Magnetic Esophageal Sphincter Augmentation to Treat Gastroesophageal Reflux Disease

Number 7.01.137
Effective Date December 1, 2016
Revision Date(s) 06/09/17; 01/01/17; 11/08/16; 01/28/16; 10/13/15; 10/13/14; 10/14/13
Replaces N/A

Policy

Magnetic esophageal sphincter augmentation is considered investigative as a treatment for all indications including but not limited to gastroesophageal reflux disease (GERD).

Commercially available esophageal sphincter augmentation device: The LINX™ Reflux Management System (Torax Medical)

Related Policies

2.01.38 Transesophageal Endoscopic Therapies for Gastroesophageal Reflux Disease
2.01.91 Peroral Endoscopic Myotomy (POEM) for Treatment of Esophageal Achalasia

Policy Guidelines

Coding

<table>
<thead>
<tr>
<th>CPT</th>
<th>Description</th>
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<tbody>
<tr>
<td>43284</td>
<td>Laparoscopy, surgical, esophageal sphincter augmentation procedure, placement of sphincter augmentation device (i.e., magnetic band), including cruroplasty when performed (new code effective 1/1/17)</td>
</tr>
<tr>
<td>43285</td>
<td>Removal of esophageal sphincter augmentation device (new code effective 1/1/17)</td>
</tr>
<tr>
<td>43289</td>
<td>Unlisted laparoscopy procedure, esophagus</td>
</tr>
</tbody>
</table>

Description

Gastroesophageal reflux disease (GERD), also known as acid reflux, is caused by a weakened muscle around
the opening between the esophagus and stomach. The weak muscle does not close the opening enough after swallowing so harmful stomach contents come back (refluxes) into the esophagus causing symptoms such as heartburn, sour taste in the mouth, cough and/or damage to the tissues of the throat. Sometimes symptoms continue in spite of intensive medical management with drugs such as proton pump inhibitors (PPIs). This policy addresses a procedure using a ring of interlinked titanium beads with magnetic cores that is implanted around the dysfunctional lower esophageal sphincter (LES) to support it and reduce the reflux symptoms. This procedure may be known as magnetic gastroesophageal junction reinforcement (MGJR).

**Background**
GERD is a common medical disorder, with estimates of 10% to 20% prevalence in developed countries. The severity of GERD varies. Many patients have mild, intermittent symptoms that do not require treatment or only require occasional use of acid blocker 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 one 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 Related Policies).

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 a laparoscopic technique the band is placed around the esophagus at the LES level of the gastroesophageal junction. The magnetic attraction of the device allows the LES to close properly after swallowing to keep stomach contents from refluxing. 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 medical therapy for the treatment of reflux. FDA has required 5-year follow-up of 100 patients from the investigational device exemption pivotal study to evaluate safety and efficacy of the device. FDA product code: LEI.

**Scope**
Medical policies are systematically developed guidelines that serve as a resource for Company staff when determining coverage for specific medical procedures, drugs or devices. Coverage for medical services is subject to the limits and conditions of the member benefit plan. Members and their providers should consult the member benefit booklet or contact a customer service representative to determine whether there are any benefit limitations applicable to this service or supply. This medical policy does not apply to Medicare Advantage.

**Benefit Application**
N/A
Rationale

This policy was created in 2012 and is reviewed annually with a literature search of the MEDLINE database. The most recent literature search was through September 2016.

Randomized controlled trials (RCTs) are necessary to establish the efficacy of treatments for gastroesophageal reflux disease (GERD). GERD has a variable natural history, with exacerbations and remissions, and, as a result, a control group is required to differentiate improvements in symptoms from the natural history of the disorder. A placebo control is optimal due to the subjective nature of the patient-reported outcome measures, which are prone to bias if the patient is not blinded to treatment assignment. Random assignment is important because of the multiple potential confounders of GERD outcomes, such as diet, smoking, and obesity. Randomization minimizes the chance that these confounders will be distributed unequally among treatment groups. It is also important to determine comparative efficacy of treatments for GERD, because numerous medical and surgical treatments are effective.

No RCTs were identified in the literature. Some nonrandomized comparative studies and case series were identified; they are reviewed next.

