MEDICAL POLICY – 7.01.137
Magnetic Esophageal Sphincter Augmentation to Treat Gastroesophageal Reflux Disease

BCBSA Ref. Policy: 7.01.137

Effective Date: Feb. 1, 2022
Last Revised: Jan. 10, 2022
Replaces: N/A

RELATED MEDICAL POLICIES:
2.01.38 Transesophageal Endoscopic Therapies for Gastroesophageal Reflux Disease
2.01.91 Peroral Endoscopic Myotomy for Treatment of Esophageal Achalasia

Introduction

GERD — gastroesophageal reflux disease — is a long-term medical condition. It’s a digestive problem that affects the ring of muscles between the esophagus (the tube that carries swallowed food to the stomach) and the stomach. When food is swallowed, the muscles at the end of the esophagus open so food can pass into the stomach. The muscles then close to prevent acid from backing up into the esophagus. In GERD, however, the ring of muscles is too weak. GERD is usually treated with changes to lifestyle and diet. A number of other treatments have been studied. One technique calls for placing a ring of magnetic beads around the base of the esophagus, just above the stomach. The ring opens to allow swallowed food into the stomach and then immediately tightens. This technique is investigational (unproven). More and longer studies are needed to find out how well such devices work.

Note: The Introduction section is for your general knowledge and is not to be taken as policy coverage criteria. The rest of the policy uses specific words and concepts familiar to medical professionals. It is intended for providers. A provider can be a person, such as a doctor, nurse, psychologist, or dentist. A provider also can be a place where medical care is given, like a hospital, clinic, or lab. This policy informs them about when a service may be covered.
Policy Coverage Criteria

<table>
<thead>
<tr>
<th>Service</th>
<th>Investigational</th>
</tr>
</thead>
<tbody>
<tr>
<td>Magnetic esophageal sphincter augmentation</td>
<td>Magnetic esophageal sphincter augmentation to treat gastroesophageal reflux disease is considered investigational.</td>
</tr>
<tr>
<td></td>
<td>Note: Commerciy available esophageal sphincter augmentation device: The LINX™ Reflux Management System (Torax Medical)</td>
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Coding

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
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<tr>
<td>CPT</td>
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<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>
<tr>
<td>43285</td>
<td>Removal of esophageal sphincter augmentation device</td>
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Related Information

N/A

Evidence Review
Description

A laparoscopically implanted ring composed of interlinked titanium beads with magnetic cores has been developed for the treatment of gastroesophageal reflux disease (GERD). The device is placed around the esophagus at the level of the gastroesophageal junction and is being evaluated in patients who have GERD symptoms, despite maximal medical therapy.

Background

Gastroesophageal Reflux Disease

GERD is defined as reflux of stomach acid into the esophagus that causes symptoms and/or mucosal injury. GERD is a common medical disorder, with estimates of 10% to 20% prevalence in developed countries.

Treatment

For patients with severe disease, chronic treatment with acid blockers is an option. For some patients, medications are inadequate to control symptoms; other patients prefer to avoid the use of indefinite, possibly lifelong medications. Surgical treatments are available for these patients, primarily a Nissen fundoplication performed either laparoscopically or by open surgery. A number of less invasive procedures are also being evaluated as an intermediate option between medical therapy and surgery (see Related Policies).

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. Magnetic sphincter augmentation is a 30-minute surgical procedure performed under general anesthesia that includes testing of the esophageal sphincter. This is a minimally invasive procedure conducted in an inpatient surgical center and requires an overnight stay. The device manufacturer claims patients resume a normal diet within 24 hours post-surgery. resonance imaging is needed for another condition. The device can be removed by a laparoscopic
procedure if severe adverse events occur or if magnetic resonance imaging is needed for another condition.

