Policy Statement

Magnetic esophageal sphincter augmentation to treat gastroesophageal reflux disease (GERD) is considered investigational.

Policy Guidelines

There are specific CPT category I codes for this procedure:

- **43284**: Laparoscopy, surgical, esophageal sphincter augmentation procedure, placement of sphincter augmentation device (i.e., magnetic band), including cruroplasty when performed
- **43285**: Removal of esophageal sphincter augmentation device

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.

Related Policies

- Transesophageal Endoscopic Therapies for Gastroesophageal Reflux Disease

Benefit Application

Benefit determinations should be based in all cases on the applicable contract language. To the extent there are any conflicts between these guidelines and the contract language, the contract language will control. 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.

Some state or federal mandates (e.g., Federal Employee Program [FEP]) prohibits plans from denying Food and Drug Administration (FDA)-approved technologies as investigational. In these instances, plans may have to consider the coverage eligibility of FDA-approved technologies on the basis of medical necessity alone.

Regulatory Status

In 2012, the LINX™ Reflux Management System (Torax Medical) was approved by the U.S. Food and Drug Administration through the premarket approval process 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 Food and Drug Administration 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. Food and Drug Administration product code: LEI.
Rationale

Background
Gastroesophageal Reflux Disease
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. The severity of GERD varies widely. Many patients have mild, intermittent symptoms that do not require treatment or only require episodic use of medications. Other patients have chronic, severe GERD that can lead to complications such as Barrett esophagus and esophageal cancer.

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 Blue Shield of California Medical Policy: Transesophageal Endoscopic Therapies for Gastroesophageal Reflux Disease on endoscopic procedures).

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. The target population is patients who have GERD symptoms despite maximum medical therapy (e.g., proton pump inhibitors) but who do not want to risk the adverse effects of a surgical procedure like Nissen fundoplication. Adverse events of the LINX Reflux Management System may include dysphagia or odynophagia. The device can be removed by a laparoscopic procedure if severe adverse events occur or if magnetic resonance imaging is needed for another condition.

Literature Review
Evidence reviews assess the clinical evidence to determine whether the use of technology improves the net health outcome. Broadly defined, health outcomes are the length of life, quality of life (QOL), and ability to function—including benefits and harms. Every clinical condition has specific outcomes that are important to patients and managing the course of that condition. Validated outcome measures are necessary to ascertain whether a condition improves or worsens; and whether the magnitude of that change is clinically significant. The net health outcome is a balance of benefits and harms.

To assess whether the evidence is sufficient to draw conclusions about the net health outcome of technology, two domains are examined: the relevance, and quality and credibility. To be relevant, studies must represent one or more intended clinical use of the technology in the intended population and compare an effective and appropriate alternative at a comparable intensity. For some conditions, the alternative will be supportive care or surveillance. The quality and credibility of the evidence depend on study design and conduct, minimizing bias and confounding that can generate incorrect findings. The randomized controlled trial (RCT) is preferred to assess efficacy; however, in some circumstances, nonrandomized studies may be adequate. RCTs are rarely large enough or long enough to capture less common adverse events and long-term effects. Other types of studies can be used for these purposes and to assess generalizability to broader clinical populations and settings of clinical practice.
Clinical Context and Therapy Purpose
The purpose of magnetic sphincter augmentation (MSA) in patients who have GERD is to provide a treatment option that is an alternative to or an improvement on existing therapies.

The question addressed in this evidence review is: Does the use of MSA improve the net health outcome in individuals with GERD who have not responded to optimal medical management? The following PICOs were used to select literature to inform this review.

Patients
The relevant population of interest are individuals with GERD who have not responded to optimal medical management.

The severity of GERD varies widely. Many patients have mild, intermittent symptoms that do not require treatment or only require episodic use of medications. Other patients have chronic, severe GERD that can lead to complications such as Barrett esophagus and esophageal cancer.

The Los Angeles (LA) classification system is used to describe the endoscopic appearance of reflux esophagitis and grade its severity. Esophagitis is confirmed by endoscopy according to a 5 grading severity scale.

Not present: No breaks (erosions) in the esophageal mucosa (edema, erythema, or friability may be present).

Grade A: One or more mucosal breaks confined to the mucosal folds, each not more than 5 mm in maximum length.
Grade B: One or more mucosal breaks more than 5 mm in maximum length, but not continuous between the tops of two mucosal folds.
Grade C: Mucosal breaks that are continuous between the tops of two or more mucosal folds, but which involve less that 75% of the esophageal circumference.
Grade D: Mucosal breaks which involve at least 75% of the esophageal circumference.

