## 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.

## Related Policies

- Transesophageal Endoscopic Therapies for Gastroesophageal Reflux Disease

## Policy

An implantable magnetic esophageal ring to treat gastroesophageal reflux disease (GERD) is considered **investigational**.

## Policy Guidelines

Effective in 2014, there is a specific HCPCS “C” code for this procedure:

- **C9737**: Laparoscopy, surgical, esophageal sphincter augmentation with device (e.g., magnetic band)

There is no specific CPT code for this procedure. It would likely be reported with the unlisted laparoscopy procedure code:

- **43289**: Unlisted laparoscopy procedure, esophagus

The Medicare carrier Novitas Solutions posted a provider bulletin in June 2013, which states that code 43280 has been incorrectly reported for this procedure and that the unlisted code 43289 should be used (https://www.novitas-solutions.com/bulletins/all/news-06192013.html).

**Effective July 1, 2015**, the following CPT codes are specific to the procedure of placing or removing an implant such as the LINX™ Reflux Management System:

- **0392T**: Laparoscopy, surgical, esophageal sphincter augmentation procedure, placement of sphincter augmentation device (i.e., magnetic band)
- **0393T**: Removal of esophageal sphincter augmentation device
Benefit Application

Benefit determinations should be based in all cases on the applicable contract language. To the extent there are any conflicts between these guidelines and the contract language, the contract language will control. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

Some state or federal mandates (e.g., Federal Employee Program (FEP)) prohibit Plans from denying Food and Drug Administration (FDA) - approved technologies as investigational. In these instances, plans may have to consider the coverage eligibility of FDA-approved technologies on the basis of medical necessity alone.

Rationale

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 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 esophagus and esophageal cancer. 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. A number of less invasive procedures are also being evaluated as an intermediate option between medical therapy and surgery (see Blue Shield of California Medical Policy: Transesophageal Endoscopic Therapies for Gastroesophageal Reflux Disease regarding endoscopic procedures).

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 is needed for another condition.

Regulatory Status

The LINX™ Reflux Management System was approved by 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. 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.

Randomized controlled trials 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.

Single-arm series are of limited usefulness for determining treatment efficacy. Improvements in symptoms in single-arm studies may be due to the variable natural history of GERD, and/or bias from the placebo and other nonspecific effects. Single-arm series can demonstrate the feasibility and potential benefit of this procedure and can be used to determine rates of adverse events. It is also important to determine comparative efficacy of treatments for GERD, because there are numerous medical and surgical treatments that are effective. Single-arm series are inadequate for determining comparative effectiveness of different treatment options; controlled trials with active comparators are required for this.

**Literature Review**

**Food and Drug Administration-Regulated Trials**

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., 2 Europe) and has published data out to 4 years. 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 proton pump inhibitor (PPI) or other antireflux 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 end point measured the rate of related device and procedure serious adverse events (SAEs). Efficacy end points were assessed off PPI therapy and measured esophageal acid exposure, total Gastroesophageal Reflux Disease-Health Related Quality of Life (GERD-HRQL) scores, and PPI usage. Subjects served as their own controls.

Results of the pivotal trial were published in 2013. In this study, the primary efficacy end point of pH normalization or greater than 50% reduction in acid exposure time when off protein pump inhibitor (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 end points 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 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.

**Nonrandomized Controlled Trials**

Two retrospective comparative studies have been identified on magnetic sphincter augmentation (MSA) with the LINX® device compared with laparoscopic Nissen fundoplication (LNF). Louie et al compared outcomes from 34 patients who had MSA with 32 patients who underwent LNF. 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 none in the fundoplication group. Sheu et al compared outcomes from 12 MSA patients with a contemporaneous case-matched cohort of patients who underwent LNF. Over half of the MSA patients were self-referred, compared with none of the patients 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.

**Observational Studies**

In 2014, Lipham et al reported on adverse events for the first 1048 implanted patients (82 institutions). Of these, 144 were implanted as part of premarket clinical trials (described above), 332 had been enrolled in a postmarket registry, and 572 were implanted outside of a postmarket registry. The 3 sources that were 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**


- NCT01940185 is a prospective, multicenter, single-arm postapproval study to monitor the safety and efficacy of the LINX® implant procedure and device with follow-up through 5 years. The study has an estimated enrollment of 200 patients, with completion expected in 2019.

