

# MEDICAL POLICY

MEDICAL POLICY DETAILS	
Medical Policy Title	Magnetic Esophageal Ring/Magnetic Sphincter Augmentation for the Treatment of Gastroesophageal Reflux Disease (GERD)
Policy Number	7.01.89
Category	Technology Assessment
Original Effective Date	02/20/14
Committee Approval Date	01/22/15, 01/21/16, 12/15/16, 12/21/17, 02/21/19, 02/20/20, 02/18/21, 02/17/22, 04/20/23
Current Effective Date	08/15/23
Archived Date	N/A
Archive Review Date	N/A
Product Disclaimer	<ul style="list-style-type: none"> <li>• If a product excludes coverage for a service, it is not covered, and medical policy criteria do not apply.</li> <li>• If a commercial product (including an Essential Plan or Child Health Plus product), medical policy criteria apply to the benefit.</li> <li>• If a Medicaid product covers a specific service, and there are no New York State Medicaid guidelines (eMedNY) criteria, medical policy criteria apply to the benefit.</li> <li>• If a Medicare product (including Medicare HMO-Dual Special Needs Program (DSNP) product) covers a specific service, and there is no national or local Medicare coverage decision for the service, medical policy criteria apply to the benefit.</li> <li>• If a Medicare HMO-Dual Special Needs Program (DSNP) product DOES NOT cover a specific service, please refer to the Medicaid Product coverage line.</li> </ul>

## POLICY STATEMENT

- I. Based upon our criteria and assessment of the peer-reviewed literature, use of a magnetic esophageal ring (e.g., LINX Reflux Management System) in the treatment of gastroesophageal reflux disease (GERD) has been medically proven to be effective and, therefore, is a **medically appropriate** treatment option in the management of GERD for individual 18 years and older, when **ALL** of the following conditions are met:
  - A. The individual has chronic, bothersome symptomatic gastroesophageal reflux (GERD) established by endoscopy, fluoroscopy or ambulatory pH testing that is inadequately controlled with individually appropriate daily proton pump inhibitor (PPI) use (unless intolerant to or contraindicated) for at least six months or a need to stop PPI therapy; **AND**
  - B. For those individuals with a hiatal hernia greater than 3 centimeters (cm), the hiatal hernia will be repaired prior to or occurring at the same time as the LINX procedure; **AND**
  - C. The LINX is being used as an alternative to surgical fundoplication for symptomatic GERD; **AND**
  - D. The procedure is being performed by a physician who has completed procedure-specific training in the use of the LINX system with privileges to perform the procedure.
- II. Based upon our criteria and assessment of the peer-reviewed literature, use of a magnetic esophageal ring (e.g., LINX Reflux Management System) for any other indication is considered **investigational**.

Refer to Corporate Medical Policy #11.01.03 Experimental and Investigational Services.

## POLICY GUIDELINES

**Medical Policy: MAGNETIC ESOPHAGEAL RING/MAGNETIC SPHINCTER AUGMENTATION FOR THE TREATMENT OF GASTROESOPHAGEAL REFLUX DISEASE (GERD)**

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- I. Prior to surgery, patients with symptoms of GERD must undergo a complete pre-operative evaluation, which should include an endoscopy, an esophageal manometry, Bravo pH testing, and an upper GI series (barium swallow). A comprehensive center is recommended for this evaluation.
- II. The patient has completed a shared decision making information session prior to the procedure to improve patient satisfaction, increase patient's knowledge of their condition, and assess readiness to make behavior changes. This shared decision making session should include instruction including but not limited to:
  - A. Explanation of the upcoming procedure and surgery
  - B. Risks and benefits of the procedure/surgery
  - C. How to manage the chronic condition
  - D. General healthcare expectations
  - E. Alternatives to the procedure/surgery
- III. Contraindications include:
  - A. Body-mass-index (BMI) over 35 Kg/m<sup>2</sup>
  - B. Esophageal motility disorder ( \*Major esophageal motility disorders include achalasia, distal esophageal spasm, hypercontractile esophagus and absent contractility. This does not include minor disorders of peristalsis, e.g., ineffective esophageal motility [IEM]).
  - C. Active esophageal or gastric cancer
  - D. Presence of electrical implant
  - E. Esophageal or gastric varices or strictures
  - F. Scleroderma
  - G. Anyone who may be allergic or is allergic to titanium, stainless steel, nickel or iron (ferrous) materials.

