

MEDICAL POLICY



SUBJECT: MAGNETIC ESOPHAGEAL RING/ MAGNETIC SPHINCTER AUGMENTATION FOR THE TREATMENT OF GASTROESOPHAGEAL REFLUX DISEASE (GERD)	EFFECTIVE DATE: 02/20/14 REVISED DATE: 01/22/15, 01/21/16, 12/15/16, 12/21/17
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<ul style="list-style-type: none">• <i>If a product excludes coverage for a service, it is not covered, and medical policy criteria do not apply.</i>• <i>If a commercial product, including an Essential Plan product, covers a specific service, medical policy criteria apply to the benefit.</i>• <i>If a Medicare product covers a specific service, and there is no national or local Medicare coverage decision for the service, medical policy criteria apply to the benefit.</i>	

POLICY STATEMENT:

Based upon our review and assessment of peer-reviewed literature, use of a magnetic esophageal ring (e.g., LINX™ Reflux Management System) in the treatment of gastroesophageal reflux disease (GERD) has not proven to be medically effective and is therefore considered **investigational**.

POLICY GUIDELINES:

The Federal Employee Health Benefit Program (FEHBP/FEP) requires that procedures, devices or laboratory tests approved by the U.S. Food and Drug Administration (FDA) may not be considered investigational and thus these procedures, devices or laboratory tests may be assessed only on the basis of their medical necessity.

DESCRIPTION:

Gastroesophageal reflux disease (GERD) is defined as reflux of stomach acid into the esophagus that causes symptoms and/or mucosal injury. 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. However, medications do not always provide adequate control of symptoms for some patients, 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, which is currently the surgical gold standard. A number of less invasive procedures are also being evaluated as an intermediate option between medical therapy and invasive surgery.

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. 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 for use of this device 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 a 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.

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RATIONALE:

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.

Current evidence consists of 2 uncontrolled and unblinded manufacturer-sponsored studies that were submitted to the FDA for device approval. These single-arm series are of limited usefulness for determining treatment efficacy and provide no information on the comparative efficacy of this procedure with other GERD treatments. The subjective outcome measures used in these two trials, such as the GERD-HRQL (Health Related Quality of Life, scores may be biased due to placebo effects with this study design. The objective measure of esophageal pH shows modest improvement compared to baseline, but this is a physiologic measure with uncertain clinical significance. Dysphagia was common in treated patients, although serious adverse events were less common, and the smaller feasibility study did not identify any serious safety concerns at up to 4 years of follow-up. The FDA has required 4 years of follow-up on the 100 subjects in the pivotal study. Independent assessment of the device by non-industry sources would also allow greater certainty. The evidence at this time is insufficient to permit conclusions concerning the effect of this device on net health outcome.

Data submitted to the U.S. Food and Drug Administration (FDA) for the LINX® Reflux Management System included 2 single-arm FDA-regulated investigational device exemption (IDE) trials with a total of 144 subjects and follow-up data between 2 and 4 years. 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. (Bonavina, et al. 2010, Lipham, et al. 2012) 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. A total of 24/44 (54.5%) subjects in the feasibility study experienced adverse events related to the device and/or procedure, and 2 subjects experienced SAEs. The most common adverse event was dysphagia (22 events in 20 subjects, which resolved in 90 days). No SAEs related to the device or procedure occurred after the first year. In the pivotal study, dysphagia was commonly observed, occurring in 68% of patients (49% mild, 16% moderate, and 5% severe), and an SAE related to the device or implantation procedure occurred in 6% (8/144) of subjects. Most cases of dysphagia self-improved or improved with endoscopic esophageal balloon dilation. Three subjects underwent device removal for severe dysphagia and/or odynophagia. Three subjects were hospitalized for nausea and/or vomiting. One subject reported the inability to vomit. No device migration was observed on radiographs taken at 12 months. Success on the subject level was defined as normalization of acid (pH <4 for ≤4.5% of time) or reduced total time (pH <4) by at least 50% relative to baseline measurements. In the feasibility study, esophageal pH testing was performed out to 36 months in only 1 of the 4 centers. The percentage of subjects who achieved success was 79.5% (31/39) at 12 months, 90% (18/20) at 24 months, and 85% (17/20) at 36 months. The proportion of patients with reduction in PPI therapy by 50% or more was 89.7% (35/39) at 12 months, 82.9% (29/35) at 24 months, and 87.5% (28/32) at 36 months. Improvement in GERD-HRQL scores by more than 50% occurred in 97.4% (38/39) of subjects at 12 months, 88.6% (31/35) at 24 months and 96.3% (26/27) at 36 months.

Results of the pivotal trial were published in 2013. (Ganz, et al. 2013) 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

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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.

CODES: Number Description

Eligibility for reimbursement is based upon the benefits set forth in the member's subscriber contract.

CODES MAY NOT BE COVERED UNDER ALL CIRCUMSTANCES. PLEASE READ THE POLICY AND GUIDELINES STATEMENTS CAREFULLY.

Codes may not be all inclusive as the AMA and CMS code updates may occur more frequently than policy updates.

Code Key: Experimental/Investigational = (E/I), Not medically necessary/ appropriate = (NMN).

CPT: 43284 (E/I) Laparoscopy, surgical, esophageal sphincter augmentation procedure, placement of sphincter augmentation device (e.g., magnetic band)

43285 (E/I) Removal of esophageal sphincter augmentation device

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HCPCS: No specific code(s)

ICD9: 530.81 Esophageal reflux

530.11 Reflux esophagitis

ICD10: K21.0 Gastro-esophageal reflux disease with esophagitis

K21.9 Gastro-esophageal reflux disease without esophagitis

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* key article

KEY WORDS:

Esophageal sphincter device, gastroesophageal reflux disease, GERD, LINX, magnetic esophageal ring, magnetic sphincter augmentation

CMS COVERAGE FOR MEDICARE PRODUCT MEMBERS

Based on our review, magnetic sphincter augmentation is not addressed in National or Regional Medicare coverage determinations or policies.