus (BE) with high-grade dysplasia (HGD), the risk of progression to cancer is relatively high, and esophageal adenocarcinoma is associated with high morbidity and a 5-year survival rate of approximately 20%.[20,21,] Therefore, intervention with esophagectomy or radiofrequency ablation (RFA) may be strongly indicated.

The purpose of endoscopic RFA in individuals who have BE with HGD is to provide a treatment option that is an alternative to or an improvement on existing therapies.

The following PICO was used to select literature to inform this review.

Populations

The relevant population of interest is individuals with BE with HGD.

Interventions

The therapy being considered is endoscopic RFA.

Comparators
The following therapies and practices are currently being used to treat BE: esophagectomy, endoscopic mucosal resection (EMR), and surveillance.

Outcome
The general outcomes of interest are symptoms (eg, pain) and functional outcomes (including swallowing).

Beneficial outcomes include reductions in progression to carcinoma and longer-term maintenance of eradication of dysplasia.

Harmful outcomes include damage to the esophagus resulting in difficulty swallowing.

Morbidity from treatment would be assessed within 30 days after the procedure.

Study Selection Criteria
Methodologically credible studies were selected using the following principles:

- To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs;
- In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies.
- To assess long-term outcomes and adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought.
- Studies with duplicative or overlapping populations were excluded.

REVIEW OF EVIDENCE

Systematic Reviews
Khetpal et al (2025) published a systematic review of 38 studies (N=2434) evaluating the efficacy and safety of 3 endoscopic modalities in patients with BE with HGD or early adenocarcinoma: endoscopic submucosal dissection (ESD), focal EMR followed by RFA (f-EMR+RFA), and complete or stepwise EMR (c-EMR).[22,] A total of 684 patients were treated with ESD, 938 with f-EMR+RFA, and 812 with c-EMR. The primary outcomes were recurrence rates and adverse events (bleeding, strictures, perforation), while secondary outcomes included complete eradication of neoplasia for f-EMR+RFA and c-EMR. The weighted pooled recurrence rates were 10.3% for ESD, 5% for f-EMR+RFA, and 7.4% for c-EMR, with no statistically significant differences ($p>.05$). Stricture formation occurred in 9.5% (ESD), 11.5% (f-EMR+RFA), and 29% (c-EMR) of patients, with both ESD and f-EMR+RFA showing significantly lower stricture rates compared to c-EMR ($p<.05$). Perforation rates were 3.7% for ESD, 1.6% for f-EMR+RFA, and 2% for c-EMR, with f-EMR+RFA demonstrating significantly lower perforation risk than ESD ($p=.01$). Bleeding rates were 3.5% (ESD), 3% (f-EMR+RFA), and 6% (c-EMR), with both ESD and f-EMR+RFA showing significantly lower bleeding risks than c-EMR ($p=.01$ and $p=.001$, respectively). Complete eradication rates of neoplasia were 92% (95% CI, 88% to 94%) for f-EMR+RFA and 94% (95% CI, 88% to 97%) for c-EMR.

Chadwick et al (2014) reported on a systematic review that compared RFA with complete EMR for the treatment of BE.[23,] Twenty studies (22 articles) were reviewed, including 2 RCTs, 10

cohort studies on EMR, and 8 cohort studies on RFA. The only study that compared RFA with EMR was an RCT by van Vilsteren et al (2011)[24,]; the other RCT was by Shaheen et al (2009, 2011; see below).[25,26,] The studies were heterogeneous in design. A total of 1087 (532 EMR, 555 RFA) patients with HGD or intramucosal carcinoma were included in the studies reviewed. The median number of resections or RFA sessions required for the eradication of BE was 2. Complete EMR and RFA eradicated BE dysplasia in 95% and 92% of patients, respectively. Eradication was maintained in 95% of EMR patients at a median follow-up of 23 months and in 94% of RFA patients at a median follow-up of 21 months. Fewer RFA patients experienced short-term adverse events (2.5%) than those who received complete EMR (12%). Esophageal strictures requiring additional treatment occurred in 4% of RFA patients and 38% of complete endoscopic resection patients.

Randomized Controlled Trials

RFA may be used alongside focal endoscopic resection. In the intention-to-treat analysis of a prospective interventional study by Phoa et al (2016) that included 132 subjects with BE and HGD or early cancer treated with endoscopic resection followed by RFA, complete eradication of neoplasia and complete eradication of intestinal metaplasia occurred in 92% and 87% of subjects, respectively.[27,] At a median follow-up of 27 months, neoplasia and intestinal metaplasia had recurred in 4% and 8% of subjects, respectively.

