**Magnetic Esophageal Ring to Treat Gastroesophageal Reflux Disease (GERD)**

**Effective:** March 1, 2017

**Next Review:** January 2018  
**Last Review:** January 2017

**IMPORTANT REMINDER**

Medical Policies are developed to provide guidance for members and providers regarding coverage in accordance with contract terms. Benefit determinations are based in all cases on the applicable contract language. To the extent there may be any conflict between the Medical Policy and contract language, the contract language takes precedence.

PLEASE NOTE: Contracts exclude from coverage, among other things, services or procedures that are considered investigational or cosmetic. Providers may bill members for services or procedures that are considered investigational or cosmetic. Providers are encouraged to inform members before rendering such services that the members are likely to be financially responsible for the cost of these services.

**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 maximum medical therapy.

**MEDICAL POLICY CRITERIA**

An implantable magnetic esophageal ring is considered **investigational** as a treatment of gastroesophageal reflux disease (GERD).

**NOTE:** A summary of the supporting rationale for the policy criteria is at the end of the policy.

**CROSS REFERENCES**

1.  [Transesophageal Endoscopic Therapies for Gastroesophageal Reflux Disease (GERD)](#), Medical Policy Manual, Surgery, Policy No. 110  
2.  [Gastric Reflux Surgery](#), Medical Policy Manual, Surgery, Policy No. 186
BACKGROUND

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 10-20% prevalence in developed countries. The severity of GERD is widely variable. Many patients have mild, intermittent symptoms that do not require treatment or only require episodic use of medications. Other patients have chronic, severe GERD that can lead to complications such as Barrett’s esophagus and esophageal cancer. For patients with severe disease, chronic treatment with acid blockers is one option. For some patients, medications are not adequate to control symptoms, and other patients prefer to avoid the use of indefinite, possibly lifelong medications. Surgical treatments are available for these patients, primarily a Nissen fundoplication performed either laparoscopically or by open surgery.

LINX PROCEDURE

The LINX™ Reflux Management System (Torax Medical®) 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. The target population is patients who have GERD symptoms despite maximum medical therapy (e.g., proton pump inhibitors) but who do not want to risk the adverse effects of a surgical procedure like Nissen fundoplication. Adverse events of the LINX™ Reflux Management System may include dysphagia or odynophagia. The device can be removed by a laparoscopic procedure if severe adverse events occur or if magnetic resonance imaging (MRI) is needed for another condition.

REGULATORY STATUS

The LINX™ Reflux Management System was approved by the U.S. Food and Drug Administration (FDA) in 2012. The LINX™ device is indicated for patients diagnosed with GERD, as defined by abnormal pH testing, and who continue to have chronic GERD symptoms despite maximum therapy for the treatment of reflux. The FDA has required 5-year follow-up of 100 patients from the investigational device exemption (IDE) pivotal study to evaluate safety and efficacy of the device.

EVIDENCE SUMMARY

NONRANDOMIZED STUDIES

Data submitted to the U.S. Food and Drug Administration (FDA) for the LINX® Reflux Management System included 2 single-arm, nonrandomized FDA-regulated investigational device exemption (IDE) trials with a total of 144 subjects and follow-up data between 2 and 4 years.[1] The feasibility IDE study enrolled 44 subjects at 4 clinical sites (2 U.S. and 2 Europe)
and has published data out to 4 years.\textsuperscript{[2,3]} The pivotal IDE study included 100 subjects from 14 clinical sites (13 U.S. and 1 Europe) who had documented symptoms of gastroesophageal reflux disease for longer than 6 months (regurgitation or heartburn that responds to acid neutralization or suppression), required daily proton pump inhibitor (PPI) or other anti-reflux drug therapy, had symptomatic improvement on PPI therapy, and had a total distal ambulatory esophageal pH less than 4 for 4.5% or more of the time when off GERD medications. The primary safety endpoint measured the rate of related device and procedure serious adverse events (SAEs). Efficacy endpoints were assessed off PPI therapy and measured esophageal acid exposure, total GERD-Health Related Quality of LIFE (HRQL) scores, and PPI usage. Subjects served as their own controls.

Results of the pivotal trial were published in 2013.\textsuperscript{[4]} In this study, the primary efficacy endpoint of pH normalization or greater than 50\% reduction in acid exposure time when off PPI was met by 64\% of the subjects. The mean total acid exposure time was reduced from 11.6\% at baseline to 5.1\% at 12 months (56\% reduction). The secondary efficacy endpoints met the study success criteria. Ninety-two percent of subjects had at least a 50\% improvement in GERD-HRQL symptom score (the mean GERD-HRQL total score decreased from 28.4 at baseline to 5.9 and 5.5 at 12 and 24 months, respectively), and 93\% had reduced PPI use (79\% and 83\% of subjects were free from daily dependence at 12 and 24 months, respectively, compared with 0\% at baseline). Dysphagia was observed in 68\% of patients postoperatively, in 11\% at 1 year, and in 4\% at 3 years. Nineteen patients underwent esophageal dilation for dysphagia. Six patients (6\%) experienced a serious adverse event (SAE) including severe dysphagia and vomiting. The device was removed in 4 of these 6 patients with a SAE and in 2 additional patients for persistent reflux and chest pain.

