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MEDICAL POLICY – 7.01.137

Magnetic Esophageal Sphincter Augmentation to Treat Gastroesophageal Reflux Disease

BCBSA Ref. Policy:	7.01.137
Effective Date:	Feb. 1, 2025
Last Revised:	Jan. 13, 2025
Replaces:	N/A

RELATED MEDICAL POLICIES:

2.01.38	Transesophageal Endoscopic Therapies for Gastroesophageal Reflux Disease
2.01.91	Peroral Endoscopic Myotomy for Treatment of Esophageal Achalasia

Select a hyperlink below to be directed to that section.

POLICY CRITERIA | CODING | RELATED INFORMATION
EVIDENCE REVIEW | REFERENCES | HISTORY

Clicking this icon returns you to the hyperlinks menu above.

Introduction

GERD — gastroesophageal reflux disease — is a long-term medical condition. It's a digestive problem that affects the ring of muscles between the esophagus (the tube that carries swallowed food to the stomach) and the stomach. When food is swallowed, the muscles at the end of the esophagus open so food can pass into the stomach. The muscles then close to prevent acid from backing up into the esophagus. In GERD, however, the ring of muscles is too weak. GERD is usually treated with changes to lifestyle and diet. A number of other treatments have been studied. One technique calls for placing a ring of magnetic beads around the base of the esophagus, just above the stomach. The ring opens to allow swallowed food into the stomach and then immediately tightens. This technique is investigational (unproven). More and longer studies are needed to find out how well such devices work.

Note: The Introduction section is for your general knowledge and is not to be taken as policy coverage criteria. The rest of the policy uses specific words and concepts familiar to medical professionals. It is intended for providers. A provider can be a person, such as a doctor, nurse, psychologist, or dentist. A provider also can be a place where medical care is given, like a hospital, clinic, or lab. This policy informs them about when a service may be covered.

Policy Coverage Criteria

Service	Investigational
Magnetic esophageal sphincter augmentation	**Magnetic esophageal sphincter augmentation to treat gastroesophageal reflux disease is considered investigational.** **Note:** Commercially available esophageal sphincter augmentation device: The LINX Reflux Management System (Torax Medical)

Coding

Code	Description
CPT	
43284	Laparoscopy, surgical, esophageal sphincter augmentation procedure, placement of sphincter augmentation device (i.e., magnetic band), including cruroplasty when performed
43285	Removal of esophageal sphincter augmentation device

Note: CPT codes, descriptions and materials are copyrighted by the American Medical Association (AMA). HCPCS codes, descriptions and materials are copyrighted by Centers for Medicare Services (CMS).

Related Information

N/A

Evidence Review

Description

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 individuals who have GERD symptoms, despite maximal medical therapy.

Background

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.

Treatment

For individuals with severe disease, chronic treatment with acid blockers is an option. For some individuals, medications are inadequate to control symptoms; other individuals prefer to avoid the use of indefinite, possibly lifelong medications. Surgical treatments are available for these individuals, 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 (see **Related Policies**).

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. Magnetic sphincter augmentation is a 30-minute surgical procedure performed under general anesthesia that includes testing of the esophageal sphincter. This is a minimally invasive procedure conducted in an inpatient surgical center and requires an overnight stay. The device manufacturer claims individuals resume a normal diet within 24 hours post-surgery. Resonance imaging is needed for another condition. The device can be removed by a laparoscopic

procedure if severe adverse events occur or if magnetic resonance imaging is needed for another condition.

Summary of Evidence

For individuals who have GERD who receive magnetic esophageal sphincter augmentation (MSA), the evidence includes one RCT comparing MSA to proton pump inhibitor (PPI) therapy, four nonrandomized studies comparing MSA to laparoscopic Nissen fundoplication (LNF), laparoscopic Toupet fundoplication (LTF), or anti-reflex mucosectomy (ARM), single-arm cohort studies, and systematic reviews comparing MSA to LNF. Relevant outcomes are symptoms, change in disease status, medication use, and treatment-related morbidity. An RCT comparing MSA to omeprazole 20 mg twice daily found significantly more patients who received MSA reported improvements in symptoms and GERD-related quality of life (QOL) at six months. A major limitation of the trial was that the patients had not received optimal medical treatment prior to enrollment. Four non-randomized comparative studies of MSA to laparoscopic fundoplication showed mixed outcomes, with some studies indicating similar improvements in QOL, PPI use, and satisfaction, while others reported no significant differences in symptom improvement but a higher rate of dysphagia in the MSA group, and another study observed transient differences in favor of fundoplication in QOL, with the MSA group having worse QOL scores at final follow-up. Limitations in these comparative studies included a lack of randomization, blinding, heterogeneity in surgical techniques, outdated MSA protocols, imbalanced baseline patient characteristics, and selection bias in treatment choice. In the two single-arm, uncontrolled pivotal trials submitted to the FDA with materials for device approval, subjects showed improvements in GERD-health related QOL (GERD-HRQL) scores and reduced PPI use. Similarly, observational comparative studies included in systematic reviews, 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 PPI use after MSA. However, the comparative studies are retrospective and nonrandomized, and may be affected by selection bias. Randomized comparisons of MSA with LNF are needed to evaluate the relative risk-benefit of these two procedures. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Ongoing and Unpublished Clinical Trials

Some ongoing and unpublished trials that might influence this policy are listed in **Table 1**.

