



Kansas City

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

Policy Number: 7.01.137
Origination: 02/2014

Last Review: 02/2019
Next Review: 02/2020

Policy

Blue Cross and Blue Shield of Kansas City (Blue KC) will not provide coverage 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

Populations	Interventions	Comparators	Outcomes
Individuals: <ul style="list-style-type: none"> With gastroesophageal reflux disease 	Interventions of interest are: <ul style="list-style-type: none"> Magnetic sphincter augmentation 	Comparators of interest are: <ul style="list-style-type: none"> Continued medical therapy Laparoscopic fundoplication 	Relevant outcomes include: <ul style="list-style-type: none"> 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 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. In the 2 single-arm, uncontrolled manufacturer-sponsored studies submitted to the U.S. Food and Drug Administration for device approval, subjects showed improvements in Gastroesophageal Reflux Disease–Health Related Quality of Life (GERD-HRQL) scores and reduced proton pump inhibitor (PPI) use. Similarly, observational comparative studies, most often comparing magnetic sphincter augmentation (MSA) with laparoscopic Nissen fundoplication, generally have shown that GERD-HRQL scores do not differ significantly between fundoplication and MSA, and patients are able to reduce PPI 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-HRQL scores) may be biased. A randomized trial is in progress; it will compare treatment with the MSA and treatment with double-dose PPIs. Randomized comparisons of MSA with laparoscopic Nissen fundoplication are also needed to evaluate the relative risk-benefit of these 2 procedures. The evidence is insufficient to determine the effects of the technology on health outcomes.

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 not adequate 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.

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 (eg, 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.

Regulatory Status

In 2012, the LINX™ Reflux Management System (Torax Medical, Shoreview, MN) 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 5-year follow-up of 100 patients from the investigational device exemption pivotal study to evaluate 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 September 14, 2018

Evidence reviews assess the clinical evidence to determine whether the use of a technology improves the net health outcome. Broadly defined, health outcomes are length of life, quality of life, and ability to function—including benefits and harms. Every clinical condition has specific outcomes that are important to patients and to 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 a technology, 2 domains are examined: the relevance and the 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.

Gastroesophageal Reflux Disease

Gastroesophageal reflux disease (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. 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.

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 use of MSA improve the net health outcome in individuals with GERD?

The following PICOTS were used to select literature to inform this review.

Patients

The relevant population of interest is individuals with GERD.

Interventions

The therapy being considered is MSA.

Comparators

The following therapies and practices are currently being used to treat GERD: continued medical therapy and Laparoscopic fundoplication.

Outcomes

The general outcomes of interest are reduction in symptoms (eg, achalasia, dyspepsia, dysphagia) and medication use, treatment-related adverse events, device failure, and progression to Barrett esophagus and esophageal cancer.

Timing

MSA is 30-minute surgical procedure performed under general anesthesia that includes testing of the esophageal sphincter. The device manufacturer claims patients resume a normal diet within 24 hours postsurgery.

Setting

MSA is a minimally invasive procedure conducted in an inpatient surgical center and requires an overnight stay.

Randomized Controlled Trials

No RCTs were identified in the literature.

Nonrandomized Comparative Studies

Retrospective comparative studies have been identified on MSA with the LINX device compared with laparoscopic Nissen fundoplication (LNF) or laparoscopic Toupet fundoplication (LTF).

A large multi-institutional retrospective cohort study by Warren et al (2016) reported on 415 patients treated with either MSA (n=201) or LNF (n=214).¹ Eligible patients were retrospectively identified from 3 centers' prospectively collected databases who met criteria if they had GERD at least partially responsive to proton pump inhibitor (PPI) treatment and positive pH testing. MSA-treated patients had lower DeMeester scores, and lower rates of biopsy-proven Barrett esophagus and hiatal hernia. Given the differences in baseline groups, the authors used propensity score matching to generate 114 matched pairs based on preoperative esophagitis, presence of Barrett esophagus, hiatal hernia, and body mass index. Mean follow-up differed for matched pair MSA (11 months) and LNF groups (16 months; $p < 0.001$). In quality of life analysis at follow-up, there was no significant difference in match-pair groups in Gastroesophageal Reflux Disease–Health-Related Quality of Life (GERD-HRQL) scores (6 for MSA vs 5 for LNF, $p = 0.54$). The proportion of patients using PPIs at follow-up was higher in the MSA group (24% vs 12%, $p = 0.02$), but more patients in the MSA group had the ability for eructation (97% vs 66%, $p < 0.001$).