Nonrandomized Controlled Trials

Three retrospective comparative studies have been identified on magnetic sphincter augmentation (MSA) with the LINX™ device compared with laparoscopic Nissen fundoplication (LNF). The largest study is from Reynolds et al., who in 2015 reported 1-year follow-up of 50 MSA and 50 LNF patients matched for disease severity. (1) To be included in the study, patients had 1) objective evidence of GERD, defined as an abnormal pH study, presence of biopsy-proven Barrett esophagus, or esophagitis grade B or greater; 2) proton pump inhibitor (PPI) therapy for a minimum of 6 months; and 3) normal esophageal motility. Some of the patients had been included in previous reports. At 1 year after surgery, the 2 groups had similar GERD-HRQL (Health-Related Quality-of-Life) scores (MSA=4.2, LNF=4.3; maximum, 50) and PPI use (MSA=17%, LNF=8.5%). There was no difference in the number of patients reporting mild gas and bloating (MSA=27.6%, LNF=27.6%), but more LNF patients reported severe gas and bloating (10.6% vs. 0%, p=0.028). More LNF patients were unable to belch (MSA=8.5%, LNF=25.5%, p=0.028) or vomit when needed (MSA=4.3%, LNF=21.3%, p<0.002).

Louie at al. compared outcomes from 34 patients who had MSA with 32 patients who underwent LNF. (2) Similar improvements were found for the 2 groups on the GERD-HRQL scale. The DeMeester score and pH normalized in both groups, but these were lower (p=0.001) in the fundoplication group. MSA allowed belching in 67% of patients compared with 0% in the fundoplication group. Sheu et al. compared outcomes from 12 MSA patients with a contemporaneous case-matched cohort of patients who underwent LNF. (3) Over half of the MSA patients were self-referred, compared with none who underwent LNF. Both procedures were effective for reflux. Severe dysphagia requiring endoscopic dilation was more frequent after MSA (50% of cases), while there was a trend for a reduction in bloating, flatulence, and diarrhea in this small retrospective study.

In 2015, Riegler et al. published 1-year results of an industry-sponsored multicenter registry (NCT01624506) that included a comparison with laparoscopic fundoplication. (4) The report included 202 MSA and 47 laparoscopic fundoplication (LF; Nissen or Toupet) patients from a planned enrollment of 734 patients. The choice of procedure was made by the surgeon at the time of laparoscopy, taking into account the presence of a large hiatal hernia along with other factors. In addition to having a greater frequency of large hiatal hernias (>3 cm, 45.7% vs. 1.6%), the LF group was older and had a greater frequency of Barrett esophagus (19.1% vs. 1.0%, p<0.001). Consistent with the greater severity of symptoms, patients who underwent LF had greater regurgitation and fewer patients who discontinued PPIs after treatment. Excessive gas and abdominal bloating (31.9% vs. 10.0%) and inability to vomit (55.6% vs. 8.7%) were significantly higher after LF than MSA. Improvements in GERD-HRQL scores were similar for the 2 groups. Follow-up to 3 years in a larger number of patients is ongoing.

Single-Arm Studies

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.(5) The feasibility IDE study enrolled 44 subjects at 4 clinical sites (2 U.S., 2 Europe) and has published data out to 4 years.(6,7) The pivotal IDE study included 100 subjects from 14 clinical sites (13 U.S., 1 Europe) who had documented symptoms of GERD for more than 6 months (regurgitation or heartburn that responds to acid neutralization or suppression), required daily 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-HRQL scores, and PPI usage. Subjects served as their own controls.

Results of the pivotal trial were published in 2013.(8) 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. 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, vs. 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 an SAE including severe dysphagia and vomiting. The device was removed in 4 of these 6 patients with an SAE and in 2 additional patients for persistent reflux and chest pain.

In 2013, Bonavina et al. published longer follow-up from some patients in the pilot and multicenter registry studies.(9) This study included a consecutive series of 100 patients who received MSA for GERD at their institution and were followed for a median of 3 years (range, 378 days to 6 years). Thirty of the patients had data beyond 5 years. The median GERD-HRQL score improved from 24 off PPIs to 2 (p<0.001), and freedom from daily dependence on PPIs was achieved in 85% of patients. The time that esophageal pH was less than 4 decreased from 8.0% to 3.2% (p<0.001). Although 3 patients had the device removed for persistent GERD, odynophagia, or dysphagia, no occurrences of device migrations or erosions were observed during follow-up.