Five-year results from 33 of the 44 patients from the feasibility IDE trial were published in 2015.\textsuperscript{[5]} For the 33 with follow-up, the mean total GERD-HRQL score decreased from 25.7 at baseline to 2.9 at year 5 (p<0.001); 93.9\% had more than 50\% reduction in total score versus baseline. On esophageal pH testing, the mean percentage of time that pH was less than 4 decreased from 11.9\% at baseline to 4.6\% at 5 years (p<0.001). At 5 years, 87.8\% had stopped PPIs.

Five-year results for the 100 patients in the pivotal IDE trial were published in 2016.\textsuperscript{[6]} Eighty-five patients had follow-up at 5 years. Of those 85, 83\% achieved had a 50\% reduction in GERD-HRQL scores (95\% CI 73\% to 91\%) and 89.4\% had a reduction of 50\% or more in average daily dose of PPI (95\% CI, 81\% to 95\%). No new major safety concerns emerged. The device was removed in 7 patients.

Retrospective comparative studies have been identified on magnetic sphincter augmentation (MSA) with the LINX device compared with laparoscopic Nissen fundoplication (LNF) or laparoscopic Toupet fundoplication (LTF). The largest study identified is a multi-institutional retrospective cohort study by Warren et al (2016) who reported on 415 patients treated with either MSA (n=201) or LNF (n=214).\textsuperscript{[7]} Eligible patients were retrospectively identified from 3 centers’ prospectively collected databases, and met criteria if they had GERD at least partially responsive to proton pump inhibitor (PPI) treatment and positive pH testing. MSA-treated patients had lower DeMeester scores, and lower rates of biopsy-proven Barrett esophagus and hiatal hernia. Given the differences in baseline groups, the authors used propensity score matching to generate 114 matched pairs based on preoperative esophagitis, presence of
Barrett esophagus, hiatal hernia, and body mass index (BMI). Mean follow-up differed for matched pair MSA and LNF groups (11 mo vs 16 mo, respectively, p<0.001). In quality of life analysis at follow-up, there was no significant difference in match-pair groups in Gastroesophageal Reflux Disease–Health-Related Quality of Life (GERD-HRQL) scores (6 for MSA vs 5 for LNF, p=0.54). The proportion of patients using PPIs at follow-up was higher in the MSA group (24% vs 12%, p=0.02), but more patients in the MSA group had the ability for eructation (97% vs 66%, p<0.001).

Also in 2016, Asti et al reported on an observational cohort study comparing MSA (n=135) and LTF (n=103), using patients identified from a prospectively collected database.[8] Eligible patients had GERD symptoms despite PPI for at least 6 months, and normal esophageal motility. In a generalized estimating equation model for the GERD-HRQL, there was no significant difference at 1 year in GERD-HRQL scores between MSA and LTF groups (odds ratio [OR] for time-treatment interaction term, 1.04; 95% confidence interval [CI], 0.89 to 1.27; p=0.578). Similarly, there was no significant difference between the MSA and LTF groups at 1 year in PPI use (OR for time-treatment interaction term, 1.18; 95% CI, 0.81 to 1.70; p=0.389).

Other nonrandomized studies were also identified.[9-20] These studies may not be relied upon to demonstrate the clinical utility of the magnetic esophageal ring or to evaluate adverse events compared to standard techniques.

**PRACTICE GUIDELINE SUMMARY**

**SOCIETY OF AMERICAN GASTROINTESTINAL AND ENDOSCOPIC SURGEONS**

In 2013, the Society of American Gastrointestinal and Endoscopic Surgeons (SAGES) published a Technology and Value Assessment guideline on the safety and effectiveness of the LINX Reflux Management System.[21] The SAGES assessment stated that safety analyses of the LINX system suggests the procedure is associated with few serious adverse events and no reported mortality, and that currently available data demonstrates a reasonable assurance as to the efficacy of the LINX Reflux Management System. The committee concluded that based on available evidence, the LINX device should be an option available to patients and providers for the management of medically refractory GERD; however, direct comparative studies between the LINX procedure and Nissen fundoplication are still needed.

**AMERICAN SOCIETY FOR GASTROINTESTINAL ENDOSCOPY**

A 2013 report on emerging technology from the American Society for Gastrointestinal Endoscopy concluded that long-term data about the safety and efficacy of the LINX device are needed.[22]

**SUMMARY**

More research is needed to know how well laparoscopically-implanted magnetic esophageal ring works for the treatment of gastroesophageal reflux disease (GERD). The available evidence consists of nonrandomized trials which are limited due to the lack of comparison against current gold standard treatments such as drug therapy or Nissen fundoplication.
surgery. High-quality data from randomized controlled trials are needed to compare the implanted magnetic esophageal ring procedure with the currently accepted treatments for GERD and to accurately assess possible adverse events associated with this procedure. Therefore, the use of laparoscopically-implanted magnetic esophageal ring is considered investigational for the treatment of GERD.

REFERENCES


CODES

NOTE: Based on the CPT description, a hiatal hernia repair should not be reported with this procedure.
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**Date of Origin:** January 2014