MEDICAL POLICY

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MEDICAL POLICY DETAILS	
Medical Policy Title	**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**
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Product Disclaimer	• *Services are contract dependent; if a product excludes coverage for a service, it is not covered, and medical policy criteria do not apply.* • *If a commercial product (including an Essential Plan or Child Health Plus product), medical policy criteria apply to the benefit.* • *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.* • *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.* • *If a Medicare HMO-Dual Special Needs Program (DSNP) product DOES NOT cover a specific service, please refer to the Medicaid Product coverage line.*

POLICY STATEMENT

I. Based upon our criteria and assessment of the peer-reviewed literature, magnetic sphincter augmentation (e.g., LINX Reflux Management System) for 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, when **ALL** of the following conditions are met:

A. The individual is 18 years of age or older;
B. 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 (6) months or a need to stop PPI therapy;
C. For individuals with a hiatal hernia greater than 3 centimeters (cm), submitted records must indicate that the hiatal hernia will be repaired prior to or at the same time as the LINX procedure;
D. The LINX device is being used as an alternative to surgical fundoplication for symptomatic GERD;
E. The procedure is being performed by a physician who has completed procedure-specific training in the use of the LINX Reflux Management System with privileges to perform the procedure; **and**
F. The individual has **NONE** of the following contraindications to implantation of the LINX device:
   1. suspected or known allergy to titanium, stainless steel, nickel, or iron (ferrous) materials;
   2. require magnetic resonance imaging (MRI) of >1.5 Tesla;
   3. obesity with a body-mass-index (BMI) >35 Kg/m^2;
   4. active esophageal or gastric cancer;

5. major esophageal motility disorder (e.g., Achalasia, distal esophageal spasm, hypercontractile esophagus and absent contractility. This does not include minor disorders of peristalsis [e.g., ineffective esophageal motility]);
6. presence of electrical implant (e.g., pacemaker, defibrillator, abdominal implant);
7. esophageal or gastric varices;
8. esophageal stricture (e.g., Schatzki's ring, or obstructive lesions); **or**
9. scleroderma.

II. Based upon our criteria and assessment of the peer-reviewed literature, use of magnetic sphincter augmentation (e.g., LINX Reflux Management System) for any other indication is considered **investigational**.

Refer to Corporate Medical Policy #11.01.03 Experimental or Investigational Services

POLICY GUIDELINES

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. Non-clinical testing has demonstrated that the LINX device is magnetic resonance (MR) conditional. This device can be scanned safely under certain conditions (e.g., static magnetic field 1.5-Tesla [1.5T]). The LINX device contains permanent magnets. The patient may feel pressure around the lower esophagus. Should the patient experience pain, the scan should be immediately discontinued and remove the patient from the MR environment (Torax Medical, 2023).

III. LINX device is a long-term implant. Explant (removal) and replacement maybe indicated at any time.

IV. 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

DESCRIPTION

Gastroesophageal reflux disease (GERD) is a common disorder characterized by classic symptoms of heartburn and regurgitation, as well as other symptoms such as pain, dysphagia, and dry cough/throat clearing). Most individuals experience symptoms of gastroesophageal reflux at some point in their lives, with a smaller number having chronic symptoms that put them at risk for complications of GERD (e.g., erosive esophagitis, dysphagia, Barrett esophagus, asthma).

The pathophysiology of GERD involves excessive exposure to stomach acid, which occurs for several reasons. There can be an incompetent barrier between the esophagus and stomach, either due to dysfunction of the lower esophageal sphincter or incompetence of the diaphragm. Another mechanism is an abnormally slow clearance of stomach acid. In this situation, delayed clearance leads to an increased reservoir of stomach acid and a greater tendency to reflux.

Guidelines on the medical management of GERD emphasize initial lifestyle modification (e.g., weight loss, smoking cessation, head of the bed elevation, elimination of food triggers) and medication therapy (e.g., antacids, proton pump inhibitors). Surgical and endoscopic procedures are options for patients who have persistent symptoms or develop complications despite optimal medical therapy.

LINX Reflux Management System (Torax Medical) was developed for the treatment of GERD. The device consists of a laparoscopically implanted ring composed 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 (LES) 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 (Torax Medical, 2023), the LINX Reflux Management System 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

In 2012, the LINX Reflux Management System was approved by the U.S. Food and Drug Administration (FDA) through the premarket approval process (P100049).The device is indicated for patients diagnosed with GERD, 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, which was completed in March 2016 and the results were published in 2019.