In 2015, Lipham et al. reported on adverse events for the first 1048 implanted patients (82 institutions).(10) Of these, 144 were implanted as part of premarket clinical trials (previously described), 332 had been enrolled in the post-market registry, and 572 were implanted outside of a post-market registry. The 3 sources used to identify adverse events were the published clinical literature along with the device’s Summary of Safety Effectiveness Data, the FDA database for device-related complications (MAUDE database), and information provided by the manufacturer. Event rates were 0.1% intra-/perioperative complications, 1.3% hospital readmissions, 5.6% endoscopic dilations, and 3.4% reoperations for device removal. The primary reason for device removal was dysphagia. Erosion of the device occurred in 1 patient (0.1%). The median device implantation was 274 days. This study is limited by the short follow-up and the voluntary reporting of adverse events outside of the registry.

### 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>NCT02505945*</td>
<td>The CALIBER Study Randomized Controlled Trial of LINX Versus Double-Dose Proton Pump Inhibitor Therapy for Reflux Disease</td>
<td>150</td>
<td>Apr 2017</td>
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<tr>
<td>NCT01940185*</td>
<td>A Post-Approval Study of the Lynx® Reflux Management System</td>
<td>200</td>
<td>Sep 2019</td>
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<tr>
<td>NCT01624506</td>
<td>Observational Study of Anti-Reflux Surgery</td>
<td>734</td>
<td>Jan 2015</td>
</tr>
<tr>
<td>NCT02923362</td>
<td>Registry of Outcomes From AntiReflux Surgery (ROARS)</td>
<td>1000</td>
<td>May 2018</td>
</tr>
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</table>

NCT: national clinical trial.
* Denotes industry-sponsored or cosponsored trial.
Summary of Evidence
The evidence for the magnetic esophageal sphincter augmentation in patients with gastroesophageal reflux disease (GERD) includes 3 retrospective comparative cohort studies along with several case series. Relevant outcomes include symptoms, change in disease status, medication use, and treatment-related morbidity. The case series include a registry study, 2 uncontrolled manufacturer-sponsored studies that were submitted to the U.S. Food and Drug Administration (FDA) for device approval, and longer follow-up of some patients from the pivotal trial and registry study. The comparative trials are retrospective and nonrandomized, may be affected by selection bias, and the subjective outcome measures used in these trials (e.g., the Gastroesophageal Reflux Disease—Health Related Quality of Life scores) may be biased due to placebo effects in these nonblinded trials. FDA has required a 5-year follow-up on the 100 subjects in the pivotal study, and a randomized trial is in progress that will compare treatment with magnetic esophageal sphincter augmentation and treatment with double-dose proton pump inhibitors. Randomized comparisons of magnetic sphincter augmentation with 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.

Practice Guidelines and Position Statements

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.(11) SAGES Technology and Value Assessment Committee 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 direct comparative studies between the LINX™ procedure and Nissen fundoplication will 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 GERD.

American Society for Gastrointestinal Endoscopy
A 2013 report on emerging technology from the American Society for Gastrointestinal Endoscopy (ASGE) concluded that long-term data about the safety and efficacy of the LINX™ device are needed.(12) The document indicates that the LINX™ band is currently being deployed laparoscopically; however, a natural orifice transluminal endoscopic surgery approach could be explored.

American Society of General Surgeons
In 2014, the American Society of General Surgeons (ASGS) published a position statement in support of the LINX procedure.(13) The ASGS recommends comprehensive management of GERD with use of medical and surgical interventions that provide safe control with minimal side effects. The society states: “Based on currently available information and the experience of their members with the procedure, they support the LINX procedure as a mechanism for controlling GERD when it is placed by properly trained laparoscopic surgeons with experience in foregut surgery and the management of GERD patients.”

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.

References

Appendix

N/A

History

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<th>Date</th>
<th>Reason</th>
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<tr>
<td>10/15/12</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>11/20/13</td>
<td>Update Related Policies. Add 2.01.91.</td>
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<tr>
<td>01/30/14</td>
<td>Update Related Policies. Change title to 2.01.38.</td>
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01/28/16  Minor update. Added CPT codes 0392T and 0393T, effective 7/1/15, to the coding table.

11/08/16  Annual review. Policy title changed to “Magnetic Esophageal Sphincter Augmentation to Treat Gastroesophageal Reflux Disease”, 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.

01/01/17  Minor Coding update; added note that CPT codes 43284 and 43285 are new codes effective 1/1/17.

06/09/17  Coding update; removed CPT codes 0392T and 0393T as they were terminated as of 1/1/17.

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