Van Vilsteren et al (2011) reported on the results of a multicenter randomized trial that compared the safety of stepwise radical endoscopic resection (SRER) with focal EMR followed by RFA for complete eradication of BE 5 cm or less with HGD or early cancer.[24,] Patients in the SRER group underwent a piecemeal EMR of 50% of BE followed by serial EMR. Patients in the EMR plus RFA group underwent focal EMR for visible lesions followed by serial RFA. Follow-up endoscopy with biopsies (4-quadrant/2 cm BE) was performed at 6 and 12 months and then annually. The main outcome measures were: stenosis rate; complications; complete histologic response for neoplasia; and complete histologic response for intestinal metaplasia (CR-IM). Complete histologic response for neoplasia was achieved in 25 (100%) of 25 SRER patients and in 21 (96%) of 22 patients receiving EMR plus RFA. CR-IM was achieved in 23 (92%) SRER patients and 21 (96%) patients receiving EMR plus RFA. The stenosis rate was significantly higher with SRER (88%) than with EMR plus RFA (14%; p<.001), resulting in more therapeutic sessions in SRER (6 vs. 3; p<.001) due to dilations. After a median follow-up of 24 months, 1 SRER patient had a recurrence of early cancer, requiring endoscopic resection. This trial confirmed that both techniques achieved comparably high rates of CR-IM and complete histologic response for neoplasia but found that SRER was associated with more complications and therapeutic sessions.

The randomized multicenter, sham-controlled trial by Shaheen et al (2009) compared RFA with surveillance alone in patients with BE and dysplasia.[25,] RFA was successful in eradicating HGD, with complete eradication at 12 months achieved in 81% of the ablation group versus 19% in the control group (p<.001). This trial also confirmed a high risk of progression to cancer in patients with HGD and established that this progression was significantly reduced in patients treated with RFA. Among 63 patients with HGD in the trial, 19% in the control group progressed to cancer versus 2.4% in the RFA group (p=.04). This represented a nearly 90% relative risk reduction for progression to cancer (relative risk, 0.1; 95% confidence interval [CI], 0.01 to 1.0; p=.04), and a number needed to treat of 6.0 to prevent 1 case of cancer over a 1-year period.

Longer-term follow-up at 2 to 3 years reported that complete eradication of dysplasia was maintained in most participants with initial HGD.[26,] For 54 patients with HGD available for follow-up, all dysplasia was eradicated in 50 (93%) of 54, and all intestinal metaplasia was eradicated in 48 (89%) of 54. After 3 years, dysplasia was eradicated in 55 (98%) of 56 subjects, and all intestinal metaplasia was eradicated in 51 (91%) of 56 subjects. More than 75% of patients with HGD remained free of intestinal metaplasia with a follow-up of longer than 3 years, with no additional therapy.

Section Summary: Radiofrequency Ablation for Barrett Esophagus With High-Grade Dysplasia
For patients who have BE with HGD, there is a relatively high risk of progression to cancer, and interventions to prevent progression are warranted. RFA results in high rates of complete eradication of dysplasia that is durable for at least 2 years. One RCT demonstrated that, following RFA, the progression from HGD to cancer is reduced by approximately 90%, with rates of esophageal strictures of 6%. Both systematic reviews demonstrated a more favorable safety profile for RFA compared to EMR.

RADIOFREQUENCY ABLATION FOR BARRETT ESOPHAGUS WITH LOW-GRADE DYSPLASIA

Clinical Context and Therapy Purpose
The purpose of endoscopic RFA in individuals who have BE with LGD is to provide a treatment option that is an alternative to or an improvement on existing therapies.

The following PICO was used to select literature to inform this review.

Populations
The relevant population of interest is individuals with BE with LGD.

Interventions
The therapy being considered is endoscopic RFA.

Comparators
The following practice is currently being used to treat BE with LGD: surveillance by gastroenterologists.

Outcome
The general outcomes of interest are symptoms (eg, pain) and functional outcomes (including swallowing).

Beneficial outcomes include reductions in progression to HGD or carcinoma and longer-term maintenance of eradication of dysplasia.

Harmful outcomes include damage to the esophagus resulting in difficulty swallowing.

Morbidity would be assessed within 30 days after the procedure. Conversion to HGD would be measured at 2 to 5 years.

Study Selection Criteria
Methodologically credible studies were selected using the following principles:

- To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs;
- In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies.
- To assess long-term outcomes and adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought.
- Studies with duplicative or overlapping populations were excluded.

Systematic Reviews
Wang et al (2022) performed a meta-analysis of 3 RCTs (N=282) comparing RFA with surveillance in patients with LGD.[28,] Nearly 90% of the patients enrolled were male; other demographic information was not reported. The primary outcome was risk of progression to HGD or esophageal adenocarcinoma. Compared with endoscopic surveillance, RFA was associated with lower odds of progression to either HGD or esophageal adenocarcinoma (risk ratio [RR], 0.25; 95% CI, 0.07 to 0.93; p=.04). The findings had moderate heterogeneity (I^2=55%), and the risk of bias was considered low. When analyzed separately, the risk of progression to HGD was significantly reduced with RFA (RR, 0.25; 95% CI, 0.07 to 0.71; p=.01; I^2=15%); however, the results for progression to esophageal adenocarcinoma were not significant (RR, 0.56; 95% CI, 0.05 to 6.76; p=.65).

Klair et al (2021) performed a systematic review and meta-analysis of comparative studies of RFA versus endoscopic surveillance in patients with BE with LGD.[29,] The primary outcome was risk of progression to HGD or esophageal adenocarcinoma. The meta-analysis included 4 studies (N=543), including 2 retrospective studies and 2 RCTs. Compared with endoscopic surveillance, RFA was associated with lower odds of progression to either HGD or esophageal adenocarcinoma (odds ratio [OR], 0.17; 95% CI, 0.04 to 0.65). Individually, the progression to HGD maintained significance compared with endoscopic surveillance (OR, 0.23; 95% CI, 0.08 to 0.61), while progression to adenocarcinoma was numerically lower (OR, 0.44; 95% CI, 0.17 to 1.16). However, the findings indicated moderate heterogeneity (I^2=0.63) and evidence of publication bias.