**Summary of Evidence**

For individuals who have GERD who receive magnetic sphincter augmentation (MSA), the evidence includes one randomized controlled trial comparing MSA to proton pump inhibitor therapy, a single nonrandomized registry study comparing MSA to laparoscopic fundoplication, single-arm cohort studies, and systematic reviews of observational studies comparing MSA to laparoscopic Nissen fundoplication (LNF). The relevant outcomes are symptoms, change in disease status, medication use, and treatment-related morbidity. A randomized controlled trial comparing MSA to omeprazole 20 mg twice daily found significantly more patients who received MSA reported improvements in symptoms and quality of life (QOL) at six months. A major limitation of the trial was that the patients had not received optimal medical treatment prior to enrollment. A prospective, observational registry study comparing MSA to laparoscopic fundoplication found similar improvements in QOL, satisfaction, and medication use. Limitations of the study included lack of randomization and blinding, heterogeneity in fundoplication techniques, use of an outdated MSA protocol, and selection bias as patients with less severe symptoms received MSA. In the two single-arm, uncontrolled pivotal trials submitted to the U.S. Food and Drug Administration (FDA) with materials for device approval, subjects showed improvements in GERD-health-related quality of life (HRQL) scores and reduced proton pump inhibitor use. Similarly, observational comparative studies included in systematic reviews, most often comparing MSA with LNF, generally have shown that GERD-HRQL scores do not differ significantly between fundoplication and MSA, and patients can reduce proton pump inhibitor use after MSA. However, the comparative studies are retrospective and nonrandomized, may be affected by selection bias. Randomized comparisons of MSA with LNF are needed to evaluate the relative risk-benefit of these two procedures. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

**Ongoing and Unpublished Clinical Trials**

Some ongoing and unpublished trials that might influence this policy are listed in Table 1.
### Table 1. Summary of Key Trials

<table>
<thead>
<tr>
<th>NCT No.</th>
<th>Trial Name</th>
<th>Planned Enrollment</th>
<th>Completion Date</th>
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<tbody>
<tr>
<td><strong>Ongoing</strong></td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>NCT02923362</td>
<td>Registry of Outcomes From AntiReflux Surgery (ROARS)</td>
<td>2500</td>
<td>May 2025 (recruiting)</td>
</tr>
<tr>
<td>NCT01940185</td>
<td>A Post-Approval Study of the Lynx® Reflux Management System</td>
<td>200</td>
<td>Oct 2025 (ongoing)</td>
</tr>
<tr>
<td>NCT04695171</td>
<td>Cohort Registry on LINX Reflux Management System or Fundoplication Clinical Study in Patients With Hiatal Hernia &gt;3 cm</td>
<td>450</td>
<td>Jan 2028 (recruiting)</td>
</tr>
<tr>
<td>NCT04253392</td>
<td>RETHINK REFLUX Registry (RETHINK REFLUX)</td>
<td>500</td>
<td>July 2032 (recruiting)</td>
</tr>
<tr>
<td><strong>Unpublished</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>NCT02429830</td>
<td>RELIEF Study: A Prospective, Multicenter Study of REflux Management With the LINX® System for Gastroesophageal REFlux Disease After Laparoscopic Sleeve Gastrectomy</td>
<td>30</td>
<td>Jun 2021 (completed)</td>
</tr>
</tbody>
</table>

NCT: national clinical trial
a Denotes industry-sponsored or cosponsored trial

### Practice Guidelines and Position Statements

The purpose of the following information is to provide reference material. Inclusion does not imply endorsement or alignment with the evidence review conclusions.

Guidelines or position statements will be considered for inclusion if they were issued by, or jointly by, a U.S. professional society, an international society with U.S. representation, or National Institute for Health and Care Excellence (NICE). Priority will be given to guidelines that are informed by a systematic review, include strength of evidence ratings, and include a description of management of conflict of interest.
Society of American Gastrointestinal and Endoscopic Surgeons

The Society of American Gastrointestinal and Endoscopic Surgeons (SAGES, 2013; updated in 2017) published a Technology and Value Assessment Committee (TAVAC) analysis on the safety and effectiveness of the LINX Reflux Management System.\(^{23}\) The SAGES indicated that safety analyses of the LINX system suggested the procedure is associated with few serious adverse events and no reported mortality, and that currently available data demonstrated a reasonable assurance as to the efficacy of the system. The report concluded that direct comparative studies between the LINX procedure and Nissen fundoplication would be needed, although based on the available evidence, the LINX device should be an option available to patients and providers for the management of medically refractory GERD.

In April 2021, guidelines for the surgical treatment of GERD were reviewed and approved by the Board of Governors of the SAGES based on a systematic review of the evidence.\(^{24}\) Key questions presented in these guidelines do not address the use of MSA.

National Institute for Health and Care Excellence

In July 2017, the National Institute for Health and Care Excellence (NICE) issued an interventional procedures guidance on laparoscopic insertion of a magnetic titanium ring for GERD.\(^{25}\) While the recommendations conclude that there are no major safety concerns with the device, they note limited evidence of short-term efficacy with inadequate quality and quantity of evidence for long-term efficacy. Accordingly, "this procedure should only be used with special arrangements for clinical governance, consent, and audit or research," and note that "long-term outcome data and comparative trials with other anti-reflux surgery would be helpful."