**DESCRIPTION**

GERD is defined as reflux of stomach acid into the esophagus that causes symptoms and/or mucosal injury. The most common symptom of GERD is heartburn. This is an uncomfortable burning sensation felt in the middle of the upper abdomen and/or lower chest. Other typical symptoms include difficulty swallowing (dysphagia) and regurgitation of fluid into the esophagus. In some cases, fluid may even reflux into the mouth. People with GERD also may develop other, atypical (extra-esophageal) symptoms such as hoarseness, throat-clearing, sore throat, wheezing, chronic cough, and even asthma.

The treatment of GERD begins with behavioral and lifestyle changes. Reduction of symptoms can be achieved in most individuals with several modifications. These include weight loss, avoidance of carbonated beverages, abstinence from smoking, reducing alcohol and caffeine intake, avoiding "trigger" foods (spicy foods, citrus or acidic foods), maintaining a low fat diet, avoiding eating or drinking several hours before going to bed, and elevating the head of the bed at night.

The severity of GERD is widely variable. 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 esophagitis, Barrett's esophagus and esophageal cancer. If symptoms are severe, or if symptoms persist despite lifestyle modifications, then medication should be considered. Acid reducing medications include proton pump inhibitors (PPIs) and histamine H<sub>2</sub>-receptor blockers (H<sub>2</sub> blockers). Medication do not stop reflux from occurring but are often effective in reducing the amount of acid in the gastric fluid. In most people, acid reduction is enough to relieve or even eliminate symptoms of GERD. In some people, however, long-term use of PPIs may be associated with an increased risk of osteoporosis and fractures of the hip, wrist, and spine.

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Medications do not always provide adequate control of symptoms for some patients, and other patients prefer to avoid the indefinite, possibly lifelong, use of medications. Surgical treatments are available for these patients. Laparoscopic fundoplication is the current standard of surgical care for GERD. The goal of a fundoplication is to reinforce the lower esophageal sphincter (LES) to recreate the barrier that stops reflux from occurring. After a fundoplication, some patients report difficulty belching or a sensation of abdominal bloating and the inability to vomit. Additional complications can result from general anesthesia, bleeding, infection, and/or injury to nearby organs. Nearby organs include the stomach, esophagus, spleen, liver, vagus nerves, aorta, vena cava, diaphragm, lungs, and heart. In both short-term (1–5 years) and long-term studies (5–10 years), the vast majority of patients report effective symptom reduction, a high level of satisfaction, and an improved quality of life after having the surgery (Slater et al. 2021). Nearly all patients are taken off of reflux medication after surgery.

Endoscopic treatments for GERD are now considered appropriate for those patients early in the GERD spectrum, as well as those with altered anatomy where standard laparoscopic surgical approaches are limited. There are currently three endoscopic devices approved by the Food and Drug Administration (FDA) in the USA being used to treat GERD: Stretta for radiofrequency therapy (Restech, Houston, TX), Esophyx-Z for Transoral Incisionless Fundoplication (TIF) (EndoGastric Solutions, Redmond, WA), and Overstitch for endoscopic suturing (Apollo Endosurgery, Austin, TX).