In their meta-analysis, Pandey et al (2018) evaluated both RCTs and observational studies to determine the efficacy of RFA in treating BE with LGD compared with surveillance.[30,] The 8 studies in the meta-analysis included 619 patients followed up for a median of 26 months. The overall pooled rate of complete eradication of intestinal metaplasia after RFA was 88.17% (95% CI, 88.13% to 88.20%; p<.001); the rate of complete eradication of dysplasia was 96.69% (95% CI, 96.67% to 96.71%; p<.001). Compared with surveillance, the rates of progression to HGD or cancer were significantly lower with RFA (OR, 0.07; 95% CI, 0.02 to 0.22). The pooled recurrence rate of intestinal metaplasia was 5.6% (95% CI, 5.57% to 5.63%; p<.001) and 9.66% (95% CI, 9.61% to 9.71%; p<.001) for dysplasia. Although the analysis was limited by its inclusion of observational cohort studies and the sample sizes of patients receiving RFA were all less than 100 patients, all studies supported the use of RFA for LGD BE. The authors concluded that RFA is safe and effective for eradicating intestinal metaplasia and dysplasia and reducing progression from LGD to HGD or cancer in the short term. Longer-term outcomes, however, warrant further research.

Section Summary: Radiofrequency Ablation for Barrett Esophagus With Low-Grade Dysplasia
The risk of progression from LGD to cancer is not well-defined, with highly variable rates reported in the published literature. Evidence from randomized and nonrandomized studies has established that RFA can achieve complete eradication of dysplasia in patients with LGD that is durable for at least 2 years. Combined rates of progression to HGD or esophageal adenocarcinoma are lower in patients with LGD treated with RFA compared with surveillance.

RADIOFREQUENCY ABLATION FOR BARRETT ESOPHAGUS WITHOUT DYSPLASIA

Clinical Context and Therapy Purpose
The purpose of endoscopic RFA in individuals who have BE without dysplasia is to provide a treatment option that is an alternative to or an improvement on existing therapies.

The following PICO was used to select literature to inform this review.

Populations
The relevant population of interest is individuals with BE without dysplasia.

Interventions
The therapy being considered is endoscopic RFA.

Comparators
The following practice is currently being used to treat BE without dysplasia: surveillance by gastroenterologists.

Outcome
The general outcomes of interest are symptoms (eg, pain) and functional outcomes (including swallowing).

Beneficial outcomes include reductions in progression to dysplasia or carcinoma and longer-term maintenance of eradication of dysplasia.

Harmful outcomes include damage to the esophagus resulting in difficulty swallowing.

Morbidity would be assessed within 30 days after the procedure. Conversion to dysplasia would be measured at 2 to 5 years.

Study Selection Criteria
Methodologically credible studies were selected using the following principles:
- To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs;
- In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies.
- To assess long-term outcomes and adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought.
- Studies with duplicative or overlapping populations were excluded.

Nonrandomized Trials

No RCTs were identified that evaluated RFA treatment of BE without dysplasia. The evidence on this issue consists of single-arm trials that have reported outcomes of RFA. There is no high-quality evidence on the comparative efficacy of RFA versus surveillance alone. Progression to cancer in cases of nondysplastic BE is lower than that for LGD or HGD, with rates in the literature ranging from 0.05% to 0.5%.[1,2,]

Fleischer et al (2008, 2010) reported on the 5-year follow-up of a single-arm study of patients with nondysplastic BE treated with RFA.[31,32,] The original study included 70 patients who underwent circumferential RFA and CR-IM, defined as complete eradication of nondysplastic BE.[31,] CR-IM was seen in 70% of patients at 1-year follow-up; patients with persistent BE underwent focal RFA. At the 2.5-year follow-up, CR-IM was found in 60 (98%) of 61 patients.[31,] At 5-year follow-up, 4-quadrant biopsies were obtained from every 1 cm of the original extent of BE, and the authors reported the proportion of patients demonstrating CR-IM.[32,] If nondysplastic BE was identified at the 5-year follow-up, focal RFA was performed 1 month later, and biopsies were repeated 2 months afterward to assess histologic response. Primary outcomes were the proportion of patients demonstrating CR-IM at a 5-year biopsy or after a single session of focal RFA. For the 5-year follow-up, there were 60 eligible patients, 50 (83%) of whom participated. Forty-six (92%) of 50 patients showed CR-IM at the 5-year biopsy visit. The 4 patients found to have BE at 5 years underwent a single session of RFA 1 month after biopsy; all 4 patients had CR-IM at subsequent rebiopsy 2 months after RFA. No strictures were noted. The authors concluded that this first report of 5-year CR-IM outcomes supported the safety, efficacy, and reduction in neoplastic progression in treating nondysplastic BE with RFA.

Section Summary: Radiofrequency Ablation for Barrett Esophagus Without Dysplasia

Nondysplastic BE has a relatively low rate of progression to cancer. Although available research has indicated that nondysplastic metaplasia can be eradicated by RFA, the risk-benefit ratio and the net effect on health outcomes is uncertain.

