



FEP Medical Policy Manual

FEP 7.01.137 Magnetic Esophageal Sphincter Augmentation to Treat Gastroesophageal Reflux Disease

Effective Policy Date: April 1, 2021

Related Policies:

None

Original Policy Date: December 2012

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 **not medically necessary**.

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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 (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 FDA product code: LEI.

RATIONALE

Summary of Evidence

For individuals who have gastroesophageal reflux disease (GERD) who receive magnetic sphincter augmentation (MSA), the evidence includes one randomized controlled trial comparing MSA to proton pump inhibitor therapy, single-arm cohort studies, and systematic reviews of observational studies comparing MSA to laparoscopic Nissen fundoplication. Relevant outcomes are symptoms, change in disease status, medication use, and treatment-related morbidity. A randomized controlled trial comparing MSA to omeprazole 20 mg twice daily found significantly more patients who received MSA reported improvements in symptoms and quality of life at 6 months. A major limitation of the trial was that the patients had not received optimal medical treatment prior to enrollment. In the 2 single-arm, uncontrolled pivotal trials submitted to the U.S. Food and Drug Administration with materials for device approval, subjects showed improvements in GERD-health-related quality of life scores and reduced proton pump inhibitor use. Similarly, observational comparative studies included in systematic reviews, most often comparing MSA with laparoscopic Nissen fundoplication, generally have shown that GERD-health-related quality of life scores do not differ significantly between fundoplication and MSA, and patients can reduce proton pump inhibitor use after MSA. However, the comparative studies are retrospective and nonrandomized, and may be affected by selection bias. Randomized comparisons of MSA with laparoscopic Nissen fundoplication are needed to evaluate the relative risk-benefit of these 2 procedures. The evidence is insufficient to determine the effects of the technology on health outcomes.

SUPPLEMENTAL INFORMATION

Practice Guidelines and Position Statements

Society of American Gastrointestinal and Endoscopic Surgeons

The Society of American Gastrointestinal and Endoscopic Surgeons (SAGES, 2013; updated in 2017) published guidelines on the safety and effectiveness of the LINX Reflux Management System.¹⁵ 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 guidelines concluded that direct comparative studies

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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 gastroesophageal reflux disease.

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.¹⁶ 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.

REFERENCES

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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.

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