Endoscopic Radiofrequency Ablation or Cryoablation for Barrett Esophagus

Policy # 00261
Original Effective Date: 06/16/2010
Current Effective Date: 02/13/2023

Applies to all products administered or underwritten by Blue Cross and Blue Shield of Louisiana and its subsidiary, HMO Louisiana, Inc.(collectively referred to as the “Company”), unless otherwise provided in the applicable contract. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.

Note: Oncologic Applications of Photodynamic Therapy, Including Barrett’s Esophagus is addressed in medical policy 00234.

Note: Confocal Laser Endomicroscopy is addressed separately in medical policy 00416.

When Services Are Eligible for Coverage
Coverage for eligible medical treatments or procedures, drugs, devices or biological products may be provided only if:

- Benefits are available in the member’s contract/certificate, and
- Medical necessity criteria and guidelines are met.

Based on review of available data, the Company may consider radiofrequency ablation (RFA) for treatment of Barrett esophagus (BE) with either high-grade dysplasia (HGD) or low-grade dysplasia (LGD) to be eligible for coverage.**

When Services Are Considered Investigational
Coverage is not available for investigational medical treatments or procedures, drugs, devices or biological products.

Based on review of available data, the Company considers radiofrequency ablation (RFA) for treatment of Barrett esophagus (BE) in the absence of dysplasia to be investigational.*

Based on review of available data, the Company considers cryoablation for Barrett esophagus (BE), with or without dysplasia to be investigational.*
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Background/Overview

Diagnosis

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

Management of Barrett Esophagus

The management of Barrett Esophagus (BE) includes the treatment of gastroesophageal reflux disease and surveillance endoscopy to detect progression to high-grade dysplasia (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 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. (Photodynamic therapy for Barrett’s Esophagus is discussed in medical policy 00234)

The CryoSpray Ablation system uses a low-pressure spray for applying liquid nitrogen through an upper endoscope. Cryotherapy allows for the 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 (ie, <1 second) delivery of a predetermined
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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 (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). 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%. 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 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.

FDA or Other Governmental Regulatory Approval
U.S. Food and Drug Administration (FDA)
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.
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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.” 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.”

Rationale/Source
This medical policy was developed through consideration of peer-reviewed medical literature generally recognized by the relevant medical community, U.S. Food and Drug Administration approval status, nationally accepted standards of medical practice and accepted standards of medical practice in this community, technology evaluation centers, reference to federal regulations, other plan medical policies, and accredited national guidelines.

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.

Summary of Evidence
For individuals who have BE with high-grade dysplasia (HGD) who receive endoscopic RFA, the evidence includes a randomized controlled trial (RCT) comparing radical endoscopic resection with focal endoscopic resection followed by RFA, one 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 one RCT has demonstrated higher rates of eradication than surveillance alone. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have BE with low-grade dysplasia (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 an 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 that the technology results in an improvement in the net health outcome.

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. 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 that the technology results in an improvement in the net health outcome.

**Supplemental Information**
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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. The ACG recommends
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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 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 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

<table>
<thead>
<tr>
<th>Recommendation</th>
<th>SOR</th>
<th>QOEa</th>
</tr>
</thead>
<tbody>
<tr>
<td>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.</td>
<td>Conditional</td>
<td>Low</td>
</tr>
<tr>
<td>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.</td>
<td>Conditional</td>
<td>Moderate</td>
</tr>
<tr>
<td>In BE patients with confirmed HGD, we recommend EET compared with surveillance.</td>
<td>Strong</td>
<td>Moderate</td>
</tr>
<tr>
<td>In BE patients with HGD/IMC, we recommend against surgery compared with EET.</td>
<td>Strong</td>
<td>Very low quality</td>
</tr>
<tr>
<td>In BE patients referred for EET, we recommend endoscopic resection of all visible lesions compared with no endoscopic resection of visible lesions.</td>
<td>Strong</td>
<td>Moderate</td>
</tr>
<tr>
<td>In BE patients with visible lesions who undergo endoscopic resection, we suggest ablation of the remaining Barrett’s segment compared with no ablation.</td>
<td>Conditional</td>
<td>Low</td>
</tr>
</tbody>
</table>
Recommendation | SOR | QOE\textsuperscript{a}  
--- | --- | ---  
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; GI: gastrointestinal; HGD: high-grade dysplasia; IMC: intramucosal cancer; LGD: low-grade dysplasia; QOE: quality of evidence; SOR: strength of recommendation.  

\textsuperscript{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 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."
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- "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."

National Comprehensive Cancer Network
National Comprehensive Cancer Network Guidelines (v.4. 2022) Esophageal and Esophagogastric Cancers make recommendations about BE and early-stage esophageal adenocarcinomas. 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.

Medicare National Coverage
There is no national coverage determination. In the absence of a national coverage determination, coverage decisions are left to the discretion of local Medicare carriers.

Ongoing and Unpublished Clinical Trials
Some currently ongoing and unpublished trials that might influence this review are listed in Table 2.