CRYOABLATION OF BARRETT ESOPHAGUS

Clinical Context and Therapy Purpose

The purpose of endoscopic cryoablation in individuals who have BE is to provide a treatment option that is an alternative to or an improvement on existing therapies.

The following PICO was used to select literature to inform this review.

Populations

The relevant population of interest is individuals with BE with or without dysplasia.

Interventions

The therapy being considered is endoscopic cryoablation.

Comparators

The following therapies and practices are currently being used to treat BE: esophagectomy, EMR, and surveillance.

Outcomes
The general outcomes of interest are symptoms (eg, pain) and functional outcomes (including swallowing).

Beneficial outcomes include reductions in progression to HGD or carcinoma and longer-term maintenance of eradication or dysplasia.

Harmful outcomes include damage to the esophagus resulting in difficulty swallowing.

Morbidity would be assessed within 30 days after the procedure.

Study Selection Criteria
Methodologically credible studies were selected using the following principles:

- To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs;
- In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies.
- To assess long-term outcomes and adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought.
- Studies with duplicative or overlapping populations were excluded.

Systematic Reviews
Several meta-analyses have evaluated the efficacy of cryotherapy in patients with BE (Tables 1, 2, and 3). Papaefthymiou et al (2024) conducted a meta-analysis comparing cryoablation with RFA in patients with BE.[33,] A total of 23 studies were identified and 4 were comparative. No significant differences in complete eradication of dysplasia or complete eradication of intestinal metaplasia were found between groups.

Tariq et al (2021) performed a meta-analysis of 14 retrospective and prospective observational studies (N=405) of patients with BE who were treated with cryotherapy.[34,] The primary outcome of proportions of patients achieving complete eradication of dysplasia and complete eradication of intestinal metaplasia were 84.8% (95% CI, 72.2% to 94.4%) and 64.2% (95% CI, 52.9% to 74.8%), respectively. Both outcomes had a high degree of heterogeneity (I^2 of 88.3% and 77.9%, respectively). Subgroup analyses of only high-quality studies revealed rates of 91.3% (95% CI, 83.0% to 97.4%; I^2=69.5%) and 71.6% (95% CI, 59.0% to 82.9% ;I^2=80.9%), respectively.

In their meta-analysis, Westerveld et al (2020) evaluated 7 prospective and retrospective cohort studies that reported outcomes of balloon cryoablation across 272 patients with BE; 3 of the included studies were previously reported in abstract form only.[35,] The pooled proportion for complete eradication of intestinal metaplasia was 85.8% (95% CI, 77.8% to 92.2%). Among 262 patients with BE with dysplasia, 238 reported complete eradication of dysplasia after cryoablation (pooled proportion, 93.8%; 95% CI, 85.5% to 98.7%). Both outcomes had a high degree of heterogeneity (I^2 of 55% and 74.2%, respectively). However, when 2 low quality studies were excluded from the analysis, results were consistent with the primary analysis. Adverse events were reported in 12.5% of patients, representing 34 adverse events. Half of the adverse events (n=16) were post-ablation stricture formation (5.8%).

Hamade et al (2019) evaluated the use of cryotherapy for BE in patients who were previously treatment-naive.[36,] Six uncontrolled trials were included in the systematic review, which included 232 patients overall. Complete eradication of intestinal metaplasia was achieved in 69.35% of cases (95% CI, 52.1% to 86.5%; I^2=89.3%). Complete eradication of dysplasia was achieved in 90.6% of cases (95% CI, 83.7% to 97.4%; I^2=75.7%). Progression to cancer occurred in 4% of cases (9/225). The pooled recurrence rate of intestinal metaplasia was 19.1 per 100 patient-years. The post-procedure stricture formation rate was 4.9%, and 3.9% of patients reported postprocedural pain.

Table 1. Comparison of Studies Included in Systematic Reviews and Meta-Analyses

Study	Papaefthymiou et al (2024)[33,]	Tariq et al (2020)[34,]	Westerveld et al (2020)[35,]	Hamade et al (2019)[36,]
Agarwal et al (2022)	●			
Alshelleh et al (2021)	●			
Canto et al (2020)	●		●	
Canto et al (2018)	●	●	●	●
Canto et al (2015)		●		●
Cheng et al (2013)		●		
Dumot et al (2009)	●			
Eluri et al (2017)		●		
Eluri et al (2024)	●			
Fasullo et al (2021)	●			
Frederiks et al (2022)	●			
Genere et al (2022)	●			
Goldberg et al (2012)		●		
Gosaine et al (2013)		●		●
Greenwald et al (2010)		●		
Halsey et al (2011)		●		
Johnston et al (2013)		●		
Kaul et al (2020)	●			
Kunzli et al (2016)	●		●	
Overwater et al (2021)	●			
Ramay et al (2017)	●	●		●
Scholvinck et al (2015)	●		●	
Sengupta et al (2015)	●			

