Medical Coverage Policy | Magnetic Esophageal Sphincter Augmentation to Treat Gastroesophageal Reflux

EFFECTIVE DATE: 01|01|2017
POLICY LAST UPDATED: 08|16|2023

OVERVIEW
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.

This policy is for the insertion only. For removal of the devices, please refer to the policy in the related policy section.

MEDICAL CRITERIA
Not applicable.

PRIOR AUTHORIZATION
Not applicable.

POLICY STATEMENT
Medicare Advantage Plans
Magnetic esophageal sphincter augmentation to treat gastroesophageal reflux disease is not covered as the evidence is insufficient to determine the effects of the technology on health outcomes

Commercial Products
Magnetic esophageal sphincter augmentation to treat gastroesophageal reflux disease is not medically necessary as the evidence is insufficient to determine the effects of the technology on health outcomes

COVERAGE
Benefits may vary between groups and contracts. Please refer to the appropriate section of the Benefit Booklet, Evidence of Coverage or Subscriber Agreement for services not medically necessary/not covered.

BACKGROUND
Gastroesophageal reflux disease (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% to 20% prevalence in developed countries. The severity of GERD varies widely. 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 esophagus and esophageal cancer. For patients with severe disease, chronic treatment with acid blockers is an option. For some patients, medications are not adequate to control symptoms; 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. A number of less invasive procedures are also being evaluated as an intermediate option between medical therapy and surgery (see review 2.01.38 on endoscopic procedures).

The LINX Reflux Management System 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 (eg, 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 is needed for another condition.

For individuals who have GERD who receive magnetic sphincter augmentation (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 for device approval, subjects showed improvements in Gastroesophageal Reflux Disease–Health Related Quality of Life (GERD-HRQL) scores and reduced proton pump inhibitor (PPI) use. Similarly, observational comparative studies, most often comparing magnetic sphincter augmentation (MSA) with laparoscopic Nissen fundoplication, generally have shown that GERD-HRQL scores do not differ significantly between fundoplication and MSA, and patients are able to reduce PPI 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; it will compare treatment with the MSA and treatment with double-dose PPIs. 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.

REGULATORY STATUS
In 2012, the LINX™ Reflux Management System (Torax Medical, Shoreview, MN) was approved by the U.S. Food and Drug Administration (FDA) through the premarket approval process for patients diagnosed with gastroesophageal reflux disease (GERD), as defined by abnormal pH testing, and who continue to have chronic GERD symptoms despite maximum therapy for the treatment of reflux. FDA 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. FDA product code: LEI.

CODING

Medicare Advantage Plans and Commercial Products
The following code(s) is not covered for Medicare Advantage Plans and not medically necessary for Commercial Products:

43284 Laparoscopy, surgical, esophageal sphincter augmentation procedure, placement of sphincter augmentation device (ie, magnetic band), including cruroplasty when performed

RELATED POLICIES

Removal of Implantable Devices

PUBLISHED

Provider Update, October 2023
Provider Update, March 2022
Provider Update, March 2021
Provider Update, April 2020
Provider Update, April 2019

REFERENCES:

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2. Centers for Medicare & Medicaid Services (CMS). Local Coverage Article: Billing and Coding: Select Minimally Invasive GERD Procedures (A56863)
3. U.S. Food and Drug Administration (FDA). Class 2 Device Recall LINX Reflux Management System. May 31, 2018. https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRES/res.cfm?id=163589. Accessed October 11, 2021.
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