- NCT01624506 is a registry to track and monitor patients treated with either the LINX® device or fundoplication in clinical practice. It began in 2010, and has an estimated enrollment of 800 patients, with completion anticipated in 2016.

**Summary of Evidence**

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. Current evidence on magnetic sphincter augmentation (MSA) consists of 2 retrospective comparative cohort studies along with
several case series, including 2 uncontrolled and unblinded manufacturer-sponsored studies that were submitted to the Food and Drug Administration (FDA) for device approval. The 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 comparative trials are retrospective and nonrandomized, and may be affected by selection bias. In addition, the subjective outcome measures used in these trials, such as the Gastroesophageal Reflux Disease-Health Related Quality of Life (GERD-HRQL) scores, may be biased due to placebo effects in these nonblinded trials. The objective measure of esophageal pH shows modest improvement compared with 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. FDA has required 5 years of follow-up on the 100 subjects in the pivotal study. Randomized comparisons of MSA with Nissen fundoplication are also needed to evaluate the relative risk-benefit of these 2 procedures. The evidence at this time is insufficient to permit conclusions concerning the effect of this device on net health outcome. It is considered investigational.

Supplemental Information

Practice Guidelines and Position Statements

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. 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.

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. The document indicates that the LINX band is currently being deployed laparoscopically; however, a natural orifice transluminal endoscopic surgery approach could be explored.

U.S. Preventive Services Task Force Recommendations

Use of magnetic esophageal rings is not a preventive service.

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


Documentation Required for Clinical Review

- No records required

Coding

This Policy relates only to the services or supplies described herein. Benefits may vary according to benefit design; therefore, contract language should be reviewed before applying the terms of the Policy. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement.

IE

The following services are considered investigational and therefore not covered for any indication.

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<th>Type</th>
<th>Code</th>
<th>Description</th>
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<td>Laparoscopy, surgical, esophageal sphincter</td>
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Medical Policy

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<td>43289</td>
<td>Removal of esophageal sphincter augmentation device (Code effective 7/1/2015)</td>
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<td>Unlisted laparoscopy procedure, esophagus</td>
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Policy History

This section provides a chronological history of the activities, updates and changes that have occurred with this Medical Policy.

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<td>10/31/2014</td>
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<tr>
<td>1/30/2015</td>
<td>Coding update</td>
<td>Administrative Review</td>
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Definitions of Decision Determinations

Medically Necessary: A treatment, procedure or drug is medically necessary only when it has been established as safe and effective for the particular symptoms or diagnosis, is not investigational or experimental, is not being provided primarily for the convenience of the patient or the provider, and is provided at the most appropriate level to treat the condition.

Investigational/Experimental: A treatment, procedure or drug is investigational when it has not been recognized as safe and effective for use in treating the particular condition in accordance with generally accepted professional medical standards. This includes services where approval by the federal or state governmental is required prior to use, but has not yet been granted.

Split Evaluation: Blue Shield of California / Blue Shield of California Life & Health Insurance Company (Blue Shield) policy review can result in a Split Evaluation, where a treatment, procedure or drug will be considered to be investigational for certain indications or conditions, but will be deemed safe and effective for other indications or conditions, and therefore potentially medically necessary in those instances.
Prior Authorization Requirements

This service (or procedure) is considered **medically necessary** in certain instances and **investigational** in others (refer to policy for details).

For instances when the indication is **medically necessary**, clinical evidence is required to determine **medical necessity**.

For instances when the indication is **investigational**, you may submit additional information to the Prior Authorization Department.

Within five days before the actual date of service, the Provider MUST confirm with Blue Shield that the member’s health plan coverage is still in effect. Blue Shield reserves the right to revoke an authorization prior to services being rendered based on cancellation of the member’s eligibility. Final determination of benefits will be made after review of the claim for limitations or exclusions.

Questions regarding the applicability of this policy should also be directed to the Prior Authorization Department. Please call 1-800-541-6652 or visit the Provider Portal www.blueshieldca.com/provider.

The materials provided to you are guidelines used by this plan to authorize, modify, or deny care for persons with similar illness or conditions. Specific care and treatment may vary depending on individual need and the benefits covered under your contract. These Policies are subject to change as new information becomes available.