Magnetic Esophageal Sphincter Augmentation to Treat Gastroesophageal Reflux Disease (GERD)

Policy Number: 7.01.137  
Last Review: 02/2020  
Origination: 02/2014  
Next Review: 02/2021

Policy
Blue Cross and Blue Shield of Kansas City (Blue KC) will not provide coverage for Magnetic Esophageal Ring to Treat Gastroesophageal Reflux Disease (GERD). This is considered investigational.

When Policy Topic is covered
Not Applicable

When Policy Topic is not covered
Magnetic esophageal sphincter augmentation to treat gastroesophageal reflux disease (GERD) is investigational.

Description of Procedure or Service

<table>
<thead>
<tr>
<th>Populations</th>
<th>Interventions</th>
<th>Comparators</th>
<th>Outcomes</th>
</tr>
</thead>
</table>
| Individuals:  
- With gastroesophageal reflux disease | Interventions of interest are:  
- Magnetic sphincter augmentation | Comparators of interest are:  
- Continued medical therapy  
- Laparoscopic fundoplication | Relevant outcomes include:  
- Symptoms  
- Change in disease status  
- Medication use  
- Treatment-related morbidity |

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 maximum medical therapy.
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 (eg, 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.

Background

Gastroesophageal Reflux Disease

GERD is defined as the 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.

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

This evidence review was created in August 2012 and has been updated regularly with searches of the MEDLINE database. The most recent literature update was performed through October 8, 2019.

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 postsurgery. 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>Guidozzi et al (2019)(^1)</td>
<td>1987-2013</td>
<td>6 comparative observational</td>
<td>Patients with GERD</td>
<td>Comparative observational studies: 1099 (24-)</td>
<td>Comparative observational</td>
<td>Range 6-44 months</td>
</tr>
<tr>
<td>Study</td>
<td>Need for PPI</td>
<td>GERD-HRQL</td>
<td>Dysphagia</td>
<td>Need for Reoperation</td>
<td></td>
<td></td>
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<tr>
<td>------------------------</td>
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<td>----------------</td>
<td>--------------------</td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Guidozzi et al (2019)</td>
<td></td>
<td></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>
<td></td>
<td></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>
<td></td>
<td></td>
</tr>
<tr>
<td>$I^2$ (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>
<td></td>
<td></td>
</tr>
<tr>
<td>Aiolfi et al (2018)</td>
<td>PPI suspension</td>
<td></td>
<td>Dysphagia requiring endoscopic dilatation</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>
<td></td>
<td></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>
<td></td>
<td></td>
</tr>
<tr>
<td>$I^2$ (p)</td>
<td>63.9% (0.016)</td>
<td>0% (0.82)</td>
<td>35% (0.19)</td>
<td>0% (0.814)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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

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

patients with GERD

Comparative observational (1 prospective, 5 retrospective cohort)

Up to 1 year
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 PPIs and actively seeking</td>
<td>Laparoscopic MSA (N=50)</td>
</tr>
</tbody>
</table>
RCT: randomized controlled trial; MSA magnetic sphincter augmentation; PPI: proton pump inhibitor.

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>Withdr calves</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bell et al (2019)\textsuperscript{a} NCT02505945</td>
<td>134</td>
<td>134</td>
<td>134</td>
<td>123</td>
<td>123</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Resolution of moderate-to-severe regurgitation (FSQ) at 6 months</td>
<td>Mean decrease in GERD-HRQL score at 6 months</td>
<td>≥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>
<td>Normal number of reflux episodes</td>
</tr>
<tr>
<td>MSA</td>
<td>42/47 (89%)</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>Omeprazole</td>
<td>101/101 (10%)</td>
<td>1</td>
<td>7/87 (8%)</td>
<td>NR</td>
<td>49.0 (IQR,31.0-76.78)</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; N: sample size; FSQ: Foregut Symptom Questionnaire; GERD-HRQL: gastroesophageal reflux disease health-related quality of life scale; NR: not reported; PPI: proton pump inhibitor. IQR: interquartile range

### Table 5. Relevance Limitations

<table>
<thead>
<tr>
<th>Study</th>
<th>Populationa</th>
<th>Interventionb</th>
<th>Comparatorc</th>
<th>Outcomesd</th>
<th>Follow-Up°</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bell et al (2019)(^a), NCT02505945</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>
<td></td>
<td></td>
</tr>
</tbody>
</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.

- **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.
- **Intervention key**: 1. Not clearly defined; 2. Version used unclear; 3. Delivery not similar intensity as comparator; 4. Not the intervention of interest.
- **Comparator key**: 1. Not clearly defined; 2. Not standard or optimal; 3. Delivery not similar intensity as intervention; 4. Not delivered effectively.
- **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.
- **Follow-Up key**: 1. Not sufficient duration for benefit; 2. Not sufficient duration for harms.

### Table 6. Study Design and Conduct Limitations

<table>
<thead>
<tr>
<th>Study</th>
<th>Allocationa</th>
<th>Blindingb</th>
<th>Selective Reportingc</th>
<th>Data Completenessd</th>
<th>Powerе</th>
<th>Statisticalf</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bell et al (2019)(^a), NCT02505945</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>
</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.


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).

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

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 had 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 (eg, 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 (eg, 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><strong>Ongoing</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>NCT02429830a</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>NCT01940185a</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.

*a Denotes industry-sponsored or cosponsored trial.

REFERENCES


Billing Coding/Physician Documentation Information

43284 Laparoscopy, surgical, esophageal sphincter augmentation procedure, placement of sphincter augmentation device (ie, magnetic band), including cruroplasty when performed (New Code 1/1/2017)
43285 Removal of esophageal sphincter augmentation device (New Code 1/1/2017)

ICD-10 Codes

K21.0, K21.9 Gastro-esophageal reflux disease with and without esophagitis code range

The Medicare carrier Novitas Solutions posted a provider bulletin in June 2013 which states that code 43280 has been incorrectly reported for this procedure and that the unlisted code 43289 should be used (https://www.novitas-solutions.com/bulletins/all/news-06192013.html).

0392T, 0393T deleted as of 1/1/2017)
C9737 was deleted 7/1/2015.

Additional Policy Key Words

N/A

Policy Implementation/Update Information

2/1/2014 New Policy; considered investigational.
2/1/2015 Added HCPCS code. No policy statement changes.
2/1/2016 Added CPT Codes. No policy statement changes.
2/1/2017 “Magnetic esophageal ring” changed to “magnetic sphincter augmentation” in policy statement; policy statement otherwise unchanged; title changed to “Magnetic Esophageal Sphincter Augmentation to Treat Gastroesophageal Reflux Disease”
2/1/18 No policy statement changes.
2/1/19 No policy statement changes.
2/1/20 No policy statement changes.
State and Federal mandates and health plan contract language, including specific provisions/exclusions, take precedence over Medical Policy and must be considered first in determining eligibility for coverage. The medical policies contained herein are for informational purposes. The medical policies do not constitute medical advice or medical care. Treating health care providers are independent contractors and are neither employees nor agents Blue KC and are solely responsible for diagnosis, treatment and medical advice. No part of this publication may be reproduced, stored in a retrieval system or transmitted, in any form or by any means, electronic, photocopying, or otherwise, without permission from Blue KC.