

Medical Policy



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Title: Barrett's Esophagus Treatments

Professional

Original Effective Date: February 26, 2009

Revision Date(s):

Current Effective Date: February 26, 2009

Institutional

Original Effective Date: February 26, 2009

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Current Effective Date: February 26, 2009

DESCRIPTION

Barrett's Esophagus (BE), a complication of GERD related chronic esophagitis, is characterized by metaplasia in the epithelial lining of the esophagus. This pre-malignant change may lead to adenocarcinoma of the esophagus. In addition to GERD, other risk factors for BE include age 50 years or older, ethnicity (Caucasian), and male sex.

Management of BE depends on the degree of dysplasia. Most patients with BE will need to undergo periodic surveillance endoscopies to ensure no progression. For BE patients with no signs of dysplasia on two consecutive endoscopic biopsies, the American College of Gastroenterology (ACG) recommends a follow-up endoscopy at three years. For patients with low-grade dysplasia (LGD) the ACG recommends annual endoscopy until there is no dysplasia. The finding of high-grade dysplasia (HGD) requires repeat endoscopies or intervention. Focal HGD (less than 5 crypts) may be followed with three month surveillance.

The ACG guidelines state that the therapeutic objective for BE are:

1. Control of symptoms of GERD, and
2. Maintenance of healed mucosa

Control of symptoms for BE may require higher than usual doses of proton pump inhibitors. Anti-reflux surgery may be necessary and can effectively control reflux symptoms in most patients but does not usually result in elimination of pre-malignant epithelium.

If BE patients are diagnosed with high-grade dysplasia there are four options according to the American College of Gastroenterology:

1. Do nothing/surveillance endoscopy and biopsy as HGD can regress to LGD or it may progress to esophageal cancer; or
2. Increase dosage of acid suppression medications, and have another endoscopic exam in 3 months; or
3. Esophagectomy; or
4. Photodynamic Therapy (PDT)

Esophagectomy remains the standard of treatment with patients with HGD and superficial adenocarcinoma. However, since the morbidity and mortality rate for esophagectomy is high, and some patients are not surgical candidates, alternative treatments have been investigated, including ablative therapy, such as argon plasma coagulation (including the Barrx-Halo System), cryotherapy, laser therapy, multi-polar electro-coagulation, radiofrequency ablation, and ultrasonic therapy. The Halo ablation system by Barrx Medical utilizes a radiofrequency generator in conjunction with a balloon ablation catheter. The radiofrequency generator provides rapid delivery of a predetermined amount of energy to a 3 cm long bipolar microelectrode ablation catheter containing 60 encircling electrode rings spaced 250 micrometers apart. The effectiveness of these ablative interventions (except for PDT) has not been established especially the long-term control of cancer risk.

In June 2003, the FDA approved Photodynamic Therapy with Photofrin for the treatment of high-grade dysplasia in patients with Barrett's Esophagus who do not undergo esophagectomy.

Several studies have demonstrated that endoscopic mucosal resection (EMR) is safe and effective for complete resection of superficial lesions, and offers the advantage of histopathological verification. Two devices for EMR have been cleared by the FDA through the 510(k) process for endoscopic mucosal resection in the upper gastrointestinal tract: 1. the Olympus Distal Attachment/EMR kit; and 2. the Cook Ireland Duette multi-band mucosectomy device.

In summary, there is adequate evidence to support the use of fundoplication, esophagectomy, endoscopic mucosal resection, and photodynamic therapy in the treatment of patients with Barrett's esophagus who have high-grade dysplasia when medical therapy has failed. On the other hand, data to support the use of other ablative interventions in the treatment of Barrett's esophagus lack well-designed, larger, randomized, double-blind studies in order to draw definitive conclusions.

