Medical Policy

Endoscopic Radiofrequency Ablation or Cryoablation for Barrett Esophagus

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Policy Number: 218
BCBSA Reference Number: 2.01.80
NCD/LCD: NA

Related Policies
- Oncologic Applications of Photodynamic Therapy, Including Barrett Esophagus, #454
- Confocal Laser Endomicroscopy, #618

Policy
Commercial Members: Managed Care (HMO and POS), PPO, and Indemnity
Medicare HMO BlueSM and Medicare PPO BlueSM Members

Radiofrequency ablation may be considered MEDICALLY NECESSARY for treatment of Barrett esophagus with high-grade dysplasia.

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 two pathologists prior to the ablation procedure.

Radiofrequency ablation is considered 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.

Cryoablation is considered INVESTIGATIONAL for Barrett esophagus, with or without dysplasia.

Prior Authorization Information

Inpatient
- For services described in this policy, precertification/preauthorization IS REQUIRED for all products if the procedure is performed inpatient.

Outpatient
- For services described in this policy, see below for products where prior authorization might be required if the procedure is performed outpatient.
Outpatient

<table>
<thead>
<tr>
<th>Outpatient</th>
<th>Commercial Managed Care (HMO and POS)</th>
<th>Prior authorization is not required.</th>
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<tbody>
<tr>
<td>Commercial PPO and Indemnity</td>
<td>Prior authorization is not required.</td>
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<tr>
<td>Medicare HMO BlueSM</td>
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<tr>
<td>Medicare PPO BlueSM</td>
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CPT Codes / HCPCS Codes / ICD Codes

Inclusion or exclusion of a code 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 as it applies to an individual member.

Providers should report all services using the most up-to-date industry-standard procedure, revenue, and diagnosis codes, including modifiers where applicable.

The following codes are included below for informational purposes only; this is not an all-inclusive list.

The above medical necessity criteria MUST be met for the following codes to be covered for Commercial Members: Managed Care (HMO and POS), PPO, Indemnity, Medicare HMO Blue and Medicare PPO Blue:

**CPT Codes**

<table>
<thead>
<tr>
<th>CPT codes</th>
<th>Code Description</th>
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</thead>
<tbody>
<tr>
<td>43229</td>
<td>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)</td>
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**ICD-10 Diagnosis Codes**

<table>
<thead>
<tr>
<th>ICD-10-CM Diagnosis codes</th>
<th>Code Description</th>
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<tbody>
<tr>
<td>D13.0</td>
<td>Benign neoplasm of esophagus</td>
</tr>
<tr>
<td>K22.710</td>
<td>Barrett's esophagus with low grade dysplasia</td>
</tr>
<tr>
<td>K22.711</td>
<td>Barrett's esophagus with high grade dysplasia</td>
</tr>
<tr>
<td>K22.719</td>
<td>Barrett's esophagus with dysplasia, unspecified</td>
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**Description**

**Barrett Esophagus and the Risk of Esophageal Carcinoma**

The esophagus is normally lined by squamous epithelium. 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 visualized by the endoscopist 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.

Intestinal metaplasia is a precursor to esophageal adenocarcinoma, and esophageal adenocarcinoma is thought to result from a stepwise accumulation of genetic abnormalities in the specialized epithelium, which results in the phenotypic expression of histologic features of LGD to HGD to carcinoma. Two large epidemiologic studies published in 2011 reported the risk of progression to cancer in patients with BE. One study reported the rate of progression to cancer in more than 8000 patients with a mean duration of follow-up of 7 years (range, 1-20 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 over 11,000 patients with BE and, after a median follow-up of 5.2 years, 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 the general population. It is based on these higher risk estimates that current surveillance recommendations have been based.

**Management of BE**

The current management of BE includes treatment of GERD 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). A 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 metachronous lesions were observed in 11% of patients after a mean of 36.7 months. In a review by Pech and Ell, the authors state 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%.

**Ablation Techniques**

Available mucosal ablation techniques that include several thermal (multipolar electrocoagulation [MPEC], argon plasma coagulation [APC], heater probe, Nd:YAG laser, KTP-YAG laser, diode laser, argon laser, and cryoablation) or nonthermal (5-ALA and Photofrin photodynamic therapy [PDT]) techniques. In a randomized phase 3 trial, PDT has been shown to significantly decrease the risk of adenocarcinoma in BE. (PDT therapy for BE is discussed in policy #454.)

