

## MEDICAL POLICY

<b>POLICY TITLE</b>	<b>ENDOSCOPIC RADIOFREQUENCY ABLATION OR CRYOABLATION FOR BARRETT'S ESOPHAGUS</b>
<b>POLICY NUMBER</b>	<b>MP 1.118</b>

<b>CLINICAL BENEFIT</b>	<input checked="" type="checkbox"/> <b>MINIMIZE SAFETY RISK OR CONCERN.</b> <input checked="" type="checkbox"/> <b>MINIMIZE HARMFUL OR INEFFECTIVE INTERVENTIONS.</b> <input type="checkbox"/> <b>ASSURE APPROPRIATE LEVEL OF CARE.</b> <input type="checkbox"/> <b>ASSURE APPROPRIATE DURATION OF SERVICE FOR INTERVENTIONS.</b> <input checked="" type="checkbox"/> <b>ASSURE THAT RECOMMENDED MEDICAL PREREQUISITES HAVE BEEN MET.</b> <input type="checkbox"/> <b>ASSURE APPROPRIATE SITE OF TREATMENT OR SERVICE.</b>
<b>Effective Date:</b>	<b>2/1/2026</b>

### POLICY

#### Radiofrequency Ablation of Barrett's Esophagus

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

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 a second pathologist\* who is an expert in gastrointestinal (GI) pathology.

\* *Two experts in GI pathology should agree on the diagnosis of low-grade dysplasia (see policy guidelines).*

Radiofrequency ablation is considered **investigational** for the treatment Barrett's esophagus when the above criteria are not met, including but not limited to Barrett's esophagus in the absence of dysplasia, as there is insufficient evidence to support a general conclusion concerning the health outcomes or benefits associated with this procedure.

#### Cryoablation for the Treatment of Barrett's Esophagus

Cryoablation (e.g., CryoSpray) is considered **investigational** for the treatment of Barrett's esophagus, with or without dysplasia, as there is insufficient evidence to support a general conclusion concerning the health outcomes or benefits associated with this procedure.

#### Policy Guidelines

Radiofrequency ablation for Barrett's esophagus with high-grade dysplasia (HGD) may be used in combination with endoscopic mucosal resection of nodular or visible lesions. 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. 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. 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 endoscopic mucosal resection.

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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. As a result, it is ideal that 2 experts in GI pathology agree on the diagnosis to confirm LGD; this may result in greater than 75% of initial diagnoses of LGD being downgraded to nondysplasia. A review by a single expert GI pathologist will also result in a large number of LGD diagnoses being downgraded, although probably not as many downgrades as achieved using 2 expert pathologists.

### **Cross-References:**

- MP 2.053 Transesophageal Endoscopic Therapies for Gastroesophageal Reflux Disease**
- MP 2.093 Confocal Laser Endomicroscopy**
- MP 2.390 Adjunctive Techniques for Screening, Surveillance, and Risk Classification of Barrett Esophagus and Esophageal Dysplasia**
- MP 4.019 Oncological Applications of Photodynamic Therapy Including Barrett's Esophagus**

### **PRODUCT VARIATIONS**

This policy is only applicable to certain programs and products administered by Capital Blue Cross and subject to benefit variations. Please see additional information below.

**FEP PPO** - Refer to FEP Medical Policy Manual. The FEP Medical Policy manual can be found at:

<https://www.fepblue.org/benefit-plans/medical-policies-and-utilization-management-guidelines/medical-policies>

### **DESCRIPTION/BACKGROUND**

In Barrett's esophagus (BE), the normal squamous epithelium is replaced by specialized columnar-type epithelium, known as intestinal metaplasia (IM). Intestinal metaplasia is a precursor to adenocarcinoma and may be treated with mucosal ablation techniques such as radiofrequency ablation (RFA) or cryoablation. Radiofrequency ablation has become the ablative treatment of choice in the management of dysplastic BE.

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

The esophagus is normally lined by squamous epithelium. Barrett's 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 (GERD). 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

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color than the background squamous mucosa. Confirmation of BE requires 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). 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%. 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. 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.

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. 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. Curvers et al (2010) tested this hypothesis in 147 patients with BE who were given an initial diagnosis of LGD. 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.

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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. 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. In this sample, 73% of subjects were downstaged.

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

The management of BE includes 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). 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%.

### ***Ablative Techniques***

Available mucosal ablation techniques that 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 significantly decrease the risk of adenocarcinoma in BE.

Radiofrequency ablation affects only the most superficial layer of the esophagus (i.e., 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 [e.g., 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%. 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.

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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.

### 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. 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 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." 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. The next-generation C2 CryoBalloon Ablation System was introduced in 2018. 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." FDA product code: GEH.