LINX Reflux Management System (Torax Medical) was developed for the treatment of GERD. The device consists of a laparoscopically implanted ring composed of 10 to 18 interlinked titanium beads with magnetic cores that is placed around the esophagus at the level of the gastroesophageal junction using standard laparoscopic techniques. 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 provides a slightly higher pressure than the reflux pressure, keeping the contents in the stomach. However, its pressure is significantly lower than the pressure generated by the esophagus when liquids or food goes down, allowing the magnetic beads to open apart allowing it to pass through the LES and LINX. After the swallow goes through, the magnetic attraction closes it back comfortably around the LES.

The LINX Reflux Management System has been evaluated in a target population consisting of patients who have GERD symptoms despite maximum medical therapy (e.g., proton pump inhibitors), but who do not want to risk the adverse effects (potential loss of ability to belch or vomit) of a surgical procedure like a Nissen fundoplication. Adverse events of the LINX Reflux Management System may include dysphagia or odynophagia. According to the manufacturer's website, a new version of LINX is available that is considered magnetic resonance (MR) conditional in a magnetic resonance imaging (MRI) system up to 1.5 Tesla (1.5T). Scanning under different conditions may result in serious injury to the patient and/or interfere with the magnetic strength and function of the device. In the event that an MRI above 1.5 Tesla (1.5T) is required, and alternative diagnostic procedures cannot be used, the LINX device can be removed. The LINX device should not be used in anyone who may be allergic or is allergic to titanium, stainless steel, nickel or iron (ferrous) materials.

### **RATIONALE**

The LINX Reflux Management System was approved by the U.S. Food and Drug Administration (FDA) in 2012. The device is indicated for patients diagnosed with GERD, as defined by abnormal pH testing, who continue to have chronic GERD symptoms despite maximum therapy for the treatment of reflux. The FDA required a five-year follow-up of 100 patients from the investigational device exemption (IDE) pivotal study, to evaluate the safety and efficacy of the device.

Data submitted to the FDA for the LINX Reflux Management System included two single-arm, FDA-regulated, investigational device exemption (IDE) trials with a total of 144 subjects, and follow-up data between two and four years. The feasibility IDE study enrolled 44 subjects at four clinical sites (two U.S. and two European) and has published data out to four years (Bonavina et al., 2010, Lipham et al., 2012). The pivotal IDE study included 100 subjects from 14 clinical sites (13 U.S. and one European) who had documented symptoms of GERD for longer than six months (regurgitation or heartburn that responds to acid neutralization or suppression), required daily proton pump inhibitor (PPI) or other anti-reflux drug therapy, had symptomatic improvement on PPI therapy, and had a total distal ambulatory esophageal pH less than four for 4.5% or more of the time when off GERD medications. The primary safety endpoint

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measured the rate of related device and procedure serious adverse events (SAEs). Efficacy endpoints were assessed off PPI therapy and measured esophageal acid exposure, total GERD Health-Related Quality of LIFE (GERD-HRQL) scores, and PPI usage. Subjects served as their own controls.

A total of 24 of the 44 subjects (54.5%) in the feasibility study experienced adverse events related to the device and/or procedure, and two subjects experienced SAEs. The most common adverse event was dysphagia (22 events in 20 subjects, which resolved in 90 days). No SAEs related to the device or procedure occurred after the first year. In the pivotal study, dysphagia was commonly observed, occurring in 68% of patients (49% mild, 16% moderate, and 5% severe), and an SAE related to the device or implantation procedure occurred in eight of the 144 subjects (6%). Most cases of dysphagia either self-improved or improved with endoscopic esophageal balloon dilation. Three subjects underwent device removal for severe dysphagia and/or odynophagia. Three subjects were hospitalized for nausea and/or vomiting. One subject reported the inability to vomit. No device migration was observed on radiographs taken at 12 months. Success on the subject level was defined as normalization of acid (pH <4 for  $\leq 4.5\%$  of time) or reduced total acid exposure time (pH <4) by at least 50%, relative to baseline measurements. In the feasibility study, esophageal pH testing was performed out to 36 months in only one of the four centers. The percentage of subjects who achieved success was 79.5% (31/39) at 12 months, 90% (18/20) at 24 months, and 85% (17/20) at 36 months. The proportion of patients with reduction in PPI therapy by 50% or more was 89.7% (35/39) at 12 months, 82.9% (29/35) at 24 months, and 87.5% (28/32) at 36 months. Improvement in GERD HRQL scores by more than 50% occurred in 97.4% (38/39) of subjects at 12 months, 88.6% (31/35) at 24 months, and 96.3% (26/27) at 36 months.