Interventions
The therapy being considered is MSA. 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. MSA is a 30-minute surgical procedure performed under general anesthesia that includes testing of the esophageal sphincter. MSA 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. The device can be removed by a laparoscopic procedure if severe adverse events occur or if magnetic resonance imaging is needed for another condition.

Comparators
The following therapies and practices are currently being used to treat GERD that has not responded to optimal medical therapy: lifestyle modifications, continued medical therapy and interventions to strengthen the lower esophageal sphincter.

Lifestyle modifications may include weight loss, elevation of the head of the bed, avoidance of meals close to bedtime, and elimination of dietary triggers. For patients with severe disease, chronic treatment with acid suppressive therapies 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 review 2.01.38 on endoscopic procedures).

In patients who continue to have symptoms despite once daily PPIs (e.g., omeprazole 20 mg),
guideline based recommendations include increasing and/or splitting the PPI dose), and
switching to a different PPI to optimize pharmacologic treatment.

Outcomes
The general outcomes of interest are a reduction in symptoms such as heartburn and
regurgitation, reduction in acid suppression medication use, QOL, treatment-related adverse
events, device failure, and progression to Barrett esophagus and esophageal cancer.

A variety of scales have been developed to measure patient and investigator-reported GERD
symptoms. Frequently used measures of QOL include the GERD-HRQ, a scale with 11 items
focusing on heartburn symptoms, dysphagia, medication effects, and the patient’s present
health condition. Each item is scored from 0 to 5, with a higher score indicating a better QOL,
and GERD-QO, a scale with 16 items clustered into the following four subscales: daily activity,
treatment effect, diet, and psychological well-being. The total score of this questionnaire is the
average of the four subscale scores. The final score can range from 0 to 100, with a higher score
indicating a better QOL.

Study Selection Criteria
To assess efficacy outcomes, we sought comparative controlled prospective trials, with a
preference for RCTs and systematic reviews of these studies.

A placebo control is optimal due to the subjective nature of the patient-reported outcome
measures, which are prone to bias if the patient is not blinded to treatment assignment. Random
assignment is important because of the multiple potential confounders of GERD outcomes, such
as diet, smoking, and obesity. GERD has a variable natural history, with exacerbations and
remissions, and, as a result, a control group is required to differentiate improvements in
symptoms from the natural history of the disorder. In the absence of such trials, we sought
comparative observational studies, with a preference for prospective studies. To assess long-
term outcomes and adverse effects, we also sought single-arm studies that captured longer
periods of follow-up and/or larger populations.

Systematic Reviews
Two recent systematic reviews compared MSA to laparoscopic Nissen fundoplication (LNF) in
patients with GERD (Table 1).1,2 Both conducted meta-analyses of comparative observational
studies and concluded that MSA and LNF had similar effects on symptoms and QOL (Table 2).
The body of evidence was limited, however, by the retrospective design of most studies, and the
reviewers concluded that RCT evidence was needed.

<table>
<thead>
<tr>
<th>Study</th>
<th>Dates</th>
<th>Trials</th>
<th>Participants</th>
<th>N (Range)</th>
<th>Design</th>
<th>Duration</th>
</tr>
</thead>
<tbody>
<tr>
<td>Aiolfi et al (2018)</td>
<td>2000-2015</td>
<td>6</td>
<td>Patients with GERD</td>
<td>2561 (23-335)</td>
<td>Comparative observational (1 prospective, 5 retrospective cohort)</td>
<td>Up to 1 year</td>
</tr>
</tbody>
</table>

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MSA: magnetic sphincter augmentation; LNF laparoscopic Nissen fundoplication; GERD: gastroesophageal reflux disease.