Study	Papaefthymiou et al (2024)[33,]	Tariq et al (2020)[34,]	Westerveld et al (2020)[35,]	Hamade et al (2019)[36,]
Shaheen et al (2011)	●			
Sitaraman et al (2016)			●	
Snady et al (2023)	●			
Spiceland et al (2019)	●			
Trindade et al (2017)	●	●		●
Trindade et al (2018)	●			
Thota et al (2018)	●	●		●
van Munster et al (2018)	●		●	
van Munster et al (2019)	●			
Verbeek et al (2015)		●		
Wang et al (2015)			●	
Wani et al (2012)		●		

Table 2. Systematic Review and Meta-Analysis Characteristics

Study	Dates	Trials	Participants	N (Range)	Design	Duration
Papaefthymiou et al (2024)[33,]	Through June 2024	23	Adults with BE and dysplasia undergoing endoscopic treatment	1604 (25 to 311)	Retrospective, prospective observational	NR
Tariq et al (2020)[34,]	2006-2016	14	Patients with biopsy-confirmed dysplastic or neoplastic BE who underwent ≥1 session of cryotherapy	405 (20 to 81)	Retrospective, prospective observational	Range, 3 to 54 months
Westerveld et al (2020)[35,]	2015-2019	7	Patients with BE treated with cryoablation	272 (5 to 120)	Retrospective, prospective observational	NR
Hamade et al (2019)[36,]	NR	6	Treatment-naive patients with BE treated with cryotherapy	282 (22 to 81)	Retrospective observational	Range, 24 to 65 months

BE: Barrett's esophagus; NR: not reported.

Table 3. Systematic Review and Meta-Analysis Results

Study	Complete eradication of dysplasia	Complete eradication of intestinal metaplasia
Papaefthymiou et al (2024)[33,]		
Total N	673	673
Cryotherapy, %	75.7	53.3
RFA, %	77.8	60.2
Pooled effect (95% CI)	OR, 0.95 (95% CI, 0.50 to 1.81)	OR, 0.57 (95% CI, 0.20 to 1.63)
I^2 (%)	57	87
Tariq et al (2020)[34,]		
Total N	405	393
Pooled effect (95% CI)	84.8% (72.2 to 94.4)	64.2% (52.9 to 74.8)
I^2 (%)	88.3	77.9
Westerveld et al (2020)[35,]		
Total N	262	272
Pooled effect (95% CI)	93.8% (85.5 to 98.7)	85.8% (77.8 to 92.2)
I^2 (%)	74.2	55
Hamade et al (2019)[36,]		
Total N	282	282
Pooled effect (95% CI)	90.6% (83.7 to 97.4)	69.35% (52.1 to 86.5)
I^2 (%)	75.7	89.3

CI: confidence interval; OR, odds ratio; RFA: radiofrequency ablation.

Prospective and Retrospective Studies

Several small prospective and retrospective uncontrolled studies of cryoablation have been published (Tables 4 and 5). These studies are heterogenous in the proportion of patients with prior BE treatment, cryoablation techniques used, and follow-up duration.

Table 4. Summary of Key Nonrandomized Studies

Study	Study Type	Country	Dates	Participants	Treatment	Follow-Up
Sachdeva et al (2025)[37,]	Retrospective, observational	US	2014 to 2024	Patients who underwent RFA or cryotherapy for dysplastic BE	Cryoablation or RFA	4.1 and 4.4 years following RFA and CBA, respectively
Agarwal et al (2022)[38,]	Retrospective, observational	US	2014-2020	Patients who underwent RFA or cryotherapy	Cryoablation or RFA	Median, 1.5 years in RFA group and 2

Study	Study Type	Country	Dates	Participants	Treatment	Follow-Up
				for dysplastic BE		years in the cryoablation group
Fasullo et al (2022)[39,]	Retrospective, observational	US	2009-2020	Patients who underwent RFA or cryotherapy for BE with LGD, HGD, or intramucosal adenocarcinoma	Cryoablation or RFA	>12 months
Sengupta et al (2015)[40,]	Retrospective, observational	US	2006-2013	Patients who underwent RFA for BE with LGD, HGD, or intramucosal carcinoma	Cryoablation	Median, 2.5 months
Shaheen et al (2010)[41,]	Retrospective, observational	US	2007-2009	Patients who had BE with HGD	Cryoablation	Mean, 10.5 months
Dumot et al (2009)[42,]	Prospective, observational	US	2005-2008	Patients who had BE with HGD or intramucosal carcinoma	Cryoablation	Median, 12 months

BE: Barrett's esophagus; HGD: high-grade dysplasia; LGD: low-grade dysplasia; RFA: radiofrequency ablation.

Table 5. Summary of Key Nonrandomized Study Results

Study	Complete eradication of dysplasia	Complete eradication of intestinal metaplasia	Downgrading of pathology stage	Elimination of cancer or downgrading of HGD	Recurrence of BE, with or without dysplasia	Recurrence of dysplastic BE
Sachdeva et al (2025)[37,]	N=681; n=610 RFA and 71 cryoablation					
RFA, per 100 patient-years					11.2	3.75
Cryotherapy, per 100 patient-years					4.4	2.83
Hazard ratio (95% CI)					Total population: 2.19 (1.18 to 4.06) After excluding	0.88 (0.39 to 1.97)

