MEDICAL POLICY

POLICY TITLE	**ENDOSCOPIC RADIOFREQUENCY ABLATION OR CRYOABLATION FOR BARRETT'S ESOPHAGUS**
POLICY NUMBER	**MP 1.118**

CLINICAL BENEFIT	☒ MINIMIZE SAFETY RISK OR CONCERN. ☒ MINIMIZE HARMFUL OR INEFFECTIVE INTERVENTIONS. ☐ ASSURE APPROPRIATE LEVEL OF CARE. ☐ ASSURE APPROPRIATE DURATION OF SERVICE FOR INTERVENTIONS. ☐ ASSURE THAT RECOMMENDED MEDICAL PREREQUISITES HAVE BEEN MET. ☐ ASSURE APPROPRIATE SITE OF TREATMENT OR SERVICE.
Effective Date:	**11/1/2024**

I. 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 GI [gastrointestinal] 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.

The National Comprehensive Cancer Network (NCCN) is a nonprofit alliance of cancer centers throughout the United States. NCCN develops the Clinical Practice Guidelines in Oncology which are recommendations aimed to help health care professionals diagnose, treat, and manage patients with cancer. Guidelines evolve continuously as new treatments and diagnostics emerge and may be used by Capital Blue Cross when determining medical necessity according to this policy.

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Policy Guidelines

Radiofrequency ablation for Barrett's esophagus with high-grade dysplasia (HGD) may be used in combination with endoscopic mucosal resection of nodular/visible lesions. The American Society for Gastrointestinal Endoscopy and the American Gastroenterological Association both recommend that a reading of high-grade dysplasia (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 patients 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.

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 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 (Curvers et al, 2010). 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.

II. PRODUCT VARIATIONS

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This policy is only applicable to certain programs and products administered by Capital Blue Cross and subject to benefit variations as discussed in Section VI. 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

III. DESCRIPTION/BACKGROUND

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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.

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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). BE occurs in the distal esophagus, may be of any length, 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 biopsy of the columnar epithelium and microscopic identification of intestinal metaplasia.

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.

The CryoSpray Ablation system uses a low-pressure spray for applying liquid nitrogen through an upper endoscope. Cryotherapy allows for treatment of uneven surfaces; however, a disadvantage of the treatment is the uneven application inherent in spraying the cryogen.

The HALO system uses radiofrequency energy and consists of 2 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 the catheter. The HALO90 or the HALO360 is 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 BE up

to 3 cm. HALO360 uses a balloon catheter that is sized to fit the individual's esophagus and is inflated to allow for circumferential ablation.

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 postablation regrowth of the normal squamous epithelium. (Note: The eradication of intestinal metaplasia does not leave behind microscopic foci). 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 to the HALO system is that it is an automated process that eliminates operator-dependent error, which may be seen with APC or MPEC.

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. 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.

The risk of treating high-grade dysplasia 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.

Practice Guidelines and Position Statements

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 technique. 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. Per their guidelines, cryotherapy may be considered as an alternative modality in patients who are unresponsive to RFA.

American Society for Gastrointestinal Endoscopy

In 2018, the American Society for Gastrointestinal Endoscopy issued guidelines on the role of endoscopy in BE-associated dysplasia and intramucosal cancer. 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 1).

Table 1. 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
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

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

American Gastroenterological Association

In 2020, the American Gastroenterological Association published a best practice clinical update on the role of endoscopic therapy in patients with BE with dysplasia and/or early cancer. This best practice document was not based on a formal systematic review; thus, no ratings for strength of recommendation and quality of evidence were not provided.

For BE with LGD, best practice advice included the following:

- "The reading of LGD in BE should be confirmed by an experienced gastrointestinal pathologist."
- "In BE patients with confirmed LGD, a repeat examination within 3–6 months with HD-WLE [high-definition white-light endoscopy] and preferably optical chromoendoscopy should be performed to rule out the presence of a visible lesion, which should prompt endoscopic resection (see section on HGD)."
- "Both BET [Barrett's endoscopic therapy] and continued surveillance are reasonable options for the management of BE patients with confirmed and persistent LGD."