Table 2. Results of Systematic Reviews of MSA Compared to LNF

<table>
<thead>
<tr>
<th>Study</th>
<th>Need for PPI</th>
<th>GERD-HRQL</th>
<th>Dysphagia</th>
<th>Need for Reoperation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Guidozzi et al (2019)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total N</td>
<td>5 studies (861)</td>
<td>3 studies (760)</td>
<td>4 studies (795)</td>
<td>4 studies (754)</td>
</tr>
<tr>
<td>Pooled effect (95% CI)</td>
<td>OR 1.08 (0.40 to 2.95); P=0.877</td>
<td>WMD 0.34 (-0.70 to 1.37); P=0.525</td>
<td>OR 0.94 (0.57 to 1.55); P=0.822</td>
<td>OR 1.23 (0.26 to 5.8); P=0.797</td>
</tr>
<tr>
<td>I² (p)</td>
<td>72% (0.007)</td>
<td>70.6% (0.033)</td>
<td>20.4% (0.288)</td>
<td>48.5% (0.12)</td>
</tr>
<tr>
<td>Aiolfi et al (2018)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total N</td>
<td>6 studies (1098)</td>
<td>6 studies (1083)</td>
<td>5 studies (535)</td>
<td>3 studies (1187)</td>
</tr>
<tr>
<td>Pooled effect (95% CI)</td>
<td>OR 0.81 (0.42 to 1.58); P=0.548</td>
<td>MD -0.48 (-1.05 to 0.09); P=0.101</td>
<td>OR 1.56 (0.61 to 3.95); P=0.119</td>
<td>OR 0.54 (0.22 to 1.34); P=0.183</td>
</tr>
<tr>
<td>I² (p)</td>
<td>63.9% (0.016)</td>
<td>0% (0.82)</td>
<td>35% (0.19)</td>
<td>0% (0.814)</td>
</tr>
</tbody>
</table>

Randomized Controlled Trial

There are no RCTs of MSA compared to LNF. There is one open-label RCT comparing MSA to twice-daily omeprazole 20 mg in 152 patients with regurgitation symptoms despite once daily omeprazole 20 mg (Table 3). The primary endpoint was the percent of patients who achieved elimination of moderate-to-severe regurgitation at 6 months, as reported by patients on the Foregut Symptom Questionnaire (FSQ). The FSQ evaluates the severity of regurgitation symptoms: none, mild (after straining or large meals), moderate (predictable with position change, lying down, straining), and severe (constant). Esophageal reflux parameters (number of reflux episodes and percentage of time with pH <4 and PPI use) were secondary endpoints. At six months, significantly more patients who received MSA reported improvements in symptoms and QOL than those in the control group (Table 4). Ninety-one percent of those who received the surgery were able to maintain discontinuation of proton pump inhibitor (PPIs) at six months. Patients who received MSA testing had less reflux, as measured by impedance-pH testing. Follow-up in randomized arms continued for 6 months after which patients in the medical therapy arm could elect to receive MSA; results for patients who crossed over to MSA were similar to those who were randomized to MSA.3

Relevance and study design and conduct limitations of the RCT conducted by Bell et al (2019) are shown in Tables 5 and 6. A major limitation of the trial was that the patients had not received optimal medical treatment prior to enrollment. Additional limitations included the use of subjective outcome measures along with an open-label design, although this is less of a concern because results were supported by better results for MSA on some objective measures (see Table 4). For patients who have not responded to optimal medical treatment, an appropriate comparator would be Nissen fundoplication.

Table 3. Summary of Key RCT Characteristics

<table>
<thead>
<tr>
<th>Study; Trial</th>
<th>Countries</th>
<th>Sites</th>
<th>Dates</th>
<th>Participants</th>
<th>Interventions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bell et al (2019)4</td>
<td>U.S.</td>
<td>21</td>
<td>2015-2017</td>
<td>152 patients with moderate to severe regurgitation symptoms while on once-daily</td>
<td>Laparoscopic MSA (N=50)</td>
</tr>
</tbody>
</table>
Table 4. Summary of Key RCT Results