In March 2018, the FDA approved an update of the LINX Reflux Management System precautions statement (P100049/S021), stating that the use of the system "in patients with a hiatal hernia larger than 3 cm should include hiatal hernia repair to reduce the hernia to less than 3 cm and that the LINX Reflux Management System has not been evaluated in patients with an unrepaired hiatal hernia greater than 3 cm, add a hiatal hernia clinical data summary in the instructions for use, update the instructions for use section to highlight the recommendation to repair a hiatal hernia, if present, at the time of the LINX Reflux Management System implantation, and update the patient information booklet to align with the instructions for use and include 5 year clinical study results."

Callahan et al. (2023) published a retrospective review of a prospective database evaluating patients who underwent MSA, laparoscopic Nissen fundoplication (LNF), Toupet fundoplication (TNF) or anti-reflux mucosectomy (ARMs). Patients were followed up at 3 weeks, 6 months, 1 year, 2 years, and 5 years post-operation. A total of 649 patients had reflux surgery during the study period from 2008 to 2021 including 356 LNF, 207 LTF, 46 MSA, and 40 ARMs procedures. These groups were imbalanced on several baseline characteristics including age, body mass index (BMI), gender, hypertension medication usage, pre-operative dysphagia, esophageal motility, and hernia type. Procedure time was significantly shorter inpatients treated with MSA or ARM compared to fundoplication ($p < 0.001$). At 3 weeks follow-up patients in the MSA group had higher reflux symptoms index scores and GERD-HRQL scores than patients in the Toupe fundoplication group (15.4 vs 9.5; p=.044 and 9.6 vs 4.8; p=.043, respectively), but these differences had resolved by 6 months with all four treatment groups showing similar outcomes. One-year follow-up data on GERD-HRQL showed a significant difference between the MSA group and ARM groups with the MSA group having worse symptoms (6.9 vs 2.5; p=.048); this difference was not observed at 2-year follow-up, but at 5 years MSA patients had worse GERD-HRQL scores compared to the Toupet fundoplication group (17.8 vs 4.9; p=.024). All groups had similar scores at all time points follow-up for gas bloating and dysphagia symptoms. Limitations of the study include lack of

randomization and blinding, imbalance of baseline patient characteristics, and changes in secular trends over the study period which resulted in predominantly younger patients with normal manometry receiving LNF.

Bonavina et al. (2021) published 3-year outcomes from a prospective, observational registry evaluating MSA and laparoscopic fundoplication in 631 patients (465 MSA; 166 laparoscopic fundoplication) enrolled between 2009 and 2014 across 22 medical centers in Europe. Patients had a diagnosis of GERD confirmed by abnormal esophageal acid exposure and chronic reflux symptoms despite daily use of PPIs. Patients with severe GERD marked by hiatal hernia >3 cm, Barrett esophagus, motility disorder, and Grade C or D esophagitis by LA classification were also included. The type of anti-reflux procedure performed was provisionally determined by the surgeon in consultation with the patient. MSA was recommended when patients met labeling requirements for MSA (hiatal hernia ≤ 3 cm, esophagitis < Grade C, absence of Barrett esophagus, and absence of motility disorders); however, the final choice of procedures was made by the surgeon at the time of laparoscopy. Various forms of laparoscopic fundoplication were performed, including Nissen (62%), Toupet (31%), and Other/Unspecified (eg, Dor; 7%). Improvements in total GERD-HRQL scores were observed in both MSA (22.0 to 4.6) and laparoscopic fundoplication (23.6 to 4.9) groups with similar increases in GERD-HRQL satisfaction. A higher proportion of patients maintained the ability to vomit in them MSA group compared to laparoscopic fundoplication (91.2% vs. 68.0%). Similar declines in PPI usage were observed in both groups (MSA 97.8% to 24.2% and laparoscopic fundoplication 95.8% to 19.5%). Limitations of the study include lack of randomization and blinding, heterogeneity in laparoscopic fundoplication techniques, and selection bias as patients with less severe symptoms received MSA.