Study	Complete eradication of dysplasia	Complete eradication of intestinal metaplasia	Downgrading of pathology stage	Elimination of cancer or downgrading of HGD	Recurrence of BE, with or without dysplasia	Recurrence of dysplastic BE
					intestinal metaplasia of the gastroesophageal junction: 1.18 (0.61 to 2.30)	
Agarwal et al (2022)[38,]	N=311; n=226 RFA and 85 cryoablation					
Cryotherapy, %	85.7	69.8	NR	NR		
RFA, %	78.3	57.3	NR	NR		
Fasullo et al (2022)[39,]	N=162; n=100 RFA and 62 cryoablation					
Cryotherapy, n %	44 (71)	41 (66.1)	NR	NR		
RFA, n %	81 (81)	64 (64)	NR	NR		
Sengupta et al (2015)[40,]	N=121					
Cryotherapy, n (%)	91 (75)	NR	NR	NR		
Shaheen et al (2010)[41,]	N=60	N=60				
Cryotherapy, n (%)	58 (97)	34 (57)	NR	NR		
Dumot et al (2009)[42,]			N=30	N=30		
Cryotherapy, n (%)	NR	NR	27 (90)	Patients with HGD: 20 (68) Patients with intramucosal carcinoma: 24 (80)		

BE: Barrett esophagus; HGD: high-grade dysplasia; NR: not reported; RFA: radiofrequency ablation.

Section Summary: Cryoablation of Barrett Esophagus

No randomized controlled trials have evaluated cryoablation for the treatment of BE. Systematic reviews and meta-analyses of observational data have reported high rates of success in

eradicating dysplasia, with low rates of complications. Meta-analyses comparing RFA with cryoablation for patients with BE indicate similar efficacy outcomes, but these data are not sufficient to determine the comparative efficacy of cryoablation and RFA.

SUPPLEMENTAL INFORMATION

The purpose of the following information is to provide reference material. Inclusion does not imply endorsement or alignment with the evidence review conclusions.

Clinical Input From Physician Specialty Societies and Academic Medical Centers

While the various physician specialty societies and academic medical centers may collaborate with and make recommendations during this process, through the provision of appropriate reviewers, input received does not represent an endorsement or position statement by the physician specialty societies or academic medical centers, unless otherwise noted.

2012 Input

In response to requests, input was received from reviewers at 6 academic medical centers and from 1 subspecialty medical society while this policy was under review in 2012. Input related to the treatment of low-grade dysplasia (LGD) was mixed, with 2 reviewers stating that radiofrequency ablation (RFA) for LGD should be investigational, 3 indicating that it should be medically necessary, and 2 indicating that it was a split decision. There was a general consensus among reviewers that there are subsets of patients with LGD who have a higher risk and should, therefore, be treated. Reviewers mentioned that factors useful in defining higher risk populations for whom treatment is warranted are the confirmation of LGD diagnosis by multiple pathologists and/or the application of clinical high-risk factors such as lesion length.

2009 Input

In response to requests, input was received from 3 academic medical centers and 1 subspecialty medical society (with 12 reviewers) while this policy was under review in 2009. All reviewers agreed that RFA (cryoablation was not included in the request) should be considered medically necessary for the treatment of Barrett esophagus (BE) with high-grade dysplasia (HGD). Reviewers were split for the use of RFA for LGD, with 9 considering it medically necessary and 4 considering it investigational.

Practice Guidelines and Position Statements

Guidelines or position statements will be considered for inclusion in 'Supplemental Information' if they were issued by, or jointly by, a US professional society, an international society with US representation, or National Institute for Health and Care Excellence (NICE). Priority will be given to guidelines that are informed by a systematic review, include strength of evidence ratings, and include a description of management of conflict of interest.

American College of Gastroenterology

In 2022, the American College of Gastroenterology (ACG) updated guidelines on the diagnosis and management of BE, which made statements about ablation techniques[43,] The ACG recommends ablation of remaining BE tissue when endoscopic eradication therapy is chosen for patients with LGD, HGD, or intramucosal carcinoma. Both RFA and cryoablation are discussed in the ACG guideline without a specific recommendation; however, the guideline notes the lack of randomized controlled trials (RCTs) for cryoablation methods and the more established evidence

for RFA. The ACG does recommend cryotherapy as an alternative in patients unresponsive to RFA.

American Gastroenterological Association
In 2024, the American Gastroenterological Association (AGA) published a clinical guideline on the role of endoscopic therapy in patients with BE and related neoplasia.[44,]

The AGA guideline made 5 recommendations for endoscopic eradication of BE:

- "In individuals with BE with HGD, the AGA recommends EET over surveillance. (Strong recommendation, moderate certainty of evidence)"
- "In individuals with BE with LGD, the AGA suggests for EET over surveillance. Patients who place a higher value on the well-defined harms and lower value on the benefits (which are uncertain) regarding reduction of esophageal cancer mortality would reasonably select surveillance endoscopy. (Conditional recommendation, low certainty of evidence)"
- "In individuals with NDBE [nondysplastic BD], the AGA suggests against the routine use of EET. (Conditional recommendation, very low certainty of evidence)"
- "In patients undergoing EET, the AGA suggests resection of visible lesions followed by ablation of the remaining BE segment over resection of the entire BE segment. (Conditional recommendation, very low certainty of evidence)"
    - "RFA is the preferred ablative modality."
- "In individuals with BE with visible neoplastic lesions that are undergoing endoscopic resection, the AGA suggests the use of either EMR [endoscopic mucosal resection] or ESD [endoscopic submucosal resection] based on lesion characteristics. (Conditional recommendation, very low certainty of evidence)"

American Society for Gastrointestinal Endoscopy
In 2018, the American Society for Gastrointestinal Endoscopy (ASGE) issued guidelines on the role of endoscopy in BE-associated dysplasia and intramucosal cancer.[45,] These guidelines made the following recommendations on endoscopic eradication therapy, consisting of endoscopic mucosal resection of visible lesions and ablative techniques that include RFA and cryotherapy (see Table 6).