<table>
<thead>
<tr>
<th>Study</th>
<th>Symptoms</th>
<th>Quality of Life</th>
<th>PPI Discontinuation</th>
<th>Impedance-pH Testing</th>
<th>Withdrawals</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
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<td></td>
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<tr>
<td>Bell et al (2019)</td>
<td>Resolution of moderate-to-severe regurgitation (FSQ) at 6 months</td>
<td>Mean decrease in GERD-HRQL score at 6 months</td>
<td>&gt;50% decrease in GERD-HRQL score at 6 months</td>
<td>Number of Reflux Events per 24 hours</td>
<td>Percentage of time with pH&lt;4 per 24 hours</td>
</tr>
<tr>
<td></td>
<td>134</td>
<td>134</td>
<td>134</td>
<td>123</td>
<td>123</td>
</tr>
<tr>
<td>MSA</td>
<td>134</td>
<td>134</td>
<td>134</td>
<td>123</td>
<td>123</td>
</tr>
<tr>
<td></td>
<td>Resolution of moderate-to-severe regurgitation (FSQ) at 6 months</td>
<td>Mean decrease in GERD-HRQL score at 6 months</td>
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<td>Percentage of time with pH&lt;4 per 24 hours</td>
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<tr>
<td></td>
<td>134</td>
<td>134</td>
<td>134</td>
<td>123</td>
<td>123</td>
</tr>
<tr>
<td>Omeprazole</td>
<td>101/101 (10%)</td>
<td>18</td>
<td>38/47 (81%)</td>
<td>43/47 (91%)</td>
<td>22.5 (IQR,13.0-40.5)</td>
</tr>
<tr>
<td></td>
<td>101/101 (10%)</td>
<td>18</td>
<td>38/47 (81%)</td>
<td>43/47 (91%)</td>
<td>22.5 (IQR,13.0-40.5)</td>
</tr>
<tr>
<td></td>
<td>134</td>
<td>134</td>
<td>134</td>
<td>123</td>
<td>123</td>
</tr>
<tr>
<td></td>
<td>Resolution of moderate-to-severe regurgitation (FSQ) at 6 months</td>
<td>Mean decrease in GERD-HRQL score at 6 months</td>
<td>&gt;50% decrease in GERD-HRQL score at 6 months</td>
<td>Number of Reflux Events per 24 hours</td>
<td>Percentage of time with pH&lt;4 per 24 hours</td>
</tr>
<tr>
<td></td>
<td>134</td>
<td>134</td>
<td>134</td>
<td>123</td>
<td>123</td>
</tr>
<tr>
<td>P-value for difference</td>
<td>&lt;0.001</td>
<td>&lt;0.002</td>
<td>&lt;0.001</td>
<td>&lt;0.001</td>
<td>0.065</td>
</tr>
</tbody>
</table>

RCT: randomized controlled trial; MSA magnetic sphincter augmentation; PPI: proton pump inhibitor.

Table 5. Relevance Limitations

<table>
<thead>
<tr>
<th>Study</th>
<th>Population</th>
<th>Intervention</th>
<th>Comparator</th>
<th>Outcomes</th>
<th>Follow-Up</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bell et al (2019)</td>
<td>4. Patients did not receive optimal medical therapy prior to study enrollment</td>
<td>2. Did not compare the intervention to Nissen fundoplication</td>
<td></td>
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<tr>
<td>NCT02505945</td>
<td></td>
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</table>

BID: twice daily; GERD: gastroesophageal reflux disease.
The study limitations stated in this table are those notable in the current review; this is not a comprehensive limitations assessment.

a Population key: 1. Intended use population unclear; 2. Clinical context is unclear; 3. Study population is unclear; 4. Study population not representative of intended use.
b Intervention key: 1. Not clearly defined; 2. Version used unclear; 3. Delivery not similar intensity as comparator; 4. Not the intervention of interest.
c Comparator key: 1. Not clearly defined; 2. Not standard or optimal; 3. Delivery not similar intensity as intervention; 4. Not delivered effectively.
d Outcomes key: 1. Key health outcomes not addressed; 2. Physiologic measures, not validated surrogates; 3. No CONSORT reporting of harms; 4. Not establish and validated measurements; 5. Clinical significant difference not prespecified; 6. Clinical significant difference not supported.

### Table 6. Study Design and Conduct Limitations

<table>
<thead>
<tr>
<th>Study</th>
<th>Allocation</th>
<th>Blinding</th>
<th>Selective Reporting</th>
<th>Data Completeness</th>
<th>Power</th>
<th>Statistical</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bell et al (2019)</td>
<td>1. Differences between groups at baseline</td>
<td>1. Not blinded</td>
<td>1. Differential loss to follow-up (12.9% in PPI group vs 0 in MSA group)</td>
<td>4. CIs for treatment effects not calculated</td>
<td></td>
<td></td>
</tr>
<tr>
<td>NCT02505945</td>
<td></td>
<td></td>
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</tbody>
</table>

CI: confidence interval; MSA: magnetic sphincter augmentation; PPI: proton pump inhibitor.

The study limitations stated in this table are those notable in the current review; this is not a comprehensive limitations assessment.


**c** Selective Reporting key: 1. Not registered; 2. Evidence of selective reporting; 3. Evidence of selective publication.