Bell et al. (2020) conducted a randomized controlled trial (RCT) with 152 patients with GERD who 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.

Louie et al. (2019) 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, esophagogastricduodenoscopy, 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.

Alicuben et al. (2018) reported low device erosion rates worldwide (0.3% at four years after device implantation). Smith et al. (2017) reported, based on the Manufacturer and User Facility Device Experience (MAUDE) database, that a total of 3,283 procedures were reviewed, with device removal occurring in 2.7% of cases. Complications post-magnetic sphincter device implantations are reportedly low, as compared to the total number of procedures performed. 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.

In two separate meta-analyses by Aiolfi et al. (2018) and Skubleny et al. (2017), 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.

Buckley et al. (2018) conducted a multicenter, prospective study of 200 consecutive patients who underwent MSA with the LINX device during repair of paraesophageal and hernias over 3 cm axial component; 78% of patients had axial hiatal hernia ≥5 cm or large paraesophageal component. Non-permanent mesh reinforcement of hiatal repair was performed in 83% of the patients. The authors reported favorable outcomes with a median of 9 months follow-up, By comparing study finding to published reports of MSA in patients with <3 cm hernias, the authors conclude that the safety and clinical efficacy of MSA are independent of initial hernia size.

Ganz et al. (2016) published five-year results for the 100 patients in the pivotal IDE trial were published. Eighty-five patients had a follow-up at 5 years. Of those 85 patients, 83% achieved a 50% reduction in GERD-HRQL scores (95% confidence interval [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.

Ganz et al. (2013) published results from the pivotal IDE study, which 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 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.

(Bonavina et al., 2010; Lipham et al., 2012) submitted data 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). 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 ≤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.

Practice Guidelines and Position Statements

In 2023, the National Institute for Health and Care Excellence (NICE) updated their interventional procedure guidance (IPG) evidence-based recommendations on laparoscopic insertion of a magnetic ring for gastro-oesophageal reflux disease. Guidelines indicate that evidence on the safety and efficacy is adequate to support using the procedure and that patient selection and procedure should be done by clinicians who have specific training in the procedure. The committee commented that the procedure has evolved, and the incidence of dysphagia and oesophageal spasm has reduced, over time.

A multi-society consensus guideline on the treatment of GERD was published with the following recommendations for magnetic sphincter augmentation (Slater et al., 2023):

- Preoperative evaluation with an EGD, manometry and pH testing for all patients with esophageal symptoms of medically refractory reflux; however, patients with Los Angeles (LA) grade C or D erosive esophagitis on endoscopy may not require pH testing to confirm the diagnosis of GERD. (Expert Opinion; GRADE recommendation was unable to be determined due to lack of evidence).
- The panel suggests that adult patients with GERD may be treated with either MSA or Nissen fundoplication based on surgeon and patient shared decision making. The choice for either procedure should be made on a patient specific basis consider other factors such as BMI and esophageal dysmotility, which are relative contraindications for MSA (Conditional recommendation based on very low certainty of evidence).
- The panel suggests that adult patients with GERD may benefit from MSA over continued PPI use. There is still a large amount unknown about this comparison.(Conditional recommendation based on moderate certainty of evidence).

In 2022, The American College of Gastroenterology (ACG) recommends consideration of MSA as an alternative to laparoscopic fundoplication for patients with regurgitation who fail medical management (strong recommendation, moderate level of evidence) (Katz et al., 2022).

In 2022, the American Gastroenterology Association's (AGA) Clinical Practice Update on the evaluation and management of GERD states MSA is an effective surgical option for patients with proven GERD whose symptoms are inadequately controlled following lifestyle and pharmacotherapy optimization (Yadlapati et al., 2022).

In 2017, 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. 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.

To date the American Society of General Surgeons (ASGS) has not issued an updated statement for the **LINX** device. In 2014, ASGS issued the following supportive statement: "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."

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

Code	Description
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

HCPCS Codes

Code	Description
No specific code(s)	

ICD10 Codes

Code	Description
K21.0	Gastro-esophageal reflux disease with esophagitis
K21.9	Gastro-esophageal reflux disease without esophagitis

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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 Local Coverage Determination (LCD) (L35080) for Select Minimally Invasive GERD Procedures. Please refer to the following LCD website for Medicare Members: [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] accessed 01/30/24.