Table 6. ASGE Guidelines on Use of Endoscopy for Barrett Esophagus and Intramucosal Cancer

Recommendation	SOR	QOE[a]
In BE patients with LGD and HGD being considered for EET, we suggest confirmation of diagnosis by at least 1 expert GI pathologist or panel of pathologists compared with review by a single pathologist.	Conditional	Low
In BE patients with LGD, we suggest EET compared with surveillance; however, patients who place a high value on avoiding adverse events related to EET may choose surveillance as the preferred option.	Conditional	Moderate
In BE patients with confirmed HGD, we recommend EET compared with surveillance.	Strong	Moderate
In BE patients with HGD/IMC, we recommend against surgery compared with EET.	Strong	Very low quality

Recommendation	SOR	QOE[a]
In BE patients referred for EET, we recommend endoscopic resection of all visible lesions compared with no endoscopic resection of visible lesions.	Strong	Moderate
In BE patients with visible lesions who undergo endoscopic resection, we suggest ablation of the remaining Barrett's segment compared with no ablation.	Conditional	Low
In BE patients with dysplasia and IMC referred for EET, we recommend against routine complete endoscopic resection of entire Barrett's segment compared with endoscopic resection of visible lesion followed by ablation of remaining Barrett's segment.	Strong	Very low
In BE patients with dysplasia and IMC who have achieved CE-IM after EET, we suggest surveillance endoscopy versus no surveillance.	Conditional	Very low

ASGE: American Society for Gastrointestinal Endoscopy; BE: Barrett esophagus; CE-IM: complete eradication of intestinal metaplasia; EET: endoscopic eradication therapy; GI: gastrointestinal; HGD: high-grade dysplasia; IMC: intramucosal cancer; LGD: low-grade dysplasia; QOE: quality of evidence; SOR: strength of recommendation.
[a]Quality assessed using GRADE system.

National Comprehensive Cancer Network

National Comprehensive Cancer Network Guidelines (v.4.2025) on esophageal and esophagogastric junction cancers make recommendations about BE and early-stage esophageal adenocarcinomas.[46,] For primary treatment; "The goal of endoscopic therapy [by endoscopic mucosal resection (EMR), endoscopic submucosal dissection (ESD), and/or ablation] is the complete removal or eradication of early-stage disease [pTis, pT1a, and selected superficial pT1b without LVI] and pre-neoplastic tissue (Barrett esophagus)."

U.S. Preventive Services Task Force Recommendations

Not applicable.

Ongoing and Unpublished Clinical Trials

Some currently ongoing and unpublished trials that might influence this review are listed in Table 7.

Table 7. Summary of Key Trials

NCT No.	Trial Name	Planned Enrollment	Completion Date
Ongoing			
Unpublished			
NCT01961778	Prospective Randomized Trial Comparing Radiofrequency Ablation (Barrx™) and Cryotherapy (truFreeze™) for the Treatment of Barrett's Esophagus With High-Grade Dysplasia and/or Early Adenocarcinoma	50	Feb 2020 (Last update posted Jan 2022)

NCT: national clinical trial.
[a]Denotes industry sponsored or co-sponsored trial.

CODING

The following codes for treatment and procedures applicable to this policy are included below for informational purposes. This may not be a comprehensive list of procedure codes applicable to this policy.

Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

The code(s) listed below are medically necessary ONLY if the procedure is performed according to the "Policy" section of this document.

CPT/HCPCS	
43229	Esophagoscopy, flexible, transoral; with ablation of tumor(s), polyp(s), or other lesion(s) (includes pre- and post-dilation and guide wire passage, when performed)
43270	Esophagogastroduodenoscopy, flexible, transoral; with ablation of tumor(s), polyp(s), or other lesion(s) (includes pre-and post-dilation and guide wire passage, when performed.)

REVISIONS	
08-03-2010	Description Section updated.
	In Policy Section: ▪ Liberalized policy to current policy language from: A. Radiofrequency ablation may be considered medically necessary for treatment of Barrett's esophagus with high-grade dysplasia. (see policy guidelines) B. Radiofrequency ablation is considered experimental / investigational for treatment of Barrett's esophagus with low-grade dysplasia or Barrett's esophagus in the absence of dysplasia. C. Cryoablation is considered experimental / investigational for Barrett's esophagus, with or without dysplasia.
	Rationale Section updated.
	In Coding Section: ▪ Added CPT Code: 43499
	References Section updated.
12-21-2010	Rationale section updated.
	Reference section updated.
03-28-2012	Description section updated.
	In the Policy section: ▪ In Item 3, B, removed "cryotherapy" and inserted "cryoablation"
	Rationale section updated.
	In the Coding section: ▪ Removed duplicate nomenclature listed with CPT code 43117 ▪ Removed CPT code 43324, deleted code, effective 01.01.2011 ▪ Added "injection" to HCPCS code J9600
	Reference section updated.
02-15-2013	In the Policy Title, inserted "Ablative" to read "Barrett's Esophagus Ablative Treatments"
	Description section updated.
	In Policy section:

