MEDICAL POLICY

Excellus
A nonprofit independent licensee of the Blue Cross Blue Shield Association

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**
Revised Effective Date	**02/18/21, 02/17/22**
Archived Date	**N/A**
Archive Review Date	**N/A**
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 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 guidelines (eMedNY)criteria, 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 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 appropriat**e treatment option in the management of GERD, when **ALL** of 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.
   B. GERD symptoms occur two or more times per week.
   C. The treatment is used as an alternative to surgical fundoplication.

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**.

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.

DESCRIPTION

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 indefinite, possibly lifelong, use of medications. Surgical treatments are available for these patients, primarily a Nissen fundoplication, which is the current gold standard and 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.

The 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 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 LINX Reflux Management System is being 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.

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 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.

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, 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.

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

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

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

REFERENCES

Aiolfi A, et al. Early results of magnetic sphincter augmentation versus fundoplication for gastroesophageal reflux disease: systematic review and meta-analysis. Int J Surg 2018 Apr;52:82-88.

Alicuben ET, et al. Regression of intestinal metaplasia following magnetic sphincter augmentation device placement. Surg Endosc 2018 Jul 25. [Epub ahead of print]

Alicuben ET, et al. Worldwide experience with erosion of the magnetic sphincter augmentation device. J Gastrointest Surg 2018 Aug;22(8):1442-1447.

ASGE Technology Committee. Magnets in the GI tract. Gastrointest Endosc 2013 Oct;78(4):561-7.

Asti E, et al. Longitudinal comparison of quality of life in patients undergoing laparoscopic Toupet fundoplication versus magnetic sphincter augmentation: observational cohort study with propensity score analysis. Medicine 2016 July;95(30):e4366.

Ayazi S, et al. Magnetic sphincter augmentation and postoperative dysphagia: characterization, clinical risk factors, and management. Journal of Gastrointestinal Surgery 2019 Aug; 10.1007/s11605-019-04331-9.

*Bell R, et al. Laparoscopic magnetic sphincter augmentation versus double-dose proton pump inhibitors for management of moderate-to-severe regurgitation in GERD: a randomized controlled trial. Gastrointest Endosc 2018 Jul 18. pii: S0016-5107(18)32848-7. [Epub ahead of print]

Bell R, et al. Magnetic sphincter augmentation superior to proton pump inhibitors for regurgitation in a 1-year randomized trial. Clin Gastroenterol Hepatol. 2020 Jul;18(8):1736-1743.

*Bonavina L, et al. Magnetic augmentation of the lower esophageal sphincter: results of a feasibility clinical trial. J Gastrointest Surg 2008 Dec;12(12):2133-40.

*Bonavina L, et al. Laparoscopic sphincter augmentation device eliminates reflux symptoms and normalizes esophageal acid exposure: one-and 2-year results of a feasibility trial. Ann Surg 2010 Nov;252(5):857-62.

Bonavina L, et al. One hundred consecutive patients treated with magnetic sphincter augmentation for gastroesophageal reflux disease: 6 years of clinical experience from a single center. J Am Coll Surg 2013 Oct;217(4):577-85.

Buckley FP 3rd, et al. Favorable results from a prospective evaluation of 200 patients with large hiatal hernias undergoing LINX magnetic sphincter augmentation. Surg Endosc 2018 Apr;32(4):1762-1768.

Chen MY, et al. Efficacy of magnetic sphincter augmentation versus Nissen fundoplication for gastroesophageal reflux disease in short term: a meta-analysis. Can J Gastroenterol Hepatol 2017;2017:9596342.

Czosnyka NM, et al. Outcomes of magnetic sphincter augmentation- A community hospital perspective. Am J Surg 2017 June;213(6):1019-1023.

Desart K, et al. Gastroesophageal reflux management with the LINX® System for gastroesophageal reflux disease following laparoscopic sleeve gastrectomy. J Gastrointest Surg 2015 Oct;19(10):1782-6.

Ferrari, D., et al. Six to 12-year outcomes of magnetic sphincter augmentation for gastroesophageal reflux disease. Sci Rep 10, 13753 (2020).

Ganz RA, et al. Esophageal sphincter device for gastroesophageal reflux disease. N Engl J Med 2013 Feb 21;368(8):719-27.

Ganz RA, et al. Long-term outcomes of patients receiving a magnetic sphincter augmentation device for gastroesophageal reflux. Clin Gastroenterol Hepatol 2016 May;14(5):671-677.

Hawalsli A, et al. Laparoscopic placement of the LINX system in management of severe reflux after sleeve gastrectomy. The American Journal of Surgery 2019 Mar;NY Vol. 217 Issue:496-499.

Katz, PO, et al. Guidelines for the diagnosis and management of gastroesophageal reflux disease. Am J Gastroenterol 2013 Mar;108(3):308-328.

Laird J. Magnetic sphincter augmentation device placement for treatment of gastroesophageal reflux. JAAPA. 2020 Dec;33(12):30-32.

Leeds, S.G., et al. The role of preoperative workup in predicting dysphagia, dilation, or explantation after magnetic sphincter augmentation. Surg Endosc 34, 3663–3668 (2020).

Lipham JC, et al. The LINX® reflux management system: confirmed safety and efficacy now at 4 years. Surg Endosc 2012 Oct;26(10):2944-9.

Lipham JC, et al. Safety analysis of first 1000 patients treated with magnetic sphincter augmentation for gastroesophageal reflux disease. Dis Esophagus 2015 May-Jun;28(4):305-11.

