Medical Policy

Surgical and Transesophageal Endoscopic Procedures to Treat Gastroesophageal Reflux Disease

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Policy Number: 920
BCBSA Reference Number: 7.01.137
NCD/LCD: N/A

Related Policies
Endoscopic Radiofrequency Ablation or Cryoablation for Barrett's Esophagus, #218

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

Prior Authorization Request Form: Surgical and Transesophageal Endoscopic Procedures to Treat Gastroesophageal Reflux Disease
This form must be completed and faxed to: Medical and Surgical: 1-888-282-0780; Medicare Advantage: 1-800-447-2994
Click here for Surgical and Transesophageal Endoscopic Procedures to Treat Gastroesophageal Reflux Disease Form, #956

Magnetic esophageal sphincter augmentation to treat gastroesophageal reflux disease is considered MEDICALLY NECESSARY when the following criteria are met:¹

- Patient has a history of severe GERD for ≥1 year with daily symptoms, AND
- Patient has tried and failed optimal non-surgical management of symptoms, including lifestyle modification, weight loss (if indicated), and daily proton pump inhibitor use for ≥ 6 months, AND
- Patient has proven gastroesophageal reflux by either endoscopy or ambulatory pH monitoring, AND
- Patient has evidence of adequate peristalsis by manometry or barium esophagram, AND
- None of the following contraindications are present:
  o Morbid obesity (BMI >35)
  o Suspected or known allergies to metals such as iron, nickel, titanium, or stainless steel
  o Grade C or D (LA classification) esophagitis
  o Scleroderma
  o Esophageal stricture or gross esophageal anatomic abnormalities
  o Suspected or confirmed esophageal or gastric cancer
Prior esophageal or gastric surgery or endoscopic intervention.

Transoral incisionless fundoplication (TIF) (ie, EsophyX®) is considered **MEDICALLY NECESSARY** as a treatment of gastroesophageal reflux disease when the following criteria are met:

1. Patient has a history of severe GERD for ≥1 year with daily symptoms, **AND**
2. Patient has tried and failed optimal non-surgical management of symptoms, including lifestyle modification, weight loss (if indicated), and daily proton pump inhibitor use for ≥ 6 months, **AND**
3. Patient has proven gastroesophageal reflux by either endoscopy, ambulatory pH monitoring, or barium esophagram, **AND**
4. None of the following contraindications are present:
   - Hiatal hernia >2cm in axial height and >2cm in greatest transverse dimension
   - Morbid obesity (BMI >35)
   - Esophagitis grade C or D
   - Barrett's esophagus > 2 cm
   - Non-healing esophageal ulcer
   - Fixed esophageal stricture or narrowing
   - Portal hypertension and/or varices
   - Active gastro-duodenal ulcer disease
   - Gastric outlet obstruction or stenosis
   - Gastroparesis
   - Prior esophageal surgery
   - Scleroderma
   - Suspected or confirmed esophageal or gastric cancer.

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 **INVESTIGATIONAL** as a treatment of gastroesophageal reflux disease.

**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.

<table>
<thead>
<tr>
<th>Commercial Managed Care (HMO and POS)</th>
<th>Prior authorization is required.*</th>
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</thead>
<tbody>
<tr>
<td>Commercial PPO and Indemnity</td>
<td>Prior authorization is not required.</td>
</tr>
<tr>
<td>Medicare HMO Blue℠</td>
<td>Prior authorization is required.*</td>
</tr>
<tr>
<td>Medicare PPO Blue℠</td>
<td>Prior authorization is not required.</td>
</tr>
</tbody>
</table>

*Prior Authorization Request Form: Surgical and Transesophageal Endoscopic Procedures to Treat Gastroesophageal Reflux Disease
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Click here for Surgical and Transesophageal Endoscopic Procedures to Treat Gastroesophageal Reflux Disease Form, #956
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>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>43210</td>
<td>Esophagastroduodenoscopy, flexible, transoral; with esophagogastric fundoplasty, partial or complete, includes duodenoscopy when performed</td>
</tr>
<tr>
<td>43284</td>
<td>Laparoscopy, surgical, esophageal sphincter augmentation procedure, placement of sphincter augmentation device (ie, magnetic band), including cruroplasty when performed</td>
</tr>
</tbody>
</table>

### ICD-10 Procedure Codes

<table>
<thead>
<tr>
<th>ICD-10-PCS procedure codes:</th>
<th>Code Description</th>
</tr>
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<tbody>
<tr>
<td>0DV48ZZ</td>
<td>Restriction of Esophagogastric Junction, Via Natural or Artificial Opening Endoscopic</td>
</tr>
<tr>
<td>0DV44CZ</td>
<td>Restriction of Esophagogastric Junction with Extraluminal Device, Percutaneous Endoscopic Approach</td>
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</table>

The following CPT codes are considered investigational for Commercial Members: Managed Care (HMO and POS), PPO, and 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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<tbody>
<tr>
<td>43201</td>
<td>Esophagoscopy, flexible, transoral; with directed submucosal injection(s), any substance</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. 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.

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. The LINX Reflux Management System is composed of a small flexible band of 10 to 18 interlinked titanium beads with magnetic cores. Using standard laparoscopic techniques, the band is placed around the esophagus at the level of the gastroesophageal junction. The magnetic attraction between the beads is intended to augment the lower esophageal sphincter to prevent gastric reflux into the esophagus, without compressing the esophageal wall. It is proposed that swallowing food or liquids creates sufficient pressure to overcome the magnetic bond between the beads, allowing the beads to separate and temporarily increase the size of the ring.

3. 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.
4. 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
LINX Reflux Management System
For individuals who have GERD who receive magnetic sphincter augmentation (MSA), the evidence includes prospective and retrospective observational comparative studies, 2 single-arm interventional trials, and a number of single-arm observational studies. Relevant outcomes are symptoms, change in disease status, medication use, and treatment-related morbidity. Based on the available literature, LINX is at least as effective as long term proton pump inhibitor therapy, has fewer long term side effects than proton pump inhibitor use, and is a less invasive approach than the other currently available surgical technique, nissen fundoplication (NF). Although there are no head to head comparisons between LINX and NF, LINX appears to have similar symptom reduction and a lower revision rate. Therefore it is considered to be medically necessary.

Transoral incisionless fundoplication (TIF)
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. 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. Based on the available literature, TIF is at least as effective as long term proton pump inhibitor therapy, has fewer long term side effects than proton pump inhibitor use, and is a less invasive approach than the other currently available surgical technique, nissen fundoplication (NF). Although there are no head to head comparisons between TIF and NF, TIF appears to have similar symptom reduction and a lower revision rate. Therefore it is considered to be medically necessary.

Other transesophageal endoscopic therapies
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**

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| 10/2018| New medically necessary indications described. Title changed. Clarified coding information. Effective 10/1/2018. The following ongoing investigational statements were transferred from policy 635:  
  - Transesophageal radiofrequency to create submucosal thermal lesions  
  - Endoscopic submucosal implantation of a prosthesis or injection of a bulking agent. |
| 1/2017 | BCBSA National medical policy review. Title changed. New references added. 1/1/2017 |
| 1/2016 | Clarified coding information.                                           |
| 11/2015| New references added from BCBSA National medical policy.                |
| 7/2015 | Clarified coding information.                                           |
| 10/2014| New references added from BCBSA National medical policy.                |
| 1/2014 | Updated to add new HCPCS code C9737.                                   |
| 12/2013| New references from BCBSA National medical policy.                      |

**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**


Endnotes

1 Based on expert opinion