**d** Data Completeness key: 1. High loss to follow-up or missing data; 2. Inadequate handling of missing data; 3. High number of crossovers; 4. Inadequate handling of crossovers; 5. Inappropriate exclusions; 6. Not intent to treat analysis (per protocol for noninferiority trials).

**e** Power key: 1. Power calculations not reported; 2. Power not calculated for primary outcome; 3. Power not based on clinically important difference.

**f** Statistical key: 1. Analysis is not appropriate for outcome type: (a) continuous; (b) binary; (c) time to event; 2. Analysis is not appropriate for multiple observations per patient; 3. Confidence intervals and/or p values not reported; 4. Comparative treatment effects not calculated.

### Single-Arm Studies

Data submitted to the FDA for the LINX Reflux Management System included 2 single-arm FDA-regulated investigational device exemption (IDE) trials (total n=144 subjects) and follow-up data between 2 and 4 years. The feasibility IDE trial enrolled 44 subjects at 4 clinical sites (2 U.S., 2 Europe) and had published data out to 4 years. The pivotal IDE trial included 100 subjects from 14 clinical sites (13 U.S., 1 Europe) who had documented symptoms of GERD for more than 6 months (regurgitation or heartburn that responds to acid neutralization or suppression), required daily PPI or other antireflux drug therapy, had symptomatic improvement on PPI therapy, and had a total distal ambulatory esophageal pH less than 4 for 4.5% or more of the time when off GERD medications. The primary safety endpoint measured the rate of related device and procedure serious adverse events. Efficacy endpoints were assessed off PPI therapy and measured esophageal acid exposure, total GERD-HRQL scores, and PPI usage. Subjects served as their own controls.

Five-year results for the 100 patients in the pivotal IDE trial were published by Ganz et al (2016). Eighty-five patients had a follow-up at five years. Of those 85, 83% achieved a 50% reduction in GERD-HRQL scores (95% CI, 73% to 91%), and 89.4% had a reduction of 50% or more in an average daily dose of PPI (95% CI, 81% to 95%). No new major safety concerns emerged. The device was removed in seven patients.

Additional single-arm observational studies have reported on outcomes after MSA in sample sizes ranging from 121 to 192 patients, some of which focused on specific subpopulations of individuals with GERD, such as those with large hiatal hernias (e.g., Rona et al [2017]).

### 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, comparative observational studies of MSA vs laparoscopic Nissen fundoplication, single-arm cohort studies, and systematic reviews of observational studies. 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 at six months. A major limitation of the trial was that the patients had not received optimal medical treatment prior to enrollment. In the two single-arm, uncontrolled manufacturer-sponsored studies submitted to the U.S. Food and Drug Administration with materials for device approval, subjects showed improvements in GERD-health-related quality of life scores and reduced proton pump inhibitor use. Similarly, observational comparative studies, most often comparing MSA with laparoscopic Nissen fundoplication, generally have shown that GERD-health-related quality of life 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, and the subjective outcome measures used in these studies (e.g., the GERD-health-related quality of life scores) may be biased. Randomized comparisons of MSA with laparoscopic Nissen fundoplication are needed to evaluate the relative risk-benefit of these two procedures. The evidence is insufficient to determine the effects of the technology on health outcomes.

Supplemental Information
Practice Guidelines and Position Statements

Society of American Gastrointestinal and Endoscopic Surgeons
The Society of American Gastrointestinal and Endoscopic Surgeons (2013) published guidelines on the safety and effectiveness of the LINX Reflux Management System. The Society 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 guidelines 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 gastroesophageal reflux disease.

American Society for Gastrointestinal Endoscopy
A report from the American Society for Gastrointestinal Endoscopy (2013) 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.

U.S. Preventive Services Task Force Recommendations
Not applicable.

Medicare National Coverage
There is no national coverage determination. In the absence of a national coverage determination, coverage decisions are left to the discretion of local Medicare carriers.

Ongoing and Unpublished Clinical Trials
Some currently ongoing and unpublished trials that might influence this review are listed in Table 7.

Table 7. Summary of Key Trials

<table>
<thead>
<tr>
<th>NCT No.</th>
<th>Trial Name</th>
<th>Planned Enrollment</th>
<th>Completion Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ongoing</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>Oct 2019</td>
</tr>
<tr>
<td>NCT02923362</td>
<td>Registry of Outcomes From AntiReflux Surgery (ROARS)</td>
<td>2500</td>
<td>May 2025</td>
</tr>
<tr>
<td>NCT01940185*</td>
<td>A Post-Approval Study of the Lynx Reflux Management System</td>
<td>200</td>
<td>Oct 2025</td>
</tr>
</tbody>
</table>

NCT: national clinical trial.
References


### Documentation for Clinical Review

- No records required

### Coding

This Policy relates only to the services or supplies described herein. Benefits may vary according to product design; therefore, contract language should be reviewed before applying the terms of the Policy. Inclusion or exclusion of codes does not constitute or imply member coverage or provider reimbursement.