Table 2. Summary of Key Trials

<table>
<thead>
<tr>
<th>NCT No.</th>
<th>Trial Name</th>
<th>Planned Enrollment</th>
<th>Completion Date</th>
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<tbody>
<tr>
<td>Ongoing</td>
<td>Multi-center Clinical Study to Evaluate the C2 CryoBalloon Focal Ablation System for the Treatment of Patients With Previously Untreated Dysplastic Barrett’s Epithelium</td>
<td>150</td>
<td>Jun 2023</td>
</tr>
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<table>
<thead>
<tr>
<th>Unpublished</th>
<th>Trial Description</th>
<th>NCT/Year</th>
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<tbody>
<tr>
<td>NCT01961778</td>
<td>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</td>
<td>50</td>
</tr>
<tr>
<td>NCT02558504</td>
<td>Clinical and Medico-economic Evaluation of Radiofrequency Ablation Versus Oesophagectomy in the Treatment of High-Grade Dysplasia in Barrett’s Oesophagus</td>
<td>87</td>
</tr>
</tbody>
</table>

NCT: national clinical trial.

References
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assessments of histologic outcomes and adverse events. Gastrointest Endosc. May 2014; 79(5): 718-731.e3. PMID 24462170
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06/03/2010 Medical Policy Committee approval
06/16/2010 Medical Policy Implementation Committee approval. New policy.
05/05/2011 Medical Policy Committee approval
05/18/2011 Medical Policy Implementation Committee approval. No change to coverage.
04/12/2012 Medical Policy Committee review
04/25/2012 Medical Policy Implementation Committee approval. Radiofrequency ablation for treatment of Barrett’s esophagus with low-grade dysplasia was changed from investigational to eligible for coverage when the initial diagnosis of low-grade dysplasia is confirmed by a second pathologist who is an expert in GI pathology. Added that treatment of Barrett’s esophagus with low-grade dysplasia in any other situation is investigational.

03/04/2013 Coding revised
04/04/2013 Medical Policy Committee review
04/24/2013 Medical Policy Implementation Committee approval. No change to coverage.
06/25/2013 Medical Policy Implementation Committee approval. Retired medical policy.
01/09/2014 Medical Policy Committee review
01/15/2014 Medical Policy Implementation Committee approval. “Based on review of available data, the Company considers radiofrequency ablation for treatment of Barrett’s esophagus in the absence of dysplasia” was changed from investigational to not medically necessary. Dropped the requirement of a second pathologist from coverage section. Brought back from retired status.

01/08/2015 Medical Policy Committee review
01/21/2015 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
08/03/2015 Coding update: ICD10 Diagnosis code section added; ICD9 Procedure code section removed.
01/07/2016 Medical Policy Committee review
01/22/2016 Medical Policy Implementation Committee approval. RFA for treatment of BE in the absence of dysplasia is considered investigational.
01/01/2017 Coding update: Removing ICD-9 Diagnosis Codes
01/05/2017 Medical Policy Committee review
01/18/2017 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
01/04/2018 Medical Policy Committee review
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01/17/2018 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
01/10/2019 Medical Policy Committee review
01/03/2020 Medical Policy Committee review
01/08/2020 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
01/07/2021 Medical Policy Committee review
01/13/2021 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
10/01/2021 Coding update
01/06/2022 Medical Policy Committee review
01/12/2022 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
01/05/2023 Medical Policy Committee review
01/11/2023 Medical Policy Implementation Committee approval. Title changed from “Endoscopic Radiofrequency Ablation or Cryoablation for Barrett’s Esophagus” to “Endoscopic Radiofrequency Ablation or Cryoablation for Barrett Esophagus”. Changed “Barrett’s” to “Barrett” throughout the policy. Coverage eligibility unchanged.

Next Scheduled Review Date: 01/2024

Coding
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Codes used to identify services associated with this policy may include (but may not be limited to) the following:

<table>
<thead>
<tr>
<th>Code Type</th>
<th>Code</th>
</tr>
</thead>
<tbody>
<tr>
<td>CPT</td>
<td>43229, 43270</td>
</tr>
<tr>
<td>HCPCS</td>
<td>No codes</td>
</tr>
<tr>
<td>ICD-10 Diagnosis</td>
<td>D13.0, K22.70, K22.710, K22.711, K22.719, K22.81-K22.89</td>
</tr>
</tbody>
</table>

*Investigational – A medical treatment, procedure, drug, device, or biological product is Investigational if the effectiveness has not been clearly tested and it has not been incorporated into standard medical practice. Any determination we make that a medical treatment, procedure, drug, device, or biological product is Investigational will be based on a consideration of the following:

A. Whether the medical treatment, procedure, drug, device, or biological product can be lawfully marketed without approval of the U.S. Food and Drug Administration (FDA) and whether such approval has been granted at the time the medical treatment, procedure, drug, device, or biological product is sought to be furnished; or

B. Whether the medical treatment, procedure, drug, device, or biological product requires further studies or clinical trials to determine its maximum tolerated dose, toxicity, safety, effectiveness, or effectiveness as compared with the standard means of treatment or diagnosis, must improve health outcomes, according to the consensus of opinion among experts as shown by reliable evidence, including:

1. Consultation with technology evaluation center(s);
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2. Credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community; or
3. Reference to federal regulations.

**Medically Necessary (or “Medical Necessity”) - Health care services, treatment, procedures, equipment, drugs, devices, items or supplies that a Provider, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury, disease or its symptoms, and that are:

A. In accordance with nationally accepted standards of medical practice;

B. Clinically appropriate, in terms of type, frequency, extent, level of care, site and duration, and considered effective for the patient's illness, injury or disease; and

C. Not primarily for the personal comfort or convenience of the patient, physician or other health care provider, and not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient's illness, injury or disease.

For these purposes, “nationally accepted standards of medical practice” means standards that are based on credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community, Physician Specialty Society recommendations and the views of Physicians practicing in relevant clinical areas and any other relevant factors.

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