Table 1. Summary of Key Trials

NCT No.	Trial Name	Planned Enrollment	Completion Date
Ongoing			
NCT05238636	The Effect of Anti-reflux Procedures (Stretta, LINX, and Fundoplication) on Physiological Parameters Contributing to Symptom Resolution in Adults With Gastro-oesophageal Reflux at a Single UK Tertiary Centre (GASP)	60	Jan 2024 (recruiting)
NCT02923362	Registry of Outcomes From AntiReflux Surgery (ROARS)	2500	May 2025 (Active, not recruiting)
NCT04695171	Cohort Registry on LINX Reflux Management System or Fundoplication Clinical Study in Patients With Hiatal Hernia >3 cm	450	Jan 2028 (recruiting)
NCT04253392[a]	RETHINK REFLUX Registry (RETHINK REFLUX)	500	July 2032 (Active, not recruiting)
Unpublished			
NCT02429830[a]	RELIEF Study: A Prospective, Multicenter Study of REflux Management With the LINX System for Gastroesophageal REFlux Disease After Laparoscopic Sleeve Gastrectomy	30	Jun 2021 (completed)
NCT01940185[a]	A Post-Approval Study of the Lynx Reflux Management System	200	Oct 2025 (completed)

NCT: national clinical trial

[a] Denotes industry-sponsored or cosponsored trial

Practice Guidelines and Position Statements

The purpose of the following information is to provide reference material. Inclusion does not imply endorsement or alignment with the policy conclusions.

Guidelines or position statements will be considered for inclusion if they were issued by, or jointly by, a US professional society, an international society with US representation, or National

Institute for Health and Care Excellence (NICE). Priority will be given to guidelines that are informed by a systematic review, include strength of evidence ratings, and include a description of management of conflict of interest.

American College of Gastroenterology

In January 2022, the American College of Gastroenterology (ACG) published a clinical guideline on the diagnosis and management of GERD.[40] Relevant recommendations concerning surgical management of refractory GERD include:

- "For patients who have regurgitation as their primary PPI [proton pump inhibitor]-refractory symptom and who have had abnormal gastroesophageal reflux documented by objective testing, we suggest consideration of antireflux surgery or TIF [transoral incisionless fundoplication] (conditional recommendation; low level of evidence).
- We recommend antireflux surgery performed by an experienced surgeon as an option for long-term treatment of patients with objective evidence of GERD, especially those who have severe reflux esophagitis (LA grade C or D), large hiatal hernias, and/or persistent, troublesome GERD symptoms (strong recommendation; moderate level of evidence).
- We recommend consideration of MSA as an alternative to laparoscopic fundoplication for patients with regurgitation who fail medical management (strong recommendation; moderate level of evidence)."

The guideline also notes that due to the paucity of long-term data on MSA outcomes and lack of randomized trials directly comparing MSA with fundoplication, "it is difficult to recommend one over the other at this time."

American Foregut Society

The American Foregut Society (AFS) issued a statement on appropriate patient selection and use of MSA, and noted that "patient selection criteria for MSA do not differ in principle from those of any other surgical procedure for reflux disease." Indications for MSA include:[41]

- "Typical GERD symptoms (i.e., heartburn, regurgitation) with break-through symptoms, intolerance to medical therapy, and/or unwillingness to take anti-reflux medications long term.

- Regurgitation despite optimized medical therapy and lifestyle modification.
- Extraesophageal symptoms with objective evidence of significant reflux disease (i.e., endoscopic evidence of [Los Angeles] Class C or D esophagitis, Barrett's esophagus or positive pH study."

The statement additionally notes that "MSA candidacy largely mirrors that for laparoscopic fundoplication. Low dysphagia rates for MSA have been found when performed in patients with normal esophageal motility." The AFS also recommends that a full hiatal dissection and cruroplasty be performed prior to implantation of an MSA device.

The AFS Bariatric Committee also issued a statement regarding the concurrent use of MSA at the time of primary bariatric surgery,[42] noting that this practice "violates many basic surgical principles and is not considered judicious use by the American Foregut Society." The statement also notes that prospective trials demonstrating the safety and efficacy of concurrent MSA are needed.

American Gastroenterological Association

The American Gastroenterological Association (AGA) issued a statement on the personalized approach to evaluating and managing individuals with GERD in 2022.[43,] The authors provided a best practice recommendation: "In patients with proven GERD, laparoscopic fundoplication and magnetic sphincter augmentation are effective surgical options, and transoral incisionless fundoplication is an effective endoscopic option in carefully selected patients."