Results of the pivotal trial were published in 2013 (Ganz et al., 2013). In that study, the primary efficacy endpoint of pH normalization or greater than 50% reduction in acid exposure time when off PPI was met by 64% of the subjects. The mean total acid exposure time was reduced from 11.6% at baseline to 5.1% at 12 months (56% reduction). The secondary efficacy endpoints met the study success criteria. Ninety-two percent of subjects had at least a 50% improvement in GERD-HRQL symptom 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% had reduced PPI use (79% and 83% of subjects were free from daily dependence at 12 and 24 months, respectively, compared with 0% at baseline). Dysphagia was observed in 68% of patients post-operatively, in 11% at one year, and in 4% at three years. Nineteen patients underwent esophageal dilation for dysphagia. Six patients (6%) experienced an SAE, including severe dysphagia and vomiting. The device was removed in four of these six patients with an SAE and in two additional patients for persistent reflux and chest pain.

In a randomized, controlled trial (RCT) conducted by Bell and colleagues (2018), 152 patients with GERD were randomized 2:1 to treatment with omeprazole 20mg twice daily (BID) (n=102) or laparoscopic magnetic sphincter augmentation (MSA) (n=50). Patients were assessed at baseline and at six months using the Foregut Symptom Questionnaire (FSQ), Reflux Disease Questionnaire (RDQ), and GERD-HRQL questionnaire. At six months, patients also underwent 24-hour impedance-pH testing evaluated by a blinded, independent laboratory. A total of 89% of MSA-treated patients reported relief of regurgitation, compared with 10% of the BID PPI group at the six-month primary endpoint. By intention-to-treat analysis, 84% of patients in the MSA group and 10% in the BID PPI group met this primary endpoint. Eighty-one percent of patients with MSA versus 8% of patients with BID PPI had 50% or more improvement in GERD-HRQL scores, and 91% remained off PPI therapy. A normal number of reflux episodes and acid exposures was observed in 91% and 89% of MSA patients, respectively, compared with 58% and 75% of BID PPI patients, at six months. No significant safety issues were observed. In MSA patients, 28% reported transient dysphagia, and 4% reported ongoing dysphagia. The authors concluded that MSA provides significantly better control of moderate-to-severe regurgitation, when compared with BID PPI.

In two separate meta-analyses by Skubleny et al. (2017) and Aiolfi et al. (2018), magnetic sphincter augmentation (MSA) was compared to fundoplication for the treatment of GERD. Three and seven observational cohort studies, respectively, were included for review, corresponding to 688 patients and 1,211 patients. Both of the studies concluded that MSA and fundoplication are safe and effective up to one-year follow-up; however, MSA is superior to fundoplication in preserving a patient's ability to vomit and belch. Limitations included the exclusion of randomized, controlled trials and short follow-up periods of the included studies.

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In 2018, Louie et al. reported one-year outcomes from the five-year, FDA-mandated study of the safety and effectiveness of MSA with the LINX Reflux Management System. A total of 200 patients were treated with MSA in a multi-center, prospective, uncontrolled trial. Effectiveness and safety were evaluated based on disease-specific questionnaires, PPI use, esophagogastroduodenoscopy, and pH testing. Predefined success criteria of achieving a 50% or greater reduction in total GERD-HRQL score was achieved by 84.3% of patients at one year. Of the 164 patients agreeing to complete esophageal pH monitoring, 76.8% achieved successful reduction in esophageal acid, 74.4% had normal esophageal acid exposure, and 72.4% had a normal DeMeester Score. The device removal rate at one year was 2.5%. One erosion and no SAEs were reported. The authors concluded that MSA is a safe and effective option for patients desiring a surgical option other than fundoplication to control their chronic symptoms of GERD.