POLICY

1. The following interventions are considered **medically necessary** for the treatment of members with Barrett's esophagus who have high-grade dysplasia when medical therapy (e.g., proton pump inhibitors, H-2 receptor, antagonists, or prokinetic agents) have failed:
 - A. Esophagectomy
 - B. Fundoplication
 - C. Photodynamic therapy
 - D. Endoscopic mucosal resection

2. The following ablative interventions are considered **experimental/investigational** for the treatment of Barrett's esophagus because their effectiveness for these indications has not been established:
- A. Argon plasma coagulation
 - B. Cryotherapy
 - C. Laser therapy
 - D. Multi-polar electro-coagulation
 - E. Radiofrequency ablation (including the Barrx-Halo System)
 - F. Ultrasonic therapy

CODING

The following codes for treatment and procedures applicable to this policy are included below for informational purposes. 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.

CPT/HCPCS

- | | |
|-------|---|
| 43100 | Excision of lesion, esophagus, with primary repair; cervical approach |
| 43101 | Excision of lesion, esophagus, with primary repair; thoracic or abdominal approach |
| 43116 | Partial esophagectomy, cervical, with free intestinal graft, including microvascular anastomosis, obtaining the graft and intestinal reconstruction |
| 43117 | Partial esophagectomy, distal two-thirds, with thoracotomy and separate abdominal incision, with or without proximal gastrectomy; with thoracic esophagogastrotomy, with or without pyloroplasty (ivor lewis) partial esophagectomy, distal two-thirds, with thoracotomy and separate abdominal incision, with or without proximal gastrectomy; with thoracic esophagogastrotomy, with or without pyloroplasty (ivor lewis) |
| 43118 | Partial esophagectomy, distal two-thirds, with thoracotomy and separate abdominal incision, with or without proximal gastrectomy; with colon interposition or small intestine reconstruction, including intestine mobilization, preparation, and anastomosis(es) |
| 43121 | Partial esophagectomy, distal two-thirds, with thoracotomy only, with or without proximal gastrectomy, with thoracic esophagogastrotomy, with or without pyloroplasty |
| 43122 | Partial esophagectomy, thoracoabdominal or abdominal approach, with or without proximal gastrectomy; with esophagogastrotomy, with or without pyloroplasty |
| 43123 | Partial esophagectomy, thoracoabdominal or abdominal approach, with or without proximal gastrectomy; with colon interposition or small intestine reconstruction, including intestine mobilization, preparation, and anastomosis(es) |
| 43124 | Total or partial esophagectomy, without reconstruction (any approach), with cervical esophagostomy |
| 43216 | Esophagoscopy, rigid or flexible; with removal of tumor(s), polyp(s), or other lesion(s) by hot biopsy forceps or bipolar cautery |
| 43226 | Esophagoscopy, rigid or flexible; with insertion of guide wire followed by dilation over guide wire |
| 43228 | Esophagoscopy, rigid or flexible; with ablation of tumor(s), polyp(s), or other lesion(s), not amenable to removal by hot biopsy forceps, bipolar cautery or snare technique |

- 43258 Upper gastrointestinal endoscopy including esophagus, stomach, and either the duodenum and/or jejunum as appropriate; with ablation of tumor(s), polyp(s), or other lesion(s) not amenable to removal by hot biopsy forceps, bipolar cautery or snare technique
- 43280 Laparoscopy, surgical, esophagogastric fundoplasty (eg, nissen, toupet procedures)
- 43324 Esophagogastric fundoplasty (eg, nissen, belsey iv, hill procedures)
- 43325 Esophagogastric fundoplasty; with fundic patch (thal-nissen procedure)
- 96570 Photodynamic therapy by endoscopic application of light to ablate abnormal tissue via activation of photosensitive drug(s); first 30 minutes (list separately in addition to code for endoscopy or bronchoscopy procedures of lung and esophagus)
- 96571 Photodynamic therapy by endoscopic application of light to ablate abnormal tissue via activation of photosensitive drug(s); each additional 15 minutes (list separately in addition to code for endoscopy or bronchoscopy procedures of lung and esophagus)
- J9600 Porfimer sodium, 75 mg

ICD-9 DIAGNOSIS

- 530.85 Barrett's esophagus
- 211.0 Benign neoplasm of esophagus (high-grade dysplasia)
- 230.1 Esophageal cancer in situ

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