Medical Policy

Transesophageal Endoscopic Therapies for Gastroesophageal Reflux Disease

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- Policy: Medicare
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Policy Number: 635
BCBSA Reference Number: 2.01.38
NCD/LCD:
National Coverage Determination (NCD) for Implantation of Anti-Gastroesophageal Reflux Device (100.9)
Local Coverage Determination (LCD): Select Minimally Invasive GERD Procedures (L35080)

Related Policies
- Endoscopic Radiofrequency Ablation or Cryoablation for Barrett's Esophagus, #218
- Periurethral Bulking Agents for the Treatment of Urinary Incontinence, #471
- Magnetic Esophageal Ring to Treat Gastroesophageal Reflux Disease, #920

Policy

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

Transoral incisionless fundoplication (TIF) (ie, EsophyX®) is considered INVESTIGATIONAL as a treatment of gastroesophageal reflux disease.

Transesophageal radiofrequency to create submucosal thermal lesions of the gastroesophageal junction (ie, the Stretta® procedure) is considered INVESTIGATIONAL as a treatment of gastroesophageal reflux disease.

Endoscopic submucosal implantation of a prosthesis or injection of a bulking agent (eg, polymethylmethacrylate beads, zirconium oxide spheres) is considered INVESTIGATIONAL as a treatment of gastroesophageal reflux disease.

Medicare HMO BlueSM and Medicare PPO BlueSM Members

Medical necessity criteria and coding guidance can be found through the links below.

National Coverage Determination (NCD) for Implantation of Anti-Gastroesophageal Reflux Device (100.9)
Endoscopic Treatment of GERD is not a covered service.

Local Coverage Determination (LCD): Select Minimally Invasive GERD Procedures (L35080)
For medical necessity criteria and coding guidance for Medicare Advantage members living outside of Massachusetts, please see the Centers for Medicare and Medicaid Services website for information regarding your specific jurisdiction at https://www.cms.gov.

Prior Authorization Information
Pre-service approval is required for all inpatient services for all products. See below for situations where prior authorization may be required or may not be required for outpatient services.
Yes indicates that prior authorization is required.
No indicates that prior authorization is not required.
N/A indicates that this service is primarily performed in an inpatient setting.

<table>
<thead>
<tr>
<th>Outpatient</th>
<th>Commercial Managed Care (HMO and POS)</th>
<th>Commercial PPO and Indemnity</th>
<th>Medicare HMO BlueSM</th>
<th>Medicare PPO BlueSM</th>
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</thead>
<tbody>
<tr>
<td></td>
<td>This is not a covered service.</td>
<td>This is not a covered service.</td>
<td>Implantation of Anti-Gastroesophageal Reflux Device: No</td>
<td>Implantation of Anti-Gastroesophageal Reflux Device: No</td>
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<tr>
<td></td>
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<td></td>
<td>Endoscopic Treatment of GERD: This is not a covered service.</td>
<td>Endoscopic Treatment of GERD: This is not a covered service.</td>
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</table>

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 following CPT codes are considered investigational for Commercial Members: Managed Care (HMO and POS), PPO, and Indemnity:

CPT Codes

<table>
<thead>
<tr>
<th>CPT codes:</th>
<th>Code Description</th>
</tr>
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<tbody>
<tr>
<td>43201</td>
<td>Esophagoscopy, flexible, transoral; with directed submucosal injection(s), any substance</td>
</tr>
<tr>
<td>43210</td>
<td>Esophagastroduodenoscopy, flexible, transoral; with esophagogastric fundoplasty, partial or complete, includes duodenoscopy when performed</td>
</tr>
<tr>
<td>43211</td>
<td>Esophagoscopy, flexible, transoral; with endoscopic mucosal resection</td>
</tr>
<tr>
<td>43212</td>
<td>Esophagoscopy, flexible, transoral; with placement of endoscopic stent (includes pre- and post-dilation and guide wire passage, when performed)</td>
</tr>
<tr>
<td>43257</td>
<td>Esophagastroduodenoscopy, flexible, transoral; with delivery of thermal energy to the muscle of lower esophageal sphincter and/or gastric cardia, for treatment of gastroesophageal reflux disease</td>
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Description
GASTROESOPHAGEAL REFLUX DISEASE
Gastroesophageal reflux disease (GERD) is a common disorder characterized by heartburn and other symptoms related to reflux of stomach acid into the esophagus. Nearly all individuals experience such symptoms at some point in their lives; a smaller number have chronic symptoms and are at risk for
complications of GERD. The prevalence of GERD has been estimated to be 10% to 20% in the Western world, with a lower prevalence in Asia.¹

Pathophysiology
The pathophysiology of GERD involves excessive exposure to stomach acid, which occurs for several reasons. There can be an incompetent barrier between the esophagus and stomach, either due to dysfunction of the lower esophageal sphincter or incompetence of the diaphragm. Another mechanism is abnormally slow clearance of stomach acid. In this situation, delayed clearance leads to an increased reservoir of stomach acid and a greater tendency to reflux.