American Foregut Society

The American Foregut Society (AFS) issued a statement on appropriate patient selection and use of MSA, and noted that "patient selection criteria for MSA do not differ in principle from those of any other surgical procedure for reflux disease." Indications for MSA include:\(^{26}\)

- "Typical GERD symptoms (ie, heartburn, regurgitation) with break-through symptoms, intolerance to medical therapy, and/or unwillingness to take anti-reflux medications long term.
- Regurgitation despite optimized medical therapy and lifestyle modification."
• Extraesophageal symptoms with objective evidence of significant reflux disease (ie, endoscopic evidence of [Los Angeles] Class C or D esophagitis, Barrett's esophagus or positive pH study."

The statement additionally notes that "MSA candidacy largely mirrors that for laparoscopic fundoplication. Low dysphagia rates for MSA have been found when performed in patients with normal esophageal motility." The AFS also recommends that a full hiatal dissection and cruroplasty be performed prior to implantation of an MSA device.

The AFS Bariatric Committee also issued a statement regarding the concurrent use of MSA at the time of primary bariatric surgery, noting that this practice "violates many basic surgical principles and is not considered judicious use by the American Foregut Society." The statement also notes that prospective trials demonstrating the safety and efficacy of concurrent MSA are needed.

American Society for Gastrointestinal Endoscopy

In 2013, a report from the American Society for Gastrointestinal Endoscopy concluded that long-term data on the safety and efficacy of the LINX device were needed. The document indicated that the LINX band is currently being deployed laparoscopically; however, a natural orifice transluminal endoscopic surgery approach could be explored.

Medicare National Coverage

There is no national coverage determination.

Regulatory Status

In 2012, the LINX™ Reflux Management System (Torax Medical) was approved by the FDA through the premarket approval process (P100049) for patients diagnosed with GERD, as defined by abnormal pH testing, and who continue to have chronic GERD symptoms despite maximal therapy for the treatment of reflux. The FDA initially required a 5-year follow-up of 100 patients from the investigational device exemption pivotal study to evaluate the safety and efficacy of the device, which was completed in March 2016. In 2018, the manufacturer initiated a device recall due to a possible separation of the bead component with the adjacent wire link
causing a potential discontinuous or open LINX device. This recall was terminated on November 4, 2020. FDA product code: LE1.

In March 2018, the FDA approved an update of the LINX® Reflux Management System precautions statement, stating that the use of the system “in patients with a hiatal hernia larger than 3 cm should include hiatal hernia repair to reduce the hernia to less than 3 cm and that the LINX Reflux Management System has not been evaluated in patients with an unrepaired hiatal hernia greater than 3 cm, add a hiatal hernia clinical data summary in the instructions for use, update the instructions for use section to highlight the recommendation to repair a hiatal hernia, if present, at the time of the LINX Reflux Management System implantation, and update the patient information booklet to align with the instructions for use and include 5 year clinical study results.”

References


Date | Comments
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10/15/12 | New Policy. Policy created with literature review through June 2012; considered investigational.
10/14/13 | Replace policy. Policy updated with literature review through July 1, 2013; reference 4 added; policy statement unchanged.
11/20/13 | Update Related Policies. Add 2.01.91.
01/30/14 | Update Related Policies. Change title to 2.01.38.
01/28/16 | Minor update. Added CPT codes 0392T and 0393T, effective 7/1/15, to the coding table.
11/08/16 | Annual review. Policy title changed to "Magnetic Esophageal Sphincter Augmentation to Treat Gastroesophageal Reflux Disease", and throughout the policy for the procedure, to match the CPT code descriptions. Policy updated with literature review through September, 2016; references added. Coding update; added CPT 43284 and 43285. Policy statement unchanged.
01/01/17 | Minor Coding update; added note that CPT codes 43284 and 43285 are new codes effective 1/1/17.
06/09/17 | Coding update; removed CPT codes 0392T and 0393T as they were terminated as of 1/1/17.
01/01/18 | Annual Review, approved December 6, 2017. Policy updated with literature review through September 2017; no references added; references 7 and 19 updated. Policy statement unchanged. Removed CPT code 43289.
02/01/19 | Annual Review, approved January 4, 2019. Policy updated with literature review through September 2018; no references added. Policy statement unchanged.
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Email AppealsDepartmentInquiries@Premera.com

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U.S. Department of Health and Human Services
200 Independence Avenue SW, Room 509F, HHH Building
Washington, D.C. 20201, 1-800-368-1019, 800-537-7697 (TDD)

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