BlueCross BlueShield Federal Employee Program.

FEP Medical Policy Manual

FEP 7.01.137 Magnetic Esophageal Sphincter Augmentation to Treat Gastroesophageal Reflux Disease

Annual Effective Policy Date: April 1, 2026

Original Policy Date: December 2012

Related Policies:

None

Magnetic Esophageal Sphincter Augmentation to Treat Gastroesophageal Reflux Disease

Description

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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 patients who have GERD symptoms, despite maximal medical therapy.

OBJECTIVE

The objective of this evidence review is to determine the efficacy of magnetic sphincter augmentation in the treatment of gastroesophageal reflux disease compared with alternative treatments.

POLICY STATEMENT

Magnetic esophageal sphincter augmentation to treat gastroesophageal reflux disease is **investigational**.

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POLICY GUIDELINES

None

BENEFIT APPLICATION

Experimental or investigational procedures, treatments, drugs, or devices are not covered (See General Exclusion Section of brochure).

FDA REGULATORY STATUS

In 2012, the LINX Reflux Management System (Ethicon; formerly Torax Medical) was approved by the U.S. Food and Drug Administration (FDA) through the premarket approval process (P100049) for patients 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 patients 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,]

RATIONALE

Summary of Evidence

For individuals who have GERD who receive magnetic esophageal sphincter augmentation (MSA), the evidence includes 1 randomized controlled trial (RCT) comparing MSA to proton pump inhibitor (PPI) therapy, 6 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 that significantly more patients who received MSA reported improvements in symptoms and quality of life (QOL) at 6 months. A major limitation of the trial was that the patients had not received optimal medical treatment prior to enrollment. Six 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 quality of life 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 2 single-arm, uncontrolled pivotal trials submitted to the FDA with materials for device approval, subjects showed improvements in 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 2 procedures. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

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SUPPLEMENTAL INFORMATION

Practice Guidelines and Position Statements

Guidelines or position statements will be considered for inclusion in 'Supplemental Information' 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.[41,] 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 [magnetic esophageal sphincter augmentation] 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:[42,]

- "Typical GERD symptoms (ie, 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 (ie, 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,[43,] 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.[44,] 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."

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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.[45,] 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.[46,] 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."

U.S. Preventive Services Task Force Recommendations

Not applicable.

Medicare National Coverage

There is no national coverage determination. In the absence of a national coverage determination, coverage decisions are left to the discretion of local Medicare carriers.

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POLICY HISTORY - THIS POLICY WAS APPROVED BY THE FEP® PHARMACY AND MEDICAL POLICY COMMITTEE ACCORDING TO THE HISTORY BELOW:

Date	Action	Description
December 2012	New policy	Policy created with literature review; considered not medically necessary.
December 2013	Replace policy	Policy updated with literature review; reference 4 added; policy statement unchanged.
December 2014	Replace policy	Policy updated with literature review, references 5-9 added; policy statement unchanged.
December 2015	Replace policy	Policy updated with literature review, references 1, 4, and 9 added. Policy statement unchanged.
March 2017	Replace policy	Policy updated with literature review through October 4, 2016; references 1- 2, 11-12, and 15-18 added. "Magnetic esophageal ring, changed to "magnetic sphincter augmentation, in policy statement; policy statement otherwise unchanged; title changed to "Magnetic Esophageal Sphincter Augmentation to Treat Gastroesophageal Reflux Disease,.
March 2018	Replace policy	Policy updated with literature review through September 11, 2017; no references added; references 7 and 19 updated. Policy statement unchanged.
March 2019	Replace policy	Policy updated with literature review through September 14, 2018; no references added. Policy statement unchanged.
March 2020	Replace policy	Policy updated with literature review through October 8, 2019; references added. Policy statement unchanged
March 2021	Replace policy	Policy updated with literature review through September 17, 2020; references added. Policy statement unchanged.
March 2022	Replace policy	Policy updated with literature review through October 12, 2021; references added. Policy statement unchanged.
March 2023	Replace policy	Policy updated with literature review through October 14, 2022; references added. Policy statement unchanged.
December 2024	Replace policy	Policy updated with literature review through September 13, 2023; references added. Policy statement unchanged.
March 2025	Replace policy	Policy updated with literature review through September 23, 2024; references added. Policy statement unchanged.
March 2026	Replace policy	Policy updated with literature review through September 24, 2025; references added. Policy statement unchanged.

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