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**
Effective Date	**02/20/14**
Revised Date	**01/22/15, 01/21/16, 12/15/16, 12/21/17, 02/21/19**
Product Disclaimer	• *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 product) or a Medicaid product covers a specific service, medical policy criteria apply to the benefit.* • *If a Medicare 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.*

POLICY STATEMENT

I. Based upon our review and assessment of 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, can be considered a **medically appropriat**e treatment option in the management of GERD when the following conditions are met:

   A. The patient presents with a diagnosis of GERD and symptoms persist despite lifestyle modifications and maximum medical therapy or intolerance to medical therapy; and
   B. GERD symptoms occur two or more times per week; and
   C. When used as an alternative treatment to surgical fundoplication.

II. Based upon our review and assessment of peer-reviewed literature, use of a magnetic esophageal ring (e.g., LINX™ Reflux Management System) for any other indication is considered **investigational**.

POLICY GUIDELINES

I. Prior to surgery, patients with symptoms of GERD must undergo a complete preoperative evaluation which should include an endoscopy, esophageal manometry, Bravo pH testing, and an upper GI series (barium swallow). A comprehensive center is recommended for this evaluation.

II. The Federal Employee Health Benefit Program (FEHBP/FEP) requires that procedures, devices or laboratory tests approved by the U.S. Food and Drug Administration (FDA) may not be considered investigational and thus these procedures, devices or laboratory tests may be assessed only on the basis of their medical necessity.

DESCRIPTION

Gastroesophageal reflux disease (GERD) is defined as reflux of stomach acid into the esophagus that causes symptoms and/or mucosal injury. 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 Barrett's esophagus and esophageal cancer. For patients with severe disease, chronic treatment with acid blockers is one option. However, medications do not always provide adequate control of symptoms for some patients, and other patients prefer to avoid the use of indefinite, possibly lifelong medications. Surgical treatments are available for these patients, primarily a Nissen fundoplication which is the current gold standard can be 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 invasive surgery.

A laparoscopically implanted ring composed of interlinked titanium beads with magnetic cores has been developed for the treatment of 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. The LINX™ Reflux Management System (Torax Medical) 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 for use of this device is patients who have GERD symptoms despite maximum medical therapy (e.g., proton pump inhibitors), but who do not want to risk the adverse effects (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 website, a new version of LINX® considered Magnetic Resonance (MR) Conditional in a magnetic resonance imaging (MRI) system up to 1.5 Tesla (1.5T) is available. 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 an MRI above 1.5 Tesla (1.5T) is required and alternative diagnostic procedures cannot be used, the LINX® device can be removed.

RATIONALE

The LINX™ Reflux Management System was approved by the U.S. Food and Drug Administration (FDA) in 2012. The LINX™ device is indicated for patients diagnosed with GERD, as defined by abnormal pH testing, and who continue to have chronic GERD symptoms despite maximum therapy for the treatment of reflux. The FDA has required 5-year follow-up of 100 patients from the investigational device exemption (IDE) pivotal study to evaluate safety and efficacy of the device.

Data submitted to the U.S. Food and Drug Administration (FDA) for the LINX® Reflux Management System included two (2) single-arm FDA-regulated investigational device exemption (IDE) trials with a total of 144 subjects and follow-up data between two (2) and four (4) years. The feasibility IDE study enrolled 44 subjects at four (4) clinical sites (2 U.S. and 2 Europe) and has published data out to four (4) years. (Bonavina, et al. 2010, Lipham, et al. 2012) The pivotal IDE study included 100 subjects from 14 clinical sites (13 U.S. and 1 Europe) who had documented symptoms of GERD for longer than six (6) 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 (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 (SAEs). Efficacy endpoints were assessed off PPI therapy and measured esophageal acid exposure, total GERD-Health Related Quality of LIFE (HRQL) scores, and PPI usage. Subjects served as their own controls. A total of 24/44 (54.5%) subjects in the feasibility study experienced adverse events related to the device and/or procedure, and two (2) 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 6% (8/144) of subjects. Most cases of dysphagia 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 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 (1) of the four (4) 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 this 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 postoperatively, in 11% at one (1) year, and in 4% at three (3) years. Nineteen patients underwent esophageal dilation for dysphagia. Six patients (6%) experienced a serious adverse event (SAE) including severe dysphagia and vomiting. The device was removed in four (4) of these six (6) patients with a SAE and in two (2) additional patients for persistent reflux and chest pain.

In a 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–Health-Related Quality of Life (GERD-HRQL) questionnaire. At six (6) 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 6-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–health-related quality of life 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 (6) months. No significant safety issues were observed. In MSA patients, 28% reported transient dysphagia; 4% reported ongoing dysphagia. The authors conclude 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 (3) and seven (7) observational cohort studies respectively were included for review corresponding to 688 patients and 1211 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 include the exclusion of randomized controlled trials and short follow-up periods of the included studies.

In 2018, Louie, et al. reported 1-year outcomes from the 5-year FDA mandated study of the safety and effectiveness of magnetic sphincter augmentation (MSA) with the LINX Reflux Management System. A total of 200 patients were treated with MSA in a multicenter, 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 Health-Related Quality of Life (GERD-HRQL) score was achieved by 84.3% of patients at one (1) 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 (1) year was 2.5%. One erosion and no serious adverse events were reported. The authors conclude magnetic sphincter augmentation 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 3283 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 (4) 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). They concluded that longer-term (3-5 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 the LINX is a reasonable treatment option for appropriately selected patients with GERD who meet indications for antireflux surgery, however it should be performed by surgeons familiar with the workup and different management alternatives of GERD and not offered in isolation. Finally, they recommend implantation of the LINX device should be covered and reimbursed by insurance for appropriate patients who meet the selection criteria.

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, 2017) found no major safety concerns. They stated 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

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 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 Local Coverage Determination (LCD) addressing Select Minimally Invasive GERD Procedures. Please refer to the following website for Medicare Members:

https://www.cms.gov/medicare-coverage-database/details/lcd-details.aspx?LCDId=35080&ver=30&SearchType=Advanced&CoverageSelection=Both&NCSelection=NCA%7cCAL%7cNCD%7cMEDCAC%7cTA%7cMCD&ArticleType=SAD%7cEd&PolicyType=Both&s=41&KeyWord=magnetic+sphincter+augmentation+LINX&KeyWordLookUp=Doc&KeyWordSearchType=Or&kq=true&bc=IAAAACAAAAAA&