In addition to troubling symptoms, some patients will have the more serious disease, which results in complications such as erosive esophagitis, dysphagia, Barrett esophagus, and esophageal carcinoma.

Pulmonary complications may result from aspiration of stomach acid into the lungs and can include asthma, pulmonary fibrosis, and bronchitis, or symptoms of chronic hoarseness, cough, and sore throat.

Treatment
Guidelines on the management of GERD emphasize initial medical management. Weight loss, smoking cessation, head of the bed elevation, and elimination of food triggers are all recommended in recent practice guidelines.¹ Proton pump inhibitors have been shown to be the most effective medical treatment. In a 2010 Cochrane systematic review, Proton pump inhibitors demonstrated superiority to H2-receptor agonists and prokinetics in both network meta-analyses and direct comparisons.²

Surgical Treatment
The most common surgical procedure used for GERD is laparoscopic Nissen fundoplication. Fundoplication involves wrapping a portion of the gastric fundus around the distal esophagus to increase lower esophageal sphincter pressure. If a hiatal hernia is present, the procedure also restores the position of the lower esophageal sphincter to the correct location. Laparoscopic fundoplication was introduced in 1991 and has been rapidly adopted because it avoids complications associated with an open procedure.

Although fundoplication results in a high proportion of patients reporting symptom relief, complications can occur, and sometimes require conversion to an open procedure. Patients who have relief of symptoms of GERD after fundoplication may have dysphagia or gas-bloat syndrome (excessive gastrointestinal gas).

Other Treatment Options
Due in part to the high prevalence of GERD, there has been interest in creating a minimally invasive transesophageal therapeutic alternative to open or laparoscopic fundoplication or chronic medical therapy. This type of procedure may be considered natural orifice transluminal surgery. Three types of procedures have been investigated.

1. Transesophageal endoscopic gastroplasty (gastroplication, transoral incisionless fundoplication) can be performed as an outpatient procedure. During this procedure, the fundus of the stomach is folded and then held in place with staples or fasteners that are deployed by the device. The endoscopic procedure is designed to recreate a valve and barrier to reflux.
2. Radiofrequency energy has been used to produce submucosal thermal lesions at the gastroesophageal junction. (This technique has also been referred to as the Stretta procedure.) Specifically, radiofrequency energy is applied through 4 electrodes inserted into the esophageal wall at multiple sites both above and below the squamocolumnar junction. The mechanism of action of the thermal lesions is not precisely known but may be related to ablation of the nerve pathways responsible for sphincter relaxation or may induce a tissue-tightening effect related to heat-induced collagen contraction and fibrosis.
3. Submucosal injection or implantation of a prosthetic or bulking agent to enhance the volume of the lower esophageal sphincter has also been investigated.

One bulking agent, pyrolytic carbon-coated zirconium oxide spheres (Durasphere), is being evaluated.
The Gatekeeper™ Reflux Repair System (Medtronic, Shoreview, MN) uses a soft, pliable, expandable prosthesis made of a polyacrylonitrile-based hydrogel. The prosthesis is implanted into the esophageal submucosa, and with time, the prosthesis absorbs water and expands, creating bulk in the region of implantation. U.S. Food and Drug Administration (FDA) product code: DQX.

Endoscopic submucosal implantation of polymethylmethacrylate beads into the lower esophageal folds has also been investigated.

**Summary**

Transesophageal endoscopic therapies are being developed for the treatment of gastroesophageal reflux disease (GERD). A variety of procedures are being evaluated, including transesophageal (or transoral) incisionless fundoplication (TIF), application of radiofrequency energy, and injection/implantation of prosthetic devices or bulking agents.