Complications post-magnetic sphincter device implantations are reportedly low, as compared to the total number of procedures performed. Based on the Manufacturer and User Facility Device Experience (MAUDE) database, which houses medical reports submitted to the FDA of suspected device-associated deaths, serious injuries, and malfunctions, Smith et al. (2017) reported that, out of a total of 3,283 procedures reviewed, device removal occurred in 2.7% of cases. No deaths, life-threatening events or device malfunctions were reported. The most common causes of removal were dysphagia, continued reflux, and device erosion into the esophagus. Alicuben et al. (2018) also reported low device erosion rates worldwide (0.3% at four years after device implantation).

The Society of American Gastrointestinal and Endoscopic Surgeons (SAGES) Technology and Value Assessment Committee published an updated analysis of the safety and effectiveness of the LINX Reflux Management System (2017). The Committee concluded that longer-term (three to five years) experience confirms the initial safety profile that led to FDA approval of the device and that the LINX device has been demonstrated to result in long-term GERD control, based on symptomatic outcomes, PPI utilization, and pH studies. The committee determined that the LINX device is a reasonable treatment option for appropriately selected patients with GERD who meet indications for anti-reflux surgery; however, it should be performed by surgeons familiar with the workup of and different management alternatives for GERD, and should not offered in isolation.

The American Society of General Surgeons (ASGS) issued a statement of support for the LINX device in 2014: “Based on currently available information and the experience of our members with the procedure we do support the LINX procedure as mechanism for controlling GERD when it is placed by properly trained laparoscopic surgeons with experience in foregut surgery and the management of GERD patients.”

An assessment of the procedure by the National Institute for Health and Care Excellence (NICE) in 2017 found no major safety concerns, but noted that there is limited evidence of long-term efficacy in quantity and quality.

**CODES**

- *Eligibility for reimbursement is based upon the benefits set forth in the member’s subscriber contract.*
- ***CODES MAY NOT BE COVERED UNDER ALL CIRCUMSTANCES. PLEASE READ THE POLICY AND GUIDELINES STATEMENTS CAREFULLY.***
- *Codes may not be all inclusive as the AMA and CMS code updates may occur more frequently than policy updates.*
- *Code Key: Experimental/Investigational = (E/I), Not medically necessary/ appropriate = (NMN).*

**CPT Codes**

<b>Code</b>	<b>Description</b>
43284	Laparoscopy, surgical, esophageal sphincter augmentation procedure, placement of sphincter augmentation device (e.g., magnetic band), including cruroplasty when performed
43285	Removal of esophageal sphincter augmentation device

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**HCPCS Codes**

<b>Code</b>	<b>Description</b>
No specific code(s)	

**ICD10 Codes**

<b>Code</b>	<b>Description</b>
K21.0	Gastro-esophageal reflux disease with esophagitis
K21.9	Gastro-esophageal reflux disease without esophagitis

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\*Key Article

### **KEY WORDS**

Esophageal sphincter device, gastroesophageal reflux disease, GERD, LINX, magnetic esophageal ring, magnetic sphincter augmentation

### **CMS COVERAGE FOR MEDICARE PRODUCT MEMBERS**

There is currently a The Local Coverage Determination (LCD) addressing Select Minimally Invasive GERD Procedures. Please refer to the following website for Medicare Members: CMS MCD

[<https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?lcdid=35080&ver=53&keyword=LINX&keywordType=starts&areaId=all&docType=NCA,CAL,NCD,MEDCAC,TA,MCD,6,3,5,1,F,P&contractOption=all&sortBy=relevance&bc=1>]