Asti et al (2016) reported on an observational cohort study comparing MSA (n=135) with LTF (n=103), using patients identified from a prospectively collected database.² Eligible patients had GERD symptoms despite PPI for at least 6 months and normal esophageal motility. In a generalized estimating equation model for the GERD-HRQL, there was no significant difference at 1 year in GERD-HRQL scores between MSA and LTF groups (odds ratio for time-treatment interaction term, 1.04; 95% confidence interval [CI], 0.89 to 1.27; $p = 0.578$). Similarly, there was no significant difference between the MSA and LTF groups at 1 year in PPI use (odds ratio for time-treatment interaction term, 1.18; 95% CI, 0.81 to 1.70; $p = 0.389$).

Reynolds et al (2015) reported on 1-year follow-up for 50 MSA and 50 LNF patients matched by disease severity.³ To be included in the study, patients had (1) objective evidence of GERD, defined as an abnormal pH study, presence of biopsy-proven Barrett esophagus, or esophagitis grade B or greater; (2) PPI therapy for a minimum of 6 months; and (3) normal esophageal motility. At 1 year after surgery, the 2 groups had similar GERD-HRQL scores (MSA=4.2 vs LNF=4.3; maximum, 50) and PPI use (MSA=17% vs LNF=8.5%). There was no difference in the number of patients reporting mild gas and bloating (MSA=27.6% vs LNF=27.6%), but more LNF patients reported severe gas and bloating (10.6% vs 0%, $p = 0.028$). More LNF patients were unable to belch (MSA=8.5% vs LNF=25.5%, $p = 0.028$) or vomit when needed (MSA=4.3% vs LNF=21.3%, $p < 0.002$).

Riegler et al (2015) published 1-year results from an industry-sponsored multicenter registry (NCT01624506) that included a comparison with laparoscopic

fundoplication.⁴ The report included 202 MSA and 47 LNF or LTF patients from a planned enrollment of 734 patients. The choice of procedure was made by the surgeon at the time of laparoscopy, taking into account the presence of a large hiatal hernia and other factors. In addition to having a greater frequency of large hiatal hernias (>3 cm, 45.7% vs 1.6%), the fundoplication group was older and had a greater frequency of Barrett esophagus (19.1% vs 1.0%, $p < 0.001$). Consistent with the greater severity of symptoms, patients who underwent fundoplication had greater regurgitation and fewer discontinued PPIs after treatment. Excessive gas and abdominal bloating (31.9% vs 10.0%) and inability to vomit (55.6% vs 8.7%) were significantly higher after fundoplication than after MSA. Improvements in GERD-HRQL scores were similar for the 2 groups.

Louie et al (2014) compared outcomes from 34 patients who had MSA with 32 patients who underwent LNF.⁵ Similar improvements were found for both groups on GERD-HRQL scores. The DeMeester score and pH normalized in both groups, but both were lower ($p = 0.001$) in the fundoplication group. MSA allowed belching in 67% of patients compared with 0% in the fundoplication group. Sheu et al (2014) retrospectively compared outcomes from 12 MSA patients with a contemporaneous case-matched cohort of patients who underwent LNF.⁶ Over half of the MSA patients were self-referred compared with none who underwent LNF. Both procedures were effective for reflux. Severe dysphagia requiring endoscopic dilation was more frequent after MSA (50% of cases), while there was a trend for a reduction in bloating, flatulence, and diarrhea in this study.

Section Summary: Nonrandomized Comparative Studies

Observational comparative studies, most often comparing MSA with LNF, have generally shown that GERD-HRQL scores do not differ significantly between fundoplication and MSA, and patients can reduce PPI use after MSA. However, these studies are limited by differences in baseline characteristics of patients treated with MSA and fundoplication. Some studies adjusted for some differences by matching for patient characteristics in their analyses, although the potential for residual confounding remains.

Single-Arm Studies

Data submitted to the U.S. Food and Drug Administration for the LINX Reflux Management System included 2 single-arm Food and Drug Administration–regulated investigational device exemption (IDE) trials (total $N = 144$ subjects) and follow-up data between 2 and 4 years.⁷ The feasibility IDE trial enrolled 44 subjects at 4 clinical sites (2 U.S., 2 Europe) and had published data out to 4 years.^{8,9} 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 end point measured the rate of related device and procedure serious adverse events. Efficacy end points were assessed off PPI therapy and measured

esophageal acid exposure, total GERD-HRQL scores, and PPI usage. Subjects served as their own controls.