For individuals who have GERD and hiatal hernia of 2 cm or less that is not controlled by proton pump inhibitors (PPIs) who receive TIF (eg, EsophyX), the evidence includes 2 randomized controlled trials (RCTs) comparing TIF with PPI therapy, nonrandomized studies comparing TIF with fundoplication, and case series with longer term follow-up. Relevant outcomes are symptoms, change in disease status, quality of life, medication use, and treatment-related morbidity. The highest quality RCT (RESPECT) was a sham-controlled together with PPI therapy while the other RCT (TEMPO) compared TIF with maximum PPI therapy. Both trials found a significant benefit of TIF on the primary outcome measure in about 65% of patients, but the sham-controlled trial found improvement in 45% of the sham-controlled group and no benefit on secondary subjective outcome measures. The nonblinded RCT found significant improvements in subjective measures but no difference in objective outcome measures when compared with PPI therapy. Together, these trials suggest a strong placebo effect of the surgery and a modest benefit of TIF in patients whose symptoms are not controlled by PPIs. For these patients, the most appropriate comparator is laparoscopic fundoplication. Studies comparing TIF with fundoplication have limitations that include earlier TIF procedures and unequal groups at baseline and are inadequate to determine relative efficacy. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have GERD and hiatal hernia of 2 cm or less that is controlled by PPIs who receive TIF (eg, EsophyX), the evidence includes 2 RCTs and observational studies with longer term follow-up. Relevant outcomes are symptoms, change in disease status, quality of life, medication use, and treatment-related morbidity. A sham-controlled trial found that the time to resume PPI therapy was longer following TIF and the remission rate was higher, indicating that TIF is more effective than no therapy. The nonblinded RCT found a benefit of TIF compared with continued PPI therapy for subjective measures, but not for the objective measures of pH normalization and esophagitis. These results raise questions about a possible placebo effect for the procedure. Also, observational studies have indicated a loss of treatment effectiveness over time. Adverse events associated with the procedure (eg, perforation) may be severe. At present, the available evidence does not support the use of this intervention in patients whose symptoms are adequately controlled by medical therapy. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have GERD who receive endoscopic radiofrequency energy (eg, Stretta), the evidence includes 4 small RCTs, a nonrandomized comparative study, and observational studies with longer term follow-up. Relevant outcomes are symptoms, change in disease status, quality of life, medication use, and treatment-related morbidity. The RCTs reported some improvements in symptoms and quality of life following treatment with radiofrequency energy compared with sham controls. However, objective measures of GERD and a meta-analysis of these studies found no significant improvements in outcomes, raising questions about the mechanism of the symptom relief. Symptom relief is reported to be lower than after fundoplication, and reoperations greater. Larger RCTs with longer follow-up, preferably compared with fundoplication, are needed to define the risks and benefits of this procedure better. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have GERD who receive esophageal or bulking agents, the evidence includes an RCT and case series. Relevant outcomes are symptoms, change in disease status, quality of life,
medication use, and treatment-related morbidity. The RCT for a single product was terminated early due to lack of efficacy, while other products have only case series to support use. High-quality data from large RCTs are needed to compare bulking procedures with both sham controls and with the currently accepted treatments for GERD (ie, drug therapy, laparoscopic fundoplication). Well-designed trials should use standardized outcome measures to examine whether subjective improvement (eg, discontinuation of medication therapy, GERD–Health-Related Quality of Life scores) is supported by objective improvement (eg, esophageal acid exposure). The evidence is insufficient to determine the effects of the technology on health outcomes.

Policy History

<table>
<thead>
<tr>
<th>Date</th>
<th>Action</th>
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<tbody>
<tr>
<td>3/2018</td>
<td>New references added from BCBSA National medical policy.</td>
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<tr>
<td>11/2016</td>
<td>New references added from BCBSA National medical policy.</td>
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<tr>
<td>1/2016</td>
<td>Clarified coding information. BCBSA National medical policy references added.</td>
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<tr>
<td>9/2015</td>
<td>Local Coverage Determination (LCD): Endoscopic Treatment of GERD (L33371) added. 9/2015.</td>
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<tr>
<td>9/2014</td>
<td>LCD Endoscopic Treatment of GERD (L33371) added. NCD Implantation of Anti-Gastroesophageal Reflux Device (100.9) updated.</td>
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<tr>
<td>7/2014</td>
<td>Updated Coding section with ICD10 procedure and diagnosis codes, effective 10/2015.</td>
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<tr>
<td>1/2014</td>
<td>Added new CPT codes 43211 and 43212. Removed deleted code 43219.</td>
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<tr>
<td>10/2013</td>
<td>Removed CPT code 43280 and diagnosis codes 530.10, 530.12, 530.13, 530.19 as these codes do not apply to the policy. Added diagnosis code 530.18</td>
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<td>9/2009</td>
<td>BCBSA National medical policy review. No changes to policy statements.</td>
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<td>9/2008</td>
<td>BCBSA National medical policy review. No changes to policy statements.</td>
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<tr>
<td>8/2007</td>
<td>BCBSA National medical policy review. No changes to policy statements.</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