REVISIONS	
	▪ In Item A, inserted "ablative" to read "The following ablative interventions are considered medically necessary…" ▪ In Item A #1, removed "Esophagectomy" ▪ In Item A #2, removed "Fundoplication" ▪ In Item A #3, removed "Endoscopic mucosal resection" ▪ In Item B, replaced "and photodynamic therapy is considered experimental / investigational for low grade dysplasia or nondysplastic Barrett's esophagus" with "medically necessary for low-grade dysplasia, when the initial diagnosis of low-grade dysplasia is confirmed by two physicians" to read "Radiofrequency ablation is considered medically necessary for low-grade dysplasia, when the initial diagnosis of low-grade dysplasia is confirmed by two physicians." ▪ Added Policy Guidelines section.
	Rationale section updated.
	In Coding section: ▪ Removed CPT codes: 43100, 43101, 43116, 43117, 43118, 43121, 43122, 43123, 43124, 43280
	Reference section updated.
07-12-2013	Description section updated.
	Rationale section updated.
	In Coding section: ▪ Added ICD-10 Diagnoses *(Effective October 1, 2014)*
	Reference section updated.
12-31-2013	In Coding section: ▪ Removed CPT codes: 43228, 43258 *(Deleted codes, effective December 31, 2013)* ▪ Added CPT codes: 43229, 43233, 43253, 43254, 43266, 43270 *(New codes, effective January 1, 2014)* ▪ Added ICD-10 Diagnosis codes *(Effective October 1, 2014)*
01-01-2015	In Coding section: ▪ Revised CPT Codes: 43216, 43226, 43229, 43233, 43253, 43254, 43266, 43270 (Effective January 1, 2015)
04-25-2016	Published 03-24-2016. Effective 04-25-2016.
	Title changed from "Barrett's Esophagus Ablative Treatments" to "Endoscopic Radiofrequency Ablation or Cryoablation for Barrett Esophagus"
	Description section updated.
	In Policy section: ▪ Policy revised to remove references to all therapies except radiofrequency ablation and cryoablation. ▪ In Item A removed "The following ablative interventions are" and "when medical therapy (e.g., proton pump inhibitors, H-2 receptor, antagonists, or prokinetic agents) have failed: Photodynamic therapy" and added"(see Policy Guidelines)" to read, "Radiofrequency ablation may be considered medically necessary for treatment of Barrett esophagus with high-grade dysplasia (see Policy Guidelines)." ▪ In Item B added "treatment of Barrett esophagus with" and "(see Policy Guidelines)" to read "Radiofrequency ablation may be considered medically necessary for treatment of Barrett esophagus with low-grade dysplasia, when the initial diagnosis of low-grade dysplasia is confirmed by 2 physicians (see Policy Guidelines)." ▪ In Item C added "when the above criteria are not met, including but not limited to Barrett esophagus" to read "Radiofrequency ablation is considered experimental / investigational for treatment of Barrett esophagus when the above criteria are not met, including but not limited to Barrett esophagus in the absence of dysplasia."

REVISIONS	
	▪ In Item D removed "The following ablative interventions are", "because their effectiveness for these indications has not been established:" and "Argon plasma coagulation, Laser therapy, Multi-polar electro-coagulation, Ultrasonic therapy" to read "Cryoablation is considered experimental / investigational for treatment of Barrett esophagus, with or without dysplasia."
	Rationale section updated
	In Coding section: ▪ Removed CPT Codes: 96570, 96571 ▪ Removed HCPCS Code: J9600
	References updated
02-01-2017	Description section updated
	In Policy section: ▪ Policy Guidelines updated to add / remove policy related abbreviations and definitions.
	Rationale section updated
	References updated
01-05-2018	Description section updated
	In Policy section: ▪ Policy Guidelines updated
	Rationale section updated
	In Coding section: ▪ Removed CPT Codes: 43216, 43226, 43233, 43235, 43253, 43254, 43257, 43266, 43325 (These codes are not appropriate for this policy topic.)
	References updated
02-18-2019	Description section updated
	Rationale section updated
	References updated
03-29-2021	Updated Description section
	In the Policy section: • Replaced "2 physicians" with "2 pathologists".
	Updated Rationale section
	In the coding section • Removed CPT code 43499 • Removed ICD-10 code D00.1
	Updated Reference Section
01-04-2022	Updated Description Section
	Updated Rationale Section
	Updated References Section
12-29-2022	Updated Description Section
	Updated Rationale Section
	Updated Coding Section ▪ Removed Coding Bullets o 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: 43229, 43270.
	Updated References Section
01-05-2024	Updated Description Section
	Updated Rationale Section
	Updated Coding Section ▪ Removed ICD-10 Codes
	Updated References Section

REVISIONS	
12-23-2024	Updated Description Section
	Updated Rationale Section
	Updated References Section
01-05-2026	Updated Description Section
	Updated Rationale Section
	Updated Reference Section

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