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FEP Medical Policy Manual

FEP 7.01.137 Magnetic Esophageal Sphincter Augmentation to Treat Gastroesophageal Reflux Disease

Effective Policy Date: April 1, 2022

Original Policy Date: December 2012

Related Policies:

None

Magnetic Esophageal Sphincter Augmentation to Treat Gastroesophageal Reflux Disease

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 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**.

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 (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,]

For individuals who have gastroesophageal reflux disease (GERD) who receive magnetic sphincter augmentation (MSA), the evidence includes 1 randomized controlled trial (RCT) comparing MSA to proton pump inhibitor (PPI) therapy, a single nonrandomized registry study comparing MSA to laparoscopic fundoplication, single-arm cohort studies, and systematic reviews of observational studies comparing MSA to laparoscopic Nissen fundoplication (LNF_. Relevant outcomes are symptoms, change in disease status, medication use, and treatment-related morbidity. A RCT comparing MSA to omeprazole 20 mg twice daily found 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. A prospective, observational registry study comparing MSA to laparoscopic fundoplication found similar improvements in QOL, satisfaction, and medication use. Limitations of the study included lack of randomization and blinding, heterogeneity in fundoplication techniques, use of an outdated MSA protocol, and selection bias as patients with less severe symptoms received MSA. In the 2 single-arm, uncontrolled pivotal trials submitted to the FDA with materials for device approval, subjects showed improvements in GERD-health-related QOL scores and reduced PPI use. Similarly, observational comparative studies included in systematic reviews, most often comparing MSA with LNF, generally have shown that GERD-health-related QOL 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.

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.

Society of American Gastrointestinal and Endoscopic Surgeons

The Society of American Gastrointestinal and Endoscopic Surgeons (SAGES, 2013; updated in 2017) published a Technology and Value Assessment Committee (TAVAC) analysis on the safety and effectiveness of the LINX Reflux Management System.[23.] The SAGES indicated that safety analyses of the LINX system suggested the procedure is associated with few serious adverse events and no reported mortality, and that currently available data demonstrated a reasonable assurance as to the efficacy of the system. The report concluded that direct comparative studies between the LINX procedure and Nissen fundoplication would be needed, although, based on the available evidence, the LINX device should be an option available to patients and providers for the management of medically refractory GERD.

In April 2021, guidelines for the surgical treatment of GERD were reviewed and approved by the Board of Governors of the SAGES based on a systematic review of the evidence.[24.] Key questions presented in these guidelines do not address the use of MSA.

National Institute for Health and Care Excellence

In July 2017, the National Institute for Health and Care Excellence (NICE) issued an interventional procedures guidance on laparoscopic insertion of a magnetic titanium ring for GERD.[25.] While the recommendations conclude that there are no major safety concerns with the device, they note limited evidence of short-term efficacy with inadequate quality and quantity of evidence for long-term efficacy. Accordingly, "this procedure should only be used with special arrangements for clinical governance, consent, and audit or research," and note that "long-term outcome data and comparative trials with other anti-reflux surgery would be helpful."

- 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,[27,] 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 Society for Gastrointestinal Endoscopy

In 2013, a report from the American Society for Gastrointestinal Endoscopy concluded that long-term data on the safety and efficacy of the LINX device were needed.[28,] The document indicated that the LINX band is currently being deployed laparoscopically; however, a natural orifice transluminal endoscopic surgery approach could be explored.

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.

Date	Action	Description
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.