Medical Policy
Transesophageal Endoscopic Therapies for Gastroesophageal Reflux Disease

Table of Contents
- Policy: Commercial
- Policy: Medicare
- Authorization Information
- Coding Information
- Description
- Policy History
- Information Pertaining to All Policies
- References

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): Endoscopic Treatment of GERD (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 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 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 link below.

National Coverage Determination (NCD) for Implantation of Anti-Gastroesophageal Reflux Device (100.9)

Endoscopic Treatment of GERD is not a covered service.
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>This is not a covered service.</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Commercial PPO and Indemnity</td>
<td>This is not a covered service.</td>
</tr>
<tr>
<td><strong>Medicare HMO Blue™</strong></td>
<td>Implantation of Anti-Gastroesophageal Reflux Device: No</td>
<td></td>
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<tr>
<td></td>
<td>Endoscopic Treatment of GERD: This is not a covered service.</td>
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<tr>
<td><strong>Medicare PPO Blue™</strong></td>
<td>Implantation of Anti-Gastroesophageal Reflux Device: No</td>
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<tr>
<td></td>
<td>Endoscopic Treatment of GERD: This is not a covered service.</td>
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</tbody>
</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:**

<table>
<thead>
<tr>
<th>CPT Codes</th>
<th>Code Description</th>
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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>Esophagogastroduodenoscopy, flexible, transoral; with esophagogastric fundopasty, 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>Esophagogastroduodenoscopy, 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>
</tr>
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</table>

**Description**
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, TIF) is an outpatient procedure. During this procedure, suture(s), staples, or fasteners are placed in the lower esophageal sphincter. The sutures/staples/fasteners are designed to strengthen and lengthen the sphincter to decrease reflux.

2. RF 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, RF 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 polycrylonitrile-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. 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 (RF) energy, and injection/implantation of prosthetic devices or bulking agents.

The evidence on TIF in patients who have GERD includes 4 small randomized controlled trials (RCTs), registry data, and numerous case series. Relevant outcomes are symptoms, change in disease status, quality of life, medication use, and treatment-related morbidity. The results from these trials are not conclusive. For example, in the largest trial, 22% more patients who underwent TIF with the EsophyX® device achieved short-term symptom relief, and there was a greater decrease in esophageal pH for TIF than for continued proton pump inhibitor (PPI) therapy. However, the mean improvement in symptoms scores did not differ between groups. The benefit appears to decrease over time, and long-term follow-up is not available for most outcomes. In the other trials, there was improvement on some outcomes but little benefit on objective outcomes such as pH measurements. The improvement in subjective symptoms in the absence of an objective benefit suggests a strong placebo effect of surgery compared with continued PPI therapy. One small RCT compared TIF with laparoscopic Nissen fundoplication, and reported no difference in short-term outcomes. Small sample size, substantial loss to follow-up, and short follow-up make conclusions uncertain. In addition, some outcomes (eg, medication use) favored the Nissen group though differences were not statistically significant. The evidence is insufficient to determine the effects of the technology on health outcomes.

The evidence on endoscopic RF energy in patients who have GERD 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 report improvements in symptoms and quality of life following treatment with RF energy, however, a meta-analysis of these same studies found no significant improvement in outcomes. Nonrandomized studies show maintenance of efficacy at 3 to 10 years, although symptom relief may be lower than after fundoplication, and reoperations greater. Larger RCTs with longer follow-up are needed to better define the risks and benefits of this procedure. The evidence is insufficient to determine the effects of the technology on health outcomes.
The evidence on esophageal bulking agents in patients who have GERD is limited. Relevant outcomes are symptoms, change in disease status, quality of life, medication use, and treatment-related morbidity. High-quality data from large RCTs are needed to compare bulking procedures with both sham controls and with the currently accepted treatments for GERD (i.e., drug therapy, laparoscopic fundoplication). Well-designed trials should use standardized outcome measures to examine whether subjective improvement (e.g., discontinuation of medication therapy, GERD–Health-Related Quality of Life scores) is supported by objective improvement (e.g., 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>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>
</tr>
<tr>
<td>9/2015</td>
<td>Local Coverage Determination (LCD): Endoscopic Treatment of GERD (L33371) added. 9/2015.</td>
</tr>
<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>
</tr>
<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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<tr>
<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


34. ASGE Standards of Practice Committee, Muthusamy VR, Lightdale JR, et al. The role of endoscopy in the management of GERD. Gastrointest Endosc. 2015;81(6):1305-1310. PMID 25863867


