FEP 7.01.137 Magnetic Esophageal Sphincter Augmentation to Treat Gastroesophageal Reflux Disease

Effective Date: April 15, 2018

Related Policies:
2.01.38 Transesophageal Endoscopic Therapies for Gastroesophageal Reflux Disease

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.

FDA REGULATORY STATUS

In 2012, the LINX™ Reflux Management System (Torax Medical, Shoreview, MN) was approved by the U.S. Food and Drug Administration through the premarket approval process 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 Food and Drug Administration initially required 5-year follow-up of 100 patients from the investigational device exemption pivotal study to evaluate safety and efficacy of the device, which was completed in March 2016. Food and Drug Administration product code: LEI.

POLICY STATEMENT

Magnetic esophageal sphincter augmentation to treat gastroesophageal reflux disease is **not medically necessary**.

BENEFIT APPLICATION

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

RATIONALE

Summary of Evidence

For individuals who have GERD who receive MSA, the evidence includes prospective and retrospective observational comparative studies, 2 single-arm interventional trials, and a number of single-arm observational studies. Relevant outcomes are symptoms, change in disease status, medication use, and treatment-related morbidity. In the 2 single-arm, uncontrolled manufacturer-sponsored studies submitted to the U.S. Food and Drug Administration with materials for device approval, subjects showed improvements in GERD-HRQL scores and reduced proton pump inhibitor use. Similarly, observational

comparative studies, most often comparing MSA with laparoscopic Nissen fundoplication, generally have shown that GERD-HRQL 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, may be affected by selection bias, and the subjective outcome measures used in these studies (eg, the GERD-HRQL scores) may be biased. A randomized trial is in progress (NCT02505945); it will compare treatment with the MSA and treatment with double-dose proton pump inhibitors. Randomized comparisons of MSA with laparoscopic Nissen fundoplication are also 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

In 2013, the Society of American Gastrointestinal and Endoscopic Surgeons published guidelines on the safety and effectiveness of the LINX Reflux Management System.[19] The Society 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 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

A 2017 report from the American Society for Gastrointestinal Endoscopy concluded that long-term data on the safety and efficacy of the LINX device were needed.[20] 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 (NCD). In the absence of an NCD, coverage decisions are left to the discretion of local Medicare carriers.

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POLICY HISTORY

Date	Action	Description
December 2012	New Policy	Policy created with literature review; considered not medically necessary.
December 2013	Update Policy	Policy updated with literature review; reference 4 added; policy statement unchanged.
December 2014	Update Policy	Policy updated with literature review, references 5-9 added; policy statement unchanged.
December 2015	Update Policy	Policy updated with literature review, references 1, 4, and 9 added. Policy statement unchanged.
March 2017	Update 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	Update Policy	Policy updated with literature review through September 11, 2017; no references added; references 7 and 19 updated. Policy statement unchanged.