Results of the pivotal trial were published by Ganz et al (2013).¹⁰ In this trial, the primary efficacy end point of pH normalization or reduction of 50% or more in acid exposure time when off PPI was met by 64% of the subjects. Mean total acid exposure time was reduced from 11.6% at baseline to 5.1% at 12 months (56% reduction). The secondary efficacy end points met the study success criteria. Ninety-two percent of subjects had at least a 50% improvement in GERD-HRQL score (the mean GERD-HRQL total score decreased from 28.4 at baseline to 5.9 and 5.5 at 12 and 24 months, respectively), and 93% reduced PPI use (79% and 83% of subjects were free from daily dependence at 12 and 24 months, respectively, vs 0% at baseline). Dysphagia was observed in 68% of patients postoperatively, in 11% at 1 year, and in 4% at 3 years. Nineteen patients underwent esophageal dilation for dysphagia. Six (6%) patients experienced a serious adverse event including severe dysphagia and vomiting. The device was removed from 4 of these 6 patients with a serious adverse event and in two others for persistent reflux and chest pain.

Five-year results from 33 of the 44 patients from the feasibility IDE trial were published by Saino et al (2015).¹¹ For the 33 with follow-up, the mean total GERD-HRQL score decreased from 25.7 at baseline to 2.9 at year 5 ($p < 0.001$); 93.9% had more than a 50% reduction in total score vs baseline. On esophageal pH testing, the mean percentage of time that pH was less than 4 decreased from 11.9% at baseline to 4.6% at 5 years ($p < 0.001$). At 5 years, 87.8% had stopped PPIs.

Five-year results for the 100 patients in the pivotal IDE trial were published by Ganz et al (2016).¹² Eighty-five patients had follow-up at 5 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 average daily dose of PPI (95% CI, 81% to 95%). No new major safety concerns emerged. The device was removed in 7 patients.

Lipham et al (2015) reported on adverse events for the first 1048 implanted patients (at 82 institutions).¹³ Of these, 144 were implanted as part of premarket clinical trials (previously described), 332 had been enrolled in the postmarket registry, and 572 were implanted outside of a postmarket registry. The three sources used to identify adverse events were the published clinical literature along with the device's Summary of Safety Effectiveness Data, the Food and Drug Administration database for device-related complications (MAUDE database), and information provided by the manufacturer. Event rates were 0.1% for intra- or perioperative complications, 1.3% for hospital readmissions, 5.6% for endoscopic dilations, and 3.4% for reoperations for device removal. The primary reason for device removal was dysphagia. Erosion of the device occurred in 1 (0.1%) patient. Median device implantation was 274 days. This study was limited by the short follow-up and the voluntary reporting of adverse events outside of the registry.

Bonavina et al (2013) published longer follow-up from patients in a pilot and a multicenter registry study.¹⁴ This study included a consecutive series of 100 patients who received MSA for GERD at their institution and were followed for a median of 3 years (range, 378 days to 6 years). Thirty patients had data beyond 5 years. Median GERD-HRQL score improved from 24 off PPIs to 2 ($p < 0.001$), and freedom from daily dependence on PPIs was achieved in 85% of patients. The time that esophageal pH was less than 4 decreased from 8.0% to 3.2% ($p < 0.001$). Although 3 patients had the device removed for persistent GERD, odynophagia, or dysphagia, no occurrences of device migrations or erosions were observed during follow-up.

Additional single-arm observational studies have reported on outcomes after MSA in sample sizes ranging from 121 to 192 patients,¹⁵⁻¹⁸ some of which focused on specific subpopulations of individuals with GERD, such as those with large hiatal hernias (eg, Rona et al [2017]).¹⁸

Summary of Evidence

For individuals who have GERD who receive MSA, the evidence includes prospective and retrospective observational comparative studies, 2 single-arm interventional trials, and single-arm observational studies. Relevant outcomes are symptoms, change in disease status, medication use, and treatment-related morbidity. In the 2 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-HRQL scores and reduced proton pump inhibitor use. Similarly, observational comparative studies, 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, and the subjective outcome measures used in these studies (eg, the GERD-HRQL scores) may be biased. A randomized trial is in progress (NCT02505945); it will compare treatment with the MSA and treatment with double-dose proton pump inhibitors. Randomized comparisons of MSA with LNF are also needed to evaluate the relative risk-benefit of these 2 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

In 2013, the Society of American Gastrointestinal and Endoscopic Surgeons published guidelines on the safety and effectiveness of the LINX Reflux Management System.¹⁹ 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 2013 report from the American Society for Gastrointestinal Endoscopy concluded that long-term data on the safety and efficacy of the LINX device were needed.²⁰ 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 unpublished trials that might influence this review are listed in Table 1.

Table 1. Summary of Key Trials

NCT No.	Trial Name	Planned Enrollment	Completion Date
Ongoing			
NCT01940185^a	A Post-Approval Study of the Lynx® Reflux Management System	200	Oct 2025
Unpublished			
NCT02505945^a	The CALIBER Study Randomized Controlled Trial of LINX Versus Double-Dose Proton Pump Inhibitor Therapy for Reflux Disease	150	Aug 2018 (completed)

NCT: national clinical trial.

^a Denotes industry-sponsored or cosponsored trial.

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

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