Multi-society Consensus Conference

A multi-society consensus guideline on the treatment of GERD was issued by the Society of American Gastrointestinal and Endoscopic Surgeons (SAGES), American Society for Gastrointestinal Endoscopy (ASGE), American Society for Metabolic and Bariatric Surgery (ASMBS), European Association for Endoscopic Surgery (EAES), Society for Surgery of the Alimentary Tract (SSAT), and the Society of Thoracic Surgeons (STS) in 2023.[44] Based on a review of the available evidence the consensus panel determined the following recommendations:

- 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. (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. (Conditional recommendation based on moderate certainty of evidence)

National Institute for Health and Care Excellence

In 2023, the NICE issued an interventional procedure guidance on laparoscopic insertion of a magnetic ring for GERD.[45] The following recommendations were based on a comprehensive literature search and review:

- "Evidence on the safety and efficacy of laparoscopic insertion of a magnetic ring for GERD is adequate to support using this procedure provided that standard arrangements are in place for clinical governance, consent, and audit."
- "Patient selection and the procedure should be done by clinicians who have specific training in the procedure and experience in upper gastrointestinal laparoscopic surgery and managing GERD."

Medicare National Coverage

There is no national coverage determination.

Regulatory Status

In 2012, the LINX Reflux Management System (Ethicon; Torax Medical) was approved by the US Food and Drug Administration (FDA) through the premarket approval process (P100049) for individuals 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 FDA initially required a 5-year follow-up of 100 individuals from the investigational device exemption pivotal study to evaluate the safety and efficacy of the device, which was completed in March 2016. In 2018, the manufacturer initiated a device recall due to a possible separation of the bead component with the adjacent wire link causing a potential discontinuous or open LINX device.[1] This recall was terminated on November 4, 2020. FDA product code: LEI.

In March 2018, the FDA approved an update of the LINX Reflux Management System precautions statement, 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."[2]

In February 2024, the FDA revised the labeling for the LINX Reflux Management System. They removed a precautionary statement about Barrett's Esophagus (BE) from the instructions for use. However, the updated labeling now includes this guidance: "LINX has not been proven to effectively treat BE by causing regression or preventing progression to cancer. Patients with BE who use LINX to manage GERD symptoms should consult their physician about ongoing BE treatment, which may include continued use of proton pump inhibitors (PPIs)."[3]

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History

Date	Comments
10/15/12	New Policy. Policy created with literature review through June 2012; considered investigational.
10/14/13	Replace policy. Policy updated with literature review through July 1, 2013; reference 4 added; policy statement unchanged.
11/20/13	Update Related Policies. Add 2.01.91.
01/30/14	Update Related Policies. Change title to 2.01.38.
11/20/14	Annual Review. Policy updated with literature review through July 15, 2014. Added information about locations of 2 regional centers involved in relevant clinical trials. References 5-9 added; others renumbered. Policy statement unchanged.
10/13/15	Annual Review. Policy updated with literature review through July 6, 2015; references 1, 4, and 9 added. Policy statement unchanged. Deleted HCPCS code C9737 removed.
01/28/16	Minor update. Added CPT codes 0392T and 0393T, effective 7/1/15, to the coding table.
11/08/16	Annual review. Policy title changed to "Magnetic Esophageal Sphincter Augmentation to Treat Gastroesophageal Reflux Disease", and throughout the policy for the procedure, to match the CPT code descriptions. Policy updated with literature review through September, 2016; references added. Coding update; added CPT 43284 and 43285. Policy statement unchanged.
01/01/17	Minor Coding update; added note that CPT codes 43284 and 43285 are new codes effective 1/1/17.
06/09/17	Coding update; removed CPT codes 0392T and 0393T as they were terminated as of 1/1/17.
01/01/18	Annual Review, approved December 6, 2017. Policy updated with literature review through September 2017; no references added; references 7 and 19 updated. Policy statement unchanged. Removed CPT code 43289.

Date	Comments
12/01/18	Annual Review, approved November 21, 2018. Policy updated with literature review; no references added. Policy statement unchanged.
02/01/19	Annual Review, approved January 4, 2019. Policy updated with literature review through September 2018; no references added. Policy statement unchanged.
02/01/20	Annual Review, approved January 9, 2020. Policy updated with literature review through October 2019; references added. Policy statement unchanged.
02/01/21	Annual Review, approved January 6, 2021. Policy updated with literature review through September 17, 2020; references added. Policy statement unchanged.
02/01/22	Annual Review, approved January 10, 2022. Policy updated with literature review through October 12, 2021; references added. Policy statement unchanged.
02/01/23	Annual Review, approved January 9, 2023. Policy updated with literature review through October 14, 2022; references added. Policy statement unchanged. Changed the wording from "patient" to "individual" throughout the policy for standardization.
02/01/25	Annual Review, approved January 13, 2025. Policy updated with literature review through September 23, 2024; references added. Policy statement unchanged.

Scope: Medical policies are systematically developed guidelines that serve as a resource for Company staff when determining coverage for specific medical procedures, drugs or devices. Coverage for medical services is subject to the limits and conditions of the member benefit plan. Members and their providers should consult the member benefit booklet or contact a customer service representative to determine whether there are any benefit limitations applicable to this service or supply. This medical policy does not apply to Medicare Advantage.