### RATIONALE

#### Summary of Evidence

For individuals who have BE with HGD who receive endoscopic RFA, the evidence includes a randomized controlled trial (RCT) comparing radical endoscopic resection with focal endoscopic resection followed by RFA, 1 RCT comparing RFA with surveillance alone, and a systematic review evaluating RCTs and a number of observational studies, some of which compared RFA with other endoscopic treatment modalities. Relevant outcomes are change in disease status, morbid events, and treatment-related morbidity and mortality. The available evidence has shown that using RFA to treat BE with HGD is at least as effective in eradicating HGD as other techniques, with a lower progression rate to cancer, and may be considered an alternative to esophagectomy. Evidence from at least 1 RCT has demonstrated higher rates of eradication than surveillance alone. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

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For individuals who have BE with LGD who receive endoscopic RFA, the evidence includes at least 3 RCTs comparing RFA with surveillance alone, a number of observational studies, and systematic reviews of these studies. Relevant outcomes are change in disease status, morbid events, and treatment-related morbidity and mortality. For patients with confirmed LGD, evidence suggests that RFA reduces progression to HGD and adenocarcinoma. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

For individuals who have BE without dysplasia who receive endoscopic RFA, the evidence includes single-arm studies reporting outcomes after RFA. Relevant outcomes are change in disease status, morbid events, and treatment-related morbidity and mortality. The available studies have suggested that nondysplastic metaplasia can be eradicated by RFA. However, the risk-benefit ratio and the net effect of RFA on health outcomes are unknown. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have BE with or without dysplasia who receive endoscopic cryoablation, the evidence includes nonrandomized studies and systematic reviews of those studies reporting outcomes after cryoablation. Relevant outcomes include change in disease status, morbid events, and treatment-related morbidity and mortality. These studies have generally demonstrated high rates of eradication of dysplasia. Recent observational studies comparing RFA with cryoablation show similar outcomes. However, there are no RCTs comparing cryoablation with surgical care or RFA. The evidence is insufficient to determine the effects of the technology on health outcomes.

### DEFINITIONS

**DYSPLASIA** refers to abnormality of development, in pathology, alteration in size, shape and organization of adult cells.

**EPITHELIUM** refers to the covering of internal and external surfaces of the body, including the lining of vessels and other small cavities. Epithelium is classified into types on the basis of the number of layers deep and the shape of the superficial cells.

**HIGH-GRADE DYSPLASIA** refers to the most advanced dysplasia with atypical changes in many of the cells and a very abnormal growth pattern of the glands. In high-grade dysplasia, the growth pattern of the glands, or rows of cells, are distorted or very irregular.

**LOW-GRADE DYSPLASIA** refers to atypical changes that do not involve most of the cells, and the growth pattern of the glands is still normal.

### DISCLAIMER

*Capital Blue Cross' medical policies are used to determine coverage for specific medical technologies, procedures, equipment, and services. These medical policies do not constitute medical advice and are subject to change as required by law or applicable clinical evidence from independent treatment guidelines. Treating providers are solely responsible for medical*

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advice and treatment of members. These policies are not a guarantee of coverage or payment. Payment of claims is subject to a determination regarding the member's benefit program and eligibility on the date of service, and a determination that the services are medically necessary and appropriate. Final processing of a claim is based upon the terms of contract that applies to the members' benefit program, including benefit limitations and exclusions. If a provider or a member has a question concerning this medical policy, please contact Capital Blue Cross' Provider Services or Member Services.

### CODING INFORMATION

**Note:** This list of codes may not be all-inclusive, and codes are subject to change at any time. The identification of a code in this section does not denote coverage as coverage is determined by the terms of member benefit information. In addition, not all covered services are eligible for separate reimbursement.

**Investigational; therefore, not covered when used to report cryoablation for the treatment of Barrett's esophagus:**

Procedure codes							
43229	43270						

**Covered when medically necessary and used to report radiofrequency ablation for the treatment of Barrett's esophagus:**

Procedure codes							
43229	43270						

ICD-10-CM Diagnosis Code	Description
K22.710	Barrett's esophagus with low grade dysplasia
K22.711	Barrett's esophagus with high grade dysplasia
K22.719	Barrett's esophagus with dysplasia, unspecified

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## POLICY HISTORY

<b>MP 1.118</b>	<b>11/23/2020 Consensus Review.</b> No change to policy statements. References updated.
	<b>10/11/2021 Consensus Review.</b> No change to policy statements. Added NCCN statement. References updated.
	<b>09/26/2022 Consensus Review.</b> No change in policy statement. Updated background. Lit review, references updated.
	<b>06/13/2023 Administrative Update.</b> New code 0398U effective 07/01/2023 added.



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<b>12/21/2023 Consensus Review.</b> No change to policy statement. Removed CPT code 0398U. Updated background and references.
<b>12/02/2024 Consensus Review.</b> No change to policy statement. Removed NCCN statement. Coding reviewed. References updated.
<b>10/08/2025 Consensus Review.</b> No change to policy statement. Updated clinical benefit, cross-references, background, regulatory status, and summary of evidence. Coding reviewed with no coding changes.

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