The CryoSpray Ablation™ system (formerly the SprayGenix™ Cryo Ablation system; CSA Medical, Lutherville, MD) uses a low-pressure spray for spraying liquid nitrogen through an upper endoscope. Cryotherapy allows for treatment of uneven surfaces; however, a disadvantage is the uneven application inherent in spraying the cryogen.

The HALO System from Barrx™ Medical (Sunnyvale, CA, acquired by Covidien in 2012, and now known as the Barrx line of products) uses radiofrequency (RF) energy and consists of 2 components, an energy generator and an ablation catheter. The generator provides rapid (ie, <1 second) delivery of a predetermined amount of RF energy to the catheter. Both the HALO90 and HALO360 are 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. The HALO360 uses a balloon catheter that is sized to fit the individual esophagus and is inflated to allow for circumferential ablation.

Ablation with RF affects only the most superficial layer of the esophagus (the mucosa), leaving the underlying tissues unharmed. Efficacy measures of the procedure include eradication of intestinal metaplasia without leaving behind microscopic (or “buried”) foci and postablation regrowth of the normal squamous epithelium. 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 “buried” foci of intestinal metaplasia has been reported to be 20% to 44% with APC and 7% with MPEC; reports using the HALO system have been 0%. Another potential advantage to the HALO system is that because it is automated, it eliminates operator-dependent error that may be seen with APC and 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.
Summary
Barrett esophagus (BE) is a condition in which 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.

The evidence for the use of endoscopic RFA for the treatment of patients who have BE with high-grade dysplasia (HGD) includes 1 randomized controlled trial (RCT) comparing radical endoscopic resection with focal endoscopic resection followed by RFA; 1 RCT comparing RFA with surveillance alone; and a number of observational studies, some of which compared RFA with other endoscopic treatment modalities. Relevant outcomes are overall survival, change in disease status, morbid events, and treatment-related morbidity and mortality. The evidence available indicates that RFA of HGD in BE has been shown to be at least as effective in eradicating HGD as other ablative techniques, with a lower progression rate to cancer, and may be considered as an alternative to esophagectomy. Evidence from at least 1 RCT demonstrates higher rates of eradication than surveillance alone. The evidence is sufficient to determine qualitatively that the technology results in a meaningful improvement in the net health outcome.

The evidence for the use of endoscopic RFA for the treatment of patients who have BE with low-grade dysplasia (LGD) includes at least 2 RCTs comparing RFA with surveillance alone, a number of observational studies, and systematic reviews of these studies. Relevant outcomes are overall survival, change in disease status, morbid events, and treatment-related morbidity and mortality. For patients confirmed to have LGD, evidence from 1 RCT suggests 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 treatment decisions for LGD. 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 qualitatively that the technology results in a meaningful improvement in the net health outcome.

The evidence for the use of RFA for the treatment of patients who have BE without dysplasia includes single-arm studies reporting outcomes after RFA. Relevant outcomes are overall survival, change in disease status, morbid events, and treatment-related morbidity and mortality. The available studies suggest 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.

The evidence for the use of cryoablation in patients who have BE (with or without dysplasia) includes noncomparative studies reporting outcomes after cryoablation. Relevant outcomes include overall survival, change in disease status, morbid events, and treatment-related morbidity and mortality. These studies generally demonstrate high rates of eradication of dysplasia. However, the available evidence does not allow comparisons with surgical care or RFA. The evidence is insufficient to determine the effects of the technology on health outcomes.

Based on the results of available evidence from RCTs and other available evidence sources that are relevant to RFA for BE with LGD, along with specialty society guidelines, clinical input was obtained. Clinical input generally supported the use of RFA for BE with LGD. Clinical input providers indicated that it is possible to define a population with a higher risk of progression by having the initial diagnosis of LGD reconfirmed by a pathologist who is an expert in gastrointestinal pathology.

Policy History

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<th>Date</th>
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<td>1/2018</td>
<td>New references added from BCBSA National medical policy.</td>
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<td>1/2016</td>
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Information Pertaining to All Blue Cross Blue Shield Medical Policies
Click on any of the following terms to access the relevant information:
Medical Policy Terms of Use
Managed Care Guidelines
Indemnity/PPO Guidelines
Clinical Exception Process
Medical Technology Assessment Guidelines

References