Louie BE, et al. Short-term outcomes using magnetic sphincter augmentation versus Nissen fundoplication for medically resistant gastroesophageal reflux disease. Ann Thorac Surg 2014 Aug;98(2):498-504.

Louie BE, et al. Objective evidence of reflux control after magnetic sphincter augmentation: one year results from a post approval study. Ann Surg 2019 Aug;270(2):302-308.

National Institute for Health and Care Excellence (NICE). Laparoscopic insertion of a magnetic titanium ring for gastro-oesophageal reflux disease. IPG 585. 26 July 2017 [https://www.nice.org.uk/guidance/ipg585/resources/laparoscopic-insertion-of-a-magnetic-titanium-ring-for-gastrooesophageal-reflux-disease-pdf-1899872170337221] accessed 01/13/2022.

Rettura F, et al. Refractory gastroesophageal reflux disease: A management update. Front Med (Lausanne). 2021 Nov 1;8:765061.

Reynolds JL, et al. Magnetic sphincter augmentation with the LINX device for gastroesophageal reflux disease after U.S. Food and Drug Administration approval. Am Surg 2014 Oct;80(10):1034-8.

Reynolds JL, et al. Laparoscopic magnetic sphincter augmentation vs laparoscopic Nissen fundoplication: A matched-pair analysis of 100 patients. J Am Coll Surg 2015 Jul;221(1):123-8.

Reynolds JL, et al. Charges, outcomes, and complications: a comparison of magnetic sphincter augmentation versus laparoscopic Nissen fundoplication for the treatment of GERD. Surg Endosc 2016 Aug;30(8):3225-3230.

Riegler M, et al. Magnetic sphincter augmentation and fundoplication for GERD in clinical practice: one-year results of a multicenter, prospective observational study. Surg Endosc May 2015;29(5):1123-9.

Riva CG, et al. Magnetic sphincter augmentation after gastric surgery. Journal of Society of Laparoendoscopic Surgeons 2019 Oct-Dec;23(4):e2019.00035.

Rona KA, et al. Efficacy of magnetic sphincter augmentation in patients with large hiatal hernias. Surg Endosc 2017 May;31(5):2096-2102.

SAGES Society of American Gastrointestinal and Endoscopic Surgeons. TAVAC Safety and effectiveness Analysis: LINX® Reflux Management System. [https://www.sages.org/publications/tavac/tavac-safety-and-effectiveness-analysis-linx-reflux-management-system] accessed 01/13/22.

Saino G, et al. Magnetic sphincter augmentation for gastroesophageal reflux at 5 years: Final results of a pilot study show long-term acid reduction and symptom improvement. J Laparoendosc Adv Surg Tech A 2015 Oct;25(10):787-92.

Schizas D, et al. et al. LINX® reflux management system to bridge the "treatment gap" in gastroesophageal reflux disease: A systematic review of 35 studies. World J Clin Cases. 2020;8(2):294-305.

Schwameis K, et al. Modern GERD treatment: feasibility of minimally invasive esophageal sphincter augmentation. Anticancer Res 2014 May;34(5):2341-5.

Schwameis K, et al. Efficacy of magnetic sphincter augmentation across the spectrum of GERD disease severity. J Am Coll Surg. 2020 Dec 30:S1072-7515(20)32518-7. Published head of print.

Sheu EG, et al. A comparative trial of laparoscopic magnetic sphincter augmentation and Nissen fundoplication. Surg Endosc 2015 Mar;29(3):505-9.

Skubleny D, et al. LINX® magnetic esophageal sphincter augmentation versus Nissen fundoplication for gastroesophageal reflux disease: a systematic review and meta-analysis. Surg Endosco 2017 Aug;31(8):3078-3084.

Smith CD, et al. Introduction of mechanical sphincter augmentation for gastroesophageal reflux disease into practice: early clinical outcomes and keys to successful adoption. J Am Coll Surg 2014 April;218(4):776-781.

Smith CD, et al. Lower esophageal sphincter augmentation for gastroesophageal reflux disease: the safety of a modern implant. J Laparoendosc Adv Surg Tech A 2017 June;27(6):586-591.

Tatum JM, et al. Removing the magnetic sphincter augmentation device: operative management and outcomes. Surgical Endoscopy 2019;33:2663–2669.

The American Society of General Surgeons. LINX Statement of Support from ASGS. 2014 [https://theasgs.org/position-statements/linx-statement-of-support-from-asgs] accessed 01/13/2022.

Warren HF, et al. Multi-institutional outcomes using magnetic sphincter augmentation versus Nissen fundoplication for chronic gastroesophageal reflux disease. Surg Endosc 2016 Aug;30(8):3289-3296.

Warren HF, et al. Manometric changes to the lower esophageal sphincter after magnetic sphincter augmentation in patients with chronic gastroesophageal reflux disease. Ann Surg 2017 July;266(1):99-104.

Warren HF, et al. Factors influencing the outcome of magnetic sphincter augmentation for chronic gastroesophageal reflux disease. Surg Endosc 2018 Jan;32(1):405-412.

Zhang H, et al. revaluation of the efficacy of magnetic sphincter augmentation for treating gastroesophageal reflux disease. Surg Endosc 2016 Sept;30(9):3684-3690.

*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=38757&ContrId=297&ver=6&ContrVer=1&CntrctrSelected=297*1&Cntrctr=297&name=&DocType=5&bc=AAAAAACAAAAA&