Magnetic Esophageal Sphincter Augmentation to Treat Gastroesophageal Reflux Disease

Introduction

GERD — gastroesophageal reflux disease — is a long-term medical condition. It’s a digestive problem that affects the ring of muscles between the esophagus (the tube that carries swallowed food to the stomach) and the stomach. When food is swallowed, the muscles at the end of the esophagus open so food can pass into the stomach. The muscles then close to prevent acid from backing up into the esophagus. In GERD, however, the ring of muscles is too weak. GERD is usually treated with changes to lifestyle and diet. A number of other treatments have been studied. One technique calls for placing a ring of magnetic beads around the base of the esophagus, just above the stomach. The ring opens to allow swallowed food into the stomach and then immediately tightens. This technique is investigational (unproven). More and longer studies are needed to find out how well such devices work.

Note: The Introduction section is for your general knowledge and is not to be taken as policy coverage criteria. The rest of the policy uses specific words and concepts familiar to medical professionals. It is intended for providers. A provider can be a person, such as a doctor, nurse, psychologist, or dentist. A provider also can be a place where medical care is given, like a hospital, clinic, or lab. This policy informs them about when a service may be covered.
Policy Coverage Criteria

<table>
<thead>
<tr>
<th>Service</th>
<th>Investigational</th>
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<tbody>
<tr>
<td>Magnetic esophageal sphincter augmentation</td>
<td>Magnetic esophageal sphincter augmentation to treat</td>
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<tr>
<td></td>
<td>gastroesophageal reflux disease is considered</td>
</tr>
<tr>
<td></td>
<td>investigational.</td>
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<tr>
<td></td>
<td><strong>Note:</strong> Commercially available esophageal</td>
</tr>
<tr>
<td></td>
<td>sphincter augmentation device: The LINX™ Reflux</td>
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<tr>
<td></td>
<td>Management System (Torax Medical)</td>
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Coding

<table>
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<tr>
<th>Code</th>
<th>Description</th>
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<tr>
<td>43284</td>
<td>Laparoscopy, surgical, esophageal sphincter augmentation procedure, placement</td>
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<tr>
<td></td>
<td>of sphincter augmentation device (ie, magnetic band), including cruroplasty</td>
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<td></td>
<td>when performed</td>
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<tr>
<td>43285</td>
<td>Removal of esophageal sphincter augmentation device</td>
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Related Information

N/A

Evidence Review
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.

Background

Gastroesophageal Reflux Disease

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.

Treatment

For patients with severe disease, chronic treatment with acid blockers is an option. For some patients, medications are inadequate 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 Related Policies).

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 having 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.

**Summary of Evidence**

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 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-Health Related Quality of Life (GERD-HQRL) scores and reduced proton pump inhibitor use. Similarly, observational comparative studies, most often comparing MSA with laparoscopic Nissen fundoplication (LNF), 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 LNF 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.

**Ongoing and Unpublished Clinical Trials**

Some trials that might influence this policy are listed in Table 1.

**Table 1. Summary of Key Trials**

<table>
<thead>
<tr>
<th>NCT No.</th>
<th>Trial Name</th>
<th>Planned Enrollment</th>
<th>Completion Date</th>
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<tr>
<td><strong>Ongoing</strong></td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>NCT01940185*</td>
<td>A Post-Approval Study of the Lynx® Reflux Management</td>
<td>200</td>
<td>Oct 2025</td>
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</table>
### 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. 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 2013 report from the American Society for Gastrointestinal Endoscopy concluded that long-term data on the safety and efficacy of the LINX device were needed. The document indicated that the LINX band is currently being deployed laparoscopically; however, a natural orifice transluminal endoscopic surgery approach could be explored.

### Medicare National Coverage

There is no national coverage determination.
Regulatory Status

In 2012, the LINX™ Reflux Management System (Torax Medical) 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.

References


### History

<table>
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<th>Date</th>
<th>Comments</th>
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<tr>
<td>10/15/12</td>
<td>New Policy. Policy created with literature review through June 2012; considered investigational.</td>
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<tr>
<td>10/14/13</td>
<td>Replace policy. Policy updated with literature review through July 1, 2013; reference 4 added; policy statement unchanged.</td>
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<td>Update Related Policies. Add 2.01.91.</td>
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<td>01/30/14</td>
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<td>01/28/16</td>
<td>Minor update. Added CPT codes 0392T and 0393T, effective 7/1/15, to the coding table.</td>
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<td>11/08/16</td>
<td>Annual review. Policy title changed to &quot;Magnetic Esophageal Sphincter Augmentation to Treat Gastroesophageal Reflux Disease&quot;, and throughout the policy for the procedure, to match the CPT code descriptions. Policy updated with literature review through September, 2016; references added. Coding update; added CPT 43284 and 43285. Policy statement unchanged.</td>
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<td>01/01/17</td>
<td>Minor Coding update; added note that CPT codes 43284 and 43285 are new codes effective 1/1/17.</td>
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<td>06/09/17</td>
<td>Coding update; removed CPT codes 0392T and 0393T as they were terminated as of 1/1/17.</td>
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<td>01/01/18</td>
<td>Annual Review, approved December 6, 2017. Policy updated with literature review through September 2017; no references added; references 7 and 19 updated. Policy statement unchanged. Removed CPT code 43289.</td>
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<tr>
<td>02/01/19</td>
<td>Annual Review, approved January 4, 2019. Policy updated with literature review through September 2018; no references added. Policy statement unchanged.</td>
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  - Qualified interpreters
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Toll free 855-332-4535, Fax 425-918-5952. TTY 800-842-5357
Email AppealsDepartmentInquiries@Premera.com

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U.S. Department of Health and Human Services
200 Independence Avenue SW, Room 509F, HHH Building
Washington, D.C. 20201, 1-800-368-1019, 800-537-7697 (TDD)

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