For BE with HGD, best practice advice included the following:

- "The reading of HGD in BE should be confirmed by an experienced gastrointestinal pathologist."
- "The diagnosis of flat HGD should prompt a repeat HD-WLE (6–8 weeks) to evaluate for the presence of a visible lesion; these visible lesions should be removed by EMR [endoscopic mucosal resection]."
- "BET is the preferred treatment, over esophagectomy, for BE patients with HGD."

Regulatory Status

In 2005, the HALO360 (now Barrx™ 360 RFA Balloon Catheter; Barrx Medical; acquired by Covidien in 2012) 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. FDA-labeled indications are for use in coagulation of bleeding and nonbleeding sites in the gastrointestinal tract and include the treatment of BE[12] 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.13 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." [14] 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.15, 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."[16] FDA product code: GEH.

IV. RATIONALE

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Summary of Evidence

For individuals who have BE with HGD who receive endoscopic RFA, the evidence includes randomized controlled trials (RCTs). One compares radical endoscopic resection with focal endoscopic resection followed by RFA, an another RCT compares RFA with surveillance alone. 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 ablative techniques, with a lower progression rate to cancer, and may be considered an alternative to esophagectomy. Two RCTs of RFA versus only endoscopic surveillance in BE showed that RFA had a high rate of complete eradication of dysplasia and IM and decreased disease progression compared with the control group. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

For individuals who have BE with LGD who receive endoscopic RFA, the evidence includes at least 2 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 from an RCT has suggested that RFA reduces progression to HGD and adenocarcinoma. Challenges exist in differentiating between nondysplastic BE and BE with LGD; making the correct diagnosis has important implications for LGD treatment decisions. One of the available RCTs required that LGD be confirmed by an expert panel, which supports the use of having a gastrointestinal pathologist confirm LGD before treatment of BE with LGD can begin. 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 noncomparative 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. However, the available evidence does not compare cryoablation with surgical care or RFA. The evidence is insufficient to determine the effects of the technology on health outcomes.

V. DEFINITIONS

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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.

VI. BENEFIT VARIATIONS

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The existence of this medical policy does not mean that this service is a covered benefit under the member's health benefit plan. Benefit determinations should be based in all cases on the applicable health benefit plan language. Medical policies do not constitute a description of benefits. A member's health benefit plan governs which services are covered, which are excluded, which are subject to benefit limits, and which require preauthorization. There are different benefit plan designs in each product administered by Capital Blue Cross. Members and providers should consult the member's health benefit plan for information or contact Capital Blue Cross for benefit information.

VII. DISCLAIMER

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Capital Blue Cross's medical policies are developed to assist in administering a member's benefits, do not constitute medical advice and are subject to change. Treating providers are solely responsible for medical advice and treatment of members. Members should discuss any medical policy related to their coverage or condition with their provider and consult their benefit information to determine if the service is covered. If there is a discrepancy between this medical policy and a member's benefit information, the benefit information will govern. If a provider or a member has a question concerning the application of this medical policy to a specific member's plan of benefits, please contact Capital Blue Cross' Provider Services or Member Services. Capital Blue Cross considers the information contained in this medical policy to be proprietary and it may only be disseminated as permitted by law.

VIII. CODING INFORMATION

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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

IX. REFERENCES

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X. *POLICY HISTORY*

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MP 1.118	**11/23/20** Consensus review. No change to policy statements. References updated.
	10/11/21 Consensus review. No change to policy statements. Added NCCN statement. References updated.
	09/26/2022 Consensus review. No change in policy statement. Updated background. Lit review, references updated.
	6/13/2023 Admin Review: New code 0398U effective 7/1/2023 added.
	12/21/2023. Consensus review. No change to policy statement. Removed CPT code 0398U. Updated background and references.

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