**IE**

The following services may be considered investigational.

<table>
<thead>
<tr>
<th>Type</th>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>CPT®</strong></td>
<td>43284</td>
<td>Laparoscopy, surgical, esophageal sphincter augmentation procedure, placement of sphincter augmentation device (i.e., magnetic band), including cruroplasty when performed</td>
</tr>
<tr>
<td></td>
<td>43285</td>
<td>Removal of esophageal sphincter augmentation device</td>
</tr>
<tr>
<td><strong>HCPCS</strong></td>
<td>None</td>
<td>None</td>
</tr>
</tbody>
</table>

### Policy History

This section provides a chronological history of the activities, updates and changes that have occurred with this Medical Policy.

<table>
<thead>
<tr>
<th>Effective Date</th>
<th>Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>06/28/2013</td>
<td>BCBSA Medical Policy adoption</td>
</tr>
<tr>
<td>10/31/2014</td>
<td>Policy revision without position change</td>
</tr>
<tr>
<td>01/30/2015</td>
<td>Coding update</td>
</tr>
<tr>
<td>12/01/2016</td>
<td>Policy title change from Magnetic Esophageal Ring to Treat Gastroesophageal Reflux Disease (GERD)</td>
</tr>
<tr>
<td></td>
<td>Policy revision without position change</td>
</tr>
<tr>
<td>10/01/2017</td>
<td>Policy revision without position change</td>
</tr>
<tr>
<td>01/01/2018</td>
<td>Policy revision without position change</td>
</tr>
<tr>
<td>12/01/2018</td>
<td>Policy revision without position change</td>
</tr>
<tr>
<td>01/01/2019</td>
<td>Policy revision without position change</td>
</tr>
<tr>
<td>02/01/2020</td>
<td>Annual review. No change to policy statement. Literature review updated</td>
</tr>
</tbody>
</table>
**Definitions of Decision Determinations**

**Medically Necessary:** Services that are Medically Necessary include only those which have been established as safe and effective, are furnished under generally accepted professional standards to treat illness, injury or medical condition, and which, as determined by Blue Shield, are: (a) consistent with Blue Shield medical policy; (b) consistent with the symptoms or diagnosis; (c) not furnished primarily for the convenience of the patient, the attending Physician or other provider; (d) furnished at the most appropriate level which can be provided safely and effectively to the patient; and (e) not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of the Member’s illness, injury, or disease.

**Investigational/Experimental:** A treatment, procedure, or drug is investigational when it has not been recognized as safe and effective for use in treating the particular condition in accordance with generally accepted professional medical standards. This includes services where approval by the federal or state governmental is required prior to use, but has not yet been granted.

**Split Evaluation:** Blue Shield of California/Blue Shield of California Life & Health Insurance Company (Blue Shield) policy review can result in a split evaluation, where a treatment, procedure, or drug will be considered to be investigational for certain indications or conditions, but will be deemed safe and effective for other indications or conditions, and therefore potentially medically necessary in those instances.

**Prior Authorization Requirements (as applicable to your plan)**

Within five days before the actual date of service, the provider must confirm with Blue Shield that the member's health plan coverage is still in effect. Blue Shield reserves the right to revoke an authorization prior to services being rendered based on cancellation of the member's eligibility. Final determination of benefits will be made after review of the claim for limitations or exclusions.

Questions regarding the applicability of this policy should be directed to the Prior Authorization Department at (800) 541-6652, or the Transplant Case Management Department at (800) 637-2066 ext. 3507708 or visit the provider portal at www.blueshieldca.com/provider.

Disclaimer: This medical policy is a guide in evaluating the medical necessity of a particular service or treatment. Blue Shield of California may consider published peer-reviewed scientific literature, national guidelines, and local standards of practice in developing its medical policy. Federal and state law, as well as contract language, including definitions and specific contract provisions/exclusions, take precedence over medical policy and must be considered first in determining covered services. Member contracts may differ in their benefits. Blue Shield reserves the right to review and update policies as appropriate.